

A critical discussion of living minors as tissue donors for transplantation
purposes in England and Wales, and Scotland.

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List of Abbreviations

AA	Accredited Assessor
BMA	British Medical Association
BTS	British Transplantation Society
CoP	Codes of Practice
DoH	Department of Health
GMC	General Medical Council
HTA	Human Tissue Authority
IA	Independent Assessor
MP	Members of Parliament
MR	Medical Risk (this abbreviation is only used in relation to a mathematical equation)
NHS	National Health Service
NHSBT	NHS Blood and Transplant
PB	Psychological Benefit (this abbreviation is only used in relation to a mathematical equation)
PR	Parental Responsibility
PR	Psychological Risk (this abbreviation is only used in relation to a mathematical equation)
SLC	Scottish Law Commission
WHO	World Health Organisation

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EWCOP 33

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Burke v General Medical Council [2005] EWCA Civ 1003, R

Chatterton v Gerson [1981] 1 All ER 257

E (A Minor)(Wardship: Medical Treatment) [1993] 1 FLR 386, Re

Evans & Anor v Alder Hey Children's NHS Foundation Trust & Anor [2018] EWCA
Civ 805

G [2012] EWCA Civ 1233, Re

Gillick v West Norfolk and Wisbech Area Health Authority [1984] QB 581

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Gillick v West Norfolk and Wisbech Area Health Authority [1985] 3 All ER 402

Hewer v Bryant [1970] 1 QB 357

J (A Minor) (Child in Care: Medical Treatment) [1992] 3 WLR 507, Re

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Anatomy Act 1832

Anatomy Act 1984

Children Act 1989

Children and Young Persons Act 1963

Children (Scotland) Act 1995

Corneal Tissue Act 1986

Human Organ and Tissue Live Transplants (Scotland) Regulations 2006

Human Organ Transplants Act 1989

Human Tissue Act 1961

Human Tissue Act 2004

Human Tissue Act 2004 (Persons who Lack Capacity to Consent and Transplants)
Regulation 2006

Human Tissue (Authorisation) (Scotland) Act 2019

Human Tissue (Scotland) Act 2006

Human Transplantation (Wales) Act 2013

Mental Capacity Act 2005

Organ Donation (Deemed Consent) Act 2019

United Nations Convention of the Rights of Children 1989

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Abstract

This research explores the regulatory framework of living minors as tissue donors for transplantation purposes in England and Wales (under 18), and Scotland (under 16). My main argument is that this regulatory framework does not adequately protect the minor donor's interests, therefore, it is in need of clarification and/or reform. When answering my research questions, listed below, I use relational autonomy and a new principle introduced in this thesis of relational parental decision-making to examine the relationships the minor donor has with others.

First, should non-regenerative tissue donation from living minors be permitted in England and Wales, and Scotland? My contention is that non-regenerative tissue donation should not be permitted because the gravity of donating it and the irreversibility of the procedure suggests that no potential psychological benefits can outweigh the medical risks, psychological harm, and long-term implications.

Secondly, who can and should provide consent/authorisation for living minors to be regenerative tissue donors? Those with parental responsibility (PR) can and should be

able to provide consent/authorisation for an incompetent minor. If a minor is competent, they should be able to provide consent/authorisation on their own behalf, and those with PR and the court should not be permitted to override this decision.

Thirdly, what test(s) should be used to determine whether consent/authorisation can be provided for a living minor to be a tissue donor? The best interests test should be reformed so the minor's view and the harm principle are given greater weight, and the addition of relational parental decision-making. The *Gillick* and 2(4) competence tests should require a minor to understand the moral, family, emotional, and long-term implications, as well as the consequences if they refuse the donation. For those aged 16- and 17- year old, section 8 should be interpreted broadly to cover tissue donation.

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Declaration

This thesis is the sole work of the author and it has not been submitted in substantially the same form for the award of a higher degree elsewhere.

Chapter 1

Introduction

This research explores the regulatory framework of living minors as tissue donors for transplantation purposes in England and Wales, and Scotland examining whether it currently protects the minor donor's interests. My main argument is that this regulatory framework does not adequately protect the minor donor's interests, therefore, it is in need of clarification and/or reform. I discuss both incompetent and competent minors by analysing who can and who should be able to provide consent/authorisation¹ for a living minor to be a tissue donor. As part of that discussion, I use the principle of relational autonomy² and develop the new and novel principle of relational parental decision-making³ in the context of tissue donation in order to examine the relationship that a minor donor has with others, including the potential recipient. Before discussing the medical and legal background of this research, I am going to set out its limitations so it is clear to the reader the scope of this research, and also establish any necessary definitions for clarity and consistency.

1.1 Scope of Research

1.1.1 Minors

Minor donors are the focus of this thesis, while some of the research may be applicable to adults this is outside the scope of this discussion, therefore, the reader should assume

¹ see chapter 3 at 3.4.1 for the discussion about the definitions of the terms consent and authorisation.

² see chapter 2 at 2.2.1 for the discussion on relational autonomy. See also Jocelyn Downie and Jennifer J Llewellyn, *Being Relational: Reflections on Relational Theory and Health Law* (UBC Press 2012); Jennifer Nedelsky, *Law's Relations: A Relational Theory of Self, Autonomy, and the Law* (OUP 2013); Edward S Dove and others, 'Elberte v Latvia: Whose tissue is it anyway – Relational autonomy or the autonomy of relations?' (2015) 15 *Medical Law International* 77.

³ see chapter 2 at 2.3 for the discussion on relational parental decision-making.

that all analysis is in relation to minors. A minor is under 18 in England and Wales,⁴ and under 16 in Scotland.⁵ I do not consider the position of 16- and 17- year olds in Scotland, since section 1(1)(b) of the Age of Legal Capacity (Scotland) Act 1991 states that ‘a person of or over the age of 16 years shall have legal capacity to enter into any transaction’. Therefore, they can provide consent on their own behalf to undergo medical procedures. If, however, they lack capacity, then the provisions of the Adults with Incapacity (Scotland) Act 2000 will apply.⁶

I have chosen to focus my research on minors for two reasons. First, there is a lack of discussion in academic literature as well as the absence of case law on the use of tissue from living minors. This academic discussion and the judgments from case law would usually provide support to the regulatory framework by aiding its interpretation to ensure its application is accurate and consistent. While this thesis is unable to accommodate this deficiency in case law, it aims to fill the void in the academic discussion. Secondly, one of the roles of the regulatory framework for tissue donation from living minors is to ensure protection of the minor donor’s interests. Therefore, it is imperative that the framework fulfils this role. My examination and analysis of the framework will enable defects to be identified, subsequently allowing reform to be suggested in order to provide a framework to better protect the minor’s interests and prevent their potential exploitation.

For the purposes of this thesis, exploitation of a minor is when their tissue is being used purely to benefit another without consideration of the implications, such as the physical

⁴ Family Law Reform Act 1969, s.1(1).

⁵ Age of Legal Capacity (Scotland) Act 1991, s.1 and s.9.

⁶ In England and Wales, the Mental Capacity Act 2005 applies and this will be discussed in chapter 6 at 6.3.1.

harm, that it may have on the minor donor. This interpretation of exploitation includes considering whether the minor is being used as a means to an end. A minor donor could potentially be exploited by those with parental responsibility (PR) as if the minor is incompetent those with PR would be providing consent on their behalf. Furthermore, a minor could also be exploited by medical professionals as they will be the individuals who conduct the donation procedure. It is unlikely that the potential recipient could exploit the minor donor because they would not be involved in the consent process nor in the donation procedure.

There are a number of terms that I could use to refer to those who are under 18 in England and Wales, and under 16 in Scotland, for example, child, infant, or young person. I have chosen to use the term minor because I required a term that could be used for every eligible individual without inviting connotations. The terms child and infant connote someone who is very young, while young person suggests a teenager. If a source has used a different term other than minor, I have been true to the quotation, however, the reader should infer that any use of alternative terms refers to those under 18 in England and Wales, or under 16 in Scotland, unless stated otherwise.

I have distinguished between different categories of minor to facilitate the discussion and advance the research questions of the thesis. First, I have separated the minors into two categories: incompetent and competent. The need to distinguish between these categories of minor is because various individuals can provide consent/authorisation for the minor to be a tissue donor. I have subsequently split competent minors into two further categories: under 16s, and 16- and 17- year olds. This is because those aged 16 and 17 in England and Wales are assumed to have capacity under the Mental Capacity

Act 2005⁷, and their ability to consent to a medical procedure is governed by section 8 of the Family Law Reform Act 1969. By contrast, minors under 16 are governed by two competency tests: the *Gillick*⁸ competence test in England and Wales, and in Scotland the competence test under section 2(4) of the Age of Legal Capacity (Scotland) Act 1991.

1.1.1.1 Living Minors

This thesis concentrates on living donation, rather than deceased donation. This means that the donor is alive during and post-donation. I have chosen to focus my research on living donation for two reasons. First, there is a lack of discussion amongst policy-makers about donation from living minors. Since the Human Tissue Act 2004 and the Human Tissue (Scotland) Act 2006, that govern the use of human tissue in England and Wales, and Scotland respectively, were enacted there has been an upheaval of the deceased donation systems from an opt-in to an opt-out system. Consequently, Parliament enacted the Human Transplantation (Wales) Act 2013 to regulate Wales, the Human Tissue (Authorisation) (Scotland) Act 2019⁹ to regulate Scotland, and the Organ Donation (Deemed Consent) Act 2019 to regulate England.¹⁰ There has, however, been

⁷ Mental Capacity Act 2005, s.1(2).

⁸ *Gillick v West Norfolk and Wisbech Area Health Authority* [1985] 3 All ER 402.

⁹ This legislation is in force from March 2021, see NHS Blood and Transplant, ‘Organ and tissue donation law in Scotland’ <<https://www.organdonation.nhs.uk/uk-laws/organ-donation-law-in-scotland/>> accessed 28/08/2020.

¹⁰ This legislation governs deceased donations from adults not minors. See also James F Douglas and Antonia J Cronin, ‘The Human Transplantation (Wales) Act 2013: An Act of Encouragement, not Enforcement’ (2015) 78(2) *Modern Law Review* 324; Jane Noyes and others, ‘Family attitudes, actions, decisions and experiences following implementation of deemed consent and the Human Transplantation (Wales) Act 2013: Mixed-method study protocol’ (2017) 7(10) *BMJ* E017287; Nicholas Page, Gary Higgs, Mitchel Langford, ‘An exploratory analysis of spatial variations in organ donation registration rates in Wales prior to the implementation of the Human Transplantation (Wales) Act 2013’ (2018) 52 *Health and Place* 18; Sarah Jane R Brown, ‘Organ donor registration in the UK: The need for informed consent for ante-mortem interventions to facilitate organ donation’ (2019) 19(2-3) *Medical Law International* 113; David M Shaw, ‘The side effects of deemed consent: Changing defaults in organ donation’ (2019) 45(7) *Journal of Medical Ethics* 435; Jessica M. Pieri and Neil H Metcalfe, ‘The Organ Donation (Deemed Consent) Act 2019’ (2020) 13(4) *InnovAiT* 242.

no change in the law of donation from living minors, but this does not necessarily mean that this law is ideal or free from defect.

Secondly, the advancements in the medicine of living donation means that the regulatory framework needs to be adapted and developed in order to sufficiently regulate these advancements.¹¹ NHS Blood and Transplant (NHSBT)¹² launched their strategy in 2020 in relation to Living Donor Kidney Transplantation, with their strategy aim ‘to match world class performance in living donor kidney transplantation.’¹³ This means that NHSBT aim to develop the medicine of kidney donation from living individuals to be at a world-class level as NHSBT recognise the importance of living donation:

Living donation plays a vital role in saving and improving lives. Its unique contribution to the organ donor pool offers more patients the possibility of a successful transplant whilst adding to the overall supply of available organs for those who are waiting.¹⁴

This aim is supported by three key objectives:

1. To increase living donor kidney transplantation activity for both adult and paediatric recipients, ensuring that donor safety and welfare is consistently sustained through best clinical practice.

¹¹ see chapter 1 at 1.2.1; NHS, ‘History of Donation’ (NHS Choices, 2015) <www.nhs.uk/tools/documents/transplant.htm> accessed 01/05/2017.

¹² NHSBT manage NHS blood donation services in England and transplant services across the UK; NHS Blood and Transplant, ‘Discover what we do’ <<https://www.nhsbt.nhs.uk/>> accessed 18/06/2020.

¹³ NHS Blood and Transplant, *Living Donor Kidney Transplantation 2020: A UK Strategy* (2020).

¹⁴ *ibid*, 3.

2. To maximise patient benefit by ensuring that all suitable recipients have equity of access to living donor kidney transplantation and that the principle of ‘transplant first’¹⁵ is embedded in best clinical practice across the UK.
3. To maximise the opportunities for suitable donors and recipients to contribute to and benefit from the shared living donor pool by ensuring that the National Living Donor Kidney Sharing Schemes are both clinically and cost-effective.¹⁶

This strategy emphasises the aim of NHSBT to increase donation from living minors. This demonstrates that they recognise the importance of the role of minor donors as they contribute to the tissue shortage by providing life-prolonging or life-saving tissue to a minor recipient. This continuing advancement in medicine by NHSBT allows more patients and their families to benefit from the donation by living minors as it will be possible to offer transplants to patients with complex needs who might not otherwise receive a transplant. If more living minors are able to donate tissue then the Human Tissue Authority (HTA)¹⁷ will have to alter their stance, which currently states that living minors are only considered as donors in rare circumstances.¹⁸ But regardless of the number of donations that occur, as donation medicine advances the ongoing assessment of its regulatory framework is imperative to ensure that the donor’s interests are continually maintained to ensure that they are not exploited.

¹⁵ Includes pre-emptive transplantation for patients not on dialysis and minimise waiting time for transplantation for patients already on dialysis.

¹⁶ NHSBT (n 13), 3.

¹⁷ see chapter 1 at 1.2.3 for explanation of the role of the Human Tissue Authority.

¹⁸ Human Tissue Authority, *Code of Practice F: Donation of solid organs and tissue for transplantation* (2017) para 44.

1.1.2 What is tissue?

Although legal and medical literature, and the HTA use both of the terms organ and tissue, in this thesis I have made a conscious choice to only use the term tissue. There are two reasons for this decision. First, the term tissue can include all types of material removed from a living human body,¹⁹ while the term organ only includes a collection of tissue such as a solid organ.²⁰ My discussion examines different types of material that can all be covered by the use of the term tissue.

Secondly, a distinction is made between regenerative tissue donation and non-regenerative tissue donation by the HTA and in the regulatory framework, and I draw on this distinction to further my research questions. Therefore, it would seem apt to use the terms regenerative tissue and non-regenerative tissue for clarity and consistency. In England and Wales, the regulation does not contain this distinction because a minor can donate both regenerative and non-regenerative tissue, but in Scotland this distinction is made because minors are not permitted to donate non-regenerative tissue.²¹ As a result of this distinction, a definition is required to determine the types of donations that are permitted. Subsequently, the discussion below about the distinction between regenerative and non-regenerative tissue and the definitions provided is only applicable to Scotland, but as the HTA also regulate the use of human tissue in England and Wales it would follow that if they were required to make this distinction in England and Wales, they would make the same distinction and use the same definitions.

¹⁹ Britannica, 'Tissue' <<https://www.britannica.com/science/tissue>> accessed 27/09/2020.

²⁰ Britannica, 'Organ' <<https://www.britannica.com/science/organ-biology>> accessed 27/09/2020.

²¹ Human Tissue (Scotland) Act 2006, s.17(4) at Appendix 1; Human Tissue Authority, *Human Tissue (Scotland) Act 2006: A guide to its implications for NHS Scotland* (2006) para 23.

A living minor can donate: blood, bone marrow, a kidney, a lobe of liver, a lobe of lung, a portion of intestine, and a segment of pancreas.²² However, the most commonly donated types of tissue are the first four listed, therefore, in this thesis I will only consider these.²³ If a lobe of lung, a portion of intestine, or a segment of pancreas donation become more common then it is my contention that as these are all types of non-regenerative tissue donation the same argument should be adopted as to other non-regenerative tissue.²⁴ Section 17(10) of the Human Tissue Act 2006 defines regenerative tissue as tissue which is ‘able to be replaced in the body of a living person by natural processes if the tissue is injured or removed’.²⁵ This would indicate that regenerative tissue includes: blood, bone marrow and a lobe of liver. There is no explicit definition as to what is defined as non-regenerative tissue, but it is likely that it would include a kidney. However, Parliamentary debate about the 2006 Bill implies that a lobe of liver is to be considered non-regenerative tissue rather than regenerative tissue.²⁶ While this debate is not legally binding, it can be used to aid interpretation of the statute and understand the intention of Parliament when passing the Bill. Even after I had consulted the Parliamentary debate it was still unclear as to the classification of a lobe of liver donation, therefore, I contacted Organ Donation Scotland and they have provided some clarification:

²² NHS Blood and Transplant, ‘Become a living donor’ <<https://www.organdonation.nhs.uk/become-a-living-donor/>> accessed 15/09/2020.

²³ see chapter 1 at 1.2.4 in Table 1 and Table 2 for statistics on tissue donation rates.

²⁴ see chapter 4. The donation of reproductive material from a living minor is outside the scope of this thesis. See Nicola J Williams, Rosamund Scott and Stephen D Wilkinson, ‘The Ethics of Uterus Transplantation’ (2018) 32(8) *Bioethics* 478; Benjamin P Jones, Amel Alghrani and J Richard Smith, ‘Re: Uterine Transplantation in transgender women: medical, legal and ethical considerations’ (2019) 126(4) *BJOG: An International Journal of Obstetrics and Gynaecology* 545; Laura O’Donovan, Nicola J Williams and Stephen D Wilkinson, ‘Ethical and Policy Issues Raised by Uterus Transplant’ (2019) 131 *British Medical Bulletin* 19.

²⁵ see Appendix 1.

²⁶ Scottish Parliament, ‘Official Report’ (30 November 2005) <<http://www.parliament.scot/parliamentarybusiness/report.aspx?r=4617&i=35916>> accessed 15/03/2019.

I appreciate that the definition of tissue in the Act is not that clear (and there's no definition of what's a solid organ), but it is generally understood that donation of the liver lobe would count as organ (rather than regenerative tissue) donation and therefore, in relation to living donation, can only be donated by an adult. Given this is a procedure which can put the donor at significant risk, it's hard to envisage circumstances where clinicians would feel it was appropriate for a living child to donate part of their liver.²⁷

Furthermore, I contacted the HTA in order to gain their perspective, and they reiterated what Organ Donation Scotland said by stating that:

Although the liver can regenerate, liver lobe donation is considered to fall within solid organ donation, rather than tissue donation. We therefore would consider applications for living liver lobe donation only from adults with capacity in Scotland.²⁸

Subsequently, this guidance provided by Organ Donation Scotland and the HTA contradicts the definition set out in the 2006 Act. Therefore, it is unclear as to the classification of a lobe of liver donation in law. Clarification in statute or professional guidance as to the classification of lobe of liver is required. In this thesis, I have chosen to class lobe of liver donation as non-regenerative tissue donation following the advice by Organ Donation Scotland and the HTA. But I note that this is considered differently by medical professionals.²⁹

There is further type of tissue donation called a domino donation, and it is defined under section 17(10) of the 2006 Act as:

²⁷ Email from Organ Donation Scotland to author (29 January 2018).

²⁸ Email from Human Tissue Authority to author (08 February 2018).

²⁹ Kim M Olthoff and others, 'Liver regeneration after living donor transplant' (2015) 21(1) Liver Transplantation 79.

“domino organ transplant operation” means a transplant operation performed on a living person by a registered medical practitioner—

- (a) which is designed to safeguard or promote the physical health of the person by transplanting organs or parts of organs into the person; and
- (b) by so doing, necessitates the removal of an organ or part of an organ from the person which in turn is intended to be used for transplantation in respect of another living person.³⁰

For this type of donation, the donor does not undergo the operation for the primary purpose of donating tissue. The primary purpose of the operation is to undergo medical treatment. An individual who undergoes a domino donation is usually someone who suffers from cystic fibrosis.³¹ Those suffering from cystic fibrosis are sometimes required to have a lung transplant, but there is a better clinical outcome if they receive both a heart and lung transplant together. Therefore, the removal of their healthy heart may prove suitable for transplant into another recipient. While there is discussion of this type of donation within the regulatory framework for completeness,³² the reforms that I propose to the framework are not designed to be applicable to domino donations. The donation of the heart is merely a by-product of the medical treatment rather than the primary reason for undergoing the operation. Therefore, there is no concern over the donor’s interests or their potential exploitation since they would have to undergo the procedure to receive a lung transplant to save or prolong their own life.

³⁰ see Appendix 1.

³¹ NHS, ‘Cystic Fibrosis’ <<https://www.nhs.uk/conditions/cystic-fibrosis/>> accessed 18/06/2020.

³² see Chapter 3 at 3.4.2.1.

1.1.3 Donor

A donation and transplantation process involves two individuals: the donor, and the recipient. The focus of this thesis is on the donor within the donation process. The donation process is the whole procedure from the start when histocompatibility is determined to find a suitable donor up to and including the post-operative care following the donation operation. The reasoning for focusing on the donor in this thesis is twofold. First, as tissue donation from a living individual is not curative or prophylactic, but medically harms the donor, it is paramount that the donor's interests are protected to prevent their exploitation. Secondly, the focus within the donation process from a medical perspective is usually on the recipient as they are the individual who is ill and is in need of the tissue in order for their life to be prolonged or saved. Once the donor has donated the tissue their role in the process ends, and yet they play the most important role in the process as it is they who provided the life-prolonging or life-saving tissue.

The donor and the recipient are separate individuals with their own needs and interests, however, in the past the importance of the donor's role and the need to consider the donor as a separate individual was seen to be somewhat overlooked. In the 1960s, when tissue donation was a new and novel medical procedure, the donor was not seen as an individual with their own medical needs separate from the recipient, but were considered to be part of the medical team whose purpose was to help the recipient:

The donor ... asked a very pointed question: would the doctors at the Peter Bent Brigham Hospital be willing to take care of him medically for the rest of his life if he gave his kidney? We stated that we neither could nor desired to make a guarantee of

that sort; we were there to help his brother and if he (the prospective donor) could help his brother, we felt that the chances of success were quite good.³³

Attitudes have since changed, and the donor is now treated as a separate individual with their own healthcare team and their own healthcare needs. The health and wellbeing of the donor is and should be as important as the health and wellbeing of the recipient. In the majority of instances when a medical procedure is required the individual undergoing the procedure is the individual in need of treatment for their illness, however, in the case of a tissue donation for a donor this is not true. The donor undergoes a medical procedure exposing themselves to medical risks in order to donate tissue to another individual. The operation does not medically benefit them in any way, in fact, it medically harms them, often temporarily, but there is a risk this damage could be permanent. Therefore, one of the roles of the regulatory framework is to ensure that safeguards are in place to protect the donor's interests and prevent their exploitation. So far, I have stated that this thesis is only considering living minor donors, and I now discuss why this is further limited to only sibling to sibling donations.

1.1.3.1 Siblings

The regulatory framework does not put restrictions on who a minor is able to donate tissue to, however, this thesis will only consider sibling to sibling donation. The reason for restricting the scope of the thesis is because it is unlikely that the HTA or the court would permit a living minor to donate tissue to anyone other than their sibling. As I will argue in Chapter 4, the donor should develop a psychological benefit from donating tissue and this is only likely to occur with sibling to sibling donations. But it is noted

³³ GEW Wolstenholme and Maeve O'Connor (eds), *Ethics in Medical Progress: with special reference to transplantation* (Little, Brown and Company 1966) 17-18.

that in certain circumstances depending on the dynamics of a particular relationship, a psychological benefit could stem from donating tissue to another family member. If a potential psychological benefit could be identified between a minor and another family, and if all of the requirements are met then the HTA or court may permit the donation to proceed. However, this discussion is outside the scope of this thesis.

A minor recipient could receive tissue from four potential donors: living adult, deceased adult, living minor, or deceased minor. But, the HTA have stated that ‘children can be considered as living organ donors only in extremely rare circumstances.’³⁴ If, as the HTA have stated, donation from a living minor is rare then a minor recipient must more commonly receive tissue from the other three potential sources. But, the HTA do not state that living donors are never used as tissue donors, only in rare circumstances. This means that there are circumstances when tissue from a living minor donor is in fact used. This most commonly occurs when tissue from an adult or a deceased minor is not sufficient to meet the clinical needs of the recipient. For example, the donor has to be histocompatible with the recipient as tissue matching is required for the donation to be successful, also tissue from adults can be too large for a minor, especially in relation to the donation of a kidney or a lobe of liver.³⁵ Subsequently, a donor who is likely to be histocompatible is that of a sibling of a potential recipient, and as they are likely to both be minors the tissue is also likely to be a more suitable size for transplantation, therefore, it would follow that sibling to sibling donations are medically ideal. While it is possible

³⁴ Human Tissue Authority, *Code of Practice F: Donation of solid organs and tissue for transplantation* (2017) para 44.

³⁵ Orlando Health ‘How Organ Size Affects the Organ Donation Process’ <<https://www.orlandohealth.com/content-hub/how-organ-size-affects-the-organ-donation-process>> accessed 16/09/2020.

that the HTA or the court could permit a non-sibling minor to donate tissue in extremely rare circumstances there is no record that such permission has ever been provided.

In order to be able to successfully restrict the discussion in this thesis by only considering siblings, I need to provide a definitive category of who is considered to be a 'sibling'. As a family may no longer be historically traditional ie a mother, a father, and a biological child(ren), there are many types of individuals who could be considered a 'sibling'. There is academic discussion on the sociological aspects of sibling relationships, however, this is outside the scope of this thesis.³⁶ The definition of sibling that I am in principle using for the purposes of this thesis is that provided by the Encyclopaedia of Human Relationships: 'a sibling relationship is a relationship one has with a sister or brother who have one or both parents in common'.³⁷ Therefore, my adaptation of this definition for the purpose of this thesis is that the donor and the recipient must share one or more biological parents.³⁸

Also, for the purposes of this thesis, the sibling donor has not been conceived for the purposes of being histocompatible with their sick sibling in order to donate tissue. The potential minor donor is likely to have already been born when the sibling recipient is diagnosed with their illness. Conceiving a minor for the purposes of donating their tissue raises ethical and philosophical debate, and these minors are referred to as a

³⁶ see Julia Brannen, Ellen Heptinstall, and Kalwant Bhopal, *Connecting Children: Care and Family Life in Later Childhood* (Routledge, 2000); Rosalind Edwards, Melanie Mauthner, and Lucy Hadfield, 'Children's sibling relationships and gendered practices: Talk, activity and dealing with change' (2005) 17(5) *Gender and Education* 499; Rosalind Edwards and others, *Sibling Identity and Relationships: Sisters and Brothers* (Routledge, 2006); Katherine Davies, 'Siblings, Stories and Self: The Sociological Significance of Young People's Sibling Relationships' (2014) 49 *Sociology* 679.

³⁷ Harry T Reis and Susan Sprecher, 'Sibling Relationships', *Encyclopaedia of Human Relationships* (2009).

³⁸ Even if a donor and recipient share both parents this does not guarantee that they are histocompatible. But regardless of what the regulatory framework states, if the donor and the recipient are not histocompatible then the donation would not take place.

saviour sibling. Discussion on whether such activities are or should be permissible is outside the scope of this thesis as they consider other areas of law such as abortion and focus less on the donation process but on whether a minor should be born purely for this purpose.³⁹ Also, this type of discussion would not include competent minors since a saviour sibling would usually donate shortly after they were born as a transplant for the recipient would likely be needed quickly.

1.1.4 Jurisdiction

The focus of this thesis will be in two legal jurisdictions: England and Wales, and Scotland. I have chosen not to include Northern Ireland in the discussion for two reasons. First, the law on tissue donation is the same as that in England and Wales, therefore, it would not add anything to the discussion on the regulatory framework of tissue donation. Secondly, the law of Northern Ireland compared to the law in England and Wales, and Scotland is different with regard to the law of capacity. As this thesis focuses on the competency tests for competent minors, consent, and authorisation, not on the law of capacity, the inclusion of Northern Ireland would not have provided a comparative element nor added anything novel to my approach. Therefore, it would have been superfluous to the discussion.

³⁹ see *Quintavalle v Human Fertilisation and Embryology Authority* [2005] UKHL 28; Roger Brownsword, 'Happy Families, Consenting Couples, and Children with Dignity: Sex Selection and Saviour Siblings' (2005) 17 *Child Family Law Quarterly* 1; Then Shih-Ning, 'The Legality of Tissue Transplants for the Benefit of Family Members in the UK and Australia: Implications for Saviour Siblings' (2009) *Medical Law International* 10; Lisa Cherkassky, 'The Human Tissue Authority and Saviour Siblings' (2015) *Journal of Bone Marrow Research* 3; Lisa Cherkassky, 'The Wrong Harvest: The Law on Saviour Siblings' (2015) *International Journal of Law, Policy and the Family* 29.

1.2 Background Information

I have now outlined the scope of the research and its limitations concluding that this thesis focuses on living minors as tissue donors for transplantation purposes to a sibling within England and Wales, and Scotland. My discussion will now consider the medical and legal background of tissue donation in order to provide context to the subsequent analysis of the regulatory framework.

1.2.1 Medical

The ability for a medical professional to remove tissue from one living individual and transplant it into another, to save or prolong the recipient's life, is a progressive area of medicine.⁴⁰ Tissue donation from a living donor for transplantation purposes is now a common procedure, but this type of medicine has continually progressed since the first cornea transplant in the Czech Republic in 1905.⁴¹ The idea of donation and transplantation of body parts is not a new one as it stems back to science fiction with the innovative ideas of authors such as Mary Shelley who wrote *Frankenstein* in 1818.⁴² Blood donation was the first commonly occurring type of tissue donation with the UK's first blood bank set up in 1937.⁴³ In 1960, the first successful kidney donation operation was performed in the UK from a living donor.⁴⁴ Following this, the first liver donation was performed in the UK in 1968 from a deceased donor with the first liver donation

⁴⁰ NHS Blood and Transplant, 'A history of donation, transfusion and transplantation' <<https://www.nhsbt.nhs.uk/who-we-are/a-history-of-donation-transfusion-and-transplantation/>> accessed 08/04/2020.

⁴¹ *ibid.*

⁴² Mary Shelley, *Frankenstein* (Lackington 1818).

⁴³ NHS Blood and Transplant (n 40).

⁴⁴ NHS, 'History of Donation' (NHS Choices, 2015) <www.nhs.uk/tools/documents/transplant.htm> accessed 01/05/2017.

from a living individual occurring in 1995.⁴⁵ The first bone marrow donation occurred in the UK in 1986.⁴⁶

1.2.2 Legal

The law has been reactive to changes in tissue donation medicine. The use of tissue from deceased individuals was first regulated by the Anatomy Act 1832. The 1832 Act allowed an individual to make a declaration donating their body after their death for the purposes of medical science. The Act put a stop to body-snatching by the ‘resurrectionists’, such as the infamous William Burke and William Hare.⁴⁷ The next legal development was the enactment of the Human Tissue Act 1961⁴⁸ which was introduced because the common law relating to the legitimate uses of the corpse for donation for transplantation purposes at this time was vague and advances in medicine needed to be legally regulated so individuals would not be exploited.⁴⁹ It also provided recognition of the pace of new medical technologies in transplantation as it coincided with medical advances in tissue donation from deceased individuals in the UK.⁵⁰ As donation medicine at this time was mostly restricted to deceased donors, the Act only covered the use of tissue from deceased persons.⁵¹

⁴⁵ *ibid.*

⁴⁶ King’s College Hospital, ‘Hospital which pioneered bone marrow transplants celebrates 1000th procedure’ <<https://www.kch.nhs.uk/news/media/press-releases/view/7916#:~:text=Prof%20Ghulam%20Mufti%2C%20Professor%20of,transplant%20centre%20in%20the%20UK.>> accessed 20/08/2020.

⁴⁷ Royal College of Surgeons, ‘Human Dissection’ <www.rcseng.ac.uk/rcs/human-dissection-factsheet> accessed 18/06/2020.

⁴⁸ as amended by the Anatomy Act 1984 and the Corneal Tissue Act 1986.

⁴⁹ Gerald Dworkin, ‘The Law Relating to Organ Transplantation in England’ (1970) 33(4) *Modern Law Review* 353.

⁵⁰ NHS Blood and Transplant (n 40).

⁵¹ Human Tissue Act 1961, Introductory Text.

The 1961 Act allowed a person, orally or in writing, to ‘request that his body or any specified part of his body be used after his death for therapeutic purposes or for medical purposes of medical education or research.’⁵² The Act also provided that the person lawfully in possession of the body (often the hospital)⁵³ may authorise removal of body parts for the purposes of medical education or research.⁵⁴ This was on the pretence of the person having ‘made such reasonable inquiry as may be practicable’, so he has no reason to believe that the deceased had expressed objections to such a process, or that ‘the surviving spouse or any surviving relative of the deceased objects to the body being so dealt with.’⁵⁵ This implied that the requisite consent for the removal of organs and tissue for scientific or medical use was provided by the hospital,⁵⁶ rather than from the deceased individual.

The 1961 Act did not contain an explicit provision that allowed the use of tissue from living individuals for any purpose, including transplantation purposes.⁵⁷ The first legislation that covered donation from living donors was the Human Organ Transplants Act 1989. This was enacted as a result of a medical scandal involving Dr Raymond Crockett. During the 1980s, it became publicly known that individuals were being flown to the UK and paid for one of their kidneys, which was transplanted into a recipient in a private hospital, through the National Kidney Centre, a private agency under the medical directorship of Dr Raymond Crockett.⁵⁸ The General Medical

⁵² Human Tissue Act 1961, s.1(1).

⁵³ The hospital would be in possession of the body because the individual would have died in hospital and the body would be stored in the mortuary until it was released for burial or cremation.

⁵⁴ Human Tissue Act 1961, s.1(2).

⁵⁵ Human Tissue Act 1961, s.1(2)(a) and (b).

⁵⁶ Margaret Brazier, ‘Organ retention and return: problems of consent’ (2003) 29 *Journal of Medical Ethics* 30, 31.

⁵⁷ David Price, ‘From Cosmos and Damien to Van Velzen: the Human Tissue Saga Continues’ (2003) 11(1) *Medical Law Review* 1, 20

⁵⁸ HL Deb 19 July 1989 vol 510 cc 842-58; Marc Stauch and Kay Wheat with John Tingle, *Sourcebook on Medical Law* (Cavendish 1998) 590.

Council (GMC) conducted an inquiry into Dr Crockett's involvement,⁵⁹ and concluded that he was guilty of serious professional misconduct, and ordered that his name was erased from the medical register.⁶⁰ At the time, there was no legislation, common law, or professional guidance permitting or prohibiting the removal or use of tissue from living donors.⁶¹ Regulation was required if such a procedure was to proceed with no risk of exploitation of the donor. Consequently, legislation on the use of tissue from living donors for transplantation purposes was enacted in England and Wales, and Scotland, namely the 1989 Act.

The 1989 Act was enacted in order to deal specifically with the problems that had arisen following the kidney sale scandal, namely the exploitation of individuals through the sale of their organs, and the lack of legislation regulating tissue donation from living donors for transplantation purposes.⁶² It appeared to be a knee-jerk response to the Dr Raymond Crockett scandal, and as a result the reasoning underpinning the 1989 Act suffered from an irrational basis.⁶³ The 1989 Act was repealed and the legislation that replaced it was the Human Tissue Act 2004, and the Human Tissue (Scotland) Act 2006. These Acts were introduced when it became publicly known that minors' organs and tissue were being retained by hospitals and similar institutions without the knowledge

⁵⁹ Janet Radcliffe Richards, 'Nepharious goings on. Kidney sales and moral arguments' (1996) 21 *Journal of Medical Philosophy* 375; S Choudry and others, 'Unrelated living organ donation: ULTRA needs to go' (2003) 29 *Journal of Medical Ethics* 169.

⁶⁰ Bob Brecher, 'The kidney trade: or, the customer is always wrong' (1990) 16 *Journal of Medical Ethics* 120, 123.

⁶¹ see Dworkin (n 49) for the argument that the 1961 Act does in fact cover tissue donation from living individuals.

⁶² Hansard (n 58).

⁶³ Choudry (n 59) 170; British Medical Association, *Organ donation in the 21st century: time for a consolidated approach* (BMA 2000) 12. See also while genetically related donation was expressly permitted, donation between non-genetically related individuals was not permitted unless certain criteria were satisfied. The reason for restricting the transplantation of organs between individuals who are not genetically related, was to ensure that tissue donation was not coerced.

or consent of their relatives.⁶⁴ This was known as the organ retention scandals and is further discussed in Chapter 3 along with the 2004 and 2006 Acts.⁶⁵ Tissue donation from living minors under the 2004 and 2006 Acts is currently regulated by the HTA.⁶⁶

1.2.3 Human Tissue Authority

The HTA are a non-departmental public body of the Department of Health and Social Care, established to ensure that human tissue is used ‘safely and ethically, and with proper consent.’⁶⁷ They regulate organisations that remove, store and use human tissue for research, medical treatment, post-mortem examination, education and training, and display in public. They also give approval for tissue and bone marrow donations from living individuals. The HTA have published a number of codes of practice in England and Wales,⁶⁸ as well as specific guidance for transplant teams, Independent Assessors (IAs)⁶⁹, and Accredited Assessors (AAs)⁷⁰ in Scotland. These codes of practice and supplementary guidance do not carry the same legal weight as legislation or

⁶⁴ Bristol Royal Infirmary, *The Report of the Public Inquiry into Children’s Heart Surgery at the Bristol Royal Infirmary 1984-1995: Learning from Bristol* (Cm 5207(I), 2001) (Kennedy Inquiry).

⁶⁵ at 3.2.

⁶⁶ Human Tissue Authority, *Human Tissue (Scotland) Act 2006: A guide to its implications for NHS Scotland* (2006) para 21; Human Tissue Authority, *Code of Practice A: Guiding Principles and the Fundamental Principle of Consent* (2017) Annex A para 1; The remit of the HTA does not extend to Scotland, instead the regulation is performed by the Scottish Ministers. However, an arrangement was entered into by the Scottish Ministers and the HTA so that the HTA is responsible for assessing applications on behalf of the Scottish Ministers; Human Tissue Authority, *Guidance for Transplant Teams, Independent Assessors, and Accredited Assessors in Scotland* (2017) para 1.

⁶⁷ Human Tissue Authority, ‘About us’ <<https://www.hta.gov.uk/about-us>> accessed 18/06/2020.

⁶⁸ Human Tissue Authority, *HTA Codes of Practice and Standards* <<https://www.hta.gov.uk/hta-codes-practice-and-standards-0>> accessed 08/02/2019; Human Tissue Authority, *Code of Practice A* (n 66) para 5.

⁶⁹ IAs act as a representative of the HTA to ensure the requirements of the 2004 Act and associated Regulations are met in all cases of living organ donation; Human Tissue Authority, *About Independent Assessors* <<https://www.hta.gov.uk/about-independent-assessors-ias>> accessed 02/02/2019.

⁷⁰ AAs assess potential bone marrow and PBSC donations from adults who lack capacity and minors who lack competence to consent. AAs act as a representative for the donor and the HTA; Human Tissue Authority, *About Accredited Assessors* <<https://www.hta.gov.uk/about-accredited-assessors>> accessed 02/03/2019.

jurisprudence and there are no formal sanctions should the codes of practice not be followed in respect of tissue donation.⁷¹

1.2.4 Donation Rate Statistics

While donation from living minors forms a small part of the total number of donations undertaken each year, they form a vital part of that total. The following statistics illustrate this point. Currently, there is a shortage of tissue in England and Wales, and Scotland.⁷² There are currently 4,220 people waiting for a transplant in the UK.⁷³

The following tables are the statistics that are provided by NHSBT in relation to donation procedures. Table 1 provides information about the number of living donors in 2019/2020. They do not provide separate statistics for adults and minors.

⁷¹ Human Tissue Act 2004, s.28.

⁷² The change in law to a system of 'opt out' in relation to deceased donation in Wales with the introduction of the Human Transplantation (Wales) Act 2013, in England with the introduction of the Organ Donation (Deemed Consent) Act 2019, and in Scotland with the introduction of the Human Tissue (Authorisation) (Scotland) Act 2019 may reduce the organ shortage. However, discussion of this is outside the scope of the thesis.

⁷³ NHS Blood and Transplant, 'Statistics about organ donation' <www.organdonation.nhs.uk/statistics/> accessed 30/08/2020. NHSBT have stated that current waiting list figures do not accurately reflect the need for an organ transplant due to the COVID-19 pandemic. This is the waiting list for the UK as there are no separate statistics for England, Wales, and Scotland.

Table 1: Living Donors (Adults and Minors)⁷⁴

	2019/2020
England	1,574
Kidney	769
Liver	18
Intestinal	0
Lung	787
Scotland	97
Kidney	97
Liver	0
Wales	0
Kidney	40
Liver	0

Table 2 provides the most up-to-date statistics about the number of blood donations that have occurred in the UK. It does not provide separate statistics for adults and minors. But as NHSBT recommend that regular donors are aged between 17 and 66,⁷⁵ and only in exceptional circumstances, such as a rare blood group a minor may be required to donate blood to a sibling, these statistics will consist predominantly, if not solely, of adult donors. The statistics are not separated into England, Wales, and Scotland.

⁷⁴ NHS Blood and Transplant (n 73); statistics correct as of 17/06/2020. NHSBT have stated that it is unclear how COVID-19 has impacted donation rates.

⁷⁵ or 70 if they have given blood before; NHS Blood and Transplant, 'Who can give blood' <<https://www.blood.co.uk/who-can-give-blood/>> accessed 15/07/2018.

Table 2: Blood Donation Rates (Adults and Minors)⁷⁶

	2016/2017	2017/2018	2018/2019	2019/2020 ⁷⁷
United Kingdom	853,469	822,517	829,867	807,805

NHSBT does not publish statistics on bone marrow donation rates in the UK.⁷⁸ But it is reported by Anthony Nolan⁷⁹ that currently in 2019-2020 they have ‘helped’ 1,109 patients.⁸⁰ This involves Anthony Nolan using their donation register to match potential bone marrow donors with patients who are suffering with blood cancer.⁸¹

While it is unclear in the statistics how many donors are minors, it is clear that tissue donation from living individuals form a vital source of tissue for potential recipients. Even though donations from living minors occur, there is a considerable lack of case law in this area, and the judgment from the recent case of *A NHS Foundation Trust v MC (by her Litigation Friend the Official Solicitor)* demonstrates the lack of judicial guidance within this area of law.⁸²

⁷⁶ NHS Blood and Transplant, ‘Number of registrations by financial year’ <<https://www.nhsbt.nhs.uk/how-you-can-help/get-involved/share-statistics/blood-donation-statistics/>> accessed 30/08/2020.

⁷⁷ This is up-to-date as of 30/08/2020.

⁷⁸ NHS Blood and Transplant, ‘The British Bone Marrow Registry’ <<https://www.bbmr.co.uk/>> accessed 18/06/2020.

⁷⁹ Anthony Nolan, ‘Facts and Stats’ <<https://www.anthonynolan.org/facts-and-stats>> accessed 18/06/2020; Anthony Nolan is a pioneering charity that saves the lives of people with blood cancer. Every day, they use their register to match remarkable individuals willing to donate their bone marrow or blood stem cells to people who desperately need lifesaving transplants.

⁸⁰ Anthony Nolan, ‘State of the Registry 2019-2020’ <https://www.anthonynolan.org/sites/default/files/2266ST_StateOfTheRegistry_1920_v6.pdf> accessed 30/08/2020; these statistics are not split into adults and minors.

⁸¹ *ibid.*

⁸² [2020] EWCOP 33 [5].

1.2.5 Case Law on Living Minors as Tissue Donors

At the time of writing, there has been no court decisions as to whether a living minor can donate tissue. There are, however, two decisions about the donation of tissue from adults who lack capacity: *Re Y (adult patient)(bone marrow transplant)*⁸³ and *A NHS Foundation Trust v MC (by her Litigation Friend the Official Solicitor)*⁸⁴. While neither of these decisions would be binding on any future case law with regard to living minors as tissue donors, they may be used to provide guidance in this area.

*Re Y (adult patient)(bone marrow transplant)*⁸⁵ concerned whether an adult who lacked capacity could legally donate bone marrow to their sibling. Connell J held that it was in Y's best interests to donate bone marrow to her sibling, and he stated that 'it is doubtful that this case would act as a useful precedent in cases where the surgery involved is more intrusive than in this case.'⁸⁶ It should be noted that this case is from 1997, therefore, the 2004 Act and 2006 Act, that currently regulate tissue donation, were not in force. Furthermore, the HTA did not have the same role in the donation process.

*A NHS Foundation Trust v MC (by her Litigation Friend the Official Solicitor)*⁸⁷ also concerned whether an adult who lacked capacity could donate bone marrow, but this was a donation to her mother.⁸⁸ Cohen J stated that:

This is the first time that an application for the extraction of bone marrow or stem cell donation by someone lacking capacity has come before the Court of Protection and the

⁸³ [1997] 2 WLR 556.

⁸⁴ *MC* (n 82).

⁸⁵ *Re Y* (n 83).

⁸⁶ *Re Y* (n 83) 562. See also SE Mumford, 'Donation without consent? Legal Developments in Bone Marrow Transplantation' (1998) 101 *British Journal of Haematology* 599.

⁸⁷ *MC* (n 82).

⁸⁸ *MC* (n 82) [1] – [2].

first time the Human Tissue Authority (HTA) has been involved in a case of this nature.⁸⁹

While this case involved an adult who lacked capacity, Cohen J noted that ‘apparently, there are about 65 individuals each year under the age of 18 for whom the HTA give approval for this sort of procedure.’⁹⁰ This further demonstrates that living minors are donating tissue, but also highlights the lack of case law in this area.

1.3 Research Questions and Aims

I mostly adopt a doctrinal ‘black-letter law’ approach, but in relation to the comparative analysis of my research I have undertaken a multidisciplinary approach.⁹¹ As part of my comparative analysis I consider both medical and legal sources, and I have used medical sources and applied them in a legal context. The regulatory framework that I have considered not only comprises of statutes, regulations, and common law, but also professional guidance and codes of practice. In addition, I have examined government reports, academic commentary, and Hansard in order to gain a more in-depth understanding of the regulatory framework as well as being able to comment on the finer issues and provide a more rounded pragmatic approach to identify the defects and propose reforms or clarification of the current law.

This thesis will aim to fill a lacuna in the tissue donation academic debate by providing an in-depth analysis of the regulatory framework of living minors as tissue donors. It will also provide practical reform proposals to the regulatory framework that could be

⁸⁹ *MC* (n 82) [5].

⁹⁰ *MC* (n 82) [19].

⁹¹ Andrew Knight and Les Ruddock, *Advanced Research Methods in the Built Environment* (Wiley-Blackwell 2009) Chp 3.

implemented by Parliament through legislation and/or by the HTA through their CoP. Furthermore, it will identify areas where further research needs to be conducted that is outside the scope of this thesis. I hope that this thesis will contribute to the ongoing discussion about how best to treat minors who donate tissue to a sibling, and that medical professionals, families and recipients, as well as policy-makers and professional bodies will find this contribution to the literature to be useful in considering how best to protect the minor donor's interests.

As demonstrated above, living minors comprise only a small percentage of the number of donation operations that occur each year. But as tissue donation from a living minor is not curative or prophylactic, but medically harms the donor, the regulatory framework that governs these donations should protect the interests of these minors and prevent their exploitation. My main argument is that the regulatory framework that currently governs living minors as tissue donors in England and Wales, and Scotland does not adequately protect the minor donor's interests, therefore, it is in need of clarification and/or reform. To demonstrate this argument, I aim to answer three questions:

- (1) Should non-regenerative tissue donation from living minors be permitted in England and Wales, and Scotland?
- (2) Who can and should provide consent/authorisation for living minors to be regenerative tissue donors?
- (3) What test(s) should be used to determine whether consent/authorisation can be provided for a living minor to be a tissue donor?

As a vast amount of literature already exists about tissue donation as well as the competency tests, it is necessary to address the issue of how this thesis aims to make a positive and original contribution to the tissue donation debate. The majority of literature considers adults as both living or deceased donors, or minors as deceased donors.⁹² I make an original contribution to this literature in that first, I apply the principle of relational autonomy to tissue donation, which has not been previously undertaken in academic literature.⁹³ Secondly, I introduce the new and novel principle of relational parental decision-making, a principle that I developed in the context of tissue donation in order to explore the relationship that an incompetent donor has with others in order for those with PR to provide consent/authorisation on their behalf.⁹⁴ Thirdly, I undertake a comparative analysis between England and Wales, and Scotland in relation to non-regenerative tissue donation using both medical and legal sources and suggest reforms to the current law in England and Wales which has not been undertaken within academic literature.⁹⁵

Fourthly, I analyse and suggest recommendations for reform of the best interests test specifically in relation to tissue donation; the majority of academic literature focuses on

⁹² John Harris, 'The Survival Lottery' (1975) 50(191) *Philosophy* 81; IH Kerridge and others, 'Death, dying and donation: organ transplantation and the diagnosis of death' (2002) 28 *Journal of Medical Ethics* 89; Michael T Morley, 'Proxy Consent to Organ Donation by Incompetents' (2002) 111 *The Yale Law Journal* 1215; HE Emson, 'It is immoral to require consent for cadaver organ donation' (2003) 29 *Journal of Medical Ethics* 125; John Harris, 'Organ procurement: dead interests, living needs' (2003) 29 *Journal of Medical Ethics* 130; TM Wilkinson, 'What's not wrong with conditional organ donation?' (2003) 29 *Journal of Medical Ethics* 163; Sheelagh McGuinness and Margaret Brazier, 'Respecting the Living Means Respecting the Dead too' (2008) 28(2) *Oxford Journal of Legal Studies* 297; David Price *Human Tissue in Transplantation and Research* (CUP 2010); Anne-Maree Farrell, David Price, and Muireann Quigley (eds) *Organ Shortage: Ethics, Law and Pragmatism* (CUP 2011).

⁹³ see Chapter 2 at 2.2.1.2.

⁹⁴ see Chapter 2 at 2.3.

⁹⁵ see Chapter 4.

the best interests test in general.⁹⁶ Fifthly, I analyse the suitability of the *Gillick*⁹⁷ competency test, section 2(4) of the Age of Legal Capacity (Scotland) Act 1991 competency test, and section 8 of the Family Law Reform Act 1969 regarding their application to tissue donation.⁹⁸

1.4 Outline of Chapters

This thesis will take the form of six chapters.

Chapter 2 provides an overview of the ethical principle of autonomy. I adopt Thomas Beauchamp and James Childress's well-respected notion of autonomy: an action, or a decision to undergo an action, is autonomous when an individual meets three requirements.⁹⁹ These requirements are that the individual acts: (1) intentionally, (2) with understanding, and (3) without control from internal states or external sources.¹⁰⁰ I focus my discussion of autonomy on the principle of relational autonomy as this will form the basis of my analysis of the three research questions in this thesis. My interpretation of relational autonomy is that if an individual makes an autonomous relational decision then that decision is made by considering the network of relationships with others. In other words, for an individual to make a decision they need to take into account their relationships with others that underpins their life, such as familial and societal relationships. The degree that a particular relationship is taken into account is dependent on the circumstances of that individual; the importance of the relationship; and the weight it has on the individual's life.

⁹⁶ see Chapter 5.

⁹⁷ *Gillick v West Norfolk and Wisbech Area Health Authority* [1985] 3 All ER 402.

⁹⁸ see Chapter 6.

⁹⁹ Tom L Beauchamp and James F Childress, *Principles of Biomedical Ethics* (OUP 2013).

¹⁰⁰ *ibid.*

Moreover, I argue that the philosophical interpretation of the principle of relational autonomy should have a legal application in medical decision-making, specifically tissue donation from a living minor. I will also demonstrate how relational decision-making can and should be applied where those with PR are making a decision on behalf of an incompetent minor in the context of tissue donation. I aim to show this by introducing the new and novel principle of relational parental decision-making. This means that when those with PR make a decision on behalf of an incompetent minor, instead of treating the minor as if they were an isolated being, I propose that the relationships that the minor has with others should be a contributing part of the decision-making.

