Section Four:

Ethics Section

Word Count: 3,396

Rachael Ellis

Doctorate in Clinical Psychology

Division of Health Research, Lancaster University

All correspondence should be sent to:
Rachael Ellis
Doctorate in Clinical Psychology
Furness College
Lancaster University
Lancaster
LA1 4YT
R.ellis2@lancaster.ac.uk

Ethics Section Contents

Research Protocol

What is the lived experience of young people during their admission to a psychiatric inpatient unit?

Thesis Supervisor: Dr Ian Smith

Clinical Psychology

Faculty of Health and Medicine (Floor C)

Furness College

Lancaster University

Lancaster

LA1 4YG

Field Supervisor[1]: [redacted]

[1] I have refrained from identifying my field supervisor as this information, in conjunction with the content of my Critical Appraisal, could be used to identify one of the services from which young people were recruited to participate in my research project.

Introduction

Specialist inpatient, also known as tier four, child and adolescent mental health services (CAMHS) are commissioned to provide assessment and intervention for children and young people experiencing severe and complex mental health difficulties which cannot be adequately treated in community services (National Health Service [NHS] England, 2014). The Department of Health (DOH) state that all children and young people should have access to ‘timely, integrated, high quality, multi-disciplinary mental health services’ (DOH, 2004, p.4) and that inpatient provision should be equipped to meet the developmental needs of children and adolescents. It is estimated that approximately 1.1 million children under the age of eighteen may benefit from CAMHS provision and that 45,000 children in the UK have a diagnosable severe mental health disorder (DOH, 2004). Although the majority of these individuals access care delivered in the community, approximately 2,500 young people require a period of inpatient care (NHS England, 2014).

Mental health difficulties in children and young people have the potential to negatively impact upon educational achievement and family functioning resulting in increased burden being placed upon social, health and educational services (DOH, 2004). It is also recognised that mental health difficulties in children and young people have been associated with an increased prevalence of offending behaviours resulting in contact with the criminal justice system (DOH, 2004). Furthermore, these far reaching systemic consequences are thought to have a long lasting influence upon functioning which has the potential to impact upon future generations.

It is recognised that a period of inpatient care represents a huge alteration to a young person’s usual environment and the systemic influences which impact upon their health and wellbeing (Colton & Pistrang, 2004). Removal of a young person from the setting in which their difficulties have developed and been maintained can be an effective intervention which allows for the delivery of treatment at an intensity that would not be practicable in a community setting.

However, it is important to recognise that when a young person enters a hospital setting for either physical or psychiatric care, they are exposed to a range of novel factors which exist within this system including power dynamics, altered expectations and the development of relationships with professionals and peers alike. Literature exploring inpatient psychiatric care refers to the ‘ward milieu’, a phrase which encompasses factors relating to both the physical environment of the ward and the atmosphere that is created (Grossoehme & Gerbetz, 2004). The ‘ward milieu’ is partly comprised of the relationships between staff and young people.

Grossoehme and Gerbetz (2004) acknowledge that it is essential that the ward is a safe place in which young people feel able to manage difficult experiences and emotions. Relationships developed with staff, ideally characterised by trust and empathy, contribute to the creation of this safe environment. Furthermore, staff working in inpatient settings face the challenging task of modelling appropriate relationships between young people and caregivers, ways of interacting which may be unfamiliar to some young people. Furthermore, the quality of the relationships developed with the staff team have been found to predict treatment outcomes (Scholte & Van der Ploeg, 2000). In their qualitative exploration of the experiences of 19 young women staying in inpatient eating disorder units, Colton and Pistrang (2004), young people valued relationships with members of staff who listened and appeared to genuinely care. It would seem that the development of these relationships was also influenced by professionals’ perceptions of the young people and their constructs of mental health difficulties such as anorexia nervosa (Colton & Pistrang, 2004). It has also been suggested that relationships between staff and young people are under the influence of factors associated with the professional's role, such as the imposition of restrictions in order to ensure safety (Haynes, Eivors & Crossley, 2011).

The experience of staying in a young person's inpatient unit has been described as 'living in an alternative reality' (Haynes et al., 2011). Haynes et al.'s (2011) qualitative exploration of the experiences of 10 young people with experience of inpatient admission emphasises the importance of the relational aspects of this experience. They report that young people describe a sense that they are removed from everyday life, a feeling which is exacerbated by disruption to previously valued relationships with family and peers. Furthermore, quantitative research conducted by Grossoehme and Gerbetz (2004) found that 105 young people rated 'just being with other adolescents' as the most important aspect of inpatient care. It is hypothesised that 'being with other adolescents' allowed for the development of a supportive atmosphere. Participants in Hayne et al (2011) also made reference to the importance of the new peer relationships developed during their admission.

The opportunity to be in the company of a number of other young people experiencing similar difficulties to oneself is considered to be a unique feature of inpatient care which warrants further investigation (Colton & Pistrang, 2004). However, it would appear that being in the company of other young people during an admission is not always perceived to be a positive aspect of the inpatient experience (Gusella, Ward, & Butler, 1998). In their qualitative exploration of the experience of hospital admission for young people with anorexia nervosa, Cotton and Pistrang (2004) reveal that young people experience a dilemma in interacting with other young people comprising a sense of being accepted and supported versus negative factors such as feeling the urge to compete with peers and witnessing the distress of others.

According to Haynes et al. (2011) young people may cope with the challenges of an inpatient admission via attempts to 'recreate reality' by inhabiting familiar roles and relating to others within the ward environment as members of an 'interim family'. The recreation of familiar interpersonal interactions are understood as attempts to alleviate discomfort associated with the loss of social roles and reduction in self-esteem which is related to a reluctance to identify with the undesirable label of being a psychiatric patient (Roe & Ronen, 2003). It is hypothesised that, via the development of close relationships with peers in the ward environment, self-esteem is bolstered as young people avoid drawing unfavourable comparisons with peers who have not experienced mental health difficulties (Haynes et al., 2011).

A young person's experience of the inpatient environment may also be influenced by their experiences of relationships with their caregivers. Upon admission to an inpatient unit, young people are exposed to threat associated with separation from their parents or carers. Attempts to negotiate this threat whilst simultaneously forming new relationships in an unfamiliar environment may therefore exert a powerful influence over how they experience the inpatient setting (Zegers, Schuengel, Van Ijzendoorn & Janssens, 2006).

Evaluation of inpatient CAMHS provision appears to suggest that these services provide acceptable and effective intervention (Green, Jacobs, Beecham, Dunn, Kroll, Tobias & Briskman, 2007). Furthermore, satisfaction levels of young people, their parents and professionals are high (Varol Tas, Guvenir & Cevrim, 2010). However, there is a paucity of research focussing on the qualitative experience of young people accessing services which attempts to explore 'how' tier four services help as to opposed to 'if' they help. The proposed investigation aims to extend existing understanding via an exploration of young people's lived experience with a specific focus on their relationships. It is posited that this research will contribute to the pre-existing evidence base by providing a qualitative perspective which aims to enhance and build upon the findings emerging from Haynes et al. (2011) and Colton and Pistrang (2004) which appear to suggest that the relational aspects of this experience are significant. This research question is also influenced by a desire to encourage young people to share their experiences, so that their voice may be considered as an important driver contributing to the development and delivery of mental health care in inpatient settings (Varol Tas et al., 2010).

Method

Participants

Approximately 6 – 8 participants, male or female, aged between 13 and 18 years who have been admitted to one of two [redacted] adolescent mental health inpatient units will be recruited for this study. This sampling approach will allow the researcher to focus on particular characteristics shared by the participants, in this case, their experience of being admitted to a young persons' psychiatric inpatient unit.

Inclusion criteria:

Any young person who has been a resident on the ward for more than two weeks will be eligible to take part in an interview. Young people will not be able to participate in an interview before they have been admitted for a period of two weeks, as it is thought that they will be less able to reflect on their experiences and the development of important relationships prior to this point. A young person may convey interest in the study prior to this point but will not be interviewed until they have been on the ward for two weeks or more.

Exclusion criteria:

A young person will be deemed unfit to participate in the research if:

- The care team states that the young person is too unwell to participate at present, e.g. experiencing significant delusional ideation which would impact upon their ability to engage.

- The clinical team's assessment indicates that the interview process is likely to have a detrimental effect on their mental health
- The clinical team's assessment indicates that the young person may have cognitive or communication difficulties that would make it too difficult to engage in a one to one interview at that time
- The clinical team's assessment indicates that the young person is unable to give informed consent
- They would require an interpreter in order to participate. This exclusion criteria has been used as it assumed that young people who do not speak English will have a considerably different experience of their admission and that the quality of the relationships with both staff and peers will be affected by this barrier to communication

Design

The research will employ a qualitative design. Data will be gathered via semi-structured one to one interviews lasting approximately one hour. The aim of these interviews is to facilitate an exploratory conversation utilising open ended questions which focus on participants' lived experiences. An interview guide (Appendix A) will be used in order to facilitate a consistent approach whilst allowing for exploration of each participant's individual experiences. Young people who have experience of being admitted to psychiatric inpatient unit will be consulted during the development of the interview schedules and related documentation.

Procedure

Participants will be recruited from two adolescent inpatient units in the [redacted] England. Initially, potential participants will be made aware of the project via the researcher's attendance at ward community meetings and the displaying of information posters on the wards (Appendix B). Participant information sheets (Appendix C) will be made available on the wards and will be given out in community meetings and in one to one psychology and nursing sessions.

Young people who are interested in taking part in the study will be asked to complete a declaration of interest form (Appendix D). Potential participants will not be able to volunteer to participate during the community meetings, instead they will be asked to consider the information provided for at least 24 hours in order to ensure that they have time to consider the information fully and do not feel pressurised to volunteer. Completed declaration of interest forms (Appendix D) will be put in a sealed blank envelope and stored in a sealed box kept on the ward.

Once a young person has indicated that they are willing to participate I will liaise with the clinical team in order to establish whether or not they meet any of the exclusion criteria. In order to ensure that the sample is as representative of the two recruitment sites as possible, attempts will be made to ensure that a range of participants take part in the interviews. As such, not every young person who volunteers to participate will be selected for interview. Potential participants over the age of 16 who are deemed fit to participate in the study will be approached to arrange a suitable time for the interview to take place. Any potential participants under the age of 16 who are deemed fit to participate in the study will be informed that their parent or guardian will be approached in order to seek consent to participate. If this is acceptable and the young person wishes to proceed, parental consent will be sought prior to any further arrangements being made.

Participants over the aged of 16 will be asked to confirm that they consent to taking part via the completion of a consent form (Appendix E). Consent forms will be completed just prior to the interview. Young people under the age of 16 will complete an assent form (Appendix F) and their parent or guardian will be provided with a parent / guardian information sheet (Appendix G) and asked to complete a parent / guardian consent form (Appendix H). This process is in line with the British Psychological Society's Code of Human Research Ethics (British Psychological Society, 2010).

Parent / guardian consent forms will be completed following discussion with the care team regarding exclusion criteria and prior to any interview arrangements being made with the young person. Young people will be approached to inform them that, due to their age, consent to participate will be sought from their parent / guardian. If this is acceptable parent / guardian consent forms (Appendix H) and information sheets (Appendix G) will be handed out by the ward staff or a member of the clinical team s they are likely to have regular contact with a young person's family during visiting times or meetings. These forms will be returned in a sealed envelope addressed to the main researcher. Once the researcher is in receipt of completed parent / guardian consent forms arrangements will be made with the young person for the interview to take place. Young people under the age of 16 will be asked to complete an assent form (Appendix F) just prior to the interview taking place.

Immediately prior to the interview the researcher will approach the nurse in charge of the ward in order to check that the information previously provided regarding exclusion criteria remains accurate. Interviews will take place in an appropriate, private venue on the wards. It is anticipated that the interview will take approximately 1 hour for each participant. Some demographic information will also be collected in order to provide a context in which each participant's individual experiences can be understood (Appendix I). The interview will be audio recorded. If possible, the digital recorder will be encrypted. Should this not be possible, any identifiable data will be transferred to an encrypted file on a password protected computer as soon as is practicably possible and the original recording will be deleted. Audio recordings will be deleted following completion of the study. The data will then be transcribed and anonymised by the chief investigator. Anonymised transcripts will be saved in an encrypted file on a password protected computer. Anonymised transcripts and completed consent forms will be scanned electronically and stored on a password protected, encrypted file space on the University server, the contents of which will be deleted 10 years after the project has been completed. Storage and deletion of this material will be the responsibility of the Research Coordinator (Doctorate in Clinical Psychology, Lancaster University).

Analysis

The data collected will be analysed using Interpretative Phenomenological Analysis (IPA). This approach aims to explore how people make sense of their experiences via the analysis of detailed first person accounts. The researcher aims to understand the meanings that are made by participants by gathering information about the ways in which they relate to the world. In order to do this effectively, it is essential that the researcher considered their own experiences and assumptions and reflects upon their role in the development of interpretations. A reflective research journal will be used alongside supervision in order to facilitate the process of analysis. Thematic validity will be checked via supervision with research supervisors.

Practical Issues

Interviews will be arranged to take place at the inpatient unit in which the young person is residing. This will require travel by the researcher. The Field Supervisor or a member of the Doctorate in Clinical Psychology administration team will aware of the date, time and location of interviews and measures will be taken to ensure that the researcher is able to communicate with the base. It is anticipated that travel expenses will be covered by Lancaster University. Recording equipment and devices used to aid transcription will be provided by Lancaster University.

Ethical Concerns

Ethical approval will be sought via submission to the Integrated Related Application System (IRAS). There are a number of ethical issues which will be considered throughout the design and implementation of this research:

Informed consent Young people over the age of 16 will not be able to take part in this research if they are unable to give consent to participate. Capacity to consent will be assessed by the care team. Young people under the age of 16 will need the consent of their parent or guardian in order to participate.

Confidentiality and Anonymity It is acknowledged that, due to the setting in which this research is taking place and the necessary liaison with the clinical team, the ward staff will be aware of who is participating in the research. However, attempts have been made to ensure that confidentiality is safeguarded as far as possible as the researcher will not have access to information about any young person unless they have expressed an interest to participate in the study. The researcher will ensure that any identifying information is removed from quotations featuring in the final piece of work in order to protect participant's identity as far as possible. Young people will be provided with information regarding anonymity and confidentiality via the participant information sheet (Appendix C) and consent form (Appendix E).

Negative or distressing impact of interviews Members of the care team will be asked to inform the researcher of any young people for whom participation in the research may be detrimental (e.g. due to current presentation or risk issues). Should a participant become distressed during the interview process they will be given the opportunity to end the interview or to take a break. If the researcher has concerns regarding the impact of the interview upon a participant, this information will be shared with the shift leader on the ward and discussed with a research supervisor. Members of the care team will be available to support participants following completion of the research interview. Information regarding support agencies for young people will be provided on the Participant information sheet (Appendix C).

Potential disclosure(s) made in interview which lead to concern with regard to service user or staff safety, or staff negative practice It is recognised that it may be necessary for the researcher to breach confidentiality if it is suggested that the safety of the participants or others may be compromised. Should this issue arise the researcher will contact the field supervisor / university supervisor in order to discuss the best course of action. If appropriate, young people who have disclosed any concerning information would be notified that it is necessary to breach confidentiality. Participants will be reminded of these limits of confidentiality prior to the start of the interview.

Timescales

It is anticipated that the research project will run in accordance with the following timescales.

Activity	Date
Submit draft research proposal & materials for ethics	April 2014
Submit ethics proposal to panel	May / June 2014
Write up introduction and method	April - November 2014
Meet pre-data collection	July / August 2014
Contacting participants	July - October 2014
Data collection & transcription of data	July – October 2014
Data analysis	July – December 2014
Write up results and discussion	September – January 2015
Submit draft	January 2015
Submit Thesis	May 2015
Submit paper for publication	July 2015

References

British Psychological Society. (2010). *Code of Human Research Ethics* (pp.1–44). Leicester: British Psychological Society. Retrieved from: http://www.bps.org.uk/sites/default/files/documents/code_of_human_research_ethics.pdf

Colton, A., & Pistrang, N. (2004). Adolescents experiences of inpatient treatment anorexia nervosa. *European Eating Disorders Review, 12*(5), 307–316. doi:10.1002/erv.587

Department of Health. (2004). *National Service Framework for Children, Young People and Maternity Services: The Mental Health and Psychological Well-being of Children and Young People*. London: Department of Health

Green, J., Jacobs, B., Beechman, J., Dunn, G., Kroll, L., Tobias, C., & Briskman, J. (2007). Inpatient treatment in child and adolescent psychiatry – a prospective study of health gain and costs. *Journal of Child Psychology and Psychiatry, 48*(12), 1259 1267. doi:10.1111/j.14697610.2007.01802.x

Grossoehme, D.H., & Gerbetz, L. (2004). Adolescents perceptions of the meaningfulness of psychiatric hospitalization. *Clinical Child Psychology and Psychiatry, 9*(4), 589 596. doi: 10.1177/1359104504046162

Gusella, J.L., Ward, A., & Butler, G.S. (1998). The experience of hospitalized adolescents: How do we meet their developmental needs? *Children's Health Care, 27*(2), 131-145. doi:10.1207/s15326888chc2702_4

Haynes, C., Eivors, A., & Crossley, J. (2011). 'Living in an alternative reality': adolescent's experiences of psychiatric inpatient care. *Child and Adolescent Mental Health, 16*(3), 150–157. doi:10.1111/j.1475-3588.2011.00598.x

National Health Service England. (2014). *C07. Tier 4 Child and Adolescent Mental*

Health Services (CAMHS). Retrieved from: http://www.england.nhs.uk/ourwork/commissioning/spec-services/npc-crg/group-c/c07/

Roe, D., & Ronen, Y. (2003). Institutionalization as experienced by the psychiatric patient: A therapeutic jurisprudence perspective. *International Journal of Law & Psychiatry, 26*(3), 317-332. doi: 10.1016/s0160-2527(03)00041-4

Scholte, E.M., & Van der Ploeg, J.D. (2000). Exploring factors governing successful residential treatment of youngsters with serious behavioural difficulties: Findings from a longitudinal study in Holland. *Childhood: A Global Journal of Child Research, 7*(2), 129–153. doi: 10.1177/0907568200007002002

Varol Tas, F.V., Guenier, T., & Cevrim, E. (2010). Patients' and their parents' satisfaction levels about the treatment in a child and adolescent mental health inpatient unit. *Journal of Psychiatric and Mental Health Nursing, 17*(9), 769–774, doi:10.1111/j.13652850.2010.0112.x

Zegers, M.A.M., Schuengel, C., Van Ijzendoorn, M.H., & Janssens, J.M.A.M. (2006). Attachment representations of institutionalized adolescents and their professional caregivers: Predicting the development of therapeutic relationships. *American Journal of Orthopsychiatry*, *76*(3), 325-334. doi: 10.1037/0002-9432.76.3.325

Appendix A: Interview Guide **Version 1: 18.06.14**

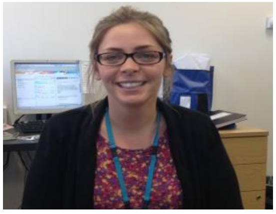
- Can you tell me a little bit about yourself? What was your life like before you came to the unit? What kind of things are you interested in? Do you have any hobbies? Are you at school or college? Who do you live with at home? (ice breaker questions)
- Who did you have around you who was important to you / who you spent time with before you came onto the unit?
- Can you tell a little a bit about the reasons you came into the unit?
- How did you feel about coming into the unit?
- How did you feel when you first came onto the unit?
- What did you want to get from your stay on the unit?
- What have you found to be the best things about being in unit? What things on the unit have helped you, or your family/carers?
- Can you tell me about aspects of being in unit that haven't been so good?
- What is it like living here with other young people?
- How do you get on with the young people on the unit?
- What is good about your relationships with other young people?
- What is not so good about your relationships with other young people?
- How do you get on with the staff on the unit? (prompt for both nursing staff and other members of staff who may offer support)
- What is good about your relationships with staff?
- What is not so good about your relationships with staff?

- How have you found being away from home?
- Have you managed to have contact with XX (see question above about who they spent time with prior to admission) whilst you have been on the unit? What type of contact? What has it been like spending less time with them whilst you have been on the unit?
- Has been in hospital changed any of your relationships with friends or family/carers at home?

Appendix B: Advertisement Poster **Version 2: 21.07.14**

Faculty of Health & Medicine

LANCASTER UNIVERSITY



Hi. My name is Rachael Ellis. I am a Trainee Clinical Psychologist hoping to carry out some research on your unit.

Are you looking for **something to do?**

Would you like to help out with some **research**?

Would you like to give your **views** about life on the unit?

Are you interested?

- **Ask psychology for more information / take an Information Sheet.**
- **Fill in a declaration of interest form (INSERT details of where to find one) and put it in the Research Box (INSERT details of where it's kept)**

Appendix C: Participant Information Sheet (Young People) **Version 2. 21.07.2014**

[redacted] [redacted]

Participant Information Sheet

What is the lived experience of young people during their admission to a psychiatric inpatient unit?

My name is Rachael Ellis. I am conducting this research as a Trainee Clinical Psychologist in the Doctorate in Clinical Psychology programme at Lancaster University. I do not work for the unit that you are staying in but I do have contact with members of the team who are helping me with this research.

What is the study about?

This study aims to find out what it is like for young people who are admitted to hospital for assessment or treatment of mental health difficulties. Not many studies have focussed on finding out about the experiences of young people. This research aims to find out more about your experiences so that services can make sure that they thinking carefully about how to best support young people in their service.

Why have I been approached?

I am asking young people who are currently staying in a young person's inpatient unit if they would like to take part in the research. However, not everyone who decides to take part will be chosen for the research. A range of young people from two inpatient units will be chosen to participate to make sure that the research represents the experiences of young people in both units.

Do I have to take part?

No. It is your decision whether you wish to take part in the study. Whether you decide to take part in the study or not, your care will not be affected in any way.

What will I be asked to do if I take part?

