ETHICS SECTION

Section Four: Ethics Section

REC Form

- (●) 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?

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○ 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 student will act as Principal Investigator

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

ETHICS SECTION

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)
Using IPA to understand the experiences of ICD shock-recipients

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

REC Name:
North West Lancaster

REC Reference Number:
13/NW/0638

Submission date:
13/08/2013

PART A: Core study information

1. ADMINISTRATIVE DETAILS

A1. Full title of the research:

Using IPA to understand the experiences of implantable cardioverter defibrillator shock-recipients

A2-1. Educational projects

Name and contact details of student(s):

Student 1

Title	Forename/Initials	Surname
Mr	Richard	Colley

Address: C16 Furness College, Lancaster University, Lancaster
Post Code: LA1 4YG
E-mail: colleyr@exchange.lancs.ac.uk
Telephone: 01524 593378
Fax: 01524 592401

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

ETHICS SECTION

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

[redacted]

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 Mr Richard Colley	☑ [redacted]

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
	Mr	Richard	Colley
Post	Trainee Clinical Psychologist		
Qualifications	Postgraduate Certificate in Primary Care Mental Health Practice MSc Addictive Behaviours Graduate Diploma in Psychology		
Employer	Lancashire Care Foundation Trust		
Work Address	C16 Furness College Lancaster University Lancaster		
Post Code	LA1 4YG		

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Work E-mail	colleyr@exchange.lancs.ac.uk
* Personal E-mail	
Work Telephone	01524 593378
* Personal Telephone/Mobile	
Fax	01524 592401

** 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

[redacted]

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:	
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.

ETHICS 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 qualitative study seeks to explore the experiences of cardiac patients who have received five or more shocks from an implantable cardiovertor defibrillator (ICD), which are devices designed to restore unstable heart rhythms by delivering electrical charges to the heart. Interviews of up to ten ICD recipients will be conducted and then analysed using Interpretative Phenomenological Analysis, allowing themes to be extracted from the accounts. It is hoped that these findings will contribute to the development of psychological therapies designed to ameliorate the distress and despair of those who experience psychological difficulties following repeated ICD shocks.

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.

The main ethical issues concern interviewing people who may be experiencing psychological difficulties about the source of their distress. This risks them experiencing distress as a consequence of participating in the study. I have addressed this issue in several ways:

Firstly, as a trainee clinical psychologist, I am trained and experienced in containing people's distress;

Secondly, I will have received supervision about how to contain the distress of people experiencing symptoms of traumatic stress and posttraumatic stress disorder from a Consultant Clinical Psychologist [redacted] who specialises in this field;

Thirdly, in the event of them requiring such support in the immediate aftermath of the interview, participants will have prompt access to a clinical psychologist [redacted] based at the site at which interviews will likely occur [redacted]

Finally, having outlined the limits of confidentiality at the start of the interview, if any issues regarding the safety of the participant or of another individual came to light during the interview I would inform him/her of the need to break confidentiality and then contact my field supervisor.

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

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- ☐ Cross-sectional study
- ☐ Database analysis
- ☐ Epidemiology
- ☐ Feasibility/ pilot study
- ☐ Laboratory study
- ☐ Metanalysis
- ☑ Qualitative research
- ☑ 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 principal objective of the study is to gain insight into how ICD shock-recipients construe and cope with their shock experiences. It is hoped that this will yield valuable information that may be used to develop psychological interventions designed to ameliorate ICD shock-related psychological distress.

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

Which experiential phenomena and interpretations thereof appear to distinguish those who experience psychological difficulties in the context of ICD shocks from those who do not?

How do ICD shock experiences relate to those linked to other traumatising phenomena?

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

Although ICDs were initially fitted primarily for primary prevention of cardiac arrest, they are increasingly being fitted for secondary prevention (i.e. in the absence of the individual having experienced a cardiac event or a dangerously unstable heart rhythm). Thus, increasing numbers of ICDs are being fitted. The devices deliver shocks of variable intensity, depending on the nature of the unstable heart rhythm they detect. They have also been shown to deliver 'inappropriate' shocks i.e. in the absence of an unstable heart rhythm. Both appropriate and inappropriate shocks have been associated with the emergence of various psychological difficulties, including anxiety, depression and posttraumatic stress disorder. Given the number of people who experience shocks and who go on to experience psychological difficulties as a result, it seems pertinent to explore shock-experiences so that psychological interventions may be developed.

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.*

A qualitative design is being proposed for this study because there is currently no research looking at the experiences of ICD-recipients who have experienced five or more shocks. This research is needed because of the increasing numbers of people who are experiencing psychological difficulties as a consequence of such shocks. Qualitative research will be able to tell us how ICD shock-recipients construe and cope with their shock experiences; this should yield valuable information that may be used to develop psychological interventions designed to ameliorate ICD shock-related psychological distress.

Approximate Timetable:

Applying for ethical approval - July-September 2013

Recruitment for the study - September/October 2013

Data gathering - September/October 2013-February 2014

Data analysis/write-up - October/November 2013-May 2014.

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Potential participants will be invited to take part in several ways:

1) By cardiac specialist nurses during routine consultations at [redacted]

2) By members of the Pacing Team, who see the patients to monitor and calibrate the devices.

3) By consultant cardiologists during patients' consultations.

4) By the team's clinical psychologist, [redacted] if she treats ICD-recipients presenting with psychological difficulties relating to their shock experiences.

