The ethics of biobanking: assessing the *right to control* problem for broad consent

1. INTRODUCTION: THE BIOBANK CONSENT DEBATE AND THE "RIGHT TO CONTROL"

Over the past two decades, there has been a great deal of debate about the proper ethical legal and regulatory framework for biobanks.[1] This debate arises against the backdrop of a broader ethical, legal and regulatory framework for medical research, a framework that has informed consent as a central requirement. Researchers are required to accompany requests for participation in their research with a disclosure of information about the nature and purpose of the research, the identity of the researcher, and any anticipated burdens, costs or risks for the participant. But in biobank research, at the point of acquisition of the biological sample from a "donor" the nature and purpose of future research, the risks and burdens of that research, and the identity of future researchers, are not yet known. One response here is that in order to meet these standards biobanks ought to make indefinitely many project-specific consent requests for each and every (relevantly different) research use of (non-anonymised) samples and data.[2] But the value of biobanks stems from the fact that they store, organise, and make readily available, very large sets of samples and information for *many* different researchers, on many different occasions, over a long, open-ended, time scale. Given the scale, heterogeneity, and long-term nature, of biobank research gaining project-specific consent is apt to be costly, administratively burdensome, and problematic. As time passes the process of re-contacting donors may itself be problematic, as people move home. Participants may not wish to be subjected to repeated requests for consent. There is also the risk that repeated instances of re-consent lead to a mere appearance or "ritual" of consent as it becomes "routinized".[3]
It has been argued that biobanks can be plausibly interpreted as adhering to informed consent standards without repeated instances of project-specific informed consent. This can be achieved by a one off consent transaction at the point of acquisition, one that makes known relevant facts about the *types* of researcher and research uses, the likely types of risks and burdens that participation or donation entails.[4] In defence of this broad consent framework, it is stressed that all informed

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1 For a useful summary of biobank ethical and regulatory debate see K. Hoeyer. The ethics of research biobanking: a critical review of the literature. Biotechnol Genet Eng Rev 2008; 25: 429-452.. See also T. Caulfield & B.M. Knoppers. Consent, privacy and research biobanks. GPS Policy Brief 2010; 1:10.
2 Also called "study specific" or "case by case" consent. C.M. Simon, et al. Active choice but not too active: public perspectives on biobank consent models. Genetics in Medicine 2011; 13: 821-831.
3 T. Ploug & S. Holm. Informed consent and routinisation. J Med Ethics 2013; 39:214-218.
4 See M.G. Hansson et al. Should donors be allowed to give broad consent to future biobank research? Lancet oncol 2006; 7: 266-269; K.S. Steinsbekk, B.K Myskja & B. Solberg. Broad consent

consent involves a specification of types of action, rather than an indefinitely fine-tuned specification of *every single action* that might be done. The same point applies for the identity of the researchers. Informed consent to participate in non-biobank research is typically not directed at a named, unique, individual. It is given to institutions, or units within an institution, (if a researcher leaves and a new one is employed, presumably even the most stringent project-specific informed consent advocate would not insist upon the ethical need for repeated consent). Once we accept the logical point that all consent is to types of action, and that research consent is to types of people occupying certain roles, there is no conceptual barrier to broad consent constituting informed consent. Broad consent frameworks need not be viewed as simply a matter of the participant being asked to give blanket consent to any or every possible use, without constraint or limitation. Broad consent involves consent to a specified, and restricted, set of actions, by a specified, and restricted, set of agents.[5] Certain types of researcher and research use can be identified and disclosed. Additional elements of protection for participants can be provided by further institutional bodies, with specified roles in assessing research proposals, monitoring and evaluating researchers and their practice.

As we have outlined it so far, the biobank consent debate is an interpretative matter: can broad consent be properly interpreted as a species of informed consent? This interpretative debate quickly reaches an impasse, with different intuitions about what constitutes informed consent. There is a different kind of argument *against* broad consent, one that does not rest upon our intuitions about whether broad consent constitutes informed consent. More specifically, broad consent frameworks—however we label them—do not afford the same kind and degree of control over the use of samples and data that project-specific consent frameworks do. The evidence suggests that biobank participants have a preference for such control. Thus Goodson and Vernon's survey of participant attitudes suggests that 'a relatively large number of individuals would want some ongoing control over their tissue after donation.'[6] Similarly, Simon *et al.* surveying biobank participants' attitudes note that 'Although their perspectives on broad consent were generally very favorable, participants did express some concerns over the model. They recognized that biobank participants would have little choice or control over the kind of research their samples would be

versus dynamic consent in biobank research: Is passive participation an ethical problem? Eur J Med Genet 2013; 21: 897-902.

5 Indeed, it is interesting to speculate whether intuitions would have been different were it labelled restricted consent (in contrast to "blanket" consent).

