# Organisation Information Document – Non-Commercially Sponsored Studies

**(Template version: 1.7 March 2024)**

## Guidance on Using This Document

Please use this document to create the outline Organisation Information Document/s that you will submit with your IRAS application. In most instances the Organisation Information Document should be localised before sharing with Participating NHS / HSC Organisations.

Questions/items marked with an asterisk\* (Questions 1-3, 5, 8 and 12-15 and 18, as well as items throughout the appendices as applicable) must be completed prior to submission of the IRAS application in all cases. Only if the localised Organisation Information Document is to be used as the Agreement between the Parties should the Sponsor or authorised delegate check the relevant check boxes at the top of each subsequent Appendix. In all cases the Sponsor authorisation at question 18 should be completed prior to submission of the outline Organisation Information Document in IRAS.

Items marked with a caret **^** are completed by the Participating NHS / HSC Organisation, after the Local Information Pack is shared and where relevant.

Remaining questions may be answered on the localised Organisation Information Document either by the Sponsor or authorised delegate prior to sharing the Local Information Pack, or by the Participating NHS / HSC Organisation (or collaboratively between the two) after the Local Information Pack is shared, as appropriate.

To provide an answer in the document, click in a box with the grey text (click here to enter text), or choose the relevant option if presented with a drop-down list.

A separate guidance document is provided and should be consulted prior to completion of this document. Please also read the question specific guidance where present.

## Study Information

|  |  |  |
| --- | --- | --- |
| 1.\* IRAS Project ID | Enter IRAS Project ID | |
| **2.\* Full Title of the Study** | Enter full title of study | |
| **3.\* Legal Name(s) of Sponsor/Co-Sponsors/Joint-Sponsors** | Enter legal name | |
| 4. Contact details of person acting on behalf of Sponsor for questions relating to study set up. Please enter details of the person who is the Sponsor’s main point of contact for all correspondence on setting up the study at this NHS / HSC organisation. This contact may be the Sponsor, a Study Manager, Clinical Research Scientist or Study Coordinator. Where a Contract Research Organisation (CRO) or Clinical Trials Unit (CTU) has been delegated to handle set up on behalf of the Sponsor, the contact at the CRO or CTU should be named here. | | |
| Name | | Enter name |
| Telephone Number | | Enter telephone number |
| Email Address | | Enter email address |
| 5.\* Are all Participating NHS / HSC Organisations undertaking the same protocol activities? | | |
| Select yes or no | | |
| If ‘No’ give details of the activities taking place at NHS / HSC organisations that you will use this outline Organisation Information Document with. Additional outline Organisation Information Documents may be required for NHS / HSC organisations undertaking different activities. | | |
| If no, give details | | |

## Participating NHS / HSC Organisation Information

|  |
| --- |
| **6. Name of Participating NHS / HSC Organisation**. If this Organisation Information Document is being used as an Agreement the name must be entered prior to agreement. |
| Enter name of participating NHS / HSC Organisation |
| 7. Location/s: Please provide detail below, where it is planned to undertake the research only at specified locations within the Participating NHS / HSC Organisation (for example, only at specific hospital(s), General Practice(s) and / or Research Unit(s) within the organisation). It is not intended that the level of detail provided here captures individual departments within the Participating NHS / HSC Organisation. |

| Location (enter text below) | Activity (enter text below) |
| --- | --- |
|  |  |
|  |  |
|  |  |

|  |  |
| --- | --- |
| **8\*. What is the role of the person responsible for research activities at the Participating NHS / HSC Organisation?**   * Principal Investigators are expected to be in place at Participating NHS / HSC Organisations where locally employed staff take responsibility for research procedures. In this scenario Principal Investigator should be selected even for single centre studies where the Chief Investigator will also be the Principal Investigator. * Where this is not the case, local collaborators are expected to be in place where central Study staff will be present at the Participating NHS / HSC Organisation to undertake research procedures (the role of the Local Collaborator is to facilitate the presence of Sponsor / CRO research staff). * Where existing data is being provided for research purposes without additional research procedures and without the presence of central research team members at the Participating NHS / HSC Organisation, select Chief Investigator. | |
| Select role | |
| **9. Contact** **details of person responsible for research activities at this Participating NHS / HSC Organisation as indicated in question 8 (if known).** If known, please enter the details of the person you have spoken to about their role in this study at this Participating NHS / HSC Organisation. If unknown, please leave blank and that person can be identified and listed here during the setup of the study. | |
| Name | Enter name |
| Post / Job Title | Enter post |
| Name of Employing Organisation | Enter name of organisation |
| Email Address | Enter email address |
| Telephone number | Enter telephone number |

## Timescales

|  |  |
| --- | --- |
| 10. Predicted Start and End Dates of the Study at this Participating NHS / HSC Organisation  The Sponsor or authorised delegate should propose a date on which it intends to start and complete research activity at this Participating NHS / HSC Organisation. Alternatively, this may be left blank when the Local Information Pack is shared, for agreement during study set up at the Participating NHS / HSC Organisation. | |
| Predicted Start Date (activities at this organisation) | Select predicted start date |
| Predicted End Date (activities at this organisation) | Select predicted end date |
| For many types of study the following dates are not applicable and this may be stated in answer. Where they are applicable, they should be provided by the Sponsor or authorised delegate before sharing the Local Information Pack, as indicative targets for agreement, or they may be negotiated between Sponsor or authorised delegate and Participating NHS / HSC Organisation after sharing the pack. | |
| Predicted Site Initiation Visit Date | Select predicted site initiation visit date |
| Predicted Start Date for participant recruitment | Select predicted start date for participant recruitment |
| Predicted End Date for participant recruitment (when the study moves into “follow up” activities.) | Select predicted end date for participant recruitment |
| Predicted End Date for all Study activities  (“last patient visit” completed and study is ready to be archived.) | Select predicted end date for all study activities |

## Participant Numbers

|  |
| --- |
| 11. How many research participants are expected at this Participating NHS / HSC Organisation?  For studies not directly involving human participants, please indicate the number of samples or data-sets to be obtained.  Please state if number of participants is per month, per year, overall, etc. |
| Enter expected participant / sample numbers |

## Study set up and delivery arrangements at Participating NHS / HSC Organisations

|  |
| --- |
| 12\*. The following are needed at the Participating NHS / HSC Organisation to deliver the study: for example, specific equipment, patient/participant groups, service support, nursing time, etc*.* Please detail any specific requirements for Participating NHS / HSC Organisations to deliver this study, including by clarifying any requirements on Participating NHS / HSC Organisations relating to monitoring / self-monitoring, for example, requirements for staff signature and delegation logs to be returned to the Sponsor and / or any particular access requirements that the Sponsor may have that it wishes to bring to the attention of the Participating NHS / HSC Organisation, likelihood of staff not employed at the Participating NHS / HSC Organisation coming on site, etc. |
| Enter details |
| 13\*. The following training will be provided by the Sponsor or authorised delegate for local research team members. Where only specific team members (e.g. the Principal Investigator) will receive this training, this should be specified. |
| Enter training that will be provided |
| 14\*. The Sponsor expects that local research team members will have the following skills and where they do not have those skills that they will undertake the relevant training before undertaking the relevant study activities*.* It would not be usual for the Sponsor to expect study specific training additional to that which it will provide. This section does however allow Sponsors to state, for example, that when they expect [training in Good Clinical Practice](https://www.hra.nhs.uk/about-us/news-updates/updated-guidance-good-clinical-practice-gcp-training/) for appropriate team members where the study is a Clinical Trial of an Investigational Medicinal Product, they will accept UK nationally recognised GCP training, training recognised on the [Transcelerate mutual recognition scheme](https://www.transcelerate-gcp-mutual-recognition.com/home), etc. |
| Enter training expectation |
| 15\*. The following funding/resources/equipment, etc. is to be provided to this Participating NHS / HSC Organisation. The Sponsor should answer this question whether this Organisation Information Document is to be used as the Agreement with the Participating NHS / HSC Organisation or not. Where the document is intended as the Agreement, further detail should be provided in Appendix 2. |
| Enter funding/resources/equipment to be provided |

|  |  |
| --- | --- |
| **16^ The Participating NHS / HSC Organisation confirms (by use of the drop-down box) that the Principal Investigator, where one is required, is aware of and has agreed to discharge their responsibilities in line with the** [**UK Policy Framework for Health and Social Care Research**](https://www.hra.nhs.uk/planning-and-improving-research/policies-standards-legislation/uk-policy-framework-health-social-care-research/)**.** | Select from drop down |
| **17^ The Participating NHS / HSC Organisation has considered and mitigated any conflict/s of interest declared by the Principal Investigator.** | Select from drop down |
| If yes, please detail conflict of interest | |