ICD patients will be invited to participate if they meet the inclusion criteria (i.e. have received five or more shocks, the last of which has occurred within twelve months of the interview; are not currently receiving psychological therapy for an unrelated psychological difficulty; and are both fluent in English and in good enough physical condition to be interviewed (see exclusion criteria)). Potential participants will receive a participant information sheet containing details of the study. They will be asked to signal their interest in participating by contacting the Chief Investigator using the details on the participant information sheet or by completing and returning to LCC the contact detail slip attached to the information sheet.

The Chief Investigator will then contact the prospective participants to answer any questions about the study and to arrange to interview them in person, should they agree to participate.

Interviews will take place at [redacted]at participants' home, or at a community location of their choosing. If sufficient volunteers are willing to be interviewed at the hospital, these individuals will be preferentially selected because of the extra support readily at hand in the event of a participant becoming particularly distressed.

At the start of each interview, participants will be advised about the limits of confidentiality so that they know disclosures that indicate someone is or has been under threat of harm from another will need to be shared and that anonymity in this context will not be preserved. They will then be asked to complete and sign a consent form. The interview will proceed following a broadly predetermined sequence of questions, although the specific order and content of questions will be influenced by participants' particular responses. Interviews will last up to approximately sixty minutes. At the end of each interview, participants will receive a debrief sheet outlining avenues of support if they experience distress following the interview.

Interview data will be transcribed verbatim and then subject to Interpretative Phenomenological Analysis. This involves coding the transcripts then using the codes to identify themes across the transcripts. In order to reduce the impact of researcher bias, this process will be undertaken in concert with the project supervisors. Initial interviews will be transcribed immediately after their completion and will be used to shape subsequent interviews.

Once the analysis is complete, the findings will be written up for the report. A summary of the report will be sent to those participants who have requested one.

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.
Service-users were invited to a formative discussion about the project and asked to contribute suggestions and feedback to help shape the design and methodology of the study. The service-users will be provided with a summary of the research, once completed.

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RESEARCH PARTICIPANTS

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

Has received 5+ ICD shocks.

Speaks fluent English.

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

Not being treated for an unrelated psychological difficulty at the point of interview.

Physical health status that makes it difficult for patients to participate; for example, those who are convalescing from a recent cardiac event or who have comorbid health difficulties that impact on their ability to engage in sustained conversation for the requisite amount of time.

Latest shock must not have occurred more than 1 year prior to 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
ICD patient invited to participate and provided with information sheet if interested	1	0	10 minutes	Cardiac nurse / cardiac clinical psychologist; [redacted]
Conversation/email exchange with Chief Investigator to discuss project and possibly arrange interview	1	0	5-60 mins	Chief Investigator; wherever prospective participant chooses.
Interview	1	0	60 mins	Chief Investigator; [redacted] participant's home, or a community location

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

Nine months from the point at which they are invited to participate until they are no longer able to withdraw their data from the study. The period between their initial invitation and their interview will be five months.

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.

Because the focus of the interview will be experiences the participants may find distressing, there is a risk of them experiencing distress as a result of the interview. A number of steps have been taken to minimise this risk. Firstly, the Chief Investigator is a trainee clinical psychologist with skills in containing people's emotional distress; secondly, the Chief Investigator will have received instruction in how to contain others' traumatic stress from a Consultant Clinical Psychologist who works exclusively with people who have been diagnosed with posttraumatic stress disorder; thirdly,

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participants who require it will have ready access to a clinical psychologist following the interview; finally, each participant will receive a debrief sheet detailing other avenues of support should they require it.

Furthermore, although prospective participants will be offered the option of being interviewed in their homes, if sufficient volunteers are willing to be interviewed at the hospital, these individuals will be preferentially selected. This is because extra support will be more readily at hand in the event of a participant becoming particularly distressed.

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 people who may be experiencing distress resultant of ICD shocks will be asked to reflect on potentially stressful aspects of their lives, they may experience some distress consequential to the interview. As a trainee clinical psychologist, the Chief Investigator has developed skills in containing emotional distress, in the event of a participant becoming distressed during the interview. By the time of interview, the Chief Investigator will have received additional instruction in how to manage others' acute traumatic stress from a Consultant Clinical Psychologist who specialises in working with people with severe posttraumatic stress disorder. Furthermore, a debrief sheet outlining appropriate support will be provided to each participant following their interview.

All of the participants will either have been seen by [redacted] clinical psychologist or will be able to see her promptly if warranted.

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

There is no direct potential benefit to participants, although the experience of being interviewed may be cathartic and the participants may derive some satisfaction from knowing that their responses could contribute to the development of interventions designed to help others who experience ICD shocks.

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

In the event of being unable to attract a sufficient number of people willing to be interviewed at Lancashire Cardiac Centre, some participants may be interviewed at home, in which case the Chief Investigator will follow the lone-worker policies of [redacted] and Lancaster University. There are no other potential risks.

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).*

Potential participants will be recruited from the ICD-patient population served by [redacted]. The activity of patients' devices is monitored by the cardiac team remotely and/or at [redacted] itself on a regular basis. Thus, clinicians at [redacted] are aware of which patients have experienced the requisite number of shocks.

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:

Only medical staff will have access to potential participants' details. At no stage will the researchers have access to

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this information, unless it has been provided by the participants themselves following their invitation to participate.

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

○ Yes ◉ No

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

Clinicians at [redacted] are aware of which patients have experienced the requisite number of shocks. They have agreed to invite those who satisfy all the inclusion/exclusion criteria when they attend their routine appointments and to pass on the participant information pack. Potential participants will be asked to contact the Chief Investigator by email or post; in the latter instance by completing a slip included in the information pack and posting it in a stamped and addressed envelope provided.

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.

Informed consent will be obtained immediately prior to the interview. Participants will be asked to read through the consent form and to ask any questions they deem necessary. Participants will be asked to indicate their agreement with each of the points made on the consent form and then to sign it.

