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)
Sample IRAS 1

1. Is your project research?

(●) Yes ( ) No

2. Select one category from the list below:

( ) Ionising Radiation for combined review of clinical trial of an investigational medicinal product

( ) Ionising Radiation and Devices form for combined review of combined trial of an investigational medicinal product and an investigational medical device

(●) Clinical investigation or other study of a 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. Is the study sponsored or funded by a device manufacturer or other commercial company?

(●) Yes ( ) No

Please select one of the following:

(●) Clinical investigation for UKCA/CE UKNI/CE marking purposes (includes investigation of a UKCA/CE UKNI/CE marked device outside its current intended purposes or in modified form)

( ) Combined clinical investigation for UKCA/CE UKNI/CE marking purposes and clinical trial of an investigational medicinal product

( ) Post-market clinical study of one or more UKCA/CE UKNI/CE marked devices within intended purposes,

involving a change to standard care or randomisation between groups

◯ Registry of a UKCA/CE UKNI/CE marked device in clinical use, involving no change to standard care or randomisation

◯ Performance evaluation of an in vitro diagnostic device (PEIVDD)

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

a) Does the study involve the use of any ionising radiation? ◯ Yes ◉ No

b) Will you be taking new human tissue samples (or other human biological samples)? ◯ Yes ◉ No

c) Will you be using existing human tissue samples (or other human biological samples)? ◯ Yes ◉ No

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

☑ England
☐ Scotland
☐ Wales
☐ Northern Ireland

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

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

4. Which applications do you require?

☑ IRAS Form
☑ Medicines and Healthcare products Regulatory Agency (MHRA) Devices Division
☐ Confidentiality Advisory Group (CAG)
☐ HM Prison and Probation Service (HMPPS)

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 the research, e.g. NHS support costs) for this study provided by an NIHR Biomedical Research Centre, NIHR Applied Research Collaboration, NIHR Patient Safety Research Collaboration, or an NIHR HealthTech Research Centre 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 Research Delivery Network (RDN) Support and inclusion in the NIHR RDN Portfolio?

Please see information button for further details.

◉ Yes ○ No

The NIHR Research Delivery Network (RDN) enables the health and care system to attract, optimise and deliver research across England e.g. by supporting the successful delivery of high-quality research, as an active partner in the research system.

If you select yes to this question, information from your IRAS submission will automatically be shared with the NIHR RDN.

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

The Chief Investigator should complete this form. The student should complete this form on behalf of the Chief Investigator. 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)

PART A: Core study information

1. ADMINISTRATIVE DETAILS

A1. Full title of the research:

A3-1. Chief Investigator:

Title Forename/Initials Surname

Post
Qualifications
ORCID ID
Employer
Work Address

Post Code
Work E-mail
* Personal E-mail
Work Telephone
* Personal Telephone/Mobile
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

Address

Post Code
E-mail
Telephone
Fax

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

Applicant's/organisation's own reference number, e.g. R & D (if available):
Sponsor's/protocol number:
Protocol Version:
Protocol Date:
Funder's reference number (enter the reference number or state not applicable):
Project website:

Registry reference number(s):
The UK Policy Framework for Health and Social Care Research sets out the principle of making information about research publicly available. Furthermore: Article 19 of the World Medical Association Declaration of Helsinki adopted in 2008 states that "every clinical trial must be registered on a publicly accessible database before recruitment of the first subject"; and the International Committee of Medical Journal Editors (ICMJE) will consider a clinical trial for publication only if it has been registered in an appropriate registry. Please see guidance for more information.

Additional reference number(s):

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.*

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

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

3. PURPOSE AND DESIGN OF THE RESEARCH

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

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

A9-2. Is there a sub-study?

◯ Yes ◯ No ◯ Not Answered

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

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

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

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.*

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?

- ☐ Design of the research
- ☐ Management of the research
- ☐ Undertaking the research
- ☐ Analysis of results
- ☐ Dissemination of findings
- ☐ None of the above

Give details of involvement, or if none please justify the absence of involvement.

A14-2. Have you tested the acceptability of using patient identifiable data in this study without consent?

Please give details.

4. RISKS AND ETHICAL ISSUES

RESEARCH PARTICIPANTS

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

Select all that apply:

- ☐ Blood
- ☐ Cancer
- ☐ Cardiovascular
- ☐ Congenital Disorders
- ☐ Dementias and Neurodegenerative Diseases
- ☐ Diabetes
- ☐ Ear
- ☐ Eye
- ☐ Generic Health Relevance
- ☐ Infection
- ☐ Inflammatory and Immune System
- ☐ Injuries and Accidents
- ☐ 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:	Years
Upper age limit:	Years

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

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

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.

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

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

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

A20. Will you withhold an intervention or procedure, which would normally be considered a part of routine care?