The final part of this chapter will consider the well-recognised and understood legal principle of consent. I focus on two aspects of consent that I feel are pertinent to the discussion in the remainder of the thesis. First, the test for informed consent which is contained in *Montgomery v Lanarkshire Health Board*¹⁰¹. Secondly, I will discuss the lawfulness of tissue donation from a living minor with application to consent concluding that unlike other medical procedures, the lawfulness of tissue donation from a living individual is established by statute which may provide some indication of the exceptional nature of this kind of medical procedure.

Chapter 3 considers the regulatory framework of tissue donation, which is a combination of legal regulation and professional guidance which includes codes of practice (CoP). The current legislation that regulates tissue donation from living minors

¹⁰¹ [2015] UKSC 11.

in England and Wales, and Scotland is the Human Tissue Act 2004, and the Human Tissue (Scotland) Act 2006 respectively. The HTA have produced a number of CoP and guidance documents that supplement this legislation. This legislation was implemented following the organ retention scandals that became public knowledge in the late 1990s and early 2000s.

There are two main arguments I intend to make in this chapter. First, as one of the aims of this thesis is to recommend reform to the regulatory framework, I need to provide a clear conception of what the regulatory framework actually says and identify where its defects lie. In order to do this, I will produce a number of tables and charts that provide a summary of the legislation and professional guidance with regard to the donation process. These tables and charts are merely a condensed and simplified form of the lengthy and complex information that is available about the donation process. I will produce them to assist the reader so there is a basis for comparison between the current framework and my proposed developments. Moreover, there is scope that they could be considered by the HTA to assist when creating a more workable conception of the donation process for medical professionals as well as donors, recipients, and the general public. I also recommend that the CoP should be reformed so there are separate CoP for adults and minors. This will allow for a more streamlined set of guidance.

Secondly, I will analyse the difference between the use of the term ‘appropriate consent’ in the 2004 Act compared to the use of the term ‘authorisation’ in the 2006 Act. I will consider whether there is a material difference between the two terms by examining the legal definitions as well as their interpretation in the CoP. I shall conclude that the difference between the two terms is superficial as the test for informed consent and

informed authorisation are identical. It would be clearer and more precise if the term consent is used and replaces authorisation in the 2006 Act with regard to tissue donation.

Chapter 4 recommends reform to the regulatory framework by considering the first question of this thesis: should minors in England and Wales be permitted to donate non-regenerative tissue? In Scotland, living minors can only donate regenerative tissue or as part of a domino transplant, thus they cannot donate non-regenerative tissue.¹⁰² In contrast, living minors in England and Wales can donate both regenerative and non-regenerative tissue.

My contention is that no living minor should be able to donate non-regenerative tissue¹⁰³ because the psychological benefits of the donation do not outweigh the immediate and long-term medical risks and potential psychological risks of the donation, even if the donation is to a sibling. Therefore, the law in England and Wales should be reformed and the Scottish approach should be adopted. I will aim to demonstrate this by comparing the two most common types of regenerative tissue donation, blood and bone marrow, with the two most common types of non-regenerative tissue donation, a kidney and a lobe of liver. I will discuss both the immediate and long-term medical risks of the different types of donation as well as any long-term implications to the minor's lifestyle as a result of being a tissue donor.

I will then move on to consider the potential psychological benefits and psychological harms a living minor donor can develop as a result of undergoing the donation process.

The majority of my discussion will focus on Kenneth Kipnis' eight discrete types of

¹⁰² Human Tissue (Scotland) Act 2006, s.17(4) at Appendix 1; HTA (n 18) para 23.

¹⁰³ except domino transplants.

vulnerabilities that are applied by Lainie Friedman Ross and Richard Thistlethwaite to tissue donation.¹⁰⁴ I will explore whether the psychological benefits outweigh the immediate and long-term medical risks and psychological risks, therefore, justifying the tissue donation.

Put simply: psychological benefit > medical risks + psychological harm

in order for the donation to be justified.

Chapter 5 will consider the second and third research questions of this thesis in relation to incompetent minors: who can and should be able to provide consent/authorisation for living minors to be regenerative tissue donors? and what test(s) should be used to determine whether consent/authorisation can be provided for a living minor to be a tissue donor? First, I conclude that those with PR can and should be able to provide consent/authorisation on behalf of an incompetent minor to be a tissue donor, as long as the decision is in the minor's best interests. Also, I propose that if those with PR have made a best interests decision which does not appear to be flawed, the court should not see necessary to override it. I argue that the best possible decision in those circumstances in the minor's interest has already been made. If the decision is considered flawed then it can be overruled by the court. Subsequently, it is irrelevant who makes the decision for the minor, either those with PR or the court, as long as the decision is in the best interests of the minor. In order to demonstrate my argument, I

¹⁰⁴ Kenneth Kipnis, *Vulnerability in research subjects: a bioethical taxonomy in: the National Bioethics Advisory Commission (NBAC), Ethical and Policy Issues in Research Involving Human Participants Volume II Commissioned Papers and Staff Analysis* (Bethesda 2001) G1–13; Kenneth Kipnis, 'Seven vulnerabilities in the pediatric research subject' (2003) 24 *Theoretical Medicine in Bioethics* 107; Lainie Friedman Ross and J Richard Thistlethwaite, 'Developing an ethics framework for living donor transplantation' (2018) *Journal of Medical Ethics* 1.

will examine the role and responsibilities of those with PR, and the role of the court in the decision-making process.

Secondly, I argue that the best interests test should continue to be used to determine whether a minor should be a tissue donor, as it allows the decision-maker to take into account a range of factors, but an additional test should be added that deals exclusively with tissue donation from living minors. In England and Wales, the best interests test is currently in the Children Act 1989, while in Scotland it is in the Children (Scotland) Act 1995. I will consider four other tests that the court and other academics have suggested could be used instead of, or in addition, to the best interests test to determine whether a minor could be a tissue donor. The alternative tests I have selected are: substituted judgement; constrained parental autonomy as defined by Lainie Friedman Ross; “strong” and “weak” family interests; and the harm threshold.

The reform that I recommend to the best interests test within section 1(3) of the 1989 Act would result in the development of the factor that considers the minor’s view in the decision-making process. I also suggest that an additional section should be added to both the 1989 Act and the 1995 Act that deals exclusively with tissue donation from living minors. It would include a factor that considers the harm of the procedure, and a requirement that takes into account the new and novel principle that I have devised, namely relational parental decision-making. The requirements in both the best interests test and this new section would need to be met in order for a donation to occur. The aim is that this test is more suitable to determine whether a living incompetent minor should be a tissue donor than the current best interests test. It simultaneously protects

the minor's interests and prevents their exploitation as well as takes account of all factors that may be relevant in the decision-making process.

Chapter 6 will consider the second question of this thesis in relation to competent minors: who can and should be able to provide consent/authorisation for living minors to be regenerative tissue donors? I will conclude that if a competent minor meets the relevant competency test then they should be able to provide consent/authorisation to be a tissue donor. As to whether they can currently do this, the law is unclear as there has been no application of tissue donation to the competency tests by the court. For those under 16 in England and Wales, the competency test is established by common law in *Gillick v West Norfolk and Wisbech Area Health Authority*¹⁰⁵, while in Scotland the test is outlined in section 2(4) of the Age of Legal Capacity (Scotland) Act 1991. For those aged 16- and 17- years old in England and Wales the test governing capacity is contained in the Mental Capacity Act 2005, and section 8 of the Family Law Reform Act 1969 permits a minor to consent to 'surgical, medical, or dental treatment' as if they were full age.

Furthermore, I will argue that those with PR currently can, but should not be permitted to override a competent minor's consent/authorisation. This is because those with PR hold their power as agents or trustees on behalf of the minor until they are mature enough to begin to make decisions for themselves. Also, I argue that once a minor is competent a court currently can but subsequently should not be able to override their decision about whether to be a tissue donor. The role of the court is to protect the

¹⁰⁵ *Gillick* (n 97).

interests of the minor, and once the minor is competent to make their own decisions then the role of the court is obsolete.

I will also answer the third research question of this thesis in relation to competent minors: what test(s) should be used to determine whether consent/authorisation can be provided for a living minor to be a tissue donor? I will propose clarification to the *Gillick* competence test and section 2(4) competence test. This clarification will mean that for a minor to be either *Gillick* or section 2(4) competent they should require an understanding of the moral, family, emotional, and long-term implications of the donation, as well as an understanding of the potential consequences if they refuse the procedure. The family implications of the decision require the minor to make a relational autonomous decision about tissue donation. In relation to those aged 16- and 17- years old, my contention is that while, *prima facie*, the term 'treatment' does not include tissue donation from living minors as it is a non-therapeutic procedure for the donor, section 8 should be interpreted broadly to cover such procedures. But interpretation and application through common law is required so there is no ambiguity.

Chapter 7 will provide suggestions and a conclusion to the thesis. It will tie together all of the issues and provide a grounded way forward for the regulatory framework of tissue donation. It will provide recommendations as to reform and clarification of the competency tests, as well as the law on consent/authorisation. It will demonstrate how both relational autonomy and relational parental decision-making should have application to tissue donation from living minors. Furthermore, I have devised tissue donation stories and I will apply my recommendations to them. I feel that this offers a practical approach displaying to the reader how these recommendations would apply in

practice. There are myriad permutations of considerations that could be presented in these stories; however, I have devised three different ones to best demonstrate how I think the regulatory framework for tissue donation from living minors should be.¹⁰⁶ The stories are as follows: (1) Daisy's Story, (2) Ryan's Story, and (3) Victoria's Story.

¹⁰⁶ These stories are not based on true events.

Chapter 2

Respect for Autonomy and Consent

2.1 Introduction

The legal regulation of tissue donation is underpinned by ethical principles, and this chapter provides an overview of the ethical principle of autonomy as it is the most relevant to the three research questions that I aim to answer in this thesis. I will adopt Thomas Beauchamp and James Childress's well-respected notion of autonomy.¹⁰⁷

I focus my discussion of autonomy on the principle of relational autonomy – for an individual to make a decision they need to take into account their relationships with others that underpin their lives, such as familial and societal relationships – as this will form the basis of my analysis of the three research questions. Moreover, I argue that the philosophical interpretation of the principle of relational autonomy should have a legal application in medical decision-making, specifically tissue donation from a living minor. I will also demonstrate how relational decision-making can and should be applied where those with parental responsibility (PR) are making a decision on behalf of an incompetent minor in the context of tissue donation. I aim to show this by introducing the new and novel principle of relational parental decision-making.

The final part of this chapter will consider the well-recognised and understood legal principle of consent. I focus on two aspects of consent that I feel are pertinent to the discussion in the remainder of the thesis. First, the test for informed consent and

¹⁰⁷ Tom L Beauchamp and James F Childress, *Principles of Biomedical Ethics* (OUP 2013).

secondly, I will apply consent to tissue donation in a way that will provide a preface for the wider discussion of consent in subsequent chapters.

2.2 Respect for Autonomy

The ethical principle that I am going to focus on in this chapter is respect for autonomy. This is one of the four principles of biomedical ethics, introduced by Thomas Beauchamp and James Childress in 1977 in their book titled *Principles of Biomedical Ethics*, and could be said to underpin the ethics of the medical profession. In their latest book, which was published in 2013, they developed these principles.¹⁰⁸ Even though there are four principles, I am only considering the principle of respect for autonomy because of its relevant application to the three research questions that I aim to answer in this thesis. I will adopt Beauchamp and Childress's well-respected notion of autonomy: an action, or a decision to undergo an action, is autonomous when an individual meets three requirements. These requirements are that the individual acts: (1) intentionally, (2) with understanding, and (3) without control from internal states or external sources.¹⁰⁹

Analysing the principle of autonomy from an academic standpoint, John Harris suggests that fully autonomous decisions are largely ideal and 'control of our destiny' is beyond the scope of our power.¹¹⁰ He argues that the best decision an individual can make is a maximally autonomous decision. This suggests that the ability to make an autonomous decision is on a sliding scale, and that at some moments an individual may be able to make a more autonomous decision than at other moments. The three requirements that

¹⁰⁸ *ibid.*

¹⁰⁹ Beauchamp and Childress (n 107) 104.

¹¹⁰ John Harris, *The Value of Life: Introduction to Medical Ethics* (Routledge 1985) 195-205.

form part of Beauchamp and Childress's notion of autonomy, mentioned in the previous paragraph, need to be met in order for a decision to be autonomous, but if Harris's suggestion is adopted, they only need to be met to a certain standard for the decision to be considered autonomous. Therefore, an individual could make two decisions at different points in time, one may be more autonomous than the other, but both decisions would be considered autonomous if they meet the three requirements. Subsequently, this means that the decision an individual makes is the decision that is most autonomous in that particular situation, therefore, the decision made could differ depending on the circumstances of the individual. In addition, Harris states that:

Autonomy is the running of one's own life according to one's lights. The fact that their lights change colour and intensity over time is no evidence at all that the later lights are either better or more 'one's own' than the earlier ones. They're just different. To be autonomous, self-determined, just is to be able to do as one wishes – not to be able to do as one will wish at some future time.¹¹¹

If as an individual gets older a change in a decision is considered sufficient to undermine the original autonomous decision, then only the decisions of an adult would be considered maximally autonomous. Consequently, a minor could never make an autonomous decision because their decision could change as they subsequently became an adult, however, a minor's decision is considered autonomous if they are competent to make that decision.

Autonomy is an individualistic principle that focuses on the autonomous individual being able to make an autonomous decision. However, interpretations of autonomy

¹¹¹ *ibid* 199.

where individuals are isolated beings do not work in practice because they emphasise individual choice and neglect the importance of relationships and interdependence.¹¹² Individuals do not live in a vacuum, but are members of a community, therefore, they do not make their decisions in a vacuum. Susan Wolf argues that ‘by depicting the moral community as a set of atomistic and self-serving individuals strips away relationships that are morally central.’¹¹³ When an individual makes a decision and, whether consciously or unconsciously, takes into account their relationships with family and society this is known as relational autonomy.

2.2.1 Relational Autonomy

Relational autonomy was originally developed as a philosophical interpretation of the principle of autonomy with a feminist underpinning. Jennifer Nedelsky states that: ‘relationships are central to people’s lives – to what we are, to the capacities we are able to develop, to what we value, what we suffer, and what we are able to enjoy.’¹¹⁴ For Nedelsky, we are all ‘constituted by networks of relationships of which [we] are a part’ be they intimate relationships with employers, or social structural relationships such as with the government.¹¹⁵ Furthermore, Edward Dove et al recognise that most individuals do not make decisions as freestanding,¹¹⁶ isolated beings, but are ‘socially, culturally and embedded individual[s]’ who ‘exercise self-determination in and through networks of relations with others.’¹¹⁷ The individual is determined by ‘the relationship

¹¹² Kimberly Strong, Ian Kerridge, and Miles Little, ‘Saviour Siblings, Parenting and the Moral Valorisation of Children’ (2014) 28(4) *Bioethics* 187, 191.

¹¹³ Susan M Wolf, ‘Introduction: Gender and Feminism’ in Susan M Wolf (eds), *Feminism and Bioethics* (OUP 1996) 16.

¹¹⁴ Jennifer Nedelsky, *Law’s Relations: A Relational Theory of Self, Autonomy, and the Law* (OUP 2013) 3.

¹¹⁵ Nedelsky (n 114) 19.

¹¹⁶ Nedelsky (n 114) 19.

¹¹⁷ Edward S Dove and others, ‘Elberte v Latvia: Whose tissue is it anyway – Relational autonomy or the autonomy of relations?’ (2015) 15 *Medical Law International* 77, 80.

through which each person interacts with others',¹¹⁸ consequently the self is relational.¹¹⁹ Although these relationships are significant, they do not result in a decision wholly determined by them.¹²⁰ If the relationship determined what decisions an individual could make then there would be no true autonomy.¹²¹ Thus, we define ourselves in relationships to others and through relationships with others.¹²²

For the purposes of this thesis, my interpretation of relational autonomy is a combination of the interpretations proposed by Nedelsky and Dove et al. My interpretation is that if an individual makes an autonomous relational decision then that decision is made by considering the networks of relationships with others. In other words, for an individual to make a decision they need to take into account their relationships with others that underpin their lives, such as familial and societal relationships. The degree that a particular relationship is taken into account is dependent on the circumstances of that individual; the importance of the relationship; and the weight it has on the individual's life. An autonomous decision allows an autonomous individual to make an intentional, voluntary, and informed decision, a relational autonomous decision meets these three requirements, while at the same time the autonomous individual takes into account their relationships with others. The focus of relational autonomy is on the individual making the decision, not on the individuals who they have relationships with.

¹¹⁸ Nedelsky (n 114) 3.

¹¹⁹ Nedelsky (n 114) 4.

¹²⁰ Jocelyn Downie and Jennifer J Llewellyn, *Being Relational: Reflections on Relational Theory and Health Law* (UBC Press 2012) 5.

¹²¹ Nedelsky (n 114) 31.

¹²² C Whitbeck, 'A Different Reality: Feminist Ontology' in Ann Garry and Marilyn Pearsall (eds), *Women, Knowledge and Reality: Explorations in Feminist Philosophy* (Unwin Hyman, 1989) 68.

Applying the principle of relational autonomy to an everyday example: Alex needs to make a decision as to whether to go to a shop for urgent provisions. If Alex is to make a relational autonomous decision then he will make this decision by considering the relationships he has with others. I will sample a number of different relationships that Alex may have with others, and will examine each type of relationship in turn.

First, consideration to be made relates to Alex's family. If Alex is a single father of two young children who cannot be left unattended, he would need to decide whether to get someone to look after them, or to take them with him. Alex would need to examine the viability of each of these options. This relationship with his children may have a pivotal effect on his decision to go shopping at that time.

Secondly, Alex needs to take into account his relationship with society. Society is a term that covers Alex's relationships with friends, his employment, and his wider relationship with society such as the need to abide by societal rules. Depending on whether Alex is employed, self-employed or unemployed this relationship may have an impact on his decision. For example, Alex may only have a limited amount of time to visit the shop before he has to start work.

Thirdly, Alex should consider his relationship with his friends when making a decision. For example, would he be willing to asking a friend to look after the children for the time necessary to go to the shop? Would he be prepared to ask a friend to do the shopping for him? Or is part of Alex's shopping a favour he is doing for a friend?

If the parameters are now narrowed and we consider that Alex has no family, no friends, and is unemployed, he still has to consider his wider relationship with society such as the need to abide by societal rules. This relationship became truly apparent if the event occurred during the COVID-19 pandemic when isolation and face covering measures were put into place. Alex may also consider the gravity of the risk to himself resulting in a decision not to go to the shop but resort to shopping online.

Theoretically, when making his decision Alex could ignore all of these relationships, however, practically it is unlikely that he would do this because these relationships will impact on whether Alex goes to the shop or not. The weighting that Alex puts on a particular relationship will likely depend on his perception of the importance of this relationship. His decision will have resulted in him having considered a combination of these relationships, subsequently his decision will be relationally autonomous. In order to assist the reader as to what factors should be considered when examining a relationship, I have devised a list of factors and applied them to the different types of relationship.

(1) type of relationship

This factor considers what category the relationship may fall into, for example, family, friends, employment, and societal. A particular relationship may fall into more than one of these categories, but each relationship is unique. Furthermore, the relationship may be on a sliding scale of influence within that category. A familial relationship may result in a close emotional bond but in contrast may be a relationship in law only.

Another relationship that an individual has with wider society is in respect of their religious beliefs. Religion is a ‘human beings’ relation to that which they regard as holy, sacred, absolute, spiritual, divine, or worthy of especial reverence.’¹²³ There are many religions throughout the world each with own texts, practices and beliefs.¹²⁴ They take different stances on various aspects of society.¹²⁵ The weighting that this relationship has on the decision will depend on their commitment to their religion.

(2) length of the relationship

The length of relationship will not necessarily determine the weight that should be attached to it. Moreover, an individual may have a relationship for only a short period of time, for example, a period of employment. But a constant relationship will allow an individual to determine if that relationship should influence their decision and the weight that should be attached to it by ‘getting to know’ the individual.

(3) potential future interaction (temporary or long-term relationship)

A relationship may be for a defined period of an individual’s life, while for example a cultural relationship will usually last a life-time. The longevity of a relationship cannot always be predicted, for example, when two individuals get married, they intend to be married for a life-time, however, their relationship may breakdown. When the decision-maker is considering a relationship, they have to be pragmatic about its potential future.

¹²³ Britannica, ‘Religion’ <<https://www.britannica.com/topic/religion>> accessed 27/09/2020.

¹²⁴ Some recognised religions include: Christianity, Hinduism, Islam, Sikhism, Buddhism, Judaism.

¹²⁵ NHS Blood and Transplant, ‘Organ donation and your beliefs’ <<https://www.organdonation.nhs.uk/helping-you-to-decide/your-faith-and-beliefs/>> accessed 27/09/2020.

(4) frequency of interaction

Frequency of interaction enables a greater level of predictability within a relationship, and will result in an individual becoming familiar with how that relationship will influence their decision. But the frequency of interaction does not necessarily determine the weight a relationship should be given.

(5) type of interaction

The type of interaction considers whether it is a voluntary interaction or a necessary interaction. Using employment as an example, the individual has a necessary interaction with their employer and their work colleagues while in the work setting. But if they choose to interact with their work colleagues outside of this work environment then this would be a voluntary interaction.

Relationships are unique, and their importance and impact on decision-making can fluctuate. They are shaped by a plethora of influences that are wide-reaching and could include, but are not limited to: financial, knowledge, cultural, religious beliefs, values, respect, gender, attitude, and third-party and community involvement and opinion. The decision-maker may consider other factors when examining a particular relationship, but as already emphasised each consideration will be dependent on the circumstances of that individual. While no one relationship will determine the outcome of the decision made, I argue that these relationships are a necessary part of the decision-making.

2.2.1.1 Relational Autonomy and the Law

The example I provided, with Alex, involved the application of relational autonomy to a common everyday decision. Relational autonomy is a philosophical concept that has

not been fully explored within a legal context. However, Roy Gilbar and Charles Foster have argued that the Court of Appeal in *ABC v St George's Healthcare NHS Trust*¹²⁶ adopted a relational approach to their decision-making.¹²⁷ They assert this 'because it [the Court of Appeal] acknowledged that any decision made by one individual has implications for her significant others.'¹²⁸ But, Gilbar and Foster did not expand on this reasoning nor provide a definition of relational autonomy. It is my contention that this reasoning is not in fact an example of relational autonomy. As I understand, and have interpreted the principle of relational autonomy, the impact of the relationship is the influence that the relative has on the individual making the decision. While Gilbar and Foster appear to consider relational autonomy to be the impact the decision has on the relationship between the individual making the decision and the relative. My interpretation of relational autonomy is that the decision is influenced by the relationship with the relative rather than the relative being influenced by the decision.

So, using the example of Alex who has two young children. My interpretation of relational autonomy is that the decision that Alex makes as to whether to go to the shop will be influenced by the fact, he cannot leave his two young children at home alone. While Gilbar and Foster's interpretation would be that if Alex made a decision to go to the shop then the impact this would have on his children would be that he would have to take them with him or they would have to be looked after by someone else. Gilbar and Foster's interpretation looks at the resultant impact of the decision. Using my interpretation of relational autonomy, the parent's decision-making thought process is: I want to go to the shop, I have a child, I cannot leave this child alone, therefore, I cannot

¹²⁶ [2017] EWCA 336.

¹²⁷ Roy Gilbar and Charles Foster, 'It's Arrived! Relational Autonomy come to Court: *ABC v St George's Healthcare NHS Trust* [2017] EWCA 336' (2017) 26 Medical Law Review 125, 132.

¹²⁸ *ibid.*

go to the shop. While Gilbar and Foster’s decision-making thought process is: if I went to the shop then I would be leaving my child alone, therefore, I cannot go to the shop. In this instance the end decision in both scenarios is the same, however, this may not be the case in every situation. Gilbar and Foster go on to state that:

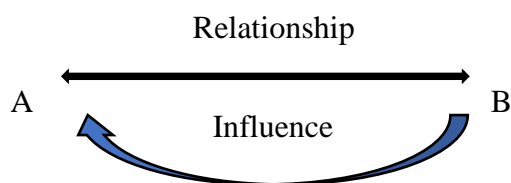
the court recognised that the personal decision of the patient to undergo genetic testing had implications for her family as a unit and for the interests of individual relatives in making informed decisions.¹²⁹

But I argue that this reasoning is flawed because the relationship should impact the decision not the other way around. Gilbar and Foster are correct in stating that a decision made by an individual has implications for the family unit, but this is not the principle of relational autonomy, as relational autonomy is the influence that a relationship has on the initial decision made by the individual, not the subsequent impact the decision has on the relationship. The following is, in diagrammatic form, my interpretation of relational autonomy, and Gilbar and Foster’s interpretation of relational autonomy:

A = the individual making the decision

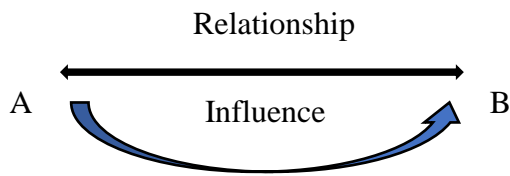
B = the individual who has a relationship with A

Figure 1: My Interpretation of Relational Autonomy



¹²⁹ Gilbar and Foster (n 127).

Figure 2: Gilbar and Foster's Interpretation of Relational Autonomy



Gilbar and Foster acknowledge their interpretation of relational autonomy into legal decision-making, but if their understanding of the concept of relational autonomy is incorrect then *ABC v St George's Healthcare NHS Trust* is not the introduction of relational decision-making by the courts. If the principle of relational autonomy is to be used by the courts within their decision-making, then it has scope to be used within all areas of medical law, including tissue donation. However, it is unclear whether courts in the future will adopt a relational approach, further analysis is required to determine whether relational decision-making with regard to medical procedures becomes the norm instead of the exception.

2.2.1.2 Relational Autonomy and Tissue Donation

Tissue donation between siblings has a familial relational underpinning due to the relationship between the donor and the recipient,¹³⁰ therefore, I am going to argue that relational autonomy should be adopted in this area of decision-making. If the minor was an autonomous individual who made decisions in isolation, they would only consider their own interests. However, a decision as to whether to donate may be influenced by the relationship the potential donor has with the intended recipient, which

¹³⁰ see Chapter 1 at 1.1.3.1 for further discussion about sibling to sibling donation; Strong, Kerridge and Little (n 112) 191; John Christman, 'Relational Autonomy, Liberal Individualism and the Social Constitution of Selves' (2004) 117 *Philosophical Studies* 143, 164.

includes the effect the donation has on the recipient's wellbeing as well as the family unit as a whole. Therefore, the decision that is made about whether to donate should take into account the relationships that the donor has with others, in particular the intended recipient. However, the focus must continue to be on the minor donor's interests rather than protecting the interests of the recipient.

There is a difference between a relationship that influences a minor, but allows them to make a relational autonomous decision, and a relationship that is a coercive influence. Coercion occurs 'if one person intentionally uses a credible and severe threat of harm or force to control another.'¹³¹ Coercive pressure may be exerted on the potential donor, knowingly or unknowingly, by those who they have a relationship with. This could include, but is not limited to, those with PR, other family members, medical professionals, and the intended recipient.¹³² If a decision to donate is made as a result of coercion then it would not be an autonomous decision. I will discuss in Chapter 3 how the Human Tissue Authority (HTA) require interviews and reports to be conducted by an Independent Assessor (IA) or Accredited Assessor (AA) as a mechanism to prevent coercive situations in cases of tissue donation from living minors consequently protecting the minor donor's interests. The need for a preventative mechanism recognises that coercion could be an issue within tissue donation.

¹³¹ Beauchamp and Childress (n 107) 138; Robert Nozick, 'Coercion' in S Morgenbesser, P Suppes, and M White (eds), *Philosophy, Science and Method: Essays in Honour of Ernest Nagel* (St Martin's 1969) 440-472; Bernard Gert 'Coercion and Freedom' in J Roland Pennock and John W Chapman (eds), *Coercion: Nomos XIV* (Aldine Atherton, 1972) 36-37. See also A Wertheimer, *Coercion* (Princeton University Press 1987).

¹³² Shih-Ning Then, *Children as Tissue Donors: Regulatory Protection, Medical Ethics and Practice* (Springer, 2018) 22.

Throughout my thesis the discussion and application of autonomy, and relational autonomy, will focus on the minor donor making the decision as to whether to donate or not, and I will argue that if the competent minor makes an autonomous decision then it should be respected by those with PR and the court. However, if a minor is incompetent and cannot make an autonomous decision as to whether to donate, then those with PR will make the decision on their behalf. But relational autonomy focuses on the individual making a decision on their own behalf and does not consider those making a decision on behalf of others, such as those with PR making a decision on behalf of an incompetent minor. I propose that there should be a concept of relational parental decision-making. This is when those with PR make decisions on behalf of an incompetent minor by taking into account the relationships that the minor has with others.

2.3 Relational Parental Decision-Making

Within legal academic literature there is no discussion about whether the relationships that a minor has with others should influence a decision made on their behalf by those with PR. If the minor is incompetent and the decision as to whether they can be a tissue donor is made by those with PR, the current law states that they should make the decision based on what is in the minor's best interests by taking into account a range of factors.¹³³ In Chapter 5, I argue that the best interests test should continue to be used to determine whether a minor should be a tissue donor as it allows the decision-maker to take into account a range of factors, but I propose that it should be reformed so that familial interests, including the relationships that the minor has with others, are incorporated into the test.¹³⁴

¹³³ Children Act 1989; Children (Scotland) Act 1995.

¹³⁴ at 5.5.

If those with PR are going to take into account the relationships of a minor then these relationships should not be coercive or be covertly influential in the decision-making process. The close intimate relationship the potential donor has with the potential recipient should not be the overriding factor when those with PR are determining whether the minor should be a donor. Furthermore, those with PR should not directly compare or weigh up the interests of the minor donor and the recipient to determine whether they should donate.¹³⁵ When those with PR make a decision on behalf of an incompetent minor, instead of treating the minor in isolation, I propose that the relationships that the minor has with others should be a contributing part of the decision-making. I have called this type of decision-making relational parental decision-making.

In order to explain this concept, I will apply it to a tissue donation example. There are two siblings who are both minors, Katrina and Chris. Chris requires a bone marrow transplant otherwise he will die, and it is proposed that Katrina could be his donor. Katrina is aged 5, thus an incompetent minor. In order to decide whether Katrina is to be a donor those with PR, her parents in this case, will need to decide whether the donation is in Katrina's best interests, by considering the best interests test set out in the relevant statute.¹³⁶ If her parents were to undertake relational parental decision-making, they would not only consider her best interests but also consider the relationships that Katrina has with others.

¹³⁵ see Chapter 5 at 5.4.2 for discussion about the best interests test considering both the minor donor and recipient.

¹³⁶ see Chapter 5 at 5.5 for discussion of the best interests test.

First, her parents would consider Katrina's relationship with Chris, this would involve analysing the impact this relationship has on Katrina, so for example they may look at whether the siblings spend voluntary time together, the closeness of their relationship, and how they interact with each other. But her parents must not conclude that Katrina should be a tissue donor purely on the basis that it will save Chris' life. This should merely form part of the decision-making process.

Secondly, the parents would need to consider the relationship that Katrina has with the family unit as a whole. Say there is a third sibling, Caitlin. As part of the relational parental decision-making Katrina's parents would need to consider the relationship that Katrina has with Caitlin. If Caitlin is a much older sibling and no longer lives with the family then this relationship could have less of an impact compared to her relationship with Caitlin if she was still living in the family home. As part of the family unit, Katrina's parents will consider their relationship with Katrina, this relationship is important since Katrina is very young so she relies heavily on their support. Other family relationships may be considered depending on who Katrina has contact with in her family, for example, grandparents may be considered if Katrina visits them regularly and has a close relationship with them. The family unit relationships that are considered will be different for each minor as it is dependent on the family dynamics.

Thirdly, her parents would need to consider Katrina's relationship with society. Society is a term that covers Katrina's relationships with friends, her school such as her teachers, and her wider relationship with society such as the need to abide by societal requirements. While Katrina's relationships with her friends and her teachers may have some weighting on the decision-making, as she is only 5 years old her relationship with

wider society is very limited, and it is likely that in this instance it would not have a significant influence on the decision.

Prescribing which relationships those with PR should take into account and how much weight should be given to each of them is difficult as it will depend on the age of the minor, the family dynamics, and the types of relationships the minor has. However, at the same time, those with PR should not be disregarding fundamental relationships or only giving them minimal weight in order to achieve their desired decision. Therefore, this decision-making is not objective, but, if those with PR were making a decision on behalf of a minor without considering relationships that are fundamental to the minor's life or giving them sufficient weighting then it should be seen as defective decision-making and should be disregarded. Earlier in this chapter I devised a list of factors that a decision-maker should use when considering a particular relationship. This list can also assist those with PR when making a decision on behalf of a minor to be a tissue donor.¹³⁷ To assist the reader I have reproduced the list here with some added discussion in relation to sibling to sibling donation.

(1) type of relationship

In the case of a tissue donation, one of the categories of relationship is the recipient. As it is a sibling to sibling donation this relationship may also involve a close emotional familial bond. However, this particular relationship will be different to other familial relationships because of the altruistic nature of the donation.

¹³⁷ at 2.2.1.

(2) length of the relationship

With sibling to sibling donation, it is likely that the donor and the recipient will have had a relationship for the majority of their life (depending on whether they are half-siblings and the age of the youngest sibling).

(3) potential future interaction (temporary or long-term relationship)

As the donor and recipient are siblings there is an expectation that their relationship will last a life-time. However, there is a risk that familial relationships can breakdown even between very close family members, therefore, the decision-maker needs to be pragmatic about the relationship's potential future.

(4) frequency of interaction

The frequency of interaction between the donor and the recipient will partially depend on their living arrangements. However, the frequency of this interaction will not necessarily determine the weight the relationship should be given.

(5) type of interaction

A relationship between siblings is a hybrid-type of interaction. If they live together then it is a necessary interaction, but it can also be a voluntary interaction if they choose to spend time together. When those with PR consider this factor, they need to particularly examine the voluntary types of interaction between the donor and the potential recipient.

There may be additional factors that those with PR may need to consider that are unique to a particular relationship. While no one relationship will determine the outcome of

the decision made on the minor's behalf, I argue that these relationships are a necessary part of the decision-making process.

So far, the discussion has focused on the ethical principle of autonomy in the form of relational autonomy and relational parental decision-making. However, the principle of autonomy needs to be conveyed into a legal principle in order for the decision-maker's decision to be legally valid. The ethical principle of autonomy is transferred into law through the legal concept of consent. Respect for autonomy allows an individual to make a decision about themselves, for example to undergo a medical procedure, and consent is the permission given by that individual for the medical professional to perform that medical procedure on them.¹³⁸ The discussion will now focus on the legal principle of consent in the context of tissue donation.

2.4 Legal Principle of Consent

The legal principle of consent is well-recognised and understood within academia, therefore, I am not going to attempt to cover ground that has already been well-trodden by previous academics.¹³⁹ However, I do wish to examine two points that I feel are pertinent to the discussion in the remainder of the thesis. First, the test for informed consent, and secondly, the lawfulness of tissue donation from a living minor in its application to consent.

¹³⁸ Franklin Miller and Alan Wertheimer, *The Ethics of Consent: Theory and Practice* (OUP, 2009) 57.

¹³⁹ *Chatterton v Gerson* [1981] 1 All ER 257; *R v Tabassum* [2000] 2 Cr App R 328; *R v Brown* [1993] 2 All ER 75; Sheila McLean, *Autonomy, Consent and the Law* (Routledge 2010); Penney Lewis, 'The Medical Exception' (2012) 65(1) *Current Legal Problems* 355.

2.4.1 Informed Consent

In order for an individual to provide informed consent they must have received information about the associated risks of the procedure from the medical professional to be able to make a decision as to whether to undergo that procedure. The current test for information disclosure is contained in *Montgomery v Lanarkshire Health Board*:

An adult person of sound mind is entitled to decide which, if any, of the available forms of treatment to undergo, and her consent must be obtained before treatment interfering with her bodily integrity is undertaken. The doctor is therefore under a duty to take reasonable care to ensure that the patient is aware of any material risks involved in any recommended treatment, and of any reasonable alternative or variant treatments. The test of materiality is whether, in the circumstances of the particular case, a reasonable person in the patient's position would be likely to attach significance to the risk, or the doctor is or should reasonably be aware that the particular patient would be likely to attach significance to it.¹⁴⁰

Lords Reed and Kerr, in *Montgomery*, stated that this test of materiality is not unrealistic because what it demands is already required by the General Medical Council (GMC).¹⁴¹

The GMC expressed that:

clear, accurate information about the risks of any proposed investigation, or treatment, presented in a way patients can understand, can help them make informed decisions. The amount of information about risks that you should share with patients will depend

¹⁴⁰ [2015] UKSC 11, [87]; this is subject to the therapeutic privilege which entitled doctors to withhold information if they reasonably consider it would be seriously detrimental to the patient's health.

¹⁴¹ *Montgomery v Lanarkshire Health Board* [2015] UKSC 11, [93].

on the individual patient and what they want or need to know. Your discussions with patients should focus on their individual situation and the risk to them.¹⁴²

The test in *Montgomery* will be analysed as well as applied to tissue donation in Chapter 3 when I consider whether there is a difference between the use of the term consent in the Human Tissue Act 2004 and the use of the term authorisation in the Human Tissue (Scotland) Act 2006.¹⁴³

2.4.2 Consent and Tissue Donation

Consent is a principle that is applicable to every type of medical procedure, ranging from the trivial, such as applying a sticking plaster, to the life-changing, such as amputation. Medical procedures that would now be considered routine, such as tissue donation, were once experimental and did not explicitly fall under the medical exception of consent. A medical procedure may start as a procedure which society, including medical professionals, think of as not acceptable, and should not be offered to individuals, such as gender reassignment or abortion.¹⁴⁴ However, over time opinions change and the view within society shifts regarding that particular medical procedure, which subsequently becomes a recognised procedure for medical professionals to offer.¹⁴⁵ This is particularly notable within the field of tissue donation.

When an innovative medical procedure is performed for the first time the lawfulness of the procedure could be called into question, and the consent that is provided by the

¹⁴² General Medical Council, *Consent: Patients and Doctors Making Decisions Together* (2008) Part 2: Making Decisions about Investigations and Treatment, para 28.

¹⁴³ at 3.4.1.

¹⁴⁴ Sara Fovargue and Alex Mullock (eds), *The Legitimacy of Medical Treatment: What Role for the Medical Exception?* (Routledge, 2015) 8.

¹⁴⁵ *ibid.*

patient may not be sufficient to absolve the medical professional from legal action.¹⁴⁶ The introduction of the Human Organ Transplant Act 1989 was the first time that tissue donation from a living individual was expressly included in legislation in England and Wales, and Scotland even though the first kidney donation from a living individual was performed in 1960.¹⁴⁷ Therefore, questions are raised as to whether the first kidney donor could have provided legally valid consent to the procedure. Lord Mustill observed that:

[consent] cannot be direct explanation for it, since much of the bodily invasion involved in surgery lies well above any point at which consent could even arguably be regarded as furnishing a defence. Why is this so? The answer must be in my opinion that proper medical treatment, for which actual or deemed consent is prerequisite, is in a category of its own.¹⁴⁸

Lord Justice Edmund Davis went further and stated that he would:

be surprised if a surgeon were successfully sued for trespass to the person or convicted of causing bodily harm to one of full age and intelligence who freely consented to act as a donor – always provided that the operation did not present unreasonable risk to the donor’s life or health. That proviso is essential. A man may declare himself ready to die for another, but the surgeon must not take him at his word.¹⁴⁹

Tissue donation from a living individual is different to other types of medical procedure. When an individual usually provides consent to a medical procedure it is because that

¹⁴⁶ *R v Tabassum* [2000] 2 Cr App R 328.

¹⁴⁷ NHS, ‘History of Donation’ (NHS Choices, 2015) <www.nhs.uk/tools/documents/transplant.htm> accessed 01/05/2017; see Chapter 1 at 1.2 for further discussion about the medical and legal history of tissue donation.

¹⁴⁸ *R v Brown* [1993] 2 All ER 75, 109.

¹⁴⁹ *ibid.*

procedure will medically benefit them. However, as will be discussed in Chapter 4, tissue donation from a living individual is not curative or prophylactic but medically harms the donor. Therefore, when an individual provides consent to be a tissue donor, they are actually consenting for a medical professional to actively harm them without a resultant medical benefit. However, Lord Justice Edmund Davies contended that:

the surgeon has quite enough on his hands without having to consider the legality of his procedure. It is admittedly unlikely that the existing law keeps many transplant teams awake at night. Nevertheless, at present they are undoubtedly exposed to an irritant and a theoretical risk of forensic indignity to which they ought not to be subjected.¹⁵⁰

Due to the nature of a tissue donation procedure the need for a statute to establish its lawfulness beyond doubt is:

connected to the lack of therapeutic benefit to the donor and could be regarded as implying that, in the absence of clear statutory authorisation, the lack of such a benefit would render the practice questionable and potentially not within the boundaries of proper medical treatment.¹⁵¹

Unlike other medical procedures, the lawfulness of tissue donation from a living individual is established by statute in England and Wales, and Scotland in the Human Tissue Act 2004, and the Human Tissue (Scotland) Act 2006 respectively. This may provide some indication of the exceptional nature of this kind of medical procedure, since all medical procedures are not included in statute in order to establish their lawfulness.

¹⁵⁰ Lord Justice E Davies, 'A Legal Look at Transplants' (1969) 62 *Journal of the Royal Society of Medicine* 633, 634.

¹⁵¹ Fovargue and Mullock (n 144) 130.

2.5 Concluding thoughts

This chapter has analysed the principle of autonomy, where I adopted Beauchamp and Childress's notion of autonomy: an action, or a decision to undergo an action, is autonomous when an individual meets three requirements. These requirements are that the individual acts: (1) intentionally, (2) with understanding, and (3) without control from internal states or external sources. I explored the principle of relational autonomy concluding that my interpretation is that if an individual makes an autonomous relational decision then that decision is made by considering the networks of relationships with others. In other words, for an individual to make a decision they need to take into account their relationships with others that underpin their lives, such as familial and societal relationships. I used the example of Alex making a decision to go to the shop to assist the reader in the application of relational autonomy. Moreover, in order to assist the reader as to what factors should be considered when examining a relationship, I devised a list of factors and applied them to the different types of relationships. I introduced the new and novel principle of relational parental decision-making, and explained it using the example of Kat, Chris, and Caitlin. I concluded that, as with relational autonomy, when those with PR are making a decision on behalf of an incompetent minor, they need to take into account the minor's relationships with others, and the list of factors can assist them when considering the weight of a particular relationship.

The next chapter will provide a clear conception of what the regulatory framework of living minors as tissue donors actually says and identify where its defects lie. The discussion will comprise of two predominant aspects, first, I will produce a number of

tables and charts that provide a summary of the legislation and professional guidance with regard to the donation process. These tables and charts are merely a condensed and simplified form of the lengthy and complex information that is available about the donation process so the regulatory framework is clear to the reader. Secondly, by developing the discussion in this chapter on the test for information disclosure established in *Montgomery* when considering the differences between the term consent as used in the 2004 Act and the term authorisation as used in the 2006 Act. I will consider whether there is a material difference between the two terms, by examining the legal definitions as well as their interpretation in the Codes of Practice. I shall conclude that the difference between the two terms is superficial as the test for informed consent and informed authorisation are identical.

Chapter 3

Regulatory Framework of Tissue Donation

3.1 Introduction

The regulatory framework of medicine is a combination of legal regulation and professional guidance, which includes codes of practice (CoP). This is evident in England and Wales, and Scotland in relation to tissue donation from living minors. The current legislation that regulates tissue donation from living minors in England and Wales, and Scotland is the Human Tissue Act 2004, and the Human Tissue (Scotland) Act 2006 respectively. The Human Tissue Authority (HTA)¹⁵² have produced a number of CoP and guidance documents that supplement this legislation. This regulatory framework was implemented following the organ retention scandals that became public knowledge in the late 1990s and early 2000s.

There are two main aspects to this chapter. First, as one of the aims of this thesis is to recommend reform to the regulatory framework, I need to provide a clear conception of what the regulatory framework actually says and identify where its defects lie. In order to do this, I will produce a number of tables and charts that provide a summary of the legislation and professional guidance with regard to the donation process. These tables and charts are merely a condensed and simplified form of the lengthy and complex information that is available about the donation process. I will produce them to assist the reader so there is a basis for comparison between the current framework and my proposed developments. Moreover, there is scope that they could be considered by the

¹⁵² see Chapter 1 at 1.2.3 for information about role of the Human Tissue Authority.

HTA to assist when creating a more workable conception of the donation process for medical professionals as well as donors, recipients, and the general public.

Secondly, I will analyse the difference between the use of the term ‘appropriate consent’ in the 2004 Act compared to the use of the term ‘authorisation’ in the 2006 Act. I will consider whether there is a material difference between the two terms, by examining the legal definitions as well as their interpretation in the CoP. I shall conclude that the difference between the two terms is superficial as the test for informed consent and informed authorisation are identical. It would be clearer and more precise if the term consent is used and replaces authorisation in the 2006 Act with regard to tissue donation.

3.2 Organ Retention Scandals

In 1999 it became public knowledge that organs and tissue were being retained after post-mortem examinations, predominantly at the Bristol Royal Infirmary and the Royal Liverpool Children’s Hospital (Alder Hey).¹⁵³ As a result, the Government launched several inquiries to investigate post-mortem practice.¹⁵⁴ These organ retention scandals resulted in the Human Tissue Act 1961 and the Human Organs Transplant Act 1989 being repealed.¹⁵⁵ This was based on the recommendation by the Chief Medical Officer in *The Removal, Retention and use of Human Organs and Tissue from Post-Mortem*

¹⁵³ Valerie M Sheach Leith, ‘Consent and nothing but consent? The organ retention scandal’ (2007) 29(7) *Sociology of Health and Illness* 1023.

¹⁵⁴ House of Commons, *The Royal Liverpool Children’s Inquiry Report* (HC12-II, The Stationery Office 1999) (Redfern Inquiry); Bristol Royal Infirmary, *The Report of the Public Inquiry into Children’s Heart Surgery at the Bristol Royal Infirmary 1984-1995: Learning from Bristol* (Cm 5207(I), 2001) (Kennedy Inquiry); Scottish Executive, *Independent Review Group on Retention of Organs at Post-Mortem: Final Report* (Crown 2001); Northern Ireland Executive, *The Human Organs Inquiry Report* (Crown 2002); HM Inspector of Anatomy, *Issacs Report: The investigation of events that followed the death of Cyril Mark Issacs* (Stationery Office 2003). See also Human Tissue Act 2004, Explanatory Notes para 5.

¹⁵⁵ The Anatomy Act 1984 was repealed in England and Wales, and amended in Scotland; see Chapter 1 at 1.2.2 for further discussion about the Human Organ Transplants Act 1989.

Examination report that the law on consent for the retention and potential use of human tissue must be amended with immediate effect:

to clarify that consent must be sought from those with parental responsibility for the retention of tissue or organs from post-mortem on children beyond the time necessary to establish the cause of death.¹⁵⁶

Legislation on the lawful storage and use of human bodies, body parts, organs and tissue from the living and the deceased was implemented in England¹⁵⁷ and Wales¹⁵⁸, under the Human Tissue Act 2004 with the introduction of an ‘appropriate consent’ regime, and in Scotland¹⁵⁹, under the Human Tissue (Scotland) Act 2006 with the introduction of an ‘authorisation’ regime. This was the first time that the regulation of tissue donation in England and Wales was separated from the regulation of tissue donation in Scotland by the enactment of two pieces of separate legislation. The reasoning for this was because Scotland wanted to enact legislation that was different from the one proposed in England and Wales. While the 2004 Act and 2006 Act provided a more comprehensive form of regulation of the use of human tissue, compared to previous legislation, they have proved to be less than satisfactory as they are supplemented with copious amounts of complex and incomplete CoP that fail to provide information that is readily understood. I am now going to discuss the 2004 Act, and the 2006 Act, the corresponding regulations, and the CoP produced by the HTA that supplement them to provide a clearer understanding of the current regulatory framework.

¹⁵⁶ Department of Health, Department for Education and Employment, and Home Office, *The removal, retention and use of human organs and tissue from post-mortem examination* (London 2001) 38; Human Tissue Act 2004, Explanatory Notes para 6.

¹⁵⁷ Human Tissue Act 2004 and the Organ Donation (Deemed) Consent Act 2019.

¹⁵⁸ Human Tissue Act 2004 and the Human Transplantation (Wales) Act 2013.

¹⁵⁹ Human Tissue (Scotland) Act 2006 and the Human Tissue (Authorisation) (Scotland) Act 2019.

3.3 Human Tissue Act 2004

The Act which currently regulates the removal, retention, and use of tissue from the living in England and Wales is the 2004 Act.¹⁶⁰ In a departure from previous legislation,¹⁶¹ the 2004 Act made ‘appropriate consent’ a fundamental principle. The ‘activities’ that are lawful if ‘appropriate consent’ has been provided are set out in section 1(1).¹⁶² Although the 2004 Act emphasises the importance of consent, it does not explicitly define ‘appropriate consent’¹⁶³, the presumption is that the informed consent test as set out in *Montgomery v Lanarkshire Health Board*¹⁶⁴ is the standard that needs to be met. The aim of the 2004 Act was only to be a framework so it did not provide extensive information about the donation procedure nor contain provisions to remedy all issues that arose in the organ retention scandals. For example, the legislation does not create civil remedies for families and individuals distressed by the non-consensual use of tissue,¹⁶⁵ which could have been an important inclusion in the Act following the events of the organ retention scandals.

The 2004 Act is supplemented by CoP that aim to provide practical guidance as to the application of the law of the use and storage of human tissue.¹⁶⁶ Although updates have been made over time with a view to produce more workable guidance, the major problem is that they continue to be long and complex documents. For instance, there

¹⁶⁰ Organ donation from deceased individuals is regulated by the Human Transplantation (Wales) Act 2013 in Wales, and by the Organ Donation (Deemed) Consent Act 2019 in England.

¹⁶¹ Human Organ Transplant Act 1989.

¹⁶² Human Tissue Act 2004, s.1(1).

¹⁶³ HC Deb 15 January 2004 vol 416 cc984-1045.

¹⁶⁴ [2015] UKSC 11, [93]; see Chapter 2 at 2.4.1 for further discussion about *Montgomery*.

¹⁶⁵ Kathleen Liddell and Alison Hall, ‘Beyond Bristol and Alder Hey: The future regulation of human tissue’ (2005) 13 *Medical Law Review* 170, 184; it is possible that compensation for wrongful retention or use in research might now be obtained through criminal inquiry compensation schemes. But otherwise wronged families and individuals will continue to find it difficult to obtain compensation; *AB v Leeds Teaching Hospital NHS Trust* [2004] EWHC 644 (QB).

¹⁶⁶ Human Tissue Act 2004, s.26(2); Human Tissue Authority, *HTA Codes of Practice and Standards* <<https://www.hta.gov.uk/hta-codes-practice-and-standards-0>> accessed 08/02/2019.

are separate CoP for the donation of a solid organ/non-regenerative tissue¹⁶⁷ (*Code of Practice F*¹⁶⁸) and the donation of regenerative tissue (*Code of Practice G*¹⁶⁹). To complicate matters further, the guidance on the principle of consent is in a separate CoP (*Code of Practice A*).¹⁷⁰ This unwieldy system requires a medical professional not only to collate information from a number of CoP, but also interpret them in practice. Following the interpretation of the CoP, the medical professional would then have to make a judgment as to whether the donation should proceed. This complicated set of guidance could lead to inadvertent breaches of the CoP by medical professionals.

It is the norm that CoP are for the use of a medical professional, and the HTA state words to this effect ‘The Codes give practical guidance to professionals carrying out activities which lie within the HTA’s remit under the HT Act.’¹⁷¹ However, they further state that ‘they will also be of interest to members of the public’¹⁷² which infers that members of the public may consult the CoP, this could include the donor, the donor’s family, the recipient and other people who are involved in the donation process. If the CoP are also targeted at a public audience then the HTA need to ensure that they are readily understood by this audience. I argue that the information within the CoP is not set out in a readily understood manner for those involved in the donation process who may want to consider the finer details of the donation process.