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?

Potential participants will be contacted by the Chief Investigator no less than four hours from the point at which they signal their interest in participating. They will be free to withdraw prior to and during their interview and to have their data removed from the study at any stage subsequently; however, they will be advised that it may not be possible to remove their data once it has been anonymised and integrated with that of the other participants.

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 financial constraints it is not possible to make provision for people who do not speak English. For the same reason, translators for people with communication difficulties cannot be provided.

A33-2. What arrangements will you make to comply with the principles of the Welsh Language Act in the provision of information to participants in Wales?

N/A

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.*

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(●) 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
- [x] 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
- [ ] Use of audio/visual recording devices
- [x] Storage of personal data on any of the following:
  - [ ] Manual files including X–rays
  - [ ] NHS computers
  - [x] Home or other personal computers
  - [x] University computers
  - [ ] Private company computers
  - [x] Laptop computers

Further details:

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.*

Recordings will be given code numbers. Data that could identify participants will only be accessible to the Chief Investigator and only at his home. Only anonymised/pseudonymised data will be transported. All data will be anonymised/pseudonymised prior to being stored. All identifiers will be omitted from the completed report.

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.*

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The Chief Investigator and the academic supervisor will have access to participants' personal data; consent will be obtained for this. The field supervisor may assist with data analysis once the data have been pseudonymised.

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

If Yes, please give details. For monetary payments, indicate how much and on what basis this has been determined.
Up to £10.00 will be reimbursed to participants to cover travel/parking expenses, once proof of said costs has been provided.

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.

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A Powerpoint presentation based on the completed report will be made publicly available on Lancaster University's website. As the report will be submitted for publication, it may also appear on the relevant journal's website.

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
- [x] 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)

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.
Participants who wish to see the results of the study will be sent a summary of them once the thesis of which it is a part has been marked.

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
- [x] 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:
The study's design was reviewed by a group comprising service-users, peers and course lecturers. Revisions to the design were made following this discussion.

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.*

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Total UK sample size: 10
Total international sample size (including UK): 10
Total in European Economic Area:

Further details:

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.*

The sample size was determined in relation to the analytic methodology. Interpretative Phenomenological Analysis requires a minimum of 6-8 participants. Such studies featuring fewer less than 10 participants are seldom published.

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.

Interpretative Phenomenological Analysis will be used to identify themes within and across participants' accounts. This will enable the Chief Investigator to analyse what has been said both parsimoniously and in depth.

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]
Qualifications
Employer
Work Address
[redacted]
Fax
Mobile
Work Email
[redacted]
Fax
Mobile
Work Email

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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 [redacted]

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

- ☐ 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: 0

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)
- ☑ Other insurance or indemnity arrangements will apply (give details below)

Lancaster University will provide insurance.

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)
- ☑ Other insurance or indemnity arrangements will apply (give details below)

Lancaster University will provide insurance.

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

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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.

☐ 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)

Lancaster University will provide insurance.

Please enclose a copy of relevant documents.

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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]	[redacted]

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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

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- ○ 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.

Signature: .....

Print Name: Richard Colley

Date: *(dd/mm/yyyy)*

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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.

Signature: .....

Print Name:

Post:

Organisation: Lancaster University

Date: *(dd/mm/yyyy)*

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[redacted] [redacted] [redacted]

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

Signature: .....

Print Name: [redacted]

[redacted]

[redacted]

[redacted]

ETHICS SECTION

Research Protocol (Version 2 - 29/10/2013)

Title: Using IPA to understand the experiences of implantable cardioverter defibrillator shock-recipients

Applicant/Trainee clinical psychologist: Rich Colley

Course supervisor: [redacted]

Field supervisor: : [redacted]

Introduction

Implantable cardioverter defibrillators (ICDs) are devices designed to treat people who experience dangerously abnormal heart rhythms. They are permanently attached to the recipient's heart, monitoring its rhythms via electrodes. In the event of detecting abnormal rhythms (i.e. too fast or too slow), they restore normal functioning by delivering electrical charges (shocks) of variable intensity depending on the nature of the rhythm (British Heart Foundation, 2012). Sometimes ICDs fire inappropriately i.e. when there is no arrhythmia to correct or when the shock delivered is of disproportionate intensity (van Rees et al., 2011). Inappropriate shocks in particular come without warning, whilst recipients of appropriate shocks will generally lose consciousness before the device fires. Shocks have been likened by those who have experienced them while conscious to being "kicked in the chest by a big horse" (Habibovic et al., 2012). Not only this, but shock-recipients also receive a six-month driving ban in the aftermath of a shock, further increasing the negative impact of the device on recipients' lives.

As of 2006, UK implantation rates were approximately 50 per million per year (NICE, 2007). Approximately 50% of recipients may experience a shock over an eleven-year period (Buxton et al.,

2006). Over a five-year period, 18% of recipients may experience inappropriate shocks (van Rees et al., 2011).

Both appropriate and inappropriate shocks have been associated with significant reductions in quality of life (Thomas et al., 2006), as well as with anxiety and depression (Buxton et al., 2006), posttraumatic stress disorder (PTSD) (Habibovic et al., 2012), anger, helplessness and fear (Deaton et al., 2003). Not only are the psychological effects of these challenges unpleasant for ICD recipients and their families but there is evidence that anxiety, traumatic stress, anger, and depression may themselves precipitate the arrhythmias which trigger shocks (Habibovic et al., 2013; Lampert et al., 2000; 2002; Whang et al., 2005).

