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 complete the questions in order. If you change the response to a question, please select 'Save' and review all the questions as your change may have affected subsequent questions.

Please enter a short title for this project (maximum 70 characters)
The SeaSHeL national prospective cohort 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) Does the study involve the use of any ionising radiation?	( ) Yes	(●) No
b) Will you be taking new human tissue samples (or other human biological samples)?	( ) Yes	(●) No
c) Will you be using existing human tissue samples (or other human biological samples)?	( ) Yes	(●) No

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

[x] England
[ ] Scotland

☐ Wales
☐ Northern Ireland

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

◉ England
○ Scotland
○ Wales
○ Northern Ireland
○ This study does not involve the NHS

4. Which applications do you require?

☑ IRAS Form
☐ Confidentiality Advisory Group (CAG)
☐ Her Majesty's Prison and Probation Service (HMPPS)

Most research projects require review by a REC within the UK Health Departments' Research Ethics Service. Is your study exempt from REC review?

○ Yes ◉ No

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

◉ Yes ○ No

5a. Are all the research costs and infrastructure costs (funding for the support and facilities needed to carry out research e.g. NHS Support costs) for this study provided by a NIHR Biomedical Research Centre, NIHR Collaboration for Leadership in Health Research and Care (CLAHRC), NIHR Patient Safety Translational Research Centre or Medtech and In Vitro Diagnostic Cooperative in all study sites?

Please see information button for further details.

○ Yes ◉ No

Please see information button for further details.

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 Portfolio?

Please see information button for further details.

◉ Yes ○ No

The NIHR Clinical Research Network provides researchers with the practical support they need to make clinical studies happen in the NHS e.g. by providing access to the people and facilities needed to carry out research "on the ground".

If you select yes to this question, you must complete a NIHR Clinical Research Network (CRN) Portfolio Application Form (PAF) immediately after completing this project filter question and before submitting other applications. Failing to complete the PAF ahead of other applications e.g. HRA Approval, may mean that you will be unable to access NIHR CRN Support for your study.

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 Confidentiality Advisory Group 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 administering questionnaires/interviews for quantitative analysis or mixed methodology study

IRAS Form (project information)

Please refer to the E-Submission and Checklist tabs for instructions on submitting this application.

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 SeaSHeL national prospective cohort study

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

REC Name:
North West- Greater Manchester East

REC Reference Number:
19/NW/0556

Submission date:
02/08/2019

PART A: Core study information

1. ADMINISTRATIVE DETAILS

A1. Full title of the research:

Prognostic factors for outcomes of idiopathic Sudden onset Sensorineural Hearing Loss: the SeaSHeL national prospective cohort study

A3-1. Chief Investigator:

	Title	Forename/Initials	Surname
	Professor	Anne	Schilder
Post	NIHR Research Professor		
Qualifications	Professor of Paediatric Otorhinolaryngology, Honorary Consultant ENT Surgeon		
ORCID ID	0000 0002 5496 4580		
Employer	evidENT Team - Ear Institute University College London		
Work Address	330 Grays Inn Road Kings Cross London		
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Work E-mail	a.schilder@ucl.ac.uk		
* Personal E-mail	a.schilder@ucl.ac.uk		

Work Telephone	2031089327
* Personal Telephone/Mobile	2031089327
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 HRA/R&D reviewers that is sent to the CI.

	Title	Forename/Initials	Surname
	Mr	Rishi	Mandavia
Address	UCL Ear Institute		
	332 Grays Inn Road, Kings Cross		
	London, United Kingdom		
Post Code	WC1X 8EE		
E-mail	r.mandavia@ucl.ac.uk		
Telephone	2031089327		
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:	124643
Protocol Version:	1
Protocol Date:	05/02/2019
Funder's reference number (enter the reference number or state not applicable):	N/A
Project website:	N/A

Additional reference number(s):

Ref.Number Description	Reference Number

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

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

○ Yes ◉ No

Please give brief details and reference numbers.

2. OVERVIEW OF THE RESEARCH

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

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

Each year, approximately 15,000 people in the United Kingdom experience sudden loss of hearing. Of those who present to the NHS, the cause is unknown in most cases despite investigation, and these cases are termed idiopathic 'sudden onset sensorineural hearing loss' (SSNHL). Treatment options for idiopathic SSNHL mainly include steroid treatments and their efficacy is not well known.

There are a number of new treatments being developed for SSNHL based upon recent discoveries regarding factors causing the condition. These treatments require rigorous testing in clinical trials before they can become available for clinical use. To allow for such trials to be run there is an urgent need for information on patient numbers and characteristics, geographical distribution, patient and treatment pathways, as well as outcomes. There is an urgent need to understand this patient population to help develop new treatments.

We will record routinely collected information of patients presenting with SSNHL (including: patient characteristics, treatment received, hearing levels). This will take place at 97 National Health Services (NHS) sites across the country with Ear, Nose, and Throat (ENT) and Audiology services. 20 of these sites will also collect quality of life information via questionnaires.

Once the data has been collected, it will be analysed to:

1) Establish the patient pathway for patients presenting with SSNHL in the NHS
2) Develop a tool that will help predict recovery for patients with SSNHL.
3) Establish the impact of SSNHL on people's quality of life.

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, HRA, 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.

Purpose and Design
The aim of this study is to develop a prediction model to predict recovery for patients with SSNHL.

The Objectives include:
1. To map the patient pathway and identify the characteristics of adult patients presenting to NHS ENT and hearing services with SSNHL.
2. To develop a prediction model to predict recovery for patients with SSNHL.
3. Establish the impact of idiopathic SSNHL on patients' quality of life (QoL)

Current treatment pathways for patients with SSNHL vary considerably with a paucity of evidence comparing the different existing treatment methods. This lack of evidence is recognised by national guidelines (including National Institute for Health and Care Excellence; American Academy of Otolaryngology-Head and Neck Surgery; and the British Academy of Audiology). There is a growing need for further research in this patient population to support the development of novel treatments and improve the patient pathway. This requires reliable information on patient demographics, geographical distribution, treatment pathways as well as outcomes.

This study will be a national multicentre prospective observational cohort study. The protocol has been developed by the study's Academic Team comprising of clinicians and researchers. It has also undergone peer review by experts, including clinicians, researchers and statisticians, with additional input from patients to ensure the study addresses their priorities.

Recruitment
Eligible sites across the United Kingdom will be identified via SFO-UK (The Student and Foundation Doctors in Otolaryngology), INTEGRATE (The National ENT Trainee Research Network), The NIHR CRN Audiology Champion Network, and the NIHR CRN. 97 NHS sites with ENT or Hearing services will act as study sites where participants will be recruited for anonymised data collection.

Idiopathic SSNHL is a relatively rare condition so we estimate we will capture 1 eligible patient per two sites every month. This is approximately 48 eligible patients per month across England.

Twenty of these sites will be used to collect quality of life data. Eligible patients will be identified by the patient's clinical team and offered the opportunity to discuss participation with a researcher. Potential participants will be given a Participant Information Sheet (PIS) and a consent form should they wish to participate.

Inclusion/Exclusion
All adult patients diagnosed with SSNHL will be included in this study. No one will be unfairly excluded from this study.

Consent
In centres where no QoL data are collected, there will be no deviation from the usual standard of care for any patient, and routinely collected patient data will be anonymised; therefore, consent is not required.

For centres where QoL data are collected, patients will be required to give written informed consent. This process will involve participants reading a Participant Information Sheet (PIS) with the opportunity to discuss concerns with a member of the research team afterwards. Efforts will be made to use the optimal communication method given the hearing impairment likely to be present in participants.

Researchers will need an up to date Good Clinical Practice certificate to ensure they are qualified to take informed consent from the patients. The person taking consent will be recorded on a delegation log.

Risks, Burdens and Benefits
There are no anticipated risks to the patients who will have their anonymous data being recorded and submitted for the study. At the select 20 centres QoL questionnaires will take approximately thirty minutes to complete so the participant's appointment may take thirty minutes longer. To mitigate this, Site leads will arrange for QoL questionnaires to be completed whilst participants are waiting for their appointment.

Though there are no direct benefits for the participant, their participation will provide information that could potentially improve the care patients with SSNHL in the future.

Confidentiality
All data collected by the research team will be anonymous and stored electronically using an encrypted database. Throughout and at the conclusion of the study, electronic files will be transferred and stored in accordance with data governance regulations (Data Protection Act 2018).

Conflict of Interest
Funding has been secured from Industry (£2000) for costs associated with administering questionnaires only.

Research duties will not interfere with duties as a health care professional as this study does not require deviation from usual management provided. All members of the research team will be asked to declare any conflicts of interest.

