Welcome to the Integrated Research Application System

IRAS Project Filter

The answers that you give to these project filter questions will determine which sections of the IRAS form that you will be asked to complete, so ensure that the filter questions are answered correctly.

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)

Enter the short title for your project here.

DMD Hub Toolkit TEST

1. Is your project research?

(●) Yes ( ) No

2. Select one category from the list below:

Ensure that the correct option is selected here. The information (green 'i') buttons in IRAS give helpful guidance notes on the different category types.

( ) 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. Is this a commercially sponsored Phase 1 or Phase 1/2a trial involving healthy volunteers?

( ) Yes (●) No

2b. Will the study involve the use of any medical device without a CE Mark, or a CE marked device which has been modified or will be used outside its intended purposes?

( ) Yes (●) No

2c. Please answer the following question:

This will only apply in some cases - use the guidance notes in IRAS to help you to decide whether this is applicable for your study.

Is this trial subject to advice from the Expert Advisory Group on Clinical Trials and the Commission on Human Medicine prior to authorisation from MHRA? ○ Yes ◉ No

2d. Please answer the following question:

Select if your trial involves gene therapy. Additional reviews will apply centrally and locally.

Is this a trial of a gene therapy medicinal product? ◉ Yes ○ No

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

Use the guidance in IRAS to decide whether this applies for your trial. Additional sections of the IRAS form will need to be completed if the answer is 'Yes'.

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

• Does the study involve exposure to radioactive materials? ◉ 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

Your local R&D office should be contacted at an early stage so that they are aware of and can support the approvals process.

4. Which applications do you require?

- ☑ IRAS Form
- ☑ Medicines and Healthcare products Regulatory Agency (MHRA) – Medicines
- ☐ Confidentiality Advisory Group (CAG)
- ☐ Her Majesty's Prison and Probation Service (HMPPS)
- ☑ Administration of Radioactive Substances Advisory Committee (ARSAC)

Select all that apply. The green 'i' guidance notes can help you to decide whether each application is necessary and this will open up different sections of the IRAS form.

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

◉ Yes ○ No

A research site is the single organisation that is responsible for conducting the research at a particular site. R&D approval must be obtained for all NHS research sites.

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.

If the answer to this is 'Yes', you will not be considered for NIHR CRN support (see below).

To apply for NIHR CRN support and inclusion in the NIHR CRN Portfolio, you will be required to electronically submit a Portfolio Application Form (PAF). Further information about the benefits of NIHR CRN support and Portfolio adoption are detailed on the IRAS form and the NIHR website.
CRN support can include: helping to set up studies quickly and effectively, supporting funding for staff and facilities to deliver research, helping to identify suitable research sites and recruit participants. More information can be found at: http://www.nihr.ac.uk/funding-and-support/study-support-service/

○ 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?

You must tick 'Yes' for question 5b if you wish to apply for support from the NIHR CRN.

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

Further information is available at http://www.ohrn.nhs.uk

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

◉ Yes ○ No

Please describe briefly the involvement of the student(s):
INCLUDE INFORMATION HERE

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

○ Yes ◉ No

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

○ Yes ◉ No

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

◯ Yes ◉ No

If the answer is 'Yes', then you may need to apply to the Health Research Authority (HRA) for approval to process data without consent and an application should be made to the Confidentiality Advisory Group (CAG)

Once you have completed the Project Filter questions, go to the 'Navigate' tab to view your forms and navigate between questions and sections. From 'Navigate' you can also download and print a Reference Only blank copy of the integrated dataset for your application.

Integrated Research Application System
Application Form for Clinical trial of an investigational medicinal product

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)
DMD Hub Toolkit TEST

PART A: Core study information

1. ADMINISTRATIVE DETAILS

A1. Full title of the research:

Enter the full title of your project here - this must match the title on other documents that have been submitted for regulatory approval.

A2-1. Educational projects

This section only applies if the study, or any part of it, is being undertaken as an educational project.

Name and contact details of student(s):

Name and contact details of academic supervisor(s):

Academic supervisor 1

Title Forename/Initials Surname

Address

Post Code
E-mail
Telephone
Fax

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

Student(s)	Academic supervisor(s)

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

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

◯ Student

◉ Academic supervisor
○ Other

A3-2. 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

** 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.

International Standard Randomised Controlled Trial Number (ISRCTN):

ClinicalTrials.gov Identifier (NCT number):

European Clinical Trials Database (EudraCT) number:

Additional reference number(s):

Ref.Number Description	Reference Number

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

◯ Yes ◉ No

Please give brief details and reference numbers.
If the application is linked to another current or previous application, add details here.

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.*

Give a brief and clear summary of the study here.

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.

Give a summary of any issues that could be foreseen here.

Use the information button (green 'i') for guidance. Think about:

- Study Drug - e.g. if unlicensed and the therapeutic benefit is unknown
- Recruitment - any issues that may be foreseen and how these will be addressed
- Informed consent - any issues that may be foreseen and how these will be addressed e.g. age appropriate consent forms, assent forms, parental consent
- Confidentiality issues e.g. how the confidentiality and security of personal data will be protected. *Consider GDPR guidelines when addressing the handling of patient data/personal details.

- Management issues - include any guidelines that will be adhered to such as Good Clinical Practice and approval by relevant bodies (Health Research Authority, Research Ethics Committee etc.)

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)

A8. Type of medicinal trial:

- ☑ Clinical trial of an unlicensed investigational medicinal product
- ☐ Clinical trial of a licensed medicinal product in new conditions of use (different from those in the SmPC, i.e. new target population, new dosage schemes, new administration route, etc.)
- ☐ Clinical trial of a licensed medicinal product used according to the SmPC
- ☐ Other (please specify)

A9-1. Phase of medicinal trial: *(Tick one category only)*

Human pharmacology (Phase I)	○ Yes	◉ No
Therapeutic exploratory trial (Phase II)	○ Yes	◉ No
Therapeutic confirmatory trial (Phase III)	◉ Yes	○ No
Therapeutic use trial (Phase IV)	○ Yes	◉ No

A9-2. Is there a sub-study?

◉ Yes ○ No ○ Not Answered

Give the full title, date and version of each sub-study and their related objectives:

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

Use the information in your study protocol to complete this section but ensure that it is in easily comprehensible language.

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

Use the information in your study protocol to complete this section but ensure that it is in easily comprehensible language.

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

Use the information in your study protocol to complete this section but ensure that it is in easily comprehensible language.

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.*

See guidance notes in IRAS for further information about what should be included here.