PTSD has been shown to affect 21% of ICD-recipients within 2 months of implantation (although this figure includes PTSD symptomatology associated with the cardiac event itself, not just the device). This prevalence has been shown to reduce to 8% at 18-month follow-up (Habibovic et al., 2012), at which point it becomes stable as symptoms become reactivated or new cases triggered by the shocks themselves or by other factors, possibly years after ICD implantation (von Känel et al., 2011).

Anecdotally, the clinical psychologist and nursing staff at [redacted] have reported increasing numbers of ICD-recipients presenting with symptoms of PTSD, particularly in the context of receiving numerous inappropriate shocks.

Quantitative research has delineated a number of factors that predict the development of PTSD symptoms in ICD recipients. These include: the number of shocks (Irvine et al., 2002; et al.; Passman et al., 2007; von Känel et al., 2011), female gender, lower level of education, dissociation at the time of the cardiac event, alexithymia (which denotes the inability to verbalise emotions), Type D personality (which denotes people who are prone to experiencing negative emotions and to inhibiting self-expression), and increased baseline helplessness, anxiety, depression and

posttraumatic stress (Habibovic et al., 2012; von Känel et al., 2011). In terms of the number of shocks received, five appears to be a critical threshold beyond which psychological difficulties are more likely to occur (Irvine et al., 2002; et al.; von Känel et al., 2011). Other predictors of PTSD identified elsewhere, such as low social support, coping style, neuroticism, and previous traumatisation (Spindler & Pedersen, 2005) have not yet been assessed.

Thus, little is understood about the specific experiential factors, and the interpretations thereof, which may account for the tendency of some ICD recipients to develop psychological difficulties in the context of ICD shocks while others do not. Furthermore, little is understood about the experiences of ICD shock-recipients more generally in terms of how they understand and respond to shocks.

Various qualitative studies have been conducted into the experiences of ICD-recipients (Bolse et al., 2005; Burke, 1996; Dickerson, 2002; Dunbar, 1993; Fridlund et al., 2000; Kamphuis et al., 2004; Tagney et al., 2003), but these have chiefly explored the process of adjusting to the device; only very seldom have studies explored the experience of the shocks themselves, and even then just tangentially and in respect of isolated shocks.

Certain factors particular to having an ICD may differentiate this experience from other potentially traumatising phenomena, such as combat or being the victim of violence. In particular, the precipitant of the trauma is still not only present but actually inside the person's body and liable to deliver a shock at any moment. This predicament may be further complicated by the fact that the device is necessary to sustain recipients' lives in the context of life-limiting heart problems. Moreover, shocks delivered by the device may re-traumatise recipients each time they occur, both because of the shocks themselves and because they are (meant to be) delivered in situations in which recipients' lives are at risk. Factors such as these arguably present therapists with unique challenges when working with such individuals.

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Current treatment includes group and individual CBT interventions to reduce PTSD symptoms, anxiety and depression (Pedersen, van den Broek, & Sears, 2007; Habibović, Burg & Pedersen, 2013), and to increase QoL (von Känel et al., 2011).

The proposed research would increase our understanding of how ICD-recipients understand their shock experiences, in order to identify potential avenues for therapeutic intervention. It may also equip ambulance crews and Accident & Emergency departments with information about how best to respond to patients who have received shocks.

Method

Participants

Up to 10 participants will be recruited, in line with guidance on conducting research utilising Interpretative Phenomenological Analysis (Smith & Osborn, 2003). The recruitment strategy incorporates a phased approach, with each phase being activated if that which preceded it has failed to generate sufficient participants. The stages are as follows:

1) In light of evidence which suggests receiving five shocks and above (irrespective of whether these are (in)appropriate) is significantly more likely to provoke psychological distress (Lüderitz et al., 1993; Irvine et al., 2002; Passman et al., 2007; von Känel et al., 2011), ICD-recipients who have experienced five or more shocks in total will be invited to participate. In order to increase the likelihood that details of the shock experiences will be retrievable by the participants a maximum of twelve months should have elapsed since the most recent shock.

2) If the above does not generate sufficient participants, the inclusion criteria will be amended to enable the participation of ICD-recipients who have experienced five or more shocks but whose most recent shock occurred within three years of their interview.

3) If the above is unsuccessful, the criteria will be amended to enable ICD-recipients who have been shocked two or more times to participate, as long as their most recent shock has occurred within three years of interview.

At each stage, potential participants will be excluded if they are receiving treatment for an unrelated psychological difficulty at the point of data collection. Furthermore, all participants will need to be physically well enough to be interviewed and will also need to be fluent in English.

All participants will be eligible for referral to LCC's clinical psychologist, with whom some may have already undergone treatment.

Procedure

Participants will be drawn from the 2000+ ICD-recipient population served by [redacted] is one of the main cardiac centres within the North-west, serving a broad geographical patch across [redacted] Approximately 240 ICDs are fitted at [redacted]er year, a number that has been steadily increasing. [redacted] reports that approximately 20 appropriate and 4 inappropriate shocks are delivered each month from the 2000+ devices that have been fitted by their team. There is anecdotal evidence from [redacted] cardiac nurses and the team's psychologist that some recipients experience episodes in which they may receive up to 40 inappropriate shocks over 20 hours.

The sample will be recruited on a targeted basis. Cardiac specialist nurses, consultant cardiologists, and members of the Pacing Team, who are collectively responsible for monitoring the activity of ICDs,

have agreed to invite patients who meet the inclusion criteria outlined above when they present for routine appointments. Recordings of the activity of ICDs are automatically taken whenever they deliver their therapy. Recipients may also download the activity of their devices remotely or have this checked in person during routine check-ups. Potential participants will be verbally invited to participate and will be provided with an information pack about the project. The packs will contain an information sheet detailing the project and a separate sheet providing the Chief Investigator's email address contact telephone number and a slip with space to input their own contact details, which they can return to the Chief Investigator by post, enabling them to be contacted at a later date. If sufficient participants volunteer, those who are willing to be interviewed at [redacted] will be selected; this is because extra support will be more readily available to them in the event of them becoming particularly distressed.