## Sponsor Authorisation

|  |  |
| --- | --- |
| **18\* Authorised on behalf of Sponsor by:** | |
| **Name** | Enter name |
| **Job Title** | Enter job title |
| **Organisation Name** | Enter organisation name |
| **Date** | Select date of authorisation |

## Appendices

## (Contents)

Appendix 1: General Provisions

Appendix 2: Study Set Up Arrangements

Appendix 3: Material Transfer Provisions

Appendix 4: Data Processing Agreement

Appendix 5: Data Sharing Agreement

Appendix 6: Intellectual Property Rights

**The Sponsor or authorised delegate should answer the question at the top of Appendix 1 and, if it intends that this Organisation Information Document will be incorporated into an exchange of correspondence to form the Agreement (“Agreement”) between itself and the Participating NHS / HSC Organisation, the questions that appear at the top of each subsequent Appendix.**

# Appendix 1: General Provisions

|  |  |
| --- | --- |
| **\*Does the Sponsor intend that this Organisation Information Document forms the Agreement between itself and the Participating NHS / HSC Organisation, or has a separate site agreement been provided?** | Select from drop down list |
| It is recommended that the Organisation Information Document is used as the Agreement between Sponsor and Participating NHS / HSC Organisation for studies that are not clinical trials or investigations. The model Non-Commercial Agreement (mNCA) should be used for clinical trials or investigations.  Where the Organisation Information Document is to be used as the Agreement between the Sponsor and Participating NHS / HSC Organisation (hereafter singly “Party” or collectively the “Parties”), this document forms a formal legal contract between the Parties. In all cases where this document is the Agreement between the Parties, this Appendix 1 applies in full.  Additionally, the Sponsor or authorised delegate should use the questions at the top of each subsequent Appendix to indicate whether or not that Appendix also forms part of the Agreement.  Text highlighted in yellow is optional, including where alternative versions of the same clause may be used. The applicable option(s) should be selected and text not to be used should be deleted prior to IRAS submission. No changes should be made to any text that does not appear in yellow highlight. | |

1. **Definitions**
   1. In this Agreement the following words shall have the following meanings:

* **Agent(s)**  
  includes, but shall not be limited to, any person undertaking a function in connection with this Agreement (including the Principal Investigator or equivalent individual indicated in question 8, any nurse or other health professional), any such person’s principal employer in the event it is not the Participating NHS / HSC Organisation and where such person is providing services to a Party under a contract for services or otherwise (including clinical academics), and / or any contracted third party providing services to a Party under a contract for services or otherwise;
* **Agreement**  
  this Agreement, including the indicated appendices;
* **Background**  
  Intellectual Property Rights and Know-How that are provided by one Party to the other Party for use in the Study (whether before or after the date of this Agreement) that do not themselves arise from the Study;
* **Clinical Data**  
  any data which relate to a specific actual or potential Participant, which may include, without limitation, medical records, medical imaging data, scans, questionnaires, readouts of individual biomedical or genetic analysis;
* **Co-Sponsor**  
  one of the organisations who divide amongst themselves both the responsibilities and the liabilities associated with sponsoring this Study. Their responsibilities and liabilities are therefore not joint and several, but are as formally agreed between the Co-Sponsors;
* **Confidential Information**  
  all information disclosed, (whether in writing, orally or by another means and whether directly or indirectly) by a Party ("**Disclosing Party**") to another Party ("**Receiving Party**") directly relating to the Study including, but not limited to information, the release of which is likely to prejudice the commercial business interests of the Disclosing Party, or which is a trade secret, including Know-How and shall also include any data disclosed which is Personal Data and / or special category Personal Data, all as defined in the Data Protection Legislation, and / or information that is otherwise confidential patient information;
* **Controller**  
  shall have the meaning set out in the Data Protection Legislation (and "Controllership” shall be construed accordingly);
* **Data Protection Legislation**  
  means the GDPR, the Data Protection Act 2018, the Privacy and Electronic Communications (EC Directive) Regulations 2003, as well as any legally enforceable NHS requirements, Codes of Practice or Guidance issued by the Information Commissioner’s Office, in each case in force from time to time in England, Northern Ireland, Scotland and / or Wales;
* **EIR**

means either the Environmental Information Regulations 2004 or the Environmental Information (Scotland) Regulations 2004, as applicable to the place of constitution of the Participating NHS / HSC Organisation or [Sponsor] / [Co-Sponsor] / [Joint-Sponsor] (if applicable);

* **FOIA**  
  means either the Freedom of Information Act 2000 or the Freedom of Information (Scotland) Act 2002, as applicable to the place of constitution of the Participating NHS / HSC Organisation or [Sponsor] / [Co-Sponsor] / [Joint-Sponsor] (if applicable);
* **Funder**  
  the organisation(s) that is / are providing support to the Study;
* **GDPR**  
  means Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data, as it forms part of the law of England and Wales, Scotland and Northern Ireland by virtue of section 3 of the European Union (Withdrawal) Act 2018 and as amended by the Data Protection, Privacy and Electronic Communications (Amendments etc) (EU Exit) Regulations 2019;
* **Intellectual Property Rights**  
  patents, trademarks, trade names, service marks, domain names copyrights, rights in and to databases (including rights to prevent the extraction or reutilisation of information from a database), design rights, topography rights and all rights or forms of protection of a similar nature or having equivalent or similar effect to any of them which may subsist anywhere in the world, whether or not any of them are registered and including applications for registration of any of them;
* **Joint-Sponsor**  
  either or both organisations who jointly accept the responsibilities and liabilities associated with sponsoring this Study. They are jointly and severally responsible for all the duties of the sponsor, such that all are responsible in the event of a failure of either or both Joint-Sponsor organisations to discharge their responsibilities;
* **Know-How**  
  all technical and other information which is not in the public domain, including but not limited to information comprising or relating to concepts, discoveries, data, designs, formulae, ideas, inventions, methods, models, procedures, designs for experiments and tests and results of experimentation and testing, processes, specifications and techniques, laboratory records, manufacturing data and information contained in submissions to regulatory authorities;
* **Material**  
  any clinical biological sample or portion thereof, derived from Participants, including any information related to such material, supplied by the Participating NHS / HSC Organisation to the [Sponsor] / [Joint Sponsors] / [either of the Co-Sponsors] or [its] / [their] nominee under Appendix 3;
* **NHS Indemnity Scheme**  
  one of the NHS Resolution Clinical Negligence Scheme for Trusts (CNST), or Clinical Negligence Scheme for General Practice (CNSGP) in England; the Clinical Negligence Fund in Northern Ireland; the Clinical Negligence and other Risks Indemnity Scheme (CNORIS) in Scotland; or the Welsh Risk Pool Service (WRPS) in Wales;
* **Participant**  
  any person who consents (where consent is necessary) and is enrolled to take part in the Study. All references to Participants in this Agreement refer to those recruited by or under the care of the Participating NHS / HSC Organisation for the purpose of the Study;
* **Personal Data**  
  any and all information, data and material of any nature received or obtained by any Party in connection with this Agreement which is personal data as defined in the Data Protection Legislation and which relates to any actual or potential Participant or their treatment or medical history;
* **Process**  
  as defined in the Data Protection Legislation (and "Processing" and "Processed" shall be construed accordingly);
* **Processor**  
  shall have the meaning set out in the Data Protection Legislation;
* **Protocol**  
  the full description of the Study, together with any amendments thereto in line with Clause 2.2.1 of this Appendix, and incorporated into this Agreement by reference;
* **Pseudonymised Data**  
  individual-level data relating to a Participant (as opposed to aggregated data) who is made no longer identified or identifiable to the recipient of that data by virtue of the replacement of personal identifiers with a code, or equivalent, and which is safeguarded as non-identifiable in accordance with this Agreement;
* **Results**  
  the research findings produced in the Study which are to be published by the Sponsor and the chief investigator, in compliance with the Protocol and applicable law;
* **Sponsor**  
  the individual, company, institution or organisation that is (or the institutions or organisations, where there is more than one sponsor under a co-sponsorship or joint-sponsorship arrangement, that are) Party to this Agreement, that takes responsibility for the initiation, management and financing (or arranging the financing) of the Study;
* **Study**  
  the research project that is the subject of this Agreement;
* **Study Data**  
  all discoveries, data, information, theories, methods, computer programmes, format of presentations and applications of the same and all manifestations or expressions of the same in physical, chemical, biological, molecular, electronic or written form arising from the performance of the Study.
  1. Any reference to a statutory provision, code or guidance shall be deemed to include reference to any subsequent modification or re-enactment of it.