At the end of the study, results (consisting of anonymous data analysed) will be disseminated via formal publication(s) to participants, families, clinicians, and members of Industry to promote awareness and discussion.

Use of tissue samples in future research
This study does not use tissue samples.

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
- [ ] 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.*

1)To develop a tool to predict recovery for patients with SSNHL

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

2)To map the patient pathway and identify the characteristics of adult patients presenting to NHS ENT and hearing services with SSNHL.

3)Establish the impact of idiopathic SSNHL on patients' quality of life

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

This study aims to develop a tool to predict the recovery of patients affected by SSNHL. This study will also provide information on patient characteristics, their geographical distribution, how they are treated, and how the condition affects their quality of life.

This research is important because it will help direct the development of future treatments for SSNHL, map the NHS patient pathway and improve the quality of care given to these patients.

This would be the first study of its kind and scale, to our knowledge, as existing studies have been limited in their sample sizes, study designs and outcomes collected. It is acknowledged there is a general lack of evidence to provide robust support for clinicians' management decisions and for providing patients with long-term outcome information at the time of diagnosis/treatment.

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.*

Study design and methodology
The research design of the study is a national multicentre prospective observational cohort study. We have selected this design, since it will enable us to map the patient pathway and identify the characteristics of adult patients presenting to NHS ENT and hearing services with SSNHL.

We will collect quality of life data of patients with SSNHL and analyse changes in quality of life to establish the impact of idiopathic SSNHL on patients' quality of life.

Our analysis plan also includes developing a prognostic model, which will allow us to predict recovery for patients with SSNHL in NHS ENT and Hearing services.

Broad Timetable
The broad timetable for this study includes:
• 12-18 months to recruit 550 patients
• 4 months to interpret and analyse the data.
• 4 months to write final reports (including a lay summary report)
• 6 months to disseminate results using the report and attending(inter)national conferences

Interviews
No interviews will take place during this study.

Interim analyses/reports
We plan to conduct monthly audits of data collected to ensure data capture targets are being met. There will be an analysis of collected data halfway through patient recruitment to allow for troubleshooting should any optimisation strategies be necessary. An interim report will be sent internally to all members of the research team around the halfway mark of data collection to update them on progress so far and estimated timelines for the future.

Observational components
The observational component includes recording anonymised, routinely collected data on patients affected by SSNHL. Anonymous data collected from medical notes will include patient characteristics, treatment(s) received, and hearing outcomes. All adult patients presenting with SSNHL at study sites will be included.

We will also collect QoL data via questionnaires at 20 sites (20 out of 97). In these cases, Site leads will approach potentially eligible patients, use the PIS to discuss participation and obtain written consent. The questionnaires will be distributed to consenting patients at their initial presentation and at their follow-up appointment at NHS hospitals.

Patient and Public Involvement
Patients affected by SSNHL were consulted through out to ensure study outcomes were in line with what they valued and prioritised. They also helped review the study design to ensure questionnaires were legible and to ensure questionnaire completion is feasible for participants.

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
- [x] Dissemination of findings
- [ ] None of the above

Give details of involvement, or if none please justify the absence of involvement.
Patients were consulted to help with study design, including reviewing participant forms to ensure legibility (e.g. PIS, consent form). Patient will be involved in study dissemination including co-authoring a lay summary report.

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
- [x] Ear
- [ ] Eye
- [ ] Generic Health Relevance
- [ ] Infection

- ☐ Inflammatory and Immune System
- ☐ Injuries and Accidents
- ☐ Mental Health
- ☐ Metabolic and Endocrine
- ☐ Musculoskeletal
- ☐ Neurological
- ☐ Oral and Gastrointestinal
- ☐ Paediatrics
- ☐ Renal and Urogenital
- ☐ Reproductive Health and Childbirth
- ☐ Respiratory
- ☐ Skin
- ☐ Stroke

Gender:	Male and female participants
Lower age limit: 16	Years
Upper age limit:	No upper age limit

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

- Adult patients (male or female) aged over 16 years of age presenting to NHS ENT and hearing services with SSNHL
AND
- Diagnosed with a hearing loss in one or both ears of 30 dB HL or more, over at least 3 contiguous frequencies, between 250, 500, 1000, 2000, 4000 and 8000 Hz
AND
- Willing and able to provide written informed consent.

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

Patients with mixed or conductive hearing loss (CHL). CHL will be defined as a 'true' air-bone gap of 15 dB HL or more in 3 or more contiguous frequencies between 500, 1000, 2000, 4000 Hz.

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
Completion of a consent form	1	0	10 minutes	Assigned site leads and research nurses will consent eligible patients at hospital follow-up appointments in outpatient clinics.
Completion of a questionnaire (Health Utility Index Mark 3 and Hearing Handicap Inventory	2	0	10 minutes	Assigned site leads and research nurses will distribute the printed validated questionnaires to

for Adults or Hearing Handicap Inventory of Elderly)				the consenting patients at hospital follow-up appointments in outpatient clinics.
Collection of and uploading of anonymous data from patient notes	1	0	20 minutes	Assigned site leads and research nurses will collect anonymous routine data from patient notes at hospital outpatient clinics.

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

We expect participants at the sites selected for quality of life (QoL) questionnaires (n=20) to be involved in the study for a total of 60 minutes (time required to read PIS, complete consent form and QoL questionnaires, at presentation and follow-up).

For participants in the remaining sites (n=77), there will be no additional time requirements to their standard treatment.

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.

Potential hazards:
There are no anticipated risks to the patients who participate in this study. Participants will receive their routine care regardless of their participation.

There is a chance that a patient may spend an additional 30 minutes in clinic to fill out consent forms and the questionnaires however we seek to mitigate this by giving them the opportunity to complete the paperwork while they wait to be seen by their clinician. They will be informed via the PIS and consent form that they may decline to participate at any moment with no subsequent effect on their healthcare.

Confidentiality:
Anonymous participants' data will be collected and stored securely on encrypted electronic databases. As the data is completely anonymised there is no risk of breaching confidentiality.

Monitoring Systems:
A system will be in place to monitor and respond to incidents at all study sites. Incident reporting forms will be used by Site leads to document and escalate incidents to Operational leads, and/or Chief Investigator if appropriate. Site leads will oversee monthly audits to ensure data capture is progressing as expected and if data capture is not progressing, they will be required to discuss with the Operational leads.

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

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

Though there are no direct benefits for the participant, their participation will provide information that could potentially improve the care patients with SSNHL in the future.

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

There are no anticipated risks for researchers. Their involvement will be limited to administering questionnaires, and uploading and processing anonymised electronic data.

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).*

At 97 centres, the Site Lead or NIHR CRN Research Nurse will undertake a daily review of ENT and audiology clinics to identify potential participants based on presenting complaints/diagnoses. Routinely collected data will be extracted anonymously from eligible participants by members of the research team.

For the select 20 centres where QoL data are collected, the Site Lead or NIHR CRN Research Nurse will identify potential patients. Eligible participants who are willing to discuss participation will be provided with a PIS describing the study and informed written consent will be obtained.

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:
Patients presenting with SSNHL who meet our eligibility criteria will be identified by their existing clinical team and their routinely collected data will be captured anonymously by members of the research team. For a subset of these patients, formal consent will be obtained for anonymous quality of life questionnaires.

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?

At the 20 centres where quality of life data will be collected, potentially eligible patients will be approached by the Site Lead or NIHR CRN Research Nurse (who would form part of the existing clinical team). A PIS will be provided and voluntary consent obtained.

At the remaining sites (n=77), fully anonymised data will be collected and there will be no change in patients' routine care therefore no consent will be required.

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.

Legal and ethical requirement for informed consent
Under the Data Protection Act (2018), there is no requirement for consent to collect anonymised data from the 97 sites.

For the 20 centres where QoL data are collected, patients will be required to give written consent.

Arrangements for seeking consent
Researchers obtaining consent will consist of junior doctors, audiologists and NIHR local CRN research nurses. The member of the research team taking consent will have an up to date Good Clinical Practice certificate and will be recorded on a delegation log. They will use a PIS to provide information to potential participants and give a copy to

them to keep and refer to. They will also explain the study and discuss any queries with the potential participant. Written informed consent will be documented using a consent form.

Participant information sheets
Patients were involved in reviewing PIS and consent forms to ensure legibility and changes were made to the wording to ensure no jargon was used.

If you are not obtaining consent, please explain why not.
N/A

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?