During the data collection phase, participants will be invited to meet with the Chief Investigator for the purpose of completing a semi-structured interview. They will be given the option of being interviewed either at [redacted] their own homes, or in a community setting.

Participants will be asked to provide informed consent prior to the interview by completing and signing a form. They will be advised that they may withdraw from the study at any time, although once their data has been integrated with that of the other participants and themes generated this may not be possible. The questions asked during the interview will broadly reflect those in the interview schedule, although their precise wording and order will vary. Additional questions will be asked to clarify and explore particular responses as the interviews unfold. The interview schedule may be altered in light of the first interviews. One or both of the project's supervisors will listen to the audio recording of one of the first interviews to help refine the interview schedule and to provide guidance around interview technique.

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The interviews will be recorded on a digital recorder, the recordings from which will then be transferred onto the Chief Investigator's password-protected laptop and the original recordings deleted within three months. Transcripts will be anonymised. Encrypted electronic versions will be stored on the Chief Investigator's password-protected laptop; paper copies will be kept in a secured box in his home and destroyed once the report has been submitted. If it is necessary to transport the recordings or electronic transcripts, they will be encrypted and emailed, then deleted once they have been accessed on password-protected computers. Electronic copies of the transcripts and consent forms will be stored securely on the University network for a period of ten years following submission of the report or for ten years following publication, whichever is the longer, at which point they will be deleted by the Academic Supervisor.

Proposed analysis

The analytic method adopted will be Interpretative Phenomenological Analysis. This method is concerned with exploring participants' lifeworld and explicating how they make sense of particular experiences (Smith & Osborn, 2003). It recognises the need for researchers to adopt an interpretative role in this process and therefore requires them to own their subjectivity (Ibid.). Like other qualitative methodologies it involves identifying themes across participants' accounts by looking for patterns within the data.

Practical concerns

Rooms for conducting interviews will need to be booked through [redacted] reception staff. Lancaster University's Doctorate in Clinical Psychology programme will cover the cost of photocopying the various sheets and forms.

Travel expenses of up to £10.00 will be paid to participants who can provide evidence of the costs they have incurred.

Ethical concerns

As participants (potentially) experiencing psychological distress resulting from their ICD shocks will be invited to reflect on (potentially) stressful aspects of their lives, there is a risk of them experiencing some distress as a consequence of the interview. In this event, as a trainee clinical psychologist I have developed skills in containing emotional distress. Additionally, I will have had further instruction in how to contain acute traumatic stress from a Consultant Clinical Psychologist who specialises in working with people who have experienced severe trauma. Furthermore, participants will receive a debrief sheet outlining appropriate support. All of the participants will either have been seen by [redacted] clinical psychologist or will have ready access to see her if it is warranted and if they consent. Finally, although prospective participants will have the option of being interviewed in their homes, if sufficient volunteers are willing to be interviewed at [redacted] these individuals will be preferentially selected owing to the availability of extra support in the event of someone becoming especially distressed.

Having explained the limits of confidentiality at the start of each interview, if any risk issues arose during it, I would inform the participant of the need to break confidentiality and contact my field supervisor. Lancaster University DClinPsy programme's lone worker policy will be adhered to in the event of participants opting for home interviews.

Timescale

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The data collection phase of the study will commence as soon as ethical approval is obtained (hopefully September 2012). A summary of the results of the study will be fed back to the participants by letter or email following completion of the report in May 2014.

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ETHICS SECTION

Appendix A

Cover Letter

To Whom it May Concern

I hereby submit my IRAS application for a qualitative study entitled:

Using IPA to understand the experiences of ICD shock-recipients

The proposed research will be undertaken as part of my doctoral thesis in Clinical Psychology at Lancaster University.

I look forward to meeting with you to discuss the project further.

Yours sincerely

Rich Colley

ETHICS SECTION

LANCASTER UNIVERSITY
DIVISION OF HEALTH RESEARCH
Doctorate In Clinical Psychology

Appendix B

PARTICIPANT INFORMATION SHEET (Version 2 – 18/09/2013)

Understanding the experiences of ICD shock-recipients

My name is Rich Colley and I am conducting this research as a trainee on the Doctorate in Clinical Psychology programme at Lancaster University, Lancaster, United Kingdom. I am conducting it in partnership with [redacted].

What is the study about?
The purpose of this study is to explore the experiences of cardiac patients who have received shocks from their Implantable Cardioverter Defibrillator. There is currently little research into this phenomenon and, as increasing numbers of ICDs are being fitted, it seems important to gain insight into how shocks are experienced and understood by those they have occurred to. It is intended that the anonymised findings will be used to develop effective therapeutic interventions to help people who experience psychological difficulties as a result of receiving ICD shocks.

Why have I been asked to take part?
Patients who have experienced five or more shocks from their device are eligible to participate. The most recent shock should have occurred within the last twelve months; this means you are more likely to clearly recall the experience. It is important that you are not currently receiving treatment for an unrelated psychological difficulty. It is important that you speak English fluently, because financial constraints mean that there are no funds to employ interpreters. It is also important that you are physically well enough to participate in the study.

What is involved?

