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)
The UK Calciphylaxis Study

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) Will you be taking new samples primarily for research purposes (i.e. not surplus or existing stored samples), including any removal of organs or tissue from the deceased?	(●) Yes	( ) No
b) Will you be using surplus tissue or existing stored samples identifiable to the researcher?	( ) Yes	(●) No
c) Will you be using only surplus tissue or existing stored samples not identifiable to the researcher?	( ) Yes	(●) No
d) Will you be processing identifiable data at any stage of the research (including in the identification of participants)?	( ) Yes	(●) No

e) Please confirm that you will be processing only anonymised or effectively pseudonymised data:

(●) Yes, only anonymised or pseudonmyised data ( ) No

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

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

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

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

4. Which review bodies are you applying to?

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

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

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

(•) Yes ( ) No

5a. Do you want your NHS R&D application(s) to be processed through the NIHR Coordinated System for gaining NHS Permission?

(•) Yes ( ) No

If yes, you must complete and submit the NIHR CSP Application Form immediately after completing this project filter, before proceeding with completing and submitting other applications.

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

( ) Yes (•) No

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

( ) Yes (•) No

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

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

( ) Yes (•) No

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

○ Yes ◉ No

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

○ Yes ◉ No

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

○ Yes ◉ No

Integrated Research Application System
Application Form for Research limited to working with human tissue samples and/or data

NHS/HSC R&D Form (project information)

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

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

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

Short title and version number: (maximum 70 characters - this will be inserted as header on all forms)
The UK Calciphylaxis Study

PART A: Core study information

1. ADMINISTRATIVE DETAILS

A1. Full title of the research:

The UK Calciphylaxis Study

A3-1. Chief Investigator:

	Title	Forename/Initials	Surname
	Dr	Smeeta	Sinha
Post	Consultant and Honorary Senior Lecturer in Nephrology		
Qualifications	MBChB MRCP PhD		
Employer	Salford Royal NHS Foundation Trust		
Work Address	Department of Renal Medicine		
	Level 2 Hope Building		
	Stott Lane, Salford		
Post Code	M6 8HD		
Work E-mail	smeeta.sinha@srft.nhs.uk		
* Personal E-mail	smeetasinha@doctors.org.uk		
Work Telephone	01612064155		
* Personal Telephone/Mobile	07872417512		
Fax			

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

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

	Title	Forename/Initials	Surname
		Rachel	Georgiou
Address	Salford Research & Development		
	Summerfield House		
	Eccles New Road		
Post Code	M5 5FP		
E-mail	rachel.georgiou@manchester.ac.uk		
Telephone	01612067032		
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):	2012/030vas
Sponsor's/protocol number:	
Protocol Version:	1
Protocol Date:	19/07/2011
Funder's reference number:	

Project website: www.calciphylaxis.org.uk

Additional reference number(s):

Ref.Number Description	Reference Number
REC Reference number	11/NW/0528

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

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

○ Yes ◉ No

Please give brief details and reference numbers.

2. OVERVIEW OF THE RESEARCH

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

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

Calciphylaxis is a rare condition which results in small arteries becoming calcified. This results in painful ulceration of the skin which in turn can result in infection and further damage to tissue. It is associated with a high mortality rate (60-80%). Consequently research into this area is important. The aims of this study are to determine the following:

1) What is the natural history of the disease?
2) What risk factors are associated with development and progression of calciphylaxis?
3) Which treatments currently in clinical practice confer a favourable outcome?
4) What are the underlying disease processes?

These aims will be achieved by collecting information on medications, clinical parameters, local laboratory tests, measuring specific proteins and molecules in blood and tissue as well as studying patient's DNA profiles.

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 UK Calciphylaxis study will be a non-intervention observational study. The study will aim to recruit any patient with chronic kidney disease who has a diagnosis of calciphylaxis from any UK renal department over a 10 year period. Patients will be given information sheets and at least 24 hours to consider involvement. Informed consent will then be obtained from patients willing to participate by a doctor specialising in renal medicine who will be fully informed and able to discuss the nature of the study, and any risks and benefits involved in participation.

The main ethical and design issues are outlined below:

1) Calciphylaxis ia a rare and poorly understood condition. Due to the rarity of the condition we will seek approval for all NHS organisations with a hub renal department.

2) Taking consent within the patient group. Patients with calciphylaxis are unwell but usually capable of providing consent. Although we accept this is a difficult time for patients there is no alternative to studying this condition. The study has been discussed with the vice chair of the Hope Kidney Patient Association who agrees that such a study is appropriate for patients with calciphylaxis. Patients may withdraw form the study at anytime. If patients lose capacity to consent they will be withdrawn from the study.

3) The following data will be collected:
a) Demographics, medications and standard laboratory variables including 12 months retrospective values will be collected at baseline.

b) Clinical information on skin lesions, symptoms, and initial treatments/interventions will be collected at baseline.

c) Monthly follow-up clinical and laboratory data will be requested until full recovery or death.

d) Blood samples will be taken at baseline, week 1 & 2, 1 month and after full healing should this occur. Samples will be frozen for testing of serum levels of promoters and inhibitors of calcification, and clotting factor deficiencies.

e) A DNA sample will be taken at baseline. Patients will be able to refuse consent for collection of DNA. DNA samples will anonymised and transported directly to the Centre for Integrated Genomic Medical Research (CIGMR), University of Manchester.

f) Any tissue that is taken for diagnostic or therapeutic purposes (i.e. skin biopsy, amputation, mastectomy etc) will be requested and collected for stored at the University of Manchester. Diagnostic blocks/slides will be anonymised at reception at the Laboratory of Regenerative Medicine in the University of Manchester and stored for future research subject to appropriate ethical approval for specific projects. Patients will be able to refuse consent for collection of tissue.

4) Data protection. Patient information will be anonymised outside the direct care centre using a unique patient code which will be generated at registration. Anonymised data and samples may be transported outside the EU for future studies.

The design of the study has been undertaken in collaboration with the International Calciphylaxis Collaborative Network involving the UK, Germany and USA. Each country is responsible for setting up its own study utilising an agreed protocol for data and biological sample collection.

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
- [x] Cohort observation
- [ ] Controlled trial without randomisation
- [ ] Cross-sectional study
- [ ] Database analysis
- [x] 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 study will aim to improve our understanding of calciphylaxis by examining:

a) What is the natural history of the disease?
b) What risk factors are associated with development and progression of calciphylaxis?
c) Which current standard treatments confer a favourable outcome?
d) What are the underlying disease processes?

