Data Sharing, Confidentiality, 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 and HCRW Statement of Activities for Participating NHS Organisations in England or Wales.

For the purposes of this Agreement, the term “Data Protection Legislation” means the Data Protection Act 2018 (DPA) and the EU General Data Protection Regulation (GDPR) including subordinate legislation and any data protection law amending, replacing, superseding or supplementing the DPA or GDPR during the term.

For the purposes of this Agreement, the term “Personal Data” has the meaning as defined in the Data Protection Legislation.

This Agreement is intended to set out the terms and conditions upon which data sharing, confidentiality, 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. Data Sharing

1.1. The parties agree to adhere to all applicable statutory requirements and mandatory codes of practice in respect of data sharing and confidentiality (including medical confidentiality) in relation to participants. For the avoidance of doubt each party shall comply at all times with the Data Protection Legislation for the purposes of performing its obligations and exercising its rights under these terms and conditions and shall not perform its obligations under this Agreement in such a way as to cause the other party to breach any of its obligations under the Data Protection Legislation.

1.2. 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.

1.3. The Sponsor agrees to use Personal Data solely in connection with the operation of the Study, or otherwise for purposes not incompatible with this original purpose (Article 5, 1 (b) GDPR), and not otherwise. In particular,

1.3.1. Not to disclose Personal Data to any person except in accordance with applicable legal requirements and codes of practice.

1.4. 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 (Article 5 GDPR).

1.5. The Sponsor agrees to ensure persons processing Personal Data under this Agreement (excluding employees, honorary employees, students, researchers, consultants and subcontractors of the Participating Organisation) are equipped to do so respectfully and safely.
1.6. The Sponsor agrees to proactively prevent data security breaches and to respond appropriately to incidents or near misses.

1.7. The Sponsor agrees to ensure data are processed using secure and up to date technology.

1.8. 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 Organisation) processing Personal Data are subject to appropriate training in the information governance responsibilities.

1.9. The Participating Organisation agrees to ensure that its employees, honorary employees, students, researchers, consultants and subcontractors processing Personal Data are equipped to do so respectfully and safely and are subject to appropriate training in the information governance responsibilities.

1.10. 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.

2. Freedom of Information

2.1. 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.

2.2. 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.

2.3. 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.

3. Confidential information

3.1. 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;

3.2. 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.
3.3. 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 and confidential patient data as confidential information disclosed by the Participating Organisation.

3.4. The receiving party agrees:

3.4.1. 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.

3.4.2. To use confidential information solely in connection with the operation of the Agreement and not otherwise.

3.4.3. Not to disclose confidential information in whole or in part to any person without the disclosing party’s prior written consent.

3.5. The provision of clause 3 shall not apply to the whole or any part of the confidential information that is:

3.5.1. lawfully obtained by the receiving party free of any duty of confidentiality;

3.5.2. 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);

3.5.3. in the public domain (other than as a result of a breach of clause 3.1 or 3.2);

3.5.4. independently discovered by employees of the receiving party without access to or use of confidential information;

3.5.5. necessarily disclosed by the receiving party pursuant to a statutory obligation;

3.5.6. disclosed with prior written consent of the disclosing party;

3.5.7. necessarily disclosed by the receiving party by virtue of its status as a public authority in terms of the FOIA or the FOI(S)A.

3.6. 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.