Sensorineural hearing loss (SSNHL) is an emergency presentation so participants will be given sufficient time to consider participation however it will not delay them receiving timely treatment. We aim to give participants up to 1 hour to consider whether they would like to participate in filling out the questio nnaires. The questionnaires may be filled out while the patients wait in a waiting room.

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)*

For the quality of life data sites, there will be no formal translations services used however site leads will be onsite to provide additional assistance in understanding material using existing resources in place at clinics.

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:
This study will only collect anonymous data and will retain the non-identifiable data. If participants lose capacity to consent during the brief period where they are filling out questionnaires, they will be withdrawn from the study. Participants will be notified and given the opportunity to discuss their withdrawal either face-to-face or in written formats (e.g. electronic mail, letters) should they wish to.

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
- ☐ Access to social care records by those outside the direct social care 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 (includes paper or film)
  - ☐ NHS computers
  - ☐ Social Care Service computers
  - ☐ Home or other personal computers
  - ☐ University computers
  - ☐ Private company computers
  - ☐ Laptop computers

Further details:
None of these activities will take place at any stage of the study. Anonymised data, including replies from questionnaires, will be collected and stored on personal computers using an encrypted online database.

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

No personal data will be collected.

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.*

All data collected will be fully anonymous with no identifiable pieces of information collected or saved on the electronic database.

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.*

Only members of the clinical team will have access to participants' personal data in order to identify potential participants. No personal data will be collected or stored during this study.

Storage and use of data after the end of the study

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

The fully anonymous data will be stored on the online encrypted database REDCap and transferred to UCL to be processed by the Academic Team. Data will be analysed and remain in England.

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

	Title	Forename/Initials	Surname
	Prof	Anne	Schilder
Post	NIHR Research Professor- ENT		
Qualifications	Professor of Paediatric Otorhinolaryngology, Honorary Consultant ENT Surgeon		
Work Address	330 Grays Inn Rd Kings Cross London		
Post Code	WC1X 8DA		
Work Email	a.schilder@ucl.ac.uk		
Work Telephone			
Fax			

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

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

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

Years: 5
Months: 0

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.*

At the conclusion of the study, electronic files will be transferred and stored in accordance with UCL's guidelines for electronic and hard copy records. Anonymous data will be stored on the password-protected online encrypted database for a period of 5 years, after which the data will be permanently erased. Study staff members will have access to the data during this time.

INCENTIVES AND PAYMENTS

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

( ) Yes (●) No

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

( ) Yes (●) No

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

○ Yes ◉ No

NOTIFICATION OF OTHER PROFESSIONALS

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

○ Yes ◉ No

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

PUBLICATION AND DISSEMINATION

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

◉ Yes ○ No

Please give details, or justify if not registering the research.
Yes: This study will be registered with ClinicalTrials.gov and locally with NHS Research and Development departments at each participating site.

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:*

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

Other: Lay summary report for participants and their families.

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

The data being collected and analysed will be fully anonymous. Data to be collected has been carefully selected to avoid identifying patients based on incidental collation of details.

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.
A written lay summary report will be published, and results will be disseminated at relevant conferences.

5. Scientific and Statistical Review

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

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

Justify and describe the review process and outcome. If the review has been undertaken but not seen by the researcher, give details of the body which has undertaken the review:
The methodology underwent formal critique by the research team, an expert prognostician, two external reviewers and the host institute's research department. Reviewers were prompted to comment on the merit of the research, design and methods, feasibility of the research, presentation of the application and scientific validity of the study.

The academic branch of the national ENT trainee collaborative, INTEGRATE, has reviewed the protocol V1.0 and suggested no changes.

The prognostic statistician reviewed the protocol V1.0, helped outline the statistical analysis, and will serve as an Academic Lead during the study (Dr. Gerjon Hannink, Radboud UMC Nijmegen, The Netherlands).

Two independent reviews of the protocol V1.0 were sought by external experts in the field and a review by the host institution's research office was performed. The outcome of these reviews led to minor operational changes (i.e. extending timeline for recruitment).

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
	Dr	Gerjon	Hannink
Department	Department of Operating Rooms		
Institution	Radboud university medical center		
Work Address	PO Box 9101		
	Nijmegen		
	Netherlands		
Post Code	6500 HB		
Telephone			
Fax			
Mobile			
E-mail	Gerjon.Hannink@radboudumc.nl		

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

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

The change in auditory function in the affected ear from initial presentation to follow-up (at any one time between 6 and 16 weeks from onset of symptoms). Auditory function will be defined as the PTA of air conduction thresholds at 250, 500, 1000, 2000, 4000 and 8000 Hz. If multiple pure tone audiograms have been carried out between 6 and 16 weeks, the most recent pure tone audiogram will be used for the calculation of auditory function.

Change in auditory function classified as:
1) Full recovery: Final PTA in affected ear within 10dB of PTA of unaffected ear (≤10dB)
2) Partial to no recovery: Final PTA in affected ear ≥ 10dB of PTA of unaffected ear.

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

Degree of change in auditory function:
• Complete recovery: Final PTA in affected ear within 10dB of PTA of unaffected ear (≤10dB)
• Marked recovery: PTA improvement ≥30 dB (and final PTA in affected ear ≥ 10dB of PTA of unaffected ear)
• Slight recovery: PTA improvement ≥10dB and 30 dB (and final PTA in affected ear ≥ 10dB of PTA of unaffected ear)
• No improvement: PTA improvement 10 dB (and final PTA in affected ear ≥ 10dB of PTA of unaffected ear)

Quality of life:
Change in QoL score from initial presentation to follow-up at any one time between 6 and 16 weeks following treatment. QoL will be measured using the Hearing Handicap Inventory for Adults (HHIA) (for patients under 60 years of age) or Hearing Handicap Inventory for Elderly (HHIE) (for patients over 60 years of age) and the Health Utility Index Mark 3 (HUI3). QoL data will be only be collected in a selection of sites.

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:	550
Total international sample size (including UK):	550
Total in European Economic Area:	550

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 total sample size required to develop a binary logistic regression model has been estimated as per TRIPOD recommendations and from a paper by Ogundimu et al(2016). The number of events per variable (EPV) has been set at 15, producing a minimally required sample size of 550 patients (number of parameters = 15).

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.

We will develop a multivariable prognostic model to predict recovery for patients with SSNHL in NHS ENT and Hearing services. Analyses will be conducted on a list of 15 specified candidate predictors. Missing outcome data at study end will be accounted for and internal validation will take place using bootstrapping techniques to calibrate the model. Statistical analysis will be carried out using R software (version 3.5.1).

The final secondary objective is to assess quality of life for patients effected by SSNHL. The mean change in HHIA, HHIE and HUI3 scores will be calculated from initial presentation to follow up (any one time between 6 and 16 weeks). We will use the non-parametric Wilcoxon and McNemar–Bowker tests with a significance level of 5% to compare results at patients' initial presentation and at their final follow up. Statistical data analysis will be carried out using the SPSS program 19.0 (SPSS, Chicago, IL, USA). QoL data will be collected from a sub-set of sites (20 out of 97).

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
	Mr	Rishi	Mandavia
Post	NIHR CLAHRC BRC Clinical Research Fellow ENT Surgery		
Qualifications	BSc, MSc, MRCS (ENT)		
Employer	UCL Ear Institute		
Work Address	evidENT 332 Grays Inn Road, Kings Cross London, United Kingdom		
Post Code	WC1X 8EE		
Telephone			
Fax			
Mobile			
Work Email	r.mandavia@ucl.ac.uk		

	Title	Forename/Initials	Surname
	Dr	Gerjon	Hannink
Post	Methodologist/Epidemiologist		
Qualifications	PhD		
Employer	Radboud university medical center		
Work Address	PO Box 9101 6500HB Nijmegen Netherlands		
Post Code			
Telephone			
Fax			
Mobile			

Work Email	Gerjon.Hannink@radboudumc.nl

Title	Forename/Initials	Surname
Dr	Yaamini	Premakumar

Post	Academic Foundation Year 2 Doctor
Qualifications	MBBS, BSc (Hons)
Employer	Chelsea and Westminster NHS Trust
Work Address	369 Fulham Rd Chelsea London
Post Code	SW10 9NH
Telephone	
Fax	
Mobile	
Work Email	yaamini.premakumar@nhs.net

Title	Forename/Initials	Surname
Miss	Maha	Khan

Post	ST5 Trainee - Otolaryngology, Head & Neck Surgery
Qualifications	MBBS MRCS ENT
Employer	Health Education North West
Work Address	
Post Code	
Telephone	
Fax	
Mobile	
Work Email	maha.khan@doctors.org.uk

Title	Forename/Initials	Surname
Mr	Nishchay	Mehta

Post	Wellcome Trust Research Fellow
Qualifications	PhD, FRCS, MBBS
Employer	UCL Ear Institute
Work Address	evidENT 332 Grays Inn Road, Kings Cross London
Post Code	WC1X 8EE
Telephone	
Fax	
Mobile	
Work Email	nishchay.mehta@doctors.org.uk

Title	Forename/Initials	Surname
Mrs	Tanjinah	Ferdous

Post	NIHR CRN Research Audiologist
Qualifications	BSc
Employer	UCL Ear Institute

Work Address	evidENT 332 Grays Inn Road, Kings Cross London
Post Code	WC1X 8EE
Telephone	
Fax	
Mobile	
Work Email	tanjinah.ferdous@nhs.net

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: Non-Commercial

If Other, please specify:

Contact person

Name of organisation	University College of London Hospital Trust
Given name	Pushpsen
Family name	Joshi
Address	Joint Research Office, UCL, 1st Floor Maple House (Suite B), 149 Tottenham Court Road
Town/city	London, United Kingdom
Post code	W1T 7DN
Country	UNITED KINGDOM
Telephone	0203 447 5696
Fax	
E-mail	pushpsen.joshi1@nhs.net

A65. Has external funding for the research been secured?