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

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

Calciphylaxis is a rare syndrome during which small arteries become calcified. This results in skin breakdown (necrosis) and is associated with a high morbidity and mortality. It is usually associated with chronic kidney disease, particularly in patients on dialysis. Small cohort studies have suggested a reported prevalence of 1-4% in dialysis populations. Reports have suggested calciphylaxis carries a mortality of 60-80% in patients on dialysis. This is usually due to superseding infection in necrotic lesions.

The cause and processes that underpin the development of calciphylaxis remain poorly understood. However, it is known that calciphylaxis results from a build up of calcium and bone like tissue (calcification) in small arteries. There has been a significant increase in our understanding of harmful vascular calcification in larger blood vessels over the last 20 years. Vascular calcification is an active cell-mediated process during which cells within the vessel wall become more like bone cells and can deposit calcium within the vessel wall. Researchers have discovered that there are several proteins and molecules circulating within the blood which can promote or prevent calcification of blood vessels. An imbalance in these proteins can affect the degree of vascular calcification. Some of these proteins and molecules are also found in calcified wounds. Whether these processes occur in calciphylaxis is not clear. Recently, a group of researchers in Germany have found that levels of one such protein are significantly reduced in patients with calciphylaxis. However, this was only a small pilot study.

There is currently little published about calciphylaxis and the published literature consists largely of case reports and

small case series. The largest published studies include retrospective studies or single centre studies across prolonged periods of times during which clinical practice has changed significantly. Data from these studies has indicated several factors may contribute to the progression of calciphylaxis and that certain patients have benefited from certain treatments. However, due to the nature of these studies it is not surprising that the published reports have conflicting information on risk factors and benefits of treatments. The UK Calciphylaxis study will therefore also aim to collect data on clinical parameters and medication prior to and during the course of the disease to assess the benefits of interventions. Before we can develop better treatments for patients it is essential that we have a better understanding of the disorder. In the proposed study we will build on what is already known but in a larger population.

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.*

The UK Calciphylaxis study will be a non-intervention cohort observational study. The study will recruit any patient with chronic kidney disease who has a diagnosis of calciphylaxis from any UK renal department (subject to R & D approval) over a 10 year period. Prospective patients will be identified, approached and recruited by their usual health care provider. Patients will be registered into the study via the study website www.calciphylaxis.org.uk. Patients will be given information sheets and at least 24 hours to consider involvement. Informed consent will then be obtained from patients willing to participate by a doctor specialising in renal medicine who will be fully informed and able to discuss the nature of the study, and any risks and benefits involved in participation. Due to the rarity of the disorder all NHS organisations will be invited to recruit patients into the study. The following data and samples will be collected:

1) Demographics, concomitant medications and standard laboratory variables including 12 months retrospective values will be collected at baseline.

2) Clinical information on skin lesions, symptoms, and initial therapeutic interventions will be collected at baseline.

3) A blood sample for DNA analysis will be taken at baseline and posted immediately at room temperature to the Centre for Integrated Genomic Medical Research (CIGMR) for extraction and storage.

4) Plasma/Serum and clotting samples will be taken at baseline, week 1 & 2, 1 month and after full healing should this occur. Samples will be frozen at –20oC or below and stored locally for 1 month. Samples will be sent to the core laboratory after 1 month and thereafter. Samples will be frozen at –80oC at the core laboratory for testing of serum levels of promoters and inhibitors of calcification, and clotting factor deficiencies.

5) 4 monthly follow-up clinical and laboratory data will be requested until full recovery or death.

6) Any tissue that is taken for diagnostic or therapeutic purposes (i.e. skin biopsy, amputation, mastectomy etc) will be requested and collected for tissue banking at the University of Manchester. Diagnostic blocks/slides will be anonymised at reception at the Laboratory of Regenerative Medicine in the University of Manchester and banked for future research subject to appropriate ethical approval for specific projects.

The design of the study has been undertaken in collaboration with the International Calciphylaxis Collaborative Network involving the UK, Germany and USA. Each country is responsible for setting up its own study utilising an agreed protocol for data and biological sample collection.

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.
Patient information sheets were reviewed and approved by Keith Pennington. Mr Pennington is the vice chair of the Hope Kidney Patient Association as well as being a kidney transplant patient who has experienced haemodialysis.

4. RISKS AND ETHICAL ISSUES

RESEARCH PARTICIPANTS

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

Select all that apply:

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

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

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

Any patient with chronic kidney disease and a clinical diagnosis of calciphylaxis, subject to informed consent.

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

Patients who cannot give informed consent

RESEARCH PROCEDURES, RISKS AND BENEFITS

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

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

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

Intervention or procedure	1	2	3	4
Seeking consent	1	0	30	local nephrologist

A19. Give details of any clinical intervention(s) or procedure(s) to be received by participants as part of the research protocol. *These include uses of medicinal products or devices, other medical treatments or assessments, mental health interventions, imaging investigations and taking samples of human biological material. Include procedures which might be received as routine clinical care outside of the research.*

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
Venepuncture	8	0	5	normal local venepuncturist

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

Patients will remain in the study until complete resolution of calciphylaxis, withdrawal or death.

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.

As this is an observational non-intervention study, there are no expected clinical risks aside from minor discomfort associated with additional venepunture.

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

There will be no direct benefit to patients.

Knowing that they are contributing towards research in improving the understanding of calciphylaxis.

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).*

a) Patients will be identified by their local nephrologist at the time of presentation of calciphylaxis lesions.
b) Patients will be approached by the local research team and provided with patient information leaflets.
c) Patients will be recruited by their local research team.

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

○ Yes ◉ No

Please give details below:

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

○ Yes ◉ No

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

Patients will initially be approached by their normal health−care provider.

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.

Patients will be given information sheets and at least 24 hours to consider involvement. Informed consent will then be obtained from patients willing to participate by a doctor specialising in renal medicine who will be fully informed and able to discuss the nature of the study, and any risks and benefits involved in participation. The doctor will be used to taking consent and will be appropriately trained.

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?

Minimum of 24 hours

A33-1. What arrangements have been made for persons who might not adequately understand verbal explanations or

written information given in English, or who have special communication needs?*(e.g. translation, use of interpreters)*

Use of local interpreter services or other support services as available.

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?

None

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

- ○ The participant and all identifiable data or tissue collected would be withdrawn from the study. Data or tissue which is not identifiable to the research team may be retained.
- ◉ The participant would be withdrawn from the study. Identifiable data or tissue already collected with consent would be retained and used in the study. No further data or tissue would be collected or any other research procedures carried out on or in relation to the participant.
- ○ The participant would continue to be included in the study.
- ○ Not applicable – informed consent will not be sought from any participants in this research.
- ○ Not applicable – it is not practicable for the research team to monitor capacity and continued capacity will be assumed.