6 M.L. Goodson & B.G. Vernon. A Study of Public Opinion on the Use of Tissue Samples from Living Subjects for Clinical Research. Journal of Clinical Pathology 2004; 57: 135-138.

used in.'[7] Steinsbekk, *et al*, defending broad consent, note the importance of control as a consideration *against* broad consent 'Providing individual biobank contributors with tools that give them increased control and maybe new rights over their contribution is probably the strongest argument for a dynamic interactive consent model.[8]

Now, by itself, a preference for control over samples and data, or a "concern" over the possible lack of control, does not constitute a conclusive objection against broad consent. Participants may want, or prefer, all sorts of things. Participants might prefer that their participation were paid for, or that they received a brand new laptop by way of thanks. It does not follow from this that the biobank *ought* to provide such things. However, there is a stronger line of argument in this area, one that has received less attention, but which, if defensible, would constitute a good moral case against broad consent frameworks. This is the idea that participants have a moral right to retain and exercise ongoing control over access to and use of their samples and data. Thus Caulfield *et al* suggest that broad consent frameworks 'do not allow patients to act meaningfully on their continuing *right to control* their health information' (emphasis added).[9] Elsewhere Caulfield expands on this line of thought, suggesting a strong connection between autonomy and a right to control:

In the realm of biobanks, autonomy is largely about the maintenance of control over something that implicates personal integrity. It implies that the research participant should retain a *right of control* over their genetic and personal information. This is, to some degree, about respecting fundamental human rights.[10]

Caulfield makes appeal to "biorights" which include "the idea that research participants have an ongoing right to control their research samples"[11]

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7 C.M. Simon, et al. Active choice but not too active: public perspectives on biobank consent models. Genetics in Medicine 2011; 13: 821-83, p. 826.
8 Steinsbekk, Myskja & Solberg, op. cit. p. 899.
9 T. Caulfield, R.E.G. Upshur & A. Daar. DNA databanks and consent: a suggested policy option involving an authorization model. BMC Med Ethics 2003; 4: 1-4, p. 4,
10 T. Caulfield. Biobanks and blanket consent: the proper place of the public good and public perception rationales. Kings Law J 2007; 18: 209-226, p.223. A similar connection between autonomy and control can be found in M.A. Rothstein, B.M Knoppers, & H.L. Harrell. Comparative approaches to biobanks and privacy. J Law Med Ethics 2016; 44: 161-172, where they suggest: 'Autonomy, meaning self-governance or self-determination, is an important principle that informs the special interests of individuals in controlling the access to and use of personal data and biological specimens' p. 162
11 T. Caulfield, Timothy & B. Murdoch. Genes, cells, and biobanks: Yes, there's still a consent problem. PLoS Biol 2017; 15: e2002654, p.3.

It might be objected at this point that this claim, about a right to control, is not widely endorsed. However, it may be that many of those opposed to broad consent would concur with Caulfield *et al.* but, armed with what is taken to be a sufficient reason to reject broad consent—that it fails to be informed consent—there is little need to unpack further reasons why broad consent is morally inadequate. The argument is worth focusing on more closely because, if it really is the case that participants have a moral right to exercise ongoing control over the use of their research samples, and broad consent fails to respect that kind of right then this would strengthen the case against broad consent, whether or not such a line of objection has yet been widely articulated. Indeed, the right to control objection would be a powerful move against broad consent. The objection identifies a moral deficiency in broad consent whether it is interpretable as informed consent or not. That is, even those who hold that broad consent is informed consent will have to address the objection that their favoured consent framework fails to properly respect an important moral right.

In order to assess the right to control objection we need to be clear about what *control* is, and what a *right* to control is, in the context of biobank participation. It will be argued here that we *do* have a fundamental moral right to control access to, and the use of, bodily samples and personal data. It will then be shown, perhaps surprisingly, that broad consent frameworks do not conflict with, breach, or disrespect such rights.

2. WHAT IS A RIGHT TO CONTROL?

To talk of *control* is to talk of the influence that our decisions and actions have. If A *controls* her model aircraft remotely, what we mean is that, her choices effect what the aircraft does. Control is to do with the efficacy of our *choices*. Our concern is with control over what *other people do* (with samples and personal data). If one party B controls what A does, B's choices about what A does bring it about, in some way, that A *does* those things. For example, consider the employer-employee relation. An employer (or a manager in a chain of command) can determine what her employees (or subordinates) *do* simply by telling them to do so.[12] This kind of control is not absolute (what the employer can command is limited), but so long as the relationship is maintained—and within the terms of the employment contract—the employer can determine what tasks the employee does, at what time, at what location, and so on.

It is important to note how this kind of control is exercised. The employer does not physically control the employee, nor does she make threats. The employer (or manager) has a distinctive kind

12 In certain states in the US the employer-employee relationship is explicitly defined in terms of the (legal) right of the employer to control what the employee does. See C.W. Summers. Employment at will in the United States: The divine right of employers. U. Pa. J. Lab. & Emp. L. 2000; 3: 65.

of power, a normative power: the power to change the (local) normative situation in specific ways by one's speech acts. The employer has the power to impose certain (limited) obligations on the employee. If the employer says "work on the Smith account this week, not Jones" the employee ought to do so, and ought to do so *because* the employer has said so.[13]

A biobank participant does not have the power to command or order the biobank to do what she wishes. She cannot, for example, insist that the biobank only use her samples for research into a condition that interests her. The biobank is not working for the participant. The biobank is working in the service of other goals (for many other people). The biobank seeks to acquire, access and use human subjects' bodily material and information derived from it for these purposes. However, where others seek to access and use "items" that we have rights over, then we, as right-holders, have a distinctive way of controlling what others do with those "items".