¹⁶⁷ see Chapter 1 at 1.1.2 for the definition of non-regenerative tissue.

¹⁶⁸ Human Tissue Authority, *Code of Practice F: Donation of solid organs and tissue for transplantation* (2017).

¹⁶⁹ Human Tissue Authority, *Code of Practice G: Donation of allogeneic bone marrow and peripheral blood stem cells for transplantation* (2017).

¹⁷⁰ Human Tissue Authority, *Code of Practice A: Guiding Principles and the Fundamental Principle of Consent* (2017).

¹⁷¹ HTA, *Code of Practice F* (n 168) para 4.

¹⁷² HTA, *Code of Practice F* (n 168) para 4.

Not only do the CoP appear overly complex, but they are also incomplete as they are expected to cover such a wide number of matters. The inclusion of CoP were a planned addition to the framework set out by the 2004 Act, but they were not produced by the HTA until the 2004 Act was enacted which meant that Members of Parliament (MPs) were uncertain on the final form of regulation as a whole when debating the 2004 Act: ‘I fear that the Bill [the 2004 Act] leaves so many aspects to be covered by codes of practice in the future that the House can have but little idea of what the actual landscape that will eventually result will look like.’¹⁷³ In some instances, MPs such as Mr Andrew Lansley, expected that the HTA in their CoP would set out relevant definitions, such as for ‘appropriate consent’.¹⁷⁴ However, this did not happen, meaning that the informed test as set out in *Montgomery* is used, and if there is a dispute over whether ‘appropriate consent’ has been provided, this is a matter that will need to be decided by the court.

I suggest that CoP can continue to be produced by the HTA, but the format and content of the CoP need to be revised. At the moment, each CoP considers both adults and minors, but I recommend that there should be one CoP that covers living adults as tissue donors, and a separate CoP that covers living minors as tissue donors. This CoP would include all of the relevant guidance that is required in order for a living minor to be a tissue donor. This includes the information on consent that is currently included within *CoP A*. Medical professionals are currently required to cross-reference between different CoP to ensure that they have all of the necessary information. This new CoP will resolve this issue and allow for a more streamlined set of guidance.

¹⁷³ Hansard (n 163).

¹⁷⁴ Hansard (n 163).

3.3.1 Tissue Donation from Living Minors in England and Wales

The 2004 Act permits the removal or use of ‘transplantable material’¹⁷⁵ from a living minor for the purpose of transplantation.¹⁷⁶ In order for a donation to proceed the conditions specified in the Human Tissue Act 2004 (Persons who Lack Capacity to Consent and Transplant) Regulations 2006 must be met.¹⁷⁷ Section 54(1) of the 2004 Act defines minors, for the purposes of the Act, as individuals under the age of 18.

My analysis of the regulatory framework will be split into two sections, first, incompetent minors, and secondly, competent minors. Within these two sections I will consider the regulation of solid organ/non-regenerative tissue, and regenerative tissue separately as these are addressed separately in the CoP. As domino transplant is a type of solid organ donation, since it involves the donation of the heart, it will be considered under solid organ/non-regenerative tissue donation.¹⁷⁸ This structure has been used in an attempt to minimise confusion when discussing the relevant legislation and CoP.

3.3.1.1 Incompetent Minor

Incompetent minors are those that cannot provide consent on their own behalf to be a tissue donor,¹⁷⁹ consequently, an individual with PR will provide consent on the minor’s behalf. Section 2(3) of the 2004 Act states that ‘appropriate consent’ means that consent of a person who has parental responsibility for him’.

¹⁷⁵ Human Tissue Act 2004 (Persons who Lack Capacity to Consent and Transplant) Regulations 2006, reg.10(1) defines ‘transplantable material’ as ‘an organ or part of an organ if it is to be used for the same purpose as the entire organ in the human body; bone marrow; and peripheral blood stem cells, where that material is removed from the body of a living person with the intention that it be transplanted into another person.’

¹⁷⁶ Human Tissue Act 2004, s.33.

¹⁷⁷ HTA, *Code of Practice F* (n 168) para 18. See also paras 35-39 for further information.

¹⁷⁸ see Chapter 1 at 1.1.2 for the definition of domino transplant.

¹⁷⁹ see Chapter 5 for further discussion of incompetent minors as tissue donors.

3.3.1.1.1 Solid Organs/Non-Regenerative Tissue

CoP F, which deals solely with the donation of solid organs/non-regenerative tissue for transplantation, contains limited information about the use of living minors as tissue donors because minors are only considered ‘in extremely rare circumstances.’¹⁸⁰ Therefore, in such cases the decision as to the lawfulness of the donation is heavily placed on court approval and HTA approval. Normally, in relation to a medical procedure, the consent of just one individual with PR suffices.¹⁸¹ However, the courts have made it clear that where a major or irreversible decision needs to be made about a minor, or where there is disagreement between those sharing PR, both parents’ consent is required or the case must be referred to the court.¹⁸² Accordingly, if non-regenerative tissue donation from a living minor is to be considered ‘a major or irreversible decision’, the courts will require the consent from all of those who have PR for the minor.

If the donation is going to proceed, then once consent has been provided by those with PR, an Independent Assessor (IA) must separately interview the potential donor, the recipient, and one of the individuals with PR to assess whether the HTA requirements have been met.¹⁸³ The HTA provide guidance on what must be covered in the interview depending on whether it is with the donor, recipient, or those with PR for the donor.¹⁸⁴ In addition, as donation between siblings is a directed donation, an interview must be undertaken with the donor and recipient together.¹⁸⁵ The purpose of this combined interview is threefold: to observe the interaction between the donor and recipient, to

¹⁸⁰ HTA, *Code of Practice F* (n 168) para 44.

¹⁸¹ General Medical Council, *Treatment and Care Towards the End of Life: good practice in decision making* (2010) para 104.

¹⁸² see *Re J (Child’s Religious Upbringing and Circumcision)* [1992] 2 FLR 1004 CA for discussion on parental disagreement over medical treatment of a minor.

¹⁸³ HTA, *Code of Practice F* (n 168) paras 35, 70 and 95; Human Tissue Act 2004 (Persons who Lack Capacity to Consent and Transplants) Regulation 2006, reg.11(3)(a) and (b).

¹⁸⁴ HTA, *Code of Practice F* (n 168) paras 37-38.

¹⁸⁵ HTA, *Code of Practice F* (n 168) para 84.

understand whether ‘duress or coercion’¹⁸⁶ are factors in the donor’s decision to donate, and to consider the issue of ‘reward’ for the donation.¹⁸⁷ These interviews are an independent safeguard to prevent the exploitation of minors as tissue donors as any concerns about coercion, or a reward should be identified during these interviews.

However, while these issues should be identified within the interview, the HTA do not go any further and undertake any risk and benefit analysis or consider the best interests of the minor donor. The absence of this extra layer of safeguards has come under criticism in the recent case of *A NHS Foundation Trust v MC (by her Litigation Friend the Official Solicitor)*¹⁸⁸, however, Cohen J did not go any further by proposing recommendations to the current system or state whether in practice safeguards should be undertaken in every tissue donation. In my opinion, this suggestion does have some foundation as it would provide a further layer of protection to the minor donor’s interests. However, the role of the medical professionals, those with PR, and court approval should ensure that the minor donor’s interests have been adequately assessed and if the donation takes place that it is in the minor’s best interests.

Once the IA has conducted the necessary interviews and produced a report it is submitted for approval by the HTA.¹⁸⁹ If a medical professional intends to consider a living minor as a tissue donor, they are advised to discuss the case with the HTA ‘at the earliest opportunity’.¹⁹⁰ But these cases must only be referred to the HTA for approval

¹⁸⁶ Even though the HTA uses both of the terms coercion and duress, for the purposes of this discussion I am only going to use the term coercion to cover both duress and coercion.

¹⁸⁷ HTA, *Code of Practice F* (n 168) para 84.

¹⁸⁸ [2020] EWCOP 33 [22].

¹⁸⁹ HTA, *Code of Practice G* (n 169) paras 11 and 29.

¹⁹⁰ HTA, *Code of Practice G* (n 169) para 44.

after court approval for the donation has been obtained.¹⁹¹ If all of these requirements are fulfilled then a living minor may donate a solid organ/non-regenerative tissue.

With regard to a domino transplant, HTA approval is not required, only court approval.¹⁹² This may be because a solid organ is being donated, specifically the heart, but because the minor is already undergoing the operation to receive a lung transplant, safeguards to protect the interests of the minor donor do not need to be quite as robust since the donation part of the procedure is secondary to the main purpose of the operation.

3.3.1.1.2 Regenerative Tissue

The donation of regenerative tissue by a living minor is a more common process, and *CoP G* provides guidance for medical professionals about the requirements for the donation process. The 2004 Act makes it an offence to remove bone marrow from a living person for the purpose of transplantation unless the HTA give permission or where the 2006 Regulations provide an exemption to the definition of transplantable material for the purpose of the Act.¹⁹³ Therefore, the HTA assess applications for the donation of regenerative tissue from minors who are incompetent, thus requiring consent from an individual who has PR.¹⁹⁴ The donation must be assessed as being in the minor's overall best interests to include not only the medical but also the emotional, psychological, and social aspects of the donation, as well as the associated potential risks.¹⁹⁵

¹⁹¹ HTA, *Code of Practice G* (n 169) para 46.

¹⁹² HTA, *Code of Practice G* (n 169) para 32.

¹⁹³ HTA, *Code of Practice G* (n 169) para 11; Human Tissue Act 2004, s.33.

¹⁹⁴ HTA, *Code of Practice G* (n 169) para 12.

¹⁹⁵ HTA, *Code of Practice G* (n 169) para 74; see Chapter 5 at 5.4 further discussion about best interests.

The level of information disclosure that is provided to those with PR when they are consenting on behalf of a minor is the same as when an individual is providing consent on their own behalf, subsequently satisfying the test in *Montgomery*.¹⁹⁶ In addition, the HTA provide specific guidance for bone marrow donation as to the amount of information that should be provided to those with PR when consenting on behalf of a minor.¹⁹⁷ Unlike for solid organ/non-regenerative tissue donation, in order for a regenerative tissue donation to proceed, the consent of only one individual with PR is necessary.¹⁹⁸ But if there is a dispute between those with PR or any doubt as to whether the decision to donate is in the minor's best interests, the matter should be referred to the Court of Protection for approval.¹⁹⁹ In such instances, the HTA would then only approve the donation if the court was of the view that donation was in the best interests of the minor donor.²⁰⁰ Normally, court approval for the removal of regenerative tissue from an incompetent minor is not required.²⁰¹

Once consent has been provided, in all cases the Accredited Assessor (AA) must undertake, or attempt to undertake, an interview with the potential donor and recipient in order to assess whether the HTA requirements have been met.²⁰² The only exception is where the donor lacks capacity, for example attempting an interview with a baby or pre-verbal minor would waste both time and resources.²⁰³ Interviews should take place with both the donor and recipient at a level appropriate to their age and understanding.²⁰⁴

¹⁹⁶ [2015] UKSC 11, [93].

¹⁹⁷ HTA, *Code of Practice G* (n 169) para 78.

¹⁹⁸ HTA, *Code of Practice G* (n 169) para 74.

¹⁹⁹ HTA, *Code of Practice G* (n 169) para 77.

²⁰⁰ HTA, *Code of Practice G* (n 169) para 77.

²⁰¹ HTA, *Code of Practice G* (n 169) para 48.

²⁰² HTA, *Code of Practice G* (n 169) paras 52, 97 and 112.

²⁰³ HTA, *Code of Practice G* (n 169) para 97.

²⁰⁴ HTA, *Code of Practice G* (n 169) para 112.

Moreover, the AA should interview younger minor donors along with those with PR who are providing the consent on their behalf.²⁰⁵ The HTA provide guidance on what must be covered in the interview depending on whether it is the donor, or the recipient.²⁰⁶ If all of these requirements are fulfilled then an incompetent minor can donate regenerative tissue.

3.3.1.2 Competent Minor

Competent minors can consent on their own behalf to be a tissue donor if they meet the requirements set out by the 2004 Act and the HTA. Section 2(2) of the 2004 Act states that, ‘subject to subsection (3), where the child concerned is alive, ‘appropriate consent’ means their consent’. The 2004 Act does not state how to assess the minor’s competence,²⁰⁷ but according to the HTA, ‘the *Gillick* test is considered to be the appropriate benchmark for assessing a child’s competence.’²⁰⁸ The *Gillick* competence test states that a minor under the age of 16 is considered to be competent to consent to a medical procedure when they ‘can demonstrate sufficient understanding and intelligence to enable them to fully understand what is proposed.’²⁰⁹ However, the courts are yet to consider whether a *Gillick* competent minor can sufficiently understand the risks and implications of being a tissue donor in order to provide appropriate consent. In relation to a minor who is 16- or 17- years old, capacity is defined in section 2(1) and section 3(1) of the Mental Capacity Act 2005; and section 8 of the Family Law

²⁰⁵ HTA, *Code of Practice G* (n 169) para 114.

²⁰⁶ HTA, *Code of Practice G* (n 169) paras 54-55.

²⁰⁷ Hansard (n 163); HTA, *Code of Practice A* (n 170) para 131.

²⁰⁸ HTA, *Code of Practice A* (n 170) paras 88 and 131; Human Tissue Authority, *Code of Practice G* (n 169) para 41.

²⁰⁹ *Gillick v West Norfolk and Wisbech Area Health Authority* [1985] 3 All ER 402, 423; see Chapter 6 at 6.2.1 for further discussion on the *Gillick* competence test.

Reform Act 1969 permits them to consent to ‘medical, dental and surgical treatment’, but whether tissue donation can be classed as medical treatment is disputed.²¹⁰

The guidance provided by the HTA state that the consent of a competent minor will be respected by the medical professional, as once the minor donor has provided consent for the donation to proceed then no other individual has a legal right to revoke it, and the decision rests with the donor who is undergoing the donation.²¹¹ Therefore, consent from an individual with PR on behalf of a competent minor will not be treated by the HTA as lawful consent.²¹²

3.3.1.2.1 Solid Organs/Non-Regenerative Tissue

As already discussed previously, there is limited information in *CoP F*, which deals solely with the donation of solid organs/non-regenerative tissue for transplantation purposes, about living minors as tissue donors. Similarly, as with tissue donation from incompetent minors, if the donation is going to proceed then once consent has been provided by the minor donor an IA must separately interview the potential donor, and the recipient to assess whether the HTA requirements have been met.²¹³ The HTA provide guidance on what must be covered in the interview depending on whether it is with the donor or recipient.²¹⁴ As with incompetent minors, since donation between siblings is a directed donation, an interview must be undertaken with the donor and the recipient together.²¹⁵ Once the IA has conducted the necessary interviews and produced

²¹⁰ HTA, *Code of Practice G* (n 169) paras 45 and 46; see Chapter 6 at 6.3 for further discussion on 16- and 17- year olds.

²¹¹ HTA, *Code of Practice A* (n 170) para 21.

²¹² HTA, *Code of Practice G* (169) para 44.

²¹³ HTA, *Code of Practice F* (n 168) paras 70 and 95; Human Tissue Act 2004 (Persons who Lack Capacity to Consent and Transplants) Regulation 2006, reg.11(3)(a) and (b).

²¹⁴ HTA, *Code of Practice F* (n 168) paras 54-55.

²¹⁵ HTA, *Code of Practice F* (n 168) para 84.

a report it is submitted for approval by the HTA.²¹⁶ If a medical professional intends to consider a living minor as a tissue donor, they are advised to discuss the case with the HTA ‘at the earliest opportunity’.²¹⁷ But these cases must only be referred to the HTA for approval after court approval for the donation has been obtained.²¹⁸ The only exception to the requirement is for a domino transplant where HTA approval is not required.²¹⁹ The HTA stipulate that court approval should be obtained before the donation proceeds even if the minor donor is competent.²²⁰

The information disclosure test in *Montgomery*²²¹ must be satisfied in order for informed consent to be provided by a minor. The HTA have provided further information as to the level of information disclosure required in order for a competent minor to consent to donating a solid organ/non-regenerative tissue.²²² All of these requirements allow for a comprehensive process of information disclosure before a minor provides consent to donate. If all the requirements are fulfilled then the donation may proceed.

3.3.1.2.2 Regenerative Tissue

The donation of regenerative tissue by a living minor is a more common process than donation of solid organs/non-regenerative tissue, and *CoP G* provides guidance for medical professionals as to the requirements for the donation process. As with donation from incompetent minors, the 2004 Act makes it an offence to remove bone marrow

²¹⁶ HTA, *Code of Practice F* (n 168) paras 11 and 29.

²¹⁷ HTA, *Code of Practice F* (n 168) para 44.

²¹⁸ HTA, *Code of Practice F* (n 168) para 46.

²¹⁹ HTA, *Code of Practice F* (n 168) para 32.

²²⁰ HTA, *Code of Practice F* (n 168) para 45.

²²¹ [2015] UKSC 11, [93].

²²² HTA, *Code of Practice F* (n 168) para 70.

from a living person for the purpose of transplantation unless the HTA give permission or where the 2006 Regulations provide an exemption to the definition of transplantable material for the purpose of the Act.²²³ In contrast to incompetent minors where HTA approval is required, competent minors fall under the exemption provided by the 2006 Regulations.²²⁴ Therefore, tissue donation from a competent minor can proceed without HTA approval.²²⁵

In all cases the AA must undertake, or attempt to undertake, an interview with the potential donor and recipient in order to assess whether the HTA requirements have been met.²²⁶ Interviews should take place both with the donor and recipient at a level appropriate to their age and understanding.²²⁷ There could be an instance where the donor is a competent minor while the recipient is much younger and have a level of understanding akin to an incompetent minor. The HTA provide guidance on what must be covered in the interview depending on whether it is with the donor, or the recipient.²²⁸ But unlike for incompetent minors or for solid organ/non-regenerative tissue donation, the HTA do not provide guidance about the amount of information disclosure for a competent minor. This would indicate that the only test that needs to be satisfied for consent to be provided is the test in *Montgomery*²²⁹. If all the requirements are fulfilled then the donation may proceed.

²²³ HTA, *Code of Practice G* (n 169) para 11; Human Tissue Act 2004, s.33.

²²⁴ HTA, *Code of Practice G* (n 169) para 11.

²²⁵ HTA, *Code of Practice G* (n 169) para 11. See also para 25.

²²⁶ HTA, *Code of Practice G* (n 169) paras 52, 97 and 112.

²²⁷ HTA, *Code of Practice G* (n 169) para 112.

²²⁸ HTA, *Code of Practice G* (n 169) paras 54-55.

²²⁹ [2015] UKSC 11, [93].

Tissue donation from a competent minor can proceed without HTA approval or court approval. Therefore, a regenerative tissue donation may proceed with a competent minor without any safeguarding approval from an independent body. The HTA have not provided a reason as to why it has decided that a regenerative tissue donation may proceed with a competent minor without any safeguarding approval from an independent body. An interview will take place with the AA, as discussed in the previous paragraph, and the role of the AA is to ensure that

the donor has an age-appropriate understanding of the procedure, to ascertain that there is no evidence of duress or coercion having been placed on the donor and to ensure there is no evidence of the donor having sought, or been offered, a reward.²³⁰

While this interview will take place, HTA approval is not required to authorise the donation. Since an AA is submitting a report to the HTA as a result of the interviews it would seem reasonable that the HTA would then approve the donation. It is unclear from the guidance what HTA approval adds to the report that is submitted by the AA, but it is my contention that where a competent minor is going to donate regenerative tissue there should be HTA approval to ensure that all of the steps of the donation procedure have been met as well as all of the legal requirements and professional guidance requirements. This would ensure that the minor donor's interests are sufficiently protected to prevent exploitation.

²³⁰ HTA, *Code of Practice G* (n 169) para 96.

3.3.2 Summary of the Regulatory Framework in England and Wales

I have produced Table 3 that provides a summary of information about whether court or HTA approval is required depending on the type of tissue being donated, and on whether the minor is competent or not.

Table 3: England and Wales: HTA and Court Approval

<i>Type of Donation</i>		<i>Court Approval</i>	<i>HTA Approval</i>
Solid Organ/Non-regenerative Tissue		√	√
Domino Transplant		√	X
Regenerative Tissue	Competent	X	X
	Incompetent	X ²³¹	√

I have also produced Table 4 that provides information about who should be interviewed depending on the type of tissue being donated, and whether the minor is competent or incompetent.

Table 4: England and Wales: IA and AA Interviews

		<i>Donor</i>	<i>Recipient</i>	<i>Those with PR for the Donor</i>	<i>Donor and Recipient together</i>
Non-Regenerative Tissue (Interview given by IA)	Competent	√	√	X	√
	Incompetent	√	√	√	√
Regenerative Tissue (Interview given by AA)	Competent	√	√	X	X
	Incompetent	√	√	√	X

²³¹ Unless there is a dispute between those with PR, or those with PR and the medical professional.

I suggest that tables such as these should be produced by the HTA as summary documents in order for the information about the donation process to be more readily understood to both medical professionals and members of the public. This information may be useful for the donor, and recipient, as well as those with PR who are providing consent on behalf of an incompetent minor so they have a clear understanding of the stages of the donation process. I have now provided a clear conception of the regulatory framework for tissue donation in England and Wales; the next section of this chapter will provide the same for Scotland.

3.4 Human Tissue (Scotland) Act 2006

The Act that currently regulates the use of human organs and tissue, including donation for the purposes of transplantation, in Scotland is the 2006 Act. While the 2004 Act and the 2006 Act contain many similar provisions, unlike the 2004 Act, the 2006 Act is not supplemented by copious CoP. Instead, there are two main sets of guidance: *Human Tissue (Scotland) Act 2006: A Guide to its Implications for NHS Scotland*, and *Guidance for Transplant Teams, Independent Assessors, and Accredited Assessors in Scotland*.²³² This allows for a more streamlined set of guidance that a medical professional is required to refer to. The reduced amount of information in the guidance may be because, unlike the 2004 Act, the 2006 Act is not a framework but is more substantive in its contents. Moreover, the 2004 Act uses the term ‘appropriate consent’ while the 2006 Act uses the term ‘authorisation’. The distinction between the two terms

²³² Human Tissue Authority, *Human Tissue (Scotland) Act 2006: A guide to its implications for NHS Scotland* (2006); Human Tissue Authority, *Guidance for Transplant Teams, Independent Assessors, and Accredited Assessors in Scotland* (2017).

is most prevalent in relation to information disclosure of the medical risks of a tissue donation procedure.

3.4.1 Appropriate Consent vs Authorisation

Before any medical procedure can be carried out, consent must be provided by either a competent individual, or someone on behalf of an incompetent individual. It must also be ‘informed’ as set out in *Montgomery*²³³. The 2004 Act in relation to tissue donation uses the term consent, but 2006 Act has instead adopted the term authorisation. Authorisation as defined by the Medical Research Council guidance in relation to the use of human tissue for transplantation purposes is:

an expression intended to convey that people have the right to express, during their lifetime, their wishes about what should happen to their bodies after death, in the expectation that those wishes will be respected.²³⁴

Scottish Parliament noted when debating the 2006 Bill that there is a difference between the term authorisation and the term consent.²³⁵ The difference is that for an individual to give authorisation they do not need to have received the same level of information disclosure about the procedure as they would have done if they were required to provide consent.²³⁶ So, this essentially means that, in the case of authorisation the procedure can be carried out without the person providing authorisation having been fully informed.

²³³ [2015] UKSC 11, [93].

²³⁴ Medical Research Council, *Summary of Legal Requirements for Research with Human Tissue in Scotland* (2006) 1; NHS Blood and Transplant, ‘The Human Tissue Scotland Act 2006’ <<https://www.odt.nhs.uk/odt-structures-and-standards/regulation/the-human-tissue-scotland-act-2006/>> accessed 15/07/2018.

²³⁵ Scottish Parliament, ‘Health Committee’ (Thursday 8th September 2005), <http://www.parliament.scot/parliamentarybusiness/report.aspx?r=1935&mode=html#iob_9030> accessed 14/03/2019.

²³⁶ *ibid.*

The use of the term authorisation was carefully considered by the Scottish Parliament before being selected. Following the organ retention scandals, Scotland's Independent Review Group on the Retention of Organs at Post-Mortem was set up to review the current law on post-mortem examinations and make recommendations for changes to that law. This review group recommended that the term consent was 'inappropriate and misleading'²³⁷ and that the term authorisation be used for two main reasons. First, providing consent to a procedure on behalf of a minor rests on their best interests, and the minor is alive when the procedure is carried out, but this obviously cannot be the case regarding a post-mortem examination. It could be argued that the post-mortem examination of a minor may be in the best interests of surviving or future family members if the minor died of a hereditary disease or in the interests of medical research for wider society, but the interpretation of best interests should be in terms of accruing benefits for the minor which cannot occur after they have died.²³⁸

Secondly, consent implies that the decision is based on fully informed disclosure in compliance with *Montgomery*, but it is feasible that a post-mortem examination presents a situation where those with PR might not want to receive detailed information about the procedure, but do not object to that procedure occurring.²³⁹ The Review Group suggested that authorisation was not constrained by this full information disclosure, therefore, those with PR may authorise procedures without having information forced on them.²⁴⁰ This even allows for authorisation to be given when those with PR have

²³⁷ Scottish Executive (n 154) para 3.

²³⁸ Scottish Executive (n 154) Summary of Recommendations 3, 25, para 11.

²³⁹ Margaret Brazier, 'Organ retention and return: problems of consent' (2002) 29 *Journal of Medical Ethics* 30, 30.

²⁴⁰ Scottish Executive (n 154) para 17; Scottish Parliament, 'Health Committee' (n 235).

refused to be given details of what exactly will happen.²⁴¹ While the reasoning for the use of the term authorisation was based on post-mortem examinations, this term has also been adopted in the 2006 Act for tissue donation. Scottish Parliament did not provide any reasoning as to why they decided to use the term authorisation for all uses of human tissue under the 2006 Act.

Even though Scottish Parliament carefully chose and used the term authorisation in the 2006 Act so it would have a different interpretation to the term consent, there are two main instances that have indicated that in fact the two terms have an identical interpretation. First, the HTA guidance contains information on what should be discussed with the donor in order for them to provide ‘informed authorisation’.²⁴² The information that must be given to the donor is:

- a) the nature of the surgical/medical procedure and medical treatments involved for the donor, and any material short and long-term risks. A material risk is where, in the circumstances, a reasonable person in the donor’s position would be likely to attach significance to the risk, or the transplant team is, or should be reasonably aware that, the donor would be likely to attach significance to it. This information should include the risk of death to the donor;
- b) the chances of the transplant being successful, and any significant side effects or complications for the recipient, and in particular the donor should be made aware of the possibility of graft failure in the recipient;
- c) the right to withdraw authorisation at any time before the removal of the transplantable material;

²⁴¹ Scottish Executive (n 154) 30.

²⁴² Human Tissue Authority, *Guidance for Transplant Teams, Independent Assessors, and Accredited Assessors in Scotland* (2017) para 68.

- d) that the decision to donate must be free of duress or coercion; and
- e) that it is an offence to give or receive a reward for the supply of, or for an offer to supply, any organ. It is also an offence to seek to find a person willing to supply any organ for reward. If found guilty of this offence a person may face up to three years in prison, a fine, or both.²⁴³

The definition of informed authorisation is contained in part a) above. This definition is identical to the test in *Montgomery* which is the legal test for informed consent. In *Montgomery* it states:

the test of materiality is whether in the circumstances of the particular case the court is satisfied that a reasonable person in the patients position would be likely to attach significance to the risk. Even if the risk be material, the doctor will not be liable if upon a reasonable assessment of his patients condition, he takes the view that a warning would be detrimental to his patients health.²⁴⁴

While the HTA guidance does not carry the same legal weight as legislation or jurisprudence, and there are no formal sanctions should the guidance not be followed, the guidance assists medical professionals when they undertake activities that are regulated by the HTA, therefore, the guidance needs to be clear and accurate.²⁴⁵ In practice, the medical professional ascertains whether informed authorisation is being provided, and since neither legislation nor case law provide a definition of authorisation they would use the CoP and professional guidance produced by the HTA to assist them. Therefore, the medical professional needs to be clear as to the test as well as its application, and the guidance should be identical to the law.

²⁴³ *ibid.*

²⁴⁴ [2015] UKSC 11, [93].

²⁴⁵ HTA, *Code of Practice F* (n 168) para 4; HTA, *Code of Practice G* (n 169) para 4.

Secondly, NHSBT provide an overview of the provisions of the 2006 Act on their website. While they do not provide a definition for authorisation, they state that ‘Authorisation equates to the principle of 'consent' on which the Human Tissue Act 2004 is based.’²⁴⁶ This suggests that they interpret authorisation in the 2006 Act to have the same definition as the term consent in the 2004 Act. The information on the NHSBT website is for the use of both medical professionals and members of the public, and if it states that authorisation has the same interpretation as consent then the test in *Montgomery* should be used for both the test of consent under the 2004 Act and the test of authorisation under the 2006 Act.

In conclusion, the difference in the terms used in the 2004 Act and the 2006 Act is superficial as the test for informed consent and informed authorisation are identical. The guidance produced by the HTA and NHSBT hold more weight than Parliamentary discussion when the 2006 Act was a Bill. If Scottish Parliament decide that the term authorisation should be given the meaning that was intended when the 2006 Bill was passed it should amend the legislation by providing a clear definition for authorisation. It is my contention that it would be clearer and more precise if the term consent is used and replaces authorisation in the 2006 Act in relation to tissue donation.

Despite this argument, I have continued to use the term consent for the discussion on England and Wales, and the term authorisation for the discussion on Scotland for the remainder of this thesis because these are the correct legal terms when discussing the relevant law. I have made this decision because I want to demonstrate the current law,

²⁴⁶ NHS Blood and Transplant, ‘The Human Tissue Scotland Act 2006’ <<https://www.odt.nhs.uk/odt-structures-and-standards/regulation/the-human-tissue-scotland-act-2006/>> accessed 04/09/2020.

and using the term consent when referring to Scotland would not be true to this, nor ease clarity for the reader when referring to Scottish sources.

3.4.2 Tissue Donation from Living Minors in Scotland

Unlike the 2004 Act, the 2006 Act puts restrictions on when a living minor can be a tissue donor. The 2006 Act allows a minor to be a tissue donor in two situations: donation of regenerative tissue, and donation as part of a domino transplant operation.²⁴⁷ Therefore, a minor cannot donate non-regenerative tissue.²⁴⁸ The 2006 Act defines, for the purposes of this Act, a minor as being an individual under the age of 16.²⁴⁹

Tissue donation from living minors is regulated by the 2006 Act, Part 4 of the Human Organ and Tissue Live Transplants (Scotland) Regulations 2006, and professional guidance. No explicit distinction is made in the legislation or professional guidance between incompetent and competent minors. Nor does the 2006 Act provide guidance on how a minor's competence should be assessed. But, the HTA state that information for medical professionals about assessing a minor's competency is available in the GMC *0-18 years guidance*.²⁵⁰ The legislation governing the competency of minors is the Age of Legal Capacity (Scotland) Act 1991, in particular the competence test under s.2(4), and if the minor is incompetent then those with PR can consent on the minor's behalf.

²⁴⁷ Human Tissue (Scotland) Act 2006, s.17(4); see Appendix 1; HTA, *Human Tissue (Scotland) Act 2006* (n 232) para 23; see Chapter 1 at 1.1.2 for the definition of regenerative tissue and a domino transplant.

²⁴⁸ see Chapter 1 at 1.1.2 for discussion on why a lobe of liver is considered non-regenerative tissue in law, while in medicine it is considered regenerative tissue.

²⁴⁹ s.60(1); this provision is in line with the Age of Legal Capacity (Scotland) Act 1991, s.1, which provides likewise.

²⁵⁰ HTA, *Guidance for Transplant Teams, Independent Assessors, and Accredited Assessors in Scotland* (n 242) para 13.

Once authorisation has been provided by the minor donor or those with PR, an IA or AA²⁵¹ must separately interview the potential donor, the recipient, and an individual with PR for the incompetent donor to assess whether the HTA requirements have been met.²⁵² The HTA provide guidance on what must be covered in the interview depending on whether it is the donor, recipient, or those with PR for the donor.²⁵³ Regulation 5(7) of the 2006 Regulations requires that the registered medical practitioner who has clinical responsibility for the donor must have referred the donation to the HTA.²⁵⁴ The report produced by the IA or AA must be submitted to the HTA. Unlike in England and Wales under the 2004 Act, court approval is not required for any type of donation from a living minor in Scotland.

3.4.2.1 Domino Transplant

In the case of a domino transplant, an IA will conduct the necessary interviews with the potential donor and recipient to assess whether the HTA requirements have been met.²⁵⁵ There is no statutory provision for someone to be interviewed on the recipient's behalf, so a recipient interview must be attempted.²⁵⁶ In addition, the HTA consider it good practice to involve those with PR in these discussions but there is no legal role for them to respond on behalf of the minor.²⁵⁷ Subsequently, the report is sent to the HTA for

²⁵¹ If the minor is donating regenerative tissue they will be interviewed by an AA, if it is a domino transplant, they will be interviewed by an IA.

²⁵² Human Organ and Tissue Live Transplants (Scotland) Regulations 2006, reg. 5(8), reg. 5(9); Human Tissue (Scotland) Act 2006, s.20.

²⁵³ Human Organ and Tissue Live Transplants (Scotland) Regulations 2006, reg. 5(10) provides information on the matters that should be discussed in an interview.

²⁵⁴ Human Organ and Tissue Live Transplants (Scotland) Regulations 2006, reg. 5(11); the information that must be contained in the donor interview on top of that previously mentioned; Human Organ and Tissue Live Transplants (Scotland) Regulations 2006, reg. 5(12); what should be contained in the interview with those with PR.

²⁵⁵ HTA, *Guidance for Transplant Teams, Independent Assessors, and Accredited Assessors in Scotland* (n 242) paras 38 and 87.

²⁵⁶ HTA, *Guidance for Transplant Teams, Independent Assessors, and Accredited Assessors in Scotland* (n 242) para 88.

²⁵⁷ HTA, *Guidance for Transplant Teams, Independent Assessors, and Accredited Assessors in Scotland* (n 242) para 88.

approval.²⁵⁸ Once authorisation has been provided and approval from the HTA obtained, the donation can proceed.

As argued in relation to England and Wales, safeguards to protect the interests of the minor donor do not need to be quite as robust since the donation part of the procedure is secondary to the main purpose of the operation.²⁵⁹ However, it is interesting to note that the safeguard in England and Wales is in the form of court approval, and HTA approval is not required, while in Scotland it is the other way around where HTA approval is required and court approval is not. There does not appear to be an explanation as to why Scotland has adopted a different approach, but because there is no court involvement in a standard donation process the safeguarding measures can only be provided by the HTA.

3.4.2.2 Regenerative Tissue

In Scotland, all potential regenerative tissue donations must be referred to an AA.²⁶⁰ The AA must interview the donor, the person with PR for the incompetent donor, and the recipient.²⁶¹ In all cases, the AA should undertake, or attempt to undertake, an interview with the donor.²⁶² This may not be possible where the donor arguably lacks capacity.²⁶³ The AA must then submit a report to the HTA. HTA approval must be in

²⁵⁸ HTA, *Guidance for Transplant Teams, Independent Assessors, and Accredited Assessors in Scotland* (n 242) para 24(f).

²⁵⁹ at 3.3.1.1.1.

²⁶⁰ HTA, *Guidance for Transplant Teams, Independent Assessors, and Accredited Assessors in Scotland* (n 242) para 8.

²⁶¹ HTA, *Guidance for Transplant Teams, Independent Assessors, and Accredited Assessors in Scotland* (n 242) para 12.

²⁶² HTA, *Guidance for Transplant Teams, Independent Assessors, and Accredited Assessors in Scotland* (n 242) para 48.

²⁶³ HTA, *Guidance for Transplant Teams, Independent Assessors, and Accredited Assessors in Scotland* (n 242) para 48.

place before the donation can proceed.²⁶⁴ This is the case whether or not the minor donor is considered competent.²⁶⁵ Once authorisation has been provided and the HTA have approved the donation it can proceed.

3.4.3 Summary of the Regulatory Framework in Scotland

Below is Table 5, which sets out when HTA and court approval is required for living minors as tissue donors in Scotland.

Table 5: Scotland: HTA and Court Approval

<i>Type of Donation</i>	<i>HTA Approval</i>	<i>Court Approval</i>
Domino Transplant	√	X
Regenerative Tissue	√	X

Table 6 sets out when IA or AA interviews need to be undertaken, depending on the type of the tissue donated and whether the minor is competent or incompetent.

Table 6: Scotland: IA and AA Interviews

		<i>Donor</i>	<i>Recipient</i>	<i>Those with PR for the Donor</i>
Domino Transplant	Competent	√	√	X
	Incompetent	√	√	√
Regenerative Tissue	Competent	√	√	X
	Incompetent	√	√	√

²⁶⁴ HTA, *Guidance for Transplant Teams, Independent Assessors, and Accredited Assessors in Scotland* (n 242) para 9.

²⁶⁵ HTA, *Guidance for Transplant Teams, Independent Assessors, and Accredited Assessors in Scotland* (n 242) para 9.

I suggest that tables such as these should be produced by the HTA as summary documents in order for the information to be more accessible to medical professionals, and those involved in the donation process. This information may be useful for the donor, recipient, or those with PR who are providing authorisation on behalf of an incompetent minor so they have a clear understanding of the stages of the donation process.

3.5 The Donation Process

The process, both legally and physically, of a living minor being a tissue donor is long and arduous. As I have already demonstrated, the professional guidance set out in complex documents does not aid understanding, therefore, I have produced the following flowcharts in order to provide an overview of the donation process. Moreover, they could be used as a checklist for a medical professional to ensure that all stages of the donation process have been completed. Figure 3 is for England and Wales, and Figure 4 is for Scotland. I have produced separate flowcharts as there are different procedures in place for the different jurisdictions.

Figure 3: England and Wales: Donation Process

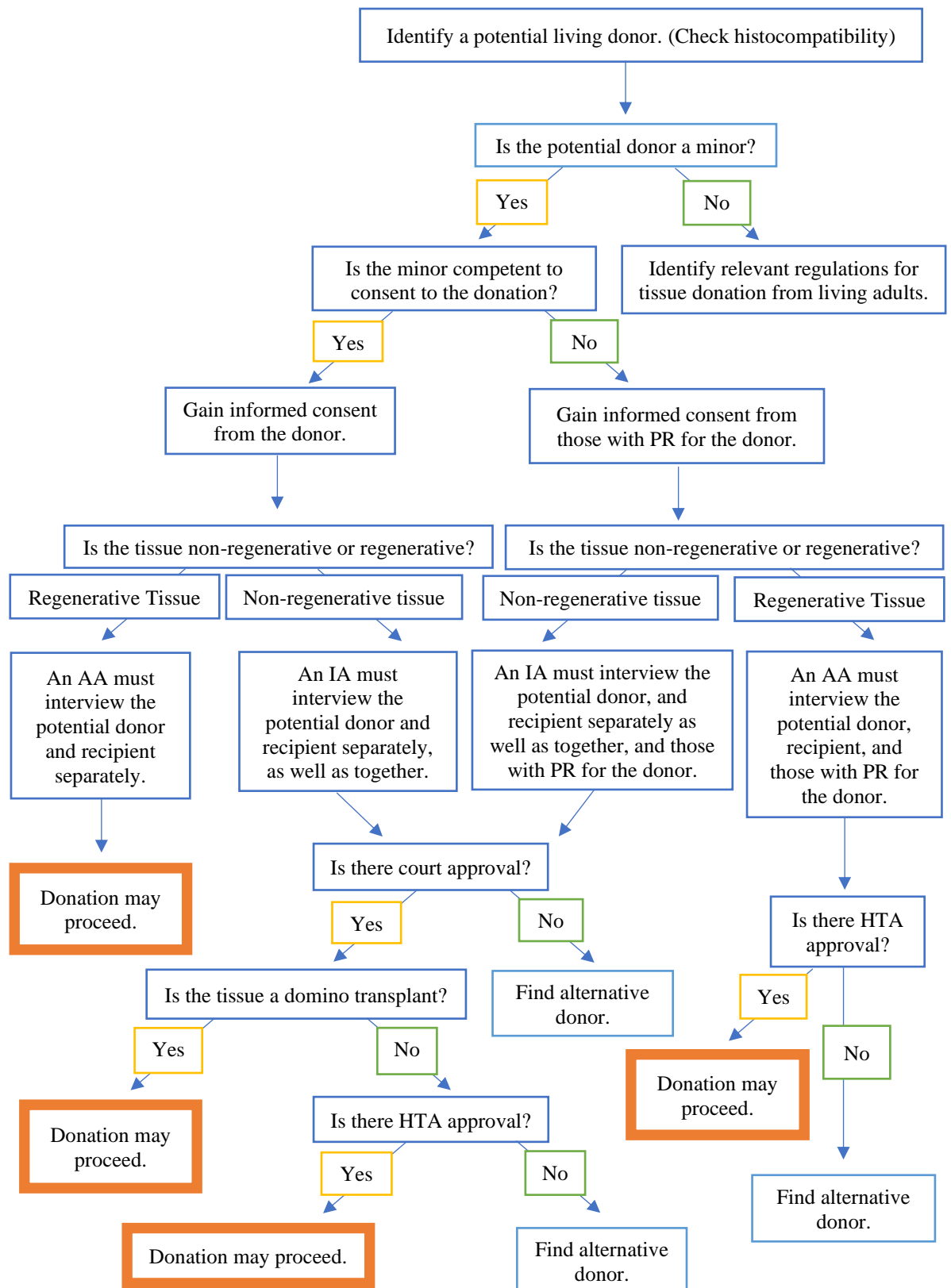
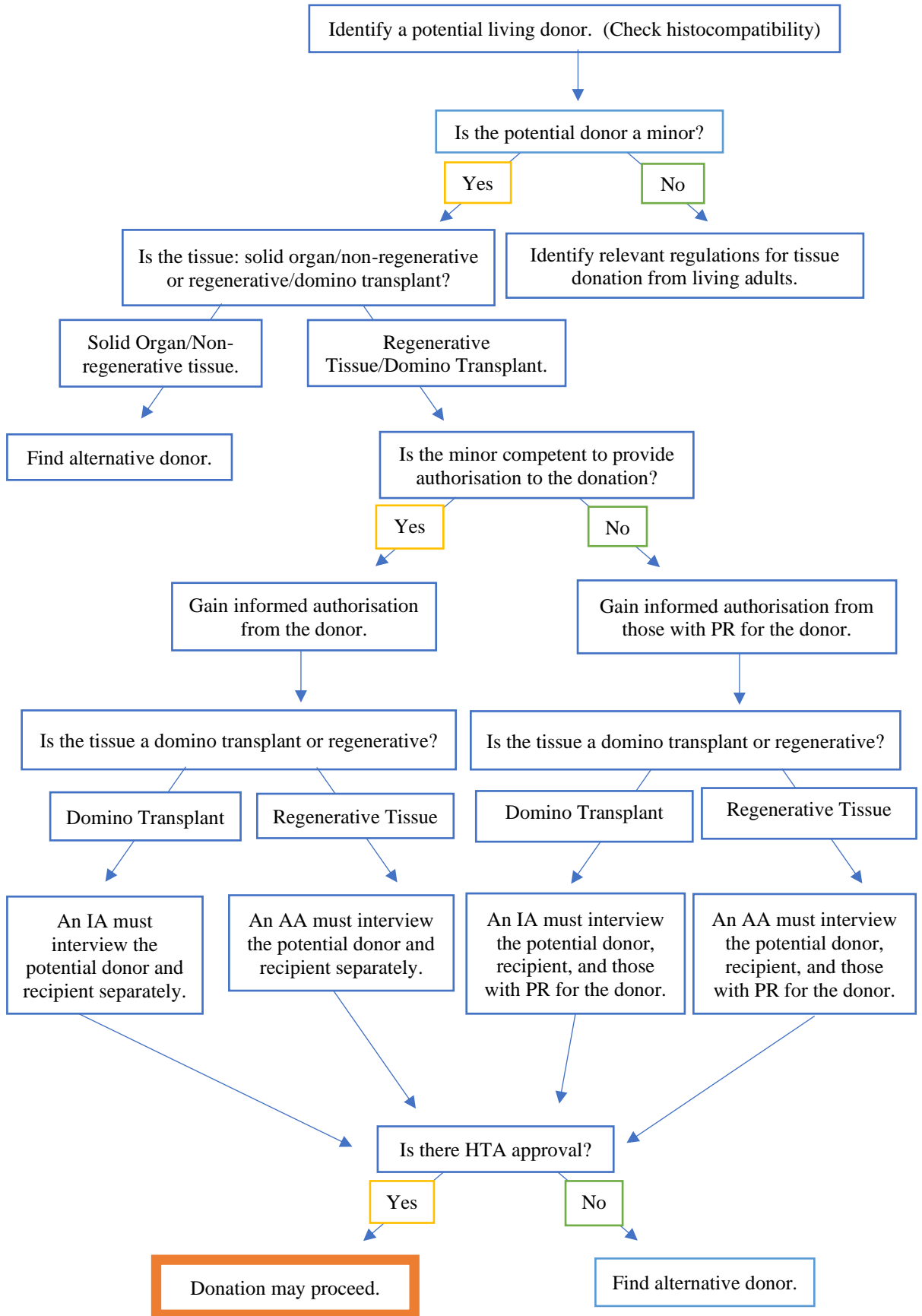


Figure 4: Scotland: Donation Process



3.6 Concluding Thoughts

In this chapter I have provided a clear conception of what the regulatory framework actually says and where its defects lie, therefore in subsequent chapters, I will make recommendations for reform in relation to tissue donation from living minors. In England and Wales, and Scotland, the regulatory framework for tissue donation from living minors consists of both law and professional guidance. I have made two main arguments: first, that tables and flowcharts, such as the ones I have produced, should be published by the HTA as summary documents. They would aid the understanding of the donation process by medical professionals and other individuals involved in the donation process such as the donor, recipient, and those with PR providing consent or authorisation on behalf of an incompetent minor. Secondly, the difference in the terms used in the 2004 Act and the 2006 Act is superficial as the test for informed consent and informed authorisation are identical. It would be clearer and more precise if the term consent is used and replaces authorisation in the 2006 Act with regard to tissue donation.

The following chapter will focus on the main difference between the 2004 Act and the 2006 Act which is that living minors in Scotland can only donate regenerative tissue or as part of a domino transplant, while living minors in England and Wales can donate both regenerative and non-regenerative tissue. I will address the first question in this thesis, should non-regenerative tissue donation from living minors be permitted in England and Wales, and Scotland? My contention is that no living minor should be able to donate non-regenerative tissue because the psychological benefits do not outweigh the serious immediate and long-term medical risks and potential psychological risks of donation, even if the donation is to a sibling.

Chapter 4

Non-regenerative Tissue Donation: England and Wales vs Scotland

4.1 Introduction

The previous chapter provided a clear conception of the regulatory framework for living minors as tissue donors in England and Wales, and Scotland. In this chapter, I recommend reform to that regulatory framework by considering the first question of this thesis: should minors in England and Wales be permitted to donate non-regenerative tissue? In Scotland, living minors can only donate regenerative tissue²⁶⁶ or as part of a domino transplant²⁶⁷, thus they cannot donate non-regenerative tissue. In contrast, living minors in England and Wales can donate both regenerative and non-regenerative tissue.

My contention is that no living minor should be able to donate non-regenerative tissue²⁶⁸ because the psychological benefits of the donation do not outweigh the immediate and long-term medical risks and potential psychological risks of the donation, even if the donation is to a sibling. Therefore, the law in England and Wales should be reformed and the Scottish approach should be adopted. I aim to demonstrate this by comparing the two most common types of regenerative tissue donation, blood and bone marrow, with the two most common types of non-regenerative tissue donation, a kidney and a lobe of liver. I will discuss both the immediate and long-term medical risks of the

²⁶⁶ see Chapter 1 at 1.1.2 for further discussion on the definition of regenerative tissue and the inclusion of a lobe of liver donation into the category of non-regenerative tissue in law.

²⁶⁷ see Chapter 1 at 1.1.2 for the definition of domino transplants. A domino transplant is “an operation which is designed to safeguard or promote the physical health of the person and by doing so necessitates the removal of an organ which is transplanted into another living person”; Human Tissue (Scotland) Act 2006, s.17(10).

²⁶⁸ except domino transplants.

different types of donation as well as any long-term implications to the minor's lifestyle as a result of being a tissue donor.

I will then move on to consider the potential psychological benefits and psychological harms a living minor donor can develop as a result of undergoing the donation process. The majority of my discussion will focus on Kenneth Kipnis' eight discrete types of vulnerabilities that are applied by Lainie Friedman Ross and Richard Thistlethwaite to tissue donation.²⁶⁹ I will explore whether these psychological benefits outweigh the immediate and long-term medical risks and psychological risks, therefore, justifying the tissue donation.

Put simply: psychological benefit > medical risks + psychological harm
in order for the donation to be justified.

4.2 Donor Risks vs Recipient Risks

Before discussing the medical risks, and the psychological risks and benefits, it is necessary to clarify why I am only considering the risks and benefits to the donor, and not to the recipient. The potential medical risks and psychological benefits that are considered should be the medical risks posed to the donor, and the psychological benefit on the donor, not the recipient. Any suggestion that the medical risks for the donor must be outweighed by the medical benefit for the recipient is incorrect for three

²⁶⁹ Kenneth Kipnis, *Vulnerability in research subjects: a bioethical taxonomy in: the National Bioethics Advisory Commission (NBAC), Ethical and Policy Issues in Research Involving Human Participants Volume II Commissioned Papers and Staff Analysis* (Bethesda, 2001) G1–13; Kenneth Kipnis, 'Seven vulnerabilities in the pediatric research subject' (2003) 24 *Theoretical Medicine in Bioethics* 107; Lainie Friedman Ross and J Richard Thistlethwaite, 'Developing an ethics framework for living donor transplantation' (2018) *Journal of Medical Ethics* 1.

reasons. First, as Aaron Spital argues medical risks and benefits are fallible.²⁷⁰ The medical risks are speculative, statistically determined, and it is not definite that all or any of the types of morbidity will materialise.

Secondly, even if these variables could be reliably estimated, a simple mathematical comparison of donor risk and recipient benefit would not be sufficient.²⁷¹ If the medical risk to the donor is very high, donation should generally not be permitted even if the predicted benefit for the recipient is greater.²⁷² Similarly, if the transplantation is going to be of no benefit to the recipient at all then it is irrelevant as to the harm it presents to the minor donor as the procedure would be futile. The medical risk to the donor should be the primary consideration since they are the individual undergoing a non-therapeutic procedure and getting no medical benefit. This is reiterated by the British Transplantation Society (BTS) in their guidance about kidney donation, which state that: ‘regardless of potential recipient benefit, the safety and welfare of the potential living donor must always take precedence over the needs of the potential transplant recipient.’²⁷³

Thirdly, deciding a donor’s suitability on the extent of the donor’s medical risk and recipient medical benefit suggests that medical factors are the only ones that matter and fails to recognise ‘the importance of personal values’,²⁷⁴ including the psychological benefit from the donation, which vary widely. In determining whether a minor can be

²⁷⁰ Aaron Spital, ‘Donor Benefits is the Key to Justified Living Organ Donation’ (2004) 13 *Cambridge Quarterly of Healthcare Ethics* 105, 106.

²⁷¹ Spital (n 270) 106.

²⁷² Spital (n 270) 106.

²⁷³ British Transplantation Society, *Living Donor Liver Transplantation* (2015) 28; British Transplantation Society, *Guidelines for Living Donor Kidney Transplantation* (2018) 12.

²⁷⁴ Spital (n 270) 106.

a tissue donor, the comparison that should be made is between the medical risk of the procedure for the donor, and the potential psychological benefit or harm the donor will develop as a result of the donation.