Further details:

Details pertaining to consent are provided in the patient information leaflet.

If you plan to retain and make further use of identifiable data/tissue following loss of capacity, you should inform participants about this when seeking their consent initially.

CONFIDENTIALITY

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

Storage and use of personal data during the study

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

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

☐ Laptop computers

Further details:
Patients will be identified by a unique number which will be generated at registration. This number will be used from the time of data entry/download outside the patients' electronic or paper records.

Personal details will be used as part of routine clinical care at the direct care centre. These details will not be transferred outside the local centre.

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

The research database will be stored within the research department on NHS trust encrypted and password protected computers. This will be in accordance with the Data Protection Act and NHS Code of Confidentiality.

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.*

Patient data will anonymised outside the direct care centre. Patients will be given a unique number at the time of registration. This will ensure anonymity outside the direct care team and local study site.

The NHS Code of Confidentiality will apply.

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.*

There will be no access to the participants' personal data outside the direct care team with exception of that required for audit and monitoring.

Storage and use of data after the end of the study

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

Analysis will take place by data handling experts (statisticians or doctors) affiliated to the hospital, University of Manchester or to the study itself.

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

	Title	Forename/Initials	Surname
	Dr	Smeeta	Sinha
Post	Consultant & Honorary Senior Lecturer in Nephrology		
Qualifications	MBChB MRCP(UK) PhD		
Work Address	Department of Renal Medicine		
	Level 2 Hope Building		
	Hope Hospital, Stott Lane, Salford		
Post Code	M6 8HD		
Work Email	smeeta.sinha@srft.nhs.uk		
Work Telephone	01612064155		
Fax			

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

◯ Less than 3 months

○ 3 – 6 months
○ 6 – 12 months
○ 12 months – 3 years
◉ Over 3 years

If longer than 12 months, please justify:
Personal data will be stored as part of routine clinical care by the direct care team.

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

Years: 15
Months:

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

Data will be held on trust and university computers backed up to organisational servers in accordance with local policy. Dr Smeeta Sinha will remain custodian of the data at all times.

INCENTIVES AND PAYMENTS

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

○ Yes ◉ No

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

○ Yes ◉ No

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

○ Yes ◉ No

NOTIFICATION OF OTHER PROFESSIONALS

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

◉ Yes ○ No

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

A49-2. Will you seek permission from the research participants to inform their GP or other health/ care professional?

◉ Yes ○ No

It should be made clear in the participant's information sheet if the GP/health professional will be informed.

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.
NIHR Database

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

Kidney Patient Association Leaflets

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

The study will not publish patient identifiable data

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.
Results will be published in patient association leaflets and to renal departments. Due to the nature of the disease and high mortality rate it will not be feasible to provide a results summary to all participating patients.

5. Scientific and Statistical Review

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

- [x] Independent external review
- [ ] Review within a company
- [x] Review within a multi−centre research group
- [ ] 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 has been sent for external review to Dr David Wheeler, Consultant Renal Physician

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.

A56. How have the statistical aspects of the research been reviewed? *Tick as appropriate:*

☐ Review by independent statistician commissioned by funder or sponsor
☐ Other review by independent statistician
☐ Review by company statistician
☐ Review by a statistician within the Chief Investigator's institution
☐ Review by a statistician within the research team or multi−centre group
☐ Review by educational supervisor
☐ Other review by individual with relevant statistical expertise
☑ No review necessary as only frequencies and associations will be assessed – details of statistical input not required

In all cases please give details below of the individual responsible for reviewing the statistical aspects. If advice has been provided in confidence, give details of the department and institution concerned.

Title Forename/Initials Surname

Department
Institution
Work Address

Post Code
Telephone
Fax
Mobile
E-mail

Please enclose a copy of any available comments or reports from a statistician.

A57. What is the primary outcome measure for the study?

This is an observational study.

A58. What are the secondary outcome measures? *(if any)*

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

Total UK sample size: 200
Total international sample size (including UK):

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 based on incidence reports and acceptability.

A61. Will participants be allocated to groups at random?

○ Yes ◉ No

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.

Data will be analysed by descriptive analysis and logistic regression.

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
	Dr	Maria	Jeziorska
Post	Senior Lecturer in Pathology		
Qualifications	PhD		
Employer	University of Manchester		
Work Address	Tissue Injury and Repair Group		
	RM1.534, Stopford Building		
	Oxford Rd, Manchester		
Post Code	M13 9PT		
Telephone	0161 275 5296		
Fax	0161 275 5289		
Mobile			
Work Email	maria.jeziorska@manchester.ac.uk		

	Title	Forename/Initials	Surname
	Prof	Philip A.	Kalra
Post	Consultant and Honorary Professor in Nephrology		
Qualifications	MD FRCP		
Employer	Salford Royal Hospitals NHS Foundation Trust		
Work Address	Department of Renal Medicine		
	Level 2 Hope Bulding		
	Stott Lane, Salford		
Post Code	M6 8HD		
Telephone	01612050509		
Fax			
Mobile			

Work Email	philip.kalra@srft.nhs.uk

Title	Forename/Initials	Surname
Dr	Robert	Oliver

Post	Salford Royal Biorepository Facility Manager
Qualifications	PhD
Employer	Salford Royal NHS Foundation Trust
Work Address	Clinical Sciences Building Salford Royal NHS Foundation Trust Stott Lane
Post Code	M6 8HD
Telephone	01612064446
Fax	
Mobile	
Work Email	robert.oliver@manchester.ac.uk

Title	Forename/Initials	Surname
Sr	Lesley	Haydock

Post	Specialist Nurse, Vascular Research
Qualifications	RCN
Employer	Salford Royal NHS Foundation Trust
Work Address	Clinical Sciences Building Salford Royal NHS Foundation Trust Stott Lane
Post Code	M6 8HD
Telephone	01612061309
Fax	
Mobile	
Work Email	lesley.haydock@srft.nhs.uk

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	Salford Royal NHS Foundation Trust
Given name	Rachel

Family name	Georgiou
Address	Summerfield House
Town/city	Eccles New Road
Post code	M5 5FP
Country	UNITED KINGDOM
Telephone	01612067032
Fax	
E-mail	rachel.georgiou@manchester.ac.uk

Is the sponsor based outside the UK?

○ Yes ◉ No

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

A65. Has external funding for the research been secured?

☑ Funding secured from one or more funders

☐ External funding application to one or more funders in progress

☐ No application for external funding will be made

What type of research project is this?