This section should clearly break down what will happen during key parts of the study e.g.
- Study design (e.g. Phase 3 open-label extension study)
- Number of participants, age, key characteristics e.g. gender
- Overview of study schedule e.g. pre-screening phase lasting xx weeks, screening phase lasting xx weeks, xx week treatment phase, xx week follow up phase
- Treatment schedule (if appropriate)
- Description of study phases and which assessments will be conducted in each e.g. pre-screening phase (list of assessments conducted), baseline phase (list of assessments conducted), Day -1 visit (list of assessments conducted), list of other study visits and assessments conducted, follow up phase (list of assessments conducted).
- If future research e.g. follow up study is planned, mention this here also.

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
- [x] Management of the research
- [x] 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.

If you are involving patients, service users, carers or members of the public in the study design, ensure that this is fully described here. It is important to consider the involvement of these important groups when designing a study. E.g. consider the involvement of patients in reviewing patient information sheets and documentation.

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
- [x] Musculoskeletal
- [x] Neurological
- [ ] Oral and Gastrointestinal
- [x] 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).

This information should come from the study protocol.

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

This information should come from the study protocol.

When listing details of all study interventions, it is useful to have a good estimate of how long each intervention will take and this can be done by consulting the study team. Having a good estimate at this stage is helpful for planning study visits and will come in useful when costing the study too. Tasks should be delegated to appropriate study personnel: limit this delegation to particular study roles such as PI, Sub-I, Research Nurse etc. or 'an appropriately qualified member of the study team' rather than naming particular members of staff, as this may cause issues if the staff members leave or change roles.

RESEARCH PROCEDURES, RISKS AND BENEFITS

A18. Give details of all non-clinical intervention(s) or pro
research protocol. *These include seeking consent, intervi*

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
Informed consent	1		60 minutes	Principal Investigator or appropriately qualified member of study team
Medical history	1		60 minutes	Principal Investigator or appropriately qualified member of study team
Questionnaire	10		30 minutes	Research Nurse or appropriately qualified member of study team

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

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

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

Intervention or procedure	1	2	3	4
Study drug infusion	20		30 minutes	Principal Investigator, Research Nurse or appropriately qualified member of study team
MRI scan	4		60 minutes	Appropriately qualified MRI technician
Blood sample	20		20 minutes	Research Nurse or appropriately qualified member of study team

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

(●) Yes ( ) No

If Yes, please give details, explain the risks and justify the need to withhold the intervention or procedure:

If the answer is yes, this needs to be fully explained and justified.

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

Give a realistic estimate based on the schedule of assessments in the protocol, including follow up period.

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.

Use the guidance notes in IRAS for further information.
It may be useful to consider:
-Potential side effects of an intervention (if known)
-Possible risks/burdens of study interventions e.g. taking blood samples or having an MRI scan and the possible discomforts associated with this.
Include plans to minimise risks and burdens, where appropriate.

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

◉ Yes ○ No

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

If yes, give full details and justification.

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

Describe this clearly. There may be no direct benefit to the research participants, but outcomes of the study may benefit patients in the future.

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.*

It is important that this is clearly described e.g plans for an extension study or to continue providing the intervention until a specified timepoint.

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

List if appropriate e.g. researchers conducting home visits (and how the risks are being addressed).

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).*

Indicate how potential participants/records/samples will be identified and by whom.

E.g. appropriate study team member/s searching the clinical database at a study site, registering the study with appropriate Patient Registries/Networks (e.g. North Star Network), referring clinicians, patients may contact the study site directly if they have seen the study on a public website e.g. clinicaltrials.gov, DMD Hub website.

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:

E.g. if patient notes/medical records will be reviewed to identify potential participants.
Also consider whether the Sponsor/Sponsor's monitoring team may also review the medical records for source data verification purposes and/or to confirm eligibility of patients to be enrolled into the trial.

A27-3. Describe what measures will be taken to ensure there is no breach of any duty of confidentiality owed to patients, service users or any other person in the process of identifying potential participants.*Indicate what steps have been or will be taken to inform patients and service users of the potential use of their records for this purpose. Describe the arrangements to ensure that the wishes of patients and service users regarding access to their records are respected. Please consult the guidance notes on this topic.*

See guidance notes for further information.

A27-4. Will researchers or individuals other than the direct care team have access to identifiable personal information of any potential participants?

(●) Yes ( ) No

A27-5. Has prior consent been obtained or will it be obtained for access to identifiable personal information?

(●) Yes ( ) No

If Yes, please give details below.

See guidance notes - consent must be explicit.
If you plan to access identifiable data without prior consent you should ensure that you have selected the option to apply to the Confidentiality Advisory Group.

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

(●) Yes ( ) No

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

If applicable, include full details here. All recruitment material must be reviewed by the REC. Consider recruitment through Patient Registry or networks e.g. North Star Network.

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

Include full details here.
E.g.
Potential participants will be contacted by the study Principal Investigator, Sub-Investigator or Research Nurse who will explain the reasons why the trial is being performed, why they may be eligible and the various risks, benefits and outcomes. This initial contact may be by letter/telephone/email/face to face.

Potential participants will be provided with a participant information sheet and given time to consider their participation in the trial (at least 24 hours).
Participants will be free to contact the research staff for further information and to ask any questions. They will also be given the opportunity to discuss their participation with their family and friends before making a decision about whether or not to participate in the trial.

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.

See guidance notes for further information and suggested wording.

E.g.
Once the participant has confirmed that they have received and considered the information provided and would like to participate, a screening appointment will be arranged. During the screening appointment, the Principal Investigator or Sub Investigator will discuss the study again before reading through the consent/assent form and asking the participant to sign to indicate their consent/assent to participate. If relevant, a parent/caregiver consent form will also be signed by the parent/caregiver. No study procedures will be performed prior to collection of consent/assent.

Wording and content of information sheets and consent/assent forms will be appropriate to the age/reading age of

the intended recipients. Verbal explanations will also be tailored to the needs of the participant/caregiver to ensure that consent is fully informed.

A copy of the information sheet and signed consent form will be given to the participant/caregiver and a copy retained in the medical notes. The original consent/assent forms will be stored in the Investigator Site File for the study. The informed consent process will be documented in the participant's medical notes prior to any testing under the study protocol.

Participants and caregivers will be informed that their participation in the research study is entirely voluntary, and that they are free to withdraw at any time.

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

See guidance notes for further information.

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?

This should be a suitable period of time to allow the participant to fully consider participation (at least 24 hours, or longer if necessary).

This should also be recorded appropriately during the consent process - i.e. document that the patient was given xx time to consider participation.

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?

See guidance notes for further information. This information may be contained in the study protocol (inclusion/exclusion criteria).

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)*

This should be fully explained - see guidance notes for further information.