- We would arrange to meet for a short interview (lasting approximately 60 minutes), during which we would discuss your experiences of receiving shocks from your device. Some examples of the topics I will ask about include: what it was like adjusting to the device; how the shocks have affected your life; and what has made the shocks easier/harder to cope with.
- The interview will take place at a convenient time and place for you, which may be at [redacted], a community location, or in your home.
- Interviews will be audio recorded and then transcribed (i.e. typed up). I will then look for patterns across what all of the participants have said in order to identify areas of similarity and difference. Care will be taken to ensure that any information that might identify participants is removed.

- The resulting report will be submitted as part of my doctoral degree and may be subsequently published in an academic journal.

Who is taking part?
I aim to interview approximately 10 cardiac patients who have experienced ICD shocks. If more than this number volunteers, I will contact those who will not be required to participate to inform them. I am happy to provide a summary of the findings to everyone who expresses an interest in participating.

Do I have to take part?
No, participation is entirely voluntary. If you do consent to take part but change your mind subsequently you may withdraw from the project at any time (although once the data have been anonymised and integrated with the responses of the other participants it may not be possible to extract all of your data; however, every effort will be made to this end, should this be your preference).

Will taking part be confidential?
Yes. If you agree to take part in the study, your participation will remain confidential. This means that nothing you say will be disclosed to anyone in such a way as to reveal your identity, and anything from the interview that I refer to in the report will be anonymised i.e. any of your identifying information will be removed or changed. However, if what is said in the interview makes me think that you or someone else is at significant risk of harm, I will have to disclose this and reveal your identity to appropriate professionals. If possible, I will tell you if I have to do this.

Any information that is included in the research report and disseminated more widely will be anonymised. If you have any concerns about this aspect of the study, please feel free to discuss them with me.

What will happen to my data?
The information you provide is confidential. The data collected for this study will be stored securely and only the lead researcher will have access to the unanonymised data.

- Audio recordings will be deleted a maximum of three months following the interview.
- At the end of the study, paper copies of anonymised transcripts will be destroyed.
- At the end of the study, anonymised transcripts will be encrypted, saved on a memory stick, and stored securely within the department of the Doctorate of Clinical Psychology at Lancaster University. They will be destroyed ten years following submission of the report or ten years following publication, whichever is the longer.

Are there any risks?
If you have experienced distress as a result of your shocks, there is a chance that you will experience some distress during or after the interview. I will be able to refer any participant to [redacted] clinical psychologist for prompt treatment, should that be required. You will also be provided with a debrief sheet after your interview, which will provide details about other sources of support should you need it.

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Will my travel costs be reimbursed?
Reasonable travel expenses will be paid up to a maximum of £10. If you use public transport you should keep your receipts

If you wish to obtain further information about the study, you may contact me using the email address provided at the end of this information sheet. Alternatively, you may also contact the study's Academic Supervisor [redacted]

You may also wish to contact the study's Field Supervisor, [redacted]

If you wish to make a complaint about any aspect of this study, you may contact: [redacted]

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

Who has reviewed this study?

This study has been reviewed and approved by the **National Research Ethics Service (NRES) Committee North West – Lancaster.**

It has also been reviewed by [redacted] **Research & Development Team** and granted approval by the same.

How do I get involved?
If you wish to discuss the project further, please complete the accompanying form and return it to [redacted] using the Stamped Addressed Envelope provided.

Alternatively, please contact me directly using the following email address: colleyr@exchange.lancs.ac.uk

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

Appendix C

LANCASTER UNIVERSITY
DIVISION OF HEALTH RESEARCH
Doctorate In Clinical Psychology

INDICATION OF INTEREST FORM

(Version 1 – 09/08/2013)

If you are interested in taking part in this research, please fill in your contact details below and return it to [redacted] in the Stamped Addressed Envelope provided. I will then give you a call/send you an email soon so we can discuss your potential involvement. If you are still interested in participating at the end of the conversation, I will then arrange a time for us to conduct the interview. There is no obligation for you to take part and you are free to change your mind at any time.

Name: ……

Phone number/Email address (depending on your preference):……..

…….

Preferred time to be contacted: ……

Thanks once again for taking the time to read through this information.

Rich Colley

Trainee clinical psychologist

colleyr@exchange.lancs.ac.uk

Doctorate in Clinical Psychology

C12 Furness College

Lancaster University

LA1 4YG

ETHICS SECTION

Appendix D

CONSENT FORM
(Version 2 - 18/09/2013)

Study Title: Understanding the experiences of ICD shock-recipients

We are asking if you would like to take part in a research project which aims to explore cardiac patients' experiences of receiving shocks from their Implantable Cardioverter Defibrillator.
Before you consent to participating in the study, we ask that you read the Participant Information Sheet and then mark each of the boxes below with your initials if you agree with the corresponding statement. If you have any questions or queries before signing this consent form please speak to the lead researcher, Rich Colley.

	Please initial box after each statement
1. I confirm that I have read the Participant Information Sheet and fully understand what is expected of me for this study.	☐
2. I confirm that I have had the opportunity to ask any questions and to have them answered.	☐
3. I understand that my interview will be audio recorded and then made into an anonymised written transcript.	☐
4. I understand that audio recordings will be kept for three months following the interview.	☐
5. I understand that I am not obliged to take part in this study and can withdraw my participation before, during, or after my interview (although, once integrated with other people's, it may not be possible to remove all my data from the analysis; however, I understand every effort will be made to achieve this).	☐
6. I understand that the information from my interview will be pooled with other participants' responses, anonymised and may be published.	☐
7. I consent to information and anonymised quotations from my interview being used in published reports, conferences and training events, and to their publication on Lancaster University's website.	☐
8. I understand that any information I give will remain strictly confidential and anonymous unless it is thought that there is a risk of harm to myself or others, in which case the lead researcher will need to share this information with his research supervisor.	☐
9. I consent to Lancaster University keeping electronic transcripts of the interview for ten years after the study has finished.	☐
10. I understand that data collected from the study may be looked at by regulatory authorities and by persons from the Trust where it is relevant to my taking part in this study. I give permission for these individuals to access this data.	☐
11. I consent to take part in this study.	☐

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Name of Participant_____ **Signature**_____
Date _____

Name of Researcher _____Signature _____Date
_____

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Appendix E

Interview Schedule (Version 1 – 09/08/2013)

The schedule covers the broad topic areas that will be covered in the interview, but questions may be added/omitted/amended depending on participants' responses.