◉ Standalone project

○ Project that is part of a programme grant

○ Project that is part of a Centre grant

○ Project that is part of a fellowship/ personal award/ research training award

○ Other

Other – please state:

Please give details of funding applications.

Organisation	Amgen (Europe) GmBH
Address	Dammstrasse 23 CH-6300 Zug Switzerland
Post Code	
Telephone	00413690300
Fax	0041413690400
Mobile	
Email	bdehmel@amgen.com

Funding Application Status: ◉ Secured ○ In progress

Amount: US $112500.00

Duration

Years: 10

Months:

If applicable, please specify the programme/ funding stream:

What is the funding stream/ programme for this research project?

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

○ Yes ◉ No

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

○ Yes ◉ No

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

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

	Title	Forename/Initials	Surname
		Rachel	Georgiou
Organisation	Salford Royal NHS Foundation Trust		
Address	Summerfield House		
	Eccles New Road		
	Salford		
Post Code	M5 5FP		
Work Email	rachel.georgiou@manchester.ac.uk		
Telephone	01612067032		
Fax			
Mobile			

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

A68-2. Select Comprehensive Local Research Network for this NHS organisation:

To support communication between the REC and R&D contacts for this study, please select the Comprehensive Local Research Network (CLRN) for this NHS organisation. This CLRN will be the Lead CLRN for your study.

-- Not Selected --

For information about support and advice available through the Lead CLRN and the CLRNs for participating sites see http://www.crncc.nihr.ac.uk/about_us/processes/csp. A map showing the CLRNs is available at http://www.crncc.nihr.ac.uk/about_us/ccrn.

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

Planned start date: 01/09/2011

Planned end date: 01/09/2021

Total duration:

Years: 10 Months: 0 Days: 0

A70. Definition of the end of trial, and justification in the case where it is not the last visit of the last subject undergoing the trial (1)

The trial will terminate at the end of the 10 year observational period

A71-1. Is this study?

- ○ Single centre
- ◉ Multicentre

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

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

Total UK sites in study 73

Does this trial involve countries outside the EU?

○ Yes ◉ No

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

☑ NHS organisations in England	53
☑ NHS organisations in Wales	6
☑ NHS organisations in Scotland	8
☑ HSC organisations in Northern Ireland	6
☐ 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	1
☐ Independent research units	
☐ Other (give details)	
Total UK sites in study:	74

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

○ Yes ◉ No

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

The study will be monitored and audited in accordance with Salford Royal NHS Foundation Trust Research & Development monitoring systems.

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.

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

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.

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

Please enclose a copy of relevant documents.

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

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

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

Please enclose a copy of relevant documents.

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)

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)

Please enclose a copy of relevant documents.

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

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

☑ NHS indemnity scheme or professional indemnity will apply (participants recruited at NHS sites only)

☐ Research includes non-NHS sites (give details of insurance/ indemnity arrangements for these sites below)

Please enclose a copy of relevant documents.

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

○ Yes ◉ No ○ Not sure

Part B: Section 5 – Use of newly obtained human tissue(or other human biological materials) for research purposes

1. What types of human tissue or other biological material will be included in the study?

Plasma/ serum, clotting samples, DNA and tissue will be collected by local health care providers. They will be analysed by the Vascular Research Group at Hope Hospital and researchers at the University of Manchester.

2. Who will collect the samples?

Plasma, serum, clotting samples and DNA will be taken for research purposes. Tissue will be obtained as a by

product of a clinical intervention eg amputation, diagnostic skin biopsy.

3. Who will the samples be removed from?

- [x] Living donors
- [ ] The deceased

4. Will informed consent be obtained from living donors for use of the samples? *Please tick as appropriate*

In this research?
(•) Yes ( ) No

In future research?
(•) Yes ( ) No ( ) Not applicable

6. Will any tissues or cells be used for human application or to carry out testing for human application in this research?

( ) Yes (•) No

8. Will the samples be stored: *[Tick as appropriate]*

In fully anonymised form? *(link to donor broken)*
( ) Yes (•) No

In linked anonymised form? *(linked to stored tissue but donor not identifiable to researchers)*
(•) Yes ( ) No

If Yes, say who will have access to the code and personal information about the donor.

Plasma, serum, clotting and DNA samples will be sent to the Vascular Research Group laboratories in the Clinical Sciences building at Hope Hospital. Samples will be labelled with a unique identification barcode and archived in the Salford
Biological Repository (SaBRe) − a purpose built facility that only deals with biological samples and with no direct links to personal data. Dedicated freezer facilities and split site storage are used.

Pathology samples will be identified by their unique patient study number and coded with a chronological code at the receiving immunocytochemistry laboratory at the University of Manchester

In a form in which the donor could be identifiable to researchers?
( ) Yes (•) No

9. What types of test or analysis will be carried out on the samples?

Consent from the time of study entry will be utilised. Samples will be tested for proteins and molecules associated with vascular calcification. DNA samples will be used to assess genetic associations with calciphylaxis

10. Will the research involve the analysis or use of human DNA in the samples?

(•) Yes ( ) No

11. Is it possible that the research could produce findings of clinical significance for donors or their relatives?

( ) Yes (•) No

12. If so, will arrangements be made to notify the individuals concerned?

○ Yes ○ No ◉ Not applicable

13. Give details of where the samples will be stored, who will have access and the custodial arrangements.

Plasma, serum and clotting will be stored at Vascular Research Group laboratories in the Clinical Sciences building at Hope Hospital for 20 years. Access will be available to researchers involved in The UK calciphylaxis Study and members of the Vascular Research Group, Salford Royal NHS Foundation Trust. Custody will remain with Dr Smeeta Sinha.

DNA will be stored at the Centre for Integrated Genomic Medical Research (CIGMR)
Imaging, Genomics and Proteomics Research Group, Faculty of Medical and Human Sciences,University of Manchester.

Tissue samples will be stored in the immunocytochemistry laboratory, Division of Laboratory & Regenerative Medicine, University of Manchester. Custody will be with Dr Maria Jeziorska, University of Manchester

14. What will happen to the samples at the end of the research? *Please tick all that apply and give further details.*

☐ Transfer to research tissue bank

(If the bank is in England, Wales or Northern Ireland the institution will require a licence from the Human Tissue Authority to store relevant material for possible further research.)

☑ Storage by research team pending ethical approval for use in another project

(Unless the researcher's institution holds a storage licence from the Human Tissue Authority, or the tissue is stored in Scotland, or it is not relevant material, a further application for ethical review should be submitted before the end of this project.)