4.3 Medical Risks of Tissue Donation

Before a minor can be a tissue donor, the medical risks of the procedure need to be considered. As with any medical procedure tissue donation poses medical risks of varying degrees for the donor. The medical risks of the donation depend partly on the type of tissue that is being donated. I will focus on the four most common types of tissue donation: blood, bone marrow, a kidney, and a lobe of liver. Blood and bone marrow donation are regenerative tissue, while a kidney and a lobe of liver are non-regenerative tissue. I am going to show that non-regenerative tissue donation poses the highest immediate and long-term medical risks as well as the most restrictive long-term implications to the minor's lifestyle.

The data I have used to compare the medical risks of regenerative tissue and non-regenerative tissue donation has been collated from a number of sources, including medical academic journal articles, the BTS, NHS Blood and Transplant (NHSBT), and information from the UK and USA Government tissue donation websites. Where possible, I have used UK sources, but if these were not available, I have used sources from the USA where similar procedures occur, and similar risk factors have been identified. Moreover, the majority of the literature focuses on the medical risks of an adult being a tissue donor rather than a minor. Unless stated, the reader can assume that the source does not identify whether it is addressing adults or minors. In this discussion

I have highlighted some of the notable medical risks, but a full table of medical risks for each type of donation is provided in the appendices.

4.3.1 Blood Donation

Blood donation is the most common form of donation in England and Wales, and Scotland. While NHSBT recommend that regular donors are aged between 17 and 66,²⁷⁵ in exceptional circumstances, such as a rare blood group, a minor may be required to donate blood to a sibling. Donating blood involves inserting a needle into the skin for 5-10 minutes,²⁷⁶ while the blood is extracted. The blood in the donor will regenerate.²⁷⁷ There may be a bruise left from the needle or, potentially, a scar. But there are no reported long-term health implications from donating blood, so it is a safe procedure with minimal discomfort for the minor donor. Therefore, almost all minors in England and Wales, and Scotland can donate blood without any immediate or long-term medical risks.

4.3.2 Bone Marrow Donation

Bone marrow donation is a more complicated procedure than a blood donation, and requires the donor to have a general anaesthetic²⁷⁸ so a needle can be inserted into the hip bone in order for bone marrow to be extracted. There will be marks on the skin

²⁷⁵ or 70 if they have given blood before; NHS Blood and Transplant, 'Who can give blood' <<https://www.blood.co.uk/who-can-give-blood/>> accessed 15/07/2018.

²⁷⁶ until 470ml of blood has been taken; NHS Blood and Transplant, 'The donation process' <<https://www.blood.co.uk/the-donation-process/>> accessed 15/07/2018. The author registered to give blood so she could have a first-hand experience of the procedure, however, on the day of donation it was decided by the nurse present that it was not medically safe to donate. Therefore, the procedure did not go ahead. The author read the documentation that was provided to a donor before donation and there was nothing notable that needed to be added to this discussion.

²⁷⁷ If the donor has donated a pint of blood then the plasma from the donation is replaced within about 24 hours. Red cells need about four to six weeks for complete replacement. At least eight weeks are required between whole blood donations; American Red Cross 'Frequently Asked Questions' <<https://www.redcrossblood.org/faq.html>> accessed 08/07/2018.

²⁷⁸ British Bone Marrow Registry, 'How Can I Help?' <<https://www.nhsbt.nhs.uk/british-bone-marrow-registry/how-can-i-help/>> accessed 16/01/2018.

made by the needle and there may be some pain and discomfort where the needle has been inserted. The minor donor would be required to stay in hospital for up to 48 hours,²⁷⁹ and have a period of recovery at home of up to five days.²⁸⁰ The bone marrow will regenerate in the donor.²⁸¹

As this donation requires general anaesthesia there are risks associated with this procedure that are independent of the bone marrow donation itself. Bone marrow must be harvested from both the anterior and posterior iliac crest, which requires turning the individual over during anaesthesia, increasing the anaesthetic risk.²⁸² It has been reported that 2.4% of donors experience a serious complication due to anaesthesia or damage to bone, nerve or muscle in their hip region.²⁸³ There is a 0.39% risk of life-threatening complications in minor donors, but these are mainly related to the general anaesthetic rather than the actual removal of the bone marrow.²⁸⁴ The two types of morbidity that pose the most likely complications following a bone marrow donation are vomiting and sore throat. The risk of them occurring are 11.8% and 7.1% respectively.²⁸⁵ While the risk of these morbidities occurring could be considered likely, the type of morbidity is not serious. This demonstrates that not only must the

²⁷⁹ *ibid.*

²⁸⁰ British Bone Marrow Registry (n 278).

²⁸¹ The level of bone marrow will be back to normal after an average of 21 days; Anthony Nolan, 'Frequently Asked Questions' <<https://www.anthonynolan.org/8-ways-you-could-save-life/donate-your-stem-cells/frequently-asked-questions>> accessed 08/07/2018.

²⁸² Rebecca D Pentz, and others, 'Designing an ethical policy for bone marrow donation by minors and other lacking capacity' (2004) 13(2) Cambridge Quarterly of Healthcare Ethics 149, 149.

²⁸³ I Mallick, 'Risks of Donating Bone Marrow' <<https://www.verywellhealth.com/the-risks-of-donating-bone-marrow-2252482>> accessed 08/07/2018; US Department of Health and Human Services, 'Donation Frequently Asked Questions' <https://bloodcell.transplant.hrsa.gov/donor/donating/donation_faqs/index.html> accessed 15/07/2018; see Appendix 2 for full list.

²⁸⁴ CD Buckner and others, 'Marrow harvesting from normal donors' (1984) 64(3) Blood 630; M Bortin and CD Buckner, 'Major complications of marrow harvesting for transplantation' (1983) 11(10) Experimental Hematology 916.

²⁸⁵ Jan Styczynski and others, 'Risk of complications during hematopoietic stem cell collection in pediatric sibling donors: a prospective European Group for Blood and Marrow Transplantation Pediatric Diseases Working Party study' (2012) 119(12) Blood 2935, 2938.

likely risk of the morbidity be considered but the seriousness of the type of morbidity. Data on minor donors is relatively scarce in relation to the donation of bone marrow,²⁸⁶ but it has been reported that two minor donors suffered with severe adverse complications, which included cardiac arrest²⁸⁷ and lung edema.²⁸⁸ These are more serious risks compared to the vomiting and sore throat that were identified in the previous data. But there have been no reported deaths following the removal of bone marrow from a minor.²⁸⁹

While bone marrow donation is a more complicated procedure and presents higher risks than blood donation, overall, there are no significant long-term health risks from being a bone marrow donor. The highest risk of morbidity is as a result of the anaesthesia not the donation itself. The statistics presented indicate that almost all minors can donate bone marrow because it is a relatively safe procedure with some discomfort for the minor.

4.3.3 A Kidney Donation

Unlike the two other types of donation already discussed, a kidney donation from a living minor is a non-regenerative tissue donation and a major surgical operation.²⁹⁰

²⁸⁶ M A Pulsipher and others, 'Safety and efficacy of allogeneic PBSC collection in normal pediatric donors: the pediatric blood and marrow transplant consortium experience (PBMTTC) 1996-2003' (2005) 35(4) *Bone Marrow Transplant* 361; Julian Sevilla and others, 'Peripheral blood progenitor cell collection adverse events for childhood allogeneic donors: variables related to the collection and safety profile' (2009) 144(6) *British Journal of Haematology* 909.

²⁸⁷ A cardiac arrest is when your heart suddenly stops pumping blood round your body, commonly because of a problem with electrical signals in your heart. When your heart stops pumping blood, your brain is starved of oxygen. This causes you to fall unconscious and stop breathing; British Heart Foundation, 'Cardiac Arrest' <<https://www.bhf.org.uk/heart-health/conditions/cardiac-arrest>> accessed 09/07/2018.

²⁸⁸ Joerg Halter and others, 'Severe events in donors after allogeneic hematopoietic stem cell donation' (2009) 94(1) *Haematologica* 94, 98; Lung edema is an abnormal build-up of fluid in the lungs. This build-up of fluid leads to shortness of breath; Medline Plus, 'Pulmonary edema' <<https://medlineplus.gov/ency/article/000140.htm>> accessed 09/07/2018.

²⁸⁹ Jan Styczynski and others (n 285) 2941.

²⁹⁰ British Transplantation Society, *Guidelines for Living Donor Kidney Transplantation* (n 273) 170.

The donor undergoes a general anaesthetic and then one of their kidneys is removed. The donor will usually remain in hospital for about three to seven days²⁹¹ with recovery at home usually lasting about six weeks involving some pain and discomfort.²⁹² Once the kidney has been removed the donor will be left with only one kidney for the remainder of their life. As with bone marrow donation, a kidney donation requires a general anaesthetic therefore there are risks associated with this procedure that are independent of the kidney donation itself.

A kidney donation poses a higher risk of morbidity as well as more serious types of morbidity compared to bone marrow donation. While the highest medical risk for a kidney donation is a 30% risk of hypertension, the most serious risk of morbidity is end stage renal disease, which has a 0.38-0.5% risk of occurring.²⁹³ This is where the remaining kidney in the donor becomes diseased and subsequently fails resulting in the donor eventually requiring a kidney transplant. Even if the potential minor donor does not present risk factors for kidney disease at the time they are evaluated to be a kidney donor they may still develop it later in life.²⁹⁴ A minor has more time for these risk factors to progress, so a 10-year old donor may have 70 years to develop the complications from a kidney donation, therefore, the lifetime risk of end stage renal

²⁹¹ American Transplant Foundation, 'Five Questions to Ask Yourself' <https://www.americantransplantfoundation.org/about-transplant/living-donation/becoming-a-living-donor/five-questions-to-ask-yourself/> accessed 15/07/2018.

²⁹² American Transplant Foundation (n 291); Michael Siebels and others, 'Risks and complications in 160 living kidney donors who underwent nephroureterectomy' (2003) 18(12) *Nephrology Dialysis Transplantations* 1, 1.

²⁹³ Kidney Research UK, 'Living with one kidney' <<http://www.kidneyresearchuk.org/health-information/living-with-one-kidney>> accessed 28/01/2018; British Transplantation Society, *Guidelines for Living Donor Kidney Transplantation* (n 273) 90-92; Kidney Link, 'Risks Involved in Living Donation' <<http://www.kidneylink.org/RisksInvolvedinLivingDonation.aspx>> accessed 15/07/2018; Hassan N Ibrahim and others, 'Long-term consequences of kidney donation' (2009) 360 *New England Journal of Medicine* 459; Hypertension is high blood pressure which if untreated increases your risk of serious problems such as heart attacks or strokes; NHS Choices, 'High Blood Pressure' <<https://www.nhs.uk/conditions/high-blood-pressure-hypertension/>> accessed 11/07/2018.

²⁹⁴ British Transplantation Society, *Guidelines for Living Donor Kidney Transplantation* (n 273) 77; see Appendix 3 for full list.

disease is greater in younger donors.²⁹⁵ Thus, living adult donors or kidneys from deceased individuals should be used instead of kidneys from living minors to reduce this risk. While there have been no reported deaths of minors as blood or bone marrow donors, the United Network for Organ Sharing data on kidney donation revealed a surgical mortality of 0.031%,²⁹⁶ while another study found a 0.02% risk of mortality from surgical complications.²⁹⁷ This demonstrates that while death from bone marrow donation was an insignificant or even a non-existent risk, in relation to kidney donation the risk of mortality is a risk that should be considered before the minor undergoes the procedure.

Following a kidney donation there are a number of long-term medical risks which result in subsequent lifestyle restrictions for a minor.²⁹⁸ If an individual has only one kidney then it can be more vulnerable to injury, so heavy contact or collision sports should be avoided.²⁹⁹ This restriction could result in a very young minor never having experienced a particular sport or a minor not being able to continue to participate in a sport that they are good at or enjoy. If the minor is incompetent then these factors would be taken into consideration when determining what is in the best interests of the minor donor. I argue that restrictions such as these should not be placed on a minor's life, even though this restriction may appear to be minimal it could have a significant impact on the minor's well-being and cause them psychological harm. For instance, they could

²⁹⁵ British Transplantation Society, *Guidelines for Living Donor Kidney Transplantation* (n 273) 248.

²⁹⁶ Dorry L Segev and others, 'Perioperative mortality and long-term survival following live kidney donation' (2010) 303 *Journal of the American Medical Association* 2248; Krista L Lentine and others, 'Risks and outcomes of living donation' (2012) 19(4) *Advances in Chronic Kidney Disease* 220.

²⁹⁷ Aarthur J Matas and others, 'Morbidity and mortality after living donor kidney donation 1999-2001: a survey of the United States transplant centres' 2003) 3 *American Journal of Transplantation* 830.

²⁹⁸ Walter Glannon, 'The Risk in Living Kidney Donation' (2018) 27 *Cambridge Quarterly of Healthcare Ethics* 29, 31.

²⁹⁹ Kidney Research UK (n 293); the sports include boxing, field hockey, football, ice hockey, martial arts and wrestling.

be excluded in participating in activities at school or with their friends or, on a more extreme level, the minor could be restricting their future job prospects if they are particularly talented at a sport. But at the same time, this does not mean that minors who lack in sporting ability should be considered as kidney donors because this restriction could have less of an impact on their life. If a minor is going to be a tissue donor then the implications of the procedure should be minimally restrictive on the minor's future.

Moreover, the BTS have noted specific considerations when assessing female minors as potential kidney donors.³⁰⁰ There is an increased risk of gestational hypertension or pre-eclampsia³⁰¹ with a woman who gets pregnant post-kidney donation.³⁰² It is recommended that a woman does not get pregnant for at least six months following the donation.³⁰³ In addition, the BTS propose that an alternative donor should be assessed before a woman who may still wish to bear children is a kidney donor.³⁰⁴ This suggests that female minors should not be considered as a kidney donor because it is unclear whether a female minor may want to bear children when they are older. But it does not mean that only male minors should be considered as a kidney donor as this could result in males being unduly pressured to be kidney donors. I argue that a minor should not be permitted to be a kidney donor because of immediate and serious risks of morbidity

³⁰⁰ Give a Kidney, 'How safe is donation?' <<http://www.giveakidney.org/how-safe-is-donation/>> accessed 16/07/2018; British Transplantation Society, *Guidelines for Living Donor Kidney Transplantation* (n 273) 254.

³⁰¹ High blood pressure and a significant amount of protein in the urine.

³⁰² Give a Kidney (n 300); British Transplantation Society, *Guidelines for Living Donor Kidney Transplantation* (n 273) 254.

³⁰³ National Kidney Foundation, 'What to Expect After Donation?' <<https://www.kidney.org/transplantation/livingdonors/what-expect-after-donation>> accessed 16/07/2018.

³⁰⁴ British Transplantation Society, *Living Donor Liver Transplantation* (n 273) 78.

and mortality as well as the potential adverse impact it could have on the minor's future especially in relation to female donors.

4.3.4 A Lobe of Liver Donation

A lobe of liver donation from a living minor is the least common type of donation that I have considered and is carried out in fewer transplant units as it is a more complicated procedure with higher medical risks.³⁰⁵ For a lobe of liver donation to take place the minor must undergo general anaesthetic, then the liver of the donor is split into the left lobe and the right lobe. One of these lobes will be removed, which can be between 40-60% of the total liver volume.³⁰⁶ The donor will be required to stay in the hospital for about seven days with recovery at home for up to eight weeks involving some pain and discomfort.³⁰⁷ Following the donation, both the lobe that was transplanted into the recipient and the lobe that remains in the donor will regenerate to the full size in about 12 weeks.³⁰⁸ In medicine, a lobe of liver is classed as regenerative tissue. However as discussed in Chapter 1,³⁰⁹ there is a contradiction as to the classification of a lobe of liver donation in law, between the definition provided by the 2006 Act and the advice given by Organ Donation Scotland and the HTA. But as stated in Chapter 1, for the purposes of this thesis I have adopted the approach by Organ Donation Scotland and the HTA by classing a lobe of liver as a non-regenerative tissue donation.

³⁰⁵ British Transplantation Society, *Living Donor Liver Transplantation* (n 273) 68

³⁰⁶ Mount Sinai, 'Liver Donation Surgery and Recovery' <<https://www.mountsinai.org/care/transplant/services/living-donor/liver-surgery-recovery>> accessed 16/07/2018.

³⁰⁷ *ibid.*

³⁰⁸ NHS Blood and Transplant, 'Living donor liver transplantation' <<http://www.odt.nhs.uk/living-donation/living-donor-liver-transplantation/>> accessed 16/07/2018.

³⁰⁹ at 1.1.2.

The short-term medical risks for a lobe of liver donation are significantly greater than both bone marrow donation and kidney donation.³¹⁰ The BTS state that there is a 21% risk of morbidity for donors following the removal of their left lobe,³¹¹ while there is a 40% risk of morbidity for donors following the removal of their right lobe.³¹² The type of morbidity that may occur are the same regardless of whether the left or right lobe is removed. The highest risk following a lobe of liver donation is a 13.2% risk of infection.³¹³ The medical risks of a lobe of liver donation presents the highest medical risks of any type of tissue donation discussed. Not only are there more potential types of morbidity but they are also more serious in nature. However, unlike with a kidney donation, a lobe of liver donation does not present long-term restrictions on a minor's life, once the liver has regenerated and the minor has fully recovered from the procedure, they should be able to live a fairly normal life.

The BTS has stated that there is a 0.1% risk of mortality if the left lobe is removed,³¹⁴ with a 0.5-1% risk of mortality if the right lobe is removed.³¹⁵ The risk of mortality following a lobe of liver donation is significantly greater than other types of tissue donation discussed. Therefore, my contention is that based on the risks of morbidity and the risk of mortality a minor should not be permitted to donate a lobe of liver.

³¹⁰ British Transplantation Society, *Living Donor Liver Transplantation* (n 273) 21. see Appendix 4 for full list.

³¹¹ British Transplantation Society, *Living Donor Liver Transplantation* (n 273) 21 and 105; British Transplantation Society, *Guidelines for Living Donor Kidney Transplantation* (n 273).

³¹² British Transplantation Society, *Living Donor Liver Transplantation* (n 273) 21 and 105; British Transplantation Society, *Guidelines for Living Donor Kidney Transplantation* (n 273).

³¹³ British Transplantation Society, *Guidelines for Living Donor Kidney Transplantation* (n 273).

³¹⁴ British Transplantation Society, *Living Donor Liver Transplantation* (n 273) 21 and 105; British Transplantation Society, *Guidelines for Living Donor Kidney Transplantation* (n 271).

³¹⁵ British Transplantation Society, *Living Donor Liver Transplantation* (n 273) 21 and 105; British Transplantation Society, *Guidelines for Living Donor Kidney Transplantation* (n 273).

4.3.5 Concluding thoughts on the medical risks of tissue donation

It can be concluded that the types of tissue donation that present the highest risks of morbidity and mortality are non-regenerative tissue donation, specifically a lobe of liver donation. A kidney donation presents the most significant long-term implications with the greatest lifestyle restrictions. But regardless of this, non-regenerative tissue donation harms the donor. The ethical principle of nonmaleficence obligates a medical professional to abstain from causing harm to others.³¹⁶ Tissue donation from a living minor would initially breach the principle of nonmaleficence as the medical professional will harm the minor donor. But instead of the procedure being justified by the subsequent medical benefit, tissue donation is justified by the psychological benefit that the minor donor develops. The justification for allowing a living minor to undergo a medical procedure is that the medical risk is outweighed by the medical benefit. As tissue donation is a non-therapeutic procedure for the donor the living minor does not receive a medical benefit from the donation. The justification for permitting the tissue donation is based on the psychological benefit the donor would develop from donating to a sibling.

Put simply: psychological benefit > medical risks + psychological harm

in order for the donation to be justified.

4.4 Psychological Benefit and Harm of Tissue Donation

When an individual undergoes a medical procedure, that procedure can be justified by the principle of beneficence, as the procedure is intending to benefit the individual

³¹⁶ Tom L Beauchamp and James F Childress, *Principles of Biomedical Ethics* (OUP 2013) 150.

involved.³¹⁷ Ian Kennedy argued that an operation was lawful as long as it was performed by medical professionals who concluded ‘that there is at least some risk of harm to the patient if surgery is not performed,’³¹⁸ suggesting that the purpose of the surgery is to benefit the patient.³¹⁹ For the procedure to be lawful, the ‘benefit’ must be identified. This raises questions when considering tissue donation, including: what is a benefit, what is the benefit from the procedure, who determines whether there will be a benefit, and from whose perspective is the benefit determined?³²⁰ I propose a number of answers to these questions.

The medical profession is likely to determine whether there is a benefit from a medical procedure based on medical evidence. However, this justification is not applicable to tissue donation from living minors, where healthy donors who are acting to benefit others are exposed to potentially harmful medical outcomes.³²¹ Whether there is a benefit to the donor from the donation would again have to be based on medical evidence, but as there would be no procedural benefit, the benefit would need to be quantified psychologically which is much more difficult to identify. In general, the focus of a medical procedure’s benefit must be on the medical professional’s intention to benefit rather than the actual benefit.³²² If the medical professional had to guarantee a benefit either medically or psychologically in order to lawfully perform a procedure, then tissue donation, or in fact any medical procedure, would not be performed. For

³¹⁷ Jane Johnson and Wendy Rogers, ‘Innovative Surgery: the ethical challenges’ (2012) 38 *Journal of Medical Ethics* 9, 9-10.

³¹⁸ Ian Kennedy, ‘Transsexualism and Single-Sex Marriage’ in Ian Kennedy (eds), *Treat Me Right: Essays in Medical Law and Ethics* (Clarendon Press 1988) 262.

³¹⁹ Sara Fovargue and Alex Mullock (eds), *The Legitimacy of Medical Treatment: What Role for the Medical Exception?* (Routledge 2015) 18-19.

³²⁰ *ibid* 19.

³²¹ Johnson and Rogers (n 317) 9-10.

³²² see Ian Kennedy and Andrew Grubb, *Medical Law* (Butterworths 2000) 768-773; Nuffield Council on Bioethics, *Human Tissue: Ethical and Legal Issues* (1995) para 6.12.

example, if the transplanted tissue fails in the recipient then it is likely that the minor donor will not develop an actual psychological benefit from the donation. If the medical procedure is performed by a medically qualified professional, within professional norms, and the medical professional intends the individual to benefit from the procedure, then it can be justified under the principle of beneficence.³²³

Psychological benefits are key when determining whether a living minor can be a tissue donor, but as psychological benefits are subjective, they cannot be quantified precisely. Therefore, in determining whether a minor can be a tissue donor the comparison is between the speculative medical risk and the unmeasurable psychological benefit. But as the only benefit that a donor can experience is psychological, it is key that it is identified where possible, and an estimation is made about either the probability that a donor will benefit from donating or the extent of any donor benefit that may occur.³²⁴ The psychological benefit will differ greatly depending on the individual. But the transplant is not guaranteed to be successful, if the tissue fails or is rejected by the recipient then the donor may not develop a psychological benefit from the donation, but instead suffer from a psychological harm because the recipient does not recover as a result of the donation. I am going to argue that the psychological benefits can outweigh the minimal medical risks of regenerative tissue donation, but the serious immediate as well as long-term medical risks of donations of non-regenerative tissue are not sufficiently outweighed by the potential psychological benefit of a living minor donating to their sibling.

³²³ Fovargue and Mullock (n 319) 24.

³²⁴ Spital (n 270) 107.

The likelihood of medical risks occurring during or following the medical procedure can be assessed from evidence-based medicine, but any judgment made regarding future psychological benefit or harm to the minor donor is highly speculative.³²⁵ Potential psychological benefit or harm could occur before, at the time of the donation, or post-donation. However, it is unclear how far into the future a medical professional would have to look to determine whether a psychological benefit may materialise or not. Judge Munby stated that it:

extends to and embraces everything that related to the child's development as a human being and to the child's present and future life as a human being. The judge must consider the child's welfare now, throughout the remainder of the child's minority and into and through adulthood... How far into the future the judge must peer... will depend upon the context and the nature of the issue. If the dispute is about whether the child should go on a school trip the judge will be concerned primarily with the present rather than the future. If the question is whether a teenager should be sterilised the judge will have to think a very long way ahead indeed.³²⁶

Even though Judge Munby was referring to how far into the future of a minor's life the court should consider, this commentary provides some indication of the extent a medical professional would have to consider when determining the benefits of a medical procedure. The psychological benefit may not materialise while the donor is undergoing the procedure or in the recovery process, it may occur much later in life when they understand the benefits of the recipient sibling remaining alive and living a reasonably normal life. However, the longer the period of time for recovery of the

³²⁵ Charles Hillel Baron, Margot Botsford, and Garrick F Cole, 'Live organ and Tissue Transplants from minor donors in Massachusetts' (1975) 55 Boston University Law Review 159,171; *Nathan v Flanagan* Civil No J74-109 (Mass, Oct 4, 1974).

³²⁶ *Re G* [2012] EWCA Civ 1233 [26].

donor, the greater the psychological benefits need to be, meaning that the medical professional will have to look further into the future to determine whether a psychological benefit may materialise. Regenerative tissue donation, such as blood and bone marrow, require short recovery periods and no long-term implications, therefore, the medical professional does not need to look so far into the future of the minor donor. There needs to be only a small psychological benefit in order to outweigh the medical risks. This is in contrast to non-regenerative tissue donation where the recovery period is much longer and there are long-term implications, therefore, the psychological benefit has to be greater to outweigh the medical risks.

4.4.1 The transplant fails in the recipient

What if the transplant fails and the recipient dies, does the minor still accrue a psychological benefit from donating? It has been suggested that the psychological benefit may even occur if the transplant fails, because the donor and family can take consolidation in that everything possible was done.³²⁷ However, contrary to this claim, if the transplantation is not successful, the donor could feel like they were complicit in the pain, the psychological anguish and ultimately the death of the recipient, and therefore, feel guilty, and that they are to blame. The minor should be aware of and, if competent, understand that the donated tissue may fail, be rejected by the recipient, or that the original cause of the tissue failure may recur and that the outcome is beyond their control.³²⁸ The minor donor may be able to control their future feelings by telling themselves that they made the best decision possible given the circumstances,

³²⁷ Laine Friedman Ross and J Richard Thistlethwaite, 'Minors as Living Solid-Organ Donors' (2008) 122 *Pediatrics* 454,455.

³²⁸ *ibid*, 458.

regardless of the outcome.³²⁹ But such feelings may not be able to be managed easily, especially by a minor donor with little or no understanding of the medical risks in the tissue donation process. If the minor donor understands that the transplant could fail in the recipient this may help minimise the potential psychological harm to the donor, but such a requirement would exclude incompetent minors from donating as they may not have this complex level of understanding.

If the minor donor does suffer from a psychological harm as a result of the failure of the transplant, with regenerative tissue they have undergone minimal medical risk. While if they have donated non-regenerative tissue the immediate and long-term risks of the donation could materialise without the donor having developed any type of psychological benefit, but instead a psychological harm. As it is not guaranteed that the transplant will be successful, or the donor will not be psychologically harmed if the transplant fails, I am arguing that a minor should not be able to donate non-regenerative tissue because the minor could have undergone a medical procedure that has not benefitted themselves, nor the recipient.

Put simply: psychological benefit < medical risks + psychological harm

therefore, the donation is NOT justified.

4.4.2 Kenneth Kipnis and the eight discrete types of vulnerability

Minors are susceptible to vulnerabilities, especially if they are a potential tissue donor.

Kipnis proposed a vulnerabilities taxonomy that explored the different types of

³²⁹ Kimberly Strong, Ian Kerridge, and Miles Little, 'Saviour Siblings, Parenting and the Moral Valorisation of Children' (2014) 28(4) Bioethics 187, 190.

vulnerabilities focusing specifically on research participants.³³⁰ He offered an analytical approach to the concept of vulnerability, arguing that rather than focusing on groups, it would be more useful to consider six discrete types of vulnerability that an individual may face: cognitive, juridic, deferential, medical, allocational, and infrastructural.³³¹ In a later work, focusing specifically on why minors may be vulnerable in medical research, Kipnis offered eight discrete types of vulnerabilities – retaining the first six, and adding two more: social and situational.³³² Friedman Ross and Thistlethwaite applied these vulnerabilities to the living adult donor context. I think this taxonomy can also provide an effective method of addressing the types of vulnerability a minor may experience within the tissue donation setting. I am going to argue that the potential psychological benefit a minor will develop from being a non-regenerative tissue donor is unmeasurable and cannot be predicted, therefore, it cannot be used to outweigh medical risks. I will demonstrate this by applying these eight vulnerabilities to tissue donation from living minors using Kipnis, and Friedman Ross and Thistlethwaites' commentary in order to assist my discussion and analysis.

4.4.2.1 Cognitive or Incapacitational

Does the potential living donor have the capacity to deliberate about and decide whether or not to participate as a living donor?³³³

This type of vulnerability refers to when a potential tissue donor lacks the ability to give informed consent/authorisation for the donation to be carried out, for example if the

³³⁰ Kipnis (n 269); Friedman Ross and Thistlethwaite (n 269).

³³¹ Kipnis (n 269); Friedman Ross and Thistlethwaite (n 269).

³³² Kipnis (n 269); Friedman Ross and Thistlethwaite (n 269).

³³³ Kipnis (n 269); Friedman Ross and Thistlethwaite (n 269).

minor is incompetent. The minor donor may be cognitively vulnerable or incapacitated because of immaturity of age or because of intellectual disabilities or mental illness. Although those with parental responsibility (PR) are able to provide consent/authorisation on behalf of an incompetent minor, the tissue donation must be deemed to be in the minor's best interests before it proceeds.³³⁴

I am arguing that minors should not be able to donate non-regenerative tissue, but especially in the case of incompetent minors as at what age is a minor aware of the psychological benefits of the donation? While the psychological benefits may not occur during the donation or immediately after it, psychological benefits that are a long way in the future are more difficult to predict with any degree of accuracy. The potential psychological benefit may be minimal or non-existent if the minor does not currently understand why they are being asked to undergo the donor operation or understand the impact it would have on the recipient.³³⁵ Thus the extent to which incompetent minors can experience psychological benefits is still unclear.³³⁶

Robert Crouch and Carl Elliott argue that one of the necessary preconditions of receiving a psychological benefit is that the donor has sufficient cognitive development to recognise the social benevolence of donation; that is, the donor must be aware not only that the tissue has been removed, but that they are helping their sibling by donating in a way that no one else could do.³³⁷ Without this understanding the minor donor may not develop the psychological benefit, even though the contrary, that a minor donor can

³³⁴ see Chapter 5 at 5.4 for discussion on best interests test.

³³⁵ Friedman Ross and Thistlethwaite (n 327) 455.

³³⁶ Kristoff Van Assche, Gilles Genicot and Sigrid Sterckx, 'Living organ procurement from the mentally incompetent: the need for more appropriate guidelines' (2014) 28(3) *Bioethics* 101, 106.

³³⁷ Robert A Crouch and Carl Elliott, 'Moral Agency and the Family: The case of living related organ transplantation' (1999) 8(3) *Cambridge Quarterly of Healthcare Ethics* 275, 282.

develop a psychological benefit even without this understanding, has routinely been suggested by American courts when authorising kidney removal from incompetent individuals.³³⁸ A similar line of argument was made in the England and Wales case of *Re Y (adult patient)(bone marrow transplant)*³³⁹ which is discussed in more detail in Chapter 5.³⁴⁰ In addition, the psychological harms of being a tissue donor may be increased for incompetent minors. Thus, they might for instance suffer as a result of their failure to understand the meaning of the tissue donation or to adapt to the unfamiliar environment of a hospital and the strain of the whole donation process.³⁴¹

This type of vulnerability may be less significant for competent minors. Moreover, a minor is more likely to be competent to consent or provide authorisation for regenerative tissue compared to non-regenerative tissue because of the lower level of understanding that is required. As incompetent minors are unlikely to be aware of the immediate psychological benefit stemming from a tissue donation and any psychological benefits may not materialise until the future then the donation process that the minor donor undergoes should have the smallest medical risk. This vulnerability falls under the psychological harm part of the equation because if the minor donor cannot understand the donation process and why they are undergoing the donation process then they will not develop the benefit that stems from it. Instead, they have undergone a medical procedure with a medical risk and not developed a psychological benefit, therefore, the equation is weighted towards the medical risk and

³³⁸ Van Assche, Genicot and Sterckx (n 336) 106; *Little v Little* (1979) 576 SW 2d 493 (Tex Ct of App), 499.

³³⁹ [1997] 2 WLR 556.

³⁴⁰ at 5.5.1.

³⁴¹ Van Assche, Genicot and Sterckx (n 336) 107.

psychological harm side. Thus, in England and Wales a minor should not be permitted to be a tissue donor, and the Scottish approach be adopted.

4.4.2.2 Juridic

Is the potential living donor liable to the authority of others who may have an independent interest in that donation?³⁴²

In relation to this type of vulnerability, the ‘authority’ referred to is meant to be legal and can refer to prisoners and military personnel, but Kipnis states that ‘the category also includes children under the authority of their parents, so for example, the juvenile [minor] whose parents seek for him to be a living donor to a twin sibling.’³⁴³ There are two issues to discuss here: the conflict of interest for those with PR for both the donor and the recipient, and the issue of twin sibling donation.

In a sibling to sibling donation the individuals who have PR for the donor and the recipient are the same people. Those with PR who give permission for their minor to donate have a potential conflict of interest by the nature of their relationship with both the donor and the recipient. As Thomas Tomlinson explains:

when the recipient is another family member parents are in a conflict of interest as protectors of their infant’s welfare. Their love and desperate hope for this other child might blind them to the real magnitude of harms their donor child would suffer.³⁴⁴

³⁴² Kipnis (n 269); Friedman Ross and Thistlethwaite (n 269).

³⁴³ Kipnis (n 269), G7; Friedman Ross and Thistlethwaite (n 269).

³⁴⁴ Thomas Tomlinson, ‘Infants and others who cannot consent to donation’ (1993) 60(1) Mount Sinai Journal of Medicine 43.

As a result of the recipient's illness, those with PR may be prone to focus more heavily on the effect of their decision on the health benefits of the recipient rather than the debilitating effects on the donor.³⁴⁵ Those with PR, when consenting on behalf of the donor, must look at what is in the best interests of the donor, and not conflate it with the benefits that it will have on the recipient. Donating non-regenerative tissue is likely to have a greater impact on the recipient because of the value of the donation compared to regenerative tissue. Therefore, the issue of the conflict of interest could introduce greater bias with a non-regenerative tissue than regenerative tissue donation. Such an issue would only arise in relation to incompetent minors, since competent minors can provide consent or authorisation on their own behalf.

Those with PR can only provide consent or authorisation on behalf of a minor to a procedure that is in their best interests, and this should act as a safeguard against potential conflicts of interests. The potential psychological benefit the donor may receive should not be artificially inflated so it appears that the donor would develop a psychological benefit resulting in the donation being in their best interests, thus justifying the tissue donation. In addition, if there is an issue with whether the tissue donation is in the donor's best interests the case should be referred to court. These safeguards do not guarantee that there will not be a conflict of interest between those with PR, so an independent assessment of the minor's interests, such as by a court, would be required in every situation to eliminate this conflict of interest. As discussed in Chapter 3, interviews by an Independent Assessor (IA) or Accredited Assessor (AA) are an independent safeguard in order to prevent the potential exploitation of minors as tissue donors as any concerns about coercion, or a reward could be identified during

³⁴⁵ Friedman Ross and Thistlethwaite (n 327) 457.

these interviews. However, while these issues could be identified within the interview, the HTA do not go any further and undertake any risk and benefit analysis or consider the best interests of the minor donor. The absence of this extra layer of safeguards has come under criticism in the recent case of *A NHS Foundation Trust v MC (by her Litigation Friend the Official Solicitor)*³⁴⁶. Since these identified, fundamental and valuable safeguards are not currently in place, this could result in an unacceptable risk so I propose that minors should not be permitted to donate non-regenerative tissue.

In relation to twin donation, a 1954 Massachusetts court ruling permitted the use of a kidney by an identical twin for transplantation into their sibling.³⁴⁷ The legal opinion reflected the probability that identical twins were so close, emotionally as well as physically that the loss of a kidney by the donor would be less devastating than the loss of an identical twin sibling.³⁴⁸ Moreover, the World Health Organisation (WHO) has stated that:

some regard the use of an identical twin as an acceptable child [minor] donor, on the basis that the outcome for the recipient is exceptional and because the relationship between identical twins is so close that restoring the health of the recipient confers major psychological benefit for the donor.³⁴⁹

However, I am challenging this argument twofold. First, that twins should not be obligated to donate tissue in order to save their siblings life purely because they are a twin. There is no legal obligation for a twin to donate to their twin, nor should an

³⁴⁶ [2020] EW COP 33 [22].

³⁴⁷ Thomas Starzl, *Memoirs of a Transplant Surgeon: the Puzzle People* (University of Pittsburgh Press 1992) 147.

³⁴⁸ *ibid.*

³⁴⁹ World Health Organisation, 'Guiding principles on human cell, tissue and organ transplantation' (2010) 90 Transplantation 229.

additional moral obligation be placed on them by the potential recipient, those with PR, or society, and an expectation by the potential recipient.³⁵⁰

Secondly, that the benefit to the donor and the benefit to the recipient of the donation should be assessed separately. As already discussed, the medical risk and psychological benefit consideration as to whether the minor should donate should focus solely on the donor and not the benefit to the recipient. The focus on the donor is to ensure that the donation promotes the donor's interests and respects the donor as an end in themselves and not merely as a utilitarian tissue source.³⁵¹ While separate clinical teams for the donor and the recipient are considered best practice, at the same time healthcare professionals must work together to ensure effective communication and co-ordination of the transplant process without compromising the independence of the donor.³⁵² In addition, if the need for the transplant is related to a genetic condition in the recipient, there is a risk that a genetically related donor may develop the same health problem in the future and ultimately also need a transplant; this may be particularly true of identical twins.³⁵³ Moreover, twins may be at a higher risk of coercion compared to other siblings because of the bond they have with their sibling. In fact, the risk of coercion and the inability to implement effective safeguards to protect the donor from coercion was one of the main reasons why Scotland does not allow non-regenerative tissue donation by living minors.

The HTA have recognised that a potential minor donor can be subject to coercion, therefore, they have put safeguards in place and require the donor, the recipient, and

³⁵⁰ Legal and moral obligations are discussed in Chapter 6 at 6.2.1.4.1.

³⁵¹ Friedman Ross and Thistlethwaite (n 327) 455.

³⁵² British Transplantation Society, *Guidelines for Living Donor Kidney Transplantation* (n 273) 32.

³⁵³ Friedman Ross and Thistlethwaite (n 327) 455.

sometimes those with PR to undergo an interview.³⁵⁴ The minor donor can be subject to coercion from, but not limited to, those with PR, the recipient, or a medical professional when donating tissue to their sibling. The Human Tissue Act 2004, which is applicable in England and Wales, allows minors to donate all types of tissue and puts safeguards in place to minimise the risk of coercion.³⁵⁵ However, when enacting the Human Tissue (Scotland) Act 2006, the Scottish Parliament did not allow a minor to donate non-regenerative tissue in Scotland ‘to protect against the possibility of coercion.’³⁵⁶ This implies that the Scottish Parliament felt that the safeguards in place in the 2004 Act to minimise the risk of coercion were not sufficient, and a ban on a minor donating non-regenerative tissue was a more appropriate outcome. However, this argument was met with some disagreement, as the General Medical Council (GMC) stated that:

While we agree that measures should be in place to protect children’s interests, we do not believe that it is appropriate to make the removal of organs or tissue from a living child an offence without exception, since exceptional circumstances can be envisaged. We propose therefore that the Bill [2006 Act] be amended to require that where such situations arise, a court ruling should be sought on whether it is appropriate to proceed.³⁵⁷

In agreement with the GMC, the British Medical Association (BMA) stated ‘that those who are able to give valid authorisation, including mature minors, should be able to be

³⁵⁴ see Chapter 3 at 3.3.2 for further information about the interviews including Tables 3 and 4.

³⁵⁵ see Chapter 3 at 3.3 for further information about the safeguards.

³⁵⁶ Scottish Parliament, ‘Health Committee Report’, <<https://archive.parliament.scot/business/committees/health/reports-05/her05-19-03.htm>> accessed 16/07/2018.

³⁵⁷ Scottish Executive, *Independent Review Group on Retention of Organs at Post-Mortem: Final Report* (Crown 2001) para 17; Scottish Parliament, ‘Health Committee’, (Thursday 8th September 2005) <http://www.parliament.scot/parliamentarybusiness/report.aspx?r=19358mode=html#iob_9030> accessed 14/03/2019.

altruistic living donors of whole organs provided there are adequate safeguards in place to avoid the risk of coercion.³⁵⁸ The BMA identified that there is a potential risk of coercion if a living donor is going to donate tissue, but they did not propose what, if any, safeguards they would implement in order to prevent this risk of coercion. Kate Maclean, a Scottish MP stated:

I agree with the BMA that no one, regardless of their age, could be coerced into making a living donation, but human nature being what it is, we cannot realistically legislate for that and we certainly cannot legislate for how people would feel afterwards.³⁵⁹

Like all individuals, minors are vulnerable to a risk of coercion, but especially in a familial setting, since they might not want to disagree with their parents or refuse to donate tissue to a sibling. Therefore, it is my contention that living minors should not be permitted to donate non-regenerative tissue due to the risk of coercion and the lack of effective safeguards in place to minimise or eliminate this risk.

4.4.2.3 Deferential

Is the potential living donor given to patterns of deferential behaviour that may mask an underlying unwillingness to participate?³⁶⁰

Deferential vulnerability may be seen in a decision made by a minor who seeks to please his or her parents or the potential recipient. In addition, a minor may also express

³⁵⁸ Scottish Parliament, 'Official Report'
<<http://www.parliament.scot/parliamentarybusiness/report.aspx?r=4617&i=35916>> accessed 15/03/2019.

³⁵⁹ *ibid.*

³⁶⁰ Kipnis (n 269); Friedman Ross and Thistlethwaite (n 269).

deferential vulnerability to requests by medical professionals. Kipnis explains that the challenge is to devise a process that eliminates as much as possible the social pressures that the potential living donor may feel.³⁶¹ It may be difficult for a healthy minor to tell those with PR, their sibling, or a medical professional that they refuse to be a living donor. For instance, if a minor refuses to donate they may feel guilty, especially if their sibling dies.³⁶² Thomas Starzl³⁶³ has noted that refusal of donation by a minor has led to ostracism within their family,³⁶⁴ this is an example of when the presence of deferential vulnerability has resulted in a psychological harm to the sibling minor who could have donated. By restricting the type of tissue a minor can donate, this reduces the donation operations available and therefore reduces the number of minors who could potentially suffer with this type of vulnerability.

4.4.2.4 Social

Does the potential living donor belong to a group whose rights and interests have been socially disvalued?³⁶⁵

In order to decide who is going to donate tissue to the potential recipient a number of members of the family may have to undergo screening in order to determine histocompatibility. When a family discuss who should undergo this test, they may look at family members who are 'expendable' or those who if suffer with post-operative issues will have less impact on the family unit, for example non-wage earners.

³⁶¹ Kipnis (n 269); Friedman Ross and Thistlethwaite (n 269).

³⁶² Friedman Ross and Thistlethwaite (n 327) 455.

³⁶³ A prominent transplant surgeon who performed the first liver transplant.

³⁶⁴ Starzl (n 347) 147.

³⁶⁵ Kipnis (n 269); Friedman Ross and Thistlethwaite (n 269).

However, I argue that an individual's potential expendability should not be a consideration when determining whether they should be a tissue donor, as this could lead to minor's being susceptible for selection as they have limited social standing within the family. The minor donor should be treated with the same deference as any other family member and should not be exploited or used as means to an end. If a minor does not earn money or 'contribute' to the family this does not mean that they are required to donate tissue in order to provide this 'contribution'. A competent minor who is of wage-earning age but is still dependent on their family may be more susceptible to coercion from their family in order to contribute through the use of their tissue. There is no direct evidence that this is a potential issue within tissue donation, however, it is still a factor that must be examined.

4.4.2.5 Medical

Has the potential living donor been selected, in part, because of the presence of a serious health-related condition in the intended recipient for which there are only less satisfactory alternative remedies?³⁶⁶

This vulnerability applies when there is a serious health-related condition in the intended recipient and there are only less satisfactory alternative remedies. A remedy is less satisfactory if it leads to either worse outcomes (higher morbidity and/or mortality) or the remedy is not readily available. For example, in relation to tissue donation a less satisfactory alternative to a kidney transplant is dialysis which has a less effective outcome and may not be readily available. Transplantation of tissue from a

³⁶⁶ Kipnis (n 269); Friedman Ross and Thistlethwaite (n 269).

living donor is the preferred treatment with better transplant and recipient survival, however, demand for tissue greatly outpaces supply. The uncertainty of whether the intended recipient will receive tissue, even from a deceased donor promptly puts pressure on potential living donors potentially thus exposing them to varying degrees of psychological harm. By prohibiting the donation of non-regenerative tissue from a living minor this would in fact be reducing the amount of tissue available to potential recipients. But as discussed in chapter 1,³⁶⁷ the number of minors who donate non-regenerative tissue is limited.

Scotland does not allow minors to donate non-regenerative tissue, but Scottish minor recipients still receive tissue from other sources. While not medically the best source of donation, minors can receive tissue from a living adult donor or a deceased donor. The change in the law with regard to deceased donation in England and Wales, and Scotland from an opt-in system to an opt-out system may increase the supply of donated tissue, but this is not guaranteed. This vulnerability would be prominent amongst both incompetent and competent living donors because of the preferred treatment option that living donation provides to the recipient of the transplant. If the recipient benefit was the main focus when considering treatment options then medical vulnerability would be prevalent and living donation would occur every time without question.

³⁶⁷ at 1.2.4.

4.4.2.6 Situational

Is the potential living donor in a situation in which medical exigency of the intended recipient prevents the education and deliberation needed by the potential living donor to decide whether to participate as a living donor?³⁶⁸

The need for a potential recipient to receive a tissue donation may be urgent, and if their sibling is quickly identified as a match, thus a potential donor, this may preclude the minor donor from receiving adequate education and having appropriate time to deliberate and make an informed decision. However, in law it is necessary that if the minor donor is competent, they receive full information about the donation process, and the informed consent test in *Montgomery*³⁶⁹ is met in all situations. In addition, in all circumstances the minor donor has to be interviewed by an AA or an IA, depending on the type of tissue donated, in order to provide an independent check that the donor is not subject to coercion by the recipient, a medical professional, those with PR or their family. The role of the AA and IA interviews is a planned and necessary safeguard and sufficient time should be set aside for the interviews to be conducted properly and a comprehensive report produced.

A competent donor should be given ample opportunity to consider the gravity of the donation process in an independent environment away from the recipient, their family, and the medical professionals in order to come to terms with what is being asked of them, and decide whether they are going to donate. Similarly, if the donor is incompetent and those with PR can consent or provide authorisation on the donor's

³⁶⁸ Kipnis (n 269); Friedman Ross and Thistlethwaite (n 269).

³⁶⁹ *Montgomery v Lanarkshire Health Board* [2015] UKSC 11, [93].

behalf, then they will need time to process: first that one of their children is sick; secondly, that their other child can likely save their sibling's life; and thirdly, whether that child should be a tissue donor, the issues associated with this and the ramifications of the decision to be made. This must not be a knee-jerk decision given the limited time constraints, all options must be carefully explored making sure that the donor's interests are the focus of the decision and any alternative courses of treatment that are also available for the recipient are fully considered. In relation to non-regenerative tissue donation there is more information about the donation process to take into account, and the decision is very likely to have a greater impact on the donor, therefore, the decision-making process could take longer and be more difficult to arrive at compared to a regenerative tissue donation.

This vulnerability potentially falls under the psychological harm part of the equation because the urgency of the donation could interfere with the education and deliberation needed by the minor donor or those with PR to make a decision. The amount of time that is required for an individual to make a decision is not a set period, but will depend on the individual and how they perceive the gravity of the decision. The potential immediate and long-term medical risks of donating non-regenerative tissue and its irreversibility means that it is a more difficult decision to make by a competent minor and those with PR compared to a decision about the donation of regenerative tissue. Thus, in relation to non-regenerative tissue there is a bigger risk of this vulnerability materialising. Subsequently, in England and Wales a minor should not be permitted to be a non-regenerative tissue donor, and the Scottish approach be adopted.

4.4.2.7 Allocational

Is the potential living donor lacking in subjectively important social goods that will be provided as a consequence of participation as a donor?³⁷⁰

This vulnerability focuses on the potential social goods a minor donor believes they will be provided with as a consequence of being a donor. Social goods can include, for example, improved community social status or improved intra-familial relationships. If the transplant is successful then the family of the minor donor may be relieved of the burden of caring for the sick minor. This could lead to more parental time for the donor, as well as a better intra-familial relationship between the donor, the recipient, and the family. In addition, the financial situation of the family could improve because they may not have to pay to take their sick child to the hospital for treatment or pay for hospital bills if it is private treatment. However, in England and Wales, and Scotland it is more common that any medical procedures will be undertaken under the NHS which is free of charge. All of these situations will benefit the minor donor, but they must be aware of and understand that these social goods may be transient or may never occur.

Both pre- and post-donation, the family may focus their attention on the recipient in the hope that the transplant will be a success and the recipient will remain alive. This may result in the minor donor feeling they are not receiving sufficient attention and being marginalised. This could mean that they may not develop the initial psychological benefit from donating to their sibling, and it could result in the minor donor developing a psychological harm. On the other hand, as a result of the donation, the minor donor

³⁷⁰ Kipnis (n 269); Friedman Ross and Thistlethwaite (n 269).

may develop greater self-esteem and could be seen as a ‘hero’ by family, friends, and the larger community for donating to their sibling.³⁷¹ But again, if the family focus their attention on the recipient rather than the minor donor, the donor may subsequently develop a sense of neglect resulting in low self-esteem, and feel that there has been a lack of appreciation after the donation,³⁷² especially if the donation was of non-regenerative tissue.

If the minor donor has donated non-regenerative tissue then they will need to receive more support from their family during recovery, compared to a minor donor who has donated regenerative tissue. But this may be diminished if the focus of the family is on the recipient rather than the minor donor. Therefore, I suggest that if the minor donor has donated regenerative tissue because the medical risks are lower and recovery process shorter the donor requires less support from their family and the potential psychological harm as a result of this type of vulnerability will be reduced.

4.4.2.8 Infrastructural

Does the political, organisational, economic, and social context of the donor care setting possess the integrity and resources needed to manage the living donation process and follow-up?³⁷³

This vulnerability examines the ability of the transplant programme and the hospital to adequately perform a donation procedure for transplantation purposes from a living

³⁷¹ Friedman Ross and Thistlethwaite (n 327) 455.

³⁷² Soren Holm, *The child as organ and tissue donor: discussions in the Danish Council of Ethics* (2004) 13(2) *Cambridge Quarterly of Healthcare Ethics* 156, 156.

³⁷³ Kipnis (n 269); Friedman Ross and Thistlethwaite (n 269).

minor. This requires a wide range of resources: not just surgeons, but appropriate intensive care unit medical professionals as well as subspecialists to deal with both expected and unexpected complications of these procedures. This vulnerability has two components: the institutional support system, as well as the social situation. The institutional support system component of this vulnerability does not have a considerable impact on a minor donor in England and Wales, or Scotland because of the high standard of health care that is available and provided by the NHS free of charge or through the private sector.

This vulnerability relates to the social situation of the potential donor themselves, not the medical risks posed by the medical procedure. Do they have an adequate support system to help them through their recovery from surgery? With regard to sibling to sibling donation this process is undertaken within a family who should be able to provide a support mechanism for the minor donor, but the emotional support mechanism will be different depending on the circumstances of the family. Therefore, I suggest that if the minor donor has donated regenerative tissue because they require less support from their family, the potential psychological harm as a result of this type of vulnerability will be reduced compared to non-regenerative tissue. Therefore, a minor should not be permitted to donate non-regenerative tissue.

4.4.3 Concluding thoughts on psychological benefits and psychological harms

A psychological benefit that is greater than the medical risks and psychological harm posed by the tissue donation is required to justify a living minor as a tissue donor.

Put simply: psychological benefit > medical risks + psychological harm

in order for the donation to be justified.