Tell me about the circumstances which led to you being fitted with an ICD.

-Why did you have it fitted?

-How did you feel about the prospect of having it fitted?

-How did those close to you feel about you having it fitted?

-How well prepared did you feel for the shocks by the cardiac team before you had the device fitted?

Tell me about your experience of having it fitted.

-What was the process leading up to the operation like?

-How was your experience in hospital?

What was it like adjusting to having the device?

-How did having the ICD affect you initially?

-What were the challenges for you?

-What were the challenges for others?

-What helped you adjust to having the device?

-What made having the device harder to adjust to?

How many times have you been shocked by your ICD?

Over what timeframe?

Have these been individual shocks or episodes of multiple shocks?

ETHICS SECTION

-Please elaborate.

How did the hospital respond to your shocks?

Tell me about your experience of being shocked

- How have the shocks affected you?
- How have the shocks affected you physically?
- How have they affected you psychologically?
- How have they affected your life?
- How have they affected those close to you?
- What has helped you cope with the shocks?
- What has made the shocks harder to cope with?
- How did you make sense of the shocks at the time?
- How do you see the experiences now?

Has the impact of the shocks changed over time?

-How?

-What made a difference?

Overall, how do you feel about your ICD?

How do you feel about the future?

What would you like to have known before making this decision?

What advice would you give to people considering having a device fitted?

LANCASTER UNIVERSITY

DIVISION OF HEALTH RESEARCH
Doctorate In Clinical Psychology

Appendix F

Debrief Sheet

(Version 1 – 09/08/2013)

If you feel you might benefit from emotional support with any of the issues that we discussed today, you can contact [redacted] and arrange an appointment to speak with the service's clinical psychologist, [redacted] will aim to see you promptly; however, if you feel you need support more urgently, please arrange to see your GP as soon as possible.

If our discussion raised any concerns for you about your ICD, please contact [redacted]

Alternative sources of support include:

The Samaritans: They are available 24 hours a day, seven days a week, to offer confidential emotional support either face-to-face or via telephone, email, text message and letter.

Phone number: 08457 90 90 90.

Email address: jo@samaritans.org.

Local branches can be found on the Samaritans' website: www.samaritans.org.

Address for correspondence: Freepost RSRB-KKBY-CYJK, Chris, PO Box 90 90, Stirling, FK8 2SA.

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Thank you once again for participating in this research.

Rich Colley

Trainee clinical psychologist

colleyr@exchange.lancs.ac.uk

Doctorate in Clinical Psychology

C12 Furness College

Lancaster University

LA1 4YG

ETHICS SECTION

Appendix G. REC Approval Letter

NRES Committee North West - Lancast
HRA NRES Centre - Manches
Barlow Hou
3rd Fl
4 Minshull Str
Manches
M1 3

Telephone: 0161 625 78
Facsimile: 0161 625 72

19 September 2013

Mr Richard Colley
C16 Furness College
Lancaster University
Lancaster
LA1 4YG

Dear Mr Colley

Study title: **Using IPA to understand the experiences of implantable cardioverter defibrillator shock-recipients**
REC reference: **13/NW/0638**
IRAS project ID: **130520**

Thank you for your email of 19 September. I can confirm the REC has received the documents listed below and that these comply with the approval conditions detailed in our letter dated 17 September 2013

Documents received

The documents received were as follows:

Document	*Version*	*Date*
Participant Consent Form	2	18 September 2013
Participant Information Sheet	2	18 September 2013
Protocol	1 09/08/13 revised	09 August 2013
REC application	3.5 revised	13 August 2013

Approved documents

The final list of approved documentation for the study is therefore as follows:

Document	*Version*	*Date*
Covering Letter		
Evidence of insurance or indemnity		15 July 2013
Interview Schedules/Topic Guides	1	09 August 2013
Investigator CV	Colley	16 August 2013

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Investigator CV	Black	
Investigator CV	Sanderson	
Investigator CV	Murray	
Letter from Sponsor		13 August 2013
Other: Indication of Interest Form	1	09 August 2013
Other: Debrief Sheet	1	09 August 2013
Participant Consent Form	2	18 September 2013
Participant Information Sheet	2	18 September 2013
Protocol	1	09 August 2013
Protocol	1 09/08/13 revised	09 August 2013
REC application	3.5	13 August 2013
REC application	3.5 revised	13 August 2013

You should ensure that the sponsor has a copy of the final documentation for the study. It is the sponsor's responsibility to ensure that the documentation is made available to R&D offices at all participating sites.