☐ Storage by research team as part of a new research tissue bank

(The institution will require a licence from the Human Tissue Authority if the bank will be storing relevant material in England, Wales or Northern Ireland. A separate application for ethical review of the tissue bank may also be submitted.)

☐ Storage by research team of biological material which is not "relevant material" for the purposes of the Human Tissue Act

☐ Disposal in accordance with the Human Tissue Authority's Code of Practice

☐ Other

☐ Not yet known

Please give further details of the proposed arrangements:

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.*

Investigator identifier	Research site		Investigator Name	
IN1 ☑				
	Institution name	Newcastle - The Newcastle upon Tyne Hospitals NHS	Forename	Suren
	Department name	Renal Medicine	Middle name	
	Street address		Family name	Kanagasundaram
	Town/city	Newcastle	Email	
	Post Code		Qualification (MD...)	
	Country		Country	
IN2 ☑				
	Institution name	Belfast - Ulster Hospital	Forename	Alastair
	Department name	Renal Medicine	Middle name	
	Street address	Upper Newtownards Road	Family name	Woodman
	Town/city		Email	
	Post Code	BT16 1RH	Qualification (MD...)	
	Country		Country	
IN3 ☑				
	Institution name	Wirral University Teaching Hospital NHS Foundation	Forename	Anindya
	Department name	Renal Medicine	Middle name	
	Street address	Arrowe Park Road, Upton	Family name	Banerjee
	Town/city	Wirral, Mersey	Email	
	Post Code	CH49 5PE	Qualification (MD...)	
	Country		Country	
IN4 ☑				
	Institution name	Birmingham Heartlands Hospital	Forename	Jyoti
	Department name	Renal Medicine	Middle name	
	Street address	Bordesley Green East	Family name	Baharani
	Town/city	Birmingham	Email	
	Post Code	B9 5ST	Qualification (MD...)	
	Country		Country	

IN5 ☑

Institution name	St Lukes Hospital	Forename	John
Department name	Renal Medicine	Middle name	
Street address	Littel Horton Lane	Family name	Stoves
Town/city	Bradford	Email	
Post Code	BD5 0NA	Qualification (MD...)	
Country		Country	

IN6 ☑

Institution name	Dumfries & Galloway Royal Infirmary	Forename	Sue
Department name	Renal Medicine	Middle name	
Street address	Bankend Road	Family name	Robertson
Town/city	Dumfries	Email	
Post Code	DG1 4AP	Qualification (MD...)	
Country		Country	

IN7 ☑

Institution name	Edinburgh Royal Infirmary	Forename	Barbara
Department name	Renal Medicine	Middle name	
Street address	51 Little France Crescent	Family name	Robson
Town/city	Edinburgh	Email	
Post Code	EH16 4SA	Qualification (MD...)	
Country		Country	

IN8 ☑

Institution name	Leeds - St James's University Hospital	Forename	Mark
Department name	Renal Medicine	Middle name	
Street address	Beckett Street	Family name	Wright
Town/city	Leeds	Email	
Post Code	LS9 7TF	Qualification (MD...)	
Country		Country	

IN9 ☑

Institution name	Leicester General Hospital	Forename	Jonathon
Department name	Renal Medicine	Middle name	
Street address	Gwendolen Road	Family name	Barratt
Town/city		Email	
Post Code	LE5 4PW	Qualification (MD...)	
Country		Country	

IN10 ☑

		Forename	Pearl

	Institution name	Liverpool - Royal Liverpool University Hospital	Middle name Family name	 Pai
	Department name	Nephrology Department	Email	
	Street address	6C Link Prescot Street	Qualification (MD...)	
	Town/city		Country	
	Post Code	L7 8XP		
	Country			

IN11 ☑

			Forename	David
			Middle name	
	Institution name	Middlesbrough - The James Cook University Hospital	Family name	Reaich
	Department name	Renal Medicine	Email	
	Street address	Marton Road	Qualification (MD...)	
	Town/city	Middlesborough	Country	
	Post Code	TS4 3BW		
	Country			

IN12 ☑

			Forename	Robert
			Middle name	
	Institution name	Northampton General Hospital	Family name	Preston
	Department name	Renal Medicine	Email	
	Street address	Cliftonville	Qualification (MD...)	
	Town/city	Northampton	Country	
	Post Code	NN1 5BD		
	Country			

IN13 ☑

			Forename	Victoria
			Middle name	
	Institution name	Oxford Radcliffe Hospitals NHS Trust	Family name	Rush
	Department name	Oxford Kidney Unit and Oxford Transplant Centre	Email	
	Street address	The Churchill Hospital, Old Road, Headington	Qualification (MD...)	
	Town/city	Oxford	Country	
	Post Code	OX3 7LE		
	Country			

IN14 ☑

			Forename	Ajay
			Middle name	
	Institution name	Lancashire Teaching Hospitals NHS Foundation Trust	Family name	Dhaygude
	Department name	Renal Medicine	Email	
	Street address	Sharoe Green Lane	Qualification (MD...)	
	Town/city	Preston	Country	
	Post Code	PR2 9HT		
	Country			

IN15 ☑

Institution name	Northern General Hospital NHS Trust	Forename	Nicholas
Department name	Sheffield Kidney Institute	Middle name	
Street address	Herries Road	Family name	Fardon
Town/city	Sheffield	Email	
Post Code	S5 7AU	Qualification (MD...)	
Country		Country	

IN16 ☑

Institution name	Royal Cornwall Hospitals NHS Trust	Forename	Lisa
Department name	Renal Unit	Middle name	
Street address		Family name	Attrill
Town/city	Truro	Email	
Post Code	TR1 3LJ	Qualification (MD...)	
Country		Country	

IN17 ☑

Institution name	Cambridge Universities NHS Foundation Trust	Forename	Sanjay
Department name	Addenbrooke's Dialysis Centre	Middle name	
Street address		Family name	Ohja
Town/city	Cambridge	Email	
Post Code	CB2 0QQ	Qualification (MD...)	
Country		Country	

IN18 ☑

Institution name	University Hospital of North Staffordshire NHS	Forename	Julie
Department name	Renal Medicine Department	Middle name	
Street address	Royal Infirmary, Princes Road	Family name	Wessels
Town/city	Stoke-on-Trent	Email	
Post Code	St4 7LN	Qualification (MD...)	
Country		Country	

IN19 ☑

Institution name	Countess of Chester Hospital NHS Foundation Trust	Forename	Anindya
		Middle name	
		Family name	Banerjee
		Email	

	Department name	Renal Unit	Qualification (MD...)	
	Street address	Countess of Chester Health Park, Liverpool Road	Country	
	Town/city	Chester		
	Post Code	CH2 1UL		
	Country			