A non-biobank example will help us here. Suppose B owns a camera. Her property right is a complex of different elements. For our purposes the two elements that matter are, first, that her property right involves a negative claim right against others touching, taking, using, destroying, her camera. Second, her property right involves a positive power to create exceptions to the claim right. She can permit certain parties to touch, take, use her camera. This power is discretionary. It is up to the right holder whether to permit anyone, it is up to her whom to permit, and for what purpose, at what time, what duration, what location and so on. She can bring these normative changes about simply by her saying so.

Property rights underpin a distinctive way of exercising control. The right holder's choices determine (within a limited domain) which actions (but not others) performed in certain ways (but not others) are permissible for certain agents (but not others). The right holder has the discretion to shape this region of the normative landscape (the region over which she is a small-scale sovereign) as she sees fit. This includes restricting the agents who may use her "item", the contexts in which they may use it, the purposes for which they may use it, the duration and manner of use. This kind of power is not the same as the power to command. If nobody wants to use B's camera, and if nobody uses B's camera, then her power to permit will make little difference to anyone else's reasons for acting. Suppose B says "Take the camera but don't use it in the rain." If A takes the camera, B's choices have determined what A may do (that is, what she is permitted to do). Here B controls what A does with the camera in a recessive way, by removing prohibitions and specifying the scope, conditions and terms of use that are permissible. Rather than introducing or imposing an

13 The employer gives reasons to the employee in a "robust" way. See D. Enoch. Authority and Reason-Giving. Philos Phenomenol Res 2014; 89: 296-332.

obligation that A did not have, B shapes A's use of the camera by her selective shaping of what is permissible for B to do (with her camera).

3. FUNDAMENTAL RIGHTS, AND THE RIGHT TO CONTROL

What about the right to control biobank samples and personal data? In our example above, the right to control is grounded in the property rights that B has over her camera. One option here would be to argue that participants have a right to control the use of their samples and data because they have relevant property rights over their samples. But this would leave the right oto control objection against broad consent framework relatively weak.

First, it is not clear that the notion of property rights is readily applicable to the governance of personal data (our interests in privacy are distinct from the kinds of interest that ground physical property rights and intellectual property rights). Second, there is considerable debate over whether the notion of property rights is applicable to bodily material (such as blood samples, tissue, or genetic material).[14] Third, property rights are, arguably, legal rights than a fundamental moral right. If any of these three concerns have weight, this would undermine the force of the right to control" objection as we have outlined it so far. But, for our purposes, we can remain agnostic about the applicability of property rights to biobank samples and data. The "right to control" objection against broad consent can be framed in terms of other less contentious rights that the participant has over her samples and personal data.

The reason why property rights give rise to a right to control is not because they are property rights *per se* but because property rights are rights of a certain form. They are rights that give a distinctive significance to the rightholder's choices. There are other rights of this form including information privacy rights and rights over the body. In each case there are claim rights that specify a zone of "exclusion" from others by giving others reasons to refrain from touching, using, inquiring, disclosing and so on. The right holder also has the discretionary power to create exceptions to her rights for whomever she chooses. Whether others act permissibly is up to the right holder. What others are permitted to do, and how, when, and so on, is all, in principle, under the control of the consentor herself.

Thus, one widely endorsed account of the fundamental nature of information privacy rights is explicitly framed in terms of a right to control: "A right to privacy is a right to control access to and uses of—places, bodies, and personal *information".*[15] Fried offers a similar formulation of the state of privacy*:* "Privacy is not simply an absence of information about us in the minds of others,

14 B. Björkman, Barbro & S.O. Hansson. Bodily rights and property rights. J Med Ethics 2006; 32: 209-214; R.E. Gold. Body parts: Property rights and the ownership of human biological materials. Georgetown University Press, 1997.

15 A. Moore. Defining privacy. J Soc Philos 2008; 39: 411–428, p. 421.

rather it is the control we have over information about ourselves."[16] The state of privacy is the state of being in control, the right to privacy is the right to control personal information. The right to control is not merely a right to control access to personal information, but also extends to others' use of our personal information: we can consent to someone's use of our personal data for the purposes of a financial transaction, but not thereby permit them to make other uses of it. Where biobanks use non-anonymised personal data then information privacy rights are directly relevant. Indeed, as one recent article on biobank regulation puts it: "The core element of privacy is to maintain control over personal information"[17]

In a similar way, rights over the body are also cast in terms of a "right to control". Debates about the ethics of abortion make appeal to a women's right to control her body (as taking precedence over an embryo or foetus' "right to life").[18] As with our personal information, not only do we have a say in who has access to our bodies, we have a say in what people do to us, or with our bodily selves, or with our bodily material. If you consent to a clinician taking blood for (your own) diagnostic purposes, the clinician is not thereby permitted to use that blood for, say, a piece of modern art, or to sell it online to a group of hematophages. Her use of the blood is restricted by what you permit her to do with it. Because biobank samples are located within the body, rights over the body are directly relevant. Such rights are not simply rights against access or intrusion. If something is located in B's body, B has a right to introduce a specification of permissible use: "A may only take X from my body *in order to use it for purposes Y, Z*".

