

SCHEDULE 1: Data Access Agreement

The Application and this Data Access Agreement (the “Agreement”) govern the terms under which access will be granted to Data held by the NIHR BioResource.

In signing the Application, the Recipient agrees to be bound by the terms and conditions for the access set out in the Agreement.

The terms of access set out here apply to both the Registered Users and the Recipient.

In response to the Recipient’s request for access to the Data, the NIHR BioResource and the Recipient agree as follows:

1. Definitions:

Applicant means all named individuals requesting access to any or all of the data supplied upon approval of the application. The lead applicant is the main contact for all correspondence, for co-applicants and any other users of the data. Once Data Access Application has been approved all Applicants will become Registered Users (defined below). Following approval if additional registered users are required an Additional Applicants form must be completed and approved before their use of the data commences.

Data means all and any Participant-related data held by NIHR BioResource and includes Personal Data, clinical or phenotypic data. It also refers to genomic sequence and accompanying genotypic data generated by the NIHR BioResource and held at the University of Cambridge High Performance Computing Service (HPC) and European Genome-Phenome Archive (EGA).

Data Access Committee consists of named individuals who are responsible for making the data access decisions for the NIHR BioResource.

Data Controller and **Data Processor** have the meanings given in the UK GDPR.

UK GDPR means the General Data Protection Regulation 2016/679.

Intellectual Property 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.

NIHR BioResource means the federation of BioResources as set out on the NIHR BioResource website, <https://bioresource.nihr.ac.uk/about-us/about-the-bioresource/> and led by the NIHR BioResource Coordinating Centre at Cambridge, and the NIHR BioResource – Rare Diseases research study (<https://bioresource.nihr.ac.uk/rare-diseases/rare-diseases/>).

Participant means a person, who has provided a sample and/or Data for the Research and has been informed of the purpose for which the Data is held by the NIHR BioResource and has given his/her informed consent thereto.

Personal Data means any Data that can be considered personal data under UK GDPR.

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

Recipient is the organisation which has signed this Agreement on behalf of the Applicants.

Registered User means a researcher (or individual conducting research under the supervision of a Registered User) named in the Data Access Application form and employed by, affiliated to or enrolled at the Recipient and who is bound by the confidentiality and non-use obligations in respect of the Data and who has signed this Agreement and has received acknowledgement of its acceptance.

Research means the detailed study being carried out by Registered Users to discover new information or reach

a new understanding in improving healthcare and services for the purpose of answering the research question specified in the Data Access Application. Details of the Registered Users' research interests are included in the Application.

2. Purpose

The Recipient agrees to use Data only for the Research, according to the consent obtained from Participants. These are available online (<https://bioresource.nihr.ac.uk/about-us/governance-and-ethics/>) The Data can only be used for the approved purpose and research project described in the application and by the Registered Users; use of the Data for a new purpose or project will require a new application and approval. Addition of Registered Users will require written permission by the NIHR BioResource upon signature of the Data Access Application by the additional Registered Users.

3. Confidentiality

The Recipient agrees to preserve, at all times, the confidentiality of Data pertaining to Participants. In particular, the Recipient undertakes not to use, or attempt to use the Data to deliberately re-identify, identify or compromise or otherwise infringe the confidentiality of information on Participants and their right to privacy.

4. Data Protection

- 4.1 The Recipient agrees that it shall maintain all appropriate procedures to ensure that all Data is only used for performance of this Agreement and is kept secure and not disclosed to any third party. The Recipient further agrees that it, and its Registered Users, are covered by and shall comply with the obligations contained in UK GDPR as amended from time to time, or equivalent national provisions no less onerous than those contained in UK GDPR. In particular, the Recipient and its Registered Users understand their duties under such legislation in relation to the handling of Data and the rights of Participants, including taking appropriate measures to respond to requests from Participants to exercise their rights.
- 4.2 The Recipient acknowledges that Cambridge University Hospitals NHS Foundation Trust is the Data Controller for the NIHR BioResource – Research Tissue Bank; that the University of Cambridge and the Cambridge University Hospitals NHS Foundation Trust are jointly the Data Controller for the NIHR BioResource – Rare Diseases research study and that the Recipient will be the Data Controller for the Research.
- 4.3 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:
 - (a) lead to the identification of any Participant, where the Data has been provided de-personalised (de-identified); or
 - (b) compromise the anonymity of any Participant in any way.
- 4.4 The Recipient agrees that it, and its Registered Users, shall not attempt to link the Data to other information or previously archived data even if access to that data has been formally granted to you, or it is freely available without restriction, without specific permission being sought for this purpose from the relevant access committees.