IN20 ☑

			Forename	John
			Middle name	
	Institution name	Southern Health & Social Care Trust	Family name	Harty
	Department name	Renal Unit, Daisy Hill Hospital	Email	
	Street address	5 Hospital Road	Qualification (MD...)	
	Town/city	Newry, County Down	Country	
	Post Code	BT35 8DR		
	Country			

IN21 ☑

			Forename	Arthur
			Middle name	
	Institution name	Victoria Hospital NHS Fife	Family name	Doyle
	Department name	Renal Unit	Email	
	Street address	Hayfield Road,	Qualification (MD...)	
	Town/city	Kircaldy	Country	
	Post Code	KY2 5AH		
	Country			

IN22 ☑

			Forename	Stanley
			Middle name	
	Institution name	Barts Health NHS Trust	Family name	Fan
	Department name	Barts & The London Renal Centre	Email	
	Street address	The Royal London Hospital, Whitechapel	Qualification (MD...)	
	Town/city	London	Country	
	Post Code	E1 1BB		
	Country			

IN23 ☑

			Forename	Colin
			Middle name	
	Institution name	York Teaching Hospitals NHS Foundation Trust	Family name	Jones
	Department name	Renal Medicine	Email	
	Street address	The York Hospital, Wigginton Road	Qualification (MD...)	
	Town/city	York	Country	
	Post Code	YO31 8HE		
	Country			

IN24 ☑

			Forename	Sunil
			Middle name	
	Institution name	Hull and East Yorkshire NHS Hospitals	Family name	Bhandari
	Department name	Renal Services	Email	
	Street address	Anlaby Road	Qualification (MD...)	
	Town/city	Hull	Country	
	Post Code	HU3 2JZ		
	Country			

IN25 ☑

			Forename	Frieder
			Middle name	
	Institution name	Peterborough & Stamford Hospitals NHS Foundation	Family name	Kleemann
	Department name	Renal Medicine	Email	
	Street address	Peterborough City Hospital, Edith Cavell Campus, Bretton Gate	Qualification (MD...)	
	Town/city	Peterborough	Country	
	Post Code	PE3 9GZ		
	Country			

IN26 ☑

			Forename	
			Middle name	
	Institution name	Aberdeen Royal Infirmary, NHS Grampian	Family name	
	Department name	Renal Medicine	Email	
	Street address	Foresterhill	Qualification (MD...)	
	Town/city	Aberdeen	Country	
	Post Code	AB25 2ZN		
	Country			

IN27 ☑

			Forename	
			Middle name	
	Institution name	Monklands Hospital,NHS Lanarkshire	Family name	
	Department name	Renal Medicine	Email	
	Street address	Monkscourt Avenue	Qualification (MD...)	
	Town/city	Airdrie	Country	
	Post Code	ML6 0JS		
	Country			

IN28 ☑

			Forename	
			Middle name	
	Institution name	Northern Health & Social Care Trust	Family name	
	Department name	Renal Service, Antrim Area Hospital	Email	
	Street address	Bush Road	Qualification (MD...)	
	Town/city	Antrim	Country	
	Post Code	BT41 2RL		

Country

IN29 ☑

Institution name	Gwynedd Hosp, Betsi Cadwaladr University Hospital
Department name	Renal Services
Street address	Penrhosgarnedd
Town/city	Bangor, Gwynedd
Post Code	LL57 2PW
Country	

Forename
Middle name
Family name
Email
Qualification (MD...)
Country

IN30 ☑

Institution name	Glan Clywd Hospital, Betsi Cadwaladr University Ho
Department name	Renal Services
Street address	
Town/city	Rhyl, Denbighshire
Post Code	LL18 5UJ
Country	

Forename
Middle name
Family name
Email
Qualification (MD...)
Country

IN31 ☑

Institution name	Wrexham Maelor Hospital
Department name	Renal Services
Street address	Croesnewydd Road
Town/city	Wrexham
Post Code	LL13 7TD
Country	

Forename
Middle name
Family name
Email
Qualification (MD...)
Country

IN32 ☑

Institution name	Basildon & Thurrock University Hospitals
Department name	Renal Services
Street address	Basildon Hospital, Nethermayne
Town/city	Basildon, Essex
Post Code	SS16 5NL
Country	

Forename
Middle name
Family name
Email
Qualification (MD...)
Country

IN33 ☑

Institution name	Belfast Health & Social Care Trust
Department name	Renal Medicine
Street address	Belfast City Hospital, 51 Lisburn Road

Forename
Middle name
Family name
Email
Qualification (MD...)

	Town/city	Belfast	Country	
	Post Code	BT9 7AB		
	Country			

IN34 ☑

		Forename	Clara
		Middle name	
Institution name	University Hospitals Birmingham NHS Foundation Tru	Family name	Day
		Email	
Department name	Renal Medicine	Qualification (MD...)	
Street address	Queen Elizabeth Hospital, Queen Elizabeth Medical Centre,	Country	
Town/city	Birmingham		
Post Code	B15 2TH		
Country			

IN35 ☑

		Forename	
		Middle name	
Institution name	Brighton and Sussex University Hospitals	Family name	
		Email	
Department name	Sussex Kidney Unit	Qualification (MD...)	
Street address	Royal Sussex County Hospital, Eastern Road	Country	
Town/city	Brighton		
Post Code	BN2 5BE		
Country			

IN36 ☑

		Forename	
		Middle name	
Institution name	North Bristol NHS Trust	Family name	
		Email	
Department name	The Richard Bright Renal Unit, Southmead Hospital	Qualification (MD...)	
Street address	Southmead Road, Westbury-on-Trym	Country	
Town/city	Bristol		
Post Code	BS10 5NB		
Country			

IN37 ☑

		Forename	
		Middle name	
Institution name	East Kent Hosp University NHS Foundation Trust	Family name	
		Email	
Department name	Renal Medicine	Qualification (MD...)	
Street address	Kent & Canterbury Hospital, Ethelbert Road	Country	
Town/city	Canterbury		
Post Code	CT1 3NG		
Country			

IN38 ☑

			Forename
			Middle name
	Institution name	Cardiff and Vale University Health Board	Family name
			Email
	Department name	Nephrology and Transplant, University Hospital of Wales	Qualification (MD...)
	Street address	Heath Park	
	Town/city	Cardiff	Country
	Post Code	CF14 4XW	
	Country		

IN39 ☑

			Forename
			Middle name
	Institution name	North Cumbria University Hospitals NHS Trust	Family name
			Email
	Department name	Renal, Cumberland Infirmary	Qualification (MD...)
	Street address	Newtown Road,	
	Town/city	Carlisle	Country
	Post Code	CA2 7HY	
	Country		