NHS sites usually have well established facilities (e.g. translators) for patients who are unable to understand English. If there is a need to do so, these facilities will be used and the participant information sheet/informed consent form can be translated.

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

This should be fully explained if relevant - see guidance notes for further information.

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?

E.g. the study team will pass on any relevant information in a timely way to study participants that may be relevant to

their continued participation. Detail how this will be achieved e.g. communication at regular study visits, telephone calls etc.

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)*

- [x] 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
- [x] 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
- [x] Storage of personal data on any of the following:
  - [x] Manual files (includes paper or film)
  - [x] NHS computers
  - [ ] Social Care Service computers
  - [ ] Home or other personal computers
  - [ ] University computers
  - [ ] Private company computers
  - [ ] Laptop computers

Further details:

* Check with the study Sponsor if any of the above are relevant e.g. if any of the data will be transferred outside of the EEA.

If relevant, it may be necessary to state that: anonymised health information may be processed and transferred to countries that do not have data protection or privacy laws that offer participants the same level of protection as the data protection and privacy laws within the UK. However, the Sponsor will make every effort to keep personal information confidential, and names will not be disclosed unless required by law. Medical information will be processed and reported for the purposes of this study only.

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

Consider GDPR Guidelines for the storage of personal data when answering this question.

E.g. only the minimum amount of personal data that are necessary for the purposes of the research will be stored, the data will be stored in locked filing cabinets in secure offices with restricted access, anonymisation of patient data.

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.*

Include safeguards that you will be putting in place to ensure participant confidentiality.

E.g. participant confidentiality will be ensured by anonymising the data that will be processed as far as possible, to ensure that data points are not personally identifiable. Include method of data anonymisation that will be used e.g. allocation of a study number to participants - how this will be done and who will have access to the link between the number and participant data that it relates to.

Other than where necessary to meet regulatory requirements, all data collected will be presented in aggregate form and information that could be used to identify an individual participant will not be included in any public disclosures of the study data or the study results.

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.*

See guidance notes for further information. Detail all individuals who will have access to participants' personal data e.g. study Sponsor, regulatory authorities (such as the FDA, EMA - may request access for audit purposes), Contract Research Organisations/Monitors working on behalf of the Sponsor.

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?

Include full details here e.g. will data be analysed by the Sponsor or be outsourced to another company? Include details of the company and their location here, including how data confidentiality will be ensured during data transfer.

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

If longer than 12 months, please justify:

NOTE: Consider GDPR regulations - personal data should only be stored/accessed for as long as it is necessary for the purposes of the study.

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.*

Include full details here, including any local policies that will be adhered to.

INCENTIVES AND PAYMENTS

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

(●) Yes ( ) No

If Yes, please give details. For monetary payments, indicate how much and on what basis this has been determined.
E.g. reimbursement of all reasonable travel, accommodation and refreshments expenses upon production of receipts.

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

If yes, please give details including the amount of any monetary payment or the basis on which this will be calculated:
Full details must be declared here.

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?

Ensure that there is a template letter to the GP included with the application.

(●) Yes ( ) No

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

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

Ensure that this is included in the consent form(s).

(●) Yes ( ) No

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

PUBLICATION AND DISSEMINATION

A50-1. 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.

E.g. registration of the trial on https://clinicaltrials.gov/

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?

Include full details here - care must be taken to ensure anonymity of patients.

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.

Include details here about how participants will be informed of the results. This can be included in the Participant Information Sheet e.g. if a website will be updated with published results that the participants can access once these results are available.

If declared here, these arrangements must be adhered to.

5. Scientific and Statistical Review

A54-1. 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:

See guidance notes for further information.

E.g. Health Research Authority (including Research Ethics Committee) approvals will be sought and recruitment will only begin once approvals are obtained from the relevant authorities for each site.

Research protocol review by experts in the relevant fields able to offer independent advice on its quality (include any details).

An independent data safety monitoring board will assess the quality of the data collected and a Clinical Trial Advisory board of experts and patient representatives will provide guidance.

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:*

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

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

Title Forename/Initials Surname

Department
Institution
Work Address

Post Code
Telephone
Fax
Mobile
E-mail

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

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

This will be included in the study protocol.

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

This will be included in the study protocol.

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

If yes, please give details of the intended method of randomisation:

E.g. name of computerised system used for randomisation.

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.

See guidance notes for further information.

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

Key members of the CI's team should be listed here. Try to limit this list to a few key individuals who are involved in the application/study.

Post

Qualifications

Employer

Work Address

Post Code

Telephone

Fax

Mobile

Work Email

A64. Details of research sponsor(s)

A64-1. Sponsor

SP1

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: Commercial

However the study is being sponsored, enter the details of a key contact person at the study Sponsor here.

If Other, please specify:

Contact person

Name of organisation
Given name
Family name
Address
Town/city
Post code
Country
Telephone
Fax
E-mail

Legal representative in the European Economic Area for the purpose of this trial

A legal representative must be appointed for a clinical trial of an investigational medicinal product if the sponsor is not established within the European Economic Area (EEA) (see article 19 of Directive 2001/20/EC). If this applies, please enclose evidence that the legal representative is established within the EEA and has accepted the role of legal representative.

Legal representative

Contact person

Name of organisation
Given name
Family name
Address
Town/city
Post code
Country
Telephone
Fax
E-mail

A65. Has external funding for the research been secured?

Please tick at least one check box.

- [x] 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
Address

Post Code
Telephone
Fax
Mobile
Email

Funding Application Status: ( ) Secured ( ) In progress

Amount:

Duration
Years:
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

If Yes, please give details of each rejected application:

Name of Research Ethics Committee or ethics authority:
Decision and date taken:
Research ethics committee reference number:

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

Your local R&D team should be informed as early as possible about the application and a key contact who is aware of the application listed here.

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 East and North Cumbria

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:

This information should be based on your plans at this stage - it can be updated later by informing the regulatory authorities of the change.

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

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

A70.

Definition of the end of trial, and justification in the case where it is not the last visit of the last subject undergoing the trial.
If it is the last visit of the last subject, please enter "LVLS". If it is not LVLS provide the definition.

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

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

- ☑ USA
- ☐ Other international (please specify)

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: 0

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

◉ Yes ○ No

A73-2. If yes, will any of these organisations be NHS organisations?

◉ Yes ○ No

If yes, details should be given in Part C.

A73-3. Approximately how much time will these organisations expect to spend on screening records and/or provision of information to potential participants, and how will the costs of these activities be funded?

Include full details here about how much time will be spent and how the organisations will be reimbursed for their time.

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

E.g. if a Contract Research Organisation (CRO) will be monitoring/auditing the research, include details here.