5. Access and Governance

- 5.1 The Recipient acknowledges that some files containing the Data are so large as to be impractical to download. The contents of the files are also likely to change based on the analysis criteria. The data analysis may be more informative when carried out on the complete set. The Recipient therefore agrees that it shall not download or otherwise copy or attempt to copy the Data held by the NIHR BioResource without obtaining the prior written permission of the Data Access Committee. This will ensure consistent use of the Data managed with appropriate version controls. The aggregate results of analysis will be

available for download as long as they do not contain Personal Data.

- 5.2 The Recipient agrees that it shall take all reasonable security precautions to keep the Data confidential, such precautions to be no less onerous than those applied in respect of the Recipient's own confidential information.
- 5.3 The Recipient agrees to only give access to Data, in whole or part, or any identifiable material derived from the Data, to a Registered User. The Recipient agrees that before it gives any Registered User access to Data, it shall first show the Registered User a copy of this Agreement and shall inform the Registered User that he or she must comply with the obligations contained in this Agreement and sign up to the provisions of this Agreement in the form set out above this Agreement. The Recipient shall provide the NIHR BioResource with a copy of the Registered User's acceptance form within thirty (30) days of the date of acceptance by the Registered User.
- 5.4 The Recipient shall not transfer, copy or in any other way disclose the Data, in whole or part, or any individual-level material derived from the Data, to a researcher who is not a Registered User. Should such researcher wish to have access to the Data, the Recipient shall either give access in accordance with clause 5.3 above or advise the researcher that he or she must either make a separate application or addition of further Registered Users to the existing Data Access Application to the NIHR BioResource for access to the Data.
- 5.5 The NIHR BioResource reserves the right to request and inspect data security and management documentation to ensure the adequacy of data protection measures.

6. Errors

The Recipient agrees to promptly notify the NIHR BioResource of any errors detected in the Data.

7. Data reissue

The Recipient accepts that Data will be reissued from time to time, with suitable versioning. If Data is reissued at the request of Participant(s) (for example the Participant withdraws from the NIHR BioResource) and/or as the result of other ethical scrutiny or errors, the Recipient agrees to destroy all earlier versions of the Data.

8. Intellectual Property

- 8.1 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.
- 8.2 The Recipient recognises and understands that the NIHR BioResource's Research Project is of a pre-competitive nature and that the results of this project may be put in the public or private domain. If the Recipient, or its Registered Users, wishes to perform functional studies with the purpose of developing treatments, then the Recipient should decide whether or not arrangements for inventorship and intellectual property rights are to be made.
- 8.3 The Recipient agrees not to use the Data or any part thereof for the creation of products for sale or for any commercial purpose without the express prior written agreement of the NIHR BioResource, such agreement to be set out in a separate contractual arrangement between the parties.
- 8.4 The Recipient understands and 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 Research, or sale of all or part of the Data on any media is not permitted.

9. Publications

- 9.1 The Recipient agrees to acknowledge in any work based in whole or part on the Data, the source of the

data, and the role of the NIHR BioResource and the relevant primary collectors and their funders. Suitable wording is provided in the “Publications Policy” given in Schedule 2.

- 9.2 The Recipient shall also declare in any such work that those who carried out the original analysis and collection of the Data bear no responsibility for the further analysis or interpretation of it by the Recipient.
- 9.3 The Recipient agrees to abide by the terms outlined in the NIHR BioResource “Publications Policy” as set out in Schedule 2.
- 9.4 The Recipient agrees that it will submit a detailed report and a summary report in plain language to the NIHR BioResource Data Access Committee, when requested, on completion of the agreed purpose. The NIHR BioResource Data Access Committee will treat the reports and all information, data, results, and conclusions contained within such reports as confidential information belonging to the Recipient. However, the summary report will be published on the NIHR BioResource website.
- 9.5 The NIHR BioResource reserves the right to request novel data derived from the Data that may enhance the data holding.

10. Termination of Agreement

- 10.1 This Agreement will terminate immediately upon any breach of the provisions of this Agreement by the Recipient or its Registered Users. The Recipient supporting the Registered User(s) in breach of the agreement will be asked to support all efforts to remove access to any Data provided locally to the Registered User(s) or disseminated beyond those named in this agreement.
- 10.2 The Recipient accepts that the changing ethical framework of scientific research may lead to: (i) alteration to the provisions of this Agreement, in which case the Recipient may accept such alterations or terminate this Agreement; or (ii) the withdrawal of this Agreement in extreme circumstances.
- 10.3 Either party shall have the right to terminate this Agreement with immediate effect upon giving written notice of termination to the other party.
- 10.4 In the event that this Agreement is terminated in accordance with this Clause 10 the Recipient shall destroy any Data it or its Registered Users hold and provide written confirmation to the NIHR BioResource of doing so.