There is much more that we might say about the nature and limits of our rights over the body, and about information privacy rights. For our purposes what matters is that such rights are of a kind that give rise to a distinctive right to control.[19] In each case there is power to specify (to whatever degree of specificity one wishes) exactly *what* is permissible, for whom, at what time, for what

16 C. Fried. 1984. Privacy. In Philosophical Dimensions of Privacy. E D. Schoeman, ed. New York: Cambridge University Press: 203-222.

17 J. Sándor & P. Bárd. 2011. Anonymity and privacy in biobanking. In Biobanks and Tissue Research. C. Lenk, J. Sándor & B. Gordijn, eds. Dordrecht: Springer: 213-230. p. 215

18 For example M.A. Warren. On the moral and legal status of abortion. The Monist 1973; 57: 43-61, p.44.

19 An anonymous reviewer for the journal raises the worry that there may not be anything properly characterizable as a "standalone" right of control operative here, over and above, that is, the various more familiar and well-grounded rights such as the right to privacy and rights over the body. In response, the argument here is against the idea that there is some kind of "right to control" samples and data that provides a moral objection to broad consent. If there is no right to control at all, then the argument is stronger still! On the other hand, if the right to control reduces to other rights, then the arguments offered here can be viewed as showing that the cluster of more fundamental rights that we do have, are not sufficient to underpin an obligation on biobanks to offer the kind of control cited by Caulfield and others.

purposes. From this point onwards, for the sake of our discussion, it will simply be accepted without further question that we *do* have these fundamental moral rights—especially rights over the body and information privacy rights—and that we *do* have the right to control the use of our biological samples and personal information.

4. THE PROBLEM FOR BROAD CONSENT

At this point it may seem that it we already have our conclusive case *against* broad consent frameworks. Certain kinds of right, including property rights, rights over the body, and information privacy rights, underpin a "right to control" others access to and use of the right-protected "item". This is an *ongoing* power that she has. Suppose B says to A "You may use my camera tomorrow". Later in the evening B sees a severe weather warning. B contacts A saying "Look, don't use the camera in the rain". When B gave permission to A to use the camera in certain ways, B did not thereby *give up* her right to control. B has an *ongoing* right to control of the normative situation and it is up to her whether to revise the scope of her permission at a later date.

In the case of biobank participation, a broad consent framework denies the participant the opportunity to exercise this ongoing right to shape the scope of her permission. First, broad consent frameworks do not provide the participant with specific current information about what is being done, or is proposed to be done, with the samples and data that she has rights over. Because she does not know what is being done, she cannot shape her permission in line with specific information about each project. Second, even if the participant were to find out what is being done with her samples and data by some other route, or if she were to change her mind about may be done, the broad consent framework does not allow the participant the option to do this. It seems that the participant has, in effect, abandoned her rights. Thus, Shickle referring to "blanket" consent, but a similar point might be made for broad consent:

Blanket consent does not permit subjects to act meaningfully on their continuing interest in their health information. The data and DNA is being treated as though it has been abandoned by its owner. Like a child that has been adopted, the 'natural parents' give up rights to control its future to biobanks as the adoptive parents.[20]

A defender of the broad consent framework might respond that the biobank participant does not completely abandon her rights: the participant retains her right to revoke her permission.

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20 D. Shickle, The consent problem within DNA biobanks. Studies in History and Philosophy of Biological and Biomedical Research, 2006; 37: 503–519, p. 510.

But a right to revoke is not the same thing as a right to control, at least if we consider the contrast between a right to *withdraw* her sample from all (future) studies, and the kind of fine-tuned control suggested by Caulfield. The right to revoke is, in effect, a single act that brings a certain kind of relationship to an end, and with it, changes the normative situation in a "final" way. The right is exercised "blindly" or, at least, not on the basis of a continuing flow of specific information offered by the biobank as a way of securing specific informed consent on a case-by-case basis. In contrast, the right to control under consideration here is a right to *continue* to *exercise specific* control over the use of one's samples on the basis of specific, relevant, information about different uses and users of those samples and data.

It is true that a case-by-case, fully informed, right to revoke, would constitute the kind of right to control under discussion here, but such a right is very unlike the "generic" right to withdraw that is part of broad consent frameworks. Indeed, if such a case-by-case model were in place, it would be hard to view it as a broad consent framework at all (insofar as the biobank would be under the same kinds of obligations to disclose specific information, on a case-by-case basis, that we find under specific consent frameworks. A coherent broad consent model is one where the right to withdraw is not offered on a case-by-case basis, and from here on we shall focus on whether this kind of broad consent framework—with a "generic" right to withdraw—is morally problematic insofar as it fails to respect, or accommodate, the (putative) right to control one's samples and data.

The key point for our purposes is that a broad consent framework fails to put the participant in a position where she can continue to *exercise* control in a specific way. We thus seem to have clarified and given a strong defence to the worry expressed earlier that that broad consent frameworks 'do not allow patients to act meaningfully on their continuing *right to control* their health information' (emphasis added).[21] Project-specific consent frameworks, by way of contrast, do respect the participants' continuing right to exercise control by allowing them the opportunity to choose what is permissible, and for whom, on a case-by-case basis.

The remainder of this discussion will accept three conclusions of our discussion so far. First, biobank participants *do* have fundamental moral rights over access to and use of their samples and personal information. Second, such rights underpin a distinctive right to control access to and use of samples and data. Third, project-specific consent offers participants a greater kind and degree of control than broad consent.