- If you decide you would like to take part we will arrange to meet at the unit to carry out an interview.
- The interview will last approximately 1 hour but we can stop for breaks if you need to.
- During the interview we will talk about your experiences of your stay in hospital. I am particularly interested in hearing about the relationships you have developed whilst you

have been hospital (with staff or other young people) and about important relationships with people at home.

- The interview will be recorded and a transcript of our conversation will be typed up and analysed.

- You can have an adult with you during the interview if you would like as long as you don't mind them hearing what you say.

Will my data be confidential?

The information you provide will be made anonymous, this means that nobody will be able to identify you from the research. This piece of work will include quotes taken from the interviews with young people. However, I will do my best to make sure that nobody can identify you from the quotes used. The results will also be submitted for publication in an academic or professional journal.

The data collected for this study will be stored securely and only the researchers conducting this study will have access to this data.

There are some limits to confidentiality. If what is said in the interview makes me think that you or someone else might get hurt I will have to break confidentiality and speak to my Supervisors about this. If I am worried about your safety I might need to talk to your care team too. If possible, these concerns will be shared with you before I pass them on.

Members of your care team will know that you are taking part in the study but this will not change any of the care that you are given.

What will happen to the results?

The results will be summarised and reported as part of a research report which is part of the Lancaster University Doctorate in Clinical Psychology.

Can I change my mind about taking part?

Yes, you can decide not to take part at any point before or during the interview. You do not have to give a reason for changing your mind. You can withdraw your data for up to two weeks after the interview has taken place and your data will be taken out of the study and destroyed. If you change your mind after two weeks it will not be possible to withdraw your data from the study.

Are there any risks?

Whilst I don't think that taking part in this study will cause you any harm, we might talk about things that are upsetting during the interview. If you get upset during the interview you can ask to take a break or we can stop the interview.

Are there any benefits to taking part?

Although you may find taking part interesting, there are no direct benefits in taking part.

Who has reviewed the project?

This research has been checked by the Research and Design Departments for [redacted]. It has also been peer reviewed by the Department of Clinical Psychology research team at Lancaster University. This project has also been reviewed at [redacted].

Where can I obtain further information about the study if I need it?

If you have any questions about the study, please contact me on the number or email address below.

Rachael Ellis (Trainee Clinical Psychologist) Email: r.ellis2@lancaster.ac.uk

Mobile: xxxxxxxxxxxx

Complaints

If you wish to make a complaint or raise concerns about any aspect of this study and do not want to speak to the researcher, you can contact:

Jane Simpson (Research Director)

Doctorate in Clinical Psychology Division of Health Research Furness College

Lancaster University Lancaster

LA1 4YG

Tel: (01524) 592730

Email: j.simpson2@lancaster.ac.uk

If you wish to speak to someone outside of the Clinical Psychology Doctorate Programme, you may also contact:

Professor Paul Bates (Associate Dean for Research)

Faculty of Health and Medicine

(Division of Biomedical and Life Sciences) Lancaster University

Lancaster LA1 4YD

Tel: (01524) 593718

Email: p.bates@lancaster.ac.uk

<u>Thank you for taking the time to read this information sheet.</u>

Resources in the event of distress

These contacts might be helpful if you need any support either following taking part in this study or in the future.

Young Minds – The voice for young people's mental health and wellbeing Web: http://www.youngminds.org.uk/

Phone: 020 7089 5050

Rethink –

Web: http://www.rethink.org/living-with-mental-illness/young-people Phone: 0300 5000 927 (Monday – Friday, 10-2)

Childline –

Web: www.childline.org.uk

Phone: 0800 1111

Appendix D: Declaration of Interest Form **Version 2. 21.07.2014**

Fill in this form if you would like to find out more about the research.

What is your full name?

____

Which ward are you staying on?

____

☐ Please tick this box if it is ok for me to talk to your care team about you taking part in this research.

1. Put this form in a blank envelope.

2. Put the envelope in the Research Box (INSERT DETAILS OF WHERE THE BOX IS STORED).

I will contact you soon to talk about the research.

Appendix E: Consent Form (Young People) **Version 2: 21.07.14**

[redacted]

Consent Form (For young people over 16)

What is the lived experience of young people during their admission to a psychiatric inpatient unit?

I am asking if you would like to take part in a research project which aims to explore the experiences of young people who are currently staying in hospital for assessment or treatment of mental health difficulties. Before you consent to participating in the study we ask that you read the participant information sheet (Version 1) and the statements below. If you agree with the statements put your initials in the box. If you have any questions or queries before signing the consent form please speak to the principal investigator, Rachael Ellis (Trainee Clinical Psychologist).

I have read the participant information sheet (Version 1) and understand what is expected of me within this study.	
I have had the chance to ask any questions and to have them answered.	
I understand that my interview will be audio recorded and that what I say will be typed up with the names and places changed so people won't be able to tell it was me.	
I understand that the words I use will be used in the final research but that people won't be able to tell who said what.	
I understand that the audio recordings will be kept until the interview has been typed up.	
I understand that I don't have to take part and that I can change my mind at any time without giving a reason. I know that if I change my mind the care I get won't change.	
I understand that I can change my mind about taking part at any point before or during the interview and that my data can be withdrawn from the study up to two weeks after the interview. I understand that after this point it might not be possible for what I say to be taken out of the research.	
It is ok for the words I say and some general information about me (but not my name) to be used in reports, publications, conferences and training events.	
I know that any information I give will be kept private and that people won't be able to tell what I said unless there is a chance that I, or another young person, might get hurt. If this happens I know that the researcher will need to share this information with her research supervisor.	
It is ok for Lancaster University to keep the typed up document of my interview on a safe computer for 10 years after the study has finished.	
It is ok for Lancaster University, the NHS Trust or people who oversee these organisations to look at the data from this research.	

Please sign if you agree to you taking part in the study.

Name__________________________**Signature**____________________________**Date**___________

Appendix F: Assent Form **Version 2. 21.07.14**

Faculty of Health & Medicine LANCASTER UNIVERSITY [redacted]

Assent Form (For young people under 16)

What is the lived experience of young people during their admission to a psychiatric inpatient unit?

I am asking if you would like to take part in a research project which aims to explore the experiences of young people who are currently staying in hospital for assessment or treatment of mental health difficulties. Both you and your parent or guardian need to read the participant information sheet (Version 1) and mark each box below with your initials if you agree. If you have any questions or queries before signing the assent form please speak to the principal investigator, Rachael Ellis (Trainee Clinical Psychologist).

My parent / guardian and I have read the participant information sheet (Version 1) and understand what is expected of me within this study.	
I have had the chance to ask any questions and to have them answered.	
I understand that my interview will be audio recorded and that what I say will be typed up with the names and places changed so people won't be able to tell it was me.	
I understand that the words I use will be used in the final research but that people won't be able to tell who said what.	
I understand that the audio recordings will be kept until the interview has been typed up.	
I understand that I don't have to take part and that I can change my mind at any time without giving a reason. I know that if I change my mind the care I get won't change.	
I understand that I can change my mind about taking part at any point before or during the interview and that my data can be withdrawn from the study up to two weeks after the interview. I understand that after this point it might not be possible for what I say to be taken out of the research.	
It is ok for the words I say and some general information about me to be used in reports, publications, conferences and training events.	
I know that any information I give will be kept private and that people won't be able to tell what I said unless there is a chance that I, or another young person, might get hurt. If this happens I know that the researcher will need to share this information with her research supervisor.	
It is ok for Lancaster University to keep the typed up document of my interview on a safe computer for 10 years after the study has finished.	
It is ok for Lancaster University, the NHS Trust or people who oversee these organisations to look at the data from this research.	

Please sign if it is ok for your parent / guardian to agree to you taking part in the study.

Name________________________ **Signature**__________________________ **Date**_______________

Appendix G: Parent / Guardian Information Sheet **Version 2. 21.07.14**

Faculty of Health & Medicine

LANCASTER UNIVERSITY

[redacted]

Parent / Carer Information Sheet

What is the lived experience of young people during their admission to a psychiatric inpatient unit?

My name is Rachael Ellis. I am conducting this research as a Trainee Clinical Psychologist in the Doctorate in Clinical Psychology programme at Lancaster University. I do not work for the unit that your child is currently admitted to but I do have contact with members of the team who are helping me with this research.

What is the study about?

This study aims to find out what it is like for young people who are admitted to hospital for assessment or treatment of mental health difficulties. Not many studies have focussed on finding out about the experiences of young people. This research aims to find out more about your child's experiences so that services can make sure that they are thinking carefully about how to best support your child.

Why has my child been approached?

I am asking young people who are currently staying in a young person's inpatient unit if they would like to take part in the research. However, not everyone who decides to take part will be chosen for the research. A range of young people from two inpatient wards will be chosen to participate to make sure that the research represents the experiences of young people in both hospitals.

Does my child have to take part?

No. This is a decision for you and your child to make together. Whether your child decides to take part in the study or not, his or her care will not be affected in any way.

What will my child be asked to do if they take part?

- If your child decides they would like to take part we will arrange to meet at the hospital to carry out an interview.
- The interview will last approximately 1 hour but we can stop for breaks if necessary.
- During the interview we will talk about your experiences of your child's stay in hospital. I am particularly interested in hearing about the relationships your child has developed

whilst they have been hospital (with staff or other young people) and about important relationships with people at home.

- The interview will be recorded and a transcript of the conversation will be typed up and analysed.
- Your child can have an adult of their choosing with them during the interview if they so wish as long as they understand that this person will be privy to the conversation.

Will my child's data be confidential?

The information your child provides will be made anonymous, this means that nobody will be able to identify your child from the research. The data collected for this study will be stored securely and only the researchers conducting this study will have access to this data. There are some limits to confidentiality. If what is said in the interview makes me think that your child or someone else is at significant risk of harm I will have to break confidentiality and speak to my Supervisors about this. If I am worried about your child's safety or wellbeing I might need to talk to the care team too. If possible, these concerns will be shared you're your child prior to being passed on. Whilst your child's care team will be aware of their participation in the study, this will not influence the care they receive in any way.

What will happen to the results?

The results will be summarised and reported as part of a Thesis, an academic requirement of the Lancaster University Doctorate in Clinical Psychology. This piece of work will include quotes taken from the interviews with young people. However, I will make sure that nobody can identify your child from the quotes used. The results may also be submitted for publication in an academic or professional journal.

Can my child change their mind about taking part?

Yes, your child can decide not to take part at any point before or during the interview. Your child does not have to give a reason for changing his / her mind. Your child can withdraw his / her data for up to two weeks after the interview has taken place and his / her data will be taken out of the study and destroyed. If your child changes his / her mind after two weeks it will not be possible to withdraw your child's data from the study.

Are there any risks?

Whilst I don't think that taking part in this study will cause your child any harm, we might talk about things that are upsetting during the interview. If your child gets upset during the interview they can ask to take a break or we can stop the interview.

Are there any benefits to taking part?

Although your child may find taking part interesting, there are no direct benefits in taking part.

Who has reviewed the project?

This research has been checked by the Research and Design Departments for [redacted]. It has also been peer reviewed by the Department of Clinical Psychology research team at Lancaster University. This project has also been reviewed at NRES Committee [redacted].

Where can I obtain further information about the study if I need it?

If you have any questions about the study, please contact me on the number or email address below.

Rachael Ellis (Trainee Clinical Psychologist) Email: r.ellis2@lancaster.ac.uk

Mobile: xxxxxxxxxxxxxxx

Complaints

If you wish to make a complaint or raise concerns about any aspect of this study and do not want to speak to the researcher, you can contact:

Jane Simpson (Research Director)

Doctorate in Clinical Psychology Division of Health Research Furness College

Lancaster University Lancaster

LA1 4YG

Tel: (01524) 592730

Email: j.simpson2@lancaster.ac.uk

If you wish to speak to someone outside of the Clinical Psychology Doctorate Programme, you may also contact:

Professor Paul Bates (Associate Dean for Research)

Faculty of Health and Medicine

(Division of Biomedical and Life Sciences) Lancaster University

Lancaster LA1 4YD

Tel: (01524) 593718

Email: p.bates@lancaster.ac.uk

Thank you for taking the time to read this information sheet.

Resources in the event of distress

These contacts might be helpful if you need any support either following taking part in this study or in the future.

Young Minds – The voice for young people's mental health and wellbeing Web: http://www.youngminds.org.uk/

Phone: 020 7089 5050

Rethink –

Web: http://www.rethink.org/living-with-mental-illness/young-people Phone: 0300 5000 927 (Monday – Friday, 10-2)

Childline –

Web: www.childline.org.uk

Phone: 0800 1111

Appendix H: Parent / Guardian Consent Form Version 1. 18.06.14

Faculty of Health & Medicine   LANCASTER UNIVERSITY   [redacted]   [redacted]

Parent / Guardian Consent Form (For young people under 16)

What is the lived experience of young people during their admission to a psychiatric inpatient unit?

I am asking if you would like to take part in a research project which aims to explore the experiences of young people who are currently staying in hospital for assessment or treatment of mental health difficulties. Before you consent to participating in the study we ask that you read the participant information sheet (Version 1) and mark each box below with your initials if you agree. If you have any questions or queries before signing the consent form please speak to the principal investigator, Rachael Ellis (Trainee Clinical Psychologist).

I confirm that I have read the participant information sheet (Version 1) and fully understand what is expected of my child within this study.	
I confirm that I have had the opportunity to ask any questions and to have them answered.	
I understand that my child's interview will be audio recorded and then made into an anonymised written transcript.	
I understand that direct quotes will be used in the final research and that these quotes will be anonymised so that my child is not identifiable.	
I understand that audio recordings will be kept until the data has been transcribed.	
I understand that my child's participation is voluntary and that he/she is free to withdraw at any time without giving any reason, and without their medical care or legal rights being affected.	
I understand that my child's data can be withdrawn from the study up to two weeks after the interview. I understand that after this point it might not be possible for my child's data to be taken out of the research.	
I understand that the information from my child's interview will be pooled with other participants' responses, anonymised and may be published.	
I consent to information and quotations from my child's interview being used in reports, conferences and training events.	
I understand that any information my child gives will remain strictly confidential and anonymous unless it is thought that there is a risk of harm to my child or others, in which case the principal investigator will need to share this information with her research supervisor.	
I consent to Lancaster University keeping anonymised, written transcriptions of the interview in a locked cabinet for 10 years after the study has finished.	
I understand that relevant sections of my child's data may be looked at by individuals from Lancaster University, from regulatory authorities or from the NHS Trust. I give permission for these Individuals to have access to my child's records.	

Please sign below if you consent for your child to take part in this study.

Name________________________ **Signature**__________________________ **Date**________________

Appendix I: Demographic Information **Version 1. 18.06.14**

Participant Number:	
Pseudonym (chosen by participant):	
Age (years and months):	
Gender:	
Duration of stay on the ward when the interview is completed:	
Number of previous admissions:	

Appendix J: Research Ethics Committee (REC) Form

Welcome to the Integrated Research Application System

IRAS Project Filter

The integrated dataset required for your project will be created from the answers you give to the following questions. The system will generate only those questions and sections which (a) apply to your study type and (b) are required by the bodies reviewing your study. Please ensure you answer all the questions before proceeding with your applications.

Please enter a short title for this project (maximum 70 characters)
Young People's Lived Experience of Admission to an Inpatient Unit

1. Is your project research?

(•) Yes ( ) No

2. Select one category from the list below:

( ) Clinical trial of an investigational medicinal product
( ) Clinical investigation or other study of a medical device
( ) Combined trial of an investigational medicinal product and an investigational medical device
( ) Other clinical trial to study a novel intervention or randomised clinical trial to compare interventions in clinical practice
( ) Basic science study involving procedures with human participants
( ) Study administering questionnaires/interviews for quantitative analysis, or using mixed quantitative/qualitative methodology
(•) Study involving qualitative methods only
( ) Study limited to working with human tissue samples (or other human biological samples) and data (specific project only)
( ) Study limited to working with data (specific project only)
( ) Research tissue bank
( ) Research database

If your work does not fit any of these categories, select the option below:

( ) Other study

2a. Please answer the following question(s):

a) Does the study involve the use of any ionising radiation?	( ) Yes	(•) No
b) Will you be taking new human tissue samples (or other human biological samples)?	( ) Yes	(•) No
c) Will you be using existing human tissue samples (or other human biological samples)?	( ) Yes	(•) No

3. In which countries of the UK will the research sites be located? *(Tick all that apply)*

[x] England
[ ] Scotland
[ ] Wales
[ ] Northern Ireland

3a. In which country of the UK will the lead NHS R&D office be located:

- (•) England
- ( ) Scotland
- ( ) Wales
- ( ) Northern Ireland
- ( ) This study does not involve the NHS

4. Which review bodies are you applying to?

- [x] NHS/HSC Research and Development offices
- [ ] Social Care Research Ethics Committee
- [x] Research Ethics Committee
- [ ] National Information Governance Board for Health and Social Care (NIGB)
- [ ] National Offender Management Service (NOMS) (Prisons & Probation)

For NHS/HSC R&D offices, the CI must create Site-Specific Information Forms for each site, in addition to the study-wide forms, and transfer them to the PIs or local collaborators.

5. Will any research sites in this study be NHS organisations?

(•) Yes ( ) No

5a. Are all the research costs and infrastructure costs for this study provided by an NIHR Biomedical Research Centre, NIHR Biomedical Research Unit, NIHR Collaboration for Leadership in Health Research and Care (CLAHRC) or NIHR Research Centre for Patient Safety & Service Quality in all study sites?

( ) Yes (•) No

If yes, NHS permission for your study will be processed through the NIHR Coordinated System for gaining NHS Permission (NIHR CSP).

5b. Do you wish to make an application for the study to be considered for NIHR Clinical Research Network (CRN) support and inclusion in the NIHR Clinical Research Network (CRN) Portfolio? Please see information button for further details.

( ) Yes (•) No

If yes, NHS permission for your study will be processed through the NIHR Coordinated System for gaining NHS Permission (NIHR CSP) and you must complete a NIHR Clinical Research Network (CRN) Portfolio Application Form immediately after completing this project filter and before completing and submitting other applications.

6. Do you plan to include any participants who are children?

(•) Yes ( ) No

7. Do you plan at any stage of the project to undertake intrusive research involving adults lacking capacity to consent for themselves?

( ) Yes (•) No

Answer Yes if you plan to recruit living participants aged 16 or over who lack capacity, or to retain them in the study following loss of capacity. Intrusive research means any research with the living requiring consent in law. This includes use of identifiable tissue samples or personal information, except where application is being made to the NIGB Ethics and Confidentiality Committee to set aside the common law duty of confidentiality in England and Wales. Please consult the guidance notes for further information on the legal frameworks for research involving adults lacking capacity in the UK.

8. Do you plan to include any participants who are prisoners or young offenders in the custody of HM Prison Service or who are offenders supervised by the probation service in England or Wales?

◯ Yes ◉ No

9. Is the study or any part of it being undertaken as an educational project?

◉ Yes ◯ No

Please describe briefly the involvement of the student(s):
The Principal Investigator (Rachael Ellis) is currently a Trainee on the Lancaster University Doctorate in Clinical Psychology (DClinPsy). This research will form part of her thesis.

9a. Is the project being undertaken in part fulfilment of a PhD or other doctorate?

◉ Yes ◯ No

10. Will this research be financially supported by the United States Department of Health and Human Services or any of its divisions, agencies or programs?

◯ Yes ◉ No

11. Will identifiable patient data be accessed outside the care team without prior consent at any stage of the project (including identification of potential participants)?

◯ Yes ◉ No

Integrated Research Application System
Application Form for Research involving qualitative methods only

NHS
Health Research Authority

Application to NHS/HSC Research Ethics Committee

The Chief Investigator should complete this form. Guidance on the questions is available wherever you see this symbol displayed. We recommend reading the guidance first. The complete guidance and a glossary are available by selecting Help.

Please define any terms or acronyms that might not be familar to lay reviewers of the application.

Short title and version number: (maximum 70 characters - this will be inserted as header on all forms)
Young People's Lived Experience of Admission to an Inpatient Unit

Please complete these details after you have booked the REC application for review.

REC Name:
North West - Lancaster

REC Reference Number:
14/NW/1094

Submission date:
23/06/2014

PART A: Core study information

1. ADMINISTRATIVE DETAILS

A1. Full title of the research:

What is the lived experience of young people during their admission to a psychiatric inpatient unit?

A2-1. Educational projects

Name and contact details of student(s):

Student 1

	Title	Forename/Initials	Surname
	Miss	Rachael	Ellis
Address	8 Woodstock Avenue		
	Newton-le-Willows		
	St Helens		
Post Code	WA12 8PR		
E-mail	r.ellis2@lancaster.ac.uk		
Telephone	07736319031		
Fax			

Give details of the educational course or degree for which this research is being undertaken:

Name and level of course/ degree:
Doctorate in Clinical Psychology

Name of educational establishment:
Lancaster University

Name and contact details of academic supervisor(s):

Academic supervisor 1

	Title Forename/Initials Surname Dr Ian Smith
Address	Clinical Psychology Faculty of Health and Medicine, Floor C Furness College, Lancaster University, Lancaster
Post Code	LA1 4YG
E-mail	i.smith@lancaster.ac.uk
Telephone	01524595282
Fax	

Please state which academic supervisor(s) has responsibility for which student(s):
Please click "Save now" before completing this table. This will ensure that all of the student and academic supervisor details are shown correctly.

Student(s)	Academic supervisor(s)
Student 1 Miss Rachael Ellis	☑ Dr Ian Smith

A copy of a current CV for the student and the academic supervisor (maximum 2 pages of A4) must be submitted with the application.

A2-2. Who will act as Chief Investigator for this study?

- (●) Student
- ( ) Academic supervisor
- ( ) Other

A3-1. Chief Investigator:

	Title Forename/Initials Surname Miss Rachael Ellis
Post	Trainee Clinical Psychologist
Qualifications	BSc Psychology MSc Psychology PG Cert in Low Intensity Therapies
Employer	Lancashire Care NHS Trust
Work Address	Clinical Psychology,Faculty of Health and Medicine Floor C, Furness College, Lancaster University Lancaster
Post Code	LA1 4YG

Work E-mail	r.ellis2@lancaster.ac.uk
* Personal E-mail	
Work Telephone	
* Personal Telephone/Mobile	07736319031
Fax	

** This information is optional. It will not be placed in the public domain or disclosed to any other third party without prior consent.*
A copy of a current CV (maximum 2 pages of A4) for the Chief Investigator must be submitted with the application.