IN40 ☑

			Forename
			Middle name
	Institution name	Mid Essex Hospital Services NHS Trust	Family name
	Department name	Renal Department	Email
	Street address	Zone A, Hospital Wing, Court Road, Broomfield	Qualification (MD...)
	Town/city	Chelmsford	Country
	Post Code	CM1 7ET	
	Country		

IN41 ☑

			Forename
			Middle name
	Institution name	Colchester Hospital University NHS Foundation Trus	Family name
			Email
	Department name	Nephrology, Colchester General Hospital	Qualification (MD...)
	Street address	Turner Road	Country
	Town/city	Colchester, Essex	
	Post Code	CO4 5JL	
	Country		

IN42 ☑

			Forename
			Middle name
	Institution name	University Hospitals Coventry and Warwickshire NHS	Family name
			Email
	Department name	Renal and Transplantation	Qualification (MD...)
	Street address	Clifford Bridge Road	

	Town/city	Coventry	Country
	Post Code	CV2 2DX	
	Country		

IN43 ☑

			Forename
			Middle name
	Institution name	NHS Ayrshire and Arran	Family name
	Department name	John Stevenson Lynch Renal Unit	Email
	Street address	University Hospital Crosshouse	Qualification (MD...)
	Town/city	Kilmarnock	Country
	Post Code	KA2 0BE	
	Country		

IN44 ☑

			Forename
			Middle name
	Institution name	Derby Hospitals NHS Foundation Trust	Family name
	Department name	Renal Services	Email
	Street address	Royal Derby Hospital, Uttoxeter Road	Qualification (MD...)
	Town/city	Derby	Country
	Post Code	DE22 3NE	
	Country		

IN45 ☑

			Forename
			Middle name
	Institution name	Western Health and Social Care Trust	Family name
	Department name	Renal Unit, Altnagelvin Area Hospital	Email
	Street address	Glenshane Road	Qualification (MD...)
	Town/city	Londonderry	Country
	Post Code	BT47 6SB	
	Country		

IN46 ☑

			Forename
			Middle name
	Institution name	Doncaster and Bassetlaw Hospitals NHS Foundation	Family name
	Department name	Renal Medicine, Doncaster Royal Hospital	Email
	Street address	Armthorpe Road	Qualification (MD...)
	Town/city	Doncaster	Country
	Post Code	DN2 5LT	
	Country		

IN47 ☑

			Forename

			Middle name
	Institution name	Dorset County Hospital NHS Foundation Trust	Family name
			Email
	Department name	Renal Unit, Dorset County Hospital	Qualification (MD...)
	Street address	Williams Avenue,	
	Town/city	Dorchester	Country
	Post Code	DT1 2JY	
	Country		

IN48 ☑

			Forename
			Middle name
	Institution name	The Dudley Group NHS Foundation Trust	Family name
			Email
	Department name	Renal	Qualification (MD...)
	Street address	Russells Hall Hospital	
	Town/city	Dudley	Country
	Post Code	DY1 2HQ	
	Country		

IN49 ☑

			Forename
			Middle name
	Institution name	NHS Tayside - Ninewells Hospital	Family name
			Email
	Department name	Renal Medicine	Qualification (MD...)
	Street address	Ninewells Hospital	
	Town/city	Dundee	Country
	Post Code	DY1 2HQ	
	Country		

IN50 ☑

			Forename
			Middle name
	Institution name	NHS Fife - Dunfermline	Family name
			Email
	Department name	Renal, Queen Margaret Hospital	Qualification (MD...)
	Street address	Whitefield Road	
	Town/city	Dunfermline	Country
	Post Code	KY12 0SU	
	Country		

IN51 ☑

			Forename
			Middle name
	Institution name	Royal Deveon and Exeter NHS Foundation Trust	Family name
			Email
	Department name	Exeter Kidney Unit	Qualification (MD...)
	Street address	Barrack Road	
	Town/city	Exeter	Country
	Post Code	EX2 5DW	
	Country		

IN52 ☑

			Forename
			Middle name
	Institution name	NHS Greater Glasgow and Clyde - Western Infirmary	Family name
			Email
	Department name	Glasgow Renal and Transplant Unit	Qualification (MD...)
	Street address	Dumbarton Road	
	Town/city	Glasgow	Country
	Post Code	G11 6NT	
	Country		

IN53 ☑

			Forename
			Middle name
	Institution name	Gloucestershire Hospitals NHS Foundation Trust	Family name
			Email
	Department name	Nephrology - Gloucestershire Royal Hospital	Qualification (MD...)
	Street address	Great Western Road	Country
	Town/city	Gloucester	
	Post Code	GL1 3NN	
	Country		

IN54 ☑

			Forename
			Middle name
	Institution name	NHS Highland - Raigmore Hospital	Family name
	Department name	Renal Unit	Email
	Street address	Old Perth Road	Qualification (MD...)
	Town/city	Inverness	
	Post Code	IV2 3UJ	Country
	Country		

IN55 ☑

			Forename
			Middle name
	Institution name	The Ipswich Hospital NHS Trust	Family name
	Department name	Renal Medicine	Email
	Street address	Heath Road	Qualification (MD...)
	Town/city	Ipswich	
	Post Code	IP4 5PD	Country
	Country		

IN56 ☑

			Forename
			Middle name
	Institution name	Royal Free London NHS Foundation Trust	Family name
			Email
	Department name	Renal Services, Royal Free Hospital	Qualification (MD...)
	Street address	Pond Street	
	Town/city	London	Country

Post Code	NW3 2QG	
Country		

IN57 ☑

		Forename
		Middle name
Institution name	King's College Hospital NHS Foundation Trust	Family name
Department name	King's Renal Unit	Email
Street address	Denmark Hill	Qualification (MD...)
Town/city	London	Country
Post Code	SE5 9RS	
Country		

IN58 ☑

		Forename
		Middle name
Institution name	Aintree University Hospitals NHS Foundation Trust	Family name
Department name	Aintree Renal Unit	Email
Street address	Longmoor Lane	Qualification (MD...)
Town/city	Liverpool	Country
Post Code	L9 7AL	
Country		

IN59 ☑

		Forename
		Middle name
Institution name	Guy's and St Thomas' NHS Foundation Trust	Family name
Department name	Kidney Services	Email
Street address	Guy's Hospital, Gret Maze Pond	Qualification (MD...)
Town/city	London	Country
Post Code	SE1 9RT	
Country		