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?

See guidance notes for further information. Include details of Data Monitoring Committee if relevant.

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?

This information can be found in the protocol and should be written in a clear and understandable way.

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.

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

Please enclose a copy of relevant documents.

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

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

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

Please enclose a copy of relevant documents.

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

If Yes, please give details of the compensation policy:

See guidance notes for further information.

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

A79. Please select the level of commercial participation in this project.

- ( ) None
- ( ) Industry funding, but not industry sponsored
- (•) Industry funding and industry sponsored
- ( ) Industry sponsored, but not industry funded

Contact person

Name of organisation

Given name
Family name
Address
Town/city
Post code
Country
Telephone
Fax
E-mail

A80. Please select the main subject area of research. Additional sub-topics may be selected, if required

- [ ] Age and Ageing
- [ ] Anaesthetics
- [ ] Cancer (includes malignant haematology
- [ ] Cardiovascular
- [ ] Clinical
- [ ] Critical Care
- [ ] Dementias and Neurodegenerative Diseases
- [ ] Dermatology
- [ ] Diabetes
- [ ] Ear, Nose and Throat
- [ ] Gastrointestinal
- [x] Genetics
- [ ] Health Services Research
- [ ] Hepatology
- [ ] Immunology and Inflammation
- [ ] Infectious Disease and Microbiology
- [ ] Injuries and Accidents
- [ ] Medicines for Children (does not include Paediatrics)
- [ ] Mental Health
- [ ] Metabolic and Endocrine
- [ ] Musculoskeletal (Rheumatoid Arthritis is a separate category)
- [ ] Nervous System Disorders
- [ ] Non-malignant Haematology
- [ ] Ophthalmology
- [ ] Oral and Dental
- [ ] Paediatrics (does not include Medicines for Children)
- [ ] Primary Care
- [ ] Public Health Research
- [ ] Renal
- [ ] Reproductive Health and Childbirth
- [ ] Respiratory
- [ ] Rheumatoid Arthritis

- [ ] Stroke
- [ ] Surgery
- [ ] Urogenital

Part B Section 1: Investigational Medicinal Products

Trial identification

1. National Competent Authority:

UK - MHRA

2. European Clinical Trials Database (EudraCT) number:

All Clinical Trials of Investigational Medicinal Products (CTIMPs) must be registered on the EudraCT database. Each trial must be issued with a unique EudraCT number.

3. Title of the trial for lay people, in easily understood, i.e. non-technical, language

4. Sponsor's protocol:

Number:
Version:
Date:

5-1. ISRCTN number, if available :

For guidance from the NIHR, see https://www.nihr.ac.uk/research-and-impact/nihr-clinical-research-network-portfolio/isrctn-registration.htm

5-2. US NCT number:

5-3. Who Universal Trial Reference Number (UTRN)

5-4. Other Identifiers:

Name	Identifier

6. Is this a resubmission?

◯ Yes ◉ No

7. Is the trial part of a Paediatric Investigation Plan?

◯ Yes ◯ No ◉ Not Answered

Identification of the sponsor responsible for the request

9. Sponsor

SP1
Contact person

Name of organisation
Given name
Family name
Address
Town/city
Post code
Country
Telephone
Fax
E-mail

B2.Legal representative in the European Economic Area for the purpose of this trial
A legal representative must be appointed for a clinical trial of an investigational medicinal product if the sponsor is not established within the European Economic Area (EEA) (see article 19 of Directive 2001/20/EC). If this applies, please enclose evidence that the legal representative is established within the EEA and has accepted the role of legal representative.

Legal Representative 1

Contact person

Name of organisation
Given name
Family name
Address
Town/city
Post code
Country
Telephone
Fax
E-mail

B3. Status of the sponsor: Commercial

B.4 Source(s) of Monetary or Material Support for the clinical trial (repeat as necessary):

B.5 Contact point designated by the sponsor for further information on the trial:

Name of organisation
Functional name of contact point
Street Address
Town/city
Post code
Country
Telephone

Fax
E-mail

Applicant identification

10. Who is responsible for the Clinical Trial Authorisation Application?

Sponsor

11. Complete the details of the applicant below even if they are provided elsewhere on the form:

Contact person

Person or organisation name:
Contact person Given name
Contact person Family name
Address
Town/city
Post code
Country
Telephone
Fax
E-mail

12. Do you want a xml file copy of the CTA form data saved on EudraCT?

◯ Yes ◉ No ◯ Not Answered

Information on each IMP.

Information on each 'bulk product' before trial-specific operations (blinding, trial specific packaging and labelling) should be provided in this section for each investigational medicinal product (IMP) being tested including each comparator, if applicable.
If the trial is performed with several products please create a separate set of the following questions for each product. If the product is a combination product please give separate information for each active substance.
Click on the first row and enter details of the product in the following screens. When you have completed the details, click on the navigate button or the "See All" link and return to this section to enter details of the next product. When you have completed details of all products please move to question 13 using the navigation screen.

Investigational medicinal products

PR1 (No Name)

Include full details of the Investigational Medicinal Product that is being studied.

13. Indicate which of the following is described below then repeat as necessary for each:

This refers to the IMP number: **PR1**
Investigational medicinal product category:
Test IMP

14. STATUS OF THE IMP
If the IMP has a marketing authorisation in the Member State concerned by this application but the trade name and marketing authorisation holder are not fixed in the protocol, go to question 14-.2

14-1. Does the IMP to be used in the trial have a marketing authorisation?

○ Yes ◉ No ○ Not Answered

14-2. Situations where an IMP to be used in the CT has a MA in the MS concerned, but the protocol allows that any brand of the IMP with a MA in that MS be administered to the trial subjects and it is not possible to clearly identify the IMP(s) in advance of the trial start

In the protocol, is treatment defined only by active substance?
◉ Yes ○ No ○ Not Answered

If 'Yes', give active substance in D.3.8 or D.3.9

In the protocol, do treatment regimens allow different combinations of marketed products used according to local clinical practice at some or all investigator sites in the MS?
○ Yes ◉ No ○ Not Answered

The products to be administered as IMPs are defined as belonging to an ATC group
○ Yes ◉ No ○ Not Answered

Other :
○ Yes ◉ No ○ Not Answered

14-3. IMPD submitted:

Full IMPD
◉ Yes ○ No ○ Not Answered

The Investigational Medicinal Product Dossier (IMPD) includes summaries of information related to the quality, manufacture and control of any IMP (including reference product and placebo) and data from non-clinical and clinical studies.