1. **Obligations of the Parties**
   1. As the mutual exchange of obligations and promises is regarded as consideration, this Agreement forms a legally binding contract.
   2. The Parties agree to comply with all relevant laws, regulations and codes of practice applicable to this Agreement including to the performance of the study. The Parties agree to comply with the World Medical Association Declaration of Helsinki, titled “Ethical Principles for Medical Research Involving Human Subjects” (where applicable) and the UK Policy Framework for Health and Social Care Research. The Parties shall conduct the study in accordance with:
      1. the Protocol, including appropriately made amendments thereto (which is / are hereby incorporated into this Agreement by reference);
      2. the terms of all relevant permissions and approvals. These may include, but are not limited to the terms and conditions of the favourable opinion given by the relevant NHS research ethics committee, where applicable.
   3. The Parties shall carry out their respective responsibilities in accordance with this Agreement.
   4. The Parties agree to comply with all applicable statutory requirements and mandatory codes of practice in respect of confidentiality (including medical confidentiality) in relation to actual and potential Study Participants and Study personnel.
   5. The Sponsor shall, on the giving of reasonable prior written notice to the Participating NHS / HSC Organisation, have the right to audit the Participating NHS / HSC Organisation’s compliance with this Agreement. The Sponsor may appoint an auditor to carry out such an audit. Such right to audit shall include access, during normal working hours to the Participating NHS / HSC Organisation's premises and to all relevant documents and other information relating to the study.
   6. The Participating NHS / HSC Organisation shall:
      1. promptly notify the Sponsor should any responsible body conduct or give notice of intent to conduct any inspection at the Participating NHS / HSC Organisation in relation to the study;
      2. allow the Sponsor to support the preparations for such inspection; and
      3. following the inspection, provide the Sponsor with the results of the inspection relevant to the study. The Sponsor will be responsible for sharing such results with the Funder if required.
   7. In accordance with Participant consent, the Participating NHS / HSC Organisation shall permit the Sponsor’s appointed representatives and any appropriately appointed monitor access to all relevant data for monitoring and source data verification. The Parties agree that such access will be arranged at mutually convenient times and on reasonable notice. Such monitoring may take such form as the Sponsor reasonably thinks appropriate including the right to inspect any facility being used for the conduct of the study, reasonable access to relevant members of staff at the Participating NHS / HSC Organisation and the right to examine any procedures or records relating to the study, subject at all times to Clause 6 of this appendix. The Sponsor will alert the Participating NHS / HSC Organisation promptly to significant issues (in the opinion of the Sponsor) relating to the conduct of the Study.
2. **Liabilities and Indemnity**
   1. Nothing in this Clause 2 shall operate so as to restrict or exclude the liability of a Party in relation to statutory or regulatory liability (including but not limited to breach of the Data Protection Legislation), death or personal injury caused by the negligence or wilful misconduct of that Party or its Agent(s), fraud or fraudulent misrepresentation or to restrict or exclude any other liability of a Party which cannot be so restricted or excluded in law.
   2. Where a Party is a non-NHS / -HSC organisation, or an NHS / HSC organisation that is not covered by an NHS Indemnity Scheme, then that Party shall maintain all proper insurance or equivalent indemnity arrangements to cover liabilities arising from its participation in the study, in respect of any claims brought by or on behalf of a Participant. Where the Party is covered by an NHS Indemnity Scheme, it shall maintain its membership therein or otherwise ensure it has appropriate cover against claims arising as a result of clinical negligence by the Party and / or its Agents brought by or on behalf of the Participants. Each Party shall provide to the other such evidence of their insurance or equivalent indemnity cover maintained pursuant to Clause 2.2 as the other Party shall from time to time reasonably request, such evidence might comprise confirmation that an NHS / HSC organisation is a member of, or otherwise covered by, one of the NHS Indemnity Schemes.

2.3.  **[SINGLE SPONSOR]** Subject to Clauses 2.4, 2.5, 2.6, 2.7 and 2.8, the Sponsor shall indemnify the Participating NHS / HSC Organisation and its Agents against any reasonable claims, proceedings and related costs, expenses, losses, damages and demands (“Claims”) to the extent they arise or result from the negligent acts or omissions of, or the wilful misconduct of the Sponsor, and / or contracted third party, in its performance of this Agreement or in connection with the Study.

**OR**

2.3.  **[CO-SPONSORS]** Subject to Clauses 2.4, 2.5, 2.6, 2.7 and 2.8, the legal entities that comprise the Sponsor, as specified under question 3 hereof (“Co-Sponsor Institutions”), shall each indemnify the Participating NHS / HSC Organisation and its Agents against any reasonable claims, proceedings and related costs, expenses, losses, damages and demands (“Claims”) in accordance with the applicable Co-Sponsor institution’s responsibilities and to the extent that the Claims arise or result from the respective negligent acts of, or omissions or wilful misconduct of a Co-Sponsor Institution, and / or contracted third party, in its respective performance of this Agreement or in connection with the Study. For the avoidance of doubt, the Co-Sponsor Institutions’ liability is not joint and several.

**OR**

2.3.  **[JOINT-SPONSORS]** Subject to Clauses 2.4, 2.5, 2.6, 2.7 and 2.8, the legal entities that comprise the Sponsor, as specified under question 3 hereof (“Joint-Sponsor Institutions”), shall each indemnify the Participating NHS / HSC Organisation and its agents against any reasonable claims, proceedings and related costs, expenses, losses, damages and demands (“Claims”) to the extent they arise or result the negligent acts or omissions of, or the wilful misconduct of either Joint-Sponsor Institution (which includes a Joint-Sponsor Institution’s respective contracted third party) in its performance of this Agreement or in connection with the Study. For the avoidance of doubt, the Joint-Sponsor Institutions’ liability is joint and several.