Please tick at least one check box.

- ☑ 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	Sensorion
Address	375, rue du Professeur Joseph Blayac Montpellier France
Post Code	34080
Telephone	+33 (0)467207730
Fax	
Mobile	
Email	contact@sensorion-pharma.com

Funding Application Status: (●) Secured ( ) In progress

Amount: 2000.00 GBP

Duration
Years: 3
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
	Mr	Cameron	Berg
Organisation	University College London Joint Research Office		
Address	1st Floor, Maple House		
	149 Tottenham Court Road		
	London		
Post Code	W1T 7BN		
Work Email	Uclh.randd@nhs.net		
Telephone	0203 447 5696		
Fax			
Mobile			

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

A68-2. Select Local Clinical Research Network for NHS Organisation identified in A68-1:

North Thames

For more information, please refer to the question specific guidance.

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

Planned start date: 01/09/2019
Planned end date: 01/05/2022
Total duration:
Years: 2 Months: 7 Days: 1

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 97

Does this trial involve countries outside the EU?

○ Yes ◉ No

A72. Which organisations in the UK will host the research?*Please indicate the type of organisation by ticking the box and give approximate numbers if known:*

☑ NHS organisations in England	97
☐ 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	
☐ Joint health and social care agencies (eg community mental health teams)	
☐ Local authorities	
☐ Phase 1 trial units	
☐ Prison establishments	
☐ Probation areas	
☐ Independent (private or voluntary sector) organisations	
☐ Educational establishments	
☐ Independent research units	
☐ Other (give details)	
Total UK sites in study:	97

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?

Site Leads will be responsible for monitoring activity at their sites including strict adherence to study protocol and they will report to Operational leads. Operational leads will have monthly meetings with the Academic-Operational Liaison at headquarters, and local Site leads to evaluate monthly data collection and to implement strategies to maximise data capture and accuracy. Incidents will be documented using Incident reporting forms. Any incidents not solved locally will be escalated to the Operational team and subsequently to the CI.

The CI will inform the sponsor should they have concerns which have arisen from monitoring activities, and/or if there are problems with oversight/monitoring procedures.

Monitoring and auditing will be conducted in accordance with the Department of Health Research Governance Framework for Health & Social Care (April, 2005), and in accordance with the Sponsor's monitoring and audit policies and procedures.

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)

The management of the research will be covered by UCL insurance for negligent harm

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)

UCL insurance provides cover for negligent harm arising from the design of the research

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)

UCL insurance provides cover for negligent harm arising from the design of the research

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 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 further information please refer to guidance.*

Investigator identifier	Research site		Investigator Name
IN1	◉ NHS/HSC Site ○ Non-NHS/HSC Site		Forename Middle name Family name Email
	Organisation name	ROYAL FREE LONDON NHS FOUNDATION TRUST	Qualification (MD...)
	Address	ROYAL FREE HOSPITAL POND STREET LONDON GREATER LONDON	Country
	Post Code	NW3 2QG	
	Country	ENGLAND	
IN2	◉ NHS/HSC Site ○ Non-NHS/HSC Site		Forename Middle name Family name Email
	Organisation name	LONDON NORTH WEST UNIVERSITY HEALTHCARE NHS TRUST	Qualification (MD...)
	Address	NORTHWICK PARK HOSPITAL WATFORD ROAD HARROW MIDDLESEX	Country
	Post Code	HA1 3UJ	
	Country	ENGLAND	
IN3	◉ NHS/HSC Site ○ Non-NHS/HSC Site		Forename Middle name Family name Email
	Organisation name	IMPERIAL COLLEGE HEALTHCARE NHS TRUST	Qualification (MD...)
	Address	ST. MARYS HOSPITAL PRAED STREET LONDON GREATER LONDON	Country
	Post Code	W2 1NY	

Country	ENGLAND	

IN4

- (●) NHS/HSC Site
- ( ) Non-NHS/HSC Site

		Forename
		Middle name
		Family name
		Email
Organisation name	UNIVERSITY HOSPITALS BRISTOL NHS FOUNDATION TRUST	Qualification (MD...)
Address	MARLBOROUGH STREET	Country
	BRISTOL AVON	
Post Code	BS1 3NU	
Country	ENGLAND	

IN5

- (●) NHS/HSC Site
- ( ) Non-NHS/HSC Site

		Forename
		Middle name
		Family name
		Email
Organisation name	ROYAL SURREY COUNTY HOSPITAL NHS FOUNDATION TRUST	Qualification (MD...)
Address	EGERTON ROAD	Country
	GUILDFORD SURREY	
Post Code	GU2 7XX	
Country	ENGLAND	

IN6

- (●) NHS/HSC Site
- ( ) Non-NHS/HSC Site

		Forename
		Middle name
		Family name
		Email
Organisation name	UNIVERSITY COLLEGE LONDON HOSPITALS NHS FOUNDATION TRUST	Qualification (MD...)
Address	250 EUSTON ROAD	Country
	LONDON GREATER LONDON	
Post Code	NW1 2PG	
Country	ENGLAND	

IN7

◉ NHS/HSC Site
○ Non-NHS/HSC Site

Organisation name	BARKING, HAVERING AND REDBRIDGE UNIVERSITY HOSPITALS NHS TRUST
Address	QUEENS HOSPITAL ROM VALLEY WAY ROMFORD ESSEX
Post Code	RM7 0AG
Country	ENGLAND

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

IN8

◉ NHS/HSC Site
○ Non-NHS/HSC Site

Organisation name	BARTS HEALTH NHS TRUST
Address	THE ROYAL LONDON HOSPITAL WHITECHAPEL LONDON GREATER LONDON
Post Code	E1 1BB
Country	ENGLAND

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

IN9

◉ NHS/HSC Site
○ Non-NHS/HSC Site

Organisation name	SURREY AND SUSSEX HEALTHCARE NHS TRUST
Address	EAST SURREY HOSPITAL CANADA AVENUE REDHILL SURREY
Post Code	RH1 5RH
Country	ENGLAND

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

IN10

- (●) NHS/HSC Site
- ( ) Non-NHS/HSC Site

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

Organisation name	BRIGHTON AND SUSSEX UNIVERSITY HOSPITALS NHS TRUST
Address	ROYAL SUSSEX COUNTY HOSPITAL EASTERN ROAD BRIGHTON EAST SUSSEX
Post Code	BN2 5BE
Country	ENGLAND

IN11

- (●) NHS/HSC Site
- ( ) Non-NHS/HSC Site

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

Organisation name	CAMBRIDGE UNIVERSITY HOSPITALS NHS FOUNDATION TRUST
Address	ADDENBROOKES HOSPITAL HILLS ROAD CAMBRIDGE CAMBRIDGESHIRE
Post Code	CB2 0QQ
Country	ENGLAND

IN13

- (●) NHS/HSC Site
- ( ) Non-NHS/HSC Site

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

Organisation name	OXFORD UNIVERSITY HOSPITALS NHS FOUNDATION TRUST
Address	JOHN RADCLIFFE HOSPITAL HEADLEY WAY HEADINGTON OXFORD OXFORDSHIRE
Post Code	OX3 9DU
Country	ENGLAND

IN14

- (●) NHS/HSC Site
- ( ) Non-NHS/HSC Site

Forename
Middle name

Family name
Email
Organisation name: FRIMLEY HEALTH NHS FOUNDATION TRUST
Qualification (MD...)
Address: PORTSMOUTH ROAD
Country
FRIMLEY CAMBERLEY SURREY
Post Code: GU16 7UJ
Country: ENGLAND

IN16

◉ NHS/HSC Site
○ Non-NHS/HSC Site

Forename
Middle name
Family name
Email
Organisation name: WESTERN SUSSEX HOSPITALS NHS FOUNDATION TRUST
Qualification (MD...)
Address: WORTHING HOSPITAL
Country
LYNDHURST ROAD
WORTHING WEST SUSSEX
Post Code: BN11 2DH
Country: ENGLAND

IN17

◉ NHS/HSC Site
○ Non-NHS/HSC Site

Forename
Middle name
Family name
Email
Organisation name: MANCHESTER UNIVERSITY NHS FOUNDATION TRUST
Qualification (MD...)
Address: COBBETT HOUSE
Country
OXFORD ROAD
MANCHESTER GREATER MANCHESTER
Post Code: M13 9WL
Country: ENGLAND

IN18

◉ NHS/HSC Site
○ Non-NHS/HSC Site

Forename
Middle name
Family name
Email
Organisation name: PENNINE ACUTE HOSPITALS NHS TRUST
Qualification (MD...)