A4. Who is the contact on behalf of the sponsor for all correspondence relating to applications for this project?
This contact will receive copies of all correspondence from REC and R&D reviewers that is sent to the CI.

	Title	Forename/Initials	Surname
	Mrs	Debbie	Knight

Address	Research Support Office B58 Bowland Main Lancaster University
Post Code	LA1 4YT
E-mail	ethics@lancaster.ac.uk
Telephone	01524592605
Fax	

A5-1. Research reference numbers. *Please give any relevant references for your study:*

Applicant's/organisation's own reference number, e.g. R & D (if available):	
Sponsor's/protocol number:	
Protocol Version:	1
Protocol Date:	19/06/2014
Funder's reference number:	
Project website:	

Additional reference number(s):

Ref.Number Description	Reference Number

Registration of research studies is encouraged wherever possible. You may be able to register your study through your NHS organisation or a register run by a medical research charity, or publish your protocol through an open access publisher. If you have registered your study please give details in the "Additional reference number(s)" section.

A5-2. Is this application linked to a previous study or another current application?

○ Yes ◉ No

Please give brief details and reference numbers.

2. OVERVIEW OF THE RESEARCH

To provide all the information required by review bodies and research information systems, we ask a number of specific questions. This section invites you to give an overview using language comprehensible to lay reviewers and members of the public. Please read the guidance notes for advice on this section.

A6-1. Summary of the study. *Please provide a brief summary of the research (maximum 300 words) using language easily understood by lay reviewers and members of the public. Where the research is reviewed by a REC within the UK Health Departments Research Ethics Service, this summary will be published on the website of the National Research Ethics Service following the ethical review.*

This research aims to contribute to our understanding of the experiences of young people who are admitted to adolescent mental health wards for assessment or treatment of a mental health problem. Young people who are recruited to take part in this study will be asked about their experiences with specific reference to the relationships they may have developed with other young people and members of their care team. It is hoped that this research will help us to better understand how the development of peer and therapeutic relationships can contribute to the effective provision of inpatient care.

A6-2. Summary of main issues. *Please summarise the main ethical, legal, or management issues arising from your study and say how you have addressed them.*

Not all studies raise significant issues. Some studies may have straightforward ethical or other issues that can be identified and managed routinely. Others may present significant issues requiring further consideration by a REC, R&D office or other review body (as appropriate to the issue). Studies that present a minimal risk to participants may raise complex organisational or legal issues. You should try to consider all the types of issues that the different reviewers may need to consider.

Informed consent – Young people over the age of 16 will not be able to take part in this research if they are unable to give consent to participate. Capacity to consent will be assessed by the care team (Mental Capacity Act, 2005). Young people under the age of 16 will need the consent of their parent or guardian in order to participate.

Confidentiality and Anonymity – It is acknowledged that, due to the setting in which this research is taking place and the necessary liaison with the clinical team, the ward staff will be aware of who is participating in the research. However, attempts have been made to ensure that confidentiality is safeguarded as far as possible as the researcher will not have access to information about any young person unless they have expressed an interest to participate in the study. The researcher will ensure that any identifying information is removed from quotations featuring in the final piece of work in order to protect participant's identity as far as possible. Young people will be provided with information regarding anonymity and confidentiality via the participant information sheet and consent form.

Negative or distressing impact of interviews – Members of the care team will be asked to inform the researcher of any young people for whom participation in the research may be detrimental (e.g. due to current presentation or risk issues). These young people will not be selected to participate as they will meet the exclusion criteria. Should a participant become distressed during the interview process they will be given the opportunity to end the interview or to take a break. If the researcher has concerns regarding the impact of the interview upon a participant, this information will be shared with the shift leader on the ward and discussed with a research supervisor. Members of the care team will be available to support participants following completion of the research interview. Information regarding support agencies for young people will be provided on the Participant information sheet.

Potential disclosure(s) made in interview which lead to concern with regard to service user or staff safety, or staff negative practice – It is recognised that it may be necessary for the researcher to breach confidentiality if it is suggested that the safety of the participants or others may be compromised. Should this issue arise the researcher will contact the field supervisor / university supervisor in order to discuss the best course of action. If appropriate, young people who have disclosed any concerning information would be notified that it is necessary to breach confidentiality. Participants will be reminded of these limits of confidentiality prior to the start of the interview.

A6-3. Proportionate review of REC application *The initial project filter has identified that your study may be suitable for proportionate review by a REC sub-committee. Please consult the current guidance notes from NRES and indicate whether you wish to apply through the proportionate review service or, taking into account your answer to A6-2, you consider there are ethical issues that require consideration at a full REC meeting.*

(●) Yes - proportionate review ( ) No - review by full REC meeting

Further comments (optional):

Note: This question only applies to the REC application.

3. PURPOSE AND DESIGN OF THE RESEARCH

A7. Select the appropriate methodology description for this research. *Please tick all that apply:*

- [ ] Case series/ case note review
- [ ] Case control
- [ ] Cohort observation
- [ ] Controlled trial without randomisation
- [ ] Cross-sectional study
- [ ] Database analysis
- [ ] Epidemiology
- [ ] Feasibility/ pilot study
- [ ] Laboratory study
- [ ] Metanalysis
- [x] Qualitative research
- [x] Questionnaire, interview or observation study
- [ ] Randomised controlled trial
- [ ] Other (please specify)

A10. What is the principal research question/objective? *Please put this in language comprehensible to a lay person.*

The proposed investigation aims to extend existing understanding via an exploration of young peoples lived experience of admission to an adolescent inpatient unit with a specific focus on their relationships. It is posited that this research will contribute to the pre-existing evidence base by providing a qualitative perspective which aims to enhance and build upon the findings emerging from Haynes et al (2011) and Colton and Pistrang (2004) which appear to suggest that the relational aspects of this experience are significant.

A11. What are the secondary research questions/objectives if applicable? *Please put this in language comprehensible to a lay person.*

A12. What is the scientific justification for the research? *Please put this in language comprehensible to a lay person.*

There are a limited number of studies which aim to explore the experience of young people who are admitted to a adolescent mental health unit. The research which does exist focuses on specific patient groups (e.g. female adolescents with eating disorders) or provides a general overview of young peoples experiences. The pre-existing research indicates that the relational aspects of an inpatient admission are significant. Therefore, this research aims to provide a qualitative exploration of the experiences of young people in order to contribute to service delivery.

A13. Please summarise your design and methodology. *It should be clear exactly what will happen to the research participant, how many times and in what order. Please complete this section in language comprehensible to the lay person. Do not simply reproduce or refer to the protocol. Further guidance is available in the guidance notes.*

Young people will recruited to take part in this study from one of two [redacted] adolescent inpatient units.

Information regarding the research will be provided via advertisement posters displayed on the ward, the lead researchers attendance at community meetings and 1:1 psychology and nursing sessions.

Young people who are interested in taking part in the research will be provided with a participant information sheet and asked to complete a declaration of interest form. This completed form will be placed in a sealed envelope in a box kept on the ward.

The lead researcher will collect completed declaration of interest forms and consult with the care team to establish if the young people who have volunteered meet any of the exclusion criteria.

Not all young people will be selected to participate. A sample of young people will be selected in order to ensure that both wards are represented.

If a young person is over the age of 16 they will be asked to provide consent via the completion of a consent form. Young people under the age of 16 will be asked to complete an assent form and their parents / guardian will be asked to complete a parent / guardian consent form.

If a young person is selected to participate, arrangements will be made to carry out a 1:1 interview lasting approximately one hour. This interview will be recorded and typed up into an anonymised transcript for analysis. The care team will be consulted immediately prior to the interview in order to confirm that the young person does not meet any exclusion criteria. Interviews will take place in an appropriate private place in the hospital grounds. The location of the interview will depend on the assessment carried out by the care team in relation to risk.

A14-1. In which aspects of the research process have you actively involved, or will you involve, patients, service users, and/or their carers, or members of the public?

- [x] Design of the research
- [ ] Management of the research
- [ ] Undertaking the research
- [ ] Analysis of results
- [ ] Dissemination of findings
- [ ] None of the above

Give details of involvement, or if none please justify the absence of involvement.
Young people who were admitted to an inpatient unit in the [redacted] were consulted during the initial design stages of this piece of research. They provided guidance regarding the research question and gave their opinions regarding practical issues relating to recruitment.

4. RISKS AND ETHICAL ISSUES

RESEARCH PARTICIPANTS

A17-1. Please list the principal inclusion criteria (list the most important, max 5000 characters).

Any young person who has been admitted to the ward for 2 weeks or more will be eligible to take part in the research. Young people will be able to declare an interest in taking part in the investigation prior to this point but will not be interviewed until they have been on the ward for a fortnight or more.

A17-2. Please list the principal exclusion criteria (list the most important, max 5000 characters).

A young person will be deemed unfit to participate in the research if:

The care team feels that the young person is too unwell to participate or that the interview process is likely to have an adverse influence on their health or well being.
The young person has cognitive or communication difficulties that would hinder their ability to engage in a one to one interview.
A young person is unable to provide informed consent.
A young person would require a translator to enable them to participate in the interview.

RESEARCH PROCEDURES, RISKS AND BENEFITS

A18. Give details of all non-clinical intervention(s) or procedure(s) that will be received by participants as part of the research protocol. *These include seeking consent, interviews, non-clinical observations and use of questionnaires.*

Please complete the columns for each intervention/procedure as follows:

1. Total number of interventions/procedures to be received by each participant as part of the research protocol.
2. If this intervention/procedure would be routinely given to participants as part of their care outside the research, how many of the total would be routine?

3. Average time taken per intervention/procedure (minutes, hours or days)
4. Details of who will conduct the intervention/procedure, and where it will take place.

Intervention or procedure	1	2	3	4
Seeking consent / assent	1	0	15 mins	Rachael Ellis (Principal Investigator) will seek consent (from young people over 16 years old) and assent (from young people under 16 years). This process will take place in a private place on the unit or, if deemed appropriate by the care team, in an alternative private room on the hospital site.
Interview	1	0	60 mins	Interviews will be conducted by Rachael Ellis (Principal Investigator) in a private place on the unit, or if deemed appropriate by the care team, in an alternative private room on the hospital site.

A21. How long do you expect each participant to be in the study in total?

I expect that each participant will be in the study for approximately one day. Participants will be able to contact the principal investigator to withdraw their data from the investigation within 2 weeks of the interview taking place.

A22. What are the potential risks and burdens for research participants and how will you minimise them?

For all studies, describe any potential adverse effects, pain, discomfort, distress, intrusion, inconvenience or changes to lifestyle. Only describe risks or burdens that could occur as a result of participation in the research. Say what steps would be taken to minimise risks and burdens as far as possible.

Members of the care team will be asked to inform the researcher of any young people for whom participation in the research may be detrimental (e.g. due to current presentation or risk issues). If a young person is likely to be adversely effected by participating in the research they will be excluded from the research. Should a participant become distressed during the interview process they will be given the opportunity to end the interview or to take a break. If the researcher has concerns regarding the impact of the interview upon a participant, this information will be shared with the shift leader on the ward and discussed with a research supervisor. It is hoped that members of the care team will be available to support participants following completion of the research interview. Information regarding support agencies for young people will be provided on the Participant information sheet.

A23. Will interviews/ questionnaires or group discussions include topics that might be sensitive, embarrassing or upsetting, or is it possible that criminal or other disclosures requiring action could occur during the study?

(●) Yes ( ) No

If Yes, please give details of procedures in place to deal with these issues:

As this research will include questions regarding a young persons experience of admission to an inpatient psychiatric unit with specific reference to the relationships they have developed as a result of this experience, there is potential for participants to experience difficult emotions during the interview process. Should a participant become distressed during the interview process they will be given the opportunity to end the interview or to take a break. If the researcher has concerns regarding the impact of the interview upon a participant, this information will be shared with the shift leader on the ward and discussed with a research supervisor. It is hoped that members of the care team will be available to support participants following completion of the research interview. Information regarding support agencies for young people will be provided on the Participant information sheet.

A24. What is the potential for benefit to research participants?

Whilst participants may find taking part in this research interesting, there are no direct benefits associated with taking part.

A26. What are the potential risks for the researchers themselves? *(if any)*

The researcher will be conducting research in an inpatient setting. Therefore, it is necessary for the researcher to be aware of any potential risk issues associated with this setting and any specific concerns regarding the young people participating. As such, the researcher will ensure that regular contact is made with care staff in each recruitment locations and that risk assessments are up to date in order to ensure safe practice is maintained.

RECRUITMENT AND INFORMED CONSENT

In this section we ask you to describe the recruitment procedures for the study. Please give separate details for different study groups where appropriate.

A27-1. How will potential participants, records or samples be identified? Who will carry this out and what resources will be used? *For example, identification may involve a disease register, computerised search of GP records, or review of medical records. Indicate whether this will be done by the direct healthcare team or by researchers acting under arrangements with the responsible care organisation(s).*

All young people staying on the units at the two recruitment sites will be provided with information regarding the study (either via advertisment posters, the lead researchers attendance at community meetings or in 1:1 nursing or psychology sessions). This will include the provision of participant information sheets and declaration of interest forms.

Young people will then volunteer to participate via completion of the declaration of interest form.

The lead researcher will consult the care team regarding young people who have volunteered to participate in order to establish if they meet any exclusion criteria.

If the young people do not meet any exclusion criteria, they will be entered into a pool of participants and 6 - 8 young people who represent both of the recruitment sites will be contacted to arrange an interview.

Consent will be sought directly from young people over the age of 16 and assent will be sought from those under 16 in addition to consent being provided by their parent / guardian.

Both parents / carers of children under the age of 16 and young people will be provided with Participant Information Sheets and given the opportunity to ask questions about the process.

A27-2. Will the identification of potential participants involve reviewing or screening the identifiable personal information of patients, service users or any other person?

○ Yes ◉ No

Please give details below:

A28. Will any participants be recruited by publicity through posters, leaflets, adverts or websites?

◉ Yes ○ No

If Yes, please give details of how and where publicity will be conducted, and enclose copy of all advertising material (with version numbers and dates).

Posters will be displayed in communal areas on each participating unit. The principal researcher will also attend community meetings in order to provide information regarding the research project and to provide young people with participant information sheets.

A29. How and by whom will potential participants first be approached?

The principal researcher will attend community meetings in order to provide information regarding the project. The research will also be publicised utilising posters displayed in communal areas. Young people will also be provided with information regarding the project via the care team.

A30-1. Will you obtain informed consent from or on behalf of research participants?

◉ Yes ○ No

If you will be obtaining consent from adult participants, please give details of who will take consent and how it will be done, with details of any steps to provide information (a written information sheet, videos, or interactive material). Arrangements for adults unable to consent for themselves should be described separately in Part B Section 6, and for *children in Part B Section 7.*

If you plan to seek informed consent from vulnerable groups, say how you will ensure that consent is voluntary and fully informed.

Participants over the aged of 16 will be asked to confirm that they consent to taking part via the completion of a consent form. Young people under the age of 16 will complete an assent form and their parent or guardian will be provided with a parent / guardian information sheet and asked to complete a parent / guardian consent form.

If you are not obtaining consent, please explain why not.

Please enclose a copy of the information sheet(s) and consent form (s).

A30-2. Will you record informed consent (or advice from consultees) in writing?

◉ Yes ◯ No

A31. How long will you allow potential participants to decide whether or not to take part?

Participants will not be allowed to volunteer to participate until they have been in receipt of the relevant information, via provision of a participant information sheet, for more than 24 hours.

A33-1. What arrangements have been made for persons who might not adequately understand verbal explanations or written information given in English, or who have special communication needs? *(e.g. translation, use of interpreters)*

Due to the financial and practical constraints associated with this study, provision will not be made for young people who do not speak English or who have significant communication difficulties to participate in the study. This exclusion criteria has been used as it assumed that young people who do not speak English or have communication difficulties will have a considerably different experience of their admission and that the quality of the relationships with both staff and peers will be affected by this barrier to communication.

A35. What steps would you take if a participant, who has given informed consent, loses capacity to consent during the study? *Tick one option only.*

◯ The participant and all identifiable data or tissue collected would be withdrawn from the study. Data or tissue which is not identifiable to the research team may be retained.

◯ The participant would be withdrawn from the study. Identifiable data or tissue already collected with consent would be retained and used in the study. No further data or tissue would be collected or any other research procedures carried out on or in relation to the participant.

◯ The participant would continue to be included in the study.

◯ Not applicable – informed consent will not be sought from any participants in this research.

◉ Not applicable – it is not practicable for the research team to monitor capacity and continued capacity will be assumed.

Further details:

CONFIDENTIALITY

In this section, personal data means any data relating to a participant who could potentially be identified. It includes pseudonymised data capable of being linked to a participant through a unique code number.

Storage and use of personal data during the study

A36. Will you be undertaking any of the following activities at any stage (including in the identification of potential participants)? *(Tick as appropriate)*

- [ ] Access to medical records by those outside the direct healthcare team
- [ ] Electronic transfer by magnetic or optical media, email or computer networks
- [ ] Sharing of personal data with other organisations
- [ ] Export of personal data outside the EEA
- [ ] Use of personal addresses, postcodes, faxes, emails or telephone numbers
- [x] Publication of direct quotations from respondents
- [ ] Publication of data that might allow identification of individuals
- [x] Use of audio/visual recording devices
- [ ] Storage of personal data on any of the following:
  - [ ] Manual files including X-rays
  - [ ] NHS computers
  - [ ] Home or other personal computers
  - [x] University computers
  - [ ] Private company computers
  - [ ] Laptop computers

Further details:
The interview will be audio recorded. If possible, the digital recorder will be encrypted. Should this not be possible, any identifiable data will be transferred to an encrypted, password protected computer as soon as is practicably possible and the original recording will be deleted. Audio recordings will be deleted following completion of the study. The data will then be transcribed and anonymised by the chief investigator. Anonymised transcripts will be saved on a encrypted, password protected file on a secure computer.

Anonymised transcripts and completed consent forms will be scanned electronically and stored on a password protected, encrypted file space on the University server, the contents of which will be deleted 10 years after the project has been completed. Storage and deletion of this material will be the responsibility of the Research Coordinator (Doctorate in Clinical Psychology, Lancaster University).

Anonymised quotations will be utilised in the final research and any subsequent publications. Participants will be made aware that direct quotations will be used and that these will be anonymised in order to ensure that they will not be identifiable from these quotes.

A38. How will you ensure the confidentiality of personal data? *Please provide a general statement of the policy and procedures for ensuring confidentiality, e.g. anonymisation or pseudonymisation of data.*

In order to maintain confidentiality of personal data pseudonyms will be assigned for each participants and all identifying information, including that relating to the identification of the service, will be removed from transcripts and the resulting final research.

A40. Who will have access to participants' personal data during the study? *Where access is by individuals outside the direct care team, please justify and say whether consent will be sought.*

Nobody outside the direct care team will have access to participants personal data during the study.

Storage and use of data after the end of the study

A43. How long will personal data be stored or accessed after the study has ended?

- (•) Less than 3 months
- ( ) 3 – 6 months
- ( ) 6 – 12 months
- ( ) 12 months – 3 years

◯ Over 3 years

INCENTIVES AND PAYMENTS

A46. Will research participants receive any payments, reimbursement of expenses or any other benefits or incentives for taking part in this research?

◯ Yes ◉ No

A47. Will individual researchers receive any personal payment over and above normal salary, or any other benefits or incentives, for taking part in this research?

◯ Yes ◉ No

A48. Does the Chief Investigator or any other investigator/collaborator have any direct personal involvement (e.g. financial, share holding, personal relationship etc.) in the organisations sponsoring or funding the research that may give rise to a possible conflict of interest?

◯ Yes ◉ No

NOTIFICATION OF OTHER PROFESSIONALS

A49-1. Will you inform the participants' General Practitioners (and/or any other health or care professional responsible for their care) that they are taking part in the study?

◯ Yes ◉ No

If Yes, please enclose a copy of the information sheet/letter for the GP/health professional with a version number and date.

PUBLICATION AND DISSEMINATION

A50. Will the research be registered on a public database?

◯ Yes ◉ No

Please give details, or justify if not registering the research.

Registration of research studies is encouraged wherever possible.
You may be able to register your study through your NHS organisation or a register run by a medical research charity, or publish your protocol through an open access publisher. If you are aware of a suitable register or other method of publication, please give details. If not, you may indicate that no suitable register exists. Please ensure that you have entered registry reference number(s) in question A5-1.

A51. How do you intend to report and disseminate the results of the study? *Tick as appropriate:*

- [x] Peer reviewed scientific journals
- [ ] Internal report
- [x] Conference presentation
- [ ] Publication on website
- [ ] Other publication

☐ Submission to regulatory authorities

☐ Access to raw data and right to publish freely by all investigators in study or by Independent Steering Committee on behalf of all investigators

☐ No plans to report or disseminate the results

☑ Other (please specify)

There is potential for the results of this investigation to be disseminated via a range of avenues:
- Publication in a peer reviewed journal
- Presentation of research at Lancaster University
- Presentation at relevant conferences
- Sharing of results with participants
- Sharing of results with recruitment sites
- Sharing of results with service user groups

A53. Will you inform participants of the results?

○ Yes ◉ No

Please give details of how you will inform participants or justify if not doing so.

The young people who participate in this research will not be contacted directly by the researcher with the results of the project as they will not be asked to provide their contact details and will no longer have contact with the service by the time the results are published. However, the results of this research will be disseminated via a range of alternative avenues as described above.

5. Scientific and Statistical Review

A54. How has the scientific quality of the research been assessed? *Tick as appropriate:*

☐ Independent external review

☐ Review within a company

☐ Review within a multi-centre research group

☑ Review within the Chief Investigator's institution or host organisation

☐ Review within the research team

☑ Review by educational supervisor

☐ Other

Justify and describe the review process and outcome. If the review has been undertaken but not seen by the researcher, give details of the body which has undertaken the review:

This project has been subjected to review within the Department of Clinical Psychology, Lancaster University and has been supervised by Academic Supervisor, Dr Ian Smith.