It will be argued, however, that it does not follow from these three claims that there is some kind of moral failing in offering a broad consent framework in contrast to a project-specific consent

21 Caulfield, Upshur & Daar, op. cit. p. 4,

framework. In order to see why, we need to be expand upon the *social* dimension of seeking and giving permission against a backdrop of such rights.

5. GIVING PERMISSION WITHOUT ONGOING CONTROL

We have been focusing on *creative* side of shaping what is permissible, how a rightholder can *choose* what is permissible, for whom, when, in what manner, and so on. However, in many social contexts, there are good reasons why permission is freely given *without* the rightholder being able to effectively revoke permission, or revise the scope of her permission.[22] For example, suppose A has taken the camera for the weekend on a hiking trip and is "out of reach". B may change her mind about what is permissible, but she cannot communicate that change of mind to A. At this point we run into a debate about whether one can change the normative situation simply by a *mental* act. Some legal philosophers hold a "mentalist" theory of permissive consent.[23] On this view, whether or not B wrongs A depends upon what A has in mind, not what A has communicated. As soon as her mind changes, A *wrongs* B by using the lens in the rain, albeit unwittingly and blamelessly. In contrast, a performative account of giving permission, holds that A cannot change the normative situation without performing an appropriate communicative act. For our current purposes we can sidestep this debate. This is because our focus here is upon the way that the rightholder can exercise *control* over what other people do *via* her power to shape what is permissible for them to do. Clearly, simply changing one's mind without telling anyone, is not apt to make a *practical* difference to others. We cannot *control* what others do in any real sense without communicating our choices to them.

In many social contexts, the rightholder knows *up front* that she will be unable to *effectively* revise or revoke her permission once it is given, simply because it will not be feasible to get in touch with the permitted party *for at least some* of the time after permission is given and the "item" is taken or "in use". In such situations, when the rightholder is deliberating about whether to give permission, she has to take into account the fact that there will be periods when she is "offline" in terms of exercising control. If she prefers to remain in control, she *need not* give permission. However, if the rightholder *freely chooses* to give permission, knowing that she will be unable to *effectively* revoke or revise such permission, this is not some kind of moral failure, nor is it a deficient normative transaction. Indeed, it would be very odd to *deny* any of us the liberty to exercise our power to permit in this way, if we see fit. Suppose B is happy to lend A the camera for the weekend, even

22 From this point on, our focus will be on the right to revise, rather than revoke permission, for broad consent frameworks allow the former but deny the latter.

23 L. Alexander, Larry. The ontology of consent. Analytic Philosophy 2014; 55: 102-113.

though A will be out of reach. We cannot argue that A *ought not* to take the camera on those terms, nor that B should be prohibited from permitting in this way if she wishes.

Although epistemic limitations provide one reason why someone might give permission knowing that they will be unable to effectively revise or revoke it, such limitations are not the only reason. Another reason for giving permission of this kind is simply because it of *value* of the parties to the transaction, that both parties agree "up front" that permission will be "fixed". One kind of everyday context where this is the case is where A seeks permission from B to use something X in order to achieve some goal Y, and where it is important for meeting the goal Y that B *not* revoke or revise her permission (or, at least, that she not have absolute discretion in how she revises it). Suppose A asks B if she may borrow her car to visit a sick relative on Sunday. Suppose A makes it clear to B that *if* B permits her to use the car, she will make plans accordingly, and she will not seek other means of transport "Look, I need to know if I can rely on this". A's plans are now *dependent* upon B remaining *steadfast* in her permission. In lending A the car, B *undertakes* a commitment not to revoke or revise her permission in any way that would block A achieving her goal. B might later revise her permission in *some* ways "Sorry, I forgot to mention, you'll need to add some oil" but *ought not* to change it in other ways that "block" A achieving her goal.

In this kind of everyday situation, B voluntarily undertakes to restrict her future options. She commits to *not* exercise control, or, at the very least, commits to certain limitations on the kind of control that she will exercise. There is nothing odd about this, or anything morally wrong with this. We find this kind of restriction of our own options in making promises (and other commitments and vows). Some promises are "positive", involving a binding undertaking to *do* something, others are negative, involving an undertaking to refrain ("I promise not to bother you with more questions"). Many kinds of *contract*—formal or informal—depend upon this kind of commitment to abide by (and not revoke or revise) the initial terms, *as freely agreed* at the start. It does not wrong the rightholder to ask her if she wishes to agree to restrict her options in this way.

Not all requests are morally innocent. Consider requests for sex from a teacher to pupil, or judge to witness on a current trial, or from a clinician to current patient. Because there are moral prohibitions on sexual contact between people who stand in those relationships, there is a derivative prohibition on *asking*. If it is wrong to ask B for permission to do X, then it is wrong to ask B to commit to fixing her permission to do X.