	Address	TRUST HEADQUARTERS NORTH MANCHESTER GENERAL HOSPITAL DELAUNAYS ROAD, CRUMPSALL MANCHESTER GREATER MANCHESTER	Country
	Post Code	M8 5RB	
	Country	ENGLAND	

IN19

(●) NHS/HSC Site
( ) Non-NHS/HSC Site

Forename
Middle name
Family name
Email

Organisation name	BRADFORD TEACHING HOSPITALS NHS FOUNDATION TRUST	Qualification (MD...)
Address	BRADFORD ROYAL INFIRMARY DUCKWORTH LANE BRADFORD WEST YORKSHIRE	Country
Post Code	BD9 6RJ	
Country	ENGLAND	

IN20

(●) NHS/HSC Site
( ) Non-NHS/HSC Site

Forename
Middle name
Family name
Email

Organisation name	GUY'S AND ST THOMAS' NHS FOUNDATION TRUST	Qualification (MD...)
Address	TRUST OFFICES GUY'S HOSPITAL GREAT MAZE POND LONDON GREATER LONDON	Country
Post Code	SE1 9RT	
Country	ENGLAND	

IN21

(●) NHS/HSC Site
( ) Non-NHS/HSC Site

Forename
Middle name
Family name
Email

Organisation name	ST GEORGE'S UNIVERSITY HOSPITALS NHS FOUNDATION TRUST	Qualification (MD...)
Address	ST GEORGE'S HOSPITAL BLACKSHAW ROAD TOOTING LONDON GREATER LONDON	Country

Post Code	SW17 0QT
Country	ENGLAND

IN22

◉ NHS/HSC Site
○ Non-NHS/HSC Site

Forename
Middle name
Family name
Email

Organisation name	LEWISHAM AND GREENWICH NHS TRUST
Address	UNIVERSITY HOSPITAL LEWISHAM LEWISHAM HIGH STREET LONDON GREATER LONDON
Post Code	SE13 6LH
Country	ENGLAND

Qualification (MD...)
Country

IN23

◉ NHS/HSC Site
○ Non-NHS/HSC Site

Forename
Middle name
Family name
Email

Organisation name	LEEDS TEACHING HOSPITALS NHS TRUST
Address	ST. JAMES'S UNIVERSITY HOSPITAL BECKETT STREET LEEDS WEST YORKSHIRE
Post Code	LS9 7TF
Country	ENGLAND

Qualification (MD...)
Country

IN24

◉ NHS/HSC Site
○ Non-NHS/HSC Site

Forename
Middle name
Family name
Email

Organisation name	LUTON AND DUNSTABLE UNIVERSITY HOSPITAL NHS FOUNDATION TRUST
Address	LEWSEY ROAD LUTON BEDFORDSHIRE
Post Code	LU4 0DZ
Country	ENGLAND

Qualification (MD...)
Country

IN25

(•) NHS/HSC Site
( ) Non-NHS/HSC Site

Organisation name	SALFORD ROYAL NHS FOUNDATION TRUST
Address	SALFORD ROYAL STOTT LANE SALFORD GREATER MANCHESTER
Post Code	M6 8HD
Country	ENGLAND

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

IN26

(•) NHS/HSC Site
( ) Non-NHS/HSC Site

Organisation name	EAST KENT HOSPITALS UNIVERSITY NHS FOUNDATION TRUST
Address	KENT & CANTERBURY HOSPITAL ETHELBERT ROAD CANTERBURY KENT
Post Code	CT1 3NG
Country	ENGLAND

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

IN27

(•) NHS/HSC Site
( ) Non-NHS/HSC Site

Organisation name	SANDWELL AND WEST BIRMINGHAM HOSPITALS NHS TRUST
Address	CITY HOSPITAL DUDLEY ROAD BIRMINGHAM WEST MIDLANDS
Post Code	B18 7QH
Country	ENGLAND

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

IN28

◉ NHS/HSC Site
○ Non-NHS/HSC Site

Organisation name	UNIVERSITY HOSPITALS BIRMINGHAM NHS FOUNDATION TRUST
Address	TRUST HQ, PO BOX 9551 QUEEN ELIZABETH MEDICAL CENTRE EDGBASTON BIRMINGHAM WEST MIDLANDS
Post Code	B15 2TH
Country	ENGLAND

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

IN29

◉ NHS/HSC Site
○ Non-NHS/HSC Site

Organisation name	ROYAL LIVERPOOL AND BROADGREEN UNIVERSITY HOSPITALS NHS TRUST
Address	ROYAL LIVERPOOL UNIVERSITY HOSPITAL PRESCOT STREET LIVERPOOL MERSEYSIDE
Post Code	L7 8XP
Country	ENGLAND

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

IN30

◉ NHS/HSC Site
○ Non-NHS/HSC Site

Organisation name	AINTREE UNIVERSITY HOSPITAL NHS FOUNDATION TRUST
Address	UNIVERSITY HOSPITAL AINTREE FAZAKERLEY HOSPITAL LOWER LANE LIVERPOOL MERSEYSIDE
Post Code	L9 7AL
Country	ENGLAND

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

IN31

◉ NHS/HSC Site
○ Non-NHS/HSC Site

Forename
Middle name

Family name
Email
Qualification (MD...)
Country

Organisation name	CHESTERFIELD ROYAL HOSPITAL NHS FOUNDATION TRUST
Address	CALOW
	CHESTERFIELD DERBYSHIRE
Post Code	S44 5BL
Country	ENGLAND

IN32

- (●) NHS/HSC Site
- ( ) Non-NHS/HSC Site

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

Organisation name	NORTH CUMBRIA UNIVERSITY HOSPITALS NHS TRUST
Address	WEST CUMBERLAND HOSPITAL
	HENSINGHAM
	WHITEHAVEN CUMBRIA
Post Code	CA28 8JG
Country	ENGLAND

IN33

- (●) NHS/HSC Site
- ( ) Non-NHS/HSC Site

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

Organisation name	TAMESIDE AND GLOSSOP INTEGRATED CARE NHS FOUNDATION TRUST
Address	TAMESIDE GENERAL HOSPITAL
	FOUNTAIN STREET
	ASHTON-UNDER-LYNE LANCASHIRE
Post Code	OL6 9RW
Country	ENGLAND

IN34

- (●) NHS/HSC Site
- ( ) Non-NHS/HSC Site

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

Organisation name	BASILDON AND THURROCK UNIVERSITY HOSPITALS NHS FOUNDATION TRUST

	Address	BASILDON HOSPITAL	Country
		NETHERMAYNE BASILDON ESSEX	
	Post Code	SS16 5NL	
	Country	ENGLAND	

IN35

◉ NHS/HSC Site
○ Non-NHS/HSC Site

		Forename
		Middle name
		Family name
		Email
Organisation name	EAST SUFFOLK AND NORTH ESSEX NHS FOUNDATION TRUST	Qualification (MD...)
Address	COLCHESTER DISTRICT GENERAL HO	Country
	TURNER ROAD	
	COLCHESTER ESSEX	
Post Code	CO4 5JL	
Country	ENGLAND	

IN36

◉ NHS/HSC Site
○ Non-NHS/HSC Site

		Forename
		Middle name
		Family name
		Email
Organisation name	DORSET COUNTY HOSPITAL NHS FOUNDATION TRUST	Qualification (MD...)
Address	DORSET COUNTY HOSPITAL	Country
	WILLIAMS AVENUE	
	DORCHESTER DORSET	
Post Code	DT1 2JY	
Country	ENGLAND	