For all studies except non-doctoral student research, please enclose a copy of any available scientific critique reports, together with any related correspondence.

For non-doctoral student research, please enclose a copy of the assessment from your educational supervisor/ institution.

A59. What is the sample size for the research? *How many participants/samples/data records do you plan to study in total? If there is more than one group, please give further details below.*

Total UK sample size:	8
Total international sample size (including UK):	8
Total in European Economic Area:	0

Further details:

Up to 8 participants will be recruited for this investigation.

A60. How was the sample size decided upon? *If a formal sample size calculation was used, indicate how this was done,* *giving sufficient information to justify and reproduce the calculation.*

Interpretative Phenomenological Analysis (IPA) studies are conducted with relatively small sample sizes in order to allow for a detailed exploration of participants experiences, perceptions and understanding.

Up to eight participants will be recruited for this investigation. The number of participants recruited will partially rely upon the richness of the data collected.

It is anticipated that by recruiting up to eight participants, analysis will allow for an in depth exploration as well as the examination of similarities and differences.

A62. Please describe the methods of analysis (statistical or other appropriate methods, e.g. for qualitative research) by which the data will be evaluated to meet the study objectives.

The data collected will be analysed using Interpretative Phenomenological Analysis (IPA). This approach aims to explore how people make sense of their experiences via the analysis of detailed first person accounts (Larkin & Thompson, 2012). The researcher aims to understand the meanings that are made by participants by gathering information about the ways in which they relate to the world. In order to do this effectively, it is essential that the researcher considered their own experiences and assumptions and reflects upon their role in the development of interpretations. A reflective research journal will be used alongside supervision in order to facilitate the process of analysis. Thematic validity will be checked via supervision with research supervisors.

6. MANAGEMENT OF THE RESEARCH

A63. Other key investigators/collaborators. *Please include all grant co-applicants, protocol co-authors and other key members of the Chief Investigator's team, including non-doctoral student researchers.*

[redacted]

A64. Details of research sponsor(s)

A64-1. Sponsor

Lead Sponsor

Status:
- ( ) NHS or HSC care organisation
- (•) Academic
- ( ) Pharmaceutical industry
- ( ) Medical device industry

Commercial status:

○ Local Authority
○ Other social care provider (including voluntary sector or private organisation)
○ Other

If Other, please specify:

Contact person

Name of organisation	Lancaster University
Given name	Debbie
Family name	Knight
Address	Research Support Office, B58 Bowland Main, Lancaster University
Town/city	Lancaster
Post code	LA1 4YT
Country	UNITED KINGDOM
Telephone	01524592605
Fax	
E-mail	ethics@lancaster.ac.uk

Is the sponsor based outside the UK?
○ Yes ◉ No

Under the Research Governance Framework for Health and Social Care, a sponsor outside the UK must appoint a legal representative established in the UK. Please consult the guidance notes.

A65. Has external funding for the research been secured?

☐ Funding secured from one or more funders
☐ External funding application to one or more funders in progress
☑ No application for external funding will be made

What type of research project is this?

◉ Standalone project
○ Project that is part of a programme grant
○ Project that is part of a Centre grant
○ Project that is part of a fellowship/ personal award/ research training award
○ Other

Other – please state:

A67. Has this or a similar application been previously rejected by a Research Ethics Committee in the UK or another country?

○ Yes ◉ No

Please provide a copy of the unfavourable opinion letter(s). You should explain in your answer to question A6-2 how the reasons for the unfavourable opinion have been addressed in this application.

A68-1. Give details of the lead NHS R&D contact for this research:

[redacted]

Details can be obtained from the NHS R&D Forum website: http://www.rdforum.nhs.uk

A69-1. How long do you expect the study to last in the UK?

Planned start date: 01/07/2014
Planned end date: 29/05/2015
Total duration:
Years: 0 Months: 10 Days: 29

A71-2. Where will the research take place? *(Tick as appropriate)*

- [x] England
- [ ] Scotland
- [ ] Wales
- [ ] Northern Ireland
- [ ] Other countries in European Economic Area

Total UK sites in study 2

Does this trial involve countries outside the EU?
○ Yes ◉ No

A72. What host organisations (NHS or other) in the UK will be responsible for the research sites? *Please indicate the type of organisation by ticking the box and give approximate numbers of planned research sites:*

- [x] NHS organisations in England 2
- [ ] NHS organisations in Wales
- [ ] NHS organisations in Scotland
- [ ] HSC organisations in Northern Ireland
- [ ] GP practices in England
- [ ] GP practices in Wales
- [ ] GP practices in Scotland
- [ ] GP practices in Northern Ireland
- [ ] Social care organisations
- [ ] Phase 1 trial units
- [ ] Prison establishments
- [ ] Probation areas

- [ ] Independent hospitals
- [ ] Educational establishments
- [ ] Independent research units
- [ ] Other (give details)

Total UK sites in study: 2

A76. Insurance/indemnity to meet potential legal liabilities

Note: in this question to NHS indemnity schemes include equivalent schemes provided by Health and Social Care (HSC) in Northern Ireland

A76-1. What arrangements will be made for insurance and/or indemnity to meet the potential legal liability of the sponsor(s) for harm to participants arising from the management of the research? *Please tick box(es) as applicable.*

Note: Where a NHS organisation has agreed to act as sponsor or co-sponsor, indemnity is provided through NHS schemes. Indicate if this applies (there is no need to provide documentary evidence). For all other sponsors, please describe the arrangements and provide evidence.

- [ ] NHS indemnity scheme will apply (NHS sponsors only)
- [x] Other insurance or indemnity arrangements will apply (give details below)

Lancaster University legal liability cover will apply

Please enclose a copy of relevant documents.

A76-2. What arrangements will be made for insurance and/ or indemnity to meet the potential legal liability of the sponsor(s) or employer(s) for harm to participants arising from the design of the research? *Please tick box(es) as applicable.*

Note: Where researchers with substantive NHS employment contracts have designed the research, indemnity is provided through NHS schemes. Indicate if this applies (there is no need to provide documentary evidence). For other protocol authors (e.g. company employees, university members), please describe the arrangements and provide evidence.

- [ ] NHS indemnity scheme will apply (protocol authors with NHS contracts only)
- [x] Other insurance or indemnity arrangements will apply (give details below)

Lancaster University legal liability cover will apply

Please enclose a copy of relevant documents.

A76-3. What arrangements will be made for insurance and/ or indemnity to meet the potential legal liability of investigators/collaborators arising from harm to participants in the conduct of the research?

Note: Where the participants are NHS patients, indemnity is provided through the NHS schemes or through professional indemnity. Indicate if this applies to the whole study (there is no need to provide documentary evidence). Where non-NHS sites are to be included in the research, including private practices, please describe the arrangements which will be made at these sites and provide evidence.

- [x] NHS indemnity scheme or professional indemnity will apply (participants recruited at NHS sites only)
- [ ] Research includes non-NHS sites (give details of insurance / indemnity arrangements for these sites below)

Please enclose a copy of relevant documents.

PART B: Section 7 - Children

1. Please specify the potential age range of children under 16 who will be included and give reasons for carrying out the research in this age group.

Young people aged between 13 and 18 years will be eligible to take part in this research as this is the age range of young people who can access adolescent inpatient services.

2. Indicate whether any children under 16 will be recruited as controls and give further details.

No children under the age of 16 will be recruited as controls.

3-2. Please describe the arrangements for seeking informed consent from a person with parental responsibility and/or from children able to give consent for themselves.

Potential participants over the age of 16 who are deemed fit to participate in the study will be approached to arrange a suitable time for the interview to take place. Any potential participants under the age of 16 who are deemed fit to participate in the study will be informed that their parent or guardian will be approached in order to seek consent to participate. If this is acceptable and the young person wishes to proceed, parental consent will be sought prior to any further arrangements being made.

Participants over the aged of 16 will be asked to confirm that they consent to taking part via the completion of a consent form. Consent forms will be completed just prior to the interview. Young people under the age of 16 will complete an assent form and their parent or guardian will be provided with a parent / guardian information sheet and asked to complete a parent / guardian consent form.

4. If you intend to provide children under 16 with information about the research and seek their consent or agreement, please outline how this process will vary according to their age and level of understanding.

All young people will be provided with a participant information sheet which has been adapted in order to make it accessible for young people. The lead researcher will ensure that young people participating in the research understand the information provided on the participant information sheet and the consent form. Young people will be provided the opportunity to ask questions regarding the information provided.

Copies of written information sheet(s) for parents and children, consent/assent form (s) and any other explanatory material should be enclosed with the application.

PART C: Overview of research sites

Please enter details of the host organisations (Local Authority, NHS or other) in the UK that will be responsible for the research sites. *For NHS sites, the host organisation is the Trust or Health Board. Where the research site is a primary care site, e.g. GP practice, please insert the host organisation (PCT or Health Board) in the Institution row and insert the research site (e.g. GP practice) in the Department row.*

Research site		Investigator/ Collaborator/ Contact	
Institution name	[redacted]	Title	[redacted]
Department name	[redacted]	First name/ Initials	[redacted]
Street address	[redacted]	Surname	[redacted]
Town/city	[redacted]		
Post Code	[redacted]		
Institution name	[redacted]	Title	[redacted]
Department name	[redacted]	First name/ Initials	[redacted]
Street address	[redacted]	Surname	[redacted]
Town/city	[redacted]		
Post Code	[redacted]		

PART D: Declarations

D1. Declaration by Chief Investigator

1. The information in this form is accurate to the best of my knowledge and belief and I take full responsibility for it.
2. I undertake to abide by the ethical principles underlying the Declaration of Helsinki and good practice guidelines on the proper conduct of research.
3. If the research is approved I undertake to adhere to the study protocol, the terms of the full application as approved and any conditions set out by review bodies in giving approval.
4. I undertake to notify review bodies of substantial amendments to the protocol or the terms of the approved application, and to seek a favourable opinion from the main REC before implementing the amendment.
5. I undertake to submit annual progress reports setting out the progress of the research, as required by review bodies.
6. I am aware of my responsibility to be up to date and comply with the requirements of the law and relevant guidelines relating to security and confidentiality of patient or other personal data, including the need to register when necessary with the appropriate Data Protection Officer. I understand that I am not permitted to disclose identifiable data to third parties unless the disclosure has the consent of the data subject or, in the case of patient data in England and Wales, the disclosure is covered by the terms of an approval under Section 251 of the NHS Act 2006.
7. I understand that research records/data may be subject to inspection by review bodies for audit purposes if required.
8. I understand that any personal data in this application will be held by review bodies and their operational managers and that this will be managed according to the principles established in the Data Protection Act 1998.
9. I understand that the information contained in this application, any supporting documentation and all correspondence with review bodies or their operational managers relating to the application:
   - Will be held by the REC (where applicable) until at least 3 years after the end of the study; and by NHS R&D offices (where the research requires NHS management permission) in accordance with the NHS Code of Practice on Records Management.
   - May be disclosed to the operational managers of review bodies, or the appointing authority for the REC (where applicable), in order to check that the application has been processed correctly or to investigate any complaint.
   - May be seen by auditors appointed to undertake accreditation of RECs (where applicable).
   - Will be subject to the provisions of the Freedom of Information Acts and may be disclosed in response to requests made under the Acts except where statutory exemptions apply.
   - May be sent by email to REC members.
10. I understand that information relating to this research, including the contact details on this application, may be held on national research information systems, and that this will be managed according to the principles established in the Data Protection Act 1998.
11. Where the research is reviewed by a REC within the UK Health Departments Research Ethics Service, I understand that the summary of this study will be published on the website of the National Research Ethics Service (NRES), together with the contact point for enquiries named below. Publication will take place no earlier than 3 months after issue of the ethics committee's final opinion or the withdrawal of the application.

Contact point for publication *(Not applicable for R&D Forms)*

NRES would like to include a contact point with the published summary of the study for those wishing to seek further information. We would be grateful if you would indicate one of the contact points below.

- (●) Chief Investigator
- ( ) Sponsor

- ◯ Studyco-ordinator
- ◯ Student
- ◯ Other – please give details
- ◯ None

Access to application for training purposes *(Not applicable for R&D Forms)*
Optional – please tick as appropriate:

☑ I would be content for members of other RECs to have access to the information in the application in confidence for training purposes. All personal identifiers and references to sponsors, funders and research units would be removed.

This section was signed electronically by Miss Rachael Ellis on 20/06/2014 15:56.

Job Title/Post:	Trainee Clinical Psychologist
Organisation:	Lancashire Care NHS Foundation Trust
Email:	r.ellis2@lancaster.ac.uk
Signature:	....
Print Name:	Rachael Ellis
Date:	13/06/2014 *(dd/mm/yyyy)*

D2. Declaration by the sponsor's representative

If there is more than one sponsor, this declaration should be signed on behalf of the co-sponsors by a representative of the lead sponsor named at A64-1.

I confirm that:

1. This research proposal has been discussed with the Chief Investigator and agreement in principle to sponsor the research is in place.
2. An appropriate process of scientific critique has demonstrated that this research proposal is worthwhile and of high scientific quality.
3. Any necessary indemnity or insurance arrangements, as described in question A76, will be in place before this research starts. Insurance or indemnity policies will be renewed for the duration of the study where necessary.
4. Arrangements will be in place before the study starts for the research team to access resources and support to deliver the research as proposed.
5. Arrangements to allocate responsibilities for the management, monitoring and reporting of the research will be in place before the research starts.
6. The duties of sponsors set out in the Research Governance Framework for Health and Social Care will be undertaken in relation to this research.
7. Where the research is reviewed by a REC within the UK Health Departments Research Ethics Service, I understand that the summary of this study will be published on the website of the National Research Ethics Service (NRES), together with the contact point for enquiries named in this application. Publication will take place no earlier than 3 months after issue of the ethics committee's final opinion or the withdrawal of the application.

This section was signed electronically by An authorised approver at ethics@lancaster.ac.uk on 23/06/2014 09:27.

Job Title/Post:	Research Support Officer
Organisation:	Lancaster University
Email:	s.c.taylor@lancaster.ac.uk

D3. Declaration for student projects by academic supervisor(s)

1. I have read and approved both the research proposal and this application. I am satisfied that the scientific content of the research is satisfactory for an educational qualification at this level.

2. I undertake to fulfil the responsibilities of the supervisor for this study as set out in the Research Governance Framework for Health and Social Care.

3. I take responsibility for ensuring that this study is conducted in accordance with the ethical principles underlying the Declaration of Helsinki and good practice guidelines on the proper conduct of research, in conjunction with clinical supervisors as appropriate.

4. I take responsibility for ensuring that the applicant is up to date and complies with the requirements of the law and relevant guidelines relating to security and confidentiality of patient and other personal data, in conjunction with clinical supervisors as appropriate.

Academic supervisor 1

This section was signed electronically by Dr Ian Smith on 20/06/2014 17:54.

Job Title/Post:	Lecturer in Research Methods
Organisation:	Lancaster University
Email:	i.

Appendix K: Research and Development (R&D) Form

Welcome to the Integrated Research Application System

IRAS Project Filter

The integrated dataset required for your project will be created from the answers you give to the following questions. The system will generate only those questions and sections which (a) apply to your study type and (b) are required by the bodies reviewing your study. Please ensure you answer all the questions before proceeding with your applications.

Please enter a short title for this project (maximum 70 characters)
Young People's Lived Experience of Admission to an Inpatient Unit

1. Is your project research?

◉ Yes ○ No

2. Select one category from the list below:

○ Clinical trial of an investigational medicinal product

○ Clinical investigation or other study of a medical device

○ Combined trial of an investigational medicinal product and an investigational medical device

○ Other clinical trial to study a novel intervention or randomised clinical trial to compare interventions in clinical practice

○ Basic science study involving procedures with human participants

○ Study administering questionnaires/interviews for quantitative analysis, or using mixed quantitative/qualitative methodology

◉ Study involving qualitative methods only

○ Study limited to working with human tissue samples (or other human biological samples) and data (specific project only)

○ Study limited to working with data (specific project only)

○ Research tissue bank

○ Research database

If your work does not fit any of these categories, select the option below:

○ Other study

2a. Please answer the following question(s):

a) Does the study involve the use of any ionising radiation?	○ Yes	◉ No
b) Will you be taking new human tissue samples (or other human biological samples)?	○ Yes	◉ No
c) Will you be using existing human tissue samples (or other human biological samples)?	○ Yes	◉ No

3. In which countries of the UK will the research sites be located? *(Tick all that apply)*

☑ England
☐ Scotland
☐ Wales
☐ Northern Ireland

3a. In which country of the UK will the lead NHS R&D office be located:

(•) England
( ) Scotland
( ) Wales
( ) Northern Ireland
( ) This study does not involve the NHS

4. Which review bodies are you applying to?

[x] NHS/HSC Research and Development offices
[ ] Social Care Research Ethics Committee
[x] Research Ethics Committee
[ ] National Information Governance Board for Health and Social Care (NIGB)
[ ] National Offender Management Service (NOMS) (Prisons & Probation)

For NHS/HSC R&D offices, the CI must create Site-Specific Information Forms for each site, in addition to the study-wide forms, and transfer them to the PIs or local collaborators.

5. Will any research sites in this study be NHS organisations?

(•) Yes ( ) No

5a. Are all the research costs and infrastructure costs for this study provided by an NIHR Biomedical Research Centre, NIHR Biomedical Research Unit, NIHR Collaboration for Leadership in Health Research and Care (CLAHRC) or NIHR Research Centre for Patient Safety & Service Quality in all study sites?

( ) Yes (•) No

If yes, NHS permission for your study will be processed through the NIHR Coordinated System for gaining NHS Permission (NIHR CSP).

5b. Do you wish to make an application for the study to be considered for NIHR Clinical Research Network (CRN) support and inclusion in the NIHR Clinical Research Network (CRN) Portfolio? Please see information button for further details.

( ) Yes (•) No

If yes, NHS permission for your study will be processed through the NIHR Coordinated System for gaining NHS Permission (NIHR CSP) and you must complete a NIHR Clinical Research Network (CRN) Portfolio Application Form immediately after completing this project filter and before completing and submitting other applications.

6. Do you plan to include any participants who are children?

(•) Yes ( ) No

7. Do you plan at any stage of the project to undertake intrusive research involving adults lacking capacity to consent for themselves?

( ) Yes (•) No

Answer Yes if you plan to recruit living participants aged 16 or over who lack capacity, or to retain them in the study following loss of capacity. Intrusive research means any research with the living requiring consent in law. This includes use of identifiable tissue samples or personal information, except where application is being made to the NIGB Ethics and Confidentiality Committee to set aside the common law duty of confidentiality in England and Wales. Please consult the guidance notes for further information on the legal frameworks for research involving adults lacking capacity in the UK.

8. Do you plan to include any participants who are prisoners or young offenders in the custody of HM Prison Service or who are offenders supervised by the probation service in England or Wales?

○ Yes ◉ No

9. Is the study or any part of it being undertaken as an educational project?

◉ Yes ○ No

Please describe briefly the involvement of the student(s):
The Principal Investigator (Rachael Ellis) is currently a Trainee on the Lancaster University Doctorate in Clinical Psychology (DClinPsy). This research will form part of her thesis.

9a. Is the project being undertaken in part fulfilment of a PhD or other doctorate?

◉ Yes ○ No

10. Will this research be financially supported by the United States Department of Health and Human Services or any of its divisions, agencies or programs?

○ Yes ◉ No

11. Will identifiable patient data be accessed outside the care team without prior consent at any stage of the project (including identification of potential participants)?

○ Yes ◉ No

Integrated Research Application System
Application Form for Research involving qualitative methods only

NHS/HSC R&D Form (project information)

Please refer to the Submission and Checklist tabs for instructions on submitting R&D applications.

The Chief Investigator should complete this form. Guidance on the questions is available wherever you see this symbol displayed. We recommend reading the guidance first. The complete guidance and a glossary are available by selecting Help.

Please define any terms or acronyms that might not be familar to lay reviewers of the application.

Short title and version number: (maximum 70 characters - this will be inserted as header on all forms)
Young People's Lived Experience of Admission to an Inpatient Unit

PART A: Core study information

1. ADMINISTRATIVE DETAILS

A1. Full title of the research:

What is the lived experience of young people during their admission to a psychiatric inpatient unit?

A2-1. Educational projects

Name and contact details of student(s):

Student 1

	Title	Forename/Initials	Surname
	Miss	Rachael	Ellis
Address	8 Woodstock Avenue		
	Newton-le-Willows		
	St Helens		
Post Code	WA12 8PR		
E-mail	r.ellis2@lancaster.ac.uk		
Telephone	07736319031		
Fax			

Give details of the educational course or degree for which this research is being undertaken:

Name and level of course/ degree:
Doctorate in Clinical Psychology

Name of educational establishment:
Lancaster University

Name and contact details of academic supervisor(s):

Academic supervisor 1

	Title	Forename/Initials	Surname
	Dr	Ian	Smith
Address	Clinical Psychology Faculty of Health and Medicine, Floor C Furness College, Lancaster University, Lancaster		
Post Code	LA1 4YG		
E-mail	i.smith@lancaster.ac.uk		
Telephone	01524595282		
Fax			

Please state which academic supervisor(s) has responsibility for which student(s):
Please click "Save now" before completing this table. This will ensure that all of the student and academic supervisor details are shown correctly.

Student(s)	**Academic supervisor(s)**
Student 1 Miss Rachael Ellis	☑ Dr Ian Smith

A copy of a current CV for the student and the academic supervisor (maximum 2 pages of A4) must be submitted with the application.

A2-2. Who will act as Chief Investigator for this study?