Simplified IMPD

◯ Yes ◉ No ◯ Not Answered

Provide justification for using simplified dossier in the covering letter

Summary of product characteristics (SmPC) only

◯ Yes ◉ No ◯ Not Answered

14-4. Has the use of the IMP been previously authorised in a clinical trial conducted by the sponsor in the Community?

◯ Yes ◉ No ◯ Not Answered

14-5. Has the IMP been designated in this indication as an orphan drug in the Community?

◯ Yes ◉ No ◯ Not Answered

Orphan drugs can be described as drugs that are not developed by the pharmaceutical industry for economic reasons but which respond to public health need (e.g. rare diseases).

14-6. Has the IMP been the subject of scientific advice related to this clinical trial?

◯ Yes ◉ No ◯ Not Answered

Please indicate source of advice and provide a copy in the CTA request:

From the CHMP?

◯ Yes ◉ No ◯ Not Answered

CHMP = Committee for Medicinal Products for Human Use

From a MS competent authority?

◯ Yes ◉ No ◯ Not Answered

This is a sub-set of questions about each IMP. To return to the list of IMPs select "See all" at the top of the page or select "Navigate". To complete further questions about this IMP select "Next".

Description of IMP

15-1. Description of IMP

Product name where applicable

Product code where applicable

ATC codes, if officially registered

Pharmaceutical form (use standard terms)

Is this a specific paediatric formulation? ◯ Yes ◉ No ◯ Not Answered

Maximum duration of treatment of a subject according to the protocol

Include full details of the IMP here.

Dose allowed

First dose for first-in-human clinical trial

Specify per day or total: ◯ per day ◯ total ◯ Not Answered

Specify total dose (number and unit)

Route of administration (relevant to the first dose):

Maximum dose allowed

Specify per day or total ◯ per day ◯ total ◯ Not Answered

Specify total dose (number and unit)

Route of administration (relevant to the maximum dose):

Routes of administration for this IMP

This is a sub-set of questions about each IMP. To return to the list of IMPs select "See all" at the top of the page or select "Navigate". To complete further questions about this IMP select "Next".

15-2. Active substances

Complete all fields that currently apply to this Active Substance in this Product. If you have IMPs with different concentrations of the Active Substance complete a new Sub-section D for each.

Active Substance 1

Name of active substance (INN or proposed INN if available):

CAS number:

Current sponsor code:

Other descriptive name:

Full Molecular formula

Chemical/biological description of the Active Substance

Strength

Concentration unit:

Concentration type:

Concentration number (only use both fields for range):

15-3. Type of IMP

Does the IMP contain an active substance:

Of chemical origin? ◯ Yes ◉ No ◯ Not Answered

Of biological / biotechnological origin?(other than Advanced Therapy IMP (ATIMP)) ◯ Yes ◉ No ◯ Not Answered

Is this a:

Advanced Therapy IMP (ATIMP) (1) ◯ Yes ◉ No ◯ Not Answered

Combination product that includes a device, but does not involve an Advanced Therapy	○ Yes ◉ No ○ Not Answered
Radiopharmaceutical medicinal product?	○ Yes ◉ No ○ Not Answered
Immunological medicinal product (e.g. vaccine, allergen, immune serum)?	○ Yes ◉ No ○ Not Answered
Plasma derived medicinal product?	○ Yes ◉ No ○ Not Answered
Extractive medicinal product?	○ Yes ◉ No ○ Not Answered
Recombinant medicinal product?	○ Yes ◉ No ○ Not Answered
Medicinal product containing genetically modified organisms?	○ Yes ◉ No ○ Not Answered
Herbal medicinal product?	○ Yes ◉ No ○ Not Answered
Homeopathic medicinal product?	○ Yes ◉ No ○ Not Answered
Another type of medicinal product?	○ Yes ◉ No ○ Not Answered

Specify the mode of action for the active substance in this medicinal product
The mode of action should briefly describe the chemical, biochemical, immunological or biological means that the IMP uses to effect its pharmaceutical action.

Is it an IMP to be used in a first-in-human clinical trial? ○ Yes ◉ No ○ Not Answered

(1,2,3,4,5) Complete sections D.4, D.5, D.6. and D.7, as applicable
(2,3) As defined in Annex 1 part IV of Directive 2001/83/EC as amended
(4) As defined in Article 2(1)(b) of Regulation 1394/2007/EC
(6) Guideline on strategies to identify and mitigate risks for first-in-human clinical trials with investigational medicinal products. EMEA/CHMP/SWP/28367/2007

Information on Placebo

20. Is there a placebo:

(•) Yes ( ) No ( ) Not Answered

PL1

Pharmaceutical form: Include information about the placebo here (if relevant).

Route of administration:

Which IMP is it a placebo for? Specify IMP Number(s) from D1

Index of Sites where the qualified person certifies batch release

21-1. IMPs and placebos for which no responsible site needs to be identified.

This section is used to identify IMPs and placebos which:

- Have an MA in the EU **and**
- Are sourced from the EU market **and**
- Are used in the trial without modification (eg not overencapsulated) **and**
- The packaging and labeling is carried out for local use only as per article 9.2 of the Directive 2005/28/EC (GCP Directive).

If all the conditions above are met, then select below the IMPs and placebos to which this applies.

This section is dedicated to finished IMPs, i.e. medicinal products randomised, packaged, labelled and certified for use in the clinical trial. In the case of multiple sites indicate the product certified by each site.

21-2. Who is responsible in the Community for the certification of the finished IMP or placebo?
This section is dedicated to finished IMPs, i.e. medicinal products randomised, packaged, labelled and certified for use in the clinical trial. If there is more than one site or more than one IMP is certified, use extra pages and give each IMP its number from section D1 or D7 In the case of multiple sites indicate the product certified by each site.

RS1

Name of the organisation:

Address

Town/city

Post code

Country

Give the manufacturing authorisation number

If no authorisation, give the reasons:

Select the relevant IMP(s) and Placebo(s) from the drop down lists.

General information on the trial

22-1. Medical condition or disease under investigation (1)

Specify the medical condition(s) to be investigated (free text) :
E.g. Duchenne Muscular Dystrophy (DMD)
Medical condition in easily understood language

Identify the therapeutic area

(1) In the case of healthy volunteer trials, the intended indication for the product under development should be provided.

22-2. MedDRA information (2)

(2) Applicants are encouraged to provide the MedDRA lower level term (LLT) if applicable and classification code.

22-3. Is any of the conditions being studied a rare disease? (3)

(•) Yes ( ) No ( ) Not Answered

(3) Refer to "Points to consider on the calculation and reporting of the prevalence of a condition for Orphan drug designation": COM/436/01 (http://www.ema.europa.eu/docs/en_GB/document_library/Regulatory_and_procedural_guideline/2009/09/WC500003773.pd

23-1. What is the primary outcome measure for the study?(max 5000 characters)

This will be included in the study protocol.