IN37

◉ NHS/HSC Site
○ Non-NHS/HSC Site

		Forename
		Middle name
		Family name
		Email
Organisation name	ROYAL CORNWALL HOSPITALS NHS TRUST	Qualification (MD...)
Address	ROYAL CORNWALL HOSPITAL	Country
	TRELISKE TRURO CORNWALL	
Post Code	TR1 3LJ	

Country	ENGLAND

IN38

- (●) NHS/HSC Site
- ( ) Non-NHS/HSC Site

Organisation name	UNIVERSITY HOSPITAL SOUTHAMPTON NHS FOUNDATION TRUST
Address	MAILPOINT 18 SOUTHAMPTON GENERAL HOSPITAL TREMONA ROAD SOUTHAMPTON HAMPSHIRE
Post Code	SO16 6YD
Country	ENGLAND

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

IN39

- (●) NHS/HSC Site
- ( ) Non-NHS/HSC Site

Organisation name	SOUTHEND UNIVERSITY HOSPITAL NHS FOUNDATION TRUST
Address	PRITTLEWELL CHASE WESTCLIFF-ON-SEA ESSEX
Post Code	SS0 0RY
Country	ENGLAND

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

IN40

- (●) NHS/HSC Site
- ( ) Non-NHS/HSC Site

Organisation name	JAMES PAGET UNIVERSITY HOSPITALS NHS FOUNDATION TRUST
Address	LOWESTOFT ROAD GORLESTON GREAT YARMOUTH NORFOLK
Post Code	NR31 6LA
Country	ENGLAND

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

IN41

(●) NHS/HSC Site
( ) Non-NHS/HSC Site

Forename
Middle name
Family name
Email

Organisation name	MID CHESHIRE HOSPITALS NHS FOUNDATION TRUST
Address	LEIGHTON HOSPITAL LEIGHTON CREWE CHESHIRE
Post Code	CW1 4QJ
Country	ENGLAND

Qualification (MD...)
Country

IN42

(●) NHS/HSC Site
( ) Non-NHS/HSC Site

Forename
Middle name
Family name
Email

Organisation name	GREAT WESTERN HOSPITALS NHS FOUNDATION TRUST
Address	GREAT WESTERN HOSPITAL MARLBOROUGH ROAD SWINDON WILTSHIRE
Post Code	SN3 6BB
Country	ENGLAND

Qualification (MD...)
Country

IN43

(●) NHS/HSC Site
( ) Non-NHS/HSC Site

Forename
Middle name
Family name
Email

Organisation name	GLOUCESTERSHIRE HOSPITALS NHS FOUNDATION TRUST
Address	TRUST HQ ALEXANDRA HOUSE CHELTENHAM GLOUCESTERSHIRE
Post Code	GL53 7AN
Country	ENGLAND

Qualification (MD...)
Country

IN44

◉ NHS/HSC Site
○ Non-NHS/HSC Site

Organisation name	NORFOLK AND NORWICH UNIVERSITY HOSPITALS NHS FOUNDATION TRUST
Address	COLNEY LANE COLNEY NORWICH NORFOLK
Post Code	NR4 7UY
Country	ENGLAND

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

IN46

◉ NHS/HSC Site
○ Non-NHS/HSC Site

Organisation name	MILTON KEYNES UNIVERSITY HOSPITAL NHS FOUNDATION TRUST
Address	STANDING WAY EAGLESTONE MILTON KEYNES BUCKINGHAMSHIRE
Post Code	MK6 5LD
Country	ENGLAND

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

IN47

◉ NHS/HSC Site
○ Non-NHS/HSC Site

Organisation name	UNIVERSITY HOSPITALS PLYMOUTH NHS TRUST
Address	DERRIFORD HOSPITAL DERRIFORD ROAD PLYMOUTH DEVON
Post Code	PL6 8DH
Country	ENGLAND

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

IN48

◉ NHS/HSC Site
○ Non-NHS/HSC Site

Forename
Middle name

Family name
Email
Qualification (MD...)
Country

Organisation name	HULL AND EAST YORKSHIRE HOSPITALS NHS TRUST
Address	HULL ROYAL INFIRMARY ANLABY ROAD HULL NORTH HUMBERSIDE
Post Code	HU3 2JZ
Country	ENGLAND

IN49

(●) NHS/HSC Site
( ) Non-NHS/HSC Site

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

Organisation name	YORK TEACHING HOSPITAL NHS FOUNDATION TRUST
Address	YORK HOSPITAL WIGGINTON ROAD YORK NORTH YORKSHIRE
Post Code	YO31 8HE
Country	ENGLAND

IN50

(●) NHS/HSC Site
( ) Non-NHS/HSC Site

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

Organisation name	BLACKPOOL TEACHING HOSPITALS NHS FOUNDATION TRUST
Address	VICTORIA HOSPITAL WHINNEY HEYS ROAD BLACKPOOL LANCASHIRE
Post Code	FY3 8NR
Country	ENGLAND

IN51

(●) NHS/HSC Site
( ) Non-NHS/HSC Site

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

Organisation name	WEST HERTFORDSHIRE HOSPITALS NHS TRUST

	Address	TRUST OFFICES WATFORD GENERAL HOSPITAL VICARAGE ROAD WATFORD HERTFORDSHIRE	Country
	Post Code	WD18 0HB	
	Country	ENGLAND	

IN52

(●) NHS/HSC Site
( ) Non-NHS/HSC Site

Forename
Middle name
Family name
Email

Organisation name	UNIVERSITY HOSPITALS OF LEICESTER NHS TRUST	Qualification (MD...)
Address	LEICESTER ROYAL INFIRMARY INFIRMARY SQUARE LEICESTER LEICESTERSHIRE	Country
Post Code	LE1 5WW	
Country	ENGLAND	

IN53

(●) NHS/HSC Site
( ) Non-NHS/HSC Site

Forename
Middle name
Family name
Email

Organisation name	NORTHAMPTON GENERAL HOSPITAL NHS TRUST	Qualification (MD...)
Address	CLIFTONVILLE NORTHAMPTON NORTHAMPTONSHIRE	Country
Post Code	NN1 5BD	
Country	ENGLAND	

IN54

(●) NHS/HSC Site
( ) Non-NHS/HSC Site

Forename
Middle name
Family name
Email

Organisation name	NORTHAMPTONSHIRE HEALTHCARE NHS FOUNDATION TRUST	Qualification (MD...)
Address	SUDBOROUGH HOUSE ST. MARYS HOSPITAL 77 LONDON ROAD KETTERING NORTHAMPTONSHIRE	Country
Post Code	NN15 7PW	

Country	ENGLAND	

IN55

◉ NHS/HSC Site
○ Non-NHS/HSC Site

		Forename
		Middle name
		Family name
		Email
Organisation name	KETTERING GENERAL HOSPITAL NHS FOUNDATION TRUST	Qualification (MD...)
Address	ROTHWELL ROAD	Country
	KETTERING NORTHAMPTONSHIRE	
Post Code	NN16 8UZ	
Country	ENGLAND	

IN56

◉ NHS/HSC Site
○ Non-NHS/HSC Site

		Forename
		Middle name
		Family name
		Email
Organisation name	WHITTINGTON HEALTH NHS TRUST	Qualification (MD...)
Address	THE WHITTINGTON HOSPITAL	Country
	MAGDALA AVENUE	
	LONDON GREATER LONDON	
Post Code	N19 5NF	
Country	ENGLAND	

IN57

◉ NHS/HSC Site
○ Non-NHS/HSC Site

		Forename
		Middle name
		Family name
		Email
Organisation name	HOMERTON UNIVERSITY HOSPITAL NHS FOUNDATION TRUST	Qualification (MD...)
Address	HOMERTON ROW	Country
	LONDON GREATER LONDON	
Post Code	E9 6SR	
Country	ENGLAND	

IN58

◉ NHS/HSC Site
○ Non-NHS/HSC Site

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

Organisation name	THE HILLINGDON HOSPITALS NHS FOUNDATION TRUST
Address	PIELD HEATH ROAD
	UXBRIDGE MIDDLESEX
Post Code	UB8 3NN
Country	ENGLAND

IN59

◉ NHS/HSC Site
○ Non-NHS/HSC Site

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

Organisation name	CHELSEA AND WESTMINSTER HOSPITAL NHS FOUNDATION TRUST
Address	CHELSEA & WESTMINSTER HOSPITAL
	369 FULHAM ROAD
	LONDON GREATER LONDON
Post Code	SW10 9NH
Country	ENGLAND