- (●) Student
- ( ) Academic supervisor
- ( ) Other

A3-1. Chief Investigator:

	Title	Forename/Initials	Surname
	Miss	Rachael	Ellis
Post	Trainee Clinical Psychologist		
Qualifications	BSc Psychology MSc Psychology PG Cert in Low Intensity Therapies		
Employer	Lancashire Care NHS Trust		
Work Address	Clinical Psychology,Faculty of Health and Medicine Floor C, Furness College, Lancaster University Lancaster		
Post Code	LA1 4YG		
Work E-mail	r.ellis2@lancaster.ac.uk		
* Personal E-mail			
Work Telephone			
* Personal Telephone/Mobile	07736319031		
Fax			

** This information is optional. It will not be placed in the public domain or disclosed to any other third party without prior consent.*
A copy of a current CV (maximum 2 pages of A4) for the Chief Investigator must be submitted with the application.

A4. Who is the contact on behalf of the sponsor for all correspondence relating to applications for this project?

This contact will receive copies of all correspondence from REC and R&D reviewers that is sent to the CI.

	Title	Forename/Initials	Surname
	Mrs	Debbie	Knight
Address	Research Support Office		
	B58 Bowland Main		
	Lancaster University		
Post Code	LA1 4YT		
E-mail	ethics@lancaster.ac.uk		
Telephone	01524592605		
Fax			

A5-1. Research reference numbers. *Please give any relevant references for your study:*

Applicant's/organisation's own reference number, e.g. R & D (if available):

Sponsor's/protocol number:

Protocol Version:

Protocol Date:

Funder's reference number:

Project website:

Additional reference number(s):

Ref.Number Description	Reference Number

Registration of research studies is encouraged wherever possible. You may be able to register your study through your NHS organisation or a register run by a medical research charity, or publish your protocol through an open access publisher. If you have registered your study please give details in the "Additional reference number(s)" section.

A5-2. Is this application linked to a previous study or another current application?

○ Yes ◉ No

Please give brief details and reference numbers.

2. OVERVIEW OF THE RESEARCH

To provide all the information required by review bodies and research information systems, we ask a number of specific questions. This section invites you to give an overview using language comprehensible to lay reviewers and members of the public. Please read the guidance notes for advice on this section.

A6-1. Summary of the study. *Please provide a brief summary of the research (maximum 300 words) using language easily understood by lay reviewers and members of the public. Where the research is reviewed by a REC within the UK Health Departments Research Ethics Service, this summary will be published on the website of the National Research Ethics Service following the ethical review.*

This research aims to contribute to our understanding of the experiences of young people who are admitted to adolescent mental health wards for assessment or treatment of a mental health problem. Young people who are recruited to take part in this study will be asked about their experiences with specific reference to the relationships they may have developed with other young people and members of their care team. It is hoped that this research will help us to better understand how the development of peer and therapeutic relationships can contribute to the effective provision of inpatient care.

A6-2. Summary of main issues. *Please summarise the main ethical, legal, or management issues arising from your study and say how you have addressed them.*

Not all studies raise significant issues. Some studies may have straightforward ethical or other issues that can be identified and managed routinely. Others may present significant issues requiring further consideration by a REC, R&D office or other review body (as appropriate to the issue). Studies that present a minimal risk to participants may raise complex organisational or legal issues. You should try to consider all the types of issues that the different reviewers may need to consider.

Informed consent – Young people over the age of 16 will not be able to take part in this research if they are unable to give consent to participate. Capacity to consent will be assessed by the care team (Mental Capacity Act, 2005). Young people under the age of 16 will need the consent of their parent or guardian in order to participate.

Confidentiality and Anonymity – It is acknowledged that, due to the setting in which this research is taking place and the necessary liaison with the clinical team, the ward staff will be aware of who is participating in the research. However, attempts have been made to ensure that confidentiality is safeguarded as far as possible as the researcher will not have access to information about any young person unless they have expressed an interest to participate in the study. The researcher will ensure that any identifying information is removed from quotations featuring in the final piece of work in order to protect participant's identity as far as possible. Young people will be provided with information regarding anonymity and confidentiality via the participant information sheet and consent form.

Negative or distressing impact of interviews – Members of the care team will be asked to inform the researcher of any young people for whom participation in the research may be detrimental (e.g. due to current presentation or risk issues). These young people will not be selected to participate as they will meet the exclusion criteria. Should a participant become distressed during the interview process they will be given the opportunity to end the interview or to take a break. If the researcher has concerns regarding the impact of the interview upon a participant, this information will be shared with the shift leader on the ward and discussed with a research supervisor. Members of the care team will be available to support participants following completion of the research interview. Information regarding support agencies for young people will be provided on the Participant information sheet.

Potential disclosure(s) made in interview which lead to concern with regard to service user or staff safety, or staff negative practice – It is recognised that it may be necessary for the researcher to breach confidentiality if it is suggested that the safety of the participants or others may be compromised. Should this issue arise the researcher will contact the field supervisor / university supervisor in order to discuss the best course of action. If appropriate, young people who have disclosed any concerning information would be notified that it is necessary to breach confidentiality. Participants will be reminded of these limits of confidentiality prior to the start of the interview.

3. PURPOSE AND DESIGN OF THE RESEARCH

A7. Select the appropriate methodology description for this research. *Please tick all that apply*:

- [ ] Case series/ case note review
- [ ] Case control
- [ ] Cohort observation
- [ ] Controlled trial without randomisation
- [ ] Cross-sectional study
- [ ] Database analysis
- [ ] Epidemiology
- [ ] Feasibility/ pilot study
- [ ] Laboratory study
- [ ] Metanalysis
- [x] Qualitative research
- [x] Questionnaire, interview or observation study
- [ ] Randomised controlled trial
- [ ] Other (please specify)

A10. What is the principal research question/objective? *Please put this in language comprehensible to a lay person.*

The proposed investigation aims to extend existing understanding via an exploration of young peoples lived experience of admission to an adolescent inpatient unit with a specific focus on their relationships. It is posited that this research will contribute to the pre-existing evidence base by providing a qualitative perspective which aims to enhance and build upon the findings emerging from Haynes et al (2011) and Colton and Pistrang (2004) which appear to suggest that the relational aspects of this experience are significant.

A11. What are the secondary research questions/objectives if applicable? *Please put this in language comprehensible to a lay person.*

A12. What is the scientific justification for the research? *Please put this in language comprehensible to a lay person.*

There are a limited number of studies which aim to explore the experience of young people who are admitted to a adolescent mental health unit. The research which does exist focuses on specific patient groups (e.g. female adolescents with eating disorders) or provides a general overview of young peoples experiences. The pre-existing research indicates that the relational aspects of an inpatient admission are significant. Therefore, this research aims to provide a qualitative exploration of the experiences of young people in order to contribute to service delivery.

A13. Please summarise your design and methodology. *It should be clear exactly what will happen to the research participant, how many times and in what order. Please complete this section in language comprehensible to the lay person. Do not simply reproduce or refer to the protocol. Further guidance is available in the guidance notes.*

Young people will recruited to take part in this study from one of two North West adolescent inpatient units.

Information regarding the research will be provided via advertisement posters displayed on the ward, the lead researchers attendance at community meetings and 1:1 psychology and nursing sessions.

Young people who are interested in taking part in the research will be provided with a participant information sheet and asked to complete a declaration of interest form. This completed form will be placed in a sealed envelope in a box kept on the ward.

The lead researcher will collect completed declaration of interest forms and consult with the care team to establish if the young people who have volunteered meet any of the exclusion criteria.

Not all young people will be selected to participate. A sample of young people will be selected in order to ensure that both wards are represented.

If a young person is over the age of 16 they will be asked to provide consent via the completion of a consent form. Young people under the age of 16 will be asked to complete an assent form and their parents / guardian will be asked to complete a parent / guardian consent form.

If a young person is selected to participate, arrangements will be made to carry out a 1:1 interview lasting approximately one hour. This interview will be recorded and typed up into an anonymised transcript for analysis. The care team will be consulted immediately prior to the interview in order to confirm that the young person does not meet any exclusion criteria. Interviews will take place in an appropriate private place in the hospital grounds. The location of the interview will depend on the assessment carried out by the care team in relation to risk.

A14-1. In which aspects of the research process have you actively involved, or will you involve, patients, service users, and/or their carers, or members of the public?

- [x] Design of the research
- [ ] Management of the research
- [ ] Undertaking the research
- [ ] Analysis of results
- [ ] Dissemination of findings
- [ ] None of the above

Give details of involvement, or if none please justify the absence of involvement.
Young people who were admitted to an inpatient unit in the North West were consulted during the initial design stages of this piece of research. They provided guidance regarding the research question and gave their opinions regarding practical issues relating to recruitment.

4. RISKS AND ETHICAL ISSUES

RESEARCH PARTICIPANTS

A15. What is the sample group or cohort to be studied in this research?

Select all that apply:

- [ ] Blood
- [ ] Cancer
- [ ] Cardiovascular
- [ ] Congenital Disorders
- [ ] Dementias and Neurodegenerative Diseases
- [ ] Diabetes
- [ ] Ear
- [ ] Eye
- [ ] Generic Health Relevance
- [ ] Infection
- [ ] Inflammatory and Immune System
- [ ] Injuries and Accidents
- [x] Mental Health
- [ ] Metabolic and Endocrine
- [ ] Musculoskeletal
- [ ] Neurological
- [ ] Oral and Gastrointestinal
- [ ] Paediatrics
- [ ] Renal and Urogenital
- [ ] Reproductive Health and Childbirth
- [ ] Respiratory
- [ ] Skin
- [ ] Stroke

Gender:	Male and female participants
Lower age limit: 13	Years
Upper age limit: 18	Years

A17-1. Please list the principal inclusion criteria (list the most important, max 5000 characters).

Any young person who has been admitted to the ward for 2 weeks or more will be eligible to take part in the research. Young people will be able to declare an interest in taking part in the investigation prior to this point but will not be interviewed until they have been on the ward for a fortnight or more.

A17-2. Please list the principal exclusion criteria (list the most important, max 5000 characters).

A young person will be deemed unfit to participate in the research if:

The care team feels that the young person is too unwell to participate or that the interview process is likely to have an adverse influence on their health or well being.
The young person has cognitive or communication difficulties that would hinder their ability to engage in a one to one interview.
A young person is unable to provide informed consent.
A young person would require a translator to enable them to participate in the interview.

RESEARCH PROCEDURES, RISKS AND BENEFITS

A18. Give details of all non-clinical intervention(s) or procedure(s) that will be received by participants as part of the research protocol. *These include seeking consent, interviews, non-clinical observations and use of questionnaires.*

Please complete the columns for each intervention/procedure as follows:

1. Total number of interventions/procedures to be received by each participant as part of the research protocol.
2. If this intervention/procedure would be routinely given to participants as part of their care outside the research, how many of the total would be routine?
3. Average time taken per intervention/procedure (minutes, hours or days)
4. Details of who will conduct the intervention/procedure, and where it will take place.

Intervention or procedure	1	2	3	4
Seeking consent / assent	1	0	15 mins	Rachael Ellis (Principal Investigator) will seek consent (from young people over 16 years old) and assent (from young people under 16 years). This process will take place in a private place on the unit or, if deemed appropriate by the care team, in an alternative private room on the hospital site.
Interview	1	0	60 mins	Interviews will be conducted by Rachael Ellis (Principal Investigator) in a private place on the unit, or if deemed appropriate by the care team, in an alternative private room on the hospital site.

A21. How long do you expect each participant to be in the study in total?

I expect that each participant will be in the study for approximately one day. Participants will be able to contact the principal investigator to withdraw their data from the investigation within 2 weeks of the interview taking place.

A22. What are the potential risks and burdens for research participants and how will you minimise them?

For all studies, describe any potential adverse effects, pain, discomfort, distress, intrusion, inconvenience or changes to lifestyle. Only describe risks or burdens that could occur as a result of participation in the research. Say what steps would be taken to minimise risks and burdens as far as possible.

Members of the care team will be asked to inform the researcher of any young people for whom participation in the research may be detrimental (e.g. due to current presentation or risk issues). If a young person is likely to be adversely effected by participating in the research they will be excluded from the research. Should a participant become distressed during the interview process they will be given the opportunity to end the interview or to take a break. If the researcher has concerns regarding the impact of the interview upon a participant, this information will be shared with the shift leader on the ward and discussed with a research supervisor. It is hoped that members of the care team will be available to support participants following completion of the research interview. Information regarding support agencies for young people will be provided on the Participant information sheet.

A23. Will interviews/ questionnaires or group discussions include topics that might be sensitive, embarrassing or upsetting, or is it possible that criminal or other disclosures requiring action could occur during the study?

(•) Yes ( ) No

If Yes, please give details of procedures in place to deal with these issues:

As this research will include questions regarding a young persons experience of admission to an inpatient psychiatric unit with specific reference to the relationships they have developed as a result of this experience, there is potential for participants to experience difficult emotions during the interview process. Should a participant become distressed during the interview process they will be given the opportunity to end the interview or to take a break. If the researcher has concerns regarding the impact of the interview upon a participant, this information will be shared with the shift leader on the ward and discussed with a research supervisor. It is hoped that members of the care team will be available to support participants following completion of the research interview. Information regarding support agencies for young people will be provided on the Participant information sheet.

A24. What is the potential for benefit to research participants?

Whilst participants may find taking part in this research interesting, there are no direct benefits associated with taking part.

A26. What are the potential risks for the researchers themselves? *(if any)*

The researcher will be conducting research in an inpatient setting. Therefore, it is necessary for the researcher to be aware of any potential risk issues associated with this setting and any specific concerns regarding the young people participating. As such, the researcher will ensure that regular contact is made with care staff in each recruitment locations and that risk assessments are up to date in order to ensure safe practice is maintained.

RECRUITMENT AND INFORMED CONSENT

In this section we ask you to describe the recruitment procedures for the study. Please give separate details for different study groups where appropriate.

A27-1. How will potential participants, records or samples be identified? Who will carry this out and what resources will be used?*For example, identification may involve a disease register, computerised search of GP records, or review of medical records. Indicate whether this will be done by the direct healthcare team or by researchers acting under arrangements with the responsible care organisation(s).*

All young people staying on the units at the two recruitment sites will be provided with information regarding the study (either via advertisment posters, the lead researchers attendance at community meetings or in 1:1 nursing or psychology sessions). This will include the provision of participant information sheets and declaration of interest forms.

Young people will then volunteer to participate via completion of the declaration of interest form.

The lead researcher will consult the care team regarding young people who have volunteered to participate in order to establish if they meet any exclusion criteria.

If the young people do not meet any exclusion criteria, they will be entered into a pool of participants and 6 - 8 young people who represent both of the recruitment sites will be contacted to arrange an interview.

Consent will be sought directly from young people over the age of 16 and assent will be sought from those under 16 in addition to consent being provided by their parent / guardian.

Both parents / carers of children under the age of 16 and young people will be provided with Participant Information Sheets and given the opportunity to ask questions about the process.

A27-2. Will the identification of potential participants involve reviewing or screening the identifiable personal information of patients, service users or any other person?

○ Yes ◉ No

Please give details below:

A28. Will any participants be recruited by publicity through posters, leaflets, adverts or websites?

◉ Yes ○ No

If Yes, please give details of how and where publicity will be conducted, and enclose copy of all advertising material (with version numbers and dates).

Posters will be displayed in communal areas on each participating unit. The principal researcher will also attend community meetings in order to provide information regarding the research project and to provide young people with participant information sheets.

A29. How and by whom will potential participants first be approached?

The principal researcher will attend community meetings in order to provide information regarding the project. The research will also be publicised utilising posters displayed in communal areas. Young people will also be provided with information regarding the project via the care team.

A30-1. Will you obtain informed consent from or on behalf of research participants?

(●) Yes ( ) No

If you will be obtaining consent from adult participants, please give details of who will take consent and how it will be done, with details of any steps to provide information (a written information sheet, videos, or interactive material). Arrangements for adults unable to consent for themselves should be described separately in Part B Section 6, and for children in Part B Section 7.

If you plan to seek informed consent from vulnerable groups, say how you will ensure that consent is voluntary and fully informed.

Participants over the aged of 16 will be asked to confirm that they consent to taking part via the completion of a consent form. Young people under the age of 16 will complete an assent form and their parent or guardian will be provided with a parent / guardian information sheet and asked to complete a parent / guardian consent form.

If you are not obtaining consent, please explain why not.

Please enclose a copy of the information sheet(s) and consent form(s).

A30-2. Will you record informed consent (or advice from consultees) in writing?

(●) Yes ( ) No

A31. How long will you allow potential participants to decide whether or not to take part?

Participants will not be allowed to volunteer to participate until they have been in receipt of the relevant information, via provision of a participant information sheet, for more than 24 hours.

A33-1. What arrangements have been made for persons who might not adequately understand verbal explanations or written information given in English, or who have special communication needs?*(e.g. translation, use of interpreters)*

Due to the financial and practical constraints associated with this study, provision will not be made for young people who do not speak English or who have significant communication difficulties to participate in the study. This exclusion criteria has been used as it assumed that young people who do not speak English or have communication difficulties will have a considerably different experience of their admission and that the quality of the relationships with both staff and peers will be affected by this barrier to communication.

A35. What steps would you take if a participant, who has given informed consent, loses capacity to consent during the study? *Tick one option only.*

( ) The participant and all identifiable data or tissue collected would be withdrawn from the study. Data or tissue which is not identifiable to the research team may be retained.

( ) The participant would be withdrawn from the study. Identifiable data or tissue already collected with consent would be retained and used in the study. No further data or tissue would be collected or any other research procedures carried out on or in relation to the participant.

( ) The participant would continue to be included in the study.

- ◯ Not applicable – informed consent will not be sought from any participants in this research.
- ◉ Not applicable – it is not practicable for the research team to monitor capacity and continued capacity will be assumed.

Further details:

CONFIDENTIALITY

In this section, personal data means any data relating to a participant who could potentially be identified. It includes pseudonymised data capable of being linked to a participant through a unique code number.

Storage and use of personal data during the study

A36. Will you be undertaking any of the following activities at any stage (including in the identification of potential participants)?*(Tick as appropriate)*

- [ ] Access to medical records by those outside the direct healthcare team
- [ ] Electronic transfer by magnetic or optical media, email or computer networks
- [ ] Sharing of personal data with other organisations
- [ ] Export of personal data outside the EEA
- [ ] Use of personal addresses, postcodes, faxes, emails or telephone numbers
- [x] Publication of direct quotations from respondents
- [ ] Publication of data that might allow identification of individuals
- [x] Use of audio/visual recording devices
- [ ] Storage of personal data on any of the following:
  - [ ] Manual files including X−rays
  - [ ] NHS computers
  - [ ] Home or other personal computers
  - [x] University computers
  - [ ] Private company computers
  - [ ] Laptop computers

Further details:
The interview will be audio recorded. If possible, the digital recorder will be encrypted. Should this not be possible, any identifiable data will be transferred to an encrypted, password protected computer as soon as is practicably possible and the original recording will be deleted. Audio recordings will be deleted following completion of the study. The data will then be transcribed and anonymised by the chief investigator. Anonymised transcripts will be saved on a encrypted, password protected file on a secure computer.

Anonymised transcripts and completed consent forms will be scanned electronically and stored on a password protected, encrypted file space on the University server, the contents of which will be deleted 10 years after the project has been completed. Storage and deletion of this material will be the responsibility of the Research Coordinator (Doctorate in Clinical Psychology, Lancaster University).

Anonymised quotations will be utilised in the final research and any subsequent publications. Participants will be made aware that direct quotations will be used and that these will be anonymised in order to ensure that they will not be identifiable from these quotes.

A37. Please describe the physical security arrangements for storage of personal data during the study?

Interviews will be audio recorded. If possible, the digital recorded will be encrypted. Should this not be possible, any identifiable data will be transferred to an encrypted, password protected computer as soon as is practicably possible. The original recording will then be deleted. Audio recordings will be deleted following completion of the study.

Data will be transcribed by the principal investigator. Anonymised transcripts will be stored on an encrypted, password protected file on a secure computer. Anonymised transcripts and completed consent forms will be scanned electronically and stored on a password protected, encrypted file space on the University server, the contents of which will be deleted 10 years after the project has been completed. Storage and deletion of this material will be the responsibility of the Research Coordinator (Doctorate in Clinical Psychology, Lancaster University).

A38. How will you ensure the confidentiality of personal data?*Please provide a general statement of the policy and procedures for ensuring confidentiality, e.g. anonymisation or pseudonymisation of data.*

In order to maintain confidentiality of personal data pseudonyms will be assigned for each participants and all identifying information, including that relating to the identification of the service, will be removed from transcripts and the resulting final research.

A40. Who will have access to participants' personal data during the study? *Where access is by individuals outside the direct care team, please justify and say whether consent will be sought.*

Nobody outside the direct care team will have access to participants personal data during the study.

Storage and use of data after the end of the study

A41. Where will the data generated by the study be analysed and by whom?

The data generated by the study will be analysed by the principal investigator in the UK. Steps will be taken to ensure that any identifiable data is stored securely on encrypted, password protected computers and that transcripts are anonymised.

A42. Who will have control of and act as the custodian for the data generated by the study?

	Title	Forename/Initials	Surname
	Dr	Jane	Simpson

Post	Resesarch Director, Doctorate in Clinical Psychology, Lancaster University
Qualifications	Current Position: Research Director / Senior lecturer in research methods in clinical psychology, Doctorate in Clinical Psychology, Division of Health Research, University of Lancaster. Academic Qualifications: Ten O levels, five A levels Lancaster Girls' Grammar School Lancaster BA (Hons) in combined French and Spanish Queen Mary and Westfield College, University of London (1983-87) BSc in psychology Birkbeck College, University of London (1992-95) PhD in psychology: "A cognitive investigation of schizophrenic delusions", University of Hertfordshire (1999). Examined by Peter McKenna and Dave Hemsley. Awarded with typographical changes. CPsychol Chartered Clinical Psychologist, British Psychological Society
Work Address	Clinical Psychology, Faculty of Health and Medicine Floor C, Furness College

	Lancaster University, Lancaster
Post Code	LA1 4YG
Work Email	j.simpson2@lancaster.ac.uk
Work Telephone	01524592858
Fax	

A43. How long will personal data be stored or accessed after the study has ended?

- (●) Less than 3 months
- ( ) 3 – 6 months
- ( ) 6 – 12 months
- ( ) 12 months – 3 years
- ( ) Over 3 years

A44. For how long will you store research data generated by the study?

