**Confidentiality, Data Protection and Freedom of Information**

For the purposes of this Agreement, the terms “the Sponsor”, “the Participating Organisation(s)” and “the Study” have the same meaning as those same terms set out in the HRA Statement of Activities for Participating NHS Organisations in England.

This Agreement is intended to set out the terms and conditions upon which confidentiality, data protection and freedom of information will be addressed for the Study.

A reference to “a party” or “the parties” is a reference to the Sponsor and/or the Participating Organisation(s).

1. Participant Confidentiality
   1. The parties agree to adhere to all applicable statutory requirements and mandatory codes of practice in respect of confidentiality (including medical confidentiality) in relation to participants.
   2. Personal Data shall not be disclosed to the Sponsor by the Participating 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.
   3. Neither the Sponsor nor the Participating Organisation shall disclose the identity of participants to third parties without the prior written consent of the participant except in accordance with applicable statutory requirements and codes of practice, including HSCIC Code of Practice on Confidential Information.
   4. The Sponsor agrees to act as Data Controller in relation to any processing of Personal Data under this Agreement. This extends to all processing that would not have taken place but for this Agreement regardless where that processing takes places. In particular, it extends to processing by the Participating Organisation where that processing is undertaken solely for the purposes of the Study.
   5. The Sponsor agrees to comply with the obligations placed on a Data Controller by the Data Protection Act 1998. This is not limited to, but includes, ensuring that:
      1. Personal Data shall be obtained only for one or more specified and lawful purposes, and shall not be further processed in any manner incompatible with that purpose or those purposes ;
      2. Personal Data are adequate, relevant and not excessive in relation to the purpose or purposes described within the protocol;
      3. Personal Data shall be accurate and, where necessary, kept up to date;

1.5.4. Personal Data shall be processed in accordance with the rights of data subjects under the Data Protection Act 1998.

* 1. The Sponsor agrees to ensure appropriate training. In particular to ensure that any persons (excluding employees, honorary employees, students, researchers, consultants and subcontractors of the Participating Site) processing Personal Data are subject to appropriate training in the information governance responsibilities.
  2. The Participating Organisation agrees to ensure that its employees, honorary employees, students, researchers, consultants and subcontractors processing Personal Data are subject to appropriate training in the information governance responsibilities.
  3. The Sponsor has in place and will comply with its Information Security Policy, which identifies the policies and processes that the Sponsor uses to ensure the confidentiality, integrity and availability of the Sponsor’s information.
  4. The Sponsor agrees to use Personal Data solely in connection with the operation of this Agreement and the Study and not otherwise. In particular:
     1. not to disclose Personal Data in whole or in part to any person without the Participating Organisation’s prior written consent;
     2. not to disclose other than pursuant to a data sharing agreement that conforms to the requirements set out in the Information Commissioner’s data sharing code of practice.
  5. The Participating Organisation agrees to act as Data Processor on behalf of the Sponsor as Data Controller for processing undertaken under this Agreement solely for the purposes of the Study. The Participating Organisation agrees to comply with the obligations placed on it as the data controller by the seventh data protection principle ("the Seventh Principle") set out in the Data Protection Act 1998, namely:
     1. to maintain technical and organisational security measures sufficient to comply at least with the obligations imposed on the Data Controller by the Seventh Principle;
     2. only to process Personal Data for and on behalf of the Data Controller, in accordance with the instructions of the Data Controller and for the purpose of the Study and to ensure the Data Controller’s compliance with the Data Protection Act 1998;
     3. to allow the Sponsor to audit the Participating Organisation’s compliance with the requirements of this clause on reasonable notice and/or to provide the Data Controller with evidence of its compliance with the obligations set out in this clause;
     4. the Participating Organisation shall obtain prior agreement of the Sponsor to store or process Personal Data at sites outside the European Economic Area (comprising the countries of the European Community, Norway, Iceland and Liechtenstein).

1. Freedom of Information
   1. Parties to this Agreement which are subject to the Environmental Information Regulations 2004 (EIR) and the Freedom of Information Act 2000 (FOIA) or the Freedom of Information (Scotland) Act 2002 (FOI(S)A) and which receive a request under EIR, FOIA or FOI(S)A 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) calendar 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, FOIA or FOI(S)A is a decision solely for the party responding to the request.
   3. Where the party responding to an EIR, FOIA or FOI(S)A request determines that it will disclose information it will notify the other party in writing, giving at least four (4) calendar days’ notice of its intended disclosure.
2. Confidential information
   1. For the purposes of this Agreement, “confidential information” means any information disclosed by one party to the other for use in this Study and identified as confidential before or at the time of disclosure or where it is not possible or practical to mark the information as confidential at the time of disclosure it shall be identified as confidential at the time of disclosure and accompanied within 15 days of said disclosure by written confirmation that the information is confidential and has been disclosed visually, orally or in any other manner;
   2. The receiving party agrees 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.
   3. Subject to clause 3.4 below, the Participating Organisation agrees to treat the results, excluding any clinical data of the Study, as confidential information disclosed by the Sponsor and the Sponsor agrees to treat Personal Data as confidential information disclosed by the Participating Organisation.
   4. The receiving party agrees:
      1. To ensure that any of its employees, students, researchers, consultants or subcontractors who participate in the operation of the Study are made aware of, and abide by, the requirement of this clause 3 and, where relevant, clause 2.
      2. To use confidential information solely in connection with the operation of the Agreement and not otherwise.
      3. Not to disclose confidential information in whole or in part to any person without the disclosing party’s prior written consent.
   5. The provision of clause 3 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 3.1 or 3.2);
      3. in the public domain (other than as a result of a breach of clause 3.1 or 3.2);
      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 Freedom of Information Act 2000;
      8. published in accordance with HRA expectations on research transparency.
   6. The restrictions contained in clauses 2 and 3 shall remain in force without limit in time in respect of Personal Data or which relates to a patient, his or her 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 5 years after the termination or expiry of this Agreement.