But a psychological benefit cannot be guaranteed, and even less so if the transplant is not a success in the recipient. The success of the donation can have a considerable impact on the donor's psychological well-being. The minor donor may not develop a psychological benefit at all, but instead suffer from a psychological harm.

If the minor donor does develop a psychological benefit, there is no guarantee at what point in the donation process this will develop or whether it will develop in the future. If the minor is very young it is unlikely that the psychological benefit will materialise immediately, but it may be delayed until the minor donor is fully aware of the donation and the impact that it had on their sibling and their family. When those with PR, the minor donor, or the medical professionals are considering the potential psychological benefits the donor may receive from the donation they will have to consider future potential benefits, but at the same time this consideration has to be reasonable. For example, if the donor was very young it may not be reasonable to consider in the decision-making process a potential psychological benefit they may receive when they are a teenager. When considering the future, the decision-maker has to examine how lives change and evolve, what may seem like a strong relationship between the minor donor and the recipient at the time of the donation may breakdown a number of years later.

Both incompetent and competent minors are susceptible to some or all of the types of vulnerability discussed, depending on the circumstances of the donation. I have

demonstrated that in relation to the donation of non-regenerative tissue, a minor donor has a higher susceptibility to these vulnerabilities. Therefore, there is a greater chance that the donor will develop a psychological harm from the donation of non-regenerative tissue compared to regenerative tissue. The only safeguards to protect a minor donor are court approval, HTA approval, and interviews by an AA or IA. However, as I discussed in Chapter 3, the primary role of the AA or IA is to minimise the risk of coercion, which is only one of the potential vulnerabilities discussed in this chapter.³⁷⁴ These safeguards do not attempt to minimise the risk of the other vulnerabilities from materialising. Furthermore, these safeguards cannot guarantee the protection of the minor donor. In this discussion I have identified different types of vulnerabilities, but this does not mean that minors should never be allowed to be a tissue donor, rather, that it is critical that these vulnerabilities be explored, and if these threats cannot be adequately addressed with safeguards, such as with non-regenerative tissue, the minor should be prevented from donating.

4.5 Concluding thoughts

The main argument in this chapter is that the law in England and Wales should be reformed. When considering the first research question of this thesis: should minors in England and Wales be permitted to donate non-regenerative tissue? My contention is that no living minor should be able to donate non-regenerative tissue because the psychological benefits of the donation do not outweigh the immediate and long-term medical risks and potential psychological harms of the donation. I have explored a number of potential vulnerabilities that a minor donor may experience when donating

³⁷⁴ at 3.3.

non-regenerative tissue and I suggest that they are not adequately safeguarded against in the current regulatory framework.

Put simply: psychological benefit < medical risks + psychological harm

therefore, the donation is NOT justified.

Therefore, the Scottish approach should be adopted in England and Wales.

The medical risks of a donation procedure are speculative, and it is not definite that all or any type of morbidity will materialise. Psychological benefits are key when determining whether a living minor could be a tissue donor, but as psychological benefits are subjective, they cannot be quantified precisely. Therefore, in determining whether a minor could be a tissue donor the comparison is between the donor's speculative medical risks and the donor's unmeasurable psychological benefit. If the vulnerabilities a minor donor may be susceptible to can be identified then this does not mean that minors should never be allowed to be a tissue donor, but rather, that it is critical that their vulnerabilities be explored, and if these threats cannot be adequately addressed with safeguards, such as with non-regenerative tissue donation, the minor should be prevented from donating. The gravity of donating non-regenerative tissue and the irreversibility of the procedure suggests that no potential psychological benefits can outweigh the potential medical risks, psychological harm and long-term implications of a living minor donating this type of tissue.

As I have argued in this chapter that minors should not be allowed to donate non-regenerative tissue, the remaining chapters will only address regenerative tissue

donation from living minors. The following chapter will consider the second and third research questions of this thesis in relation to incompetent minors: who can and should be able to provide consent/authorisation for living minors to be regenerative tissue donors? and what test(s) should be used to determine whether consent/authorisation can be provided for a living minor to be a tissue donor? First, I conclude that those with PR can and should be able to provide consent/authorisation on behalf of an incompetent minor to be a tissue donor as long as it is in their best interests. Secondly, I argue that the best interests test should continue to be used to determine whether a minor should be a tissue donor, as it allows the decision-maker to take into account a range of factors. However, it should be amended by developing the factor that considers the minor's view in the decision-making process. Also, I recommend that an additional section should be added that deals exclusively with tissue donation from living minors.

Chapter 5

Incompetent Minors as Regenerative Tissue Donors

5.1 Introduction

In this chapter I will consider the second and third research questions of this thesis in relation to incompetent minors: who can and should be able to provide consent/authorisation for living minors to be regenerative tissue donors? and what test(s) should be used to determine whether consent/authorisation can be provided for a living minor to be a tissue donor? First, I conclude that those with parental responsibility (PR) can and should be able to provide consent/authorisation on behalf of an incompetent minor to be a tissue donor as long as it is in their best interests. Also, I propose that if those with PR have made a best interests decision which does not appear to be flawed, the court should not see necessary to override it because I argue that the best possible decision in those circumstances has already been made. It is irrelevant who makes the decision for the minor, either those with PR or the court, as long as the decision is in the best interests of the minor.

Secondly, I argue that the best interests test should continue to be used to determine whether a minor should be a tissue donor, as it allows the decision-maker to take into account a range of factors. However, I suggest that it should be amended by developing the factor that considers the minor's view in the decision-making process. Furthermore, I recommend that an additional section should be added that deals exclusively with tissue donation from living minors. It would include a factor that considers the harm of the procedure, and a requirement that takes into account relational parental decision-

making. The requirements in both the best interests test and this additional section would need to be met in order for a donation to occur.

In order to demonstrate my argument, I will set out the role and responsibilities of those with PR, and the role of the court in the decision-making process. In England and Wales, the best interests test is contained in the Children Act 1989, while in Scotland it is contained in the Children (Scotland) Act 1995. The best interests test applies to all medical procedures, but I shall argue that in England and Wales it fails to adequately consider the potential donor's view in the decision-making process. Furthermore, the best interests test fails to give sufficient weight to the potential harm of tissue donation; and the test does not consider the relationships that the minor donor has with their family with whom their interests are inextricably bound up, such as a decision that incorporates the principle of relational parental decision-making. I will consider four other tests that the court and other academics have suggested could be used instead of or in addition to the best interests test to determine whether a minor could be a tissue donor. The alternative tests I have selected are: substituted judgement; constrained parental autonomy as defined by Lainie Friedman Ross; "strong" and "weak" family interests; and the harm threshold.

5.2 Parental Responsibility

Minors who are incompetent, particularly pre-verbal or the very young, cannot make healthcare decisions for themselves, and so this responsibility must fall on someone who can make those decisions. In the first instance, to those with PR, and if not, to the court. Legislation determines who has PR for a minor. In England and Wales, PR is defined in section 3(1) of the 1989 Act as 'all the rights, duties, powers, responsibilities

and authority which by law a parent of a child has in relation to the child and his property.’ These rights are not defined further in the Act,³⁷⁵ but case law clarifies that those with PR have a right to give consent for a medical procedure on behalf of a minor.³⁷⁶ In Scotland, the equivalent provisions are more specific, and those with PR under section 1(1) of the 1995 have the responsibility:

- (a) to safeguard and promote the child’s health, development and welfare;
- (b) to provide, in a manner appropriate to the stage of development of the child-
 - (i) direction;
 - (ii) guidance, to the child;
- (c) if the child is not living with the parent, to maintain personal relations and direct contact with the child on a regular basis; and
- (d) to act as the child’s legal representative

but only in so far as compliance with this section is practicable and in the interests of the child.

The 1995 Act in Scotland explicitly includes the right to provide authorisation on behalf of a minor to undergo a medical procedure.³⁷⁷

In England and Wales, and Scotland when the minor’s father and mother are married to each other at the time the minor is born, both will automatically have PR for that minor.³⁷⁸ If they are not married, then the woman who gave birth will be the minor’s legal mother, and also have PR for the minor. In this situation, the unmarried father,

³⁷⁵ Sarah Elliston, *The Best Interests of the Child in Healthcare* (Routledge 2007) 28.

³⁷⁶ *Gillick v West Norfolk and Wisbech Area Health Authority* [1985] 3 All ER 402, 432.

³⁷⁷ Children (Scotland) Act 1995, s.1.

³⁷⁸ Children Act 1989, s.2(1); Children (Scotland) Act 1995, s.3(1).

may acquire PR if certain conditions are fulfilled.³⁷⁹ In England and Wales, and Scotland it is explicitly stated, in statute, that ‘more than one person may have parental responsibility for the same child at the same time.’³⁸⁰ In general, in relation to a medical procedure, if two individuals share PR, consent of only one of those with PR is required.³⁸¹ However, the Human Tissue Authority (HTA) state in *Code of Practice G*, which is applicable only in England and Wales, that consent of only one person with PR is required.³⁸² But where there is more than one person who has PR, and there is a dispute between them, the matter should be referred to court for them to make a decision on how to proceed.³⁸³ Even though there is no specific guidance on this in Scotland, there is no evidence to suggest that Scotland would take a contrary view to the one adopted in England and Wales.

In conclusion, those with PR can and should be able to provide consent/authorisation on behalf of an incompetent minor to be a tissue donor if it is in the minor’s best interests. As to what constitutes ‘best interests’ and also the role of the minor donor in the decision-making process this is examined at 5.4 in this chapter. I will now consider the role of the court in the decision-making process.

5.3 The Court

The court has a role to play in making a decision when those with PR or those with PR and the medical professionals disagree between themselves, or if there is any doubt as

³⁷⁹ Children Act 1989, s.2(2). See Children Act 1989, s.4 as amended by the Adoption and Children Act 2002; Children (Scotland) Act 1995, s.4 and s.4A.

³⁸⁰ Children Act 1989, s.2(5); Children (Scotland) Act 1995, s.2(2) respectively.

³⁸¹ Children Act 1989, s.2(7); Children (Scotland) Act 1995, s.2(2); General Medical Council, *Treatment and Care Towards the End of Life* (2010) para 104.

³⁸² Human Tissue Authority, *Code of Practice G: Donation of allogeneic bone marrow and peripheral blood stem cells for transplantation* (2017) para 74.

³⁸³ HTA, *Code of Practice G* (n 382) para 77; See *Re J (Child’s Religious Upbringing and Circumcision)* [1999] 2 FLR 1004 CA for discussion on parental disagreement over medical treatment of a minor.

to whether the medical procedure is in the best interests of the minor. The case could have been brought under a specific issue order,³⁸⁴ or the court will be invoking their inherent jurisdiction – the *parens patriae* jurisdiction.³⁸⁵ However, in Scotland, the inherent jurisdiction is used specifically in relation to adults who lack capacity and its scope for use in respect of a minor’s medical procedure is unclear.³⁸⁶ In theory, the court can consider any person who lacks capacity regardless of age.³⁸⁷ There is ambiguity as to whether the inherent jurisdiction confers the court with the same power over the minor as those with PR or whether it confers the court with extra-parental powers. If it is the latter, then the court can make decision on behalf of a minor, as those with PR can, but it can also override a decision made by those with PR on behalf of the minor.

The authority that those with PR have over a minor, also known as parental authority, is not absolute.³⁸⁸ While those with PR are generally presumed to be best placed to make decisions for the minor, as they know the minor better than anyone else, the threshold for court intervention will be met if a person with PR makes a decision that will potentially cause ‘significant harm’ to the minor.³⁸⁹ It is unclear what is considered to be significant harm. In *Re Z*, in the Court of Appeal, Sir Thomas Bingham stated that:

³⁸⁴ Children Act 1989, s.8; Children (Scotland) Act 1995, s.11(2).

³⁸⁵ Children Act 1989, s.11 and s.100; *Re X (A Minor)(Wardship: restriction on publication)* [1975] 1 All ER 697 at 706; *South Glamorgan County Council v Wand B* [1993] 1 FCR 626. See also John Seymour, ‘Parens Patriae and Wardship powers: their nature and origins’ (1994) 14(2) Oxford Journal of Legal Studies 159; Graeme Laurie, ‘Parens Patriae jurisdiction in the medico-legal context: the vagaries of judicial activism’ (1999) 3(1) Edinburgh Law Review 96.

³⁸⁶ see *L, Petitioner*, 1996 SCLR 538, CS; *Law Hospital NHS Trust v Lord Advocate* 1996 SCLR 49, IHCS.

³⁸⁷ Alexander B Wilkinson and Kenneth Norrie, *The Law Relating to Parent and Child in Scotland* (W Green, 1999) para 853.

³⁸⁸ Jeanne Snelling, ‘Minors and Contested Medical-Surgical Treatment: Where Are We with Best Interests?’ (2016) 25(1) Cambridge Quarterly of Healthcare Ethics 50, 50.

³⁸⁹ Snelling (n 388), 50; *Re Wyatt (A child) (Medical Treatment: Parent’s Consent)* [2004] EWHC 2247 [34] per Hedley J.

I would for my part accept without reservation that the decision of a devoted and responsible parent should be treated with respect. It should certainly not be disregarded or lightly set aside. But the role of the court is to exercise an independent and objective judgment. If that judgment is in accord with that of the devoted and responsible parent, well and good. If it is not, then it is the duty of the court, after giving due weight to the view of the devoted and responsible parent, to give effect to its own judgment. That is what it is there for. Its judgment may of course be wrong. So may that of the parents. But once the jurisdiction of the court is invoked its clear duty is to reach and express the best judgment it can.³⁹⁰

In agreement with Douglas Diekema, it is my opinion that not all decisions should trigger court intervention as those with PR should be allowed to make decisions on behalf of their minors with ‘sufficient space and freedom from intrusion by others’.³⁹¹ But it is unclear what is considered ‘sufficient space and freedom’.

In both the Charlie Gard and Alfie Evans litigation,³⁹² the courts made clear that they have the power to make medical decisions for minors at the point that the minor’s welfare is engaged.³⁹³ In other words, the threshold for judicial intervention in disputes about medical care for a minor is at the point when the procedure is not in the best interests of the minor. Cressida Auckland and Imogen Goold argue that *prima facie* decision-making authority about a minor’s medical care should rest with the minor’s

³⁹⁰ *Re Z (a minor) (freedom of publication)* [1995] 4 All ER 961, 986.

³⁹¹ Douglas S Diekema, ‘Parental Refusals of Medical Treatment: The Harm Principle as Threshold for State Intervention’ (2004) 25 *Theoretical Medicine* 243, 244.

³⁹² *Evans & Anor v Alder Hey Children’s NHS Foundation Trust & Anor* [2018] EWCA Civ 805; *Yates and Gard v Great Ormond Street Hospital* [2017] EWCA Civ 410.

³⁹³ Cressida Auckland and Imogen Goold, ‘Parental Rights, Best Interests and Significant Harms: who should have the final say over a child’s medical care?’ (2019) 78(2) *Cambridge Law Journal* 287, 287. See also Natasha Hammond-Browning, ‘When Doctors and Parents Don’t Agree: The story of Charlie Gard’ (2017) 14 *Journal of Bioethical Inquiry* 461; Emma Cave and Emma Nottingham, ‘Who knows best (interests)? The case of Charlie Gard’ (2018) 26(3) *Medical Law Review* 500.

parents, affording them the ability to choose between the range of medical options available.³⁹⁴ Their reasoning is that many decisions about minors are not solely medical decisions, but decisions involving a number of different aspects of the minor's interests and values that those with PR are best placed to understand.³⁹⁵ I proposed in Chapter 2 that my introduction of the concept of relational parental decision-making should form part of the decision-making when determining whether a minor should be a tissue donor.³⁹⁶ Since those with PR are best placed to identify the relationships that the minor has with others, as well as give them sufficient weighting and apply them to the decision-making process, it would follow that those with PR would have decision-making authority. But Lord Fraser in *Gillick v West Norfolk and Wisbech Area Health Authority* stated:

parental rights to control a child do not exist for the benefit of the parent. They exist for the benefit of the child and they are justified only in so far as they enable the parent to perform his duties towards the child, and towards other children in the family.³⁹⁷

It is my view that only when those with PR have not made a best interests decision, should the court become involved. Court intervention can be seen as an independent perspective on the decisions made by those with PR, and will provide a judgment taking all factors on the impact of the decision into account.

Sarah Elliston has argued that for the decision of those with PR to be overridden by the court, the court's decision will be a "better" one.³⁹⁸ In other words, the court's decision

³⁹⁴ Auckland and Goold (n 393), 287.

³⁹⁵ Auckland and Goold (n 393), 288.

³⁹⁶ at 2.3.

³⁹⁷ *Gillick* (n 376) 170.

³⁹⁸ Elliston (n 375) 20.

would be better for the minor than a decision made by those with PR. This prompts me to ask the following questions: what is considered to be a “better” decision in relation to a minor’s medical procedure? Does the decision have to be what is “best” for the minor or is “better” enough? I will now offer possible answers to these questions. Whether a decision is better for the minor is dependent on a number of factors. I argue that it must be better overall rather than better in relation to only one aspect of the decision. Whether a decision is considered better will depend on the factors that the decision-maker has taken into account when making the decision and, what weight these factors have been given. A number of factors are considered in a best interests decision, such as the harm, physical, emotional, and psychological needs of the minor.³⁹⁹ For instance, if the decision-maker just focuses on the psychological needs of the minor then one decision could be better than another, but at the same time this decision may not be better if they had only considered the physical needs of the minor instead. The decision-making process should collectively take account of all of the factors and decide what is best overall rather than focusing on one particular aspect of the decision.

If those with PR made a best interests decision on behalf of minor then theoretically the court could not make a better decision since a best interests decision should be the best possible decision made in those particular circumstances. If the court could make a better decision, it must be ascertained what this decision is better than. If those with PR have failed to make a best interests decision then the court can make a better decision. Their better decision will be the best decision for the minor, ie the best interests decision, in other words, better decision = the best interests decision = best decision.

³⁹⁹ see 5.4 for a discussion of the best interests test.

Furthermore, Elliston has argued that when overriding parental decisions the court should only be concerned with ensuring that the ‘significant interests of the minor are not put at risk and that the decision made by those with parental responsibility meet a reasonableness standard.’⁴⁰⁰ She argues that to go further would be to usurp the legitimate authority and function of those with PR.⁴⁰¹ But, if the court is only considering whether the decision made by those with PR is reasonable, then they are not considering whether those with PR have met the best interests standard. Moreover, this still leaves the unanswered question of what is considered reasonable? Or reasonable for whom? Elliston does not provide a definition.

Elliston purports to use these two different tests to decide whether a court should override the decision of those with PR, namely, the better decision test and the reasonableness test, but both fail to provide a clear test for a court to use and apply. I suggest that the more appropriate test is the one that is currently used, which is whether those with PR have made a best interests decision for the minor. If those with PR have not made a best interests decision, then the court can and should be able to override that decision and make a best interests decision on the minor’s behalf. If those with PR have made a best interests decision which does not appear to be flawed, the court should not see necessary to override it because the best possible decision for the minor in those circumstances has already been made. It is irrelevant who makes the decision for the minor, either those with PR or the court, as long as the decision is in the best interests of the minor.

⁴⁰⁰ Elliston (n 375) 2.

⁴⁰¹ Elliston (n 375) 3.

5.4 The Best Interests Test

Those with PR make decisions that should be in the minor's best interests.⁴⁰²

Determining best interests is a 'critical equation [that] cannot be done with mathematics or any precision'.⁴⁰³ The issue of whether a procedure is in the best interests of a minor is simplest when the procedure is for the medical benefit of the minor.⁴⁰⁴ There is difficulty in determining what is in a minor's best interests where the benefit is indirect; for instance, in tissue donation from a living minor. Loretta Kopelman has questioned:

whether we can really know what is in people's best interest. The best interest standard ... seems to suppose we can always agree about what is best, consider all options, calculate all their benefits and harms, and pick the alternative that maximises benefits and minimises harms ... This is not just a daunting task, but virtually impossible, especially when one contemplates the myriad possibilities of the indefinite future.⁴⁰⁵

Even where the relevant factors can be agreed, Claire Breen has stated that:

... in spite of the decision-makers best efforts, there remains a wide variety of circumstances that cannot be accounted for both in the present and in the future, which may distort the validity of the decision as being in the child's best interests. Consequently, according such ability to a decision-maker is to bestow upon him or her shamen-like qualities for the prediction of future events.⁴⁰⁶

Before the enactment of the relevant legislation in the different jurisdictions, the 1989 Act and the 1995 Act, the factors to be taken into account when determining best

⁴⁰² *An NHS Trust v MB* [2006] EWHC 507 (Fam).

⁴⁰³ *Re J (a minor) (wardship: medical treatment)* [1990] 3 All ER 930, 938 per Lord Donaldson.

⁴⁰⁴ PDG Skegg, 'Consent to Medical Procedures on Minors' (1973) 36(4) *Modern Law Review* 370, 377.

⁴⁰⁵ Loretta M Kopelman, 'The best interests standard as threshold, ideal and standard of reasonableness' (1997) 22(3) *Journal of Medicine and Philosophy* 271, 284.

⁴⁰⁶ Claire Breen, *The Standard of the Best Interests of the Child: A Western Tradition in International and Comparative Law, International Studies in Human Rights* Vol.72 (Martinus Nijhoff 2002) 17.

interests or, as it was known, the welfare of the minor, were set out in common law. In *re McGrath* Lindley LJ said that:

the word welfare must be taken in its widest sense. The moral and religious welfare of the child must be considered as well as its physical well-being, nor can the ties of affection be disregarded.⁴⁰⁷

In England and Wales, the current law on the best interests test for minors is contained in the 1989 Act. For proceedings under the Act, when a court determines any question with respect to the upbringing of a minor, ‘the child’s welfare shall be the court’s paramount consideration.’⁴⁰⁸ The same principle is found in the 1995 Scottish Act when a court is making an order in respect of PR or guardianship.⁴⁰⁹ This is reiterated in professional guidance where the General Medical Council (GMC), British Medical Association (BMA), and Nuffield Council on Bioethics all emphasise that decisions should be made in the minor’s best interests:

Doctors should always act in the best interest of children and young people.⁴¹⁰ The moral authority behind parental responsibility depends in large part on the entirely reasonable supposition that parents will act in the best interests of their children.⁴¹¹ ... the best interests of a baby must be a central consideration in determining whether and how to treat him or her.⁴¹²

⁴⁰⁷ [1893] 1 Ch 143, 148.

⁴⁰⁸ Children Act 1989, s.1(1).

⁴⁰⁹ Children (Scotland) Act 1995, s11(1) and 11(7)(a).

⁴¹⁰ General Medical Council, *0-18 years: guidance for all doctors* (2007) para 8.

⁴¹¹ British Medical Association, *Parental Responsibility* (Ethics Department, 2008) 2.

⁴¹² Nuffield Council on Bioethics, *Critical care decisions in fetal and neonatal medicine: ethical issues* (2006) para 10.

This is also confirmed in international law, Article 18 of the United Nations Convention of the Rights of Children (UNCRC) states that:

Parents or, as the case may be, legal guardians, have the primary responsibility for the upbringing and development of the child. The best interests of the child will be their basic concern.

In England and Wales, the 1989 Act contains a welfare “checklist” that a court must consider when making, varying or discharging an order. Under section 3(1) of the 1989 Act, the court must consider:

- (a) the ascertainable wishes and feelings of the child concerned (considered in light of the child’s age and understanding);
- (b) the child’s physical, emotional and/or education needs;
- (c) the likely effect on the child of any change in his/her circumstances;
- (d) the child’s age, sex, background and any other characteristics, which the court considers relevant;
- (e) any harm which the child has suffered or is at risk of suffering;
- (f) how capable each of the child’s parents, and any other person in relation to whom the court considers the question to be relevant, is of meeting his/her needs;
- (g) the range of powers available to the court under the Children Act 1989 in the proceedings in question.⁴¹³

In contrast, in Scotland, following the recommendations of the Scottish Law Commission, there is no general welfare checklist.⁴¹⁴ The Scottish Law Commission

⁴¹³ Children Act 1989, s.1(3).

⁴¹⁴ Scottish Law Commission, *Report on Family Law* (HC Paper [Session 1992-93]) (HMSO, 1992) Law Commission No. 135; The Law Commission, *Family Law Review of Child Law Guardianship and*

argued that section 3(2) of the Law Reform (Parent and Child) (Scotland) Act 1986, which was the legislation in force at the time of the recommendations, already refers to the paramountcy of the minor's welfare and that embraces 'practically everything' that would be in a checklist, however long.⁴¹⁵

*Re A (Medical Treatment: Male Sterilisation)*⁴¹⁶ has provided some guidance as to how the best interests test set out in the 1989 Act should be assessed. It requires the judge to draw up a balance sheet document that considers the benefits and the risks of the medical procedure. However, this simple way of weighing up the medical risks and benefits to the donor does not indicate what other factors the judge should take into account, such as whether the list should contain only medical factors or include other aspects such as social or emotional elements. Also, it is not clear as to how much weight should be placed on each risk or benefit.

The notable difference between the 1989 Act and the 1995 Act is in relation to the minor's own views.⁴¹⁷ The 1995 Act specifically mentions the need to involve the minor when making a decision on their behalf, while the 1989 Act states 'the ascertainable wishes and feelings of the child concerned'. The Scottish Law Commission (SLC) suggested that a minor's own views should be taken into account in their own right, and even though the 1995 Act does not have a welfare checklist, unlike the 1989 Act, there is a separate subsection that deals with the minor's views.⁴¹⁸ I argue

Custody (Law Com. No. 172, 1988) paras 3.17 to 3.21. The checklist recommended by the Commission was essentially the same as that enacted in the Children Act, although there are some differences in wording.

⁴¹⁵ Scottish Law Commission (n 414) para 5.23.

⁴¹⁶ *Re A (medical treatment: male sterilisation)* [2000] 1 FCR 193, 206 per Thorpe LJ.

⁴¹⁷ Scottish Law Commission (n 414) para 5.23.

⁴¹⁸ Scottish Law Commission (n 414) para 5.23.

that, in relation to tissue donation, even though the minor is incompetent they can express their opinion about the donation which should be given weight by those with PR in the decision-making process and the legislative provision should be framed the same as in Scotland.

5.4.1 The minor's role in the decision-making process

As part of the best interests test, specific mention is made in the 1995 Act of the need to involve the minor when making a decision on their behalf.⁴¹⁹ A court is required to take into account the minor's age and maturity and so far, as practicable:

- (i) give him an opportunity to indicate whether he wishes to express his views;
- (ii) if he does so wish, give him an opportunity to express them; and
- (iii) have regard to such views as he may express.⁴²⁰

In section 11(10) of the 1995 Act, it is stated that a minor aged 12 and above is presumed to be of sufficient age and maturity to form a view about whether to undergo the medical procedure. There is no equivalent provision in the 1989 Act, and there is no minimum age restriction for a minor to participate in either statute. The 1995 Act deals more comprehensively with a minor's view on the decision compared to the 1989 Act. I suggest that this shows that Scottish Parliament wanted to give the minor's view greater weighting, therefore, they adopted a different approach to the one taken in the 1989 Act in England and Wales.

⁴¹⁹ Children (Scotland) Act 1995, s.6.

⁴²⁰ Children (Scotland) Act 1995, s.11(7)(b).

The need to consider the minor's views in relation to tissue donation is set out in professional guidance. The HTA state in *Code of Practice G* that the minor donor should be provided with information about the procedure and its risks to an appropriate level.⁴²¹ This is reiterated by the GMC who have stated in their guidance that medical professionals 'should involve children and young people as much as possible in decisions about their care, even when they are not able to make decisions on their own'.⁴²² The Royal College of Paediatrics states that 'paediatricians must listen to children and young people and respect their views.'⁴²³ The level of communication required for the minor donor depends on their ability to understand the donation procedure,⁴²⁴ and 'understanding can be assisted by involving a play therapist, psychologist or specialist nurse in the communication process.'⁴²⁵ In some instances, it is clear when a minor is agreeing to the medical procedure; for example, they may voluntarily hold out their arm for a nurse to take blood. However, very young minors, for instance pre-verbal minors, may not be able to show any indication. Another indication as to the minor donor's view could be if the procedures surrounding the tissue donation, such as tests to determine histocompatibility, cause them to suffer medical, psychological or emotional harm, not usually experienced by a minor donor. The presence of any of these types of harm may indicate that the minor should not be considered as a tissue donor.

Taking account of a minor's view could be considered to be assent, although not legally binding in England and Wales, and Scotland it is 'an active agreement to participate and

⁴²¹ HTA, *Code of Practice G* (n 382) para 80.

⁴²² General Medical Council (n 410) para 23.

⁴²³ Royal College of Paediatrics, *Good Medical Practice in Paediatrics and Child Health: Duties and Responsibilities of Paediatricians* (RCP 2002) para 21.

⁴²⁴ HTA, *Code of Practice G* (n 382) para 80.

⁴²⁵ HTA, *Code of Practice G* (n 382) para 82.

not a mere failure to object.⁴²⁶ Minors may be able to assent to the tissue donation, but this is not the same as providing informed consent or informed authorisation as it will not conclusively determine whether the procedure will occur. Even though the minor donor would not be providing consent or authorisation they can still be given information about the medical procedure in a simple format that they can understand so they can express their opinion.

If a minor donor has been provided with basic information about the donation, but makes a statement such as ‘I don’t want to give my sister my bone marrow because she took my toy’ or ‘I want to have the operation because mummy said I will get lots of sweets’, then it is apparent that their understanding is not developed enough for their opinion to carry a significant weight in the decision-making process. While their reasoning does not have to reach the standard of the *Gillick* competence or section 2(4) competence tests,⁴²⁷ the minor’s reasoning cannot be superficial or based on receiving a reward for donating as this invokes a risk of coercion. However, if the minor says ‘I don’t want to give her my bone marrow because it will hurt me a lot’, or ‘I want to have the operation because it will help my sister get better’, even though they might not understand why the procedure will hurt them or why it will help their sister, they have some understanding of the donation procedure. The amount of weight given to a minor’s views will be dependent on their level of understanding. Lynn Hagger has suggested that:

⁴²⁶ L Friedman Ross, R Thistlethwaite and the Committee on Bioethics, ‘Minors as Living Solid Organ Donors’ (2008) 122(2) *Paediatrics* 454, 458.

⁴²⁷ see Chapter 6 at 6.2.1 and 6.2.2 for further information about the competency tests.

[a]ll children, whatever their age and circumstances, can provide valuable perceptions that can improve their clinical care ... with appropriate techniques, children as young as four can make helpful comments about their experience of health services.⁴²⁸

The role of the minor's views serves only to help the decision-maker determine what, on balance, is in the minor's best interests.⁴²⁹ It does not mean that the decision-maker would regard the minor's own views as decisive.⁴³⁰ Therefore, the minor's view is consultative rather than authoritative.⁴³¹ But, the decision-maker should still take into account the minor's view regardless of whether it is in agreement with those with PR or the medical professional.

If the 1989 Act was to be reformed to adopt the same wording as the 1995 Act in order to emphasise the use of the minor's view in the decision-making process it would read as follows, with the amendments in italics:

- (a) *the minor's age and maturity and so far, as practicable:*
 - (i) *give him an opportunity to indicate whether he wishes to express his views;*
 - (ii) *if he does so wish, give him an opportunity to express them; and*
 - (iii) *have regard to such views as he may express;*
- (b) the child's physical, emotional and/or education needs;
- (c) the likely effect on the child of any change in his/her circumstances;

⁴²⁸ Lynn Hagger, *The Child as Vulnerable Patient: Protection and Empowerment* (Routledge 2009) 56.

⁴²⁹ David Archard and Marit Skivenes, 'Balancing a Child's Best Interests and a Child's View' (2009) 17(1) *International Journal of Children's Rights* 1, 17.

⁴³⁰ Elliston (n 375) 16.

⁴³¹ Archard and Skivenes (n 429) 15.

- (d) the child's age, sex, background and any other characteristics, which the court considers relevant;
- (e) any harm which the child has suffered or is at risk of suffering;
- (f) how capable each of the child's parents, and any other person in relation to whom the court considers the question to be relevant, is of meeting his/her needs;
- (g) the range of powers available to the court under the Children Act 1989 in the proceedings in question.

5.4.2 Donor Interests vs Recipient Interests

Tissue donation is different to other medical procedures as it directly affects two individuals. In Chapter 4, I clarified why I was only considering the risks and benefits to the donor, and not to the recipient in relation to non-regenerative tissue.⁴³² I will now argue that when considering whether a minor should be a tissue donor, *only* the best interests of the minor donor should be considered and not those of the potential recipient. In contrast, Elliston has suggested that the interests of both minors should be given equal weight.⁴³³ However, this creates a conflict between the donor and the recipient as a tissue donation is a non-therapeutic procedure for the donor, whether it is in their best interests will rest on factors other than just the medical risks and benefits. If both the donor and the recipient's interests are to be considered together then there are many more factors that have to be taken into account, and there is a risk that the donor's interests could be unreasonably marginalised and not given priority in a particular area because of the profound effect the donation would have on the recipient's life.

⁴³² at 4.2.

⁴³³ Elliston (n 375) 22.

If the decision-making process in relation to tissue donation needs to consider the best interests of two minors simultaneously the way that the best interests test is framed would have to be modified. The current test makes it difficult to take into account the interests of both the donor and the recipient at the same time.⁴³⁴ This view is taken by the Department of Health (DoH), they state in guidance on bone marrow donation from incompetent minors that receiving a bone marrow donation will clearly be in the interests of the recipient minor, however:

in relation to medical interventions it is not acceptable for the needs of one sibling to be balanced against the needs of another. The legal test is whether donating bone marrow is in the best interest of the healthy child.⁴³⁵

In the remainder of this thesis, any discussion about the best interests test focuses on the donor's best interests and does not take into account the recipient's interests.

5.5 Proposed Reforms of the Best Interests Test

This section of the chapter will focus on the third research question of this thesis: what test(s) should be used to determine whether consent/authorisation can be provided for a living minor to be a tissue donor? The best interests test currently applies to all types of medical procedures including tissue donation. But I argue that there are two main criticisms of the best interests test in relation to tissue donation. First, that it does not give sufficient weight to the potential harm to the donor of a tissue donation procedure. Tissue donation is a non-therapeutic procedure for the donor; therefore, it is paramount

⁴³⁴ Elliston (n 375) 22.

⁴³⁵ Department of Health, *Reference Guide to Consent for Examination and Treatment* (DoH 2001) Chp 3, para 16.

that both the potential medical and psychological harms are considered before a decision is made as to whether the minor should donate. Secondly, the test does not consider the relationships that the minor donor has with their family with whom their interests are inextricably bound up, such as a decision that incorporates the principle relational parental decision-making.⁴³⁶ As discussed in Chapter 2, relational parental decision-making should form part of the decision-making process.⁴³⁷ As a result of these criticisms, I shall consider four other tests to determine whether they could be used instead of or in addition to the best interests test to determine whether a minor could be a tissue donor.

The alternative tests I have selected are: substituted judgement; constrained parental autonomy as defined by Friedman Ross; ‘strong’ and ‘weak’ family interests; and the harm threshold. I have selected these particular tests because substituted judgement was considered by a court in England and Wales to determine whether an individual who lacks capacity should undergo a medical procedure.⁴³⁸ Both constrained parental autonomy, and ‘strong’ and ‘weak’ family interests are tests defined by academics that take into account the relational aspect of the decision-making process. Finally, the harm threshold is a test that focuses on the harm that a medical procedure inflicts on the individual, which is particularly notable in tissue donation since it is a non-therapeutic procedure for the donor. I will now consider each test in turn analysing its strengths and weaknesses and concluding whether it is a suitable test to be used in relation to living minors as tissue donors.

⁴³⁶ Lainie Friedman Ross, *Children, Families, and Healthcare* (OUP 1998) 43.

⁴³⁷ at 2.3.

⁴³⁸ *Re Y (adult patient)(bone marrow transplant)* [1997] 2 WLR 556.

5.5.1 Substituted Judgement

The substituted judgement test allows the decision-maker to choose what they think the minor would have decided if the minor was competent.⁴³⁹ The test could allow the decision-maker to consent to or authorise tissue donation, even though it poses a risk to the potential donor, because they believe that the donor would have chosen to donate, had they been able to do so.⁴⁴⁰ There has been one case in England and Wales that considered this test. In *In re Y (adult patient)(bone marrow transplant)*,⁴⁴¹ the High Court authorised a bone marrow donation from Y, a 25-year old woman with physical and learning disabilities, to her sister, who was likely to die without it. In a rather convoluted chain of reasoning, Connell J concluded that the bone marrow donation would, in fact, be in Y's interests. It was argued that Y's mother would be extremely distressed if Y's sister died, and she would also be obliged to assume the care of Y's sister's young daughter.⁴⁴² Subsequently, this would limit the amount of time the mother could spend with Y.⁴⁴³ But the deciding factor seemed to be the impact that non-intervention would have had on the relationship between Y and her mother:

It was to the emotional, psychological and social benefit of the defendant to act as donor to her sister because in this way her positive relationship with her mother was most likely to be prolonged. The disadvantages to the defendant of the harvesting procedure were very small. The bone marrow donated by the defendant would cause her no loss and she would suffer no real long-term risk.⁴⁴⁴

⁴³⁹ SE Mumford, 'Donation without consent?' *Legal Developments in Bone Marrow Transplantation* (1998) 101(4) *British Journal of Haematology* 599, 600.

⁴⁴⁰ Mumford (n 439) 600.

⁴⁴¹ *Re Y* (n 438).

⁴⁴² *Re Y* (n 438) 599.

⁴⁴³ *Re Y* (n 438) 599.

⁴⁴⁴ *Re Y* (n 438) 562.

In this case, it is unclear whether the court was concerned with Y's best interests or her better interests, which is a similar argument to that taken by Elliston that I discussed earlier in this chapter.⁴⁴⁵ In relation to that argument, I concluded that the court is unable to use and apply the better decision test as it is unclear and unworkable when attempting to make a judgment. The reason is because if the decision-maker made a best interests decision on behalf of the minor then theoretically a better decision could not be made as the best possible decision has already been made in those particular circumstances. In relation to *Re Y*, it may be in her better interests to improve her relationship with her mother, but whether, when considering all of the factors, it is in her best interests to undergo non-therapeutic medical procedure in order to do so is less obvious.⁴⁴⁶ Taking into account her psychological well-being, the court concluded that she should donate bone marrow to her sister.⁴⁴⁷

Re Y has been criticised for a number of reasons, including the apparent weak evidence relied upon by the court.⁴⁴⁸ Trying to determine how someone would act is difficult, especially if they have never been competent, and making a decision based on substituted judgement has been described as 'equivalent to guesswork'.⁴⁴⁹ An incompetent minor would never have been able to consent to or authorise a medical procedure, therefore, trying to determine what decision they would make about a medical procedure is difficult since there is no previous pattern of decision-making to examine.

⁴⁴⁵ see Chapter 5 at 5.3.

⁴⁴⁶ Laurie (n 385) 103.

⁴⁴⁷ Mumford (n 439) 599.

⁴⁴⁸ Shih-Ning Then, 'Best interests: The 'best' way for courts to decide if young children should act as bone marrow donors?' (2017) 17 *Medical Law International* 3, 25; Andrew Grubb, 'Commentary: Adult incompetent: Legality of Non-therapeutic Procedure: *Re Y*' (1996) 4 *Medical Law Review* 204, 206.

⁴⁴⁹ Sheila McLean, 'Consent and the law: review of the current provisions in the Human Fertilisation and Embryology Act 1990 for the UK Health Ministers' (1997) 3(6) *Human Reproduction Update* 593, 602.

I argue that the substituted judgement test would not be suitable to use to decide whether a minor should be a tissue donor as it is based on speculative evidence. It cannot be conclusively decided what weight the minor donor would place on different factors such as the medical risks, their psychological well-being, or the impact of the donation on the recipient. The decision-maker could erroneously place greater weight on the impact the donation would have on the recipient, by arguing that the minor donor would want to donate so their sibling becomes healthy or remains alive. This presents a risk of exploitation of the potential minor donor as they could be a means to an end. As the decision-maker is predicting what the minor may have decided if they were competent, the decision-maker's decision could be accepted without question unless explicit evidence is provided contrary to the reasoning given. The HTA have put in safeguards to try to prevent the coercion of minor donors through the use of HTA and/or court approval. It may be argued that those with PR are best placed to determine what decision the minor donor would make if they were competent as they know the minor better than anyone else, but this could potentially lead to the exploitation of the minor donor if those with PR were to base their decision on weak evidence. Therefore, I argue that the substituted judgement test should not be used as a replacement to or in addition to the current best interests test.

5.5.2 Constrained Parental Autonomy as defined by Lainie Friedman Ross

Friedman Ross has argued that those with PR are the best decision-makers for a minor since they are generally presumed to be best placed to determine what is in their minor's interests as they know the minor better than anyone else.⁴⁵⁰ She has suggested a model

⁴⁵⁰ Friedman Ross (n 436) 131-141.

of constrained parental autonomy that allows those with PR to trade the best interests of one minor against the familial interests as long as all of the basic needs of that minor are secured.⁴⁵¹ In other words, those with PR do not have to necessarily act in the best interests of the minor if that decision promotes the interests of the family as a whole, as long as those with PR have met the basic needs of the minor. Friedman Ross defines “basic needs” as ‘the basic goods, skills, and liberties, and opportunities essential for the adequate development and full exercise of moral personality.’⁴⁵² I am arguing that this model is not suitable to replace or as an addition to the current best interests test to determine whether a living minor should be a tissue donor because it is too broad and focuses too much on the interests of the recipient minor and the family unit as a whole, rather than on the potential donor.

Often in families, the well-being of one minor is intertwined with the well-being of other family members,⁴⁵³ and decisions are made collectively to improve the interests of the family as a whole. This is particularly true in relation to tissue donation where the donor and recipient are siblings. Allowing a minor to be a tissue donor promotes the interests of the family as a whole since the transplant would be life-saving or life-prolonging for the recipient resulting in the family staying intact. Under this model of constrained parental autonomy, those with PR have a wide discretionary power in making decisions for incompetent minors.⁴⁵⁴ But, if those with PR do not fulfil all of the basic needs of the minor, then court intervention is justified.⁴⁵⁵

⁴⁵¹ Friedman Ross (n 436) 131-141.

⁴⁵² Friedman Ross (n 436) 5-6.

⁴⁵³ Friedman Ross (n 436) 114.

⁴⁵⁴ Friedman Ross (n 436) 120.

⁴⁵⁵ Friedman Ross (n 436) 24.

Friedman Ross suggests three criteria that need to be fulfilled in order for court intervention in parental decision-making to be justified.⁴⁵⁶ First, medical professionals must agree that the medical procedure is non-experimental and medically appropriate for the minor.⁴⁵⁷ Secondly, denial of that medical procedure would result in the deprivation of the minor donor's basic needs.⁴⁵⁸ Finally, the anticipated result of the medical procedure gives the minor donor 'a chance for normal healthy growth or a life worth living' from the minor donor's own perspective.⁴⁵⁹ Friedman Ross argues that the low risk of long-term morbidity means that donation of bone marrow satisfies these conditions.⁴⁶⁰ She argues that those with PR should be allowed to authorise a minor's participation in intra-familial donations that entail minimal risk.⁴⁶¹ Donations that entail significant medical risks and harms, such as non-regenerative tissue donation, seriously threatens the normal healthy growth and life of the minor donor so would contravene the third condition.⁴⁶² Thus, those with PR cannot "sacrifice" one minor for another even if it is for the wider interests of the family.⁴⁶³

Unlike the best interests test, the constrained parental autonomy model allows the familial interests of the family including the interests of the recipient, as they are part of the family unit, to be taken into account. However, there is a risk that the interests of the donor will not be the paramount consideration as those with PR only need to maintain the basic needs of the minor donor rather than meet the higher threshold of the best interests test. Moreover, Friedman Ross' model may allow those with PR to use

⁴⁵⁶ Friedman Ross (n 436) 140.

⁴⁵⁷ Friedman Ross (n 436) 140.

⁴⁵⁸ Friedman Ross (n 436) 140.

⁴⁵⁹ Friedman Ross (n 436) 140.

⁴⁶⁰ Friedman Ross (n 436) 113-115.

⁴⁶¹ Friedman Ross (n 436) 115; however, I have argued in Chapter 4 that no minor should be permitted to donate non-regenerative tissue.

⁴⁶² Friedman Ross (n 436) 115.

⁴⁶³ Friedman Ross (n 436) 115.

their minor as a means to an end, as long as they simultaneously respect the basic needs of the minor.⁴⁶⁴ This means that a minor could be used purely as a tissue donor with little consideration for their interests and welfare as long as only their basic needs are met. The threshold for a minor's basic needs to be met is low.

The recipient's interests and those of the wider family should be a consideration, but should not solely determine whether the donation takes place because otherwise the donation would always take place without ever considering the interests of the donor. Those with PR should not be able to make decisions purely for the benefit of the family unit, while only having to maintain the basic needs of the minor donor as this does not protect them from potential exploitation. The idea of including a test that fulfils the principle of relational parental decision-making as an addition to the best interest test is attractive and will be further explored in the next section.⁴⁶⁵ But, the familial interests should not be the dominant factor when determining whether a minor should be a tissue donor, therefore, the best interests test should contain a model of constrained parental autonomy as defined by Friedman Ross.

5.5.3 'Strong' and 'Weak' Family Interests

As with the constrained parental autonomy model, the strong and weak interests model also considers wider family interests when making a decision. But unlike the constrained parental autonomy model, I argue that the weak family interests model should be part of an additional test to the best interests test specifically for living minors as tissue donors. Paul Baines puts forward an argument that two senses of family interests may be discerned, a weak sense, which is the amalgamated interests of family

⁴⁶⁴ Friedman Ross (n 436) 114.

⁴⁶⁵ at 5.5.3.

members, and a strong sense, in that the family itself has interests over and above the interests of the individuals.⁴⁶⁶ The strong sense requires that:

familial considerations must be taken into account in medical decision-making, and that sometimes these considerations have a greater claim on healthcare professionals than do the best interest of the pediatric patient.⁴⁶⁷

The strong conception is that the family is intrinsically valuable, over and above the benefits to individuals of being in a family.⁴⁶⁸ Friedman Ross commented on the strong conception and argued that:

parents perceive themselves as a representative of the family's interests, and this can be separated from their role as representatives of their own interests. As such parents can serve as both moderator and disputant in intimate family decisions.⁴⁶⁹

Her claim is that in theory those with PR can stand above the family and take a more objective view of the decisions, but that this does not mean that those with PR will act in this way.⁴⁷⁰ In situations where those with PR have to decide as both 'moderator and disputant', it is difficult for those with PR to be objective.⁴⁷¹ On some occasions, those with PR must make decisions that are not in a particular minor's best interests, but are for the good of others in the family.⁴⁷² These decisions cannot be justified by the minor donor's interests, but can only be justified by the family interests.⁴⁷³ As with the constrained parental autonomy model, I argue that the strong sense focuses too much

⁴⁶⁶ Paul Baines, 'Family Interests and Medical Decisions for Children' (2017) 31(8) *Bioethics* 599.

⁴⁶⁷ Hilde Lindemann, 'Why families matter' (2014) 134 *Pediatrics* 134, S98.

⁴⁶⁸ Baines (n 466) 604.

⁴⁶⁹ Baines (n 466) 605; Friedman Ross (n 436) 32.

⁴⁷⁰ Baines (n 466) 605.

⁴⁷¹ Baines (n 466) 605.

⁴⁷² Baines (n 466) 606.

⁴⁷³ Baines (n 466) 606.

on the wider family interests and neglects the interests of the minor donor. This means that in some situations, the wider family is given greater consideration than the minor's interests meaning that there is a risk that the minor could be used as a means to an end as a tissue donor. If the strong sense model was used in determining whether a minor should be a tissue donor there is a risk that the minor's interests may not be considered at all because it will always be in the family interests for the minor to donate and provide the recipient sibling with a life-saving or life-prolonging transplant.

Baines argues that the weak sense of family interests is a more plausible model⁴⁷⁴ because it views family interests as no more than the combined interests of family members.⁴⁷⁵ This type of model has previously been suggested by Andrew Bainham who argued for a 'collective family interest' characterised as:

... children are not just individuals, with individual interests. They are also members of a family unit and have an interest which forms part of the collective interests of the unit ... There may also be a collective interest of the family (of which they are part) which needs to be taken into account ... in some instances, the combined interests of the parents and the family taken as a whole may outweigh the interests of a particular child.⁴⁷⁶

This links with the concept of relational parental decision-making that was discussed in Chapter 2.⁴⁷⁷ Instead of those with PR making a decision as if the minor is an isolated being, the relationships that the minor maintains should be a contributing part of the

⁴⁷⁴ Baines (n 466) 599.

⁴⁷⁵ Baines (n 466) 602.

⁴⁷⁶ Baines (n 466) 602; A Bainham, 'Honour thy father and thy mother: Children's rights and children's duties' in Gillian Douglas and Leslie Seba (eds) *Children's rights and traditional values* (Ashgate 1998) Chp 6, 199.

⁴⁷⁷ at 2.3.

decision-making, resulting in relational parental decision-making. In other words, for those with PR to make a decision on behalf of a minor they need to take into account the minor's relationships with others that underpin their lives, such as familial and societal relationships. The degree that a particular relationship is taken into account is dependent on the situation; including the importance of the relationship and the weight it has on the individual's life. The minor's interests are still the paramount consideration but the familial relationships that a minor donor has are also a consideration in the decision-making process. All members of a family can be affected by decisions for one family member:

Decisions about a child's course of treatment affect not only the life and welfare of that child, but they often involve very significant financial, relational, and emotional consequences for the rest of the family.⁴⁷⁸

It is unlikely that any particular course will offer each individual maximal benefit, and so there needs to be a balancing of the interests of the individual family members.⁴⁷⁹ If so, the interests of the family members should be amalgamated.⁴⁸⁰ The weak interests model is more suitable to be an addition to the best interests test. It reflects the concept of relational parental decision-making in that decisions are made through networks of relationships and decisions are not made in isolation. Family interests are important in the tissue donation decision-making process since the donation is between siblings and has a direct impact on the family. As this model does not encompass other factors that the best interests test already covers, which I argue should continue to be considered in

⁴⁷⁸ Baines (n 466) 602; Erica K Salter, 'Deciding for the child: a comprehensive analysis of the best interest standard' (2012) 33(3) *Theoretical Medicine and Bioethics* 180, 183.

⁴⁷⁹ Baines (n 466) 602.

⁴⁸⁰ Baines (n 466) 600.

the decision-making process, this weak interests model would be an addition to the best interests test rather than a replacement for it.

The checklist in section 1(3) of the 1989 Act, which is applicable in England and Wales, is far-reaching as it applies to all aspects of a minor's welfare and upbringing. Therefore, as I am arguing that relational parental decision-making should only form part of the decision-making for tissue donation it needs to be contained in a separate section of the 1989 Act rather than incorporated into the best interests test. I am now going to demonstrate how this reform would apply in practice. The new factor would be set out in section 1A of the 1989 Act and it would state: 'the inclusion of relational parental decision-making'. If this factor was not explicitly incorporated into the statute, but just a factor that the decision-maker should take into account when deciding whether a minor should be a tissue donor, there is a risk that it could be overlooked and not given sufficient weight. Therefore, if it is incorporated into the 1989 Act, regardless of whether those with PR or the court is the decision-maker, relational parental decision-making will be a consideration when determining whether it is in a minor's best interests to be a tissue donor. Subsequently, the additional test under section 1A of the 1989 Act, set out in italics would state:

(1) In relation to tissue donation from a living minor, the following additional factor must be considered in addition to the best interests test as stated at section 1(3):

(a) the inclusion of relational parental decision-making.

This reform would only be applicable in England and Wales as the 1995 Act in Scotland does not have a general welfare checklist, therefore, it could not be incorporated directly after the best interests test as has been suggested in England and Wales.