13/NW/0638	**Please quote this number on all correspondence**

Yours sincerely

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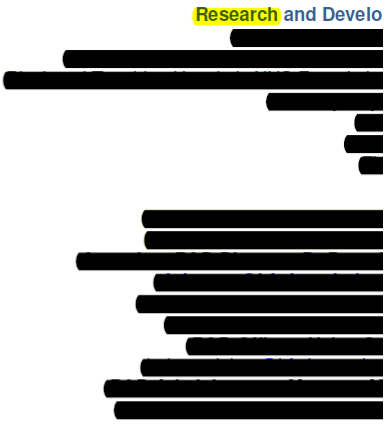
Appendix H. R&D Approval Letter



9th October 2013

Mr Richard Colley
Trainee Clinical Psychologist
Lancashire Care Foundation Trust
C16 Furness College
Lancaster University
Lancaster
LA1 4YG

Dear Mr Colley

R&D:	RD 0844
REC Number:	13/NW/0638
Lead Researcher:	Mr Richard Colley
Project Title:	Using IPA to understand the experiences of ICD shock-recipients

I am pleased to inform you that the research approval administration process for your project has been completed successfully. The Trust grants approval for this research project to take place and is satisfied it passes site assessment requirements. The table in appendix 1 details the documents approved. Approval however is based upon the following conditions:

- On your first visit you must present yourself to the R&D Department and bring with you photographic ID.

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Appendix I. Notice of Amendment Form

Notice of Amendment 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)
Using IPA to understand the experiences of ICD shock-recipients

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:

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- (●) 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?

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○ 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 student will act as Principal Investigator

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

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NOTICE OF SUBSTANTIAL AMENDMENT

Please use this form to notify the main REC of substantial amendments to all research other than clinical trials of investigational medicinal products (CTIMPs).
The form should be completed by the Chief Investigator using language comprehensible to a lay person.

Details of Chief Investigator:

	Title	Forename/Initials	Surname
	Mr	Richard	Colley
Work Address	C16 Furness College		
	Lancaster University		
	Lancaster		
PostCode	LA1 4YG		
Email	colleyr@exchange.lancs.ac.uk		
Telephone	01524 593378		
Fax	01524 592401		

Full title of study:	Using IPA to understand the experiences of implantable cardioverter defibrillator shock-recipients
Lead sponsor:	Lancaster University
Name of REC:	North West Lancaster
REC reference number:	13/NW/0638
Name of lead R&D office:	Blackpool Teaching Hospitals NHS Foundation Trust
Date study commenced:	19/09/2013
Protocol reference (if applicable), current version and date:	Version 2 29/10/2013
Amendment number and date:	1 / 29/10/2013

Type of amendment

(a) Amendment to information previously given in IRAS

◉ Yes ○ No

If yes, please refer to relevant sections of IRAS in the "summary of changes" below.

(b) Amendment to the protocol

◉ Yes ○ No

If yes, please submit either the revised protocol with a new version number and date, highlighting changes in bold, or a document listing the changes and giving both the previous and revised text.

(c) Amendment to the information sheet(s) and consent form(s) for participants, or to any other supporting

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documentation for the study

○ Yes ◉ No

If yes, please submit all revised documents with new version numbers and dates, highlighting new text in bold.

Is this a modified version of an amendment previously notified and not approved?

○ Yes ◉ No

Summary of changes

Briefly summarise the main changes proposed in this amendment. Explain the purpose of the changes and their significance for the study.
If this is a modified amendment, please explain how the modifications address the concerns raised previously by the ethics committee.
If the amendment significantly alters the research design or methodology, or could otherwise affect the scientific value of the study, supporting scientific information should be given (or enclosed separately). Indicate whether or not additional scientific critique has been obtained.

I wish to amend the inclusion criteria in order to increase the size of the sample population. I would like to do this in a phased way, with the second stage being activated if suitable numbers of participants are not generated by the first. The stages are:

1) ICD-recipients who have been shocked a minimum of five times and who have experienced their most recent shock within three years of the interview.

2) ICD-recipients who have experienced two or more shocks and who have experienced at least one in the last three years.

Any other relevant information

Applicants may indicate any specific issues relating to the amendment, on which the opinion of a reviewing body is sought.

Contrary to expectation, insufficient numbers of ICD-recipients who meet the existing criteria have not been identified. We believe that altering the criteria in the ways proposed will not affect the scientific validity of the study.

List of enclosed documents

Document	*Version*	*Date*
Protocol	2	29/10/2013

Declaration by Chief Investigator

1. *I confirm that the information in this form is accurate to the best of my knowledge and I take full responsibility for it.*
2. *I consider that it would be reasonable for the proposed amendment to be implemented.*

Date: .....

Declaration by the sponsor's representative

I confirm the sponsor's support for this substantial amendment.

Signature: .....

ETHICS SECTION

Appendix J. Amendment Approval Letter

18 November 2013

Mr Richard Colley
C16 Furness College
Lancaster University
Lancaster
LA1 4YG

Dear Mr Colley

Study title:	**Using IPA to understand the experiences of implantable cardioverter defibrillator shock-recipients**
REC reference:	**13/NW/0638**
Amendment number:	**1**
Amendment date:	**29 October 2013**
IRAS project ID:	**130520**

- Amend the inclusion criteria.

The above amendment was reviewed by the Sub-Committee in correspondence.

Ethical opinion

The members of the Committee taking part in the review gave a favourable ethical opinion of the amendment on the basis described in the notice of amendment form and supporting documentation.

Approved documents

The documents reviewed and approved at the meeting were:

Document	Version	Date
Notice of Substantial Amendment (non-CTIMPs)	1	29 October 2013
Protocol	2	29 October 2013

Membership of the Committee

The members of the Committee who took part in the review are listed on the attached sheet.

R&D approval

All investigators and research collaborators in the NHS should notify the R&D office for the relevant NHS care organisation of this amendment and check whether it affects R&D approval of the research.

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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.

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/

13/NW/0638:	**Please quote this number on all correspondence**

Yours sincerely

[redacted]
Chair

E-mail: nrescommittee.northwest-lancaster@nhs.net

Enclosures: *List of names and professions of members who took part in the review*