* 1. Subject to Clauses 2.3, 2.5, 2.6 and 2.8, the Participating NHS / HSC Organisation shall indemnify the [Sponsor] / [each of the Co-Sponsors] / [each of the Joint-Sponsors] and [its] / [their respective] Agents, against any reasonable claims, proceedings and related costs, expenses, losses, damages and demands to the extent they arise or result from the negligent acts or omissions of, or the wilful misconduct of the Participating NHS / HSC Organisation, or its Agents, in its performance of this Agreement or in connection with the Study.
  2. An indemnity under Clauses 2.3 or 2.4 shall only apply if the indemnified Party:
     1. informs the Party providing the indemnity in writing as soon as reasonably practicable following receipt of notice of the claim or proceedings;
     2. upon the indemnifying Party’s request and at the indemnifying Party’s cost gives the indemnifying Party full control of the claim or proceedings and provides all reasonable assistance; and
     3. makes no admission in respect of such claim or proceedings other than with the prior written consent of the indemnifying Party.
  3. Any indemnity under Clauses 2.3 or 2.4 shall not apply to the extent any claims, proceedings and related costs, expenses, losses, damages or demands arise or result from the negligent acts or omissions or wilful misconduct or breach of statutory duty of the indemnified Party, or its Agent(s).
  4. The indemnity under clause 2.3 shall not apply to the extent any claims, proceedings and related costs, expenses, losses, damages or demands arise or result from:
     1. Participating NHS / HSC Organisation carrying out a treatment or procedure that would be routinely undertaken at or for that Participating NHS / HSC Organisation as part of National Health Service treatment; or
     2. Participating NHS / HSC Organisation preparing, manufacturing or assembling any equipment which is not done in accordance
        1. with the Protocol; or
        2. with written instructions of the manufacturer; or
        3. (where such instructions differ from the instructions of the manufacturer) other written instructions of the Sponsor.
  5. No Party shall be liable to another in contract, tort / delict, breach of statutory duty or otherwise for any loss of profits, revenue, reputation, business opportunity, contracts, or any indirect, consequential or economic loss arising directly or indirectly out of or in connection with this Agreement.
  6. If a Party incurs any loss or damage (including costs and expenses) arising or resulting from this Agreement (“Loss”) and:
     1. All Parties are NHS bodies as defined in Section 9(4) of the National Health Service Act 2006 or Section 17 of the National Health Service (Scotland) Act 1978 or Section 7 (4) of the NHS (Wales) Act 2006 or Articles 16 and 26 of the Health and Personal Social Services (Northern Ireland) Order 1972, which established the Boards and Central Services Agency respectively and Article 10 of the Health and Personal Social Services (Northern Ireland) Order 1991: which established Trusts in Northern Ireland as appropriate, or are otherwise bodies covered by an NHS Indemnity Scheme; or
     2. One or more Party is a NHS / HSC body or otherwise covered by an NHS Indemnity Scheme and the other Party (ies) is a NHS Foundation Trust; or
     3. All Parties are NHS Foundation Trusts;

Then clauses 2.10, 2.11 and 2.12 shall apply.

* 1. If all Parties are NHS / HSC bodies / NHS Foundation Trusts in England, Wales or Northern Ireland or non-NHS / -HSC bodies and are indemnified by the same NHS Indemnity Scheme and the Party incurring any Loss can recover such Loss under one of the NHS Indemnity Schemes, then such Party shall rely on the cover provided by their NHS Indemnity Scheme and not seek to recover the Loss from the other Party (ies). Where the other Party (ies) caused or contributed to the Loss, it undertakes to notify the relevant NHS Indemnity Scheme(s) to take this into account in determining the future levies of all Parties in respect of the NHS Indemnity Schemes.
  2. If:
     1. The Parties are members of the same NHS / HSC Indemnity Scheme in England, Wales or Northern Ireland and the Party incurring the Loss is not indemnified for that Loss by its NHS Indemnity Scheme; or
     2. All Parties are covered by the same NHS Indemnity Scheme in Scotland; or
     3. The Parties are NHS bodies / Foundation Trusts established in different jurisdictions within the United Kingdom, or are bodies otherwise covered by different NHS Indemnity Schemes;

Then the Parties shall apportion such Loss between themselves according to their respective responsibility for such Loss.

* 1. If one or more Parties are NHS Foundation Trusts and the Party incurring the Loss is not responsible for all or part of the Loss and is not indemnified in respect of the Loss by one of the NHS Indemnity Schemes then the Party incurring the Loss shall be entitled to recover the Loss from the other Party (ies) pursuant to the provisions of this Agreement.

2.13. **[SINGLE SPONSOR]** Subject to clause 2.1 and 2.7 the liability of the Participating NHS / HSC Organisation to the Sponsor and the liability of the Sponsor to the Participating NHS / HSC Organisation arising out of or in connection with any breach of this Agreement or any act or omission of either Party in connection with the performance of the Study shall not exceed the greater of the amount of fees payable by the Sponsor to the Participating NHS / HSC Organisation under this Agreement or one hundred thousand (£100,000 GBP) pounds. For the avoidance of doubt, this cap applies also but not exclusively to the indemnities offered under clauses 2.3 and 2.4.

**OR**

2.13. **[CO-SPONSORS]** Subject to clause 2.1 and 2.7 the liability of the Participating NHS / HSC Organisation to the Co-Sponsors and the liability of each of the Co-Sponsors to the Participating NHS / HSC Organisation arising out of or in connection with any breach of this Agreement or any act or omission of either Party in connection with the performance of the Study shall not exceed the greater of the amount of fees payable by the Co-Sponsors to the Participating NHS / HSC Organisation under this Agreement or one hundred thousand (£100,000 GBP) pounds in respect of all, not each, Co-Sponsors. For the avoidance of doubt, this cap applies also but not exclusively to the indemnities offered under clauses 2.3 and 2.4.

**OR**

2.13. **[JOINT-SPONSORS]** Subject to clause 2.1 and 2.7 the liability of the Participating NHS / HSC Organisation to the Joint-Sponsors and the liability of the Joint-Sponsors to the Participating NHS / HSC Organisation arising out of or in connection with any breach of this Agreement or any act or omission of either Party in connection with the performance of the Study shall not exceed the greater of the amount of fees payable by the Joint-Sponsors to the Participating NHS / HSC Organisation under this Agreement or one hundred thousand (£100,000 GBP) pounds in respect of all, not each, Joint-Sponsors. For the avoidance of doubt, this cap applies also but not exclusively to the indemnities offered under clauses 2.3 and 2.4.

* 1. Notwithstanding Clause 2.13, in the case of equipment loaned by or on behalf of the Sponsor to the Participating NHS / HSC Organisation for the purposes of the Study, the Participating NHS / HSC Organisation’s liability for damage to or loss of that equipment arising from its negligence shall exclude fair wear and tear and shall not exceed the replacement value of the equipment.
  2. **[OPTION FOR NON-NHS SPONSORS ONLY]** The [Sponsor] / [Co-Sponsors[ / [Joint-Sponsors] [agree] / [agrees] that in respect of any personal injury or death of any Participant as a result of participation in the Study, [it] / [they] will provide no-fault compensation and will be insured to pay out on any such claims.