Alternatively, it is suggested that it should constitute a standalone section that deals explicitly with tissue donation in the 1995 Act. This would alleviate the concern I raised previously that if the factor was not explicitly incorporated into the statute, but just a factor that the decision-maker should take into account when deciding whether a living minor should be a tissue donor, there is a risk that it would be overlooked and not given sufficient weight. Therefore, I would implement section 6A to include the recommended provision. However, this additional section could be included anywhere within the statute as it is a standalone section involving only living minors as tissue donors. Subsequently, the additional test under section 6A of the 1995 Act, set out in italics, would state:

(1) In relation to tissue donation from a living minor, the following factor must be considered when determining whether it is in the minor's best interests to undergo the procedure:

(a) the inclusion of relational parental decision-making.

5.5.4 Harm Threshold

Under section 1(3)(e) of the 1989 Act, 'any harm which the child has suffered or is at risk of suffering' is already a factor when determining the best interests of a minor, and similarly in Scotland under the 1995 Act the harm or risk of harm of the procedure would be a factor considered by the decision-maker. But my contention is that sufficient weight is not placed on this factor in relation to tissue donation. Douglas Diekema has

argued that best interests can be difficult to define, are conceived differently by those with PR and the court, and do not represent the standard applied in practice.⁴⁸¹ He proposes a harm standard, and contends that:

the biggest problem with a best interest standard is not its subjectivity, but that it represents that wrong standard. State intervention is not justified because a decision is contrary to the child's best interest, but because it places the child at significant risk of serious harm. Discussing the child's 'best interest' fails to focus on the relevant standard for determining when state action is justified. The harm standard focuses discussion in the proper place.⁴⁸²

He suggests that harm is, in fact, the central concept to be considered when determining whether a minor should undergo a medical procedure.⁴⁸³ If the threshold for court intervention is determined by the amount of harm placed on the child as a result of the decision, then it would follow that the test should place more emphasis on the harm of the procedure.

According to Diekema's harm threshold test, a medical professional is justified in seeking court intervention when those with PR make a decision that 'significantly increase[s] the likelihood of serious harm as compared to other options.'⁴⁸⁴ If, however, the decision as to whether a minor can donate tissue is purely based on whether it medically harms the minor, it would never be permitted because donating tissue inflicts harm on them. But if the standard is "serious harm" as indicated by Diekema, then

⁴⁸¹ Douglas S Diekema, 'Parental Refusals of Medical Treatment: The Harm Principle as Threshold for State Intervention' (2004) 25 *Theoretical Medicine* 243, 247.

⁴⁸² Diekema (n 482) 253.

⁴⁸³ Rosalind J McDougall and Lauren Notini, 'Overriding parents' medical decisions for their children: a systematic review of normative literature' (2013) 40(7) *Journal of Medical Ethics* 448, 450.

⁴⁸⁴ Diekema (n 482) 252.

regenerative tissue donation would be permitted since it only amounts to minimal harm. So far, a presumption is being made that “harm” only covers medical harm. While Diekema does not explicitly define “harm”, his discussion suggests that relevant harms go beyond the medical, including the minor’s future autonomy.⁴⁸⁵ For instance, it would be considered a harm if the decision made by those with PR restricts the minor’s autonomous future decision-making abilities, such as life-style restrictions posed following kidney donation.⁴⁸⁶ Diekema has proposed a series of eight conditions that ‘must [all] be met before considering the use of state intervention to require medical treatment of children over parental objections.’⁴⁸⁷ These are:

- (1) The refusal puts the child at ‘significant risk of serious harm’
- (2) The harm is imminent
- (3) The refused intervention is necessary to prevent the harm
- (4) The refused intervention is ‘of proven efficacy’
- (5) The projected benefit to burden ratio of the refused intervention is ‘significantly more favourable’ than that associated with the parents’ preferred option
- (6) No other option would prevent serious harm to the child in a way that is more acceptable to the parents
- (7) The state would intervene in ‘all other similar situations; regardless of the nature of the parents’ reasons’
- (8) Most parents agree that the state intervention was reasonable.⁴⁸⁸

⁴⁸⁵ Diekema (n 482) 251; Douglas S Diekema, ‘Parental refusals of recommended medical interventions’ in Douglas S Diekema, Mark R Mercurio, and Mary B Adam (eds), *Clinical Ethics in Pediatrics: A Case-Based Textbook* (2011 CUP) 15-16; Douglas S Diekema, ‘Revisiting the best interest standard: uses and misuses’ (2011) 22(2) *Journal of Clinical ethics* 128, 132.

⁴⁸⁶ see Chapter 4 at 4.3.3 for further discussion about the life-style restrictions of kidney donation.

⁴⁸⁷ Diekema (n 482) 252.

⁴⁸⁸ Diekema (n 482) 252.

Diekema proposed that these criteria come into play when those with PR have refused to consent to or authorise a medical procedure, and the court's intervention would be the final arbiter in determining whether that procedure should occur. If these criteria are applied to tissue donation, then some aspects of them would have to be adapted. They would be used where there has been some disagreement between those with PR and the medical professionals or between those with PR.

If these are applied to tissue donation, the first criterion is fulfilled because as I discussed in Chapter 4, regenerative tissue donation does not normally pose a significant medical risk of harm to the minor.⁴⁸⁹ Moving on to the second criterion, the harm would be imminent as it would be as a direct result of the donation procedure. Thirdly, if the donation did not proceed, then the harm to the donor would never occur. In relation to the efficacy of the procedure, regenerative tissue donations are common procedures with a high success rate. However, there are always risks of morbidity and mortality that cannot be avoided with any type of medical procedure. If the fifth criterion is applied to tissue donation, either the minor donates or they do not, there is no alternative option. Therefore, this criterion would rest on whether the psychological benefit (PB) outweighs the medical risk (MR) and the psychological risk (PR) of the procedure, if $PB > MR + PR$ then the donation is justified and can proceed.⁴⁹⁰ The sixth criterion would have to be disregarded for tissue donation, since refusal of the tissue donation procedure would not prevent any serious harm to the minor donor.

The seventh criterion relates to the court's intervention. The court does not automatically become involved when a minor is a tissue donor since the HTA do not

⁴⁸⁹ at 4.3.1 and 4.3.2.

⁴⁹⁰ see Chapter 4 at 4.4 for further discussion and application of this equation.

require court approval for a regenerative tissue donation from a living incompetent minor to proceed, only HTA approval is required.⁴⁹¹ The court would only intervene when those with PR make a decision that is not in the minor's best interests. It is questionable whether those with PR would agree that court intervention was reasonable. Some may argue that it is a decision made within a family, so it is a private decision that should not be interfered with. On the other hand, it may be argued that court intervention is an independent check and an extra safeguard. Since the decision has to be authorised by the HTA who provides an independent check, court intervention should not be automatically required.

Diekema, whose views are supported by other academics, argues that the harm threshold is more readily understood by medical professionals and those with PR, compared to the best interests test. This is because medical professionals are more familiar with medical risks as they deal with them on a day-to-day basis, and those with PR would have the medical risks explained to them by the medical professional as part of the consent or authorisation process.⁴⁹² However, Giles Birchley claims that this argument is problematic because although harm may appear a readily understandable concept, this hides the fact that judgements about harm are often complex.⁴⁹³ This was made apparent in Chapter 4 when I presented the risks of morbidity and mortality for the different types of tissue donation.⁴⁹⁴

⁴⁹¹ see Chapter 3 and Tables 3-6 for further discussion about the requirements.

⁴⁹² Elliston (n 375) 28; Seema K Shah, 'Does research with children violate the best interests standard? An empirical and conceptual analysis' (2013) 8 *Northwest Journal of Law and Social Policy* 121; Diekema, 'Revisiting the best interest standard' (n 486).

⁴⁹³ Giles Birchley, 'Harm is all you need? Best interests and disputes about parental decision-making' (2015) 42(2) *Journal of Medical Ethics* 111, 112.

⁴⁹⁴ see Chapter 4 at 4.3 and Appendices 5,6 and 7.

Unlike the best interests test, the harm threshold test does not contain all of the factors that need to be considered when making a decision, such as the psychological and emotional impact of the medical procedure.⁴⁹⁵ In a best interests decision, the true extent of the harm of the procedure could be concealed if the decision-maker gives more weight to the factors that benefit the minor donor than just focus on the harm that the procedure poses. I am arguing that the potential harm of the medical procedure is already a factor when determining whether it is in a minor's best interests to be a tissue donor, but more weight should be given to this factor when considering tissue donation because it is a non-therapeutic procedure for the donor.

As Diekema has identified, if harm is the only factor considered when determining whether a minor can be a tissue donor, then it would never be permitted. The best interests test in section 1(3) is a list of factors that provides no indication of the weight that should be given to each factor. As I have argued that the potential harm of the medical procedure should be given more weight, the best interests test would have to be amended to reflect this. But as the best interests test is generic and covers all types of medical procedures I cannot amend the current test. Instead, I recommend that a caveat needs to be included in a section after section 1(3) of the 1989 Act stating that in relation to tissue donation from living minors section 1(3)(e) should be given the greatest weight when the decision-maker is determining whether the procedure is in the minor's best interests. Subsequently, this factor could be included in the new section 1A that I recommended in the previous section that focuses specifically on tissue donation. The new section, set out in italics, will state:

⁴⁹⁵ Birchley (n 494) 112.

- (2) *In relation to tissue donation from a living minor when considering the best interests test in section 1(3), the factor under section 1(3)(e) should be given the greatest weight.*

This reform would only be applicable in England and Wales as the 1995 Act in Scotland does not have a general welfare checklist. But I suggest that it should be included in the 1995 Act because this would alleviate the concern I raised previously that if the factor was not explicitly incorporated into the statute, but just a factor that the decision-maker should take into account when deciding whether a living minor should be a tissue donor, there is a risk that it could be overlooked and not given sufficient weight. Therefore, I would include it in a standalone section, in fact it could be included in the new section 6A that I devised in the previous section that covers relational parental decision-making. The new section, set out in italics, will state:

- (2) *In relation to tissue donation from a living minor when considering their best interests, the consideration of the harm of the procedure should be given the greatest weight.*

5.6 Concluding thoughts

In this chapter I considered the second research question of this thesis in relation to incompetent minors: who can and should be able to provide consent/authorisation for living minors to be regenerative tissue donors? I concluded that those with PR can and should be able to provide consent/authorisation on behalf of an incompetent minor to be a tissue donor as long as it is in their best interests. Also, I proposed that if those with PR have made a best interests decision which does not appear to be flawed, the court should not see necessary to override it because the best possible decision in the

minor's interest has already been made. It is irrelevant who makes the decision for the minor, either those with PR or the court, as long as the decision is in the best interests of the minor.

I also examined the third research question of this thesis in relation to incompetent minors: what test(s) should be used to determine whether consent/authorisation can be provided for a living minor to be a tissue donor? I have recommended reform to the best interests test in section 1(3) of the 1989 Act, which would result in the development of the factor that considers the minor's view in the decision-making process. Furthermore, I have implemented an additional test in both the 1989 Act and the 1995 Act that is specific to tissue donation. This test introduces the additional requirement that the minor donor's familial relationships have to be incorporated into the decision-making process through relational parental decision-making. Also, that the harm principle is given the greatest weight when considering the minor's best interests. The aim is that the combination of the best interests test and this new test is more suitable to determine whether an incompetent living minor should be a tissue donor than just the current best interests test. It simultaneously protects the minor's interests and prevents their exploitation as well as takes account of all factors that may be relevant in the decision-making process. Subsequently, my argument is that the amended best interests test under section 1(3) of the 1989 Act would read as follows, with the amendments in italics:

- (a) *the minor's age and maturity and so far, as practicable:*
 - (i) *give him an opportunity to indicate whether he wishes to express his views;*
 - (ii) *if he does so wish, give him an opportunity to express them; and*

- (iii) *have regard to such views as he may express;*
- (b) the child's physical, emotional and/or education needs;
- (c) the likely effect on the child of any change in his/her circumstances;
- (d) the child's age, sex, background and any other characteristics, which the court considers relevant;
- (e) any harm which the child has suffered or is at risk of suffering;
- (f) how capable each of the child's parents, and any other person in relation to whom the court considers the question to be relevant, is of meeting his/her needs;
- (g) the range of powers available to the court under the Children Act 1989 in the proceedings in question.

Subsequently, there would be an additional section in the 1989 Act which would read as follows, in italics:

Section 1A

- (1) *In relation to tissue donation from a living minor, the following additional factor must be considered in addition to the best interests test as stated at section 1(3):*
 - (a) *the inclusion of relational parental decision-making.*
- (2) *In relation to tissue donation from a living minor when considering the best interests test in section 1(3), the factor under section 1(3)(e) should be given the greatest weight.*

In Scotland, I have recommended that an additional section in the 1995 Act would read as follows, in italics:

Section 6A

- (1) *In relation to tissue donation from a living minor, the following additional factor must be considered when determining whether it is in the minor's best interests to undergo the procedure:*
 - (a) *the inclusion of relational parental decision-making.*

- (2) *In relation to tissue donation from a living minor when considering their best interests the consideration of the harm of the procedure should be given the greatest weight.*

In the following chapter, I will consider the second and third research questions of this thesis in relation to a competent minor: who can and should be able to provide consent/authorisation for living minors to be regenerative tissue donors? and what test(s) should be used to determine whether consent/authorisation can be provided for a living minor to be a tissue donor? I conclude that if a minor meets the relevant competency test, they should be able to provide consent or authorisation on their own behalf. I recommend clarification to the *Gillick*⁴⁹⁶ competence test and section 2(4) of the Age of Legal Capacity (Scotland) Act 1991 competence test which are applicable to under 16s as well as section 8 of the Family Law Reform Act 1969. Furthermore, I argue that those with PR currently can, but should not be permitted to override a

⁴⁹⁶ *Gillick* (n 376).

competent minor's consent/authorisation, and once a minor is competent a court can but should not be able to override their decision about whether to be a tissue donor.

Chapter 6

Competent Minors as Regenerative Tissue Donors

6.1 Introduction

In this chapter I will consider the second and third research questions of this thesis in relation to competent minors: who can and should be able to provide consent/authorisation for living minors to be regenerative tissue donors? and what test(s) should be used to determine whether consent/authorisation can be provided for a living minor to be a tissue donor? This chapter is the longest in this thesis because it covers all competent minors in both England and Wales, and Scotland, but I have chosen to incorporate all competent minors into this one chapter to avoid repetition of argument.

I conclude that if a minor meets the relevant competency test, they should be able to provide consent or authorisation on their own behalf to be a tissue donor. As to whether they can currently do this, the law is unclear as there has been no application by the court of tissue donation to the competency tests. For those under 16 in England and Wales, the competency test is established by common law in *Gillick v West Norfolk and Wisbech Area Health Authority*⁴⁹⁷, while in Scotland the test is outlined in section 2(4) of the Age of Legal Capacity (Scotland) Act 1991. I will argue that for a minor to be either *Gillick* or section 2(4) competent they should require an understanding of the moral, family, emotional, and long-term implications of the donation, as well as an understanding of the potential consequences if they refuse the procedure.

⁴⁹⁷ [1985] 3 All ER 402.

For those aged 16- and 17- years old in England and Wales the test that governs capacity is contained in the Mental Capacity Act 2005, and section 8 of the Family Law Reform Act 1969. It permits a minor to consent to ‘surgical, medical, or dental treatment’ as if they were full age. Section 8 uses the term ‘treatment’ and my contention is that while, *prima facie*, the term ‘treatment’ does not include tissue donation from living minors as it is a non-therapeutic procedure for the donor, section 8 should be interpreted broadly to cover such procedures.

Furthermore, I argue that those with parental responsibility (PR) currently can, but should not be permitted to override a competent minor’s consent/authorisation for three reasons, including that those with PR hold their power as agents or trustees on behalf of the minor until they are mature enough to begin to make decisions for themselves. Also, I argue that once a minor is competent a court can, but should not be able to, override their decision about whether to be a tissue donor. The role of the court is to protect the interests of the minor, and once the minor is competent to make their own decisions then the role of the court is obsolete.

6.2 Minors under 16

A minor can be considered competent under the age of 16, and the competency test in England and Wales is from the common law as set out in *Gillick v West Norfolk and Wisbech Area Health Authority*⁴⁹⁸ while the competency test in Scotland is enshrined in statute in section 2(4) of the 1991 Act. As these are two separate tests for two separate jurisdictions, I will deal with them separately.

⁴⁹⁸ *Gillick* (n 498).

When the 1991 Act was introduced in Scotland, tissue donation by living minors was permitted under the Human Organ Transplants Act 1989, which was later repealed by the Human Tissue (Scotland) Act 2006.⁴⁹⁹ Under the 2006 Act, a living minor can only donate regenerative tissue or tissue as a result of a domino transplant operation. Therefore, medical professionals will never be required to apply the section 2(4) competency test to a minor who would be providing authorisation to a non-regenerative tissue donation, such as donation of a kidney or a lobe of liver. This is in contrast to the *Gillick* competence test, which, in practice, will be applied to all types of tissue donation as the Human Tissue Act 2004, the applicable legislation in England and Wales, does not put restrictions on the type of tissue a minor can donate.⁵⁰⁰ However, as I have argued in Chapter 4, minors in England and Wales should not be permitted to donate non-regenerative tissue, therefore, in the discussion which follows I will only focus on the application of the *Gillick* test to the donation of regenerative tissue.

6.2.1 *Gillick v West Norfolk and Wisbech Area Health Authority*

The *Gillick* competence test is a common law evidential test of capacity for those under 16 in England and Wales. Even though the case of *Gillick* was specifically about consent to contraceptive treatment, the judgment had implications for all types of medical procedures. Following the decision, minors under the age of 16, if deemed competent, are able to consent to medical procedures on their own behalf.

The background of the *Gillick* competence test has been well-trodden by previous academics, therefore, I will not attempt to cover this ground again.⁵⁰¹ *Gillick* was

⁴⁹⁹ see Chapter 3 at 3.4 for further discussion of the Human Tissue (Scotland) Act 2006.

⁵⁰⁰ see Chapter 3 at 3.3 for further discussion of the Human Tissue Act 2004.

⁵⁰¹ Department of Health and Social Security, *Family planning services for young people* (HN 80(46, 1980); *Gillick v West Norfolk and Wisbech Area Health Authority* [1984] QB 581; *Gillick v West Norfolk*

decided in the House of Lords by a 3-2 majority, and Lords Scarman and Fraser diverged in their approaches to minor competence. Lord Scarman's approach centred on assessing a minor's competency by their understanding and knowledge of the medical procedure proposed. Lord Fraser, in contrast, set out a five-point test which focused on the specific facts of *Gillick*, and sought to make it a condition that the proposed medical procedure would be in the best interests of the minor. I am going to examine these approaches in more detail because it is my opinion that as the two tests are different this could result in different outcomes as to whether a minor is considered competent to be a tissue donor.

6.2.1.1 Lord Scarman

Lord Scarman took the view that once a minor 'achieves sufficient understanding and intelligence to enable him or her to understand fully what is proposed',⁵⁰² then the parental right to determine whether they have a medical procedure terminates or 'yields to the child's right to make his own decisions.'⁵⁰³ While Lord Scarman did not define 'sufficient understanding and intelligence', he stated that the court must take into account:

moral and family questions, especially her relationship with her parents; long-term problems associated with the emotional impact of pregnancy and its termination; and there are the risks to health of sexual intercourse at her age, risks which contraception may diminish but cannot eliminate.⁵⁰⁴

and Wisbech Area Health Authority [1985] 1 All ER 533 (Court of Appeal); SP de Cruz, 'Parents, Doctors and Children: the Gillick Case and Beyond' (1987) *Journal of Social Welfare Law* 93; Glanville Williams. 'The Gillick Saga' (1985) *New Law Journal* 1156.

⁵⁰² *Gillick* (n 498) 423.

⁵⁰³ *Gillick* (n 498) 422.

⁵⁰⁴ *Gillick* (n 498) 424.

It thus appears that in order for a minor to be deemed competent they must have ‘sufficient maturity’ to understand the moral, family, emotional, and long-term implications of their decision for that particular medical procedure.⁵⁰⁵ Applying this same approach to tissue donation, a minor donor must understand the moral implications of the decision to donate which includes, but is not limited to, whether they have a moral duty to donate to their sibling. In addition, they must understand the relational consideration of their decision as would occur in a relational autonomous decision;⁵⁰⁶ the emotional impact of the donation; and any long-term medical risks, potential complications, and restrictions on their future lifestyle choices.

6.2.1.2 Lord Fraser

In contrast to Lord Scarman, Lord Fraser set out a five-point test which was based on the specific facts of *Gillick*. He stated, in relation to the consent of a minor under 16, that:

[p]rovided the patient ... is capable of understanding what is proposed, and of expressing his or her own wishes, I see no good reason for holding that he or she lacks the capacity to express them validly and effectively and to authorise the medical man to make the examination or give the treatment which he advises.⁵⁰⁷

Lord Fraser set out a checklist of five factors (often referred to as ‘the Fraser Guidelines’) for doctors to consider when assessing a minor’s competence. Where the girl refuses to tell her parents, the doctor is justified in proceeding without the parents’

⁵⁰⁵ Kirsty Moreton, ‘Gillick reinstated: Judging Mid-Childhood Competence in Healthcare Law’ (2015) 23(2) Medical Law Review 303, 305.

⁵⁰⁶ See Chapter 2 at 2.2.1 for further discussion on relational autonomy.

⁵⁰⁷ *Gillick* (n 498) 409.

consent or even knowledge provided that the doctor is satisfied on the following matters:

(1) that the girl (although under 16 years of age) will understand his advice; (2) that he cannot persuade her to inform her parents or to allow him to inform the parents that she is seeking contraceptive advice; (3) that she is very likely to be or to continue having sexual intercourse with or without contraceptive treatment; (4) that unless she receives contraceptive advice or treatment her physical or mental health or both are likely to suffer; (5) that her best interests require him to give her contraceptive advice, treatment or both without the parental consent.⁵⁰⁸

This test is specific to contraceptive advice and treatment, which was the issue in *Gillick*. However, if the five factors are applied to tissue donation then only points (1), (4), and (5) are relevant because point (3) is specific to contraceptive advice and treatment. In addition, point (2) may only be applicable in certain circumstances because it is unlikely that those with PR would be unaware that one of their children was donating tissue to a sibling. In order to fulfil the requirement of point (1) the minor donor would have to understand the tissue donation process, including pre- and post-operative care and assessment.

For point (4) the minor's physical health will not be affected if they do not donate. But their mental health may suffer if the proposed recipient is their sibling because if the sibling does not receive the tissue then this could result in the continuation of the sibling's illness or even lead to their death. As discussed in Chapter 4, when considering whether a minor should donate tissue the medical professional needs to consider the

⁵⁰⁸ *Gillick* (n 498) 413.

associated medical risks (MR), psychological benefits (PB) and psychological risks (PR) of donating. If $PB > MR + PR$ then the minor can donate tissue. Finally, for point (5) the doctor must be satisfied that the tissue donation is in the minor's best interests. This involves the consideration of a number of different factors such as harm, physical, emotional, and psychological needs of the minor.⁵⁰⁹ The medical professional would have to be satisfied that points (1), (4), and (5) have been met before deciding whether a minor was competent to be a tissue donor.

6.2.1.3 Lord Scarman vs Lord Fraser

In relation to *Gillick* competence, I am going to adopt Lord Scarman's approach in this thesis because it is a functional test and not an outcome test. This means that those assessing the competence of a minor must focus on the minor's functional ability to make the decision, and not determine their competence based on the outcome of that decision. Therefore, the competency of the minor donor will be dependent on whether they have sufficient understanding and intelligence to understand the tissue donation they may undergo, rather than whether they make a particular decision in agreement with the medical professionals, those with PR, or the court. If a competent minor provides consent to a procedure which is not in their best interests and they have sufficient ability to understand the proposed procedure, then their decision should be respected by medical professionals, their family, and the court. There have been cases where the court has been unwilling to find that a minor is competent if their decision

⁵⁰⁹ see Chapter 5 at 5.4 for further information about the best interests test.

conflicts with the court's view of what is in their best interests.⁵¹⁰ However, in *An NHS Trust v ABC & A Local Authority*⁵¹¹ for example Mostyn J said that:

she can then be lawfully prescribed with contraception even if the result of that would lead her to take steps which are wholly contrary to her best interests. So, the question of best interests does not really inform the primary decision I have to make which is whether she has the necessary capacity.⁵¹²

I agree with the view taken by Mostyn J that whether the procedure is in the minor's best interests does not inform whether they are competent, because a court should be deciding whether a minor has the sufficient ability to understand the proposed procedure; therefore, the consideration of whether the procedure is in their best interests is irrelevant. Moreover, the court should not be permitted to decide that minors who make a decision that is not in agreement with the court, so not considered to be in their best interests, are thereby demonstrating that they are not mature enough to make them, otherwise, minors would never be competent to consent to procedures that are not considered to be in their best interests.

6.2.1.4 Proposed Clarification of the *Gillick* competence test

In this section I will examine the *Gillick* competence test in detail and apply it to tissue donation. I will recommend that clarification of the *Gillick* competence test is required. I will argue that if a minor in England and Wales meets the requirements of the *Gillick* competence test, in relation to the donation of regenerative tissue, then they should be

⁵¹⁰ *Re E (A Minor)(Wardship: Medical Treatment)* [1993] 1 FLR 386; Rachel Taylor, 'Reversing the Retreat from *Gillick* – R (Axon) v Secretary of State for Health' (2007) 19 Child and Family Law Quarterly 81, 82; JA Devereux, DP Jones and DL Dickenson, 'Can children withhold consent to treatment?' (1993) 306 BMJ 1459.

⁵¹¹ [2014] EWHC 1445.

⁵¹² *ABC* (n 512) [10].

able to provide consent on their own behalf. I will argue that for a minor to be *Gillick* competent they require an understanding of the moral, family, emotional, and long-term implications of the donation, as well as an understanding of the potential consequences if they refuse the procedure.

Even though *Gillick* was a decision that was made in the specific context of contraceptive advice and treatment, the *Gillick* competence test has been applied to a wide range of medical procedures.⁵¹³ Indeed, in that case Lord Fraser said:

It seems to me verging on the absurd to suggest that a girl or boy aged 15 could not effectively consent, for example, to have a medical examination of some trivial injury to his body or even to have a broken bone set.⁵¹⁴

Lord Templeman was a dissenting judge in *Gillick*, but he provided a similar example: ‘a doctor with the consent of an intelligent boy or girl of 15 could in my opinion safely remove tonsils or a troublesome appendix.’⁵¹⁵ These examples are therapeutic procedures that are intended to medically benefit the minor, they are forms of medical treatment. Under the *Gillick* competence test minors can be competent to consent to these procedures if they have sufficient understanding of them. However, a question arises as to whether a minor can be competent to consent to a tissue donation. The degree of understanding required by the minor, in law, is different depending on the complexity of the medical procedure and the risks involved. For example, understanding what the donation of a lobe of liver entails is more difficult than understanding the procedure of donating blood. While the *Gillick* competence test has

⁵¹³ Moreton (n 506) 306.

⁵¹⁴ *Gillick* (n 498) 409.

⁵¹⁵ *Gillick* (n 498) 409.

been applied to more complex medical procedures, such as blood transfusions⁵¹⁶ and abortions⁵¹⁷ it has yet to be applied by the court to tissue donation.

As part of Lord Scarman's test, in order for a minor to be *Gillick* competent they need to understand the proposed procedure as well as the moral, family, emotional, and long-term implications of it.⁵¹⁸ The minor is required to have sufficient understanding of what the medical procedure entails as well as any pre- and post-operative care and assessments, including the anaesthetic process (if this is required). Moreover, they must understand the long-term implications of the procedure which involves understanding the temporary and permanent life-style restrictions following the procedure.⁵¹⁹ I will now consider these parts of the test separately by examining them in relation to tissue donation.

6.2.1.4.1 Moral implications of the decision

The first question that needs to be answered is: does a minor have an obligation to donate tissue to their sibling to potentially save their life? An obligation can take the form of either a moral obligation or a legal obligation. While these types of obligations have similarities, their main difference lies in 'the specific nature of legal rules, and the form of sanction applied in the case of non-conformity.'⁵²⁰ In relation to a moral obligation, 'disapproval is expressed in an attempt to elicit guilt, shame, or remorse, and possibly a change in behaviour.'⁵²¹ In contrast, a breach of a legal obligation can result

⁵¹⁶ *Re E* (n 511); *Re S (A Minor)(Consent to Medical Treatment)* [1994] 2 FLR 1065; *Re L (Medical Treatment: Gillick Competency)* [1998] 2 FLR 810.

⁵¹⁷ *An NHS Trust v ABC & A Local Authority* [2014] EWHC 1445.

⁵¹⁸ *Gillick* (n 498) 424.

⁵¹⁹ see Chapter 4 at 4.3.3 and 4.3.4 for further discussion on lifestyle restrictions of tissue donation.

⁵²⁰ Barry Lyons, 'Obliging Children' (2011) 19 *Medical Law Review* 55, 64.

⁵²¹ HLA Hart, *The Concept of Law* (Clarendon Press 1961) 165-76.

in specific sanctions being imposed.⁵²² While adults are subject to both moral and legal obligations, it is questionable whether minors can also be subject to these obligations. Minors are certainly subject to legal obligations, for instance, at the age of 10 they are under an obligation to obey the criminal law at the risk of sanctions should they breach it.⁵²³ But there is no legal obligation for a minor in England, Wales, or Scotland to donate tissue to a sibling.

My view, in respect of a moral obligation, is that minors should not have this moral obligation to donate tissue to a sibling. My reasoning for this view is that individual family members do not have obligations towards each other, and in the case of the relationship between siblings this relationship is not entered into voluntarily.⁵²⁴ A minor does not choose to have a sibling. Glannon and Friedman Ross suggest that where a moral obligation is imposed depends on the level of intimacy between the individuals:

there must be a certain degree of intimacy within the family for there to be moral obligations between family members, an intimacy that develops over time through shared needs and interests. The greater the degree of intimacy in the relationship, the greater the obligation we have to those with whom we stand in that relationship.⁵²⁵

However, the potential impact that a tissue donation could have on the recipient has prompted some kidney donors to say ‘I had to do it, I couldn’t have backed out, not that I had the feeling of being trapped, because the doctors offered to get me out. I just had

⁵²² Hart (n 522) 165-76.

⁵²³ Children and Young Persons Act 1963, s.16.

⁵²⁴ Walter Glannon and Lainie Friedman Ross, ‘Do Genetic Relationships Create Moral Obligations in Organ Transplantation?’ (2002) 11(2) Cambridge Quarterly Healthcare Ethics 153, 156.

⁵²⁵ *ibid* 157.

to do it.⁵²⁶ Statements such as these indicate that the minor donor may feel as if they have a moral obligation imposed on them whether consequences ensued or not from failing to meet the moral obligation. It has been argued, in opposition to my view, that tissue donation is a general moral obligation and that failure to do so is morally indefensible.⁵²⁷ Those who propose the moral obligation model argue that minors possess significant and potentially burdensome moral obligations with regard to healthcare.⁵²⁸ In some situations, it becomes obligatory for the minor to sacrifice their personal interests for the good of another member of the family or the family unit as a whole.⁵²⁹ However, as I argued in relation to incompetent minors,⁵³⁰ the recipient's interests and those of the wider family should be a consideration but should not solely determine whether the donation takes place because otherwise the donation would always take place without ever considering the interests of the donor. Therefore, as it is not obligatory for the minor to sacrifice themselves for the benefit of the family unit, this could potentially reduce the risk of exploitation to the minor donor.

One approach to the argument that a minor should have a moral obligation to donate tissue is Peter Singer's position on the ethics of famine relief.⁵³¹ He articulates two general principles of varying demandingness, either are sufficient for an obligation of tissue donation:

⁵²⁶ Tom L. Beauchamp and James F. Childress, *Principles of Biomedical Ethics* (OUP 2013) 43; Carl H. Fellner, 'Organ Donation for whose sake?' (1973) 79 *Annals of Internal Medicine* 591.

⁵²⁷ Ben Almassi, 'Trust and the Duty of Organ Donation' (2014) 28(6) *Bioethics* 275, 275.

⁵²⁸ Lyons (n 521) 66-67.

⁵²⁹ T. John and others, 'Children's consent and Paediatric Research: Is it Appropriate for Healthy Children to be the Decision-makers in clinical research?' (2008) 93 *Archives of Disease in Childhood* 379, 382.

⁵³⁰ see Chapter 5 at 5.5.2 and 5.5.3.

⁵³¹ Peter Singer, 'Famine, affluence, and morality' (1972) 1(3) *Philosophy and Public Affairs* 229.

- (i) if it is in our power to prevent something bad from happening, without thereby sacrificing anything of comparable moral importance, we ought, morally to do it.
- (ii) if it is in our power to prevent something very bad from happening, without thereby sacrificing anything morally significant, we ought, morally to do it.⁵³²

Therefore, if the risks of the tissue donation are not considered to be sacrificing anything of moral importance or morally significant then according to Singer the tissue donation should be performed. Using an example, the American case of *McFall and Shimp*⁵³³, while is not legally binding in England, Wales, or Scotland, provides reasoning as to why a moral obligation may be owed by an individual to their relative in relation to a tissue donation.⁵³⁴ Robert McFall was a 39- year old who had aplastic anaemia.⁵³⁵ His adult cousin, David Shimp, refused to donate bone marrow, citing his immediate family responsibilities as having more weight than his cousin’s need.⁵³⁶ The court refused to force the bone marrow donation.⁵³⁷ Judge John P Flaherty Jr stated that:

one human being is under no legal compulsion to give aid or to take action to save [another] human being ... [Yet] in the view of the courts, the refusal of the defendant [Shimp] is morally indefensible.⁵³⁸

Beauchamp and Childress have commented on this case arguing that the judge’s moral assessment is questionable because it is unclear if Shimp had in fact bypassed an

⁵³² Singer (n 532).

⁵³³ 10 Pa. D. & C. 3d 90 (July 26, 1978).

⁵³⁴ See Rebecca D Pentz and others, ‘Designing an Ethical Policy for Bone Marrow Donation by Minors and Others Lacking Capacity’ (2004) 13(2) Cambridge Quarterly Healthcare Ethics 149.

⁵³⁵ *McFall* (n 534) 90.

⁵³⁶ *McFall* (n 534) 90.

⁵³⁷ *McFall* (n 534) 92.

⁵³⁸ *McFall* (n 534) 91.

obligation.⁵³⁹ Beauchamp and Childress list five conditions which if met results in an individual having an obligation to make a beneficent act:

Condition 1: Y is at risk of significant loss of or danger to life, health, or some other basic interest.

Condition 2: X's action is necessary (singly or in concert with others) to prevent this loss or damage.

Condition 3: X's action (singly or in concert with others) will probably prevent this loss or damage.

Condition 4: X's action would not present significant risks, costs or burdens to X.

Condition 5: the benefit that Y can be expected to gain outweighs any harms, costs or burdens that X is likely to incur.⁵⁴⁰

I argue that no moral obligation should be imposed on a minor to donate tissue to their sibling, even if the conditions proposed by Beauchamp and Childress are met. To demonstrate this, I am going to apply these conditions to *McFall v Shimp*. Condition 1 was fulfilled as McFall was at risk of significant loss of or danger to life since he suffered from aplastic anaemia and required a bone marrow transplant. Furthermore, in compliance with condition 2, Shimp's action is necessary to prevent this loss since he is histocompatible and can donate bone marrow to McFall.

Condition 3 has not been fulfilled.⁵⁴¹ This third condition is problematic because if there is a small probability of saving millions of lives at a minimal cost to an individual then it is not plausible to hold that an individual has no obligation to act.⁵⁴² Condition

⁵³⁹ Beauchamp and Childress (n 527) 207.

⁵⁴⁰ Beauchamp and Childress (n 527) 207.

⁵⁴¹ Beauchamp and Childress (n 527) 207.

⁵⁴² Beauchamp and Childress (n 527) 207.

3 could be interpreted to show that ‘there must be some appropriate proportionality between probability of success, the value of outcome to be achieved, and the sacrifice that the agent would incur’, or that there should be ‘a high ratio of probable benefit relative to the sacrifice made.’⁵⁴³ In this particular case, McFall’s chance of surviving one year, at the time, following a successful transplantation would have only increased from 25% to between 40% and 60%⁵⁴⁴ These statistics are speculative and there is a risk that the transplantation would not be a success, therefore, it is difficult to determine whether the principle of beneficence can demand a particular course of action in this case.

Moreover, Shimp was concerned about condition 4 as he had been informed that bone marrow donations required 100 to 150 punctures of the pelvic bone.⁵⁴⁵ These punctures can be painlessly performed under anaesthesia, and the major risk at the time was a 1 in 10,000 chance of death from anaesthesia.⁵⁴⁶ Shimp, however, believed that the risks were greater and that they outweighed the probability and magnitude of benefit to McFall, subsequently, condition 5 would not be satisfied. Therefore, in the opinion of Beauchamp and Childress, Shimp did not have an obligation to donate to McFall since all of the conditions were not fulfilled. It is my opinion that the decision as to whether a minor is a tissue donor should focus on the minor donor’s interests rather than weighing up the interests of the donor and the recipient which is condition 5. The donor and recipient are separate individuals and whether they undergo a medical procedure should be based on their own interests and not conflated with others.⁵⁴⁷

⁵⁴³ Beauchamp and Childress (n 527) 207.

⁵⁴⁴ Beauchamp and Childress (n 527) 207.

⁵⁴⁵ Beauchamp and Childress (n 527) 207.

⁵⁴⁶ Beauchamp and Childress (n 527) 207.

⁵⁴⁷ see Chapter 5 at 5.4.2 for a discussion on determining the best interests of an incompetent minor donor separate from the recipient.

In relation to this potential moral obligation, Herbert Hart argued that there is confusion between ‘the assertion that someone was *obliged* to do something and the assertion that he had an *obligation* to do it.’⁵⁴⁸ The essential difference lies in the notion of coercion and the concept of voluntariness. Whether an adult fulfils any moral or legal obligation, or not, is down to choice. If the adult chooses not to perform an act when under an obligation to do so, they face reactive attitudes and possible sanctions. If, on the other hand, an adult is obliged to perform an act, then they will be coerced or compelled to do so. In other words, an individual can refuse to fulfil their obligations, moral or legal, and face the punishment from the court or society. But, being obliged to do something is premised on the notion that that thing will be done. This reasoning, when applied to living minors, suggests that an incompetent minor is obliged to be a tissue donor since those with PR make the decision on their behalf while a competent minor could have an obligation to be a tissue donor since they make a decision on their own behalf. But if adults are not obliged nor have an obligation to donate tissue to a relative then neither should a minor. A minor should have a choice as to whether to donate tissue without the fear of eliciting guilt, shame, or remorse from society if they fail to undergo the donation.

Therefore, in relation to the competency test, a minor donor should be required to understand that there is no moral duty to donate to their sibling.⁵⁴⁹ But the moral considerations under Lord Scarman’s test encompasses more than just whether a minor has a moral duty to donate. Just because there is no moral duty does not mean that there

⁵⁴⁸ Hart (n 522) 80; *emphasis added*.

⁵⁴⁹ Susan Zinner, ‘Cognitive Development and Pediatric Consent to Organ Donation’ (2004) 13 Cambridge Quarterly of Healthcare Ethics 125, 129.

is a complete absence of moral considerations. In a decision about whether a minor donates tissue to their sibling the moral considerations will form part of the reasoning, since their tissue could result in a life-saving or life-prolonging transplant for the recipient. The minor needs to understand the moral considerations of the decision as well as the moral pressures that those, with PR, the sibling, or the wider community may place on them to donate tissue. A failure to understand these moral considerations, or being susceptible to the moral pressures placed on them would result in the minor being considered incompetent.

6.2.1.4.2 Family implications of the decision

A factor when determining whether a minor is competent is that of the minor's relationship with their parents and family. Looking at it more broadly, relational considerations should be a factor in determining a minor's competence, encompassing the impact the minor's decision has on their family as whole, this would include both their parents and their siblings.⁵⁵⁰ This stems from the concept of relational autonomy discussed in Chapter 2,⁵⁵¹ which involves recognition and acceptance of the fact that most people do not make decisions as freestanding,⁵⁵² isolated beings, but are 'socially, culturally and embedded individual[s]' who 'exercise self-determination in and through networks of relations with others'.⁵⁵³ In order to be competent, the minor donor should understand that familial considerations can have a twofold impact on their decision-making.

⁵⁵⁰ *Re E* (n 511).

⁵⁵¹ at 2.2.1.

⁵⁵² Jennifer Nedelsky, *Law's Relations: A Relational Theory of Self, Autonomy, and Law* (OUP 2011) 19.

⁵⁵³ Edward S Dove and others, 'Elberte v. Latvia: Whose tissue is it anyway – Relational Autonomy or the Autonomy of Relations?' (2015) 15 *Medical Law International* 79, 80.

First, due to the nature of the procedure, it is inevitable that the minor donor will consider their family since it is a donation to a sibling, but this factor should not solely determine the outcome of the decision. In *An NHS Trust v ABC & A Local Authority*,⁵⁵⁴ Mostyn J stated that if A continued with the pregnancy then ‘her family and, indeed, social services will need to give her considerable support and assistance’ while in the event of termination ‘her family will need to be, at her side and to assist her and support her’.⁵⁵⁵ The support that the minor donor receives from their family, regardless of the decision they make, will enable them to either have a successful recovery from the procedure or manage the consequences of refusing to donate.

Secondly, the impact that familial considerations have on their decision-making could be negative, for instance their family may not support the minor’s decision. As was noted in the Danish Council of Ethics Report, on organ and tissue donation from living donors, donating tissue within a family ‘is not a simple case of gift giving’ because a tissue cannot be moved from one family member to another without often-profound consequences for the family dynamics.⁵⁵⁶ These consequences could result in the donor receiving an elevated status within the family as the donation could lead to a member of the family recovering from an illness. But the familial dynamics will mostly be emotional and psychological.

Minors may be susceptible to coercion, and might be more easily influenced than other family members because they need to impress or please their parents, or do the ‘right’

⁵⁵⁴ *ABC* (n 518).

⁵⁵⁵ *ABC* (n 518) [15].

⁵⁵⁶ Soren Holm, ‘The Child as Organ Donor and Tissue Donor: Discussions in the Danish Council of Ethics’ (2004) 13 *Cambridge Quarterly of Healthcare Ethics* 156, 157.

thing, or may be pressured by their sibling to donate.⁵⁵⁷ Minors should be able to discuss their decision with their parents so that they can receive ‘the necessary information to make the decision and help in deciding what her wishes are.’⁵⁵⁸ If a minor is to be deemed *Gillick* competent, they need to be able to make an autonomous decision that is free from family pressure, so they must cast aside direct and indirect opinions. They need to be aware of both the positive and negative aspects of family considerations, and make a relational autonomous decision, but at the same time they must not base their decision solely on the impact the donation would have on their family.

6.2.1.4.3 Emotional implications of the decision

In this section, I argue that not only should a minor donor understand the physical implications of the donation on themselves, they should also understand the emotional implications of the decision. In *Re E (A Minor)(Wardship: Medical Treatment)*⁵⁵⁹, a 15 year old boy, A, who had leukaemia, refused a blood transfusion because of his Jehovah’s Witness beliefs.⁵⁶⁰ Ward J explained the level of understanding required by A to be considered *Gillick* competent:

He may have some concept of the fact that he will die, but as to the manner of his death and the extent to his and his family’s suffering I find he has not the ability to turn his mind to it nor the will to do so.⁵⁶¹

Similarly, in *Re S (A Minor)(Consent to Medical Treatment)*⁵⁶² Johnson J concluded that ‘for the decision to carry weight she should have a greater understanding of the

⁵⁵⁷ see further discussion about a minor’s vulnerabilities in Chapter 4 at 4.4.2.

⁵⁵⁸ *Moreton* (n 506) 312.

⁵⁵⁹ *Re E* (n 511).

⁵⁶⁰ *Re E* (n 511) 388.

⁵⁶¹ *Re E* (n 511) 391.

⁵⁶² [1994] 2 FLR 1065.

manner of the death and pain and the distress.⁵⁶³ These cases indicate that a minor needs to have an understanding of the emotional and psychological distress their decision may have on themselves.

In relation to tissue donation, this would involve the minor donor understanding the emotional implications of undergoing a procedure that is medically harming them, in order to benefit their sibling. To be competent, they would be required to understand the emotional implications of the donation, regardless of whether the donation was successful. Indeed, if the donation was not a success then they may feel guilty or a sense of failure. The minor donor should be aware of and understand that the donated tissue may fail, be rejected by the recipient, or that the original cause of the tissue failure may recur and that the outcome is beyond their control.⁵⁶⁴ One argument is that the minor donor may be able to control their future feelings by telling themselves that they made the best decision possible given the circumstances, regardless of the outcome, but this is not guaranteed.⁵⁶⁵ However, if the donation was a success then they may feel happiness and a sense of relief. The emotional implications of an unsuccessful donation are more difficult for a minor donor to understand than those of a successful donation, but if the minor is aware that they may occur then this could help minimise any negative impact it could have on them.

⁵⁶³ *Re S* (n 563) 1076.

⁵⁶⁴ Laine Friedman Ross and J Richard Thistlethwaite, 'Minors as Living Solid-Organ Donors' (2008) 122 *Pediatrics* 454, 458.

⁵⁶⁵ Kimberly Strong, Ian Kerridge, and Miles Little, 'Saviour Siblings, Parenting and the Moral Valorisation of Children' (2014) 28(4) *Bioethics* 187, 190.

6.2.1.4.4 Long-term implications of the decision

The long-term implications of a tissue donation include the future medical risks and any lifestyle restrictions following it. For instance, a minor would be required to understand whether they are predisposed to particular medical complications as a result of a donation, and any check-ups or measures needed in order to prevent such complications from occurring. In relation to lifestyle restrictions, these are more common with non-regenerative tissue donation than regenerative tissue donation, but a minor would be required to understand whether they have to make any lifestyle changes in the future as a result of being a tissue donor.

This requirement of the *Gillick* competence test expects the minor to be able to consider implications in the future that may not materialise for a number of years. While minors may find it easy to consider the immediate impact of the donation, it may be harder for them to consider the future implications as this will require them to have foresight. Determining what will happen in the future can be difficult to predict, while they can take the advice of the medical professionals about the future medical risks these are not definitive. But at the same time, the *Gillick* competence test does not require the minor to understand every possible consequence of the donation procedure to be competent. If the threshold for competency was set too high then no minor would be able to meet the test and be competent to consent to being a tissue donor.

6.2.1.4.5 Refusal of the procedure

Even though understanding the implications of refusing the procedure was not explicitly included within Lord Scarman's competency test, subsequent jurisprudence has incorporated it into the test. I argue that for a minor to be *Gillick* competent they should

understand the consequences of refusing the medical procedure. This is in agreement with Lord Donaldson who stated:

what is involved is not merely an ability to understand the nature of the proposed treatment ... but a full understanding and appreciation of the consequences both of the treatment, in terms of intended and possible side-effects and equally important, the anticipated consequences of a failure to treat.⁵⁶⁶

The approach taken by Lord Donaldson has been reiterated in guidance produced by the General Medical Council (GMC) for medical professionals which states that:

you must decide whether a young person is able to understand the nature, purpose and possible consequences of investigations or treatments you propose, as well as the consequences of not having the treatment.⁵⁶⁷

In contrast, the Department of Health's (DoH) guidance on consent does not require the minor to understand the consequences of not having the treatment:

in the case of *Gillick*, the court held that children who have sufficient understanding and intelligence to enable them to understand fully what is involved in a proposed intervention will also have the capacity to consent to that intervention.⁵⁶⁸

Thus, there appears to be conflicting guidance for medical professionals as to whether a minor is required to understand the consequences of refusing a medical procedure. Therefore, it is unclear for medical professionals within their guidance as to whether a

⁵⁶⁶ *Re R (A Minor)(Wardship: Medical Treatment)* [1991] 4 All ER 177, 187.

⁵⁶⁷ General Medical Council, *0-18: Guidance for all doctors* (2007) para 24.

⁵⁶⁸ Department of Health, *Reference Guide to Consent for Examination or Treatment* (2009) 16.

minor should understand the refusal of a medical procedure or not in order to be competent.

Even if a minor was required to understand the refusal of the procedure to be competent, Stephen Gilmore and Jonathan Herring have raised doubts about whether a minor is actually capable of understanding the implications of not having a medical procedure.⁵⁶⁹ They suggest that this requirement would be setting the threshold for competency too high for minors. They use the example of a 10-year-old who cuts himself at school and needs a sticking plaster. He only needs to understand what it means to have a plaster in order to consent; he does not need to understand the nature of septicaemia as a possible consequence of not having the plaster.⁵⁷⁰ There are a range of medical procedures varying from the simple to the complex, and the level of understanding required for refusing the procedure varies. A procedure could be simple for a minor to understand but have complex consequences if refused. Therefore, a minor could have sufficient understanding of the procedure, but not of the refusal and so would be found incompetent. In contrast, if it was a complex procedure but had simple consequences if refused, it is likely that if they were found to have a sufficient understanding of procedure then they would also understand the consequences and be found competent.

A distinction can be drawn between a minor having to understand the consequences of refusing a medical procedure and refusing to be a tissue donor, because if a minor refuses to consent to be a donor then there are no medical consequences for them. But if they refuse to donate, are they required to understand the medical consequences for

⁵⁶⁹ Stephen Gilmore and Jonathan Herring, 'No is the Hardest Word: Consent and Children's Autonomy' (2011) 23 *Child and Family Law Quarterly* 3, 11.

⁵⁷⁰ Gilmore and Herring (n 570) 11.

the potential recipient? This would involve a minor donor having to understand the recipient's condition and the medical consequences if they did not receive the transplant. I argue that the threshold for competency would be too high for a minor donor if they were required to understand the medical consequences for another individual. Therefore, for a minor to be competent to consent to being a tissue donor they should be required to understand that if they refuse there would be no medical impact on them, but it would have an impact on the potential recipient. They should be expected to understand an outline of the consequences but not be expected to understand the finer details of the impact it would have on the potential recipient, even if the recipient is a sibling, as this would set the competency threshold too high.

I have now considered and applied the *Gillick* competence test to tissue donation which is applicable to minors under 16 in England and Wales. I have argued that if a minor in England and Wales meets the requirements of the *Gillick* competence test in relation to the donation of regenerative tissue, then they should be able to provide consent on their own behalf. Furthermore, in order for a minor to be *Gillick* competent they require an understanding of the moral, family, emotional, and long-term implications of the donation, as well as an understanding of the potential consequences if they refuse the procedure. I will now consider the competency test applicable in Scotland under section 2(4) of the 1991 Act and apply it to tissue donation.

6.2.2 Age of Legal Capacity (Scotland) Act 1991

Unlike the *Gillick* competence test in England and Wales, the Scottish competence test is enshrined in statute under section 2(4) of the 1991 Act. The 1991 Act was introduced as a result of the Scottish Law Commission's (SLC) *Report on the Legal Capacity and*

Responsibility of Minors and Pupils.⁵⁷¹ The 1991 Act provides an exception to the general rule that a minor under 16 has no capacity to enter into legal transactions.⁵⁷²

Section 2(4) of the Act sets out the medical treatment exception and states that:

A person under the age of 16 years shall have legal capacity to consent on his own behalf to any surgical, medical or dental procedure or treatment where, in the opinion of a qualified medical practitioner attending him, he is capable of understanding the nature and possible consequences of the procedure or treatment.

The SLC considered section 8 of the Family Law Reform Act 1969, which applies to England and Wales, when deciding on the definition of ‘medical treatment’ to use in section 2(4).⁵⁷³ Section 8 states that ‘surgical, medical or dental treatment’⁵⁷⁴ includes:

any procedure undertaken for the purposes of diagnosis and any procedure (including, in particular, the administration of anaesthetic) ancillary to surgical, medical or dental treatment.⁵⁷⁵

The SLC acknowledged that this definition in section 8 did not cover medical procedures that were not considered treatment such as tissue donation, and so, it adopted the explicit phrasing of ‘procedure or treatment’ in order to encompass all types of medical procedures within the definition. This wider definition allows a minor to provide authorisation for experimental and non-therapeutic procedures, therefore, there is no debate as to whether tissue donation is included under this definition.

⁵⁷¹ Scottish Law Commission, *Report on the Legal Capacity and Responsibility of Minors and Pupils* (Cmd 110, 1987).

⁵⁷² Age of Legal Capacity (Scotland) Act 1991, s.2(1).