Years: 10
Months:

A45. Please give details of the long term arrangements for storage of research data after the study has ended. *Say where data will be stored, who will have access and the arrangements to ensure security.*

Anonymised transcripts and completed consent forms will be scanned electronically and stored on a password protected, encrypted file space on the University server, the contents of which will be deleted 10 years after the project has been completed. Storage and deletion of this material will be the responsibility of the Research Coordinator (Doctorate in Clinical Psychology, Lancaster University).

INCENTIVES AND PAYMENTS

A46. Will research participants receive any payments, reimbursement of expenses or any other benefits or incentives for taking part in this research?

( ) Yes (●) No

A47. Will individual researchers receive any personal payment over and above normal salary, or any other benefits or incentives, for taking part in this research?

( ) Yes (●) No

A48. Does the Chief Investigator or any other investigator/collaborator have any direct personal involvement (e.g. financial, share holding, personal relationship etc.) in the organisations sponsoring or funding the research that may give rise to a possible conflict of interest?

( ) Yes (●) No

NOTIFICATION OF OTHER PROFESSIONALS

A49-1. Will you inform the participants' General Practitioners (and/or any other health or care professional responsible

for their care) that they are taking part in the study?

○ Yes ◉ No

If Yes, please enclose a copy of the information sheet/letter for the GP/health professional with a version number and date.

PUBLICATION AND DISSEMINATION

A50. Will the research be registered on a public database?

○ Yes ◉ No

Please give details, or justify if not registering the research.

Registration of research studies is encouraged wherever possible.
You may be able to register your study through your NHS organisation or a register run by a medical research charity, or publish your protocol through an open access publisher. If you are aware of a suitable register or other method of publication, please give details. If not, you may indicate that no suitable register exists. Please ensure that you have entered registry reference number(s) in question A5-1.

A51. How do you intend to report and disseminate the results of the study? *Tick as appropriate:*

- [x] Peer reviewed scientific journals
- [ ] Internal report
- [x] Conference presentation
- [ ] Publication on website
- [ ] Other publication
- [ ] Submission to regulatory authorities
- [ ] Access to raw data and right to publish freely by all investigators in study or by Independent Steering Committee on behalf of all investigators
- [ ] No plans to report or disseminate the results
- [x] Other (please specify)

There is potential for the results of this investigation to be disseminated via a range of avenues:
- Publication in a peer reviewed journal
- Presentation of research at Lancaster University
- Presentation at relevant conferences
- Sharing of results with participants
- Sharing of results with recruitment sites
- Sharing of results with service user groups

A52. If you will be using identifiable personal data, how will you ensure that anonymity will be maintained when publishing the results?

Young people will select a pseudonym by which they wish to be referred. Care will be taken to ensure that all identifying information relating to the recruitment sites or specific young people is removed from the final publication.

A53. Will you inform participants of the results?

○ Yes ◉ No

Please give details of how you will inform participants or justify if not doing so.
The young people who participate in this research will not be contacted directly by the researcher with the results of the project as they will not be asked to provide their contact details and will no longer have contact with the service by the time the results are published. However, the results of this research will be disseminated via a range of alternative avenues as described above.

5. Scientific and Statistical Review

A54. How has the scientific quality of the research been assessed? *Tick as appropriate:*

- [ ] Independent external review
- [ ] Review within a company
- [ ] Review within a multi−centre research group
- [x] Review within the Chief Investigator's institution or host organisation
- [ ] Review within the research team
- [x] Review by educational supervisor
- [ ] Other

Justify and describe the review process and outcome. If the review has been undertaken but not seen by the researcher, give details of the body which has undertaken the review:
This project has been subjected to review within the Department of Clinical Psychology, Lancaster University and has been supervised by Academic Supervisor, Dr Ian Smith.

For all studies except non-doctoral student research, please enclose a copy of any available scientific critique reports, together with any related correspondence.

For non-doctoral student research, please enclose a copy of the assessment from your educational supervisor/ institution.

A59. What is the sample size for the research? *How many participants/samples/data records do you plan to study in total? If there is more than one group, please give further details below.*

Total UK sample size:	8
Total international sample size (including UK):	8
Total in European Economic Area:	0

Further details:
Up to 8 participants will be recruited for this investigation.

A60. How was the sample size decided upon? *If a formal sample size calculation was used, indicate how this was done, giving sufficient information to justify and reproduce the calculation.*

Interpretative Phenomenological Analysis (IPA) studies are conducted with relatively small sample sizes in order to allow for a detailed exploration of participants experiences, perceptions and understanding.

Up to eight participants will be recruited for this investigation. The number of participants recruited will partially rely upon the richness of the data collected.

It is anticipated that by recruiting up to eight participants, analysis will allow for an in depth exploration as well as the examination of similarities and differences.

A62. Please describe the methods of analysis (statistical or other appropriate methods, e.g. for qualitative research) by which the data will be evaluated to meet the study objectives.

The data collected will be analysed using Interpretative Phenomenological Analysis (IPA). This approach aims to explore how people make sense of their experiences via the analysis of detailed first person accounts (Larkin & Thompson, 2012). The researcher aims to understand the meanings that are made by participants by gathering information about the ways in which they relate to the world. In order to do this effectively, it is essential that the researcher considered their own experiences and assumptions and reflects upon their role in the development of interpretations. A reflective research journal will be used alongside supervision in order to facilitate the process of analysis. Thematic validity will be checked via supervision with research supervisors.

6. MANAGEMENT OF THE RESEARCH

A63. Other key investigators/collaborators. *Please include all grant co–applicants, protocol co–authors and other key members of the Chief Investigator's team, including non-doctoral student researchers.*

	Title	Forename/Initials	Surname
	[redacted]	[redacted]	[redacted]
Post	[redacted]		
Qualifications	[redacted]		
Employer	[redacted]		
Work Address	[redacted]		
Post Code	[redacted]		
Telephone	[redacted]		
Fax			
Mobile			
Work Email	[redacted]		

A64. Details of research sponsor(s)

A64-1. Sponsor

Lead Sponsor

Status:
- ◯ NHS or HSC care organisation
- ◉ Academic
- ◯ Pharmaceutical industry
- ◯ Medical device industry
- ◯ Local Authority
- ◯ Other social care provider (including voluntary sector or private organisation)
- ◯ Other

Commercial status:

If Other, please specify:

Contact person

Name of organisation	Lancaster University
Given name	Debbie
Family name	Knight
Address	Research Support Office, B58 Bowland Main, Lancaster University
Town/city	Lancaster
Post code	LA1 4YT
Country	UNITED KINGDOM
Telephone	01524592605
Fax	
E-mail	ethics@lancaster.ac.uk

Is the sponsor based outside the UK?

◯ Yes ◉ No

Under the Research Governance Framework for Health and Social Care, a sponsor outside the UK must appoint a legal representative established in the UK. Please consult the guidance notes.

A65. Has external funding for the research been secured?

- [ ] Funding secured from one or more funders
- [ ] External funding application to one or more funders in progress
- [x] No application for external funding will be made

What type of research project is this?

- (●) Standalone project
- ( ) Project that is part of a programme grant
- ( ) Project that is part of a Centre grant
- ( ) Project that is part of a fellowship/ personal award/ research training award
- ( ) Other

Other – please state:

A66. Has responsibility for any specific research activities or procedures been delegated to a subcontractor (other than a co-sponsor listed in A64-1) ? *Please give details of subcontractors if applicable.*

( ) Yes (●) No

A67. Has this or a similar application been previously rejected by a Research Ethics Committee in the UK or another country?

( ) Yes (●) No

Please provide a copy of the unfavourable opinion letter(s). You should explain in your answer to question A6-2 how the reasons for the unfavourable opinion have been addressed in this application.

A68-1. Give details of the lead NHS R&D contact for this research:

	Title	Forename/Initials	Surname
	[redacted]	[redacted]	[redacted]
Organisation	[redacted]		
Address	[redacted]		
Post Code	[redacted]		
Work Email	[redacted]		
Telephone	[redacted]		
Fax			
Mobile			

Details can be obtained from the NHS R&D Forum website: http://www.rdforum.nhs.uk

A69-1. How long do you expect the study to last in the UK?

Planned start date: 01/07/2014
Planned end date: 29/05/2015
Total duration:
Years: 0 Months: 10 Days: 29

A71-1. Is this study?

- ◯ Single centre
- ◉ Multicentre

A71-2. Where will the research take place? *(Tick as appropriate)*

- ☑ England
- ☐ Scotland
- ☐ Wales
- ☐ Northern Ireland
- ☐ Other countries in European Economic Area

Total UK sites in study 2

Does this trial involve countries outside the EU?
◯ Yes ◉ No

A72. What host organisations (NHS or other) in the UK will be responsible for the research sites? *Please indicate the type of organisation by ticking the box and give approximate numbers of planned research sites:*

☑ NHS organisations in England	2
☐ NHS organisations in Wales	
☐ NHS organisations in Scotland	
☐ HSC organisations in Northern Ireland	
☐ GP practices in England	
☐ GP practices in Wales	
☐ GP practices in Scotland	
☐ GP practices in Northern Ireland	
☐ Social care organisations	
☐ Phase 1 trial units	
☐ Prison establishments	
☐ Probation areas	
☐ Independent hospitals	
☐ Educational establishments	
☐ Independent research units	
☐ Other (give details)	
Total UK sites in study:	2

A73-1. Will potential participants be identified through any organisations other than the research sites listed above?

◯ Yes ◉ No

A74. What arrangements are in place for monitoring and auditing the conduct of the research?

Dr Ian Smith (Academic Supervisor) and [redacted] will be supervising the research. Supervisory contracts have been drawn up in order to make supervisory roles explicit and ensure that supervision meetings are regular. The data collected will also be available for audit by the audit department of the relevant NHS Trusts where the research is being conducted.

A76. Insurance/ indemnity to meet potential legal liabilities

Note: in this question to NHS indemnity schemes include equivalent schemes provided by Health and Social Care (HSC) in Northern Ireland

A76-1. What arrangements will be made for insurance and/or indemnity to meet the potential legal liability of the sponsor(s) for harm to participants arising from the management of the research? *Please tick box(es) as applicable.*

Note: Where a NHS organisation has agreed to act as sponsor or co-sponsor, indemnity is provided through NHS schemes. Indicate if this applies (there is no need to provide documentary evidence). For all other sponsors, please describe the arrangements and provide evidence.

- [ ] NHS indemnity scheme will apply (NHS sponsors only)
- [x] Other insurance or indemnity arrangements will apply (give details below)

Lancaster University legal liability cover will apply

Please enclose a copy of relevant documents.

A76-2. What arrangements will be made for insurance and/ or indemnity to meet the potential legal liability of the sponsor(s) or employer(s) for harm to participants arising from the design of the research? *Please tick box(es) as applicable.*

Note: Where researchers with substantive NHS employment contracts have designed the research, indemnity is provided through NHS schemes. Indicate if this applies (there is no need to provide documentary evidence). For other protocol authors (e.g. company employees, university members), please describe the arrangements and provide evidence.

- [ ] NHS indemnity scheme will apply (protocol authors with NHS contracts only)
- [x] Other insurance or indemnity arrangements will apply (give details below)

Lancaster University legal liability cover will apply

Please enclose a copy of relevant documents.

A76-3. What arrangements will be made for insurance and/ or indemnity to meet the potential legal liability of investigators/collaborators arising from harm to participants in the conduct of the research?

Note: Where the participants are NHS patients, indemnity is provided through the NHS schemes or through professional indemnity. Indicate if this applies to the whole study (there is no need to provide documentary evidence). Where non-NHS sites are to be included in the research, including private practices, please describe the arrangements which will be made at these sites and provide evidence.

- [x] NHS indemnity scheme or professional indemnity will apply (participants recruited at NHS sites only)
- [ ] Research includes non-NHS sites (give details of insurance/ indemnity arrangements for these sites below)

Please enclose a copy of relevant documents.

A78. Could the research lead to the development of a new product/process or the generation of intellectual property?

(•) Yes ( ) No ( ) Not sure

PART B: Section 7 - Children

1. Please specify the potential age range of children under 16 who will be included and give reasons for carrying out the research in this age group.

Young people aged between 13 and 18 years will be eligible to take part in this research as this is the age range of young people who can access adolescent inpatient services.

2. Indicate whether any children under 16 will be recruited as controls and give further details.

No children under the age of 16 will be recruited as controls.

3-2. Please describe the arrangements for seeking informed consent from a person with parental responsibility and/or from children able to give consent for themselves.

Potential participants over the age of 16 who are deemed fit to participate in the study will be approached to arrange a suitable time for the interview to take place. Any potential participants under the age of 16 who are deemed fit to participate in the study will be informed that their parent or guardian will be approached in order to seek consent to participate. If this is acceptable and the young person wishes to proceed, parental consent will be sought prior to any further arrangements being made.

Participants over the aged of 16 will be asked to confirm that they consent to taking part via the completion of a consent form. Consent forms will be completed just prior to the interview. Young people under the age of 16 will complete an assent form and their parent or guardian will be provided with a parent / guardian information sheet and asked to complete a parent / guardian consent form.

4. If you intend to provide children under 16 with information about the research and seek their consent or agreement, please outline how this process will vary according to their age and level of understanding.

All young people will be provided with a participant information sheet which has been adapted in order to make it accessible for young people. The lead researcher will ensure that young people participating in the research understand the information provided on the participant information sheet and the consent form. Young people will be provided the opportunity to ask questions regarding the information provided.

Copies of written information sheet(s) for parents and children, consent/assent form(s) and any other explanatory material should be enclosed with the application.

PART C: Overview of research sites

Please enter details of the host organisations (Local Authority, NHS or other) in the UK that will be responsible for the research sites. *For NHS sites, the host organisation is the Trust or Health Board. Where the research site is a primary care site, e.g. GP practice, please insert the host organisation (PCT or Health Board) in the Institution row and insert the research site (e.g. GP practice) in the Department row.*

Research site		Investigator/ Collaborator/ Contact	
Institution name	[redacted]	Title	[redacted]
Department name	[redacted]	First name/ Initials	[redacted]
Street address	[redacted]	Surname	[redacted]
Town/city	[redacted]		
Post Code	[redacted]		
Institution name	[redacted]	Title	[redacted]
Department name	[redacted]	First name/ Initials	[redacted]
Street address	[redacted]	Surname	[redacted]
Town/city	[redacted]		
Post Code	[redacted]		

PART D: Declarations

D1. Declaration by Chief Investigator

1. The information in this form is accurate to the best of my knowledge and belief and I take full responsibility for it.

2. I undertake to abide by the ethical principles underlying the Declaration of Helsinki and good practice guidelines on the proper conduct of research.

3. If the research is approved I undertake to adhere to the study protocol, the terms of the full application as approved and any conditions set out by review bodies in giving approval.

4. I undertake to notify review bodies of substantial amendments to the protocol or the terms of the approved application, and to seek a favourable opinion from the main REC before implementing the amendment.

5. I undertake to submit annual progress reports setting out the progress of the research, as required by review bodies.

6. I am aware of my responsibility to be up to date and comply with the requirements of the law and relevant guidelines relating to security and confidentiality of patient or other personal data, including the need to register when necessary with the appropriate Data Protection Officer. I understand that I am not permitted to disclose identifiable data to third parties unless the disclosure has the consent of the data subject or, in the case of patient data in England and Wales, the disclosure is covered by the terms of an approval under Section 251 of the NHS Act 2006.

7. I understand that research records/data may be subject to inspection by review bodies for audit purposes if required.

8. I understand that any personal data in this application will be held by review bodies and their operational managers and that this will be managed according to the principles established in the Data Protection Act 1998.

9. I understand that the information contained in this application, any supporting documentation and all correspondence with review bodies or their operational managers relating to the application:

   - Will be held by the REC (where applicable) until at least 3 years after the end of the study; and by NHS R&D offices (where the research requires NHS management permission) in accordance with the NHS Code of Practice on Records Management.
   - May be disclosed to the operational managers of review bodies, or the appointing authority for the REC (where applicable), in order to check that the application has been processed correctly or to investigate any complaint.
   - May be seen by auditors appointed to undertake accreditation of RECs (where applicable).
   - Will be subject to the provisions of the Freedom of Information Acts and may be disclosed in response to requests made under the Acts except where statutory exemptions apply.
   - May be sent by email to REC members.

10. I understand that information relating to this research, including the contact details on this application, may be held on national research information systems, and that this will be managed according to the principles established in the Data Protection Act 1998.

11. Where the research is reviewed by a REC within the UK Health Departments Research Ethics Service, I understand that the summary of this study will be published on the website of the National Research Ethics Service (NRES), together with the contact point for enquiries named below. Publication will take place no earlier than 3 months after issue of the ethics committee's final opinion or the withdrawal of the application.

Contact point for publication*(Not applicable for R&D Forms)*

NRES would like to include a contact point with the published summary of the study for those wishing to seek further information. We would be grateful if you would indicate one of the contact points below.

◉ Chief Investigator

○ Sponsor

- ◯ Study co-ordinator
- ◯ Student
- ◯ Other – please give details
- ◯ None

Access to application for training purposes *(Not applicable for R&D Forms)*
Optional – please tick as appropriate:

☑ I would be content for members of other RECs to have access to the information in the application in confidence for training purposes. All personal identifiers and references to sponsors, funders and research units would be removed.

This section was signed electronically by Miss Rachael Ellis on 13/06/2014 16:09.

Job Title/Post:	Trainee Clinical Psychologist
Organisation:	Lancashire Care NHS Foundation Trust
Email:	r.ellis2@lancaster.ac.uk

Signature: ....

Print Name: Rachael Ellis

Date: 13/06/2014 *(dd/mm/yyyy)*

D2. Declaration by the sponsor's representative

If there is more than one sponsor, this declaration should be signed on behalf of the co-sponsors by a representative of the lead sponsor named at A64-1.

I confirm that:

1. This research proposal has been discussed with the Chief Investigator and agreement in principle to sponsor the research is in place.

2. An appropriate process of scientific critique has demonstrated that this research proposal is worthwhile and of high scientific quality.

3. Any necessary indemnity or insurance arrangements, as described in question A76, will be in place before this research starts. Insurance or indemnity policies will be renewed for the duration of the study where necessary.

4. Arrangements will be in place before the study starts for the research team to access resources and support to deliver the research as proposed.

5. Arrangements to allocate responsibilities for the management, monitoring and reporting of the research will be in place before the research starts.

6. The duties of sponsors set out in the Research Governance Framework for Health and Social Care will be undertaken in relation to this research.

7. Where the research is reviewed by a REC within the UK Health Departments Research Ethics Service, I understand that the summary of this study will be published on the website of the National Research Ethics Service (NRES), together with the contact point for enquiries named in this application. Publication will take place no earlier than 3 months after issue of the ethics committee's final opinion or the withdrawal of the application.

This section was signed electronically by An authorised approver at ethics@lancaster.ac.uk on 18/06/2014 12:39.

Job Title/Post:	Research Support Manager
Organisation:	Lancaster University
Email:	y.fox@lancaster.ac.uk

D3. Declaration for student projects by academic supervisor(s)

1. I have read and approved both the research proposal and this application. I am satisfied that the scientific content of the research is satisfactory for an educational qualification at this level.

2. I undertake to fulfil the responsibilities of the supervisor for this study as set out in the Research Governance Framework for Health and Social Care.

3. I take responsibility for ensuring that this study is conducted in accordance with the ethical principles underlying the Declaration of Helsinki and good practice guidelines on the proper conduct of research, in conjunction with clinical supervisors as appropriate.

4. I take responsibility for ensuring that the applicant is up to date and complies with the requirements of the law and relevant guidelines relating to security and confidentiality of patient and other personal data, in conjunction with clinical supervisors as appropriate.

Academic supervisor 1

This section was signed electronically by Dr Ian Smith on 13/06/2014 16:21.

Job Title/Post:	Lecturer in Research Methods
Organisation:	Lancaster University
Email:	i.smith@lancaster.ac.uk

Appendix L: Exemplar Site Specific Information (SSI) Form

NHS SSI IRAS Version 3.5

Welcome to the Integrated Research Application System

IRAS Project Filter

The integrated dataset required for your project will be created from the answers you give to the following questions. The system will generate only those questions and sections which (a) apply to your study type and (b) are required by the bodies reviewing your study. Please ensure you answer all the questions before proceeding with your applications.

Please enter a short title for this project (maximum 70 characters)
Young People's Lived Experience of Admission to an Inpatient Unit

1. Is your project research?

(●) Yes ( ) No

2. Select one category from the list below:

( ) Clinical trial of an investigational medicinal product
( ) Clinical investigation or other study of a medical device
( ) Combined trial of an investigational medicinal product and an investigational medical device
( ) Other clinical trial to study a novel intervention or randomised clinical trial to compare interventions in clinical practice
( ) Basic science study involving procedures with human participants
( ) Study administering questionnaires/interviews for quantitative analysis, or using mixed quantitative/qualitative methodology
(●) Study involving qualitative methods only
( ) Study limited to working with human tissue samples (or other human biological samples) and data (specific project only)
( ) Study limited to working with data (specific project only)
( ) Research tissue bank
( ) Research database

If your work does not fit any of these categories, select the option below:

( ) Other study

2a. Please answer the following question(s):

a) Does the study involve the use of any ionising radiation?	( ) Yes	(●) No
b) Will you be taking new human tissue samples (or other human biological samples)?	( ) Yes	(●) No
c) Will you be using existing human tissue samples (or other human biological samples)?	( ) Yes	(●) No

3. In which countries of the UK will the research sites be located? *(Tick all that apply)*

[x] England
[ ] Scotland
[ ] Wales
[ ] Northern Ireland

3a. In which country of the UK will the lead NHS R&D office be located:

- (•) England
- ( ) Scotland
- ( ) Wales
- ( ) Northern Ireland
- ( ) This study does not involve the NHS

4. Which review bodies are you applying to?

- [x] NHS/HSC Research and Development offices
- [ ] Social Care Research Ethics Committee
- [x] Research Ethics Committee
- [ ] National Information Governance Board for Health and Social Care (NIGB)
- [ ] National Offender Management Service (NOMS) (Prisons & Probation)

For NHS/HSC R&D offices, the CI must create Site-Specific Information Forms for each site, in addition to the study-wide forms, and transfer them to the PIs or local collaborators.