IN60

◉ NHS/HSC Site
○ Non-NHS/HSC Site

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

Organisation name	UNIVERSITY HOSPITALS OF NORTH MIDLANDS NHS TRUST
Address	NEWCASTLE ROAD
	STOKE-ON-TRENT STAFFORDSHIRE
Post Code	ST4 6QG
Country	ENGLAND

IN61

- (●) NHS/HSC Site
- ( ) Non-NHS/HSC Site

Organisation name	UNIVERSITY HOSPITALS COVENTRY AND WARWICKSHIRE NHS TRUST
Address	WALSGRAVE GENERAL HOSPITAL CLIFFORD BRIDGE ROAD COVENTRY WEST MIDLANDS
Post Code	CV2 2DX
Country	ENGLAND

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

IN62

- (●) NHS/HSC Site
- ( ) Non-NHS/HSC Site

Organisation name	WIRRAL UNIVERSITY TEACHING HOSPITAL NHS FOUNDATION TRUST
Address	ARROWE PARK HOSPITAL ARROWE PARK ROAD UPTON WIRRAL MERSEYSIDE
Post Code	CH49 5PE
Country	ENGLAND

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

IN63

- (●) NHS/HSC Site
- ( ) Non-NHS/HSC Site

Organisation name	EAST LANCASHIRE HOSPITALS NHS TRUST
Address	ROYAL BLACKBURN HOSPITAL HASLINGDEN ROAD BLACKBURN LANCASHIRE
Post Code	BB2 3HH
Country	ENGLAND

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

IN64

- (●) NHS/HSC Site
- ( ) Non-NHS/HSC Site

Forename
Middle name

Family name
Email
Qualification (MD...)
Country

Organisation name	BOLTON NHS FOUNDATION TRUST
Address	THE ROYAL BOLTON HOSPITAL MINERVA ROAD FARNWORTH BOLTON LANCASHIRE
Post Code	BL4 0JR
Country	ENGLAND

IN65

(●) NHS/HSC Site
( ) Non-NHS/HSC Site

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

Organisation name	LANCASHIRE TEACHING HOSPITALS NHS FOUNDATION TRUST
Address	CHIEF EXECUTIVE'S OFFICE ROYAL PRESTON HOSPITAL SHAROE GREEN LANE, FULWOOD PRESTON LANCASHIRE
Post Code	PR2 9HT
Country	ENGLAND

IN66

(●) NHS/HSC Site
( ) Non-NHS/HSC Site

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

Organisation name	SOUTHPORT AND ORMSKIRK HOSPITAL NHS TRUST
Address	TOWN LANE SOUTHPORT MERSEYSIDE
Post Code	PR8 6PN
Country	ENGLAND

IN67

(●) NHS/HSC Site
( ) Non-NHS/HSC Site

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

Organisation name	WARRINGTON AND HALTON HOSPITALS NHS FOUNDATION TRUST

	Address	WARRINGTON HOSPITAL LOVELY LANE WARRINGTON CHESHIRE	Country
	Post Code	WA5 1QG	
	Country	ENGLAND	

IN68

(●) NHS/HSC Site
( ) Non-NHS/HSC Site

Forename
Middle name
Family name
Email

Organisation name	UNIVERSITY HOSPITALS OF MORECAMBE BAY NHS FOUNDATION TRUST	Qualification (MD...)
Address	WESTMORLAND GENERAL HOSPITAL BURTON ROAD KENDAL CUMBRIA	Country
Post Code	LA9 7RG	
Country	ENGLAND	

IN70

(●) NHS/HSC Site
( ) Non-NHS/HSC Site

Forename
Middle name
Family name
Email

Organisation name	THE NEWCASTLE UPON TYNE HOSPITALS NHS FOUNDATION TRUST	Qualification (MD...)
Address	FREEMAN HOSPITAL FREEMAN ROAD HIGH HEATON NEWCASTLE-UPON-TYNE TYNE AND WEAR	Country
Post Code	NE7 7DN	
Country	ENGLAND	

IN71

(●) NHS/HSC Site
( ) Non-NHS/HSC Site

Forename
Middle name
Family name
Email

Organisation name	SOUTH TYNESIDE NHS FOUNDATION TRUST	Qualification (MD...)
Address	SOUTH TYNESIDE DISTRICT HOSPITAL HARTON LANE SOUTH SHIELDS TYNE AND WEAR	Country
Post Code	NE34 0PL	

Country	ENGLAND

IN72

- (●) NHS/HSC Site
- ( ) Non-NHS/HSC Site

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

Organisation name	SOUTH TEES HOSPITALS NHS FOUNDATION TRUST
Address	JAMES COOK UNIVERSITY HOSPITAL MARTON ROAD MIDDLESBROUGH CLEVELAND
Post Code	TS4 3BW
Country	ENGLAND

IN73

- (●) NHS/HSC Site
- ( ) Non-NHS/HSC Site

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

Organisation name	CITY HOSPITALS SUNDERLAND NHS FOUNDATION TRUST
Address	SUNDERLAND ROYAL HOSPITAL KAYLL ROAD SUNDERLAND TYNE AND WEAR
Post Code	SR4 7TP
Country	ENGLAND

IN74

- (●) NHS/HSC Site
- ( ) Non-NHS/HSC Site

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

Organisation name	COUNTY DURHAM AND DARLINGTON NHS FOUNDATION TRUST
Address	DARLINGTON MEMORIAL HOSPITAL HOLLYHURST ROAD DARLINGTON COUNTY DURHAM
Post Code	DL3 6HX
Country	ENGLAND

IN75

◉ NHS/HSC Site
○ Non-NHS/HSC Site

Organisation name	NORTHERN LINCOLNSHIRE AND GOOLE NHS FOUNDATION TRUST
Address	DIANA PRINCESS OF WALES HOSPITAL SCARTHO ROAD GRIMSBY SOUTH HUMBERSIDE
Post Code	DN33 2BA
Country	ENGLAND

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

IN76

◉ NHS/HSC Site
○ Non-NHS/HSC Site

Organisation name	BUCKINGHAMSHIRE HEALTHCARE NHS TRUST
Address	AMERSHAM HOSPITAL WHIELDEN STREET AMERSHAM BUCKINGHAMSHIRE
Post Code	HP7 0JD
Country	ENGLAND

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

IN77

◉ NHS/HSC Site
○ Non-NHS/HSC Site

Organisation name	TORBAY AND SOUTH DEVON NHS FOUNDATION TRUST
Address	HENGRAVE HOUSE TORBAY HOSPITAL NEWTON ROAD TORQUAY DEVON
Post Code	TQ2 7AA
Country	ENGLAND

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

IN78

- (●) NHS/HSC Site
- ( ) Non-NHS/HSC Site

Organisation name	ROYAL DEVON AND EXETER NHS FOUNDATION TRUST
Address	ROYAL DEVON & EXETER HOSPITAL BARRACK ROAD EXETER DEVON
Post Code	EX2 5DW
Country	ENGLAND

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

IN79

- (●) NHS/HSC Site
- ( ) Non-NHS/HSC Site

Organisation name	ROYAL UNITED HOSPITALS BATH NHS FOUNDATION TRUST
Address	COMBE PARK BATH AVON
Post Code	BA1 3NG
Country	ENGLAND

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

IN80

- (●) NHS/HSC Site
- ( ) Non-NHS/HSC Site

Organisation name	NORTH BRISTOL NHS TRUST
Address	SOUTHMEAD HOSPITAL SOUTHMEAD ROAD WESTBURY-ON-TRYM BRISTOL AVON
Post Code	BS10 5NB
Country	ENGLAND

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

IN81

- (●) NHS/HSC Site
- ( ) Non-NHS/HSC Site

Forename
Middle name

Family name
Email
Qualification (MD...)
Country

Organisation name	TAUNTON AND SOMERSET NHS FOUNDATION TRUST
Address	MUSGROVE PARK HOSPITAL TAUNTON SOMERSET
Post Code	TA1 5DA
Country	ENGLAND

IN82

- (●) NHS/HSC Site
- ( ) Non-NHS/HSC Site

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

Organisation name	YEOVIL DISTRICT HOSPITAL NHS FOUNDATION TRUST
Address	YEOVIL DISTRICT HOSPITAL HIGHER KINGSTON YEOVIL SOMERSET
Post Code	BA21 4AT
Country	ENGLAND

IN83

- (●) NHS/HSC Site
- ( ) Non-NHS/HSC Site

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

Organisation name	WESTON AREA HEALTH NHS TRUST
Address	WESTON GENERAL HOSPITAL GRANGE ROAD UPHILL WESTON-SUPER-MARE AVON
Post Code	BS23 4TQ
Country	ENGLAND