⁵⁷³ see below at 6.3.2.

⁵⁷⁴ Family Law Reform Act 1969, s.8(1).

⁵⁷⁵ Family Law Reform Act 1969, s.8(2).

6.2.2.1 Proposed Clarification of the section 2(4) competence test

In this section I will examine the section 2(4) competence test in detail and apply it to tissue donation. I will recommend that clarification of the section 2(4) competence test is required. I will argue that if a minor in Scotland meets the requirements of the section 2(4) competence test, in relation to the donation of regenerative tissue, then they should be able to provide authorisation on their own behalf. Section 2(4) requires that the minor ‘is capable of understanding the nature and possible consequences of the procedure or treatment’. However, the Act does not define what kind of understanding the minor should have, and there is no Scottish legal authority defining or applying section 2(4) to a minor’s authorisation to a medical procedure, let alone any application to tissue donation.

Section 2(4) refers to the ‘nature’ of the procedure, which suggests that a minor should understand what the medical procedure itself entails, as well as any pre- and post-operative care and assessment. Furthermore, they must be capable of understanding the ‘possible consequences of the procedure’, which suggests understanding both the medical consequences of the procedure as well as the temporary or permanent lifestyle restrictions following the procedure. The SLC cited Lord Scarman’s judgement in *Gillick* with approval,⁵⁷⁶ indicating that a minor needs to have the ability to make a mature judgement, taking into account broader considerations – more than a mere understanding of the medical procedure. However, the explicit wording of section 2(4) does not seem to be as far reaching as the one proposed by Lord Scarman, as there is no mention that a minor must consider the moral, family or emotional considerations of

⁵⁷⁶ Scottish Law Commission (n 572) paras 3.72-3.77.

their decision. Nor does it mention whether the minor has to understand the consequences if they refuse the medical procedure.

In my opinion, when the Scottish courts apply section 2(4), they should require a minor to have an understanding that is akin to what is required under the *Gillick* competence test. A minor donor should be required to understand that there is no moral duty to donate to their sibling.⁵⁷⁷ But just because there is no moral duty it does not mean that there is a complete absence of moral considerations. The minor donor needs to understand the moral considerations of the decision as well as the moral pressures that the family, the sibling, or the wider community may place on them to donate tissue. A failure to understand these moral considerations, or being susceptible to the moral pressures placed on them would result in the minor being considered incompetent.

The minor donor would be required to understand the impact of the decision on the family dynamics and the family unit as a whole, similar to the competency test in *Gillick*, before they can be considered competent. In other words, the relational considerations of the donation cannot be ignored. If a minor donor exercises their relational autonomy then they would be making the decision taking into consideration the relationships they have with others. This includes the relationship they have with their sibling, who is also the potential recipient. As previously discussed,⁵⁷⁸ family considerations could have both positive and negative aspects on the minor's psychological well-being. This understanding could prevent or reduce the risk of the minor donor suffering from a negative psychological impact of the donation because they would understand the risks before undergoing the donation.

⁵⁷⁷ Zinner (n 550) 129.

⁵⁷⁸ see Chapter 4 at 4.4.2.

Furthermore, the *Gillick* competence test requires the minor to understand the emotional considerations of the decision, but there is no mention of this in section 2(4). Emotional considerations of a tissue donation could be both positive and negative, and if the negative emotions materialise their impact could be reduced if the minor donor has a prior understanding of them. Therefore, to be competent, they should be required to understand the emotional implications of the donation, regardless of whether the donation was successful. Indeed, if the donation was not a success then the minor donor may feel guilt or a sense of failure, but should be aware of and understand that the donated tissue may fail, be rejected by the recipient, or that the original cause of the organ failure may recur and that the outcome is beyond their control.⁵⁷⁹

As with the *Gillick* competence test, I argue that a minor should be required to understand the consequences if they refuse the medical procedure. But because of the nature of a tissue donation procedure, it is my contention that for a minor to be competent to provide authorisation to be a tissue donor they should be required to understand that if they refuse there would be no medical impact on them, but it would have an impact on the potential recipient. I argue that the minor donor should be expected to understand an outline of the consequences but not be expected to understand the finer details of the impact it would have on the potential recipient, even if the recipient is a sibling, as this would set the competency threshold too high.

In Scotland, a clear stance was taken on whether best interests is considered in the section 2(4) competence test. The SLC recommended that it should not be included

⁵⁷⁹ Friedman Ross and Thistlethwaite (n 565) 458.

because it would be ‘too restrictive’ and could prevent minors from being deemed competent because medical professionals may have different concepts of what is in the minor’s best interests.⁵⁸⁰ For instance, if a tissue donation is going to be in a minor donor’s best interests then a number of factors should be taken into account to determine this, such as harm, physical, emotional, and psychological needs of the minor. But as tissue donation is a non-therapeutic procedure that medically harms the minor donor, in order for it to be justified the psychological benefits have to outweigh the medical risks and psychological risks. But as discussed in Chapter 4,⁵⁸¹ psychological benefits cannot be measured and are dependent on the minor, thus assessed on a case-by-case basis. Therefore, the weight placed on a minor’s psychological benefit is open to interpretation.

To avoid the differing opinions of medical professionals as to a minor’s best interests, it was suggested that a second medical professional must agree that a minor should undergo that particular medical procedure. However, the SLC rejected this because it would be too cumbersome and the medical professional may seek a second opinion from a colleague known to be sympathetic towards the proposed medical procedure.⁵⁸² This indicates that if a minor is competent under the 1991 Act and makes a decision then this decision is respected even if it is not in their best interests.⁵⁸³ I argue that this is the preferable interpretation of the section 2(4) competency test because it allows a competent minor’s autonomy to be respected by others. Therefore, if a minor is competent to consent to being a tissue donor, they should be free to make a decision

⁵⁸⁰ Scottish Law Commission (n 572) para 3.76.

⁵⁸¹ at 4.4.

⁵⁸² Scottish Law Commission (n 572) paras 3.75 and 3.77.

⁵⁸³ Scottish Law Commission (n 572) para 3.77.

even if this is not considered to be in their best interests and it conflicts with the opinion of those with PR, the medical professionals, or the court.

In conclusion, clarification is required to understand the finer details of the section 2(4) competency test and its application to tissue donation. Once the court has applied this test to a living minor as a tissue donor then it can be clarified as to what approach the court will take, and what the minor is required to understand to be a tissue donor. But it is my argument that for a minor to be competent under the section 2(4) competency test they should have an understanding that is akin to what is required under the *Gillick* competence test. I have now considered the competency tests in England and Wales, and Scotland in relation to those under 16 and I will now move on to consider minors who are aged 16- and 17- years old.

6.3 16- and 17- year olds

For those aged 16 and 17 in England and Wales, they are assumed to have capacity under the 2005 Act. The ability for a minor to be able to consent to medical treatment is found in section 8 of the 1969 Act. I do not consider the position of 16- and 17- year olds in Scotland, since section 1(1)(b) of the Age of Legal Capacity (Scotland) Act 1991 states that ‘a person of or over the age of 16 years shall have legal capacity to enter into any transaction’.⁵⁸⁴

6.3.1 Mental Capacity Act 2005

The 2005 Act contains the statutory test of capacity for those aged 16 and above in England and Wales. Section 1(2) states that ‘a person must be assumed to have capacity

⁵⁸⁴ see Chapter 1 at 1.1.1 for further information.

unless it is established that he lacks capacity'. Therefore, 16- and 17- year olds are assumed to have capacity unless it can be proved otherwise. Section 1(4) states that 'a person is not to be treated as unable to make a decision merely because he makes an unwise decision.' This means that those aged 16 or 17 can make a decision that is not in their best interests. A 16- or 17- year old lacks capacity if 'at the material time he is unable to make a decision for himself in relation to the matter because of an impairment of, or a disturbance in the functioning of, the mind or brain.'⁵⁸⁵ Section 3(1) states that a minor is 'unable to make a decision for himself if he is unable':

(a) to understand the information relevant to the decision⁵⁸⁶

(b) to retain that information⁵⁸⁷

(c) to use or weigh that information as part of the process of making the decision,⁵⁸⁸ or

(d) to communicate his decision (whether by talking, using sign language or any other means)⁵⁸⁹

This demonstrates that minors, to have capacity to be a tissue donor, would have to understand the information relevant to the type of tissue donation they would be undergoing, retain this information, and then use or weigh up the information in order to make and communicate their decision. The *Mental Capacity Act 2005: Code of Practice* provides further clarification that 'relevant information' includes 'the likely effects of deciding one way or another or making no decision at all.'⁵⁹⁰ This indicates that in order for a 16- or 17- year old to have capacity they must also be able to understand the consequences of not undergoing the procedure. Therefore, in order for

⁵⁸⁵ Mental Capacity Act 2005, s.2(1).

⁵⁸⁶ Further guidance about the interpretation of this criteria is provided in the Department of Constitutional Affairs, *Mental Capacity Act 2005 Code of Practice* (TSO 2007) paras 4.16-4.19.

⁵⁸⁷ Department of Constitutional Affairs (n 587) para 4.20.

⁵⁸⁸ Department of Constitutional Affairs (n 587) paras 4.21 and 4.22.

⁵⁸⁹ Department of Constitutional Affairs (n 587) paras 4.23-4.25.

⁵⁹⁰ Department of Constitutional Affairs (n 587) para 4.16.

a 16- or 17- year old to meet the requirements of ‘relevant information’ in relation to tissue donation, they would be required to understand the consequences of refusing to be a tissue donor. Even if the minor is assumed to have capacity under the 2005 Act, it does not automatically result in them being able to provide consent to be a tissue donor. They must also meet the requirements under section 8 of the Family Law Reform Act 1969. Section 8 permits a minor to provide consent to ‘surgical, medical, or dental treatment’ as if they were of full age.

6.3.2 Family Law Reform Act 1969

The 1969 Act was introduced as a result of Parliament’s response to the *Report of the Committee on the Age of Majority* produced by the Latey Committee.⁵⁹¹ In relation to consent to a medical treatment, the Latey Committee recommended that ‘without prejudice to any consent that may otherwise be lawful, the consent of young persons aged 16 and over to medical or dental treatment shall be as valid as the consent of a person of full age.’⁵⁹² This recommendation formed the basis for section 8 of the 1969 Act which is the relevant legislation when determining whether 16- and 17- year olds can provide consent to be a tissue donor.

6.3.2.1 Section 8

Section 8(1) states that:

the consent of a minor who has attained the age of sixteen years to any surgical, medical, or dental treatment which, in the absence of consent, would constitute a trespass to his person, shall be as effective as it would be if he were of full age; and where a minor has

⁵⁹¹ Latey Committee, *Report on the Committee on the Age of Majority* (Cmnd 3342 (1967)).

⁵⁹² Latey Committee (n 592) para 484, Recommendation.

by virtue of this section given an effective consent to any treatment it shall not be necessary to obtain any consent for it from his parent or guardian.

In other words, this section allows those of 16 years and above to provide consent to surgical, medical or dental treatment without the need to obtain any consent from those with PR. Section 8(2) provides further clarification as to the scope of section 8(1) by stating that ‘surgical, medical, or dental treatment’:

includes any procedure undertaken for the purposes of diagnosis, and this section applies to any procedure (including, in particular, the administration of anaesthetic) which is ancillary to any treatment as it applies to that treatment.

6.3.2.2 Proposed Clarification of section 8

Section 8 of the 1969 Act uses the term ‘treatment’ with regard to the types of medical procedures that a 16- or 17- year old can provide consent for. My contention is that while, *prima facie*, the term ‘treatment’ does not include tissue donation from living minors as it is a non-therapeutic procedure for the donor, section 8 should be interpreted broadly to cover such procedures. My reasons for this are twofold. First, that the 2004 Act explicitly states that minors can provide consent to be a tissue donor.⁵⁹³ Secondly, that the HTA’s *Code of Practice G* states that consent by a minor donor who has capacity is effective as if they were of full age.⁵⁹⁴ Before analysing the reasons for the use of the term ‘treatment’ it is necessary to consider in-depth the definition of ‘treatment’.

⁵⁹³ Human Tissue Act 2004, s.2(2).

⁵⁹⁴ Human Tissue Authority, *Code of Practice G: Donation of Allogeneic Bone Marrow and Peripheral Blood Stem Cells for Transplantation* (April 2017) para 45.

6.3.2.2.1 What is ‘treatment’?

The term ‘treatment’ in the dictionary means ‘the use of drugs, exercises etc to cure a person of an illness or injury’.⁵⁹⁵ A treatment is a therapeutic procedure as it has an identifiable and measurable intention to benefit the individual, either physically or psychologically. It indicates that it is an accepted method, within society, of curing or improving a particular illness or injury by a medical professional. The courts have held that treatment suggests that it benefits the patient.⁵⁹⁶ On the other hand, the term ‘procedure’ is defined as ‘a medical operation’.⁵⁹⁷ Although there is a clear distinction between these two definitions, the terms treatment and procedure may be used synonymously in everyday vernacular. A procedure can be considered to be both therapeutic and non-therapeutic. For instance, the removal of tonsils is both a treatment as well as a therapeutic procedure because it is remedying the illness of infected tonsils and it is a medical act performed on the individual by a medical professional.

Tissue donation is a non-therapeutic procedure for the donor, it does not alleviate any injury, illness or ailment, but instead actively harms the donor for the benefit of the recipient. Thus, it cannot be considered to be a medical treatment, but instead, can be classed as a medical procedure. As Ian Kennedy stated in the 1980s:

⁵⁹⁵ Cambridge Dictionary, ‘Treatment’ <<https://dictionary.cambridge.org/dictionary/english/treatment>> accessed 07/10/2018.

⁵⁹⁶ see *R(Burke) v General Medical Council* [2005] EWCA Civ 1003; *Portsmouth Hospitals NHS Trust v Wyatt dand another* [2005] EWCA Civ 1181 (Fam); *Re J (A Minor)(Child in Care: Medical Treatment)* [1992] 3 WLR 507.

⁵⁹⁷ Cambridge Dictionary, ‘Procedure’ <<https://dictionary.cambridge.org/dictionary/english/procedure>> accessed 07/10/2018.

the assumption was made that, if something was described as treatment, it was ipso facto justified. The word ‘treatment’ was enough. And treatment was what the doctor said was treatment. The law did not enquire further.⁵⁹⁸

Therefore, if the medical professionals concluded that tissue donation was considered a treatment, then it was classed as such. However, the paternalistic approach of the medical profession which was present in the 1980s has now shifted to a more patient-centred approach.⁵⁹⁹ Consequently, more than just ‘the stamp of the medical professional’ is required to determine whether something is treatment.⁶⁰⁰ A patient is now more likely to question a medical professional’s advice rather than accept it as correct, and allowing a medical professional to determine whether it is a medical treatment is now unlikely to be accepted. Lord Donaldson stated in obiter, in *Re W (A Minor)(Medical Treatment)*⁶⁰¹, in the 1990s, in relation to tissue donation that ‘so far as the donor is concerned [the donation of organs or tissues] do not constitute either treatment or diagnosis.’⁶⁰² Furthermore, Nolan LJ in the same case stated: ‘a case in which a child of any age consented to donate an organ: such a case is not, of course, covered by section 8 of the Family Law Reform Act 1969.’⁶⁰³ Subsequently, tissue donation from a living minor is not considered to be ‘treatment’.

When the 1991 Act was being discussed as a Bill, the SLC considered section 8 of the 1969 Act when deciding on the definition of ‘medical treatment’ to use in section 2(4) of the 1991 Act. The SLC concluded that the definition in section 8 of the 1969 Act did

⁵⁹⁸ Ian Kennedy, ‘Emerging Problems of Medicine, Technology and the Law’ in Ian Kennedy (ed), *Treat Me Right: Essays in Medical Law and Ethics* (Clarendon Press 1988) 8.

⁵⁹⁹ *Montgomery v Lanarkshire Health Board* [2015] UKSC 11.

⁶⁰⁰ Kennedy (n 599) 26; see Chapter 6 at 6.2.2 for further discussion on the Age of Legal Capacity (Scotland) Act 1991.

⁶⁰¹ *Re W (A Minor)(Medical Treatment)* [1992] 4 All ER 627.

⁶⁰² *Re W* (n 602) 635.

⁶⁰³ *Re W* (n 602) 647.

not cover medical procedures that were not considered treatment, such as non-therapeutic procedures, which included tissue donation. Therefore, in the 1991 Act Parliament adopted the explicit phrasing of ‘procedure or treatment’ in order to encompass all types of medical procedures within this definition. This wider definition allows a minor to provide authorisation for experimental and non-therapeutic procedures, including tissue donation. This demonstrates that there is ambiguity over the interpretation of the term treatment, and the SLC wanted to ensure that all types of medical procedures were considered under the 1991 Act. Therefore, if a literal interpretation of the term treatment in section 8 of the 1969 Act is used this could result in tissue donation being excluded from the scope of the section.

6.3.2.2.2 Reasoning for the use of the term ‘treatment’ in section 8

The reasons why Parliament used the term ‘treatment’ in section 8 is unclear as there was no discussion by the Latey Committee in the *Report of the Committee on the Age of Majority*⁶⁰⁴, nor consideration by either House of Parliament that was reported in Hansard, when the Family Law Reform Bill was being passed. Most of the academic commentary around the area of the definition of ‘treatment’ focuses on the medical exception in criminal law, and not the use of the term in section 8 of the 1969 Act.⁶⁰⁵

In 1967, when the Latey Committee was providing recommendations for law reform and their report was produced, tissue donation from living minors was a procedure that was not performed in England and Wales. In the 1960s tissue donation from deceased individuals, both adults and minors, was performed, but donation from living

⁶⁰⁴ Latey Committee (n 592).

⁶⁰⁵ see Sara Fovargue and Alex Mullock (eds), *The Legitimacy of Medical Treatment: What Role for the Medical Exception?* (Routledge 2015) for further discussion on the use of the term ‘treatment’ within the medical exception in criminal law.

individuals had not been medically developed. Therefore, these procedures were not in the consciousness of the Latey Committee. In addition, when discussing the Bill, MPs would not have been aware of these procedures either. When the term treatment was decided upon, those involved in drafting the legislation would not have been aware that they were excluding tissue donation from living minors by using this particular term. It is impossible for legislators to be expected to use wording in statutes that would cover all future medical procedures that might be developed. The interpretation of the term treatment in the 1960s, when this Act was enacted, would be different to how it would be interpreted in the 2020s. Although case law can be flexible and accommodate developing interpretations of terminology, there have been no decisions on the interpretation of treatment in section 8. This would suggest that tissue donation from living minors was not a deliberate exclusion from the section.

However, there is reasoning to suggest that the Latey Committee used the term treatment to exclude the types of tissue donation that were available in the 1960s. This is implied from the express recommendation by the Latey Committee that those under the age of 18 should not be able to consent to give blood.⁶⁰⁶ The Ministry of Health provided the following explanation as to why 18 was chosen as the age when individuals can donate blood:

18 was generally adopted as the minimum age by the blood transfusion services formed at the beginning of the last war. Although the Ministry has no record of the reasons for selecting 18 the probably ones are that by this age, growth is very largely completed

⁶⁰⁶ Latey Committee (n 592) paras 485-489.

and the psychological and physical changes of puberty are over; and that 18 was the minimum age for serving in the Armed Forces.⁶⁰⁷

There appears to be no logic as to why the age an individual can donate blood should be dependent on the age they can join the army. A more compelling argument is one based on the medical impact on the individual. The medical objections to lowering the age to 16 are that the minor is still growing, that blood volume will not have reached the same level as that in an adult, and it seems unwise for the health of the minor to induce anaemia deliberately, even for a short duration, under such circumstances.⁶⁰⁸ Therefore, the wording of section 8 may have been used in order to ensure that section 8 did not cover blood donation.

The reasoning for the use of the term treatment is unclear, and the discussion of this term implies that treatment does not include tissue donation. However, such literal interpretation of the term does not have to be adopted by the court, the mischief rule could be used so that section 8 incorporates all types of medical procedures. The 1969 Act was enacted in the 1960s and as medicine advances the interpretation of section 8 should be adapted to evolve with these changes.

6.3.2.2.3 Broad interpretation of section 8

It is my argument that the court should adopt a wide interpretation of the meaning of treatment in section 8 of the 1969 Act to incorporate tissue donation. There are two reasons to suggest that legislation and professional guidance that is specific to tissue donation allows 16- and 17- year olds to be able to provide consent to be a tissue donor.

⁶⁰⁷ Latey Committee (n 592) para 486.

⁶⁰⁸ Latey Committee (n 592) para 488.

First, section 2(2) of the 2004 Act explicitly states that subject to subsection (3), where the minor concerned is alive and has capacity to consent themselves, ‘appropriate consent’ means their consent. Therefore, if a minor has capacity, they can provide consent to be a tissue donor. The 2004 Act defines minor for the purposes of this Act as being under the age of 18.⁶⁰⁹ Subsequently, if a 16- or 17- year old has capacity under the 2005 Act then they can provide consent to be a tissue donor. If section 8 of the 1969 Act was interpreted to exclude tissue donation, then this interpretation would conflict with the 2004 Act which could result in confusion for the medical professionals as they would be unsure which legislation should be followed.

Secondly, the HTA in *Code of Practice G* makes explicit reference to the 1969 Act.⁶¹⁰ In *Code of Practice G* paragraphs 45-47 deal specifically with ‘Children aged 16 and 17’. Paragraph 45 states:

Children aged 16 or 17 are presumed to have capacity unless there is evidence to suggest otherwise. Where a child is over 16 section 8(1) of the Family Law Reform Act 1969 states that the decision of a child shall be as effective as that of an adult.⁶¹¹

This guidance was produced in 2017 and is currently the most up-to-date, I suggest that it would not make reference to the 1969 Act if it was not considered applicable in relation to tissue donation. Moreover, paragraph 47 states that:

If the HTA receives a referral where it appears that the donor may have competence the HTA may:

⁶⁰⁹ Human Tissue Act 2004, s.54(1).

⁶¹⁰ HTA, *Code of Practice G* (n 595) para 45.

⁶¹¹ HTA, *Code of Practice G* (n 595) para 45.

- a) request that the clinician referring the case provides the HTA with details of the competence assessment that was undertaken for the child;
- b) following that, if the matter remains unclear, the HTA may make an application to the Court of Protection under the Children Act 1989 for the court to decide if the donor child is competent to make their own decisions about medical treatment. The court would then decide whether the child had competence to consent to the procedure for him or herself.⁶¹²

This further suggests that a 16- or 17- year old should be able to consent to be a tissue donor themselves, and a decision that a minor donor is not competent will not be taken lightly by the HTA, but reassessed accordingly. Using the reason that section 8 of the 1969 Act does not encompass tissue donation because the term ‘treatment’ should have a narrow interpretation, as the reason for not allowing a 16- or 17- year old to consent to being a tissue donor, is unlikely to be accepted by the HTA as a valid reason for finding that a minor is deemed incompetent. One of the reasons guidance is produced by the HTA is to assist medical professionals in their understanding of relevant law. If section 8 of the 1969 Act was interpreted to exclude tissue donation, then the HTA guidance would be inconsistent with section 8.

In addition, it is implied by the introduction of competency tests for those under 16, that 16- and 17- year olds should also be able to be competent to provide consent to be a tissue donor. When the 1969 Act was enacted those under 16 could not provide consent for any medical procedures, and had to rely on their parents or guardians to provide it. However, the law has evolved through common law in England and Wales, and statute in Scotland, to allow a minor under the age of 16 to be competent to consent to medical

⁶¹² HTA, *Code of Practice G* (n 595) para 45.

procedures. The *Gillick*⁶¹³ competence test and section 2(4) competence test permit a minor under 16 to be competent if they have sufficient understanding and intelligence to enable them to fully understand what is proposed. If the law now allows a minor under 16 to consent to be a tissue donor, then it would be consistent if section 8 was interpreted to allow a 16- or 17- year old, who ostensibly has the same or a higher level of understanding and intelligence, to also be allowed to provide consent.

In conclusion, while the literal interpretation of treatment does not incorporate tissue donation, the language of the 1969 Act can remain intact so long as the courts provide a clear and wider interpretation of term treatment in section 8. This interpretation would result in it being consistent with both the 2004 Act and the HTA CoP, as well as encompass the current medical technology that is available. This may result in the term treatment being given a similar interpretation to the term procedure so it covers all therapeutic and non-therapeutic procedures.

I have now established that a competent minor should be able to provide consent/authorisation to be a tissue donor if they meet the appropriate test. I have also suggested clarification to the current law in respect of the *Gillick* competence test, section 2(4) competence test, and section 8 of the 1969 Act. I am now going to consider whether those with PR currently can, and whether they should be able to override a decision made by a competent minor in respect of tissue donation.

⁶¹³ *Gillick* (n 498).

6.4 Parental Responsibility

In this section, I shall outline the current law for England and Wales, and Scotland separately as well as highlight its uncertainties. I will argue that those with PR currently can, but should not be permitted to override a competent minor's consent/authorisation for three reasons. First, those with PR hold their power as agents or trustees on behalf of the minor until they are mature enough to begin to make decisions for themselves.⁶¹⁴ In other words, when a minor is competent and able to make decisions for themselves, the need for a proxy decision-maker becomes obsolete. Secondly, the HTA, in England and Wales, have stated that consent from those with PR on behalf of a competent minor will not be treated by the HTA as lawful consent.⁶¹⁵ Thirdly, the wording of section 8 implies that consent from those with PR is not required.

6.4.1 The current law in England and Wales

The legal issue pertaining to whether those with PR can override the consent of a competent minor, in England and Wales, was not clarified in *Gillick*, with Lord Scarman asserting that the parental right is terminated, while Lord Fraser was more circumspect by allowing the parental right to continue even after the minor is competent.⁶¹⁶ Lord Scarman stated that:

I would hold that as a matter of law the parental right to determine whether or not their minor child below the age of 16 will have medical treatment terminates if and when the child achieves a sufficient understanding and intelligence to enable him or her to

⁶¹⁴ Jonathan Montgomery, 'Children as Property' [1988] 51 Modern Law Review 323, 323-324.

⁶¹⁵ HTA, *Code of Practice G* (n 595) para 44.

⁶¹⁶ Gillian Douglas, 'The Retreat from *Gillick*' (1992) 55(4) Medical Law Review 569, 574.

understand fully what is proposed. It will be a question of fact whether a child seeking advice has sufficient understanding of what is involved to give a consent valid in law.⁶¹⁷

However, in *R(on the application of Axon) v Secretary of State for Health*,⁶¹⁸ Silber J referred to this quote and held that the parental right to make decisions terminated once the minor is competent.⁶¹⁹

Furthermore, Lord Scarman, in *Gillick*, stated that ‘parental rights are derived from parental duty and exist only so long as they are needed for the protection of the person and property of the child’,⁶²⁰ and that ‘until the child achieves the capacity to consent, the parental right to make the decision continues save only in exceptional circumstances.’⁶²¹ It would thus follow that, apart from the court, the only person able to consent would be a competent minor. In contrast, Lord Fraser in *Gillick* referred favourably to *Hewer v Bryant*,⁶²² where Lord Denning MR described the parental right as:

a dwindling right which the courts will hesitate to enforce against the wishes of the child, and the more so the older he is. It starts with a right of control and ends with little more than advice.⁶²³

In agreement with Lord Denning, Lord Fraser argued that those with PR retain a right to consent on behalf of the minor which may only be disregarded if it is in the minor’s

⁶¹⁷ *Gillick* (n 498) 423.

⁶¹⁸ [2006] EWHC 37 (Admin).

⁶¹⁹ *Axon* (n 619) 56.

⁶²⁰ *Gillick* (n 498) 420.

⁶²¹ *Gillick* (n 498) 418.

⁶²² [1970] 1 QB 357.

⁶²³ *Hewer* (n 623) 369.

best interests to do so.⁶²⁴ Lord Donaldson also followed this line of argument, and said that while competent minors can provide consent it did not remove the power of those with PR to do so.⁶²⁵ He devised an analogy in *Re R (A Minor)(Wardship: Medical Treatment)*,⁶²⁶ which stated that consent is merely:

a key which unlocks a door. Furthermore, whilst in the case of an adult of full capacity there will usually only be one keyholder, namely the patient, in the ordinary family unit where a young child is the patient there will be two keyholders, namely the parents, with a several as well as joint right to turn the key and unlock the door.⁶²⁷

In *Re W (A Minor)(Medical Treatment)*,⁶²⁸ Lord Donaldson adopted a different analogy for consent, relying on a military description:

On reflection I regret my use in *Re R* of the keyholder analogy, because keys can lock as well as unlock. I now prefer the analogy of the legal 'flak-jacket' which protects the doctor from claims by the litigious whether he acquires it from his patient, who may be a minor over the age of 16 or a *Gillick* competent child under that age, or from another person having parental responsibilities which include a right to consent to treatment of the minor. Anyone who gives him a flak jacket (ie consent) may take it back, but the doctor only needs one and so long as he continues to have one, he has the legal right to proceed.⁶²⁹

This shows that both competent minors and those with PR can consent on behalf of a minor to undergo a medical procedure. The right of those with PR to consent on behalf

⁶²⁴ *Gillick* (n 498) 411.

⁶²⁵ *Re R* (n 567) 184.

⁶²⁶ *Re R* (n 567) 184.

⁶²⁷ *Re R* (n 567) 184.

⁶²⁸ *Re W* (n 602).

⁶²⁹ *Re W* (n 602) 635.

of the minor would not yield; rather a minor becomes an individual who can provide consent, alongside those with PR.⁶³⁰ A competent minor does not gain any greater legal standing than those with PR and it does not give a minor a right to veto.⁶³¹ Subsequently, it is unclear whose consent would take the overriding stance. While both the cases of *Re R* and *Re W* were in relation to the refusal of a medical procedure, I feel that it is appropriate and necessary to consider them since they are the leading authorities with regard to parental rights of competent minors.

6.4.2 The current law in Scotland

The legal landscape in Scotland is also unclear, with a similar discussion undertaken in Scotland as to whether those with PR can provide authorisation once the minor is competent under section 2(4) of the 1991 Act. The House of Lords, in a debate when discussing the Age of Legal Capacity (Scotland) Bill, noted that the issue of parental rights within the Bill were not well defined.⁶³² They agreed with the SLC report that the Bill did not affect parental rights, and that those with PR would still be entitled to exercise parental rights on behalf of their minor.⁶³³ However, the 1991 Act must be read in conjunction with section 15(5) of the 1995 Act, which states that ‘a person may act as a child’s legal representative only if the child is not capable of acting on his or her own behalf.’ This suggests a similar standpoint to that taken by Lord Scarman in the case of *Gillick*, that those with PR can only make a decision on behalf of a minor if they are deemed incompetent, and that those with PR lose their right once the minor is

⁶³⁰ Jo Bridgeman, ‘Old Enough to Know Best?’ (1993) 13 Legal Studies 69, 73.

⁶³¹ Stephen Parker and John Dewar, ‘*Re R (A Minor)* [1991] 3 WLR 592’ (1992) 14(2) Journal of Social Welfare and Family Law 143, 147.

⁶³² HL Deb 01 July 1991, vol 520, cols 866-82.

⁶³³ Hansard (n 633); Latey Committee (n 592) para 3.81.

competent. In *Houston Applicant*,⁶³⁴ a Scottish case concerning those with PR overriding a competent minor's refusal, Sheriff McGowan stated that:

It seems to me illogical that, on the one hand a person under the age of 16 should be granted the power to decide upon medical treatment for himself while, on the other hand, his parents have the right to override his decision. I am inclined to the view that the minor's decision is paramount and cannot be overridden. The 1991 Act itself does not provide any mechanism for resolving a dispute between minor and guardian but it seems to me that logic demands that the minor's decision is paramount.⁶³⁵

This is the opposing view to that taken by the House of Lords and the SLC in the discussion of the 1991 Bill. However, Sheriff McGowan acknowledges that the 1991 Act is unclear about disputes between minors and those with PR, therefore it would be for a court to make the necessary judgement.

6.4.3 Proposed Reform to the current law

I have established that both in England and Wales, and in Scotland those with PR can override the consent/authorisation of a competent minor. I am now going to answer the following question: should those with PR be able to override the consent/authorisation of a competent minor? The simple answer to this question is no, and the following is my reasoning for the stance I have taken on this issue. I accept that when a minor is incapable of understanding the nature of a medical procedure and therefore in need of their interests to be protected, those with PR may give legally effective consent or authorisation, thus they have a right of complete control over the minor.⁶³⁶ However,

⁶³⁴ 1996 SCLR 943.

⁶³⁵ *Houston* (n 635) 945.

⁶³⁶ *Montgomery* (n 615) 324.

as a minor matures they start to make decisions for themselves, and this also facilitates their continuing growth.⁶³⁷ As the minor makes more decisions for themselves their understanding and ability to make decisions will develop over time. Amy Gutmann has written:

The justification for defining adolescents as legal minors is that their own capacities for free exercise are limited and can be more fully developed by paternalistic supervision. We assume that as those capacities gradually develop, the freedom to exercise them stimulates their further development.⁶³⁸

As a minor becomes more independent, they are able to make more decisions that will have a greater impact on them in their day-to-day life, often known as becoming mature. This is also applicable in relation to medical procedures. A minor will be able to provide consent or authorisation for a sticking plaster at a younger age compared to providing consent or authorisation to have their tonsils removed. Those with PR have a role as a safety mechanism so minors do not make decisions that are against their interests. This role should dwindle as the minor matures, and once the minor is competent then this role should become obsolete. The minor no longer requires those with PR to make decisions on their behalf because the minor can make these decisions for themselves and is best placed to decide a course of action.

As a competent minor is able to provide consent/authorisation for the procedure on their own behalf, it seems absurd that those with PR would have a concurrent right to provide consent/authorisation for the procedure or alternatively be able to override the

⁶³⁷ Montgomery (n 615) 324.

⁶³⁸ Amy Gutmann, 'Children, Paternalism, and Education: A Liberal Argument' (1980) 9(4) *Philosophy and Public Affairs* 338, 355.

consent/authorisation of a competent minor. If both the competent minor and those with PR could provide consent/authorisation then which consent/authorisation should the medical professionals rely on? Or does it not matter? When considering tissue donation, if the competent minor refused to donate then the consent/authorisation of those with PR would not be accepted as the minor could not be forced to donate tissue. But if the competent minor provides consent/authorisation for the procedure, can those with PR override this consent/authorisation? Allowing those with PR to have any right over a competent minor creates a risk that the autonomous decisions of the competent minor would not be respected. If a minor meets the competency test then they should be the sole determinant as to whether they provide consent/authorisation, regardless of whether those with PR agree with this course of action or not.

The involvement of those with PR in a tissue donation procedure is only encouraged by the HTA, it is not a requirement. Furthermore, consent/authorisation from those with PR on behalf of a competent minor will not be considered legally valid by the HTA. In *Code of Practice G*, it states that:

consent from a person with parental responsibility on behalf of a legally competent child will not be treated by the HTA as lawful consent. Parental involvement in the child's decision making should be encouraged, but the HTA considers that parents cannot make medical treatment decisions on behalf of a child who can make his or her own medical treatment decisions.⁶³⁹

This demonstrates that those with PR can be involved in the decision-making process, but their consent will not be accepted as lawful. This indicates that the HTA promote

⁶³⁹ HTA, *Code of Practice G* (n 595) para 44.

the practice to respect the autonomous decision of a competent minor as well as taking into account relational autonomy.⁶⁴⁰ A minor who is relationally autonomous would look to their relationships with others, including those who have PR, and then make a decision taking into account their relationships. It is natural that the minor would not make their decision in isolation but would discuss the process with others to ensure that they make the decision that is best suited to them, and the HTA promote communication and discussion. This HTA guidance is only applicable in England and Wales, and while the HTA have not provided explicit guidance in Scotland in relation to this there is no evidence that suggests a contrary stance would be taken in Scotland.

The arguments presented above are applicable to those aged 16- and 17- years old, but there is an additional argument that lies in concentrating upon the words in section 8(1): ‘where a minor has by virtue of this section given an effective consent to any treatment it shall not be necessary to obtain any consent for it from his parent or guardian.’ In other words, if a minor provides consent then the consent from those with PR is not required. The medical professional only needs the consent from the minor in order to proceed with the tissue donation. Furthermore, in section 8(1) it is stated that the consent is ‘as effective as it would be if he were of full age.’ If the minor was 18, an adult, their ability to consent would have two separate effects.⁶⁴¹ First, their consent would be fully effective, so it could not be overridden by those with PR. In other words, if the minor provided consent for the procedure to occur then those with PR could not override the decision and prevent the medical procedure from proceeding. Secondly, a failure to give consent would be fully effective as a veto, and no one else would be in a position to consent. This means that the minor would be solely responsible for any

⁶⁴⁰ see Chapter 2 at 2.2.1 for further discussion on relational autonomy.

⁶⁴¹ *Re W* (n 602) 634.

medical procedure they undergo, only their consent is required, and if they failed to provide consent then the medical procedure could not go ahead.

There is, however, an argument that has been presented by John Murphy that suggests that, in fact, those with PR do maintain a right to provide consent on behalf of the minor until they reach the age of majority, 18.⁶⁴² This argument rests on the wording in section 8(3) of the 1969 Act which states that ‘nothing in this section shall be construed as making ineffective any consent which would have been effective if this section had not been enacted.’⁶⁴³ The impact of section 8(3) is twofold.⁶⁴⁴ First, the rights of consent vested in a minor at common law (if any existed) prior to the enactment of the 1969 are preserved.⁶⁴⁵ However, it is the second point that is most pertinent to this discussion. This section preserved the common law as it existed immediately before the 1969 Act, which gave an effective power of parental consent for all minors up to the age of 21, the then age of majority.⁶⁴⁶ Which means that it preserves the right of those with PR to provide consent in respect of a minor aged 16 and 17.⁶⁴⁷ But the preservation of the latter is subject to the caveat that such a right is ‘liable to be, if it has not already been, extinguished upon the attainment of capacity by the minor in question.’⁶⁴⁸ If the rights have not been extinguished once the minor is competent, it can lead to concurrent powers of consent between the 16- and 17- year old and those with PR.

⁶⁴² John Murphy, ‘W(h)ither Adolescent Autonomy?’ (1992) 14(6) *Journal of Social Welfare and Family Law* 529, 534.

⁶⁴³ Murphy (n 643) 534.

⁶⁴⁴ Murphy (n 643) 534.

⁶⁴⁵ Murphy (n 643) 534.

⁶⁴⁶ *Re W* (n 602) 634.

⁶⁴⁷ Murphy (n 643) 534.

⁶⁴⁸ Murphy (n 643) 534.

If those aged 16 and 17 have a right to consent to a medical procedure, then even if concurrent powers existed, the minor would have the overriding decision as to whether they undergo the medical procedure or not. Lord Justice Balcombe in *Re W (A Minor)(Medical Treatment)*⁶⁴⁹ argued that section 8 could not confer an absolute right on the minor.⁶⁵⁰ He stated that the purpose of this section was ‘to enable a 16 year old to consent to medical treatment which, in the absence of consent by the minor or its parents, would constitute a trespass to the person.’⁶⁵¹ This would suggest that in theory section 8 does not operate to prevent parental consent remaining effective.⁶⁵² However, in practice, this section allows those with PR to provide consent on behalf of the minor if the minor was not competent to do so, rather than allowing those with PR to override the minor’s consent.

My argument that those with PR should not be able to consent on behalf of a competent minor is further supported by the discussions of the Latey Committee. One of the reasons for the recommendations to change the age of majority was because medical professionals were unable to treat the minor until parental consent for the minor had been provided. Cases were occurring where minors between the ages of 16 and the age of majority, 21, were living away from home and required medical treatment.⁶⁵³ This treatment had not reached the emergency stage yet which meant that the medical professionals could not proceed without valid consent. Medical professionals were unable to treat the minor until parental consent had been provided, and if the minor lived away from home it could be difficult to contact their parents.⁶⁵⁴ This caused practical

⁶⁴⁹ *Re W* (n 602).

⁶⁵⁰ *Re W* (n 602) 641.

⁶⁵¹ *Re W* (n 602) 641.

⁶⁵² *Re W* (n 602) 641.

⁶⁵³ Latey Committee (n 592) para 477.

⁶⁵⁴ Latey Committee (n 592) para 477.

issues for the medical professionals, and the parents may not be aware that the minor required a medical procedure if they were not in regular contact with them.

To prevent this issue, the Latey Committee recommended that minors should be allowed to provide consent themselves without the need for consent from their parents. However, the Latey Committee stated that a medical professional should ‘for reasons of ethics and prudence, make contact with the parents of a minor in every case ... unless the minor refuses permission.’⁶⁵⁵ This appears to be more of a courtesy rather than a legal requirement. As already stated, if the minor provides the consent then the medical professional can legally proceed with the medical procedure. Informing those with PR every time the minor undergoes a medical procedure is unnecessary and excessive, but where the minor is undergoing a procedure that requires the support from their family to aid recovery, it may be suggested that those with PR are informed. For example, in tissue donation it was discussed in Chapter 4 that a minor is vulnerable and requires a support system to help them recover from the tissue donation. Their family can provide an emotional support mechanism for the donor; however, this will differ depending on the circumstances of the family.⁶⁵⁶

In conclusion, in this section I argued that those with PR currently can, but should not be permitted to override a competent minor’s consent/authorisation for three reasons. This includes because when a minor is competent and able to make decisions for themselves, the need for a proxy decision-maker becomes obsolete. I will now consider whether a court can and should be able to override a competent minor’s decision in respect of tissue donation.

⁶⁵⁵ Latey Committee (n 592) para 482.

⁶⁵⁶ see Chapter 4 at 4.4.2 for further discussion about emotional support from the family.

6.5 The Court

While the court can make decisions on behalf of an incompetent minor by invoking their inherent jurisdiction, the *parens patriae* jurisdiction, it is unclear whether such a jurisdiction can be invoked over a competent minor.⁶⁵⁷ It is my view that once a minor is competent a court should not be able to override their decision about whether to be a tissue donor. The role of the court is to protect the interests of the minor, and once the minor is competent to make their own decisions then the role of the court is obsolete. Although the legal authorities that govern this area of law in England and Wales, and Scotland are different, the legal principles that stem from them are the same, therefore, I am going to deal with the issues together to avoid repetition.

As argued in the previous section, those with PR should lose their right to provide consent/authorisation on behalf of a minor once they are competent, the question is whether this also applies to the court. The simple answer is yes it should do. In Scotland, the 1991 Act must be read in conjunction with the 1995 Act. Section 11 of that Act allows the court to make an order in relation to PR, parental rights, and guardianship. When a court has before it a question as to the care and upbringing of a minor, it must treat the welfare of the minor as the paramount consideration in determining the order to be made.⁶⁵⁸ But it does not go further than that, this suggests that when a court is required to make an order it must treat the welfare of the minor as the paramount consideration, but it is unclear whether a court can make an order to override a competent minor's decision.

⁶⁵⁷ see Chapter 5 at 5.3 for further information about *parens patriae*.

⁶⁵⁸ Children (Scotland) Act 1995, s.11(7).

In England and Wales, if the view of Lord Scarman in *Gillick* is adopted, when a competent minor provides consent to a medical procedure the right of those with PR to exercise control in respect of that matter ‘yields’⁶⁵⁹ and if a court can only act in the same way as a responsible parent their right will also yield. Thus, the court would have no authority to act outside parental powers.⁶⁶⁰ As John Seymour has stated:

It must not be overlooked that the *parens patriae* jurisdiction confers powers not only to protect the young, but also to control them. At a time when the law is giving increasing recognition to the children’s autonomy ... it is necessary fully to consider the implications of judicial claims to possess powers which are not defined by reference to current conceptions of the parent-child relationship.⁶⁶¹

However, a court may override a decision made by those with PR on behalf of a minor which suggests that the court has wider powers than those with PR. Lord Donaldson stated in *Re R* that:

The court has the right and, in appropriate cases, duty to override the decision of the parents or other guardians. If it can override such consents, as it undoubtedly can, I see no reason why it would not be able, and in appropriate cases, willing, to override decisions by *Gillick* competent children.⁶⁶²

He goes on to explain that:

⁶⁵⁹ *Gillick* (n 498) 422 per Lord Scarman.

⁶⁶⁰ Graeme Laurie, ‘Parents patriae jurisdiction in the medico-legal context: the vagaries of judicial activism’ (1999) *Edinburgh Law Review* 95, 105.

⁶⁶¹ John Seymour, ‘Parens Patriae and Wardship Powers: Their Nature and Origins’ (1994) 14(2) *Oxford Journal of Legal Studies* 159, 160.

⁶⁶² *Re R* (n 567) 187.

[T]he practical jurisdiction [of a court exercising *parens patriae*] is wider than that of parents ... [T]his jurisdiction is not derivative from the parent's rights and responsibilities, but derives from, or is, the delegated performance of the duties of the Crown to protect its subjects and particular children...⁶⁶³

Furthermore, Lord Donaldson held that because the power of the court is wider than that of those with PR, it could override the consent of a competent minor.⁶⁶⁴ In *Re W*⁶⁶⁵, Lord Donaldson restated his view, expressed in *Re R*⁶⁶⁶, that:

There is ample authority for the proposition that the inherent powers of the court under its *parens patriae* are theoretically limitless and that they certainly extend beyond the powers of a natural parent.⁶⁶⁷

In his view, there could be no doubt that since the court's powers extended beyond those with PR, the *parens patriae* jurisdiction could be exercised to override the refusal of a *Gillick* competent minor.⁶⁶⁸ In *Re L (Medical Treatment: Gillick Competency)*⁶⁶⁹, Sir Stephen Brown P stated that even if the court had found L to be *Gillick* competent, it would still have made the order for the blood transfusion to go ahead by overruling her decision because it was in her interests to have the transfusion.⁶⁷⁰ This indicates that even if a minor is competent, the court can overrule their decision, especially if it is in the minor's interests to do so. But in my contention that a court should not be able to overrule a competent minor's decision. The role of the court is to protect the interests

⁶⁶³ *Re R* (n 567)186.

⁶⁶⁴ *Re R* (n 567).

⁶⁶⁵ *Re W* (n 602).

⁶⁶⁶ *Re R* (n 567).

⁶⁶⁷ *Re W* (n 602) 637.

⁶⁶⁸ *Re W* (n 602) 637. A similar decision was reached by Balcombe LJ (643) and by Nolan LJ (646).

⁶⁶⁹ *Re L* (n 517).

⁶⁷⁰ *Re L* (n 517) 813.

of the minor when they are unable to do so themselves. Once a minor is competent this role is obsolete and should not be exercised over the minor.

A court should not conclude that a minor is incompetent because they do not agree with the decision the minor has made or anticipate that their decision will change in the future. However, it was demonstrated in *Re E (A Minor)(Wardship: Medical Treatment)*⁶⁷¹ that a court can do this, when Ward J found that E was incompetent and held that it was in his best interests to have a blood transfusion despite, as a Jehovah's Witness, his refusal of it. Notably, once E reached 18, he refused all further blood transfusions, he succumbed to his illness and died as a result.⁶⁷² However, as Emily Jackson has stated, 'this was not because he had suddenly acquired an understanding of what it would be like to die, rather he had simply achieved the status of adulthood.'⁶⁷³ At best, the additional two years enable E to become more solid in his convictions and better prepared to realise the full implications of his ultimate decision.⁶⁷⁴ If the court was to act on a presumption that a minor's view will change as they get older then no minor would be able to make a decision. It is my argument that if a minor meets the competency test then they should be the sole determinant as to whether they provide consent or authorisation, regardless of whether the court agrees with that decision or the procedure is in their best interests or not.

In relation to 16- and 17- year olds, my argument that a court should not be able to override a competent minor's decision is strengthened by the wording in section 8(1).

⁶⁷¹ *Re E* (n 511).

⁶⁷² Emily Jackson, *Medical Law: Text, Cases, and Materials* (OUP 2016) 303; and n.416 p120-121.

⁶⁷³ Jackson (n 673) 303.

⁶⁷⁴ Margaret Brazier and Caroline Bridge, 'Coercion or Caring: analysing adolescent autonomy' (1996) 16(1) *Legal Studies* 84, 104.

Examining section 8(1) more closely, it states that the consent is ‘as effective as it would be if he were of full age’. In other words, a minor can provide consent ‘as effective as it would be if he were of full age’. If an adult has capacity, they can provide consent to a medical procedure that cannot be overruled by a court, nor can the court provide consent on behalf of the adult, regardless of whether the decision is in the adult’s best interests or not. Therefore, if a 16- or 17- year old can consent under section 8 as if they were an adult, it would follow that the court cannot overrule the consent provided by the 16- or 17- year old, nor provide consent on their behalf. Therefore, a 16- or 17- year old who is competent can provide consent to be a tissue donor, and this decision should not be able to be overruled by a court.

6.6 Concluding thoughts

In this chapter I considered the second research question of this thesis: who can and should be able to provide consent/authorisation for living minors to be regenerative tissue donors? I concluded that if a competent minor meets the relevant competency test then they should be able to provide consent/authorisation for them to be a tissue donor. As to whether they can currently do this, the law is unclear as there has been no application of tissue donation to the *Gillick* competency test, section 2(4) competency test or section 8 of the 1969 Act by the court. In order to ensure that a medical professional is correctly applying these tests within the tissue donation process clarification is required. This lack of clarity and precision results in uncertainty that is not conducive to effective decision-making. Furthermore, I argued that those with PR and the court currently can but should not be permitted to override a competent minor’s consent/authorisation to tissue donation because when a minor is competent and able to make decisions for themselves, the need for a proxy decision-maker becomes obsolete.

I also examined the third research question of this thesis in relation to competent minors: what test(s) should be used to determine whether consent/authorisation can be provided for a living minor to be a tissue donor? I have proposed clarification of the *Gillick* competence test and section 2(4) competence test. This clarification means that in order for a minor to be competent under either of these tests they should require an understanding of the moral, family, emotional, and long-term implications of the donation, as well as an understanding of the potential consequences if they refuse the procedure. In relation to those aged 16- and 17- years old, my contention is that while, *prima facie*, the term ‘treatment’ does not include tissue donation from living minors as it is a non-therapeutic procedure for the donor, section 8 should be interpreted broadly to cover such procedures. But interpretation and application through common law is required so there is no ambiguity.

I have now answered all three research questions in this thesis, therefore, in the following chapter I will evaluate my success in achieving my aims and outline the various conclusions that I have reached and propose any reforms to the current regulatory framework.

Chapter 7

Conclusion

7.1 Proposed Reforms to the Regulatory Framework

I have now considered all of the issues I consider relevant within the tissue donation debate in respect of living minors, and provided answers with in-depth reasoning to my three research questions I posed at the start of this thesis. I will now demonstrate how the proposed reforms/clarifications to the current regulatory framework would apply in practice. My main argument, in this thesis, is that the regulatory framework that currently governs living minors as tissue donors in England and Wales, and Scotland does not adequately protect the minor donor's interests, and I would suggest it is in need of clarification and/or reform. To reiterate my research questions:

- (1) Should non-regenerative tissue donation from living minors be permitted in England and Wales, and Scotland?
- (2) Who can and should provide consent/authorisation for living minors to be regenerative tissue donors?
- (3) What test(s) should be used to determine whether consent/authorisation can be provided for a living minor to be a tissue donor?

The recommendations I have proposed will not just exist in the abstract, but will be applied in practice, so I feel that the best way to demonstrate how my recommendations apply to the donation process is to set out three realistic donation stories that cover

common likely scenarios. These stories will follow the donation process flowcharts as set out in Figures 3 and 4.⁶⁷⁵

I have previously discussed and offered robust argument that no living minor should be able to donate non-regenerative tissue which is the approach taken in the Scottish legislation, the Human Tissue (Scotland) Act 2006. My overarching argument being that the psychological benefits do not outweigh the immediate and long-term medical risks and potential psychological harms of the donation, even if the donation is to a sibling, therefore, the donation cannot be justified.