1. **Publicity**
   1. [Neither Party] / [None of the Parties] shall use the name, logo or registered image of the other [Party] / [Parties] or the Agents of such other Party or Parties in any publicity, advertising or press release, related to this Agreement, without the prior written approval of an authorised representative of that Party or those Parties.
   2. The content and timing of any publicity, advertising or press release shall be agreed by [both] / [all] Parties, such agreement not to be unreasonably withheld.
2. **Publication**
3. In accordance with all relevant laws, regulations and codes of practice, it is agreed that the Sponsor has an obligation to and shall publish the results of the full Study and that the Participating NHS / HSC Organisation shall not publish any Study Data, including through presentation or submission of an abstract, without the prior permission in writing from the Sponsor (which shall not be unreasonably withheld or delayed).
4. **Freedom of Information**
   1. Parties to this Agreement which are subject to the EIR or and the FOIA and which receive a request under EIR, or FOIA to disclose any information that belongs to another Party shall notify and consult that Party, as soon as reasonably practicable, and in any event, not later than seven (7) working days after receiving the request.
   2. The Parties acknowledge and agree that the decision on whether any exemption applies to a request for disclosure of recorded information under EIR or FOIA is a decision solely for the Party responding to the request.
   3. Where the Party responding to an EIR or FOIA request determines that it will disclose information it will notify the other Party in writing, giving at least four (4) working days’ notice of its intended disclosure.
5. **Confidentiality**
   1. Subject to Clause 5 above, the Participating NHS / HSC Organisation agrees to treat the Results, excluding any Clinical Data of the Study, as Confidential Information of the Sponsor and the Sponsor agrees to treat Personal Data, Pseudonymised Data and confidential patient information as Confidential Information.
   2. The Receiving Party agrees:
      1. To take all reasonable steps to protect the confidentiality of the Confidential Information and to prevent it from being disclosed otherwise than in accordance with this Agreement.
      2. To ensure that any of its Agents who participate in the operation of the Study are made aware of, and abide by, the requirement of this Clause 6.2.
      3. To use Confidential Information solely in connection with the operation of the Agreement and not otherwise, except in the case where the Confidential Information is Personal Data and / or confidential patient information, where it may be used solely on the basis of maintaining the common law duty of confidentiality and in accordance with the requirements of the Data Protection Legislation, including but not limited to an appropriate legal basis / special category condition, appropriate transparency information and that the purpose is not incompatible with the original purpose.
      4. Not to disclose Confidential Information in whole or in part to any person without the Disclosing Party’s prior written consent or, where the Confidential Information is Personal Data and / or confidential patient information, without maintaining the common law duty of confidentiality and in accordance with the requirements of the Data Protection Legislation, including but not limited to an appropriate legal basis / special category condition, appropriate transparency information and that the purpose is not incompatible with the original purpose.
      5. That in the event of a Party visiting the establishment of another Party, the visiting Party undertakes that any further Confidential Information that may come to the visiting Party’s knowledge as a result of any such visit, shall be treated as Confidential Information in accordance with this Clause 6.
   3. The provision of Clause 6.2 shall not apply to the whole or any part of the confidential information that is:
      1. lawfully obtained by the Receiving Party free of any duty of confidentiality;
      2. already in the possession of the Receiving Party and which the Receiving Party can show from written records was already in its possession (other than as a result of a breach of Clause 6.2.1 or 6.2.2);
      3. in the public domain (other than as a result of a breach of Clause 6.2.1 or 6.2.2);
      4. independently discovered by employees of the Receiving Party without access to or use of Confidential Information;
      5. necessarily disclosed by the Receiving Party pursuant to a statutory obligation;
      6. disclosed with prior written consent of the Disclosing Party;
      7. necessarily disclosed by the Receiving Party by virtue of its status as a public authority in terms of the EIR or the FOIA;
      8. published in accordance with the provisions of Clause 4.
   4. The restrictions contained in Clause 6.2 shall remain in force without limit in time in respect of Personal Data and any other information which relates to a patient, their treatment and / or medical records. Save as aforesaid and unless otherwise expressly set out in this Agreement, these clauses shall remain in force for a period of ten (10) years after the termination or expiry of this Agreement.
6. **Order of Precedence**
   1. Should there be any inconsistency between the Protocol and the terms of this Agreement, or any other document incorporated herein, the terms of the Protocol shall prevail to the extent of any inconsistency except insofar as the inconsistency relates to Appendix 1 Clauses 2, 4, 5 and 6 of this Agreement, and when they form part of this Agreement Appendices 4, 5 and 6, whereby the terms of this Agreement shall prevail.
7. **Termination**
   1. This Agreement may be terminated immediately by notice in writing by [either] / [any] Party if [the other] / [another] Party is:
      1. in material or continuing breach of any of its obligations under this Agreement and fails to remedy the breach (if capable of remedy) for a period of thirty (30) calendar days after written notice by the non-breaching Party; or
      2. declared insolvent or has an administrator or receiver appointed over all or any part of its assets or ceases or threatens to cease to carry on its business.
   2. Subject to Clause 8.4, the Sponsor may terminate this Agreement by notice in writing:
      1. if the regulatory permissions and approvals previously granted to perform the Study are withdrawn;
      2. if funding is withdrawn or terminated for any reason or if it has been agreed that there are insufficient funds available to continue the Study;
      3. if advised to do so by the Study management or oversight committee / group, or other similar arrangements as defined in the Protocol;
      4. in the event of cessation of supply of medical devices, equipment or similar necessary for the Study, or information or resources critical to the Study.
   3. Subject to Clause 8.4, any Party may terminate this Agreement by notice in writing if the Principal Investigator or Local Collaborator becomes unavailable to continue their supervision of the Study for any reason and a replacement acceptable to both Parties is not found.
   4. In the event of termination or expiry of this Agreement, or if the Participating NHS / HSC Organisation chooses to cease Participant recruitment in accordance with Clause 8.6, the following provisions shall apply:
      1. The Parties shall work together to facilitate an orderly cessation of the Study at the Participating NHS / HSC Organisation (or cessation of recruitment of Participants, where the Participating NHS / HSC Organisation has chosen to cease recruiting in accordance with Clause 8.6), taking into account the rights, safety, well-being and continuity of treatment (if appropriate) of the Participants and applicable law.
      2. The Sponsor shall, subject to the prior compliance of the Participating NHS / HSC Organisation with its obligations on termination, upon receipt of a valid invoice submitted in accordance with Appendix 2, pay the Participating NHS / HSC Organisation any outstanding monies due to the Participating NHS / HSC Organisation as at the date of termination.
      3. The Participating NHS / HSC Organisation shall ensure that there is prompt refund to the Sponsor of the amount, if any, by which the cumulative cost paid by the Sponsor to the Participating NHS / HSC Organisation under this Agreement exceeds the actual commitments incurred by the Participating NHS / HSC Organisation up to the date of termination, or cessation of Participant recruitment, and any other costs in accordance with Appendix 2 and, in the event of cessation of recruitment of Participants, where the Participating NHS / HSC Organisation has chosen to cease recruiting in accordance with Clause 8.6, an amendment in writing signed by the Sponsor and the Trial Site shall be made to any payments due under Appendix 2 to reflect the reduction in recruitment numbers.
      4. The Participating NHS / HSC Organisation shall provide to the Sponsor all Study Data and other relevant information and / or data relating to work undertaken by the Participating NHS / HSC Organisation prior to and including the date of termination and co-operate with all reasonable requests from the Sponsor including any continued monitoring of Participants in accordance with the Protocol.
      5. Where applicable, the Participating NHS / HSC Organisation shall ensure that all reasonable instructions by the Sponsor as regards the return or disposal of all unused supplies, or medical devices or other equipment or items previously provided to the Participating NHS / HSC Organisation for the purposes of the Study are complied with.
      6. The Participating NHS / HSC Organisation shall ensure that the instructions of the Sponsor regarding the transfer and / or storage of all information, material or data relating to the Study collected by the Trial Site in the course of carrying out the Study are complied with.
      7. Unless otherwise agreed in writing with the Sponsor, the costs and expenses of returning, dispatching, transferring or storing items shall be in accordance with Appendix 2.
   5. Termination under this Clause 8 will be without prejudice to any other rights or remedies of either Party under this Agreement or at law and will not affect any accrued rights or liabilities of either Party at the date of termination.
   6. The Participating NHS / HSC Organisation will notify the Sponsor contact named at Question 4 if, for any reason, it elects to cease Participant recruitment.