◯ Yes ◯ No

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

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.

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?

A25. What arrangements are being made for continued provision of the intervention for participants, if appropriate, once the research has finished? *May apply to any clinical intervention, including a drug, medical device, mental health intervention, complementary therapy, physiotherapy, dietary manipulation, lifestyle change, etc.*

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

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 social care or GP records, or review of medical records. Indicate whether this will be done by the direct care team or by researchers acting under arrangements with the responsible care organisation(s).*

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

◯ Yes ◯ No

Please give details below:

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

◯ Yes ◯ No

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

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

◯ Yes ◯ No

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

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

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

A30-3. Why is it not practicable for either the researcher's organisation, or the current holder of the information required by the researcher, to seek or obtain patient consent for proposed use of patient identifiable information?

A32. Will you recruit any participants who are involved in current research or have recently been involved in any research prior to recruitment?

◯ Yes
◯ No
◯ Not Known

If Yes, please give details and justify their inclusion. If Not Known, what steps will you take to find out?

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)*

A34. What arrangements will you make to ensure participants receive any information that becomes available during the course of the research that may be relevant to their continued participation?

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

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

Further details:

CONFIDENTIALITY

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

Storage and use of personal data during the study

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

- ☐ Access to medical records by those outside the direct healthcare team
- ☐ 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:

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

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.*

A39. Please specify whether identifiers will be held in the same database as the clinical data, or in a separate database and linked through a unique study or case number. *If held separately, please specify how and at what point the separation will occur. If held in the same database, will the identifiers be encrypted? If so, specify what will be encrypted and who will continue to have access.*

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.*

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?

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

Title Forename/Initials Surname

Post
Qualifications
Work Address

Post Code
Work Email
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:
Months:

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

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

A50-1. Will the research be registered on a public database?

The UK Policy Framework for Health and Social Care Research sets out the principle of making information about research publicly available. Furthermore: Article 19 of the World Medical Association Declaration of Helsinki adopted in 2008 states that "every clinical trial must be registered on a publicly accessible database before recruitment of the first subject"; and the International Committee of Medical Journal Editors (ICMJE) will consider a clinical trial for publication only if it has been registered in an appropriate registry. Please see guidance for more information.

◯ Yes ◯ No

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

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)

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

A53. How and when will you inform participants of the study results?

If there will be no arrangements in place to inform participants please justify this.

5. Scientific and Statistical Review

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

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

Title Forename/Initials Surname

Department
Institution
Work Address

Post Code
Telephone
Fax
Mobile
E-mail

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

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

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

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

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

Further details:

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

A61-1. 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.

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.*

A64. Details of research sponsor(s)

A64-1. Sponsor

A64-2. Please explain how the responsibilities of sponsorship will be assigned between the co-sponsors listed in A64-1

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:

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

Organisation
Address

Post Code
Work Email
Telephone
Fax
Mobile

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

A68-2. Select the Regional Research Delivery Network for the NHS Organisation identified in A68-1:

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:
Planned end date:
Total duration:
Years: Months: Days:

A69-2. How long do you expect the study to last in all countries?

Planned start date:
Planned end date:
Planned end date (clinical interventions):
Planned end date (all trial procedures):
Total duration:
Years: Months: Days:

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

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
- ☐ 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:

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?

A75-1. What arrangements will be made to review interim safety and efficacy data from the trial? Will a formal data monitoring committee or equivalent body be convened?

If a formal DMC is to be convened, please forward details of the membership and standard operating procedures to the Research Ethics Committee when available. The REC should also be notified of DMC recommendations and receive summary reports of interim analyses.

A75-2. What are the criteria for electively stopping the trial or other research prematurely?

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)

Please enclose a copy of relevant documents.

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

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

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

Please enclose a copy of relevant documents.

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

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

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

Please enclose a copy of relevant documents.

A77. Has the sponsor(s) made arrangements for payment of compensation in the event of harm to the research participants where no legal liability arises?

○ Yes ○ No

Please enclose a copy of relevant documents.

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

○ Yes ○ No ○ Not sure

Part B: Section 2

A. General information

Information in this sub-section will be included in applications to the Research Ethics Committee and NHS R & D offices at the research sites.

1. Is the manufacturer (or other organisation responsible for developing the device) the same organisation named as lead sponsor for this study?

○ Yes ○ No

Organisation
Address

Post Code
Country
Telephone
Fax
Mobile
E-mail

2. Details of the medical devices to be used in the study

3-1. Further details of the purpose of the study

Does the study involve:

- ◯ Investigation of a new medical device
- ◯ Investigation of new implantable material
- ◯ Use of an existing product outside the terms of its UKCA/CE UKNI/CE marked intended purpose
- ◯ Use of a modified product
- ◯ Use of an existing product within its UKCA/CE UKNI/CE marked intended purpose

3-2. Please give further details below including the following:

Description of any new device, materials, method of use or operation with a summary of the intended purpose.