Timepoint(s) of evaluation of this end point (max 800 characters)

The protocol will usually identify a single primary end point but there may be a co-primary end point in some cases and/or a number of secondary end points.

23-2. Secondary end point(s) (max 5000 characters)

Timepoint(s) of evaluation of this end point (max 800 characters)

24. What is the scope of the trial?

Select all relevant options.

Diagnosis	○ Yes	◉ No	○ Not Answered
Prophylaxis	○ Yes	◉ No	○ Not Answered
Therapy	○ Yes	◉ No	○ Not Answered
Safety	◉ Yes	○ No	○ Not Answered
Efficacy	◉ Yes	○ No	○ Not Answered
Pharmacokinetic	○ Yes	◉ No	○ Not Answered
Pharmacodynamic	○ Yes	◉ No	○ Not Answered
Bioequivalence	○ Yes	◉ No	○ Not Answered
Dose Response	○ Yes	◉ No	○ Not Answered
Pharmacogenetic	○ Yes	◉ No	○ Not Answered
Pharmacogenomic	○ Yes	◉ No	○ Not Answered
Pharmacoeconomic	○ Yes	◉ No	○ Not Answered
Others	○ Yes	◉ No	○ Not Answered

Specify:

25-1. Trial type and phase [(1)]

Human pharmacology (Phase I)	○ Yes	◉ No	○ Not Answered
Therapeutic exploratory (Phase II)	○ Yes	◉ No	○ Not Answered
Therapeutic confirmatory (Phase III)	◉ Yes	○ No	○ Not Answered
Therapeutic use (Phase IV)	○ Yes	◉ No	○ Not Answered

[(1)] The descriptions of the trial types provided are those recommended in preference to Phases. See page 5 of Community guideline CPMP/ICH/291/95. The development of a new indication after initial approval of a medicine should be considered as a new development plan.

Design of the Trial

26-1. Is the trial design controlled?

(●) Yes ( ) No ( ) Not Answered

Specify:

Randomised	(●) Yes	( ) No	( ) Not Answered
Open	( ) Yes	(●) No	( ) Not Answered
Single blind	( ) Yes	(●) No	( ) Not Answered
Double blind	(●) Yes	( ) No	( ) Not Answered
Parallel group	( ) Yes	(●) No	( ) Not Answered
Cross over	( ) Yes	(●) No	( ) Not Answered
Other	( ) Yes	(●) No	( ) Not Answered

Select all relevant options.

26-2. If controlled, specify the comparator:

Other medicinal product(s)	( ) Yes	(●) No	( ) Not Answered
Placebo	(●) Yes	( ) No	( ) Not Answered
Other	( ) Yes	(●) No	( ) Not Answered

Number of treatment arms in the trial

26-3. Single site in the Member State concerned (see also section G):

( ) Yes (●) No ( ) Not Answered

26-4. Multiple sites in the Member State concerned (see also section G):

(●) Yes ( ) No ( ) Not Answered

Number of sites anticipated in Member State concerned

26-5. Multiple Member States

( ) Yes (●) No ( ) Not Answered

Number of sites anticipated in the Community.

26-6. Trial being conducted both within and outside the EEA

(●) Yes ( ) No ( ) Not Answered

Trial conducted completely outside EEA

( ) Yes (●) No ( ) Not Answered

Specify the countries in which trial sites are planned

Specify the number of sites anticipated outside of the EEA

26-7. Recruitment start date

This will be based on current projections.

Recruitment start date in MS

In any country

Population of Trial Subjects

27. What is the age span of the trial subjects?

Less than 18 years	Yes / No / Not Answered	Approx no of participants: 0

Please specify the estimated number of participants planned in each age range for the whole trial:

In Utero	No / Not Answered	Approx no of participants: 0
Preterm newborn infants (up to gestational age less than 37 weeks)	No / Not Answered	Approx no of participants: 0
Newborn (0-27 days)	No / Not Answered	Approx no of participants: 0
Infant and toddler (28 days - 23 months)	No / Not Answered	Approx no of participants: 0
Children (2-11 years)	Yes / Not Answered	Approx no of participants: 0
Adolescent (12-17 years)	Yes / Not Answered	Approx no of participants: 0
Adult (18-64 years)	Yes / No / Not Answered	Approx no of participants: 0
Elderly (geater than 65 years)	No / Not Answered	Approx no of participants: 0

The number of participants will be initial estimates. Applicants will not be required to update this information nor do they constitute an authorisation or restriction on the inclusion of these numbers of patients in the trial.

28. What is the gender of the trial subjects?

Female	Yes	No	Not Answered
Male	Yes	No	Not Answered

29. Please select the categories of the trial subjects:

Healthy volunteers	No		Not Answered
Patients	Yes	No	Not Answered
Specific vulnerable populations	No		Not Answered

30. Planned number of subjects to be included:

In the member state

For a multinational trial:

In the European community:

In the whole clinical trial:

31. Plans for treatment or care after a subject has ended his/her participation in the trial. ***If it is different from the expected normal treatment, please specify:***

It is important that this is clearly described e.g plans for an extension study or to continue providing the intervention until a specified timepoint.

Central technical facilities to be used in the conduct of the trial

32. Other principal Investigators *(for a multicentre trial)*

IN1

Include details of the PI at each centre for a multicentre trial.

Given name
Family name
Qualification (MD...)
Institution name
Institution department name
Street address
Town/city
Post Code
Country
Telephone
Fax
E-mail

For multi-centre trials where the CI is also a local PI, please list the CI as a PI at G2 (single-centre).

33. Central technical facilities to be used in the conduct of the trial. *Laboratory or other technical facility, in which the measurement or assessment of the main evaluation criteria are centralised.*

Organisation

Central technical facility organisation name
Central technical facility organisation department
Contact person Given name
Contact person Family name
Street address
Town/city
Post code
Country
Work Telephone
Fax
E-mail

Enter the details of any duties subcontracted to this central technical facility in this trial:

Routine clinical pathology testing	○ Yes	◉ No	○ Not Answered
Clinical chemistry	○ Yes	◉ No	○ Not Answered
Clinical haematology	○ Yes	◉ No	○ Not Answered
Clinical microbiology	○ Yes	◉ No	○ Not Answered
Histopathology	○ Yes	◉ No	○ Not Answered

Serology / endocrinology	◯ Yes ◉ No ◯ Not Answered
Analytical chemistry	◯ Yes ◉ No ◯ Not Answered
ECG analysis / review	◯ Yes ◉ No ◯ Not Answered
Medical image analysis/ review - X-ray, MRI, ultrasound, etc.	◯ Yes ◉ No ◯ Not Answered
Primary/ surrogate endpoint test	◯ Yes ◉ No ◯ Not Answered
Other	◯ Yes ◉ No ◯ Not Answered

Organisations to whom the sponsor has transferred trial related duties and functions

34. Network organisation details

Include details if relevant.