IN60 ☑

		Forename
		Middle name
Institution name	St George's Healthcare NHS Trust	Family name
Department name	Renal Medicine	Email
Street address	Blackshaw Road, Tooting	Qualification (MD...)
Town/city	London	Country
Post Code	SW17 0QT	
Country		

IN61 ☑

		Forename

	Institution name	Imperial College Healthcare NHS Trust	Middle name Family name Email	
	Department name	Imperial Renal and Transplant Centre, Hammersmith Hospital	Qualification (MD...)	
	Street address	Du Cane Road	Country	
	Town/city	London		
	Post Code	W12 0HS		
	Country			

IN62 ☑

	Institution name	Central Manchester NHS Foundation Trust	Forename Middle name Family name Email	
	Department name	Renal Medicine	Qualification (MD...)	
	Street address	Oxford Road	Country	
	Town/city	Manchester		
	Post Code	M13 9WL		
	Country			

IN63 ☑

	Institution name	Norfolk and Norwich University Hospitals NHS FT	Forename Middle name Family name Email	
	Department name	Renal Medicine	Qualification (MD...)	
	Street address	Colney Lane	Country	
	Town/city	Norwich		
	Post Code	NR4 7UY		
	Country			

IN64 ☑

	Institution name	Nottingham University Hospitals NHS Trust	Forename Middle name Family name Email	Matthew Hall
	Department name	Renal and Transplant Unit, City Hospital	Qualification (MD...)	
	Street address	Hucknall Road	Country	
	Town/city	Nottingham		
	Post Code	NG5 1PB		
	Country			

IN65 ☑

	Institution name	Plymouth Hospitals NHS Trust	Forename Middle name Family name Email	
	Department name	Renal Medicine	Qualification (MD...)	
	Street address	Derriford Road, Crownhill	Country	
	Town/city	Plymouth, Devon		
	Post Code	PL6 8DH		
	Country			

IN66 ☑

Institution name	Portsmouth Hospitals NHS Trust	Forename Middle name Family name
Department name	Wessex Renal and Transplant Service	Email Qualification (MD...)
Street address	Queen Alexandra Hospital, Cosham	Country
Town/city	Portsmouth	
Post Code	PO6 3LY	
Country		

IN68 ☑

Institution name	Southend University Hospital NHS Foundation Trust	Forename Middle name Family name Email
Department name	Nephrology	Qualification (MD...)
Street address	Prittlewell Chase	
Town/city	Westcliff-on-sea, Essex	Country
Post Code	SS0 ORY	
Country		

IN69 ☑

Institution name	Epsom & St Helier University Hospitals NHS Trust	Forename Middle name Family name Email
Department name	South West Thames Renal & Transplantation Unit	Qualification (MD...)
Street address	St Helier Hospital, Wrythe Lane	Country
Town/city	Carshalton, Surrey	
Post Code	SM5 1AA	
Country		

IN70 ☑

Institution name	East and North Hertforshire NHS Trust	Forename Middle name Family name
Department name	Renal Medicine	Email
Street address	Coreys Mill Lane	Qualification (MD...)
Town/city	Stevenage, Hertfordshire	
Post Code	SG1 4AB	Country
Country		

IN71 ☑

Forename

	Institution name	City Hospitals Sunderland NHS Foundation Trust	Middle name Family name	
	Department name	Department of Renal Medicine	Email Qualification (MD...)	
	Street address	Kayll Road		
	Town/city	Sunderland	Country	
	Post Code	SR4 7TP		
	Country			

IN72 ☑

	Institution name	Abertawe Bro Morgannwg University Health Board	Forename Middle name Family name	
	Department name	Renal Services, Morriston Hospital	Email Qualification (MD...)	
	Street address	Heol Maes Eglwys, Morriston	Country	
	Town/city	Swansea, Wales		
	Post Code	SA6 6NL		
	Country			

IN73 ☑

	Institution name	The Shrewsbury and Telford Hospital NHS Trust	Forename Middle name Family name	
	Department name	Renal Department	Email	
	Street address	Mytton Oak Road	Qualification (MD...)	
	Town/city	Shrewsbury	Country	
	Post Code	SY3 8XQ		
	Country			

IN74 ☑

	Institution name	The Royal Wolverhampton NHS Trust	Forename Middle name Family name	
	Department name	Renal Department, New Cross Hospital	Email Qualification (MD...)	
	Street address	Wednesfield Road		
	Town/city	Wolverhamptom	Country	
	Post Code	WV10 0QP		
	Country			

IN77 ☐

◉ NHS site
○ Non-NHS site

Country: England

	Organisation name	MID ESSEX HOSPITAL SERVICES NHS TRUST	Forename: Sumith Middle name: Family name: Abeygunasekara Email: Sumith.Abeygunasekara@meht.nhs.uk Qualification (MD...): Country: UNITED KINGDOM

Address	BROOMFIELD HOSPITAL COURT ROAD CHELMSFORD ESSEX
Post Code	CM1 7ET

IN78 ☐

◉ NHS site
○ Non-NHS site

Country: England

Organisation name	ROYAL BERKSHIRE NHS FOUNDATION TRUST
Address	ROYAL BERKSHIRE HOSPITAL LONDON ROAD READING BERKSHIRE
Post Code	RG1 5AN

Forename	Oliver
Middle name	
Family name	Flossmann
Email	Oliver.flossman@royalberkshire.nhs.uk
Qualification (MD...)	
Country	UNITED KINGDOM

IN79 ☐

◉ NHS site
○ Non-NHS site

Country: England

Organisation name	HARROGATE AND DISTRICT NHS FOUNDATION TRUST
Address	STRAYSIDE WING HARROGATE DISTRICT HOSPITAL LANCASTER PARK ROAD HARROGATE NORTH YORKSHIRE
Post Code	HG2 7SX

Forename	Benjamin
Middle name	
Family name	Walker
Email	BENJAMIN.WALKER@hdft.nhs.uk
Qualification (MD...)	
Country	UNITED KINGDOM

PART D: Declarations

D1. Declaration by Chief Investigator

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

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

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

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

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

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

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

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

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

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

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

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

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

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

(•) Chief Investigator

( ) Sponsor

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

Access to application for training purposes *(Not applicable for R&D Forms)*

Optional – please tick as appropriate:

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

Signature: .....

Print Name: Smeeta Sinha

Date: 19/07/2011 *(dd/mm/yyyy)*

D2. Declaration by the sponsor's representative

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

I confirm that:

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

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

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

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

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

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

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

Signature: .....

Print Name: Rachel Georgiou

Post: Research Governance Manager

Organisation: Salford Royal NHS Foundation Trust

Date: 19/07/2011 *(dd/mm/yyyy)*