# Appendix 2: Study Set Up Arrangements

|  |  |
| --- | --- |
| Where this Organisation Information Document is to be used as the Agreement between Sponsor and Participating NHS / HSC Organisation, please select from the two options below. | |
| **\***Are there funds being provided to this Participating NHS / HSC Organisation by the Sponsor? If no, Part A of this appendix should be left blank. If yes, Part A of this Appendix forms part of the Agreement between the Participating NHS / HSC Organisation and the Sponsor. | Select yes or no. |
| **\***Are there resources / equipment, etc. being provided to this Participating NHS / HSC Organisation by the Sponsor? If no, Part B of this Appendix should be left blank. If yes, Part B of this Appendix forms part of the Agreement between the Participating NHS / HSC Organisation and the Sponsor. | Select yes or no. |

### A. Financial Arrangements

The overall, study-wide recruitment for this study is competitive with a maximum figure of [X] Participants. Once this target has been reached, the Sponsor will notify the Participating NHS / HSC Organisation. No additional per participant payments will be made by the Sponsor to the Participating NHS / HSC Organisation for Participants consented after such notification becomes effective.

|  |  |  |
| --- | --- | --- |
|  | **\*Area of Cost** | **\*Payment (£ Sterling)** |
| 1**\*** | Click here to enter text | Click here to enter text |
| 2**\*** | Click here to enter text | Click here to enter text |
| 3**\*** | Click here to enter text | Click here to enter text |
| 4**\*** | Click here to enter text | Click here to enter text |
| 5**\*** | Click here to enter text | Click here to enter text |

* Payments by the Sponsor during the course of the Study are dependent on continued availability of funds from the Funder. In the event of a change to the availability of funds, the Participating NHS / HSC Organisation will be notified and a decision would be made about the continuation of the Study at the Participating NHS / HSC Organisation.
* The Sponsor reserves the right to amend / withhold final payments in cases where the Participating NHS / HSC Organisation has not performed their duties according to the terms of the Protocol and / or this Agreement.
* The Participating NHS / HSC Organisation is expected to keep accurate accounts of all costs incurred in the performance of the Agreement. Financial records, including substantiating documents, shall be retained by the Participating NHS / HSC Organisation for a period of five (5) years from the date of submission of the final expenditure report, except that records pertaining to audits, appeals, litigation or settlement of claims arising out of performance of the Agreement shall be retained until such audits, appeals, litigation or claims have been disposed of.
* All costs incurred under the Agreement may be subject to audit by the Sponsor. The Participating NHS / HSC Organisation shall allow the appropriate Sponsor representatives (including the Funder) access to records where necessary to support costs relating to this Agreement.
* Payment shall be made in Pounds Sterling according to this Appendix 2 on presentation of VAT (if applicable) invoices from the Participating NHS / HSC Organisation.
* Details of requested payments, including Participant identification number(s) (where applicable) and amounts requested, must be submitted with each invoice.
* At the end of the Study any outstanding amounts must be submitted by the Participating NHS / HSC Organisation within the timeframe reasonably requested by the Sponsor, after which any outstanding invoices will not be paid.

If VAT is payable, then the Sponsor shall pay the VAT in addition to the payment of the agreed costs on presentation of a VAT invoice in which the VAT is stated as a separate item. Such invoices should quote the Participating NHS / HSC Organisation’s VAT registration number. If VAT is not payable, then the Sponsor shall issue a VAT exemption certificate.

Schedule of payments and details of payment arrangements

**\***Invoices to be submitted [Insert FREQUENCY OR INTERVAL e.g. quarterly in arrears following the start of the study at the Participating NHS / HSC Organisation] to:

[Insert JOB TITLE, NAME OF BODY & ADDRESS]

**^**Payment to be made by cheque payable to:

[Insert NAME OF PARTICIPATING NHS / HSC ORGANISATION]

**^**and remitted to:

[Insert JOB TITLE/POSITION]

[Insert ADDRESS]

**^**Or arrange bank transfer to: [Insert BANK NAME].

**^**Sort code: [Insert SORT CODE]

**^**Account: [Insert ACCOUNT NUMBER]

**^**And send the relevant paperwork to [Insert ADDRESSEE FOR PAPERWORK]at the above address.

*Invoices must be paid promptly [within xx days of receipt]. No payment shall be made in the case where invoices are not presented in a complete, accurate and timely fashion and funding has been irrecoverably reclaimed by the Funder as a result of such delay or inadequacy.*

### B. Supplies Arrangements

Any equipment, materials, consumables, software or other items being provided by the Sponsor or procured by the Participating NHS / HSC Organisation for use in the Study shall be specified below.

Note 1: Parties should complete the table below. If the Participating NHS / HSC Organisation is to procure any items and is to be reimbursed by the Sponsor this should be specified in this Appendix. Similarly if the Participating NHS / HSC Organisation is to pay the Sponsor for any items provided to the Participating NHS / HSC Organisation by or on behalf of the Sponsor this should be specified in this Appendix.

Note 2: Parties should specify in this Appendix, as appropriate, arrangements for:

- Ownership of items

- Insurance

- Storage instructions

- Instructions for use, return and / or destruction

- Any training to be provided

- Maintenance of equipment

| **Item** | **Quantity** | **Frequency of supply** | **Responsibility to supply / procure**  **(either Sponsor or Participating NHS / HSC Organisation only)** |
| --- | --- | --- | --- |
| Click here to enter text | Click here to enter text | Click here to enter text | Click here to enter text |
| Click here to enter text | Click here to enter text | Click here to enter text | Click here to enter text |
| Click here to enter text | Click here to enter text | Click here to enter text | Click here to enter text |
| Click here to enter text | Click here to enter text | Click here to enter text | Click here to enter text |
| Click here to enter text | Click here to enter text | Click here to enter text | Click here to enter text |

# Appendix 3: Material Transfer Provisions

|  |  |
| --- | --- |
| Where this Organisation Information Document is to be used as the Agreement between Sponsor and Participating NHS / HSC Organisation, please select an option below. | |
| **\***Does this study involve the transfer of Material from this Participating NHS / HSC Organisation to the Sponsor or its Agents? If no, this Appendix does not form part of this Agreement. If yes, these provisions form part of the Agreement between the Sponsor and this Participating NHS / HSC organisation. | Select yes or no. |