But nobody is claiming that biobanks should not make *any* requests for participation. The "right to control" objection is that it is wrong for biobanks to make their requests in such a way that the permission is *fixed* "up front" without further opportunity to revise, and without the establishment of channels of communication that would give the participant ongoing, and updated, information

that would be relevant to deciding whether to permit this or that use of her sample or data. The objection is that it is somehow wrong to ask the participant to undertake to refrain from exercising her right to control. But we have seen that there is nothing wrong *per se* with doing so. We also noted that epistemic and communicative considerations are relevant here. Suppose A wants to take B's camera on a yachting trip across the Atlantic. It is *possible* for A to get in touch B, but expensive via a satellite phone. The costs of communication give A reasons to ask B for "steadfast" permission. If B does not like this, she need not give permission.

If there is nothing intrinsically wrong with requesting "fixed" permission, there may still be reasons why it is wrong for a biobank to request permission in the "fixed" way that broad consent entails. Let us consider some examples.

6. BIOBANK REQUESTS: ARE THERE SPECICAL OBLIGATIONS TO OFFER CONTROL?

We might object that broad consent participation requests are wrong precisely because they do not allow the participant the opportunity to exercise her ongoing right to control". Here we need to remind ourselves of the difference between, first, a denial of the opportunity to exercise the right to control *because no permission is sought or given* and, on the other hand, a self-imposed commitment not to exercise the right of control. In terms of the former, Greely notes the implications of simply using already-acquired samples *without any permission at all*.

> Abandoning the consent requirement, however, would [. . .] *violate the subject's dignitary interest in controlling* her medical records or tissues. One can imagine an unconsenting subject of such research exploding with "It's my blood, damn it. How can they use it without my permission?" (emphasis added)[24]

There is a great deal of difference between denying someone the opportunity to exercise their right at all, and asking someone to freely undertake to restrict their exercise of that right. Broad consent involves the latter kind of restriction, not the former.

One thought that we might have at this point is that biobank recruitment involves more exacting and demanding standards for gaining permission, at least in comparison to our everyday social transactions (like borrowing a friend's camera) noted above. There is nothing analogous to *informed consent* requirements for borrowing a friend's camera. A medical researcher, bound by obligations to gain informed consent, does not have the discretion to propose research in whatever manner she chooses (e.g, by simply saying "Do you want to take part in this research?"). Medical research

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24 T. H. Greely. Breaking the stalemate: a prospective regulatory framework for unforseen research uses of human tissue samples and health information. Wake Forest L. Rev 1999; 34: 737-766, p. 758.

recruitment requires *informed* consent, which, in turn, places on obligations on the researcher as to *how* she makes her request.

But there are two problems with this line of thought, if it is meant to pose an objection to broad consent. The first point is that an informed consent paradigm is *not* about giving the participant the opportunity to shape the scope of her permission, or introduce terms and conditions on her permission. Informed consent differs from everyday consent in that it requires the communication of certain kinds of information "up front", in order that the addressee may make a "fully informed" *binary* decision, a decision whether to consent, or not, but this is not to give the addressee the discretion to shape her permission in any way she sees fit. For example, suppose the proposed research involves taking four blood samples in total, over a period of four weeks. Suppose the participant only wants the researcher to take two blood samples in total. The fact that she would *prefer* to permit *that*, rather than the actions proposed, does not oblige the researcher to *offer* to do so, nor even to offer her the opportunity to revise the scope of what she is being asked to permit. Similarly, the participant is not offered the opportunity to freely introduce conditions on her permission: "OK, you can take the blood, but only if you buy me a laptop". Or, rather, she *can* "say" these things, but not as any effective part of the consent transaction. To put it bluntly, *all* informed consent involves a limitation on the addressee's "right to control" by offering the addressee a binary choice, albeit one enable by a full explicit disclosure of relevant information.

But offering an informed binary choice, rather than engaging in a person-by-person individual "negotiation" of the scope of permission, is entirely legitimate. Indeed, there are at least four good reasons why researchers make "fixed" binary informed consent requests. First, the proposed research is set up with research goals in mind (finding something out, or testing a hypothesis) which, in turn, shapes the actions that the research will involve. The fact that a participant might *want* to do something different, something that *changes* the nature of the research, is problematic (or may render the research impossible). This feeds into a second point. The researcher will typically not need a *particular* individual (there may be some exceptions with very rare medical conditions), if one person will not participate on the terms proposed, another is likely to do so. There is thus no incentive to allow any particular addressee the opportunity to shape permission as *she* would wish. Third, in terms of the administrative and bureaucratic side of the recruitment process, it will typically be expedient to have a *form* of recruitment that is applicable to many (and if people do not like it, they need not participate). Here rough principles of justice may come into play. To allow one participant the opportunity to exercise control over what is permissible, or the terms of permission, whilst denying that opportunity to others, is unfair. The informed consent process itself is subject to

prior formal assessment by review bodies which, in turn, places limits on the discretion that the researcher has to engage in anything like individual bargaining or negotiation about the scope and terms of permission. When the ethics committee evaluates the research proposal and its informed consent mechanisms, the assumption is that each participant will be offered the same proposal, not that some will "barter" or "bargain" a better "deal".

Note too that in non-biobank research, it would be unusual for the participant to be offered the opportunity to revise the scope of her permission at a later date. Participants will have the right to *withdraw*, but not to shape her permission (or introduce conditions upon it) in any way that she sees fit. Suppose our participant above decides after three weeks that "three blood samples is enough". She is not given the option of *continuing* to participate but controlling what is permissible, her only option is to withdraw (or to continue *on the terms agreed*). This kind of "fixed" recruitment does not infringe upon, or disrespect the participants liberty or her "right to control" what happens to her, or what is done to her. It *offers* the participant a proposed way of exercising those rights and she is under no obligation to assent to such an offer, if it is not in line with her preferences. If she does choose to consent, then she chooses to consent *on those terms*. Once again, this is an *exercise* of her discretion, not some kind of infringement of it.

