

Data Sharing Agreement (Non-Commercial Research Studies)

Between

The Confederation, Hillingdon CIC

OF Link 1A, Civic Centre, High Street, Uxbridge, UB8 1UW

“Sponsor”

AND

KING EDWARDS AND SWAKELEYS MEDICAL CENTRE E86024

“Participating GP Practices”

Which are collectively referred to as the **“Parties”** or individually referred to as a **“Party”**

NOW

WHEREAS the Sponsor is an NHS organisation / University / OTHER;

WHEREAS the Co-sponsors / Joint-Sponsors are an NHS organisation /OTHER

WHEREAS The Sponsor has previously contracted or otherwise engages with the Participating GPs/Practices to undertake the clinical research Study/Studies.

WHEREAS the Participating GPs/Practices is a joint Controller of the Sponsor of Personal Data Processed for the purpose of the Study/Studies, the Sponsor intends to govern this Data Sharing/Processing through this Agreement, in addition to existing contracting and in compliance with its obligations as a Controller under GDPR Article 28(3).

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Schedule 1: **List of Research Studies Subject to this Agreement**

In respect of the clinical research Studies the above Parties HEREBY AGREE AS FOLLOWS:

1. Definitions

1.1 The following words and phrases 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, any nurse or other health professional), any such person's principal employer in the event it is not the Participating Site 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, together with the schedule annexed hereto;
- **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;
- **Controller**
shall have the meaning set out in the Data Protection Legislation;
- **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; and, as a result of the favourable decision from the competent authorities of the EU on the adequacy of the UK data protection regime will include the requirements set out or referenced in Part Three, Title VII, Article 71(1) of the Withdrawal Agreement signed by the UK and the EU in December 2019;

- **Data Subject**
as defined in the Data Protection Legislation;

Joint-Sponsor

either or both organisations who jointly accept the responsibilities and liabilities associated with sponsoring the Studies listed. 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;

- **Participant**

any person who consents (where consent is necessary) and is enrolled to take part in any of the Studies listed at Schedule 1. All references to Participants in this Agreement refer to those recruited by or through the Participating Site;

- **Participating Site**

the contracting body for the Site/s;

- **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 Data Protection Legislation and which relates to any Participant or his or her treatment or medical history;

- **Principal Investigator or PI**

the leader responsible for a team of individuals conducting any one of the Studies listed in Schedule 1 at the Site;

- **Process**

as defined in the Data Protection Legislation (and "Processing" and "Processed" shall be construed accordingly);

- **Processor**

shall have the meaning as set out in the Data Protection Legislation;

- **Site**

any premises occupied by the Participating GPs/Practices in which or through which the Study/Studies will be conducted;

- **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) signatory to this Agreement;

- **Study**

any one or more of the clinical research Studies that are the subject of this Agreement, as listed to Schedule 1 of this Agreement.

1.2 As the mutual exchange of obligations and promises is regarded as consideration, this Agreement forms a legally binding contract.

1.3 Any reference to a statutory provision, code or guidance shall be deemed to include reference to any subsequent modification or re-enactment of it.

2. Data Protection

2.1 Data Processing Terms

- 2.1.1 For the purposes of the Data Protection Legislation, the Sponsor is the Controller and the Participating Site is the Sponsor's Processor in relation to all Processing of Personal Data that is Processed for the purpose of the Studies listed under Schedule 1 and for any future research use under the Controllorship of the Sponsor, that would not have taken place but for this Agreement regardless where that Processing takes place.
- 2.1.2 The Parties acknowledge that whereas the Sponsor is the Controller in accordance with Clause 2.1.1, the Participating Site is the Controller of the Personal Data collected for the purpose of providing clinical care to the Participants. This Personal Data may be the same Personal Data, collected transparently and processed for research and for improving care purposes under the separate Controllorships of the Sponsor and Participating Site.
- 2.1.3 Where the Participating Site is the Sponsor's Processor and thus where the Processing is undertaken by the Participating Site for the purposes of the Study, Clauses 2.1.4 to 2.1.8 below will apply. For the avoidance of doubt, such Clauses do not apply where the Participating Site is Processing the Participant's Personal Data as a Controller.
- 2.1.4 The Participating Site 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;
- 2.1.5 The Participating Site agrees to comply with the obligations applicable to Processors described by Article 28 GDPR including, but not limited to, the following:
- a. 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);
 - b. to not engage another Processor without the prior written authorisation of the Sponsor (Article 28(2));
 - c. to Process the Personal Data only on documented instructions from the Sponsor unless required to do otherwise by legislation, in which case the Participating Site 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));
 - d. to ensure that personnel authorised to Process Personal Data are under confidentiality obligations (Article 28(3)(b));
 - e. to take all measures required by Article 32 GDPR in relation to the security of processing (Article 28(3c));
 - f. to respect the conditions described in Article 28(2) and (4) for engaging another Processor (Article 28(3)(d));

- g. 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));
- h. 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 Site (Article 28(3)(f));
- i. 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 Site as Controller for the purpose of clinical care or other legal purposes; and
- j. to maintain a record of Processing activities as required by Article 30(2) GDPR.

2.1.6 The Participating Site shall ensure that:

- a. its Agents do not Process Personal Data except in accordance with this Agreement (and in particular the applicable research protocol);
- b. 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:
 - (i) are aware and comply with the Participating Site's duties under this Clause;
 - (ii) 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
 - (iii) 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.

2.1.7 The Participating Site agrees to:

- a. allow the Sponsor(s) or another auditor appointed by the Sponsor(s) to audit the Participating Site's compliance with the obligations described by this Agreement, 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 Site and/or to provide the Sponsor with evidence of its compliance with the obligations set out in this Agreement; and
- b. obtain prior agreement of the Sponsor to store or Process Personal Data outside the UK and the European Economic Area.

- 2.1.8 Where the Participating Site 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.

3. Term

- 3.1 This Agreement will commence on the date the final signatory signed the Agreement and shall remain in effect until the Participating Site is no longer Processing Personal Data under this Agreement, or earlier termination in accordance with clause 4 of this Agreement.

4. Termination

- 4.1 This Agreement may be terminated immediately by notice in writing by [either] / [any] Party if [the other] / [another] Party is:
- 4.1.1 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 30 calendar days after written notice by the non-breaching Party; or
 - 4.1.2 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.
- 4.2 Termination under Clause 4 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.


5. Agreement and Modification

- 5.1 Any amendments to this Agreement shall be valid only if made in writing and signed by authorised signatories of the Parties.
- 5.2 This Agreement may be executed in counterparts, each of which will be deemed an original, but all of which together shall constitute one and the same instrument.

6. Sign Off*

6.1 Each Party represents that it has ‘redlined’ or otherwise called attention to all changes that it made and sent to the other Party in previously-sent drafts of this Agreement, including but not limited to drafts of the schedule.

Signed by the duly authorised representatives of the Parties.

<p>Signed for and on behalf of:</p> <p>The Confederation, Hillingdon CIC</p> <p>Signature: </p> <p>Title: Noreen Groves, Associate Director of Transformation</p> <p>Date: 02.05.2023</p>	<p>Signed for and on behalf of:</p> <p>KING EDWARDS AND SWAKLEYS MEDICAL CENTRE E86024</p> <p>Signature: Alpna Chavda</p> <p>Title: Practice Manager</p> <p>Date: 02.05.2023</p>
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* Duly authorised scanned signatures shall be mutually acceptable and e-mail deemed a valid medium for exchanging signed copies of this Agreement, which may be executed in counterpart.

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