1. In accordance with the Protocol, the Participating NHS / HSC Organisation shall send Material to the [Sponsor] / [Joint-Sponsors] / [a Co-Sponsor] or, in accordance with Clause 7 below, to a third party nominated by the [Sponsor] / [Joint-Sponsors] / [either of the Co-Sponsor].
2. The Participating NHS / HSC Organisation warrants that all Material has been collected with appropriate informed consent and has been collected and handled in accordance with applicable law (including, without limitation, the Human Tissue Act 2004 or the Human Tissue (Scotland) Act 2006 (as the case may be)) and as required by the Protocol.
3. Subject to Clause 2 above, the Materials are supplied without any warranty, expressed or implied, including as to their properties, merchantable quality, fitness for any particular purpose, or that the Materials are free of extraneous or biologically active contaminants which may be present in the Materials.
4. The [Sponsor] / [Joint-Sponsors] / [one of the Co-Sponsor] shall ensure, or procure through an agreement with the [Sponsor’s] / [Joint-Sponsors’] / [Co-Sponsor’s] nominee as stated in Clause 1 above that:
   1. the Material is used in accordance with the Protocol, the consent of the Participant, and the ethics approval for the study;
   2. the Material is handled and stored in accordance with applicable law;
   3. the Material shall not be redistributed or released to any person other than in accordance with the Protocol or for the purpose of undertaking other studies approved by an appropriate ethics committee and in accordance with the Participant’s consent.
5. The Parties shall comply with all relevant laws, regulations and codes of practice governing the research use of human biological material.
6. The Participating NHS / HSC Organisation and the [Sponsor] / [Joint-Sponsors] / [a Co-Sponsor] shall each be responsible for keeping a record of the Material that has been transferred according to this Appendix.
7. To the extent permitted by law the Participating NHS / HSC Organisation and its staff shall not be liable for any consequences of the supply to or the use by the [Sponsor] / [Joint-Sponsors] / [Co-Sponsor] of the Material or of the supply to or the use by any third party to whom the [Sponsor] / [Joint-Sponsors] / [a Co-Sponsor]subsequently provides the Material or the [Sponsor’s] / [Joint-Sponsors’] / [Co-Sponsor’s] nominee as stated in Clause 1 above, save to the extent that any liability which arises is a result of the negligence of the Participating NHS / HSC Organisation.
8. The [Sponsor] / [Joint-Sponsors] / [Co-Sponsor]undertake(s) that, in the event that Material is provided to a third party in accordance with Clause 2 above, [it] / [they] shall require that such third party shall undertake to handle any Material related to the Study in accordance with all applicable statutory requirements and codes of practice and under terms no less onerous than those set out in this Appendix.
9. Any surplus Material that is not returned to the Participating NHS / HSC Organisation or retained for future research (in line with Participant consent) shall be destroyed in accordance with applicable law (including, without limitation, the Human Tissue Act 2004 or the Human Tissue (Scotland) Act 2006 (as the case may be)).

*\*This Appendix does not remove the need for the Sponsor to clearly lay out in their Protocol (and to potential Participants in the Participant information) at a minimum the following information for all Material taken: 1) The nature of the Materials, 2) The reason that the Material is being taken, 3) where the Material is to be sent and, 4) what will happen to any remaining Material once it has been processed / analysed, et cetera for the purposes of this Study (for example return, retention or destruction). Detailed guidance on what information should be included in a Protocol may be found on the HRA website:* [*www.hra.nhs.uk*](https://www.hra.nhs.uk/)

# Appendix 4: Data Processing Agreement

|  |  |
| --- | --- |
| Where this Organisation Information Document is to be used as the Agreement between Sponsor and Participating NHS / HSC Organisation, please select an option below. | |
| **\***Doesthis study involve any Processing of Personal Data by this Participating NHS / HSC Organisation on behalf of the Sponsor. If no, this appendix does not form part of this Agreement. If yes, these provisions form part of the Agreement between the Sponsor and this Participating NHS / HSC Organisation.  For the avoidance of doubt, when used, these provisions are intended to form a legally binding contractual obligation for the purposes of compliance with the GDPR, specifically GDPR Article 28 (3). | Select yes or no. |

1. For the purposes of the Data Protection Legislation, the Sponsor is the Controller and the Participating NHS / HSC Organisation is the Sponsor's Processor in relation to all Processing of Personal Data that is Processed for the purpose of this Study and for any future research use under the Controllership of the Sponsor, that would not have taken place but for this Agreement regardless where that Processing takes place.
2. The Parties acknowledge that whereas the Sponsor is the Controller in accordance with Clause 1 of this Appendix, the Participating NHS / HSC Organisation is the Controller of the Personal Data collected for the purpose of providing clinical care to the Participants. This Personal Data, Processed for care purposes under the controllership of the Participating NHS / HSC Organisation, may be the same Personal Data that is Processed for research purposes under the separate Controllership of the Sponsor in accordance with this Agreement.
3. Where the Participating NHS / HSC Organisation is the Sponsor's Processor and thus where the Processing is undertaken by the Participating NHS / HSC Organisation for the purposes of the Study, Clauses 5.a. to 5.j. below will apply. For the avoidance of doubt, such Clauses do not apply where the Participating NHS / HSC Organisation is Processing the Participant Personal Data as a Controller.
4. The Participating NHS / HSC Organisation agrees only to Process Personal Data for and on behalf of the Sponsor in accordance with the instructions of the Sponsor and for the purpose of the Study and to ensure the Sponsor’s compliance with the Data Protection Legislation;
5. The Participating NHS / HSC Organisation agrees to comply with the obligations applicable to Processors described by Article 28 GDPR including, but not limited to, the following:
   1. to implement and maintain appropriate technical and organisational security measures sufficient to comply at least with the obligations imposed on the Controller by Article 28(1);
   2. to not engage another processor without the prior written authorisation of the Sponsor (Article 28(2)) [DELETE IF THE STUDY DOES NOT INVOLVE PICS, such authorisation for engaging Participant Identification Centres (PICs) being hereby given. The Participating NHS / HSC Organisation will notify the Sponsor of any new PIC engaged in advance of that PIC’s commencement of PIC activities and the Sponsor will notify the Participating NHS / HSC Organisation of any objections in a timely manner];
   3. to Process the Personal Data only on documented instructions from the Sponsor unless required to do otherwise by legislation, in which case the Participating NHS / HSC Organisation shall notify the Sponsor before processing, or as soon as possible after processing if legislation requires that the Processing occurs immediately, unless legislation prohibits such notification on important grounds of public interest (Article 28(3)(a));
   4. to ensure that personnel authorised to Process Personal Data are under confidentiality obligations (Article 28(3)(b));
   5. to take all measures required by Article 32 GDPR in relation to the security of Processing (Article 28(3)(c));
   6. to respect the conditions described in Article 28(2) and (4) for engaging another Processor (Article 28(3)(d));
   7. to, taking into account the nature of the Processing, assist the Sponsor, by appropriate technical and organisational measures, insofar as this is possible, to respond to requests for exercising Data Subjects’ rights (Article 28(3)(e));
   8. to assist the Controller, to ensure compliance with the obligations pursuant to Articles 32 to 36 GDPR taking into account the nature of the Processing and the information available to the Participating NHS / HSC Organisation (Article 28(3)(f));
   9. to, at the choice of the Sponsor, destroy or return all Personal Data to the Sponsor at the expiry or early termination of the Agreement, unless storage is legally required (Article 28(3)(g)) or where that Personal Data is held by the Participating NHS / HSC Organisation as Controller for the purpose of clinical care or other legal purposes; and
   10. to maintain a record of Processing activities as required by Article 30(2) GDPR.
6. The Participating NHS / HSC Organisation shall ensure that:
   1. its Agents do not process Personal Data except in accordance with this Agreement (and in particular the Protocol);
   2. it takes all reasonable steps to ensure the reliability and integrity of any of its Agents who have access to the Personal Data and ensure they:
      1. are aware and comply with the Participating NHS / HSC Organisation 's duties under this clause;
      2. are subject to mandatory training in their information governance responsibilities and have appropriate contracts including sanctions, including for breach of confidence or misuse of data; and
      3. are informed of the confidential nature of the Personal Data and understand the responsibilities for information governance, including their obligation to process Personal Data securely and to only disseminate or disclose for lawful and appropriate purposes.
7. The Participating NHS / HSC Organisation agrees to:
   1. allow the Sponsor(s) or another auditor appointed by the Sponsor(s) to audit the Participating NHS / HSC Organisation’s compliance with the obligations described by this Appendix, Data Protection Legislation in general and Article 28 GDPR in particular, on reasonable notice subject to the Sponsor complying with all relevant health and safety and security policies of the Participating NHS / HSC Organisation and / or to provide the Sponsor with evidence of its compliance with the obligations set out in this Agreement; and;
   2. obtain prior agreement of the Sponsor to store or Process Personal Data outside the UK and European Economic Area.
8. Where the Participating NHS / HSC Organisation stores or otherwise Processes Personal Data outside of the UK and the European Economic Area as the Sponsor’s Processor, it warrants that it does so in compliance with the Data Protection Legislation.