Composition of any new implantable materials, including summary of biocompatibility findings from studies to date.

A summary of any modifications to UKCA/CE UKNI/CE marked devices.

A summary of any proposed changes to the UKCA/CE UKNI/CE marked intended purpose.

For all products with UKCA/CE UKNI/CE mark please attach instructions for use.

A. Additional information for notifications to the Competent Authority

1. Study Acronym

2. Protocol

Protocol Code Number:

Protocol Version:

Protocol Date:

3. Is this the first submission to the MHRA or a re-submission?

- ◯ First submission
- ◯ Re-submission

6. Is this Study:

◯ UK Only ◯ Multi-Country

8. Please select all categories below that apply:

- ☐ UKCA/CE UKNI/CE-marking of the device (pivotal study)
- ☐ First-in-Man study
- ☐ Feasibility/pilot study
- ☐ Post-market study

9. Has the study been the subject of a scientific review/opinion (Expert Panel)?

◯ Yes ◯ No

If yes, please provide a copy of the review as part of your application.

10. Does the study involve the use of devices used in combination with other devices or equipment?

◯ Yes ◯ No

11. Are there any ongoing or completed studies related to any investigational device(s) appearing in this application?

◯ Yes ◯ No

12. Please describe the population of your clinical investigation:

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

13. What is the medical condition of the sample group or cohort to be studied in this research?

14. Please specify if you plan to recruit:

- ☐ Children
- ☐ Pregnant women

☐ Adults unable to give their consent (please specify)

15. Description of the Study

Please tick all that apply

☐ Randomised
☐ Comparative
☐ Open
☐ Blinded
☐ Double-blinded
☐ Cross-over
☐ Parallel Arms
☐ Other (please specify)

16. Will the proposed study use a device comparator?

◯ Yes ◯ No

19. Will the proposed study use one or several Non-Investigational Medicinal Products (for example, an anticoagulation treatment)?

◯ Yes ◯ No

20. Will the proposed study use a new medicinal substance (not approved for use in the UK)?

◯ Yes ◯ No

21. Will the proposed study use an approved medicinal substance within the scope of the Marketing Authorisation indications?

◯ Yes ◯ No

22. What are the clinical procedures exclusively planned for this clinical investigation, and which differ from the usual care?

23. Will you be taking new human tissue samples (or other human biological samples)?

Note: The yes/no responses for this question are read only and are populated from the project filter page. If response is 'Yes', additional details should be entered in the text field provided here.

24. Will you be using existing human tissue samples (or other human biological samples)?

Note: The yes/no responses for this question are read only and are populated from the project filter page. If response is 'Yes', additional details should be entered in the text field provided here.

25. Number of Subjects

Number of subjects in the UK: Number of subjects globally:

26. Who is the Coordinating Investigator with overall responsibility for the study globally?
This must be an appropriately qualified practitioner to comply with ENISO14155. The Coordinating Investigator is responsible for co-ordinating the work in a multi-site trial (if applicable).

Title Forename/Initials Surname

Post
Qualifications
Work E-mail
Work Telephone
Investigational Site Name
Investigational site Address

27. National coordinating investigator (for a multicentre trial) **or principal investigator** (for a single centre trial)

◯ National coordinating investigator
◯ Principal investigator

Given name
Family name
Qualification (MD...)
ORCID ID
Institution name
Institution department name
Street address
Town/city
Post Code
Country
Work E-mail
* Personal E-mail
Work Telephone
* Personal Telephone/Mobile
Fax

28. Application to Research Ethics Committee

MHRA does not accept approvals from independent ethics committees. Manufacturers should seek the opinion of a

National Research Ethics Service (NRES) (or equivalent services in Scotland, Wales and Northern Ireland) appointed ethics committee in all cases.

Applications to the Research Ethics Committee (REC) and MHRA may be made in parallel. Please enter details below of the relevant REC for this investigation if known at the time of submission to MHRA. A copy of the ethical opinion should be provided when available.

Name of REC:

Address:

Email:

REC reference for this investigation:

Copy of REC opinion:

- ◯ Enclosed
- ◯ To follow

29. Does the Clinical Investigation Plan specify that all deviations will be reported to MHRA?

◯ Yes ◯ No

30. Please confirm that the Serious Adverse Event reporting planned in the Clinical Investigation Plan, is in accordance with the MEDDEV guidance:

◯ Yes ◯ No

31. Contact Person - Name and address of a Contact Point who may be contacted directly for information about this application. As per MHRA Policy, if the applicant is different from the legal manufacturer, the contact person of the legal manufacturer should be copied into all correspondence with MHRA.