5. Will any research sites in this study be NHS organisations?

(•) Yes ( ) No

5a. Are all the research costs and infrastructure costs for this study provided by an NIHR Biomedical Research Centre, NIHR Biomedical Research Unit, NIHR Collaboration for Leadership in Health Research and Care (CLAHRC) or NIHR Research Centre for Patient Safety & Service Quality in all study sites?

( ) Yes (•) No

If yes, NHS permission for your study will be processed through the NIHR Coordinated System for gaining NHS Permission (NIHR CSP).

5b. Do you wish to make an application for the study to be considered for NIHR Clinical Research Network (CRN) support and inclusion in the NIHR Clinical Research Network (CRN) Portfolio? Please see information button for further details.

( ) Yes (•) No

If yes, NHS permission for your study will be processed through the NIHR Coordinated System for gaining NHS Permission (NIHR CSP) and you must complete a NIHR Clinical Research Network (CRN) Portfolio Application Form immediately after completing this project filter and before completing and submitting other applications.

6. Do you plan to include any participants who are children?

(•) Yes ( ) No

7. Do you plan at any stage of the project to undertake intrusive research involving adults lacking capacity to consent for themselves?

( ) Yes (•) No

Answer Yes if you plan to recruit living participants aged 16 or over who lack capacity, or to retain them in the study following loss of capacity. Intrusive research means any research with the living requiring consent in law. This includes use of identifiable tissue samples or personal information, except where application is being made to the NIGB Ethics and Confidentiality Committee to set aside the common law duty of confidentiality in England and Wales. Please consult the guidance notes for further information on the legal frameworks for research involving adults lacking capacity in the UK.

8. Do you plan to include any participants who are prisoners or young offenders in the custody of HM Prison Service or who are offenders supervised by the probation service in England or Wales?

○ Yes ◉ No

9. Is the study or any part of it being undertaken as an educational project?

◉ Yes ○ No

Please describe briefly the involvement of the student(s):
The Principal Investigator (Rachael Ellis) is currently a Trainee on the Lancaster University Doctorate in Clinical Psychology (DClinPsy). This research will form part of her thesis.

9a. Is the project being undertaken in part fulfilment of a PhD or other doctorate?

◉ Yes ○ No

10. Will this research be financially supported by the United States Department of Health and Human Services or any of its divisions, agencies or programs?

○ Yes ◉ No

11. Will identifiable patient data be accessed outside the care team without prior consent at any stage of the project (including identification of potential participants)?

○ Yes ◉ No

Site-Specific Information Form (NHS sites)

Is the site hosting this research a NHS site or a non-NHS site? *NHS sites include Health and Social Care organisations in Northern Ireland. The sites hosting the research are the sites in which or through which research procedures are conducted.*

- (x) NHS site
- ( ) Non-NHS site

This question must be completed before proceeding. The filter will customise the form, disabling questions which are not relevant to this application.

One Site-Specific Information Form should be completed for each research site and submitted to the relevant R&D office with the documents in the checklist. See guidance notes.

The data in this box is populated from Part A:

Title of research:
What is the lived experience of young people during their admission to a psychiatric inpatient unit?

Short title: Young People's Lived Experience of Admission to an Inpatient Unit

Chief Investigator:	Title	Forename/Initials	Surname
	Miss	Rachael	Ellis

Name of NHS Research Ethics Committee to which application for ethical review is being made:
North West - Lancaster

Project reference number from above REC: 14/NW/1094

1-1. Give the name of the NHS organisation responsible for this research site

[redacted]

1-3. In which country is the research site located?

- (x) England
- ( )
- ( ) Scotland
- ( ) Northern Ireland

1-4. Is the research site a GP practice or other Primary Care Organisation?

( ) Yes (x) No

2. Who is the Principal Investigator or Local Collaborator for this research at this site?

Select the appropriate title: ○ Principal Investigator
◉ Local Collaborator

	Title	Forename/Initials	Surname
	[redacted]	[redacted]	[redacted]
Post			
Qualifications	[redacted]		
Organisation	[redacted]		
Work Address	[redacted]		
PostCode	[redacted]		
Work E-mail	[redacted]		
Work Telephone	[redacted]		
Mobile	[redacted]		
Fax	[redacted]		

a) Approximately how much time will this person allocate to conducting this research? *Please provide your response in terms of Whole Time Equivalents (WTE).*
[redacted] will not be committing any of her time to conducting this research aside from maintaining contact with the lead investigator in order to arrange access to the participants. She will act as a contact for this recruitment site.

b) Does this person hold a current substantive employment contract, Honorary Clinical Contract or Honorary Research Contract with the NHS organisation or accepted by the NHS organisation? ◉ Yes ○ No

A copy of a current CV for the Principal Investigator (maximum 2 pages of A4) must be submitted with this form.

3. Please give details of all locations, departments, groups or units at which or through which research procedures will be conducted at this site and describe the activity that will take place.

Please list all locations/departments etc where research procedures will be conducted within the NHS organisation, describing the involvement in a few words. Where access to specific facilities will be required these should also be listed for each location.

Name the main location/department first. Give details of any research procedures to be carried out off site, for example in participants' homes.

	Location	Activity/facilities
1	[redacted]	Recruitment and interviewing of participants will occur at this site.

5. Please give details of all other members of the research team at this site.

6. Does the Principal Investigator or any other member of the site research team have any direct personal involvement (e.g. financial, share-holding, personal relationship etc) in the organisation sponsoring or funding the research that may give rise to a possible conflict of interest?

○ Yes ◉ No

7. What is the proposed local start and end date for the research at this site?

Start date:	01/07/2014
End date:	29/05/2015
Duration (Months):	10

-1. Give details of all non-clinical intervention(s) or procedure(s) that will be received by participants as part of the research protocol. *(These include seeking consent, interviews, non-clinical observations and use of questionnaires.)*

Columns 1-4 have been completed with information from A18 as below:

1. *Total number of interventions/procedures to be received by each participant as part of the research protocol.*
2. *If this intervention would have been routinely given to participants as part of their care, how many of the total would have been routine?*
3. *Average time taken per intervention (minutes, hours or days)*
4. *Details of who will conduct the procedure, and where it will take place*

Please complete Column 5 with details of the names of individuals or names of staff groups who will conduct the procedure at this site.

Intervention or procedure	1	2	3	4	5
Seeking consent / assent	1	0	15 mins	Rachael Ellis (Principal Investigator) will seek consent (from young people over 16 years old) and assent (from young people under 16 years). This process will take place in a private place on the unit or, if deemed appropriate by the care team, in an alternative private room on the hospital site.	
Interview	1	0	60 mins	Interviews will be conducted by Rachael Ellis (Principal Investigator) in a private place on the unit, or if deemed appropriate by the care team, in an alternative private room on the hospital site.	

8-2. Will any aspects of the research at this site be conducted in a different way to that described in Part A or the protocol?

○ Yes ◉ No

If Yes, please note any relevant changes to the information in the above table.

Are there any changes other than those noted in the table?

10. How many research participants/samples is it expected will be recruited/obtained from this site?

Up to 8 participants will be recruited from this site.

11. Give details of how potential participants will be identified locally and who will be making the first approach to them to take part in the study.

Participants will be recruited from all the young people staying at [redacted] who do not meet the exclusion criteria. Participants will be approached by the lead investigator (Rachael Ellis) via the provision of information in community meetings. Participants may also be provided with Participant Information Sheets in sessions with members of the care team. Information will also be provided via advertisement posters displayed on the wards.

12. Who will be responsible for obtaining informed consent at this site? What expertise and training do these persons have in obtaining consent for research purposes?

Name	Expertise/training
Rachael Ellis	The principal investigator (Rachael Ellis) will be obtaining consent prior to the interviews taking place.

15-1. Is there an independent contact point where potential participants can seek general advice about taking part in research?

Young people will be able to discuss taking part in the research with members of their care team.

15-2. Is there a contact point where potential participants can seek further details about this specific research project?

No

16. Are there any changes that should be made to the generic content of the information sheet to reflect site-specific issues in the conduct of the study? *A substantial amendment may need to be discussed with the Chief Investigator and submitted to the main REC.*

No

Please provide a copy on headed paper of the participant information sheet and consent form that will be used locally. Unless indicated above, this must be the same generic version submitted to/approved by the main REC for the study while including relevant local information about the site, investigator and contact points for participants (see guidance notes).

17. What local arrangements have been made for participants who might not adequately understand verbal explanations or written information given in English, or who have special communication needs? *(e.g. translation, use of interpreters etc.)*

Young people who do not speak English as their first language will not be eligible to participate in the study. This exclusion criteria has been used as it assumed that young people who do not speak English will have a considerably different experience of their admission and that the quality of the relationships with both staff and peers will be affected by this barrier to communication

18. What local arrangements will be made to inform the GP or other health care professionals responsible for the care of the participants?

The care team on the ward will be consulted regarding a young persons involvement in the study and, due to the interviews taking place on the ward, will be aware when a young person has completed their interview. The investigator will consult with the ward team in order to ensure that the young person is provided with support should they become upset or distressed during the interview process.

19. What arrangements (e.g. facilities, staffing, psychosocial support, emergency procedures) will be in place at the site, where appropriate, to minimise the risks to participants and staff and deal with the consequences of any harm?

Members of the care team will be asked to inform the researcher of any young people for whom participation in the research may be detrimental (e.g. due to current presentation or risk issues). Should a participant become distressed during the interview process they will be given the opportunity to end the interview or to take a break. If the researcher has concerns regarding the impact of the interview upon a participant, this information will be shared with the shift leader on the ward and discussed with a research supervisor. Members of the care team will be available to support participants following completion of the research interview. Information regarding support agencies for young people will be provided on the Participant information sheet.

20. What are the arrangements for the supervision of the conduct of the research at this site? *Please give the name and contact details of any supervisor not already listed in the application.*

This study will be supervised by Dr Ian Smith (Lancaster University) and [redacted] . Additional support will be offered by [redacted]).

21. What external funding will be provided for the research at this site?

- ◯ Funded by commercial sponsor
- ◯ Other funding
- ◉ No external funding

How will the costs of the research be covered?
Any additional costs arising from the research, such as travel expenses for the researcher, will be claimed from the researchers employer (Lancashire Care NHS Foundation Trust).

23. Authorisations required prior to R&D approval

The local research team are responsible for contacting the local NHS R&D office about the research project. Where the research project is proposed to be coordinated centrally and therefore there is no local research team, it is the responsibility of the central research team to instigate this contact with local R&D.

NHS R&D offices can offer advice and support on the set-up of a research project at their organisation, including information on local arrangements for support services relevant to the project. These support services may include clinical supervisors, line managers, service managers, support department managers, pharmacy, data protection officers or finance managers depending on the nature of the research.

Obtaining the necessary support service authorisations is not a pre-requisite to submission of an application for NHS research permission, but all appropriate authorisations must be in place before NHS research permission will be granted. Processes for obtaining authorisations will be subject to local arrangements, but the minimum expectation is that the local R&D office has been contacted to notify it of the proposed research project and to discuss the project's needs **prior** to submission of the application for NHS research permission via IRAS.

Failure to engage with local NHS R&D offices **prior** to submission may lead to unnecessary delays in the process of this application for NHS research permissions.

Declaration:
☑ **I confirm that the relevant NHS organisation R&D office has been contacted to discuss the needs of the project and local arrangements for support services. I understand that failure to engage with the local NHS R&D office before submission of this application may result in unnecessary delays in obtaining NHS research permission for this project.**

Please give the name and contact details for the NHS R&D office staff member you have discussed this application with:
Please note that for some sites the NHS R&D office contact may not be physically based at the site. For contact details refer to the guidance for this question.

	Title	Forename/Initials	Surname
	[redacted]	[redacted]	[redacted]
Work E-mail	[redacted]		
Work Telephone	[redacted]		

Declaration by Principal Investigator or Local Collaborator

1. The information in this form is accurate to the best of my knowledge and I take full responsibility for it.

2. I undertake to abide by the ethical principles underpinning the World Medical Association's Declaration of Helsinki and relevant good practice guidelines in the conduct of research.

3. If the research is approved by the main REC and NHS organisation, I undertake to adhere to the study protocol, the terms of the application of which the main REC has given a favourable opinion and the conditions requested by the NHS organisation, and to inform the NHS organisation within local timelines of any subsequent amendments to the protocol.

4. If the research is approved, I undertake to abide by the principles of the Research Governance Framework for Health and Social Care.

5. I am aware of my responsibility to be up to date and comply with the requirements of the law and relevant guidelines relating to the conduct of research.

6. I undertake to disclose any conflicts of interest that may arise during the course of this research, and take responsibility for ensuring that all staff involved in the research are aware of their responsibilities to disclose conflicts of interest.

7. I understand and agree that study files, documents, research records and data may be subject to inspection by the NHS organisation, the sponsor or an independent body for monitoring, audit and inspection purposes.

8. I take responsibility for ensuring that staff involved in the research at this site hold appropriate contracts for the duration of the research, are familiar with the Research Governance Framework, the NHS organisation's Data Protection Policy and all other relevant policies and guidelines, and are appropriately trained and experienced.

9. I undertake to complete any progress and/or final reports as requested by the NHS organisation and understand that continuation of permission to conduct research within the NHS organisation is dependent on satisfactory completion of such reports.

10. I undertake to maintain a project file for this research in accordance with the NHS organisation's policy.

11. I take responsibility for ensuring that all serious adverse events are handled within the NHS organisation's policy for reporting and handling of adverse events.

12. I understand that information relating to this research, including the contact details on this application, will be held by the R&D office and may be held on national research information systems, and that this will be managed according to the principles established in the Data Protection Act 1998.

13. I understand that the information contained in this application, any supporting documentation and all correspondence with the R&D office and/or the REC system relating to the application will be subject to the provisions of the Freedom of Information Acts and may be disclosed in response to requests made under the Acts except where statutory exemptions apply.

This section was signed electronically by Miss Rachael Ellis on 13/06/2014 15:43.

Job Title/Post:	Trainee Clinical Psychologist
Organisation:	Lancashire Care NHS Foundation Trust
Email:	r.ellis2@lancaster.ac.uk

Appendix M: Provisional Approval Letter Received from REC

Health Research Authority
National Research Ethics Service

NRES Committee North West - Lancaster
Barlow House
3rd Floor
4 Minshull Street
Manchester
M1 3DZ

Telephone: 0161 625 7818
Fax:0161 625 7299

16 July 2014

[redacted]

Dear Miss Ellis

Study Title:	**What is the lived experience of young people during their admission to a psychiatric inpatient unit?**
REC reference:	**14/NW/1094**
IRAS project ID:	**153145**

The Research Ethics Committee reviewed the above application at the meeting held on 10 July 2014. Thank you for attending by telephone to discuss the application.

Provisional opinion

The Committee is unable to give an ethical opinion on the basis of the information and documentation received so far. Before confirming its opinion, the Committee requests that you provide the further information set out below.

Authority to consider your response and to confirm the Committee's final opinion has been delegated to the Chair.

Further information or clarification required

a. The Committee would like to see the Participant Information Sheet revised to
   i) Include the fact that they can have a family member present with them during the interview if they wish
   ii) Make clear that the staff will be aware of their participation in the study
   iii) Correct the typographical errors on the parent version
b. The Committee would like to see poster revised, after consultation with children of the same age, to make it more age appropriate
c. The Committee would like to see the Consent Form revised to
   i) Include the name and signature of the person taking consent at the bottom
   ii) Omit the point "I understand that the information from my interview will be mixed in with what other young people say and that people won't be able

to tell who said what"

If you would find it helpful to discuss any of the matters raised above or seek further clarification from a member of the Committee, you are welcome to contact Carol Ebenezer whose contact details are on this letter.

When submitting a response to the Committee, the requested information should be electronically submitted from IRAS. A step-by-step guide on submitting your response to the REC provisional opinion is available on the HRA website using the following link: http://www.hra.nhs.uk/nhs-research-ethics-committee-rec-submitting-response-provisional-opinion/

Please submit revised documentation where appropriate underlining or otherwise highlighting the changes which have been made and giving revised version numbers and dates. You do not have to make any changes to the REC application form unless you have been specifically requested to do so by the REC.

The Committee will confirm the final ethical opinion within a maximum of 60 days from the date of initial receipt of the application, excluding the time taken by you to respond fully to the above points. A response should be submitted by no later than 15 August 2014.

Summary of the discussion at the meeting

The Chair contacted you and thanked you for being available to discuss the study.

Recruitment arrangements and access to health information, and fair participant selection

The Committee considered it important to let the participants know that the staff will be aware of their participation in the study.

The Committee noted that not everyone who volunteers will be selected and asked whether it would be possible to give them a thank you card or note if they are not chosen, as many will have rejection issues. You agreed to this.

The Committee accepted that communication difficulties would make it difficult to include non-English speakers in this study.

Care and protection of research participants; respect for potential and enrolled participants' welfare and dignity

The Committee asked whether it would be possible for the 13-15 year olds to have a family member present during the interview for support. You stated that you can give them that option but would explain that the person would hear what they were saying so you would need to ensure they are comfortable with that.

The Committee asked that the participants not be allowed to choose their own pseudonym as this may lead to breach of confidentiality, for instance, if they choose a celebrity name and tell others who they were. You agreed to this.

Informed consent process and the adequacy and completeness of participant information

The Chair advised that the decision letter would include a request for changes to the paperwork.

Suitability of supporting information

The Committee did not think the poster was age appropriate, in particular use of war propaganda, and advised you to run it past a group of children of this age who will not be involved in the research to see whether they understand the references or whether they have better ideas of what would be appropriate to them. Any changes should then be submitted to the Committee for approval.

Other general comments
The Committee asked whether there would be any benefit in giving a copy of the transcripts to the participants to ensure accuracy. You said that they are often not on site long enough to do this and you would be unable to contact them. The Committee accepted this.

You had no questions for the Committee

Documents reviewed

The documents reviewed at the meeting were:

Document	*Version*	*Date*
Copies of advertisement materials for research participants [Advertisement Poster Version 1]	1	18 June 2014
Evidence of Sponsor insurance or indemnity (non NHS Sponsors only) [Insurance Documents]	1	18 June 2014
Interview schedules or topic guides for participants [Interview Schedule Version 1]	1	18 June 2014
IRAS Checklist XML [Checklist_23062014]		23 June 2014
Other [Declaration of interest form (Version 1)]	1	13 June 2014
Other [Demographic Information (Version 1)]	1	13 June 2014
Participant consent form [Consent Form (Parent Guardian Version 1)]	1	19 June 2014
Participant consent form [Assent Form (Version 1)]	1	19 June 2014
Participant consent form [Consent Form (Young People Version 1)]	1	19 June 2014
Participant information sheet (PIS) [Participant Information Sheet Parent Version 1]	1	18 June 2014
Participant information sheet (PIS) [Participant Information Sheet (Young People Version 1)]	1	18 June 2014
REC Application Form [REC_Form_23062014]		23 June 2014
Research protocol or project proposal [Protocol]	1	19 June 2014
Summary CV for Chief Investigator (CI) [Summary CV for Chief Investigator (CI) 13.06.14]	1	13 June 2014
Summary CV for supervisor (student research) [Academic Supervisor CV]	1	04 June 2014

Membership of the Committee

The members of the Committee who were present at the meeting are listed on the attached sheet

Statement of compliance

The Committee is constituted in accordance with the Governance Arrangements for Research Ethics Committees and complies fully with the Standard Operating Procedures for Research Ethics Committees in the UK.

14/NW/1094 **Please quote this number on all correspondence**

Yours sincerely

pp.

Dr Lisa Booth
Chair

Email: nrescommittee.northwest-lancaster@nhs.net

Enclosures: *List of names and professions of members who were present at the meeting and those who submitted written comments.*

Copy to: *Mrs Debbie Knight*
[redacted]

NRES Committee North West - Lancaster

Attendance at Committee meeting on 10 July 2014

Committee Members:

Name	*Profession*	*Present*	*Notes*
[redacted]	Lecturer	No	
[redacted]	Pharmacist	Yes	
[redacted]	Senior Lecturer / Chair	Yes	
[redacted]	Service Improvement Manager	Yes	Co-opted from Preston
[redacted]	Lay Member	No	
[redacted]	Lay Member	Yes	
[redacted]	Lecturer in Medical Ethics	No	
[redacted]	Consultant Paediatrician	No	
[redacted]	Senior Clinical Tutor	Yes	
[redacted]	Retired GP	No	
[redacted]	Nurse (Retired)	Yes	
[redacted]	Professor of Speech Pathology	No	
[redacted]	Consultant in Dental Public Health (retired)	Yes	

Also in attendance:

Name	*Position (or reason for attending)*
Mrs Carol Ebenezer	REC Manager
Maggie O'Connor	REC Assistant

Appendix N: Response to Provisional Approval Letter

21st July 2014

Dr Lisa Booth

NRES Committee North West – Lancaster

Barlow House

3rd Floor

4 Minshull Street

Manchester

M1 3DZ

Dear Dr Booth,

Study Title: What is the lived experience of young people during their admission to a psychiatric inpatient unit?

REC Reference: 14/NW/1094

IRAS Project ID: 153145

Thank you for your letter dated 16th July 2014. I have now made the amendments requested as detailed below.

a. Both the Young Peoples and Parents Participant Information Sheets have been amended in order to reflect the fact that young people can be accompanied by an adult should they so wish and that the staff will be aware of their participation in the study. Typographical errors have also been amended.

b. The Advertisement Poster has also been amended. As I have already consulted with young people at [redacted] regarding the design of this poster I have made the amendments without repeating this process. The young people involved in the initial consultation indicated that they would like to see bright and colourful posters. Therefore, I have continued to be mindful of this in the revised design. I have removed the propaganda reference and included a photograph of myself in the hope that this will render the document more age appropriate.

c. The consent forms have been revised in order to ensure that there is space for a signature at the bottom. This was included in the original version but there appears to have been a change in formatting when the documents are opened. I have also deleted the phrase 'I understand that the information from my interview will be mixed in with what other young people say and that people wont be able to tell who said what' in accordance with recommendations from the Committee and [redacted] R&D.

d. I have also amended the declaration of interest form in accordance with recommendations from [redacted] by including a tick box to ensure that young people are aware that staff will be contacted regarding their participation in the study.