So it cannot be the mere fact that biobank participation requires *informed* consent that implies that it is wrong for the biobank not to give the participant an effective say in what she would like to permit or the conditions she would like to place on that permission. If it is wrong for the biobank, it is wrong for all medical research (and, indeed, wrong for all and every request for permission from institutions where the request is of a binary "accept" or "refuse" form, without the option to exercise one's discretion in "sculpting" what is permissible).

But now it may be objected that biobank consent is different from other kinds of medical research in that biobank participation is for long term, open-ended, research by *many* different researchers for many different specific purposes. Whilst this may be true, it does not directly provide a case against broad consent *per se*. We saw above that non-biobank research recruitment, fails to offer the participant a say in setting the terms of permission, so why should the *long term* or *ongoing* nature of the biobank case make any difference?

It might be argued at this point that there *is* a difference in that, in the biobank case, unlike non-biobank medical research, we have more than one candidate framework for managing the *ongoing* relationship between the biobank and the participant with regard to the use of her sample and personal data. If we then fix upon the contrast between project-specific consent and broad consent, the former affords the participant no ongoing control, whilst the project-specific option does. We might then argue that if there are these two options, then the biobank is obliged to offer the *better*

one. Surely *offering more control* is better than *offering less*. But this line of argument is weak. Once we start drawing a contrast between broad consent and other candidate frameworks, with an eye to satisfying participants preferences, then why stop at project-specific consent. Many participants, I assume, would prefer to have their participation secured by a large financial "gift", or the offer of a new laptop. But the fact that participants would prefer this does not imply that they are being wronged in any way by *not* being offered such a thing, nor does it follow that simply because such a framework is possible, and would be preferred to some other framework, that the biobank is thereby under any obligation to offer it.

It might be argued, in response, that the offer of a laptop is clearly *supererogatory*: a good or benefit is provided but there is no obligation to provide it. In contrast, the "right to control" objection is about the *rights* that the participant has. But this line of response is problematic. We have seen that a "fixed" proposal that does not allow the option of revision does not infringe those rights, it offers an opportunity to *exercise* those rights, in a specified way, but with no obligation to do so. The objector cannot reply that there is something morally suspect about this kind of self-restriction in general. Promises, and other kinds of voluntary undertaking of obligations, involve this kind of self-restriction too.

A final line of response might run like this: the biobank researcher is obliged to secure participation via a properly informed consent, and *only* project-specific consent constitutes properly informed consent. This line of objection problematic first, because project-specific consent also places limits on the "right to control" as noted above. Second, it also undercuts the force of the "right to control" objection as an *independent* and substantive line of objection. We noted the "impasse" in the biobank consent debate where there is deep disagreement about whether broad consent "counts as" properly informed consent. The seeming advantage of the "right to control" objection is that made appeal to some morally salient feature, one where broad consent seems to differ from project-specific consent in a clear way. If broad consent does count as informed consent, the worry about the right to control would still be in play. To fall back on the "broad consent is not properly informed consent" objection, is to return us to the impasse that we started with.

It might be argued that both project-specific consent *and* broad consent are wrong, and that a full respect for the "right to control" implies a *radically* discretionary, *radically* individual, case-by-case, form of request-permission transaction, where each individual is given *as detailed a "say" as she chooses* in how to shape her permission.[25] If the lines of argument above are correct, they apply

25 It should be noted that at some point, all consent frameworks, including "flexible" ones like dynamic consent (J. Kaye, et al. Dynamic consent: a patient interface for twenty-first century research networks. Eur J Hum Genet 2015; 23: 141-146) and "meta-consent" (T. Ploug & S. Holm. Meta Consent–A Flexible Solution to the Problem of Secondary Use of Health Data. Bioethics 2016;

equally here: there is nothing *wrong* with asking people to undertake to restrict their liberty, nothing wrong with not offering people full discretion in shaping what is proposed, but merely offering them a binary choice.

7. BROAD CONSENT VS DYNAMIC CONSENT: KEEPING TRACK OF DIFFERENT REASONS FOR COMMUNICATING WITH PARTICIPANTS[26]

Our discussion has primarily focused upon whether a putative right to control might be part of a decisive argument in favour of one kind of consent framework for biobanks (specific re-consent) rather than a one-off broad consent. The former seemed to accommodate and respect the right to control whilst the latter does not. But there may be good reasons why biobanks ought to disclose information about the research that they enable that are *not* grounded in an obligation to secure specific informed consent for each use. Making information available to participants, and to the public more generally, may be an important part of securing a "social license" for biobank research. Making information available in this way may increase trust in the biobanks (and in scientific research more generally) by creating an environment where biobanks are viewed as being transparent. Such transparency and social license may improve recruitment (if people feel properly engaged with, and trusting of, the biobank and its activities).