Organisation
Contact person Given name
Contact person Middle name
Contact person Family name
Street address
Town/city
PostCode
Country
Telephone number
Fax number
E-mail

Activities carried out by the network

Organisations to whom the sponsor has transferred trial related duties and functions

35. Subcontractor organisations.
Enter details of central CRO facilities supplying services for at least this Member State.

Organisation
Department
Contact person Given name
Contact person Family name
Street address
Town/city
PostCode
Country
Telephone number
Fax
E-mail

Enter the details of any duties/ functions subcontracted to this sponsor's subcontractor facility in this trial

All tasks of the sponsor:	○ Yes	◉ No	○ Not Answered
Monitoring:	○ Yes	◉ No	○ Not Answered
Regulatory (e.g. preparation of applications to CA and Ethics Committee):	○ Yes	◉ No	○ Not Answered
Investigator recruitment:	○ Yes	◉ No	○ Not Answered
IVRS(1) - treatment randomisation:	○ Yes	◉ No	○ Not Answered
Data management:	○ Yes	◉ No	○ Not Answered
E-data capture:	○ Yes	◉ No	○ Not Answered

SUSAR reporting:	◯ Yes ◉ No ◯ Not Answered
Quality assurance auditing:	◯ Yes ◉ No ◯ Not Answered
Statistical analysis:	◯ Yes ◉ No ◯ Not Answered
Medical writing:	◯ Yes ◉ No ◯ Not Answered
Other duties subcontracted:	◯ Yes ◉ No ◯ Not Answered

Ethics Committee

36. Type of application
Please tick the Ethics Committee box and give information of the Ethics committee concerned.

Ethics committee ☑

37-1. Name and address of ethics committee:

This information will be based on the Ethics Committee that you are applying to for review of the application.

Organisation
Work Address

PostCode
Country
Fax

37-2. Date of submission:

37-3. Current status of Ethics Committee Opinion at the time of submission to the National Competent Authority:

○ To be requested ◉ Pending ○ Given

EudraCT Checklist

38. *For details of the documents required for applications to the MHRA in the UK please see*
http://www.mhra.gov.uk/Howweregulate/Medicines/Licensingofmedicines/Clinicaltrials/Applyingforaclinicaltrialauthorisation/Whattosend/index.htm

PART B: Section 3 – Exposure to ionising radiation

Complete sub-sections A and/or B as applicable with input from relevant experts. It is advisable to discuss the proposed research at an early stage with (a) a Medical Physics Expert and (b) a Clinical Radiation Expert, who will carry out the required assessments for sub-sections C and D. The lead MPE can also facilitate the completion of sub-sections A and/or B if necessary.

1. Does the study involve exposure to radioactive materials?

◉ Yes ○ No

To update the response above, go to the Project Filter Question 2 'Does the study involve exposure to radioactive materials?' and select an option.

2. Does the study involve other diagnostic or therapeutic ionising radiation?

◉ Yes ○ No

A. Radioactive materials

Details of radioactive materials

A1. Complete the table below for each radionuclide to be administered.

Type of investigation/therapy:	
Radionuclide:	
Chemical form:	
Proposed activity (MBq):	
Route of administration:	
Number of administrations per participant:	
Effective dose or target tissue dose per administration:	

A2. Details of study participants

Will any of the study participants be patients? ◉ Yes ○ No

Will any of the study participants be healthy volunteers? ◉ Yes ○ No

Details of patients to be studied:

Number (whole study)	Age range	Sex	Clinical condition	Total effective or target tissue dose per individual

Details of healthy volunteers to be studied:

Number (whole study)	Age range	Sex	Total effective dose per individual

A3. What steps will you take to exclude women who are pregnant or who could become pregnant during the study?
Give details of screening procedures and advice to be given to women of child-bearing age.

A4. ARSAC research certificates

An ARSAC research certificate will be required at each research site where the study involves administration of exposures which are additional to normal care. Most of the information required by ARSAC can be generated automatically from Part A and Part B Section 3 of IRAS once completed. The ARSAC research application form can be launched from the Site-Specific Information Form for the site in IRAS.

B. Other ionising radiation

B1. Details of other ionising radiation

Give details by completing the table below:

Procedure	No of procedures	Estimated procedure dose *(use national Diagnostic Reference Levels where available)*

C. Dose and risk assessment

C1. What is the total participant dose from all the exposures in A1 and/or B1, and what component of this is the additional dose over and above standard practice? What are the risks associated with these two doses (total and additional)?

The dose and risk assessment should be set out below. This should be prepared by a Medical Physics Expert (MPE) who is a registered clinical scientist registered with the Health Professions Council and has expertise relevant to the planned exposures. Where the study involves different types of exposure (for example, both radioactive materials and other ionising radiation, or more than one imaging method), advice may need to be sought from other MPEs with relevant expertise. The lead MPE should produce a combined assessment for the ethics committee, giving the names of any other MPEs who have contributed to the assessment. Further guidance is available by clicking on the information button.

This should be completed by/with the support of a Medical Physics Expert - if the study is being conducted within an NHS Hospital Trust, there should be a nominated member of staff or nominated members of staff who can carry out the assessment and sign this off. Ask your local R&D office if you are unsure who to contact.

Special attention must be paid to pregnant/potentially pregnant women or those who are breast feeding, or other potentially vulnerable groups.

C2. Declaration by lead Medical Physics Expert

I am satisfied that the information in sub-sections A and/or B and the assessment in sub-section C provide a reasonable estimate of the ionising radiation exposure planned in this research and the associated risks.

Signature:…….. Date:

C3. Details of person acting as lead Medical Physics Expert

Title Forename/Initials Surname

Post

Details of clinical scientist registration with the Health Professions Council:

Registration no CS

Organisation

Address

Post Code

Telephone

Fax

Mobile

Email

D. Clinical assessment

This sub-section should be completed by a Clinical Radiation Expert (CRE) who is a registered doctor or dentist with clinical expertise relevant to the planned exposures. The assessment should cover potential exposure at all research sites, taking account of possible variation in normal clinical practice. Where the study involves different types of exposure (for example, both radiotherapy and other ionising radiation), advice may need to be sought from other CREs with relevant expertise. The lead CRE should produce a combined assessment for the ethics committee, giving the names of any other CREs who have contributed to the assessment. The guidance notes give advice to Chief Investigators on who can act as lead Clinical Radiation Expert (CRE) and advice for the CRE on the assessment of exposures having regard to IRMER.