# Appendix 5: Data Sharing Agreement

|  |  |
| --- | --- |
| Where this Organisation Information Document is to be used as the Agreement between Sponsor and Participating NHS / HSC Organisation, please select an option below. | |
| **\***Does this study involve the transfer of Personal Data or Pseudonymised Data from this Participating NHS / HSC Organisation to the Sponsor or its Agents? If no, this Appendix does not form part of this Agreement. If yes, these provisions form part of the Agreement between the Sponsor and this Participating NHS / HSC Organisation. | Select yes or no. |

1. Neither Personal Data, nor Pseudonymised Data of actual or potential Participants shall be disclosed to the Sponsor by the Participating NHS / HSC Organisation, save where this is required directly or indirectly to satisfy the requirements of the Protocol, or for the purpose of monitoring or reporting adverse events, or in relation to a claim or proceeding brought by a Participant in connection with the Study.
2. The Sponsor agrees to use Personal Data and / or Pseudonymised Data supplied under this Agreement solely in connection with the operation of the Agreement, or otherwise for purposes not incompatible with this original purpose (GDPR Article 5(1)(b)), and not otherwise. In particular:
   1. not to disclose Personal Data and / or Pseudonymised Data to any person except in accordance with applicable legal requirements and codes of practice.
3. The Sponsor agrees to comply with the obligations placed on a Controller by the Data Protection Legislation. This is not limited to, but includes, being responsible for and able to demonstrate compliance with the principles relating to Processing of Personal Data (GDPR Article 5).
4. The Sponsor agrees to ensure persons Processing Personal Data and / or Pseudonymised Data under this Agreement are equipped to do so respectfully and safely. In particular to ensure that:
5. any persons (excluding employees, honorary employees, students, researchers, consultants and subcontractors of the Participating NHS / HSC Organisation) Processing Personal Data and / or Pseudonymised Data understand the responsibilities for information governance, including their obligation to Process Personal Data and / or Pseudonymised Data securely and to only disseminate or disclose for lawful and appropriate purposes.
6. any persons (excluding employees, honorary employees, students, researchers, consultants and subcontractors of the Participating NHS / HSC Organisation) have appropriate contracts providing for personal accountability and sanctions for breach of confidence or misuse of data including deliberate or avoidable data breaches.
7. The Sponsor agrees to proactively prevent data security breaches and to respond appropriately to incidents or near misses. In particular to:
8. ensure that Personal Data and / or Pseudonymised Data are only accessible to persons who need it for the purposes of the Study, or for other purposes that are not incompatible with that purpose and that are not incompatible with the Participant consent, and to remove access as soon as reasonably possible once it is no longer needed;
9. ensure all access to Personal Data and / or Pseudonymised Data on IT systems processed for Study purposes can be attributed to individuals.
10. review processes to identify and improve processes which have caused breaches or near misses, or which force persons Processing Personal Data and / or Pseudonymised Data to use workarounds which compromise data security;
11. adopt measures to identify and resist cyber-attacks against services and to respond to relevant external security advice;
12. take action immediately following a data breach or near miss.
13. The Sponsor agrees to ensure Personal Data and / or Pseudonymised Data are Processed using secure and up to date technology. In particular to:
14. ensure no unsupported operating systems, software or internet browsers are used to support the Processing of Personal Data and / or Pseudonymised data for the purposes of the study;
15. put in place a strategy for protecting relevant IT systems from cyber threats which is based on a proven cyber security framework such as Cyber Essentials;
16. ensure IT suppliers are held accountable via contracts for protecting Personal Data and / or Pseudonymised Data they Process and for meeting all relevant information governance requirements.

# Appendix 6: Intellectual Property Rights

|  |  |
| --- | --- |
| Where this Organisation Information Document is to be used as the Agreement between Participating NHS / HSC Organisation, please select an option below. | |
| **\***Does this study require the protection of Background Intellectual Property Rights, or is there potential for the generation of new Intellectual Property? If no, this Appendix does not form part of this Agreement. If yes, these provisions form part of the Agreement between the Sponsor and this Participating NHS / HSC Organisation. | Select yes or no. |

1. All Background Intellectual Property Rights (including licences) and Background Know-How and their improvements used in connection with the Study shall remain the property of the Party introducing the same and the exercise of such rights for purposes of the Study shall not knowingly infringe any third party’s rights.
2. All Intellectual Property Rights and Know-How in the Protocol and other documents and information disclosed by the Sponsor, and in the Study Data, excluding clinical procedures developed or used by the Participating NHS / HSC Organisation independently of the Study, shall belong to the Sponsor. The Participating NHS / HSC Organisation hereby assigns all such Intellectual Property Rights, and undertakes to disclose all such Know-How, to the Sponsor.
3. Subject to Clauses 1 and 2, all Intellectual Property Rights deriving or arising from the Material or any derivations of the Material provided to the Sponsor by the Participating NHS / HSC Organisation shall belong to the Sponsor.
4. At any time within the duration of the Study, the Participating NHS / HSC Organisation shall at the request and expense of the Sponsor execute all such documents and do all acts necessary to fully vest the Intellectual Property Rights in the Sponsor. To give effect to this Clause 4, the Participating NHS / HSC Organisation shall ensure that its Agents involved in the Study assign such Intellectual Property Rights falling within Clauses 2 and 3 and disclose such Know-How to the Participating NHS / HSC Organisation.
5. Subject to this Clause 5 and Clause 6, nothing in this Appendix shall be construed so as to prevent or hinder the Participating NHS / HSC Organisation from using its own Know-How or Study Data that is Clinical Data gained during the performance of the Study, at its own risk, in the furtherance of its normal activities of providing clinical care to the extent that such use does not result in the disclosure or misuse of Confidential Information or the infringement of an Intellectual Property Right of the Sponsor, or their Funder. This Clause 5 does not permit the disclosure of any of the Study Data, all of which remain confidential until publication of the results. Any Study Data not so published remains the Confidential Information of the Sponsor, or their Funder.
6. The Participating NHS / HSC Organisation may, with the prior written permission of the Sponsor (such permission not to be unreasonably withheld), use Study Data gained during the performance of the Study, at its own risk, in the furtherance of its normal activities of commissioning clinical services, teaching and research to the extent that such use does not result in the disclosure or misuse of Confidential Information or the infringement of an Intellectual Property Right of the Sponsor or their Funder. This Clause 6 does not permit the disclosure of any of the Study Data, all of which remain confidential until publication of the results of the Study.

**Authorisation When Using This Organisation Information Document as An Agreement**

|  |  |
| --- | --- |
| **Authorisation on behalf of Participating NHS / HSC Organisation**  It is not intended that this confirmation requires wet-ink signatures, or a passing of hard copies between the Sponsor and Participating NHS / HSC Organisation. Instead, Sponsors are expected to accept confirmation by email from an individual empowered by the Participating NHS / HSC Organisation to agree to the commencement of research (including any budgetary responsibility, where the study involves the transfer of funds). | |
| **^ Authorised on behalf of Participating NHS / HSC Organisation by:** | |
| **Name** | Enter name |
| **Job Title** | Enter job title |
| **Organisation Name** | Enter organisation name |
| **Date** | Select date of authorisation |