I concluded that the types of tissue donation that present the highest risks of morbidity and mortality are non-regenerative tissue donation. A kidney donation presents the most significant long-term implications with the greatest lifestyle restrictions. The justification for permitting the tissue donation is based on the psychological benefit the donor would develop from donating to a sibling. But a psychological benefit cannot be guaranteed, and even less so if the transplant is not a success in the recipient. I demonstrated that in relation to the donation of non-regenerative tissue, a minor donor has a higher susceptibility to particular vulnerabilities. Therefore, there is a greater chance that the donor will develop a psychological harm from the donation of non-regenerative tissue compared to regenerative tissue. I, therefore, propose that the Human Tissue Act 2004, in England and Wales, should subsequently be reformed to include a restriction to prevent living minors from being permitted to donate non-regenerative tissue. Consequently, all of the following stories involve the donation of regenerative tissue, specifically bone marrow.

⁶⁷⁵ See Chapter 3 at 3.5.

7.2 Daisy's Story

Daisy is 6-years old and lives with her half-brother Joshua who is 1-year old. Daisy's mother and biological father are divorced and live separately but have shared parental responsibility (PR) for Daisy. Daisy's mother has re-married and Daisy now has a step-father who is Joshua's father. Daisy also has a close emotional bond with her paternal grandparents who she has regular contact with.

Joshua is in need of a bone marrow transplant in order to save his life. I have not specified a jurisdiction because the steps of the donation process are the same in England and Wales, and Scotland for this type of donation, the documented procedural steps are in a different order.

Step 1: Identify a potential living donor (check histocompatibility)

This step is performed by the medical professionals, and as part of the process, a number of individuals would be tested to check their suitability as a tissue match for Joshua. This would include Daisy, Joshua's parents, and other family members. Those with PR for Daisy, ie her parents, would have provided the consent for her to undergo the histocompatibility tests. Following the histocompatibility tests, it was determined that Daisy was the best match to donate bone marrow to Joshua. Even though Daisy is histocompatible, it does not automatically mean that Daisy will donate the tissue, all the steps of the donation process need to be met for the donation to proceed.

Step 2: Is the potential donor a minor?

Yes, Daisy is a minor because she is 6-years old, which is under the age of 18 in England and Wales, and under 16 in Scotland.

Step 3: Is the minor competent to consent to the donation?

No, Daisy is not competent to consent to the bone marrow donation. I have previously stated that this story applies equally to England and Wales, and Scotland, however, the current law in Scotland uses the term authorisation rather than consent. But I argued that the difference between the terms consent and authorisation is superficial as the test for informed consent and informed authorisation are identical. Therefore, it is my contention that it would be clearer and more precise if the term consent replaces the term authorisation in the Human Tissue (Scotland) Act 2006 in relation to tissue donation. Subsequently, if my recommendation is implemented the term consent would be used throughout all donation processes.

Step 4: Gain informed consent from those with PR

As Daisy is incompetent, those with PR will be able to provide consent on her behalf to be a tissue donor if it is deemed to be in her best interests. I have suggested a reform in the body of my thesis to the best interests test, which is set out in italics, and I have applied this new test to the circumstances of Daisy:

- (a) *the minor's age and maturity and so far, as practicable:*
 - (i) *give him [her] an opportunity to indicate whether he[she] wishes to express his [her] views;*

Daisy is 6-years old and has limited maturity. But she should be given the opportunity to indicate whether she wants to express her views about the decision. As I will discuss at step 6, Daisy will be interviewed by an Accredited Assessor (AA) which will involve them explaining to her about the donation procedure and Joshua's illness. She understands that she can help Joshua, but this understanding is limited to knowing that

she would need time off school, have to stay in hospital, and the procedure would cause her pain.

(ii) *if he [she] does so wish, give him [her] an opportunity to express them;*

If Daisy wishes to express her views about the potential donation procedure then she should be given an opportunity to do this away from her parents and Joshua. This may be in the presence of medical professionals, her teachers, or her grandparents. If Daisy has a trusting relationship with someone, she may be more open about how she feels. This will allow her to ask any questions and express her own views in an independent, more-relaxed, informal environment. Daisy does not have to necessarily express her views through verbal communication, but can do this through her actions. While spending time with her grandparents, Daisy drew a picture that showed herself, her mum, her step-father, her biological father, and Joshua. In the picture Joshua is no longer ill, and she wrote on the picture that ‘she helped Joshua feel better’.

(iii) *have regard to such views as he [she] may express;*

When Daisy’s parents are making a decision on her behalf, they should have regard to Daisy’s views. Daisy’s views are that she wants to help Joshua, which involves her donating bone marrow, therefore this should be a factor in the decision-making process.

(b) *the child’s physical, emotional and/or education needs;*

Daisy’s emotional needs involve her seeing her brother recover from his illness and live a fairly normal life. Her physical needs are those related to the potential medical risks of the bone marrow donation. The risks of morbidity of a bone marrow donation are low, and there have been no reported deaths. This criterion also involves the medical and emotional support that can be provided to Daisy in order for her to fully recover

from the operation. The medical support would be provided by the NHS, and the emotional support by her close family, including her parents and grandparents.

(c) the likely effect on the child of any change in his/her circumstances;

In relation to changes in circumstances, if it was deemed that Daisy was no longer able to donate bone marrow to Joshua she would not be considered as a potential tissue donor, similarly if Joshua no longer needed a transplant Daisy would not be required to donate bone marrow.

(d) the child's age, sex, background and any other characteristics, which the court considers relevant;

Daisy is 6-years old and female, there are no other characteristics that are considered relevant to take into account in the decision-making process that pertain to bone marrow donation.

(e) any harm which the child has suffered or is at risk of suffering;

Daisy's parents will be fully informed about the potential medical risks by medical professionals. The test of information disclosure under *Montgomery* is that the doctor is 'under a duty to take reasonable care to ensure that the patient is aware of any material risks involved in any recommended treatment, and of any reasonable alternative or variant treatments.' The immediate potential medical risks that Daisy would be exposed to are minimal with the majority of risks as a result of the anaesthesia. Daisy would need a period of recovery, but there are no reported long-term medical risks. In these circumstances the medical risks posed to Daisy are considered minimal, therefore the

risk of harm does not outweigh the other factors considered in the test. So, the donation could take place.

- (f) how capable each of the child's parents, and any other person in relation to whom the court considers the question to be relevant, is of meeting his/her needs;

Daisy's parents can meet her needs.

- (g) the range of powers available to the court under the Children Act 1989 in the proceedings in question;

There are no indications that court intervention is required in this case. Daisy's parents are in agreement about the decision they are going to make, and no one has raised concerns that the bone marrow donation is not in Daisy's best interests.

Furthermore, I have recommended an additional section that should be incorporated into the 1989 Act under Section 1A, set out in italics, and I will apply it to Daisy:

- (1) *In relation to tissue donation from a living minor, the following additional factor must be considered in addition to the best interests test as stated in section 1(3):*
 - (a) *the inclusion of relational parental decision-making.*

In this thesis, I have devised the new and novel principle of relational parental decision-making. This means that when those with PR make a decision on behalf of an incompetent minor, instead of treating the minor as if they were an isolated being, I proposed that the relationships that the minor has with others should be a contributing

part of the decision-making. I provided a list of factors that the decision-maker could take into account when considering each relationship. These are:

- (1) type of relationship
- (2) length of relationship
- (3) potential future interaction (temporary or long-term relationship)
- (4) frequency of interaction
- (5) type of interaction

The relationships that Daisy has are as follows:

- (a) Joshua (the potential recipient)
- (b) Daisy's biological mother and father
- (c) Daisy's wider family to include paternal grandparents and step-father
- (d) Daisy's friends

Taking each relationship in turn and applying it to the five factors:

(a) Joshua (the potential recipient)

- (1) type of relationship – familial relationship as Joshua is Daisy's half-brother.
- (2) length of the relationship – 1-year.
- (3) potential future interaction (temporary or long-term relationship) – as siblings they will be expected to have a familial relationship for a lifetime. The relationship between Daisy and Joshua is currently a close emotional bond, and there is no evidence to suggest that their relationship will breakdown in the immediate future.

- (4) frequency of interaction – Daisy and Joshua interact on a daily basis because they live together as part of the family unit. They also spend time apart as Daisy goes to school in the day time and stays with her biological father at the weekend.
- (5) type of interaction – they have necessary interactions when they spend time with their parents, but they also have voluntary interactions. Daisy enjoys spending time with her brother. Daisy understands that they have the same mother, but have a different father.

This relationship has a positive impact on Daisy, and can be given significant weight in the decision-making process. There is potential for a future emotional relationship between them if Joshua survives. Daisy gets upset about Joshua's illness and has told her parents, grandparents, medical professionals and teachers that she wants Joshua to get better.

(b) Daisy's biological mother and father

- (1) type of relationship – familial relationship.
- (2) length of the relationship with Daisy – 6-years; her parents got divorced when she was 3 years old.
- (3) potential future interaction (temporary or long-term relationship) – Daisy enjoys spending time with both of her parents. Daisy's mother and father have an amicable relationship and there is no evidence to suggest that Daisy would be prevented from spending time with her mother or father in the immediate future.

- (4) frequency of interaction – Daisy interacts with her mother on a daily basis as she lives with her. Daisy interacts with her father at the weekend when she stays at his house.
- (5) type of interaction – Daisy’s relationship is necessary with her mother since she lives with her. Daisy’s relationship with her father is voluntary as she has a choice if she wants to spend time with him. She always chooses to see her father, and if she was able to, she would like to spend more time with him.

These relationships have a positive impact on Daisy. Daisy’s father has less of a conflict of interest compared to Daisy’s mother since he is not biologically related to Joshua. However, Daisy’s father consents for Daisy to undergo the donation procedure. Furthermore, Daisy’s father’s house can be used by Daisy as a caring, loving and supportive environment away from Joshua, her mother and step-father to help her recover from the donation if required or preferred. Therefore, should Daisy’s mother and step-father focus their efforts and attention on Joshua at any point and neglect Daisy’s emotional needs, Daisy has an alternative environment to visit which is beneficial to Daisy.

(c) Daisy’s wider family

- (1) type of relationship – familial relationship. Daisy’s wider family include her paternal grandparents and step-father.
- (2) length of the relationship –
Daisy has had a relationship with her grandparents for 6 years.
Daisy’s relationship with her step-father has been for 2 years.

(3) potential future interaction (temporary or long-term relationship) –
Daisy’s grandparents are seniors; however, it is likely that they will be able to continue to interact with Daisy for many years to come.

Daisy’s mother and step-father have been together 2 years and are married. Their relationship is good and they intend to stay together, so it is likely that her step-father will be involved in Daisy’s life in the immediate future.

(4) frequency of interaction –

Daisy interacts with her grandparents weekly, and during school holidays.

Daisy interacts with her step-father on a daily basis as they live in the same house.

(5) type of interaction –

Daisy’s interaction with her grandparents is voluntary as she chooses to spend time with them.

With regard to Daisy’s relationship with her step-father this is necessary as she lives with him. Daisy does not choose to spend time with her step-father, it is not voluntary their relationship could be described as amicable.

The relationship that Daisy has with her grandparents is positive, she talks to them about Joshua and his illness. They provide an independent, supportive, loving and caring environment for Daisy. They are not biologically related to Joshua and have no contact with him; therefore, their primary focus is on Daisy’s interests. This is beneficial to Daisy as it will allow her to communicate freely with her grandparents with no risk of

them pressuring her to undergo the procedure. But they do not have suitable accommodation for her to recover from the donation, if necessary.

In respect of her relationship with her step-father, it is a necessary relationship. He has no impact on the decision being made on behalf of Daisy because he does not have PR for her. The relationship that Daisy has with her grandparents will have greater weighting in the decision-making process than her relationship with her step-father.

(d) Daisy's friends

- (1) type of relationship – societal relationship. Daisy has a number of friends at school.
- (2) length of the relationship – Daisy has been at school for around 1 year.
- (3) potential future interaction (temporary or long-term relationship) – friendships can be temporary especially at Daisy's age. If Daisy did undergo the donation procedure, she will have time off school, but her friends would be able to visit her as she is recovering.
- (4) frequency of interaction – Daisy interacts with her friends daily at school, and during school holidays.
- (5) type of interaction – this relationship is voluntary. Daisy chooses to spend time with her friends.

While this is a positive relationship for Daisy, it will hold minimal weight in the decision-making process. There is no evidence to suggest that Daisy has told her friends about Joshua's illness or that she will be friends with them for any significant period of time.

- (2) *In relation to tissue donation from a living minor when considering the best interests test in section 1(3), the factor under section 1(3)(e) should be given the greatest weight.*

In these circumstances, the medical risks posed to Daisy are considered minimal, therefore, the risk of harm does not outweigh the other factors considered in the best interests test. So, the donation could take place.

If this scenario was set in Scotland, then those with PR would consider the best interests of the minor, but there is no test set out in 1995 Act. But I have recommended an additional section to be included in the 1995 Act under Section 6A, set out in italics:

- (1) *In relation to tissue donation from a living minor, the following factor must be considered when determining whether it is in the minor's best interests to undergo the procedure:*
- (a) *the inclusion of relational parental decision-making.*
- (2) *In relation to tissue donation from a living minor when considering their best interests the consideration of the harm of the procedure should be given the greatest weight.*

The application to Daisy is the same as discussed in England and Wales under the 1989 Act.

In conclusion, taking into account all of the factors in the best interests test which includes giving weight to Daisy's views, and considering the principle of relational

parental decision-making requiring her relationships to be examined with Joshua, her parents, and her grandparents, it is in Daisy's best interests to donate bone marrow to her brother Joshua. Therefore, her parents can provide consent on her behalf. Only the consent of either her mother or father is legally required, but both of her parents agree with the proposed procedure.

Step 5: Is the tissue non-regenerative or regenerative?

The tissue that is requested for donation is regenerative tissue as it is bone marrow.

Step 6: AA must interview the donor, the recipient and those with PR for the donor

As Daisy is donating regenerative tissue the interviews will be undertaken by an AA. The AA will interview both Daisy and Joshua separately. Furthermore, as Daisy is incompetent the AA will also interview her biological parents. As Daisy is 6-years old there may be some issues with Daisy's ability to communicate effectively with the AA. However, the AA must attempt to undertake an interview as Daisy is not a baby nor a pre-verbal minor. It is imperative that the interview is undertaken at a level appropriate to Daisy's age and understanding. Joshua is 1-year old, therefore, is a pre-verbal minor. Subsequently, it may be a waste of time and resources for an AA to attempt to undertake an interview with him. Once the interviews have been completed, the AA will write a report and submit it to the HTA. The following matters must be covered in the interview report submitted by the AA:

- (a) whether there is any evidence of duress or coercion affecting the decision to give consent;
- (b) whether there is any evidence of an offer or a reward;

- (c) whether there were any difficulties in communicating with the person(s) interviewed, and if so, an explanation of how these difficulties were overcome.

Following the interview with Daisy's biological parents, the AA concluded that there is no evidence of any duress or coercion affecting their decision-making. There is no evidence of an offer or reward being given to Daisy or Daisy's parents if she undergoes the bone marrow donation. Any issues with Daisy's ability to communicate is addressed fully in the report. But it is concluded that she understands that Joshua is ill and she will get visibly upset when her mother and step-father discuss it.

Furthermore, the report of the interview with Daisy, as she is the donor, must also contain:

- (a) the information given to the person interviewed as to the nature of the medical procedure and the risk involved in the removal of the transplantable material;
- (b) the full name of the person who gave that information to the person interviewed, and their qualification to give it;
- (c) the capacity of the person interviewed to understand the nature of the medical procedure, the risk involved and that consent may be withdrawn at any time before the removal of the transplantable material.

At the time when Daisy's parents provided consent on behalf of Daisy, they would have been given information about the nature of the tissue donation procedure and the medical risks involved in order for the consent to be compliant with the legal test in

Montgomery. The name and qualifications of the medical professional who provided this information to Daisy's parents would be recorded in the report. Daisy is incompetent and, therefore, does not have the ability to fully understand the nature of the medical procedure and the risks involved. However, the procedure and Joshua's illness would have been explained to Daisy in a simple format.

Step 7: Is there HTA approval?

The HTA would assess the report that has been produced by the AA and ensure that all of the regulatory requirements have been met. In this case, there were no issues identified in the interview with the AA and all regulatory steps have been fulfilled, therefore, the HTA would give approval for the donation to proceed.

In this case all of the requirements have been fulfilled, therefore, Daisy would be allowed to donate bone marrow to Joshua.

7.3 Ryan's Story

Ryan is 15-years old and lives with his brother Simon who is 5-years old. They also have an older brother called Anthony who is 21-years old and no longer lives in the family home. Ryan, Simon, and Anthony all share the same biological parents, and both parents share PR for Ryan.

Simon is in need of a bone marrow transplant in order to save his life. I have not specified a jurisdiction because the steps of the donation process are largely the same in England and Wales, and Scotland for this type of donation, there is just one major difference which I will address in my discussion.

Step 1: Identify a potential living donor (check histocompatibility)

This step is performed by the medical professionals, and as part of the process, a number of individuals would be tested to check their suitability as a tissue match. This would include Ryan, Ryan's parents, Anthony, and other family members. Following the histocompatibility tests, it was determined that Ryan was the best match to donate bone marrow to Simon. Even though Ryan is histocompatible, it does not automatically mean that he will donate the tissue, all the steps of the donation process need to be met for the donation to proceed.

Step 2: Is the potential donor a minor?

Yes, Ryan is a minor because he is 15-years old, which is under the age of 18 in England and Wales, and under 16 in Scotland.

Step 3: Is the minor competent to provide consent?

I have previously stated that this story applies equally to England and Wales, and Scotland, however, the current law in Scotland uses the term authorisation rather than consent. But I argue that the difference between the terms consent and authorisation is superficial as the test for informed consent and informed authorisation are identical. Therefore, it is my contention that it would be clearer and more precise if the term consent replaces the term authorisation in the 2006 Act in relation to tissue donation. Subsequently, if my recommendation is implemented the term consent would be used throughout all the donation processes.

Ryan is 15-years old, and in order to be competent he needs to meet the requirements under the *Gillick* competence test or section 2(4) competence test. I have argued that both of the tests should have identical requirements, therefore if he meets these requirements, he would be competent in both England and Wales, and Scotland. For Ryan to be competent, he must have an understanding of the moral, family, emotional, and long-term implications of the donation, as well as an understanding of the potential consequences if he refuses the procedure.

(1) Moral implications of the decision

Ryan should understand that there is no moral duty to donate to Simon. But moral considerations may form part of Ryan's reasoning, since his tissue could result in a life-saving transplant for Simon. Ryan understands the moral considerations of the decision as well as the fact that moral pressures that his parents, Simon, Anthony or the wider community may place on him to donate bone marrow. He needs to disregard any intentional or inadvertent pressures placed on him by others when making his decision.

(2) Family implications of the decision

A factor when determining whether Ryan is competent is his understanding of the family implications of the decision. This includes Ryan's relationship with his parents, Simon, Anthony, and the wider family. Ryan should be able to discuss his decision with his parents, in an environment free from pressure, and raise any concerns he may have as well as ask any questions. His family needs to support him in his decision-making by providing him with unbiased information. Ryan's familial relationships are further discussed below at step 4 when considering relational autonomy.

(3) Emotional implications of the decision

To be competent, Ryan would be required to understand the emotional implications of the donation, regardless of whether the donation was successful. Indeed, if the donation was not a success then he may feel guilt or a sense of failure. Ryan is aware of and understands that the donated tissue may fail, be rejected by Simon, or that the original cause of the tissue failure may recur and that the outcome is beyond his control. It is not guaranteed that he is able to manage these feelings, but since he understands that these feelings may materialise, he may be able to better manage them by asking for support.

(4) Long-term implications of the donation

The long-term implications of a tissue donation are the future medical risks and any lifestyle restrictions following it. In relation to a bone marrow donation there are no long-term medical risks or lifestyle restrictions that have been recorded.

(5) Refusal of the procedure

Ryan understands that if he refuses to donate bone marrow there would be no medical impact on him, but it would have an impact on Simon. Ryan is only expected to understand an outline of the impact it would have on Simon and is not expected to understand the finer details of Simon's illness.

Ryan meets all of these requirements as he has a sufficient understanding and intelligence to enable him to fully understand what is proposed. Therefore, the medical professional will deem him competent to provide consent to donate bone marrow.

Step 4: Gain informed consent from the donor

In order to legally provide consent the test for information disclosure under *Montgomery* needs to be satisfied. The test under *Montgomery* is that the doctor is ‘under a duty to take reasonable care to ensure that the patient is aware of any material risks involved in any recommended treatment, and of any reasonable alternative or variant treatments.’ Therefore, Ryan would be informed of the immediate and long-term medical risks of undergoing the bone marrow donation. The test of materiality is ‘whether, in the circumstances of the particular case, a reasonable person in the patient’s position would be likely to attach significance to the risk, or the doctor is or should reasonably be aware that the particular patient would be likely to attach significance to it.’ Subsequently the medical professional would be required to inform Ryan of any type of medical risks that he is likely to attach particular significance to.

I have argued in the main body of my thesis that the philosophical interpretation of the principle of relational autonomy should have a legal application in medical decision-making, specifically tissue donation from a living minor. My interpretation of relational autonomy is that if an individual makes an autonomous relational decision then that decision is made by considering the networks of relationships with others. In other words, for an individual to make a decision they need to take into account their relationships with others that underpin their lives, such as familial and societal relationships. I have provided a list of factors that the decision-maker could take into account when considering each relationship (see Daisy’s story for the full list). Ryan’s relationships are as follows:

- (a) Simon (the potential recipient)
- (b) Ryan’s mother and father

- (c) Ryan's wider family which includes Anthony his brother
- (d) Ryan's friends

Taking each relationship in turn and applying it to the five factors:

(a) Simon (potential recipient)

- (1) type of relationship – familial relationship as Simon is Ryan's brother.
- (2) length of the relationship – 5 years.
- (3) potential future interaction (temporary or long-term relationship) – as siblings they will be expected to have a familial relationship for a life-time. The relationship between Ryan and Simon is currently a close emotional bond, but it should be noted that there is a 10 year age gap between the siblings, and Ryan may leave home in the next 3 years for university.
- (4) frequency of interaction – Ryan and Simon interact on a daily basis because they live together.
- (5) type of interaction – they have necessary interactions when they spend time with their parents, but they also have voluntary interaction. Ryan enjoys spending time with his brother. Ryan uses his pocket money to buy Simon gifts.

This relationship has a positive impact on Ryan, and should be given significant weight in his decision-making. Ryan requested that he was tested to see if he was histocompatible, and he has spent time researching Simon's illness on the internet. Ryan is very concerned about Simon and wants to ensure he recovers from this illness. However, Ryan is also aware that recovery is not definite.

(b) Ryan's mother and father

- (1) type of relationship – familial relationship.
- (2) length of the relationship with Ryan –15 years.
- (3) potential future interaction (temporary or long-term relationship) – Ryan enjoys spending time with both of his parents, together and separately. He has a close emotional relationship with them both, and there is no evidence to suggest that this relationship would change in the future, even if he were to leave the family home.
- (4) frequency of interaction – Ryan interacts with his parents on a daily basis.
- (5) type of interaction – Ryan's interaction with his parents is both necessary and voluntary. It is necessary because he lives with his parents, but he voluntarily chooses to spend time with them at the weekend and goes on holiday.

This is a positive relationship for Ryan. While his parents have strongly suggested to Ryan that he should consider donating to Simon because they do not want to see Simon die, they understand that it is Ryan's decision. They have provided a supportive environment for him to discuss the procedure with them and have stated that they will support Ryan, regardless of the decision he makes, and ensure that he successfully recovers physically if he undergoes the procedure. This relationship will have significant weight in the decision-making procedure, but Ryan should not allow any pressure from his parents to determine his decision.

(c) Ryan's wider family

- (1) type of relationship – familial relationship. The only other familial relationship that Ryan has is with his older brother Anthony who no longer lives at home.
- (2) length of the relationship –15 years.
- (3) potential future interaction (temporary or long-term relationship) – Anthony has not lived at home for 5 years, but Ryan continues to have a close emotional relationship with him. It is likely that this relationship will continue as Ryan gets older, but this is not guaranteed. There is always a risk that their relationship will breakdown, however, there is no evidence to suggest this will happen in the immediate future.
- (4) frequency of interaction – Ryan interacts with Anthony at family events and visits him on a weekly basis.
- (5) type of interaction – the interaction at family events is necessary, however, Ryan and Anthony voluntarily spend time together.

This relationship has a positive impact on Ryan. Ryan has spoken to Anthony about Simon's illness and the decision he has to make. Anthony also provides an environment where Ryan can stay if he needed space away from his parents and Simon either when making his decision, or to aid his recovery from the donation which is beneficial to Ryan. However, Anthony lives in rented accommodation and works office hours.

(d) Ryan's friends

- (1) type of relationship – societal relationship. Ryan has a number of friends at school as well as at sporting clubs.

- (2) length of the relationship – these friendships differ in length of time from a few months to a number of years.
- (3) potential future interaction (temporary or long-term relationship) – some of these friendships will be temporary, but other friendships may last longer. If Ryan underwent the bone marrow donation, then he would be required to have time off school, and not be able to participate in sport for a short period of time while he recovers, but he will still continue to be able to interact with his friends over social media. Ryan plays rugby for his school and if donation takes place during the rugby season he may not be able to participate.
- (4) frequency of interaction – Ryan interacts with his friends on a daily basis. He sees them at school, and interacts with them over social media in the evenings and at weekends.
- (5) type of interaction – Ryan’s interactions with his friends are voluntary because he chooses to spend time with them.

These friendships are positive relationships for Ryan. Ryan’s close friends can provide a supportive environment for him to discuss Simon’s illness and his decision as to whether to donate. However, these relationships are unlikely to carry much weight in the decision-making process. He will continue to be able to interact with his friends online during the donation process, and they would be able to visit him in hospital or at home while he recovers.

Ryan would take a number of factors into account in the decision-making process, including all of these relationships, but he will give greater weight to his relationship

with Simon, Anthony, and his parents. Ryan has decided that he wants to provide consent to donate bone marrow to Simon.

If Ryan's parents did not want Ryan to undergo the bone marrow donation, for instance they wanted Simon to receive tissue from another donor, it is my argument that those with PR should not be permitted to override a competent minor's consent. This is because those with PR hold their power as agents or trustees on behalf of the minor until they are mature enough to begin to make decisions for themselves. Therefore, I suggest that even if Ryan's parents disagreed with his decision, because Ryan is competent his decision should be respected by his parents.

Step 5: Is the tissue non-regenerative or regenerative?

The tissue that is potentially being donated is regenerative tissue as it is bone marrow.

Step 6: An AA must interview the potential donor and recipient

As Ryan is potentially donating regenerative tissue the interviews will be undertaken by an AA. The AA will interview both Ryan and Simon separately. As Simon is 5-years old there may be some issues with Simon's ability to communicate effectively with the AA. However, the AA must attempt to undertake an interview as Simon is not a baby nor a pre-verbal minor. It is imperative that the interview is undertaken at a level appropriate to Simon's age and understanding. Once both interviews have been completed, the AA will write a report and submit that to the HTA. The following matters must be covered in the report submitted by the AA:

- (a) whether there is any evidence of duress or coercion affecting the decision to give consent;

- (b) whether there is any evidence of an offer or a reward;
- (c) whether there were any difficulties in communicating with the person interviewed, and if so, an explanation of how these difficulties were overcome.

In relation to Ryan's decision-making there is no evidence of any duress or coercion affecting his decision. He has identified pressures that have been placed on him by Simon and his parents, but has attempted to ensure that they do not influence his decision. His parents have acknowledged that it is solely for Ryan to make the decision. There is no offer or reward should he decide to donate his tissue. There are no difficulties with his ability to communicate.

Furthermore, the report of the interview with Ryan, as he is the donor, must also contain:

- (a) the information given to the person interviewed as to the nature of the medical procedure and the risk involved in the removal of the transplantable material;
- (b) the full name of the person who gave that information to the person interviewed, and their qualification to give it;
- (c) the capacity of the person interviewed to understand the nature of the medical procedure, the risk involved and that consent may be withdrawn at any time before the removal of the transplantable material.

Ryan will have been provided with information about the nature of the tissue donation and the risks involved in order for his consent to be legally valid and in compliance with *Montgomery*. The name and qualifications of the medical professional who provided

this information to Ryan would be recorded in the report. Ryan is *Gillick* and section 2(4) competent as he has the ability to understand the nature of the medical procedure and the risks involved. He will also need to be aware that at any point before the bone marrow is removed from his body, he can withdraw his consent.

Step 7: Is there HTA approval?

As Ryan is a competent minor donating regenerative tissue this step would not be required in England and Wales, but it would be a requirement in Scotland. However, it is my contention that where a competent minor is going to donate regenerative tissue there should be HTA approval to ensure that appropriate safeguards are in place. They would also ensure that all regulatory requirements have been fulfilled, so the minor donor's interests are sufficiently protected to prevent their exploitation. If this recommendation was implemented in England and Wales, the HTA would assess the report that had been produced by the AA to ensure that all of the regulatory requirements had been met. In this case, there were no issues identified in the interview with the AA and all regulatory steps have been fulfilled, therefore, the HTA would provide approval for the donation to proceed.

In this case all of the requirements have been fulfilled, therefore, Ryan would be allowed to donate bone marrow to Simon.

7.4 Victoria's Story

Victoria is 17-years old and lives with her younger brother Ben who is 2-years old. They live with their biological parents. Victoria has a twin sister called Jessica who no longer lives in the family home. Victoria has a boyfriend, James, who she has been in

a relationship with for 3 years. Victoria is in further education and works part-time at the weekend and evenings in retail.

Jessica is in need of a bone marrow transplant in order to save her life. This story is set in England and Wales because Victoria would be considered an adult in Scotland, so the adult regulatory framework would apply.

Step 1: Identify a potential living donor (check histocompatibility)

This step is performed by the medical professionals, and as part of the process, a number of individuals would be tested to check their suitability as a tissue match. This would include Jessica, Victoria's parents, Ben, and other family members. Following the histocompatibility tests, it was determined that Victoria was the best match to donate bone marrow to Jessica, her twin. Even though Victoria is histocompatible, it does not automatically mean that she will donate the tissue, all the steps of the donation process need to be met for the donation to proceed.

Step 2: Is the potential donor a minor?

Yes, Victoria is a minor because she is 17-years old, which is under the age of 18 in England and Wales.

Step 3: Is the minor competent to consent to the donation?

Victoria is assumed to have capacity under section 1(2) of the Mental Capacity Act 2005. There are no concerns about Victoria's capacity under section 3(1) as she is able to understand the information relevant to the tissue donation decision; to retain that

information; to use or weigh that information as part of the process of making the decision about tissue donation; and to communicate her decision.

Even though Victoria is assumed to have capacity under the 2005 Act, it does not automatically result in her being able to provide consent to be a tissue donor for Jessica. The requirements under section 8 of the Family Law Reform Act 1969 need to be fulfilled which are that Victoria can consent to ‘any surgical, medical, or dental treatment’. Section 8 uses the term ‘treatment’ and while the literal interpretation of treatment does not incorporate tissue donation, it is my contention that section 8 should be given a broad interpretation. Therefore, a bone marrow donation would fall under ‘surgical, medical, or dental treatment’, so the requirements under the 2005 Act and section 8 have been met.

Step 4: Gain informed consent from the donor

In order for Victoria to provide legally valid consent the test for information disclosure under *Montgomery* needs to be satisfied. The test of information disclosure under *Montgomery* has been covered in step 4 of Ryan’s story. Victoria would be informed of the immediate and long-term medical risks of undergoing the bone marrow donation. Also, the medical professional would be required to inform Victoria of any type of medical risks that she is likely to attach particular significance to.

I have argued that the philosophical interpretation of the principle of relational autonomy should have a legal application in medical decision-making, specifically tissue donation from a living minor. My interpretation of relational autonomy is that if an individual makes an autonomous relational decision then that decision is made by

considering the networks of relationships with others. In other words, for an individual to make a decision they need to take into account their relationships with others that underpin their lives, such as familial and societal relationships. I have provided a list of factors that the decision-maker could take into account when considering each relationship (see Daisy's story for the full list). Victoria's relationships are as follows:

- (a) Jessica (the potential recipient) – twin sister
- (b) Victoria's mother and father
- (c) Victoria's wider family including Ben
- (d) Victoria's employer and colleagues
- (e) Victoria's friends

Taking each relationship in turn and applying it to the five factors:

(a) Jessica (potential recipient)

- (1) type of relationship – familial relationship as Victoria and Jessica are twin sisters.
- (2) length of the relationship – 17 years.
- (3) potential future interaction (temporary or long-term relationship) – as siblings they will be expected to have a familial relationship for a lifetime. However, Victoria and Jessica do not have a close emotional bond and it is unlikely that they will have any future interaction when they are adults.
- (4) frequency of interaction – as Jessica no longer lives at home, they have minimal interaction. They are forced to spend time together at family events.

- (5) type of interaction – they have necessary interactions at family events.

There are no voluntary interactions.

This relationship has a negative impact on Victoria. Even though they are twins, Victoria does not currently have a close emotional bond with Jessica, and there are no signs that this relationship will change. Their parents are aware of this position. Therefore, this strained relationship should carry weight in the decision-making process since Victoria would be medically harming herself to benefit Jessica who she has no meaningful relationship with.

(b) Victoria's mother and father

- (1) type of relationship – familial relationship.
- (2) length of the relationship with Victoria – 17 years.
- (3) potential future interaction (temporary or long-term relationship) – Victoria has an amicable relationship with her parents. She currently lives with her parents, but it is expected she will start university next year, and she will move into university accommodation.
- (4) frequency of interaction – Victoria interacts with them on a daily basis because she lives with them.
- (5) type of interaction – this is a necessary interaction. Victoria does not voluntarily choose to spend time with her parents.

This relationship has a negative impact on Victoria. Her parents are putting a lot of pressure on her to donate, and are asking her to leave the family home if she refuses to donate. However, Victoria is attempting to ignore this pressure and maintains that her

decision is that she does not want to donate bone marrow to her sister. This relationship should have considerable weight in Victoria's decision-making. There is a real risk that Victoria will lose her relationship with her parents if she refuses to donate bone marrow, but since she currently has little or no close emotional relationship with her parents, this does not concern her.

(c) Victoria's wider family

- (1) type of relationship – familial relationship. The only other notable familial relationship that Victoria has is with her younger brother Ben.
- (2) length of the relationship – 2 years.
- (3) potential future interaction (temporary or long-term relationship) – as siblings they will be expected to have a familial relationship for a lifetime. However, there is a risk that this relationship will breakdown when Victoria goes to university next year. Furthermore, there is a 15 year age gap between the siblings.
- (4) frequency of interaction – Victoria interacts with Ben on a daily basis because they live together.
- (5) type of interaction – the interactions are both necessary and voluntary. The interaction is necessary as it is part of the living arrangements; however, Victoria chooses to spend time with Ben. She babysits him, picks him up from nursery, and takes him to the park.

Victoria is aware that this relationship is not likely to be a significant relationship in the future. If Victoria's parents request her to leave then it is likely that her relationship with Ben will also disappear since she will no longer have necessary interaction, and it

is unlikely that her parents would permit her to have voluntary interaction. In addition, Victoria is leaving for university next year.

(d) Victoria's employer and colleagues

- (1) type of relationship – societal relationship.
- (2) length of the relationship – Victoria has had a job for around 12 months, it is a part-time job.
- (3) potential future interaction (temporary or long-term relationship) – this employment will only last for around another 12 months, as she will resign when she goes to university. Victoria uses her employment so she can be self-sufficient, she also makes a financial contribution to the household.
- (4) frequency of interaction – Victoria interacts with her employer and colleagues at weekends and evenings.
- (5) type of interaction – the interaction is necessary as Victoria does not choose to spend time with her employer or colleagues outside of work.

This relationship will have minimal weight in Victoria's decision-making. Victoria will need time off work to undergo the procedure. At the moment, Victoria has not informed her employer or colleagues that Jessica is ill because she does not intend to undergo the donation.

(e) Victoria's friends

- (1) type of relationship – societal relationship. Victoria is insular but has a boyfriend.
- (2) length of the relationship – 3 years.

- (3) potential future interaction (temporary or long-term relationship) – Victoria intends to remain in a relationship with James, but this is not guaranteed. Victoria and James will likely study at the same university next year and intend to live together. If Victoria underwent the donation procedure then James could visit her when she recovers and they could continue to interact over social media.
- (4) frequency of interaction – they interact daily, and they stay overnight at each other’s houses.
- (5) type of interaction – this relationship is voluntary; Victoria chooses to have a close relationship with James.

This relationship has a positive impact on Victoria as she has been able to speak to James about the decision she intends to make, and he has provided a supportive environment for her away from the pressures of her family. She also has the opportunity to stay at James’s house if her parents request that she leaves the family home for refusing to donate to Jessica. This relationship is likely to have significant weight in Victoria’s decision-making due to their close loving relationship.

Victoria will take into account a number of factors when making a decision, which includes her relationships with others, particularly Jessica. Victoria has decided that she does not want to consent to donate bone marrow to Jessica. As Victoria has capacity to make this decision, I suggest that it should not be overridden by her parents or the court. If this matter subsequently went to court, it is likely that the court would take a pragmatic approach, and it is unlikely that the court would force Victoria to donate. Nor should the court conclude that she lacks capacity to make a decision merely because

they disagree with her decision. Her relational autonomous decision should be respected by others, even if this results in Jessica not being able to receive life-saving bone marrow.

Step 5: Is the tissue non-regenerative or regenerative?

The tissue that is potentially being donated is regenerative tissue as it is bone marrow.

Step 6: An AA must interview the potential donor and recipient separately

As Victoria has not provided consent to be a tissue donor the donation process would stop and no interview would be undertaken by an AA. If, on the other hand, Victoria did provide consent, then the AA interviews would take the form of those discussed in Ryan's story.

Step 7: Is there HTA approval?

Currently in England and Wales, this step is not part of the donation process. However, it is my contention that where a competent minor is going to donate regenerative tissue there should be HTA approval to ensure that appropriate safeguards are in place. The HTA would also ensure that all regulatory requirements have been fulfilled, so the minor donor's interests are sufficiently protected to prevent their exploitation. If this recommendation was implemented in England and Wales, the HTA would assess the report that has been produced by the AA to ensure that all of the regulatory requirements have been met.

In this case, as Victoria has not provided consent to the bone marrow donation, and no AA interview has been undertaken, if the HTA were involved in this process they would not give approval for the donation to proceed.

The donation process fails at step 4, therefore, Victoria would not donate bone marrow to Jessica.

7.5 Concluding thoughts

These three stories have demonstrated how my recommendations of reform and/or clarification of the current regulatory framework would apply in practice. I suggest that these reforms would provide additional safeguards to protect the minor donor's interests subsequently reducing the potential risk of their exploitation. As donation medicine advances, the continual assessment of its regulatory framework is imperative to ensure that it robust and not subject to misinterpretation. I hope that this thesis contributes to the ongoing discussion about how best to treat minors who donate tissue to a sibling, and that medical professionals, families and recipients, as well as policy-makers and professional bodies will find this contribution to the literature to be useful in considering how best to protect the minor donor's interests.

Appendix 1

Section 17 of the Human Tissue (Scotland) Act 2006

17 Restrictions on transplants involving live donor

- (1) Subject to subsections (3) to (5) and (8), a person commits an offence—
- (a) if—
 - (i) the person removes an organ, part of an organ, or any tissue from the body of a living child intending that it be used for transplantation; and
 - (ii) when the person removes the organ, part or tissue, the person knows, or might reasonably be expected to know, that the other person from whose body the person removes it is a living child;
 - (b) if—
 - (i) the person removes an organ or part of an organ from the body of a living adult intending that it be used for transplantation; and
 - (ii) when the person removes the organ or part, the person knows, or might reasonably be expected to know, that the adult from whose body the person removes it is alive; or
 - (c) if—
 - (i) the person removes any tissue from the body of a living adult with incapacity intending that it be used for transplantation; and

- (ii) when the person removes the tissue the person knows, or might reasonably be expected to know, that the adult from whose body the person removes it is alive and an adult with incapacity.
- (2) Subject to subsections (3) to (5) and (8), a person commits an offence—
 - (a) if—
 - (i) the person uses for transplantation an organ, part of an organ or any tissue which has come from the body of a living child; and
 - (ii) when the person does so, the person knows, or might reasonably be expected to know, that it has come from the body of a living child;
 - (b) if—
 - (i) the person uses for transplantation an organ or part of an organ which has come from the body of a living adult; and
 - (ii) when the person does so, the person knows, or might reasonably be expected to know, that it has come from the body of a living adult; or
 - (c) if—
 - (i) the person uses for transplantation any tissue which has come from the body of a living adult with incapacity; and
 - (ii) when the person does so, the person knows, or might reasonably be expected to know, that it has

come from the body of a living adult with incapacity.

- (3) The Scottish Ministers may by regulations provide that subsection (1)(b) or (2)(b) does not apply in a case where—
- (a) the Ministers are satisfied that—
 - (i) no reward has been or is to be given in contravention of section 20; and
 - (ii) such other conditions as may be specified in the regulations are satisfied; and
 - (b) such other requirements as may be specified in the regulations are complied with.
- (4) The Scottish Ministers may by regulations provide that subsection (1)(a) or (c) or (2)(a) or (c) does not apply in a case where—
- (a) a person—
 - (i) removes regenerative tissue; or
 - (ii) uses such tissue;
 - (b) the Ministers are satisfied that—
 - (i) no reward has been or is to be given in contravention of section 20;
 - (ii) such other conditions, as may be specified in the regulations are satisfied; and
 - (c) such other requirements as may be specified in the regulations are complied with.
- (5) The Scottish Ministers may by regulations provide that subsection (1)(a) or (b) or (2)(a) or (b) does not apply in a case where—

- (a) a person—
 - (i) removes an organ or part of an organ as described in subsection (6); or
 - (ii) uses such an organ or part so removed;
 - (b) the Ministers are satisfied that—
 - (i) no reward has been or is to be given in contravention of section 20;
 - (ii) such other conditions, as may be specified in the regulations are satisfied; and
 - (c) such other requirements as may be specified in the regulations are complied with.
- (6) The organ or part of an organ is one that—
- (a) during a domino organ transplant operation, is necessarily removed from—
 - (i) a child; or
 - (ii) an adult with incapacity; and
 - (b) is in turn intended to be used for transplantation in respect of another living person.
- (7) Regulations under subsection (3), (4) or (5) must include provision as to appeals against decisions made in relation to matters which fall to be decided under the regulations.
- (8) Where under—
- (a) subsection (3) an exception from subsection (1)(b) or (2)(b) is in force, a person does not commit an offence under subsection

- (1)(b) or, as the case may be, (2)(b) if the person reasonably believes that the exception applies;
- (b) subsection (4) an exception from subsection (1)(a) or (c) or (2)(a) or (c) is in force, a person does not commit an offence under subsection (1)(a) or (c) or (2)(a) or (c), as the case may be, if the person reasonably believes that the exception applies;
- (c) subsection (5) an exception from subsection (1)(a) or (b) or (2)(a) or (b) is in force, a person does not commit an offence under subsection (1)(a) or (b) or (2)(a) or (b), as the case may be, if the person reasonably believes that the exception applies.
- (9) A person guilty of an offence under this section is liable on summary conviction to—
- (a) imprisonment for a term not exceeding 12 months;
- (b) a fine not exceeding level 5 on the standard scale; or
- (c) both.
- (10) In this section—
- “adult with incapacity” is—
- (a) for the purposes of subsections (1)(c) and (2)(c), an adult to whom section 18 applies;
- (b) for the purposes of subsection (6)(a)(ii), an adult in respect of whom section 47 of the Adults with Incapacity (Scotland) Act 2000 (asp 4) applies in relation to the domino organ transplant operation in question;
- “domino organ transplant operation” means a transplant operation performed on a living person by a registered medical practitioner—

- (a) which is designed to safeguard or promote the physical health of the person by transplanting organs or parts of organs into the person; and
- (b) by so doing, necessitates the removal of an organ or part of an organ from the person which in turn is intended to be used for transplantation in respect of another living person;

“regenerative tissue” means tissue which is able to be replaced in the body of a living person by natural processes if the tissue is injured or removed;

“reward” means any description of financial or other material advantage, but does not include any payment in money or money's worth for defraying or reimbursing—

- (a) the cost of removing, transporting, preparing, preserving or storing the organ (or part) or tissue;
- (b) any liability incurred in respect of expenses incurred by a third party in, or in connection with, any of the activities referred to in paragraph (a);
- (c) any expenses or loss of earnings incurred by the person from whose body the organ (or part) or tissue comes so far as reasonably and directly attributable to the person's supplying it from the person's body.

Appendix 2

Risks of Morbidity for a Bone Marrow Donation

Type of Morbidity	Risk of it Occurring (%)
Vomiting ⁶⁷⁶	11.8
Sore throat ⁶⁷⁷	7.1
Decreased blood pressure ⁶⁷⁸	6.4
Tachycardia ⁶⁷⁹	4.2
Bradycardia ⁶⁸⁰	0.6

⁶⁷⁶ Jan Styczynski and others, 'Risk of complications during hematopoietic stem cell collection in pediatric sibling donors: a prospective European Group for Blood and Marrow Transplantation Pediatric Diseases Working Party study, (2012) 119(12) Blood 2935, 2938.

⁶⁷⁷ Styczynski (n 677) 2938.

⁶⁷⁸ Styczynski (n 677) 2938.

⁶⁷⁹ Styczynski (n 677) 2938; Tachycardia is a condition where your heart suddenly beats much faster than normal. A normal resting heart rate is 60 to 100 beats per minute. But with tachycardia your heart rate suddenly goes above 100 bpm; NHS Choices, 'Supraventricular tachycardia' <<https://www.nhs.uk/conditions/supraventricular-tachycardia-svt/>> accessed 08/07/2018.

⁶⁸⁰ Styczynski (n 677) 2938; Bradycardia is a condition where your heart suddenly beats more slowly than normal. A normal resting heart rate is 60 to 100 beats per minute. But with bradycardia your heart rate is below 60 bpm; NHS Choices, 'Heart Block' <<https://www.nhs.uk/conditions/heart-block/>> accessed 09/07/2018.

Appendix 3

Risks of Morbidity for a Kidney Donation

Type of Morbidity	Risk of it Occurring (%)
Hypertension ⁶⁸¹	30
Large amounts of protein in the urine ⁶⁸²	11-45
Hernia ⁶⁸³	0.6
End Stage Renal Disease (ESRD) ⁶⁸⁴	0.38-0.5
Chronic disabling pain ⁶⁸⁵	12
Chronic neuropathic pain ⁶⁸⁶	14

⁶⁸¹ Kidney Research UK, 'Living with one kidney' <<http://www.kidneyresearchuk.org/health-information/living-with-one-kidney>> accessed 28/01/2018; British Transplantation Society, *Guidelines for Living Donor Kidney Transplantation* (2018) 90 and 92; Kidney Link, 'Risks Involved in Living Donation' <<http://www.kidneylink.org/RisksInvolvedinLivingDonation.aspx>> accessed 15/07/2018; Hassan N Ibrahim and others, 'Long-term consequences of kidney donation' (2009) 360 *New England Journal of Medicine* 459; Hypertension is high blood pressure which if untreated increases your risk of serious problems such as heart attacks or strokes; NHS Choices, 'High Blood Pressure' <<https://www.nhs.uk/conditions/high-blood-pressure-hypertension/>> accessed 11/07/2018.

⁶⁸² This large variation mainly depends on the criteria used to define proteinuria; Claudia Ponticelli and others, 'Proteinuria after kidney transplantation' (2012) 25(9) *Transplantation International* 909; People with proteinuria have urine containing an abnormal amount of protein. The condition is often a sign of kidney disease. Healthy kidneys do not allow a significant amount of protein to pass through their filters. But damaged filters may let proteins leak from the blood into the urine; Web MD, 'Protein in Urine' <<https://www.webmd.com/a-to-z-guides/proteinuria-protein-in-urine>> accessed 11/07/2018.

⁶⁸³ Michael Siebels and others, 'Risks and complications in 160 living kidney donors who underwent nephroureterectomy' (2003) 18(12) *Nephrology Dialysis Transplantation* 1, 1; A hernia occurs when an internal part of the body pushes through a weakness in the muscle or surrounding tissue wall; NHS Choices, 'Hernia' <<https://www.nhs.uk/conditions/hernia/>> accessed 11/07/2018.

⁶⁸⁴ Abimereki Muzaale and others, 'Risk of end-stage renal disease following live kidney donation (2014) 311 *Journal of the American Medical Association* 579; ESRD is the failure of the remaining kidney.

⁶⁸⁵ Margaret Owen and others, 'Chronic pain following donor nephrectomy – a study of incidence, nature and impact of chronic post nephrectomy pain' (2010) 14 *European Journal of Pain* 732.

⁶⁸⁶ Owen and others (n 686); Neuropathic pain is a chronic pain condition. It is usually the result of, or accompanied by, an injury, disease, or infection; Healthline, 'What You Should Know About Neuropathic Pain' <<https://www.healthline.com/health/neuropathic-pain>> accessed 11/07/2018; Neuropathic pain is often the result of nerve damage or a malfunctioning nervous system. The impact of nerve damage is a change in nerve function both at the site of the injury and areas around it; Web MD, 'Neuropathic Pain Management' <<https://www.webmd.com/pain-management/guide/neuropathic-pain#1>> accessed 11/07/2018.

Appendix 4

Risks of Morbidity for a Lobe of Liver Donation

Type of Morbidity	Risk of it Occurring (%)
Biliary leak ⁶⁸⁷	8.1
Biliary stricture ⁶⁸⁸	0.6
Incisional hernia ⁶⁸⁹	6.6
Bowel obstruction ⁶⁹⁰	1.6
Deep vein thrombosis ⁶⁹¹	0.8
Pulmonary embolism ⁶⁹²	0.9
Infections ⁶⁹³	13.2
Hepatic artery thrombosis/Portal vein thrombosis ⁶⁹⁴	0.5
Unplanned re-exploration	2.7

⁶⁸⁷ British Transplantation Society (n 682); A small hole anywhere along the bile ducts can cause bile to leak into the abdominal cavity. Bile is a digestive fluid produced by the liver and stored in the gallbladder and is used by the body to break down fats so they can be absorbed; Michigan Medicine, ‘Bile Duct Leaks’ <<https://www.uofmhealth.org/conditions-treatments/digestive-and-liver-health/bile-duct-leaks>> accessed 11/07/2018.

⁶⁸⁸ British Transplantation Society (n 682); A bile duct stricture is an abnormal narrowing of the common bile duct, the tube that moves bile from the liver to the small intestine; Medline Plus, ‘Bile duct stricture’ <<https://medlineplus.gov/ency/article/000220.htm>> accessed 11/07/2018.

⁶⁸⁹ British Transplantation Society (n 682); An incisional hernia is a hernia that occurs through a previously made incision in the abdominal wall, ie the scar left from a previous surgical operation; The British Hernia Centre, ‘Incisional Hernia’ <<https://www.hernia.org/types/incisional-hernia/>> accessed 11/07/2018.

⁶⁹⁰ British Transplantation Society (n 682); An intestinal obstruction occurs when food or stool cannot move through the intestines. The obstruction can be complete or partial; Medline Plus, ‘Intestinal Obstruction’ <<https://medlineplus.gov/intestinalobstruction.html>> accessed 11/07/18.

⁶⁹¹ Thrombosis is a blood clot that develops within a deep vein in the body. It can cause pain and swelling in the leg and may lead to complications such as pulmonary embolism; NHS Choices, ‘Deep Vein Thrombosis’ <<https://www.nhs.uk/conditions/deep-vein-thrombosis-dvt/>> accessed 09/07/2018; A pulmonary embolism is a blocked blood vessel in your lungs. It can be life-threatening if not treated quickly; NHS Choices, ‘Pulmonary Embolism’ <<https://www.nhs.uk/conditions/pulmonary-embolism/>> accessed 09/07/2018.

⁶⁹² NHS Choices ‘Pulmonary Embolism’ (n 692).

⁶⁹³ British Transplantation Society (n 682).

⁶⁹⁴ Portal vein thrombosis (PVT) is a blood clot of the portal vein, also known as the hepatic portal vein. This vein allows blood to flow from the intestines to the liver. A PVT blocks this blood flow; Healthline, ‘Portal Vein Thrombosis’ <<https://www.healthline.com/health/portal-vein-thrombosis>> accessed 11/07/18.

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