11. Legal statement

- 11.1 The Recipient acknowledges that the NIHR BioResource and all other parties involved in the creation, funding or protection of the Data:
 - 11.1.1 make no warranty or representation, express or implied as to the accuracy, quality or comprehensiveness of the Data; and
 - 11.1.2 exclude to the fullest extent permitted by law all liability for actions, claims, proceedings, demands, losses (including but not limited to loss of profit), costs, awards, damages and payments made by the Recipient that may arise (whether directly or indirectly) in any way whatsoever from the Recipient’s use of the Data, or from the unavailability of, or break in access to the Data for whatever reason.
- 11.2 The Recipient understands that all the Data is protected by copyright and other intellectual property rights, such that duplication or sale of all of or part of the Data on any media is not permitted under any circumstances, except with the prior written consent of the NIHR BioResource.

12. Governing Law

This Agreement (and any dispute, controversy, proceedings or claim of whatever nature arising out of this

Agreement or its formation) shall be construed, interpreted and governed by the laws of England and Wales and shall be subject to the exclusive jurisdiction of the English courts.

13. Industry Usage Costs

I understand that this study will be subject to the Industry Usage Costs outlined in Schedule 4, if conducted by an industry/commercial organisation, or in partnership with. Final costs will be agreed with NIHR BioResource upon approval of this application and detailed in Schedule 4

SCHEDULE 2: Publication Policy for Recipients

The primary purpose of the NIHR BioResource is to support Research and answer important methodological and biological questions.

The NIHR BioResource anticipates that the Data generated will be used by others, for medical research or development of new analytical methods. A more detailed list of NIHR BioResource aims is provided on the NIHR BioResource website:

<https://bioresource.nihr.ac.uk/about-us/about-the-bioresource/> .

It is NIHR policy that all publications involving use of Data that has been obtained through NIHR funded research should use Open Access and the Recipient should provide the Open Access.

<https://www.nihr.ac.uk/documents/nihr-open-access-policy-for-publications-submitted-on-or-after-1-june-2022/28999>

Authors who use NIHR BioResource Data **must** acknowledge the NIHR BioResource using the wording which is currently found on the NIHR BioResource website:

<https://bioresource.nihr.ac.uk/researchers/researchers/acknowledgement/>

The author shall also ensure that the logos used in the heading of this Agreement are used in presentations, posters and reports (image files can be provided on request).

While acknowledgement is the usual route, any manuscript that makes substantial use of primary Data from the NIHR BioResource should include the NIHR BioResource as an author. The position of the NIHR BioResource citation within the authorship list is to be agreed with the Publications Committee on a case-by-case basis.

Publications Committee contact email:
publications@bioresource.nihr.ac.uk

This contact should be used to submit manuscripts for review by the committee before submission or to notify us of accepted or new in press publications.

Please contact us immediately if a journal requests access to the data during review or if data needs to be made publicly accessible for publication e.g., EGA accession so this can be actioned in a timely manner. Recipients should note that the NIHR BioResource bears no responsibility for the further analysis or interpretation of these data, over and above that published by the NIHR BioResource.

SCHEDULE 3: Plain language summary guidelines

The study name and plain language summary will be published on the NIHR BioResource website following application approval. These should explain to non-technical members of the public the aim of the Research using simple language and explaining all abbreviations and technical terms.

The summary must make clear what the specific purpose is, who will be using the Data (organisations rather than individual names), what will happen to the data, the expected outputs and benefits to patients. Please include any potential disclosure risks and how these will be addressed.

Use of a readability scoring application to test the reading age of the summary before application submission will highlight any text of high complexity or requiring a reading age greater than age 12. Websites such as readability formulas (<https://www.readabilityformulas.com/>), readable (<https://readable.com/>) or Grammarly (<https://www.grammarly.com>) can provide such functionality, though we cannot assure confidentiality of any text uploaded for testing to public websites.

Advice on how to write an appropriate plain language summary can also be found at: <https://www.plainlanguage.gov/examples/> or view examples from New Scientist or similar publicly accessible scientific journals.

SCHEDULE 4: Indicative Usage Costs for Industry**Research Industry Organisations: current cost guidelines**

Private and commercial organisations will be subject to costs based on the size of the request.

The following are typical costs for a study. Individual study costs will be set according to the study protocol.

Request size	Cost
Pilot	£8,000
Small	£10,000
Medium	£25,000
Large	£50,000

NIHR BioResource reserves the right to change costs at any time without notice.

SMEs who can provide evidence of status will be offered reduced rates.