The person listed as the contact must be an employee of the manufacturer, or the manufacturer's appointed representative (UK Responsible Person, Authorised Representative (only for studies in Northern Ireland) or CRO Representative). It is the manufacturer's responsibility to approve all responses prior to submission to MHRA.

Title Forename/Initials Surname

Organisation

Post

Work Address

PostCode

Country

Telephone

Fax

Mobile

E-mail

32. Status of the applicant / contact person:

- ◯ Authorised representative of the manufacturer (only for studies in Northern Ireland)
- ◯ EU Legal Representative of the manufacturer (only for studies in Northern Ireland)
- ◯ Sponsor (only for studies in Northern Ireland)
- ◯ UK Responsible Person for the manufacturer
- ◯ Manufacturer
- ◯ CRO
- ◯ Other

33. Full name and postal address of the manufacturer:

Title Forename/Initials Surname

Organisation
Post
Address

Post Code
Country
Telephone
Fax
Mobile
E-mail

34. Payment of Fees (contact email required)

To refer to the guidance on MHRA fees please consult:
https://www.gov.uk/government/publications/mhra-fees/current-mhra-fees

Please specify who should be invoiced:
Full Company Name:
Address:
Registered Tax/VAT Number:
Invoicing Contact Email:
Invoicing Contact Telephone:

C: Investigational Medical Devices

Investigational Medical Device(s) undergoing clinical trial

36. Investigational Medical Devices

PART B: Investigational Medical Devices

B1. Name of Device or Device Component:

B2. Name of Manufacturer:

B3. Model Number of Device:

B4. Description of the Device:

B5. Intended Use in this Study:

PART B: Status of IMD

B6. Is the Device?

- ◯ UKCA/CE UKNI/CE-marked and used within the UKCA/CE UKNI/CE-marked indications (PMCF study)
- ◯ UKCA/CE UKNI/CE-marked but used outside of the UKCA/CE UKNI/CE-marked indications
- ◯ A modification of a UKCA/CE UKNI/CE-marked device
- ◯ New Device

PART B: Previous Use

B7. Has the device been previously used in exceptional use circumstances?

◯ Yes ◯ No

PART B: Classification & UKCA/CE UKNI/CE-marking

B8. Please provide the GMDN code for this device, if known:

B9. Please provide the reference of your Notified Body / UK Approved Body if available:

Notified Body / UK Approved Body number:

Details of certification:

B11. What is the proposed classification:

- ◯ AIMD
- ◯ III
- ◯ IIb
- ◯ IIa

◯ I

Please provide a rationale for the classification:

Is the classification in accordance with:

◯ UKMDR2002 (Part II, Annex IX, and Part III, Annex IX, of the UK Medical Devices Regulations 2002 [as modified by Part II of Schedule 2A to the UK Medical Devices Regulations 2002])

◯ EU MDR (Annex VIII of the Medical Devices Regulation 2017/745)

B12. Please confirm at what stage you intend to UKCA/CE UKNI/CE-mark the investigational device:

B13. Does the device have a measuring function?

◯ Yes ◯ No

PART B: Biological Safety

B14. Is the investigational device implanted or invasive, or will it come into contact with injured skin or substances for eventual infusion/reinfusion?

◯ Yes ◯ No

B17. Is the IMD in contact with intact skin?

◯ Yes ◯ No

PART B: Sterilisation

B18. Does the device require sterilisation?

◯ Yes ◯ No

PART B: Animal Tissues

B27. Does the device contain animal tissues or any material of animal origin?

◯ Yes ◯ No

PART B: Electrical Safety

B28. Is the device an active medical device?

◯ Yes ◯ No

PART B: Radiation Safety

B29. Does the study involve the use of any radiation (e.g. x-ray, LASER, ultrasound, light, UV, IR, sound)?

◯ Yes ◯ No

PART B: Software and Programmable Devices

B31. Does the IMD contain a software component?

◯ Yes ◯ No

PART B: Machinery

B45. Is this device also machinery within the meaning of point (a) of the second paragraph of Article 2 of Directive 2006/42/EC (as implemented by the Supply of Machinery (Safety) Regulations 2008)?

◯ Yes ◯ No

PART B: Ancillary medicinal substance/ human blood

B46. Does the Investigational Medical Device contain a human blood derivative or a medicinal substance which, on its own, could be classified as a medicinal product?

◯ Yes ◯ No

PART B: Non-viable human tissues and cells

B47. Does the device contain human tissues and cells or any material of human origin? (only applicable in Northern Ireland)

◯ Yes ◯ No

Part B: Number of Devices

B48. Number of Devices

Number of Devices in the UK:
Number of devices globally:

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.*

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.*

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