Recent developments in information technology not only make it possible for biobanks to make information readily, and speedily, available to mass audiences (e.g. by a website, RSS or twitter feed), it is also possible to allow different people to *tailor* the information that is made available to them. So called "dynamic consent" frameworks involve this kind of individually tailored information platform. .[27] A wide range of continuous, interactive, personalized, channels of communication is offered between researchers and data subjects. It might seem that dynamic consent has to be a variant upon specific re-consent, but this is not the case. It is entirely coherent that a broad consent framework might *also* be one that makes information about biobank activities available (to participants and other parties) and it might even do so in an individually tailored way. But, if there are good reasons for biobanks to develop this rich kind of communicative framework, is it not the case that broad consent and specific consent are likely to end up being pretty much the same in

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30: 721-732.) involve fixed elements. Not everything is up for negotiation, nor should it be. So there is no categorical distinction between broad consent and these other forms of consent, only a matter of degree.

26 The discussion in this section is in response to, and aided by, some helpful and insightful comments and suggestions by two (anonymous) referees for this journal.

27 Kaye et al., op cit. Also , J. Kaye. From single biobanks to international networks: developing e-governance. Human genetics 2011; 130: 377.

practice, and, in terms of our discussion here, if this does happen, would that mean that new technologies will simply lead to participants having the kind of right to control suggested by Caulfield and others.

There are two points to make here. First, although a broad consent framework might *in fact* make available information to participants, insofar as it is broad consent framework the *reasons* why it does so (and why it is *obliged* to do so) are not by way of achieving some kind of specific, case-by-case consent. Suppose a jurisdiction decides that biobanks ought to make information available to others but for *reasons not directly to do gaining specific informed consent*. If it really is a broad consent framework, then it is permissible for the biobank to use samples and data *without* requiring specific authorisation for new uses or users. Although information is being made available, the normative role played by such communicative acts, and the normative significance of the responses (or lack of responses) to such acts, is not the same as it is in specific informed consent frameworks.

The second point concerns the right to control and draws upon the observation discussed earlier, that a right to *withdraw* ones permission does imply an attenuated right of control (but not a right to continue to exercise control in a positive way on a case by case basis. It is true that greater information disclosure, including information that might be tailored to individual participants would put participants into a better position, in terms of the information that they have, for them to make a decision whether to revoke their consent. But if the framework is a broad consent one, then the right to revoke is a generic, broad, one, not a right to revoke consent on a case-by-case basis. As such the participant does not have a right to control her samples or data in a case-by-case way.

In sum, the fact that there may be good reasons for keeping participants informed, does not imply a rejection of a broad consent framework, nor does it imply a collapse of broad consent into dynamic consent if broad consent were to be accompanied by such information flows. If we are to be clear about the place and limits of the putative right to control under discussion here, we need to be careful in our moral bookkeeping, as it were, to keep track of the reasons *why* information is, and ought to be, communicated.

8. CONCLUSION

We began our discussion by accepting that we *do* have a right to control access to and use of our own bodily material and personal data and, after some clarification, showed how such a right is grounded in more fundamental rights. Where we have claim rights *against* others doing things to or with our right-protected "items" coupled with the discretionary power to create whatever kind of

exception we wish, for whomever we wish, our *choices* have a significance for what others do, by shaping what is permissible for them to do.

But there is nothing wrong *per se* with making requests for permission that do not allow the participant to continue to exercise full discretionary control, either because such control will not be feasible, or because the exercise of such control is not valuable or desirable (for one or other of the parties, or both). There is nothing wrong with a person freely undertaking to restrict her own liberty, contract and promise both involve this, and both are of considerable moral *value*, not morally wrong.

Our discussion has steered away from the "is broad consent informed consent?" debate, so nothing we have said here solves that debate. More generally, it should be stressed that the discussion here does not imply that biobanks *should* adopt a broad consent framework, in contrast to a project-specific one. All that we have aimed to show is that doing so does not wrong the participant by failing to respect her "right to control".

There are other considerations that may favour project-specific consent. Some participants may *prefer* to have the kind of case-by-case control that is provided by project-specific consent frameworks. If such preferences are widespread and strong enough to lead to mass *refusal to participate* on such terms, it may be better for the biobank to offer the consent framework that helps secure participation. But prudential considerations like these can be weighed up against other considerations (such as cost, feasibility, risks of self-selecting bias and so on); *rights* by way of contrast are meant to be "trumps", considerations that aren't readily balanced against non-normative considerations like cost. Nothing said here tells us anything about whether, in the end, the cost-benefit ratio of a project-specific framework is *more* favourable than that of broad consent (though, it should be noted, the point just made about refraining from participating because one does not like the consent framework applies to project-specific consent too). There may be *indirect* moral considerations too. As noted above, project-specific consent may help to promote other social goods, such as a sense of participation and involvement in current research. Such involvement *may* have other social benefits in terms of promoting trust in, and a favourable attitude towards, new kinds of medical research that might be viewed with suspicion. But, as we also noted, such goods and benefits may be achieved on a broad consent framework too.

The key point argued for here is that there is no reason to *reject* broad consent *because* such a framework for recruitment and participation infringes, or fails to adequately respect, the participants' "right to control". The "right to control" objection thus does not provide some "solution" to the impasse in the biobank consent debate. What the "solution" is to that impasse, must remain a matter for another occasion (or, more likely, a large set of occasions).