IN84

- (●) NHS/HSC Site
- ( ) Non-NHS/HSC Site

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

Organisation name	CROYDON HEALTH SERVICES NHS TRUST

	Address	CROYDON UNIVERSITY HOSPITAL LONDON ROAD THORNTON HEATH SURREY	Country
	Post Code	CR7 7YE	
	Country	ENGLAND	

IN85

(●) NHS/HSC Site
( ) Non-NHS/HSC Site

Forename
Middle name
Family name
Email

Organisation name	KINGSTON HOSPITAL NHS FOUNDATION TRUST	Qualification (MD...)
Address	GALSWORTHY ROAD KINGSTON UPON THAMES SURREY	Country
Post Code	KT2 7QB	
Country	ENGLAND	

IN86

(●) NHS/HSC Site
( ) Non-NHS/HSC Site

Forename
Middle name
Family name
Email

Organisation name	EPSOM AND ST HELIER UNIVERSITY HOSPITALS NHS TRUST	Qualification (MD...)
Address	ST HELIER HOSPITAL WRYTHE LANE CARSHALTON SURREY	Country
Post Code	SM5 1AA	
Country	ENGLAND	

IN87

(●) NHS/HSC Site
( ) Non-NHS/HSC Site

Forename
Middle name
Family name
Email

Organisation name	KING'S COLLEGE HOSPITAL NHS FOUNDATION TRUST	Qualification (MD...)
Address	DENMARK HILL LONDON GREATER LONDON	Country
Post Code	SE5 9RS	

Country	ENGLAND	

IN88

◉ NHS/HSC Site
○ Non-NHS/HSC Site

		Forename
		Middle name
		Family name
		Email
Organisation name	MEDWAY NHS FOUNDATION TRUST	Qualification (MD...)
Address	MEDWAY MARITIME HOSPITAL WINDMILL ROAD GILLINGHAM KENT	Country
Post Code	ME7 5NY	
Country	ENGLAND	

IN89

◉ NHS/HSC Site
○ Non-NHS/HSC Site

		Forename
		Middle name
		Family name
		Email
Organisation name	MAIDSTONE AND TUNBRIDGE WELLS NHS TRUST	Qualification (MD...)
Address	MAIDSTONE HOSPITAL HERMITAGE LANE MAIDSTONE KENT	Country
Post Code	ME16 9QQ	
Country	ENGLAND	

IN90

◉ NHS/HSC Site
○ Non-NHS/HSC Site

		Forename
		Middle name
		Family name
		Email
Organisation name	SHREWSBURY AND TELFORD HOSPITAL NHS TRUST	Qualification (MD...)
Address	MYTTON OAK ROAD SHREWSBURY SHROPSHIRE	Country
Post Code	SY3 8XQ	
Country	ENGLAND	

IN91

◉ NHS/HSC Site
○ Non-NHS/HSC Site

Organisation name	ASHFORD AND ST PETER'S HOSPITALS NHS FOUNDATION TRUST
Address	ST PETERS HOSPITAL GUILDFORD ROAD CHERTSEY SURREY
Post Code	KT16 0PZ
Country	ENGLAND

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

IN92

◉ NHS/HSC Site
○ Non-NHS/HSC Site

Organisation name	SHEFFIELD TEACHING HOSPITALS NHS FOUNDATION TRUST
Address	NORTHERN GENERAL HOSPITAL HERRIES ROAD SHEFFIELD SOUTH YORKSHIRE
Post Code	S5 7AU
Country	ENGLAND

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

IN93

◉ NHS/HSC Site
○ Non-NHS/HSC Site

Organisation name	DONCASTER AND BASSETLAW TEACHING HOSPITALS NHS FOUNDATION TRUST
Address	DONCASTER ROYAL INFIRMARY ARMTHORPE ROAD DONCASTER SOUTH YORKSHIRE
Post Code	DN2 5LT
Country	ENGLAND

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

IN94

◉ NHS/HSC Site
○ Non-NHS/HSC Site

Organisation name	BARNSLEY HOSPITAL NHS FOUNDATION TRUST
Address	GAWBER ROAD BARNSLEY SOUTH YORKSHIRE
Post Code	S75 2EP
Country	ENGLAND

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

IN95

◉ NHS/HSC Site
○ Non-NHS/HSC Site

Organisation name	NOTTINGHAM UNIVERSITY HOSPITALS NHS TRUST
Address	TRUST HEADQUARTERS QUEENS MEDICAL CENTRE DERBY ROAD NOTTINGHAM NOTTINGHAMSHIRE
Post Code	NG7 2UH
Country	ENGLAND

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

IN96

◉ NHS/HSC Site
○ Non-NHS/HSC Site

Organisation name	UNIVERSITY HOSPITALS OF DERBY AND BURTON NHS FOUNDATION TRUST
Address	ROYAL DERBY HOSPITAL UTTOXETER ROAD DERBY DERBYSHIRE
Post Code	DE22 3NE
Country	ENGLAND

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

IN97

◉ NHS/HSC Site
○ Non-NHS/HSC Site

Forename
Middle name

Family name
Email
Qualification (MD...)
Country

Organisation name	THE ROYAL BOURNEMOUTH AND CHRISTCHURCH HOSPITALS NHS FOUNDATION TRUST
Address	ROYAL BOURNEMOUTH GENERAL HOSPITAL CASTLE LANE EAST BOURNEMOUTH DORSET
Post Code	BH7 7DW
Country	ENGLAND

IN98

(●) NHS/HSC Site
( ) Non-NHS/HSC Site

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

Organisation name	POOLE HOSPITAL NHS FOUNDATION TRUST
Address	LONGFLEET ROAD POOLE DORSET
Post Code	BH15 2JB
Country	ENGLAND

IN99

(●) NHS/HSC Site
( ) Non-NHS/HSC Site

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

Organisation name	SALISBURY NHS FOUNDATION TRUST
Address	SALISBURY DISTRICT HOSPITAL ODSTOCK ROAD SALISBURY WILTSHIRE
Post Code	SP2 8BJ
Country	ENGLAND

IN100

(●) NHS/HSC Site
( ) Non-NHS/HSC Site

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

Organisation name	SOUTH WARWICKSHIRE NHS FOUNDATION TRUST

	Address	WARWICK HOSPITAL LAKIN ROAD WARWICK WARWICKSHIRE	Country
	Post Code	CV34 5BW	
	Country	ENGLAND	

IN101

(●) NHS/HSC Site

( ) Non-NHS/HSC Site

Forename
Middle name
Family name
Email

Organisation name	WORCESTERSHIRE ACUTE HOSPITALS NHS TRUST	Qualification (MD...)
Address	WORCESTERSHIRE ROYAL HOSPITAL CHARLES HASTINGS WAY WORCESTER WORCESTERSHIRE	Country
Post Code	WR5 1DD	
Country	ENGLAND	

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 fulfil the responsibilities of the chief investigator for this study as set out in the UK Policy Framework for Health and Social Care Research.

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

4. 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.

5. 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.

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

7. 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.

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

9. 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 2018.

10. 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.

11. 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 2018.

12. 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 Health Research Authority (HRA) together with the contact point for enquiries named below. Publication will take place no earlier than 3 months after the issue of the ethics committee's final opinion or the withdrawal of the application.

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

HRA would like to include a contact point with the published summary of the study for those wishing to seek further

information. We would be grateful if you would indicate one of the contact points below.

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

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

Optional – please tick as appropriate:

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

This section was signed electronically by Professor Anne Schilder on 01/08/2019 16:20.

Job Title/Post:	Director NIHR UCLH BRC Hearing Theme
Organisation:	University College London
Email:	a.schilder@ucl.ac.uk

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 responsibilities of sponsors set out in the UK Policy Framework for Health and Social Care Research will be fulfilled in relation to this research.

   Please note: *The declarations below do not form part of the application for approval above. They will not be considered by the Research Ethics Committee.*

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.

8. Specifically, for submissions to the Research Ethics Committees (RECs) I declare that any and all clinical trials approved by the HRA since 30th September 2013 (as defined on IRAS categories as clinical trials of medicines, devices, combination of medicines and devices or other clinical trials) have been registered on a publically accessible register in compliance with the HRA registration requirements for the UK, or that any deferral granted by the HRA still applies.

This section was signed electronically by Mr Pushpsen Joshi on 01/08/2019 16:41.

Job Title/Post:	Research Governance Manager
Organisation:	Joint Resaerch Office of UCL & UCLH
Email:	pushpsen.joshi1@nhs.net