Yours sincerely,

Rachael Ellis (Trainee Clinical Psychologist and Chief Investigator)

Appendix O: Approval Letter Received from REC

1

NHS
Health Research Authority
National Research Ethics Service

NRES Committee North West - Lancaster
Barlow House
3rd Floor
4 Minshull Street
Manchester
M1 3DZ

Telephone: 0161 625 7818
Fax:0161 625 7299

23 July 2014

[redacted]

Dear Miss Ellis

Study title:	**What is the lived experience of young people during their admission to a psychiatric inpatient unit?**
REC reference:	**14/NW/1094**
IRAS project ID:	**153145**

Thank you for your response to the Committee's request for further information on the above research and for the revised documentation.

The further information has been considered on behalf of the Committee by the Chair.

We plan to publish your research summary wording for the above study on the HRA website, together with your contact details. Publication will be no earlier than three months from the date of this opinion letter. Should you wish to provide a substitute contact point, require further information, or wish to make a request to postpone publication, please contact the REC Manager, Mrs Carol Ebenezer, nrescommittee.northwest-lancaster@nhs.net.

Confirmation of ethical opinion

On behalf of the Committee, I am pleased to confirm a favourable ethical opinion for the above research on the basis described in the application form, protocol and supporting documentation as revised, subject to the conditions specified below.

Conditions of the favourable opinion

The favourable opinion is subject to the following conditions being met prior to the start of the study.

Management permission or approval must be obtained from each host organisation prior to the start of the study at the site concerned.

Management permission ("R&D approval") should be sought from all NHS organisations involved in the study in accordance with NHS research governance arrangements.

Guidance on applying for NHS permission for research is available in the Integrated Research Application System or at http://www.rdforum.nhs.uk.

Where a NHS organisation's role in the study is limited to identifying and referring potential participants to research sites ("participant identification centre"), guidance should be sought from the R&D office on the information it requires to give permission for this activity.

For non-NHS sites, site management permission should be obtained in accordance with the procedures of the relevant host organisation.

Sponsors are not required to notify the Committee of approvals from host organisations

Registration of Clinical Trials

All clinical trials (defined as the first four categories on the IRAS filter page) must be registered on a publically accessible database within 6 weeks of recruitment of the first participant (for medical device studies, within the timeline determined by the current registration and publication trees).

There is no requirement to separately notify the REC but you should do so at the earliest opportunity e.g when submitting an amendment. We will audit the registration details as part of the annual progress reporting process.

To ensure transparency in research, we strongly recommend that all research is registered but for non clinical trials this is not currently mandatory.

If a sponsor wishes to contest the need for registration they should contact Catherine Blewett (catherineblewett@nhs.net), the HRA does not, however, expect exceptions to be made. Guidance on where to register is provided within IRAS.

It is the responsibility of the sponsor to ensure that all the conditions are complied with before the start of the study or its initiation at a particular site (as applicable).

Ethical review of research sites

NHS sites

The favourable opinion applies to all NHS sites taking part in the study, subject to management permission being obtained from the NHS/HSC R&D office prior to the start of the study (see "Conditions of the favourable opinion" below).

Approved documents

The final list of documents reviewed and approved by the Committee is as follows:

Document	*Version*	*Date*
Copies of advertisement materials for research participants [Advertisement Poster Version 1]	2	21 July 2014
Covering letter on headed paper [Cover Letter re: Ammendments]	1	21 July 2014
Evidence of Sponsor insurance or indemnity (non NHS Sponsors only) [Insurance Documents]	1	18 June 2014
Interview schedules or topic guides for participants [Interview Schedule Version 1]	1	18 June 2014
IRAS Checklist XML [Checklist_23062014]		23 June 2014
IRAS Checklist XML [Checklist_22072014]		22 July 2014
Other [Demographic Information (Version 1)]	1	13 June 2014
Other [Declaration of interest form (Version 1)]	2	21 July 2014

3

Participant consent form [Assent Form (Version 1)]	2	21 July 2014
Participant consent form [Consent Form (Young People Version 1)]	2	21 July 2014
Participant consent form [Consent Form (Parent Guardian Version 1)]	1	19 June 2014
Participant information sheet (PIS) [Participant Information Sheet (Young People Version 1)]	2	21 July 2014
Participant information sheet (PIS) [Participant Information Sheet (Young People Version 1)]	1	18 June 2014
Participant information sheet (PIS) [Participant Information Sheet Parent Version 1]	2	21 July 2014
Participant information sheet (PIS) [Participant Information Sheet Parent Version 1]	1	18 June 2014
REC Application Form [REC_Form_23062014]		23 June 2014
Research protocol or project proposal [Protocol]	1	19 June 2014
Summary CV for Chief Investigator (CI) [Summary CV for Chief Investigator (CI) 13.06.14]	1	13 June 2014
Summary CV for supervisor (student research) [Academic Supervisor CV]	1	04 June 2014

Statement of compliance

The Committee is constituted in accordance with the Governance Arrangements for Research Ethics Committees and complies fully with the Standard Operating Procedures for Research Ethics Committees in the UK.

After ethical review

Reporting requirements

The attached document *"After ethical review – guidance for researchers"* gives detailed guidance on reporting requirements for studies with a favourable opinion, including:

- Notifying substantial amendments
- Adding new sites and investigators
- Notification of serious breaches of the protocol
- Progress and safety reports
- Notifying the end of the study

The HRA website also provides guidance on these topics, which is updated in the light of changes in reporting requirements or procedures.

Feedback

You are invited to give your view of the service that you have received from the National Research Ethics Service and the application procedure. If you wish to make your views known please use the feedback form available on the HRA website: http://www.hra.nhs.uk/about-the-hra/governance/quality-assurance/

We are pleased to welcome researchers and R & D staff at our NRES committee members' training days – see details at http://www.hra.nhs.uk/hra-training/

14/NW/1094 Please quote this number on all correspondence

4
With the Committee's best wishes for the success of this project.

Yours sincerely

Dr Lisa Booth
Chair

Email:nrescommittee.northwest-lancaster@nhs.net

Enclosures:	"After ethical review – guidance for researchers"
Copy to:	*Mrs Debbie Knight* [redacted]

Appendix P: Approval Letters Received from R&D Departments

[redacted]

23rd July 2014

Miss Rachael Ellis
Trainee Clinical Psychologist
Lancashire Care NHS Trust
Clinical Psychology
Faculty of Health and Medicine
Floor C, Furness College
Lancaster University
Lancaster, LA1 4YG

Dear *Miss Ellis*,

Re: NHS Trust Permission to Proceed

Project Reference: 14/14

Project Title: What is the lived experience of young people during their admission to a psychiatric inpatient unit?

I am pleased to inform you that the above project has received research governance permission.

Please take the time to read through this letter carefully and contact me if you would like any further information. You will need this letter as proof of your permission.

Trust R&D permission covers all locations within the Trust; however you will only be allowed to recruit from the sites/services you have indicated in section 3 of the SSI application form. If you would like to expand recruitment into other services in the Trust that are not on the original SSI then you must contact the R&D department immediately to discuss this before doing so.

You also must ensure you have liaised with and obtained the agreement of individual service/ward managers before commencing recruitment in that service and you must contact the relevant service/ward managers prior to accessing the service to make an appointment to visit before you can commence your study in the trust.

Please make sure that you take your Trust permission letter with you when accessing Trust premises and please include the Trust reference number on any correspondence/emails so that the services are assured permission has been granted.

[redacted]

[redacted]

Honorary Research contracts (HRC)
All researchers with no contractual relationship with any NHS body, who are to interact with individuals in a way that **directly affects the quality of their care**, should hold Honorary Research NHS contracts. Researchers have a contractual relationship with an NHS body either when they are employees or when they are contracted to provide NHS services, for example as independent practitioners or when they are employed by an independent practitioner (*Research Governance Framework for Health and Social Care,* 2005). If a researcher does not require an HRC, they would require a Letter of Access (LoA). For more information on whether you or any of your research team will require an HRC or LoA please liaise with this office. It is your responsibility to inform us if any of your team do not hold Honorary Research NHS contracts/Letters of Access.

Staff involved in research in NHS organisations may frequently change during the course of a research project. Any changes to the research team or any changes in the circumstances of researchers that may have an impact on their suitability to conduct research MUST be notified to the Trust immediately by the Principal Investigator (or nominated person) so that the necessary arrangements can be put in place

Research Governance
The Research Governance Sponsor for this study is Lancaster University. Whilst conducting this study you must fully comply with the Research Governance Framework. This can be accessed at:
http://www.dh.gov.uk/PublicationsAndStatistics/Publications/PublicationsPolicyAndGuidance/PublicationsPolicyAndGuidanceArticle/fs/en?CONTENT_ID=4108962&chk=Wde1Tv
For further information or guidance concerning your responsibilities, please contact your research governance sponsor or your local R&D office.

Good Clinical Practice (GCP)
GCP is an international ethical and scientific quality standard for designing, conducting, recording and reporting trials that involve the participation of human subjects. It is the responsibility of all researchers who are carrying out a research project involving NHS patients and carers to complete GCP training and to update this every 2 years. All training certificates must be forwarded to the R&D department to comply with Trust permission. Please note that student projects are exempt from this process.

Risk and Incident Reporting
Much effort goes into designing and planning high quality research which reduces risk; however untoward incidents or unexpected events (i.e. not noted in the protocol) may occur in any research project. Where these events take place on trust premises, or involve trust service users, carers or staff, you must report the incident within 48 hours via the Trust incident reporting system. If you are in any doubt whatsoever whether an incident should be reported, please contact us for support and guidance.

Regardless of who your employer is when undertaking the research within [redacted] you must adhere to trust policies and procedures at all times.

[redacted]

[redacted]

Confidentiality and Information Governance
All personnel working on this project are bound by a duty of confidentiality. All material accessed in the trust must be treated in accordance with the Data Protection Act (1998) For good practice guidance on information governance contact us.

Protocol / Substantial Amendments
You must ensure that the approved protocol is followed at all times. Should you need to amend the protocol, please follow the Research Ethics Committee procedures and inform all NHS organisations participating in your research.

Monitoring / Participant Recruitment Details
If your study duration is less than one year, you will be required to complete an end of study feedback report on completion. However if your study duration is more than one year, you will be required to complete a short electronic progress report annually and an end of study report on completion. As part of this requirement, please ensure that you are able to supply an accurate breakdown of research participant numbers for this trust (recruitment target, actual numbers recruited). To reduce bureaucracy, progress reporting is kept to a minimum; however, if you fail to supply the information requested, the trust may withdraw permission.

Recruitment
Please provide the trust details of your recruitment numbers when requested. If you have any concerns with recruitment please contact the R&D team immediately for assistance.

Final Reports
At the end of your research study, we will request a final summary report so that your findings are made available to local NHS staff. The details from this report may be published on the NHS Trust internet site to ensure findings are disseminated as widely as possible to stakeholders. You may also be invited to present your findings to the Trust at an event or meeting.

On behalf of this Trust, may I wish you every success with your research. Please do not hesitate to contact us for further information or guidance.

[redacted]

[redacted]

[redacted]
R&D Director
On Behalf of the Research Governance Sub-Committee

Cc: ethics@lancaster.ac.uk
[redacted]

[redacted]

[redacted]

Standardised Process for Electronic Approval of Research

[redacted]

29 July 2014

[redacted]

Miss Rachael Ellis
Clinical Psychology
Faculty of Health and Medicine
Floor C, Furness College
Lancaster University
Lancaster
LA1 4YG

Information for ID Badge if required:
Research Project Ref No: 841
Expiry Date: 29/06/2015
You must take this letter with you.

Dear Miss Ellis

Re: NHS Permission for Research

Project Reference: 841
REC Reference Number: 14/NW/1094
Sponsor: Lancaster University
Project Title: What is the lived experience of young people during their admission to a psychiatric inpatient unit?
Date of Permission: 29 July 2014

Further to your request for permission to conduct the above research study at this Trust, we are pleased to inform you that this Trust has given NHS permission for the research. **Your NHS permission to conduct research at this site is only valid upon receipt of a signed 'Conditions for NHS Permission Reply Slip' which is enclosed**.

Please take the time to read the attached conditions for NHS permission. Please contact the R&D Office should you require any further information. You will need this letter as proof of NHS permission. Please note when contacting the R&D office about your study you must always provide the project reference numbers provided above.

NHS permission for the above research has been granted on the basis described in the IRAS application form, Protocol and supporting documentation.

The documents reviewed were:

Protocol
Participant Information Sheet, Version 2, dated 21/07/2014
Parent/Carer Information Sheet, Version 1, dated 18/06/2014
Participant Consent Form (For young people over 16), Version 2, dated 21/07/2014

[redacted]

Parent / Guardian Consent Form (For young people under 16), Version 1, dated 18/06/2014
Assent Form (For young people under 16), Version 2, dated 21/07/2014
Declaration of Interest, Version 2, dated 21/07/2014
Demographic Information, Version 1, dated 18/06/2014
Interview Schedule, Version 1, dated 18/06/2014
Advertisement Poster, Version 2, dated 21/07/2014
REC letter giving favourable ethical opinion, dated 23/07/2014

Permission is granted on the understanding that the study is conducted in accordance with the Research Governance Framework, ICH GCP (if applicable), and NHS Trust policies and procedures. Permission is only granted for the activities for which a favourable opinion has been given by the Ethics.

Permission covers all locations within the Trust, however, you should ensure you have liaised with and obtained the agreement of individual service/ward managers before commencing your research.

We would like to point out that hosting research studies incurs costs for the Trust such as: staff time, usage of rooms, arrangements for governance of research. We can confirm that in this instance we will not charge for these. However, we would like to remind you that Trust costs should be considered and costed at the earliest stage in the development of any future proposals.

May I wish you every success with your research.

Yours sincerely

[redacted]

[redacted]

cc : Sponsor: Lancaster University

Enc: Approval Conditions Leaflet
Induction & ID Badge Information

Study Ref Number: 841
Study Title: What is the lived experience of young people during their admission to a psychiatric inpatient unit?

Conditions for NHS Permission Reply Slip

In order for your NHS permission to be valid, please return this form to the address below to confirm that you have read and understood the conditions of NHS permission to conduct research.

1. I confirm that I have read and understand my duties and responsibilities as part of the conditions for permission to conduct research at this site.

2. I understand that I must submit the following information to the Trust's R&D department:

    - Recruitment figures on a monthly basis
    - New researcher details prior to them commencing on the research project
    - Any amendments submitted to the Ethics Committee
    - Changes to the status of the research project
    - Any urgent safety measure incorporated
    - Untoward Incidents and Unexpected Events within 24 hours of their occurrence
    - A final summary report
    - A copy of the Ethics letter confirming receipt of the End of Study Declaration

3. I understand I must complete and return in a timely manner any audit forms sent to me by the Trust.

4. I understand that I must gain permission from the trust in order to publish or place information of the current research into the public domain.

Signed…………………………………………………………………………………….

PRINT NAME………………………………………………………………………….

Date…………………………………………………………………………………

Estimated Start date to commence research at this Trust …………………………….

Which site will you approach first? …………………………………………………….

Expected recruitment target at this Trust? …………………………………………….

Please return to: [redacted]

[redacted]

v2.1

[redacted]

Our ref: 841

[redacted]

29 July 2014

Miss Rachael Ellis
Clinical Psychology
Faculty of Health and Medicine
Floor C, Furness College
Lancaster University
Lancaster
LA1 4YG

Dear Miss Ellis

Letter of Access for Research

As an existing NHS employee you do not require an additional honorary research contract with this NHS organisation. We are satisfied that the research activities that you will undertake in this NHS organisation are commensurate with the activities you undertake for your employer. Your employer is fully responsible for ensuring such checks as are necessary have been carried out. Your employer has confirmed in writing to this NHS organisation that the necessary pre-engagement check are in place in accordance with the role you plan to carry out in this organisation. This letter confirms your right of access to conduct research through [redacted] for the purpose and on the terms and conditions set out below. This right of access commences on **29/07/2014** and ends on **29/05/2015** unless terminated earlier in accordance with the clauses below.

You have a right of access to conduct such research as confirmed in writing in the letter of permission for research from this NHS organisation. Please note that you cannot start the research until the Principal Investigator for the research project has received a letter from us giving permission to conduct the project.

You are considered to be a legal visitor to [redacted] premises. You are not entitled to any form of payment or access to other benefits provided by this organisation to employees and this letter does not give rise to any other relationship between you and this NHS organisation, in particular that of an employee.

While undertaking research through [redacted] you will remain accountable to your employer Lancashire Care NHS Foundation Trust but you are required to follow the reasonable instructions of the relevant service manager(s) in this NHS organisation or those given on her/his behalf in relation to the terms of this right of access.

Where any third party claim is made, whether or not legal proceedings are issued, arising out of or in connection with your right of access, you are required to co-operate fully with any investigation by this NHS organisation in connection with any such claim and to give all such assistance as may reasonably be required regarding the conduct of any legal proceedings.

You must act in accordance with [redacted] policies and procedures, which are available to you upon request, and the Research Governance Framework.

[redacted]

v2.1

You are required to co-operate with [redacted] in discharging its duties under the Health and Safety at Work etc Act 1974 and other health and safety legislation and to take reasonable care for the health and safety of yourself and others while on [redacted] premises. Although you are not a contract holder, you must observe the same standards of care and propriety in dealing with patients, staff, visitors, equipment and premises as is expected of a contract holder and you must act appropriately, responsibly and professionally at all times.

You are required to ensure that all information regarding patients or staff remains secure and *strictly confidential* at all times. You must ensure that you understand and comply with the requirements of the NHS Confidentiality Code of Practice (http://www.dh.gov.uk/assetRoot/04/06/92/54/04069254.pdf) and the Data Protection Act 1998. Furthermore you should be aware that under the Act, unauthorised disclosure of information is an offence and such disclosures may lead to prosecution.

[redacted] will not indemnify you against any liability incurred as a result of any breach of confidentiality or breach of the Data Protection Act 1998. Any breach of the Data Protection Act 1998 may result in legal action against you and/or your substantive employer.

You should ensure that, where you are issued with an identity or security card, a bleep number, email or library account, keys or protective clothing, these are returned upon termination of this arrangement. Please also ensure that while on the premises you wear your ID badge at all times, or are able to prove your identity if challenged. Please note that this NHS organisation accepts no responsibility for damage to or loss of personal property.

We may terminate your right to attend at any time either by giving seven days' written *notice to you or* immediately without any notice if you are in breach of any of the terms or conditions described in this letter or if you commit any act that we reasonably consider to amount to serious misconduct or to be disruptive and/or prejudicial to the interests and/or business of this NHS organisation or if you are convicted of any criminal offence. Where applicable, your substantive employer will initiate your Independent Safeguarding Authority (ISA) registration in-line with the phasing strategy adopted within the NHS and the applicable legislation. Once you are ISA-registered, your employer will continue to monitor your ISA registration status via the on-line ISA service. Should you cease to be ISA-registered, this letter of access is immediately terminated. Your substantive employer will immediately withdraw you from undertaking this or any other regulated activity and you MUST stop undertaking any regulated activity.

Your substantive employer is responsible for your conduct during this research project and may in the circumstances described above instigate disciplinary action against you.

If your circumstances change in relation to your health, criminal record, professional registration or ISA registration, or any other aspect that may impact on your suitability to conduct research, or your role in research changes, you must inform the NHS organisation that employs you through its normal procedures. You must also inform your nominated manager in this NHS organisation.

Yours sincerely

[redacted]

pp [redacted]

[redacted]

Appendix Q: Correspondence with REC Regarding Participant Numbers

From: Ellis, Rachael [mailto:r.ellis2@lancaster.ac.uk]
Sent: 06 May 2015 10:23
To: Lancaster NRESCommittee.NorthWest- (HEALTH RESEARCH AUTHORITY)
Cc: Smith, Ian; Ethics (RSO) Enquiries
Subject: REC Ref 14/NW/1094 Enquiry

To whom it may concern,

RE: REC Ref 14/NW/1094
Study Title: What is the lived experience of young people during their admission to a psychiatric inpatient unit?

I am writing to detail my enquiry for yourselves following a telephone conversation with your colleague this morning.

I am currently reviewing my ethics submission and have noted that on my research protocol I have stated that I will recruit approximately 6 - 8 young people. Due to the quality of the data collected and the interest expressed from young people at the recruitment sites, I ultimately recruited 10 young people in total. The recruitment is now complete and there will be no further recruitment for this study.

However, I just reviewed the REC form and noticed that whilst I noted that the number of participants recruited would rely upon the richness of the data collected (Section A60) I have noted that (in Section A59) that I will recruit up to 8 young people.

This morning I have contacted my sponsor (Lancaster University) on the advice of your colleague. A representative from Lancaster University advised that I contact yourselves as they defer all decisions regarding possible amendments back to yourselves.

I apologise for these discrepancies and would be grateful if you could let me know what, if any, action to take.

Yours sincerely,
Rachael Ellis

Trainee Clinical Psychologist
Clinical Psychology

Faculty of Health and Medicine

Floor

Furness College

Lancaster University

Lancaster

LA1 4YG
Email: r.ellis2@lancaster.ac.uk

Dear Rachel,

I spoke with the REC Manager and she has said that all you will need to do is detail this in your Annual Progress Report which is due on the anniversary of the favourable ethical opinion i.e. in 79 days. I attach a blank Progress Report form for you so when it's the 23rd of July, you can send it back to us.

I hope this helps.

Kind regards,

Regina

Regina Caden | REC Assistant

RES Committee North West - Lancaster

Health Research Authority
3rd Floor, Barlow House, 4 Minshull St., Manchester, M1 3DZ
E: nrescommittee.northwest-lancaster@nhs.net | T: 0161 625 7819 | www.hra.nhs.uk