Special attention must be paid to pregnant/potentially pregnant women or those who are breast feeding, or other potentially vulnerable groups.

D1. Will the exposure exceed the exposure that might be received as part of normal care at any proposed research site?

◉ Yes ○ No

D2. Assessment of additional exposure

Explain how the planned exposure compares with normal practice and assess whether it is appropriate, using language comprehensible to a lay person. Consideration should be given to the specific objectives of the exposure, the characteristics of participants, the potential diagnostic or therapeutic benefits to the participant, the potential benefits to society, the risk to the participant and the availability of alternative techniques involving less, or no, ionising radiation.

If pregnant or breast-feeding mothers are to be studied give reasons and details of special radiation protection measures to be taken.

This should be completed by/with the support of a Clinical Radiation Expert - if the study is being conducted within an NHS Hospital Trust, there should be a nominated member of staff or nominated members of staff who can carry out the assessment and sign this off. Ask your local R&D office if you are unsure of who to contact.

D3. Declaration by lead Clinical Radiation Expert

I am satisfied that the exposure to ionising radiation planned in this research study (as defined in A1 and/or B1) is reasonable and that the risks are adequately described in the participant information sheet for the study.

Signature:…….. Date:

D4. Details of lead Clinical Radiation Expert

Title Forename/Initials Surname

Post

Details of professional registration ◉ General Medical Council ○ General Dental Council

Registration no

Organisation

Address

Post Code

Telephone

Fax

Mobile

Email

Employers responsible for radiation facilities at research sites must have written procedures to meet the requirements of the Ionising Radiation (Medical Exposure) Regulations 2000 (IRMER). R & D offices for NHS sites will seek confirmation from local radiation experts that local IRMER authorisation procedures have been followed. Where the local Medical Physics

Expert or IRMER Practitioner disagrees with the assessments made in this Section and/or the care organisation is unable to adhere to the protocol, this should be discussed with the Chief Investigator and the lead experts for the study. Any necessary variation in the protocol or participant information sheet at particular sites should be notified to the main REC as a substantial amendment and an ethical opinion sought.

Part B: Section 4 – Use of residual or existing stored human tissue(or other human biological materials)

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

E.g. blood. muscle biopsy etc.

2. Will the samples be released to the researcher:

In fully anonymised form? *(link to stored tissue and data is broken)*

○ Yes ◉ No

In linked anonymised form? *(linked to stored tissue but donor not identifiable to researchers)*

◉ Yes ○ No

In a form in which the donor could be identifiable to researchers?

○ Yes ◉ No

3. Has consent been obtained previously to use the samples for research

◉ Consent has been given for all samples

○ Consent has been given for some of the samples

○ No consent has been given

4. Please outline what consents are already in place, distinguishing between different groups of samples where appropriate.

See guidance notes for further information.

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

○ Yes ◉ No

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

Give full details here.

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

◉ Yes ○ No

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

◉ Yes ○ No

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

○ Yes

○ No
◉ Not applicable

12. Who is the holder of the samples?

Please tick either/both boxes as applicable.

Include full details here about where the samples will be held and who is responsible for them.

☑ NHS pathology department(s) / diagnostic archive(s)
Specific details of each department/archive are not required

☑ Other research tissue bank(s) or sample collection(s)
Please provide further details of each bank/collection below

Name of the research tissue bank (or other collection):

Does the bank/collection hold a licence from the Human Tissue Authority to store tissue for research?

○ Yes ○ No

See https://www.hta.gov.uk/ for further information.

REC reference no. (if the bank/collection is ethically approved):

Details of organisation with responsibility for the bank/collection:

Organisation:

Title Forename/Initials Surname

Address

Post Code
Telephone
Fax
Mobile
Email
Contact point

13. Will any of the samples be imported from outside the UK?

◉ Yes ○ No

If Yes, please give further details and justify the use of imported samples. Summarise what arrangements have been made, where appropriate, to seek consent from donors and ethical review in the exporting country.

See guidance notes and HTA Code of Practice for further details.

14. Please give details of where the samples will be stored, who will have access and the custodial arrangements.

Ask the team at the storage facility if you are unsure.

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

☐ Return to current holder of the samples

☐ Transfer to another tissue bank

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

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

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

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

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

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

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

☐ Other

☐ Not yet known

Please give further details of the proposed arrangements:

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

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

E.g. blood, muscle biopsy etc.

2. Who will collect the samples?

Include full details - avoid using staff names as these may change throughout the study - e.g. appropriately qualified Research Nurse who will be delegated this activity.

3. Who will the samples be removed from?

- [x] Living donors
- [ ] The deceased

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

In this research?

(•) Yes ( ) No

In future research?

(•) Yes ( ) No ( ) Not applicable

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

( ) Yes (•) No

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

In fully anonymised form? *(link to donor broken)*

( ) Yes ( ) No

In linked anonymised form? *(linked to stored tissue but donor not identifiable to researchers)*

(•) Yes ( ) No

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

In a form in which the donor could be identifiable to researchers?

( ) Yes ( ) No

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

Include full details here.
E.g. standard safety laboratory tests such as haematology, chemistry, virus serology, diagnostic confirmation testing, immunology testing.

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

◉ Yes ○ No

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

◉ Yes ○ No

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

○ Yes ◉ No ○ Not applicable

If No, please justify. If Yes, say what arrangements will be made and give details of the support or counselling service.

See guidance notes for further information.

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

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

☐ Transfer to research tissue bank

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

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

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

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

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

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

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

☐ Other

☐ Not yet known

Please give further details of the proposed arrangements:

*Samples are very valuable resources so you may want to consider storing them for possible future research. The plans for the use of samples should be written here and in the participant information sheet/informed consent form.

PART B: Section 7 - Children

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

Give full details of age range and why the research is being carried out in children.

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

3-1. Please describe the arrangements for seeking informed consent from a person with parental responsibility or another legal representative.

E.g. parent/caregiver information sheet and informed consent form.

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

E.g. assent forms for different age ranges, differing in content and style, tailored to the age of the children.

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

5. Is it possible that a child might need to be treated urgently as part of the trial before it is possible to identify and seek consent from a person with parental responsibility or another legal representative?

○ Yes ◉ No

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 Qualification (MD...) Country

Participant Identification Centres

PIC Type	Centre	Individual(s)
◉ NHS (England) ◯ NHS (outside England) ◯ Non-NHS		E-mail: