**Data Access Agreement for the Supply of Data**

This Agreement is made by and between:

a) **Cambridge University Hospitals NHS Foundation Trust** Hills Road Cambridge CB2 0QQ (“the Provider”); and

b) **[insert]**, (“the Recipient”)

Each a “Party” and together “the Parties”

This Agreement, including its Appendices, records the terms under which the Provider will make available to the Recipient the Data

The Recipient will hold the Data on the terms of this Agreement. The Recipient hereby agrees to comply and ensure that all personnel who work with the Data comply with the following terms and conditions:

**1. Definitions**

**Approved Application** means the finalised version of the application that is the subject of the Approved Project.

**Approved Project** means the research project “INSERT PROJECT TITLE” set out in the application (INSERT APPLICATION REFERENCE) to the Provider as approved by the Provider’s Data Access Committee and/or Steering Committee on [ ], such approval is attached at Appendix 1.

**Applicable Law** means all applicable laws, including without limitation the Human Tissue Act 2004 and the Data Protection Legislation.

**Background Intellectual Property** means in respect of a party any Intellectual Property Rights owned by, licensed to or otherwise controlled by that party prior to the Effective Date, or created, developed or acquired after the Effective Date independently of, or for a purpose unrelated to, the Agreement.

**Data** meansall de-identified data relating to Participants which is processed in connection with the Approved Project and set out in Appendix 1.

**Data Protection Legislation** means the Data Protection Act 2018, as amended from time to time, and any successor legislation in the UK, the General Data Protection Regulation (EU) 2016/679 (“GDPR”) as it forms part of the Law of England and Wales pursuant to the European Union (Withdrawal) Act 2018 and as amended by the Data Protection, Privacy and Electronic Communications (Amendments etc.) (EU Exit) Regulations 2019 and 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.

**Effective Date** shall mean date of signature of this Agreement.

**Intellectual Property Rights** means (i) patents, designs, trademarks and trade names (whether registered or unregistered), copyright and related rights, database rights, inventions, know-how and confidential information; (ii) all other intellectual property rights and similar or equivalent rights anywhere in the world which currently exist or are recognised in the future; and (iii) applications, extensions and renewals in relation to any such rights.

**Participant** shall mean a person who has consented to take part in the NIHR BioResourceTissue Bank(REC Reference 22/EE/0230 and REC Reference 13/EE/0325) and has consented for the use of their de-identified data to be used by Provider-approved researchers.

**Publication** means, without limitation, articles published in print journals, electronic journals, reviews, books, posters, press releases and other written and/or verbal presentations of research.

**Registered User**means a researcher named in the Approved Application form and employed by, affiliated to or enrolled at the Recipient, who the Recipient is responsible for ensuring is bound by the confidentiality and non-use obligations set out in this Agreement in respect of the Data and who has signed as having read and acknowledged the terms of this Agreement.

**Results** meansresults, data and algorithms that are developed by the recipient in the Approved Project, including without limitation AI, machine learning and software based analytical and diagnostic tools, the identification of novel drug targets, biomarkers or molecular diagnostics.

**SDE** means the Provider’s secure data environment.

**2. PROVISION of DATA**

2.1 The Provider:

2.1.1 provides to the Registered User access to the Data as specified in Appendix 1to this Agreement; and

2.1.2 confirms that it is entitled to provide access to the Data to the Recipient and that consent covering the intended use as described in the Approved Application has been obtained from the relevant Participants.

2.2 The Recipient:

2.2.1 agrees to use Data solely for the purposes of the Approved Project and not for any other purpose;

2.2.2 acknowledges that the Data is provided on an “as is*”* basis without any warranty of satisfactory quality or fitness for a particular purpose or use or any other warranty, express or implied;

2.2.3 agrees that only Registered Users may have access to the Data for the purpose of the Approved Project and to ensure that Registered Users are aware of and comply with the terms of this Agreement by signing this Agreement confirming that they have read and acknowledge the terms of the Agreement. The addition of Registered Users will require written permission by the Provider. Any additional Registered Users will need to sign and return a copy of this Agreement confirming that they have read and acknowledged this Agreement;

2.2.4 agrees to obtain the prior written consent of the Provider if there is any material change to the proposed use of the Data in the Approved application. Any amendment to this Agreement shall be valid only if made in writing and signed by authorised signatories of the Parties;

2.2.5 warrants that all work using the Data will be carried out in compliance and in accordance with Applicable Laws, regulations, policies, ethical requirements and approvals applicable to the research under the Approved Project and handling and protection of data including the Registered User Responsibility terms set out in Appendix 2; and

2.2.6 in the event that the Provider provides access to the Data to permit a download of the Data*,* will retain Data in a secure network system as regards Data at such standard as would be reasonably expected for the storage of valuable and proprietary and/or sensitive/confidential data. Without prejudice to the generality of the foregoing the Recipient shall store the Data on secure, encrypted ISO 27001 certified storage and server via secure file transfer.

2.3 Nothing included in this Agreement shall prevent the Provider from being able to distribute Data from the same Participants to other entities.

**3. Data Protection**

3.1 Provider shall provide access to the Data in a de-identified form, so that individual Participants cannot be identified by Recipient.

3.2 Recipient agrees to:

3.2.1 preserve at all times, the confidentiality of information pertaining to Participants. The Recipient agrees that it, and its Registered Users, shall not analyse or make any use of the Data in such a way that has the potential to lead to the identification of any Participant or compromise or otherwise infringe the confidentiality of information on the Participants and their right to privacy. If Recipient becomes aware of any unauthorized use or disclosure of the Data, Recipient shall promptly contact Provider and co-operate with any investigation made by the Provider in connection with the same;

3.2.2 shall maintain all appropriate procedures to ensure that the Data is only used for the performance of this Agreement and that it and its Registered Users, shall comply with the Data Protection Legislation in respect of the Data.

3.2.3 not attempt to link the Data to other information or archive data available for the data sets provided, even if access to that data has been formally granted to it, or it is freely available without restriction, without specific permission being sought for this purpose from the Provider’s access committees;

3.2.4 keep the Data secure by implementing organisational and technological measures appropriate to the nature and sensitivity of the data to prevent the unauthorised or accidental access, use or disclosure of the Data; and

3.2.5 in the event that the Provider provides access to the Data to permit a download of the Data, to delete any copies of the Data from its hard drives and movable media and destroy all physical copies of the Data at the expiry of the storage period described in the Protocol or on termination of this Agreement (if earlier). This obligation does not extend to automatically generated computer back-up or archival copies generated in the ordinary course of the Recipient’s University’s procedures, provided that the Recipient makes no further use of those copies

**4. INSPECTIONS/AUDITS**

4.1 On reasonable notice to Recipient, and in order to confirm or investigate compliance with the provisions of this Agreement, Provider may itself or via appropriate third parties, choose to inspect the premises and other relevant facilities of the Recipient, in order to review the security, storage (if applicable) or other arrangements for the Data; and/or request such additional information about the Project and/or its progress.

4.2 Provider will bear the costs of such inspections/audits unless a default within the procedures and processes of Recipient is discovered, in which case Recipient will be obliged to reimburse the reasonable costs of Provider and any relevant third parties.

**5. PAYMENT/FEES [For Industry or Academic projects with exceptional costs]**

5.1 In consideration for the provision of [access to the] Data, Recipient shall pay to Provider [insert amount] as more fully described in Appendix 3.

5.2 Payment will be made within 30 days of receipt of Provider’s invoice. No payment shall be made in the case where invoices are not presented in a complete, accurate and timely fashion.

**6. Publication**

6.1 The Recipient will acknowledge, and inform on submission and going to press, the Provider as the source of the Data in any publication reporting on its use in accordance with normal academic practice and using the wording on the Provider’s website: <https://bioresource.nihr.ac.uk/using-our-bioresource/acknowledging-the-bioresource/>

6.2 If the Recipient wishes to include in a publication any information which has been provided by the Provider with the Data and which was clearly marked as “confidential” and “proprietary” at the point of disclosure (“Confidential Information”), the Recipient must obtain prior written permission from the Provider, providing a copy of the text to allow a reasonable period for review before publication takes place, such permission not to be unreasonably withheld or delayed.

6.3 The Recipient will submit a detailed report and a summary report in plain language to the Provider, when requested, on completion of the Approved Project. The Provider will treat the detailed reports and all information, data, results, and conclusions contained within such report as confidential information belonging to the Recipient. The summary non-confidential report will be published on the Provider’s website.

6.4 The Recipient shall declare in the detailed report referred to in clause 6.3 above that the Provider bears no responsibility for any analysis or interpretation of the Data by the Recipient.

[6.5 -Academic Only;] The Provider reserves the right to request novel data derived from the Data that may enhance the data holding.

7. **INTELLECTUAL PROPERTY**

7.1 The Recipient recognises that nothing in this Agreement shall operate to transfer to the Recipient or its Registered Users any Intellectual Property Rights in or relating to the Data. Title to the Data is and remains in the ownership of the Provider.

7.2 Nothing in this Agreement shall affect ownership of the Background Intellectual Property Rights of either Party.

7.3 Recipient shall own all right, title and interest in and to the Results.

7.4 Recipient acknowledges that the Data is protected by copyright and other intellectual property rights, and that duplication of the Data, except as reasonably required to carry out the Approved Project, or sale of all or part of the Data on any media is not permitted.

8**. Notices**

8.1 Notices required under this Agreement will be in writing and will be delivered by email to the addresses set out below or (in the event of a failure to deliver an email) by post to the Provider or the Recipient and will be deemed to be given, in the case of delivery by email, upon receipt at the Recipient’s email server (unless an automatic response indicating an undeliverable message is received) and, in the case of delivery by post, on the date of delivery (or, if not a business day, on the first business day thereafter).

The contact persons designated for this purpose by the Parties are:

**On behalf of Provider On behalf of Recipient**

Name: NIHR BioResource Director Name:

Email: nbr@bioresource.nihr.ac.uk Email:

Tel. no: 0800 090 22 33 Tel no.

**9. Duration and Termination of Agreement**

9.1 This Agreement shall come into force as of Effective Date and shall remain in force until completion of the Approved Project or otherwise terminated in accordance with this clause 9.

9.2 This Agreement may be terminated before the completion of the Approved Project by either Party subject to a minimum of thirty (30) days written notice to the other Party.

9.3 The Provider has the right to terminate this Agreement with immediate effect at any time by means of written notice to Recipient if the ethical approval for the Approved Project and/or NIHR BioResourceTissue Bank **(**REC Reference 22/EE/0230 and REC Reference 13/EE/0325) project is withdrawn or if the Recipient is in breach of this Agreement. In the case of any termination, the Recipient shall immediately discontinue all use of the Data and, at the Provider's discretion, promptly destroy (at the Recipient’s own cost) all Data and provide written confirmation that this has been completed. If requested, the Recipient must certify that it has complied in full with any such requirement of the Provider.

**10. Liability and Indemnity**

10.1 Except to the extent prohibited by law, and subject to the Provider’s obligation in clause 2.1.2, Recipient assumes all liability for damages which may arise from its receipt, use storage or disposal, as applicable, of the Data. The Provider will not be liable to the Recipient for any loss, claim or demand made by the Recipient, or made against the Registered Users by any other party, due to or arising from its use, storage or disposal of the Data by the Recipient Institution, except to the extent the law otherwise requires.

10.2 The liability of either party for any breach of this Agreement or arising in any other way out of the subject matter of this Agreement, will not extend to loss of business or profit, or to any indirect or consequential damages or losses and shall not exceed the greater of £500,000 or the value of this Agreement.

10.3 Recipient shall indemnify and hold Provider harmless from any third-party claim, including reasonable legal fees, due to or arising out of Recipient’s use, handling and if applicable, storage or disposal of Data or any negligence or wilful misconduct of the Recipient.

**11. law and jurisdiction**

12.1 This Agreement shall be governed by English Law, and the English Courts shall have exclusive jurisdiction to deal with any dispute which may arise out of or in connection with this Letter Agreement.

 **12. Miscellaneous**

12.1 Recipient will not subcontract the performance of any of its obligations under this Agreement or any part thereof without having first obtained the prior written consent of the Provider. If consent is granted, Recipient shall ensure that any subcontractor or third-party provider shall handle Data in accordance with terms at least as stringent as those of this Agreement. Recipient shall be responsible for the acts, defaults and omissions of its subcontractors as if they were the Recipient’s own, and any consent given will not relieve the Recipient of any of its obligations under this Data Access Agreement.

12.2 No provision of this Agreement may be amended or modified, except by the agreement duly authorized and executed by both Parties.

12.3 A waiver by either party, whether express or implied, in enforcing or exercising any of its rights or remedies hereunder will not constitute a waiver of such right or remedy.

12.4 Recipient acknowledges that Provider is subject to the requirements of the Freedom of Information Act 2000 (FOIA) and shall provide all necessary assistance and cooperation as reasonably requested by Provider to enable Provider to comply with its obligations under the FOIA. Provider shall notify Recipient of any request for information under the FOIA to the extent legally permissible and shall limit disclosure of Recipient information to that strictly necessary to comply with its obligations under the FOIA.

12.5 This Agreement including its Appendices, contains the entire understanding between the Parties in relation to the Approved Project. This Agreement supersedes all other agreements, negotiations, representations and undertakings, whether written or oral of prior date between the Parties relating to the Approved Project.

**Signatures**

For and on behalf of **Provider institution**: For and on behalf of **Recipient institution**

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Name and title Name and title

Date: Date:

**Registered User acknowledgement:**

**I hereby acknowledge that I have read and understand the terms of this Agreement**

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Name and title

Date:

**Appendix 1**

**Approved Project**

*[Insert Provider approved application and summary of data to be provided as confirmed in finalised application and relevant approval – see definition of Approved Project]*

**APPENDIX 2**

**REGISTERED USER RESPONSIBILTY TERMS**

Registered Users wishing to access the Data for an Approved Project shall comply with these specific Registered User responsibilities in addition to any requirements on the Registered Users in the main body of the Agreement.

The Provider reserves the right to require the Registered Users to have completed a Safe Researcher Training (SRT) course in the last two years before they can access the Data.

1. **Conditions of use**

The Data accessed by the Recipient and the Registered Users under the Agreement is de-identified data and accordingly each Registered User agrees not to share the Data with anyone other than Registered Users named in the Approved Project and only to use the Data for the Approved Project.

Registered Users will contact the Data Access Committee (dac@nihrbioresource.ac.uk) for advice if they have concerns regarding the permitted scope of the Approved Project.

Registered Users will comply with all the requirements set out in the main body of the Agreement. In addition, Registered Users will:

* Adhere to all relevant Data Protection Legislation.
* Not export or download individual-level data from the Provider’s High Performance Computing platform (“HPC”), Secure Research Computing Platform (“SRCP”) or Secure Data Environment (“SDE”) to any other platform including personal computers unless explicitly approved in writing by the Provider.
* Not reference individual-level data in research reports.

Registered Users acknowledge that any data uploaded to the HPC/SDE must be approved by the Provider’s HPC/SDE Administrator before upload. Personal identifiable data must not be loaded into the HPC/SDE.

In special cases, to be reviewed on a case-by-case basis, individual-level data may be linked with data from other studies to identify/remove duplicates. The approach to identify duplicate participants across datasets from different sources must be approved by the Provider and it needs to be requested in writing.

1. **Additional conditions of use for data download**

On a case per case basis, the Provider’s Data Access Committee can advise that DAA can be fulfilled via a data download. This requires the following additional conditions of use:

* The Registered User shall destroy the downloaded data or otherwise render them permanently inaccessible, when the Approved Project is finished or when the funds end.
* The Registered User shall email the dac@bioresource.nihr.ac.uk to confirm the end of the Approved Project and destruction of the downloaded data. Data needs to be securely deleted (remove it from the trash bin too) For the avoidance of doubt, the Registered User shall not be required to destroy results data or other data subject to the provision of the data access application being complied with.
* Minimum security and Information Governance requirements for the end user environment:
	+ Registered User will only access the Data using a computer owned or approved by the Recipient.
	+ The computer must be encrypted.
	+ Registered User must lock the computer when not in use.
	+ The computer must be password protected (minimum 12 characters) or protected by MFA.
	+ The computer must have endpoint protection solution installed and must be configured to receive regular operating system and third-party application updates.
	+ Registered User organization must have organization and technical controls in place to adequately protect shared downloaded data such as Information Security policies, Incident Response plans and proof of compliance with Cybersecurity and data protection standards such as ISO 27001, Cybersecurity Essentials or NHS Data Security and Protection toolkit.
1. **Notification**

If any Data is lost or disclosed or the Registered User and/or Recipient becomes aware of any misuse of the Data or any security breach that could compromise the privacy of the Participants, the Recipient and the Registered User shall promptly notify the Provider’s Data Access Committee (by email to dac@bioresource.ac.uk) within 24 hours of awareness.

**Appendix 3 [For Industry or Academic projects with exceptional costs]**

1. **Payment Terms**

|  |  |
| --- | --- |
| Approved Project |  |
| Principal Investigator |  |
| Invoicing contact |
| Name |  |
| Telephone |  |
| Email |  |
| Address |  |
| Business/University |  |
| Grant Code |  |

1. **Cost Schedule**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Description** | **Milestone date** | **Cost (GBP)** | **Milestone year** | **Comment** |
|  |  |  |  |  |
|  |  |  |  |  |
|  |  |  |  |  |
|  |  |  |  |  |

Additional cost to the value of £3,625 per month (plus VAT) in the first instance for the use of the Provider’s SDE hosted by Aridhia. Cost re-evaluation following the first month of use will consider the number of users accessing the environment and the hours of access per day. Access to the SDE is intended for a period of three months in total.