The NIHR BioResource for Translational Research in Common and Rare Diseases (the “NIHR BioResource”) will consider applications for access to its data for research. On the application being accepted, access to relevant data will be granted according to the Data Access Agreement.

All applicants, regardless of Institution, must complete this Application Form. There are 10 Sections in all. Please complete all of Sections 1 through 9 and the Addendum if there are more than 2 Co-Applicants. Section 10 is for NIHR BioResource use only.

**Consortium**

If this Application is on behalf of a Consortium, the lead Institution should complete the Application but all applicants who will have hands-on access to the Data from all Institutions should be listed.

**Name of applicant and co-applicants, including affiliation and contact details:**

Please ensure that full postal and **email address** is included for **each applicant**. Institutional email addresses must be used. These email addresses are used for granting access to data, and only these applicants may access the Data. PhD student applicants **must** include their supervisor as a Co-Applicant and provide their full contact details in the Addendum.

**The NIHR BioResource reminds the Recipient and Registered Users that this document should be read in conjunction with the Data Access Agreement, appended as Schedule 1. In particular they may not download or otherwise copy or share the Data, nor use it for any purpose other than that agreed, unless they have received prior written agreement from the Data Access Committee. Should the Data Access Committee discover that the Recipient or any of its Registered Users have downloaded, copied or shared the Data without its permission, it will terminate the Agreement immediately.**

**1 Organisation (Recipient):**

|  |  |
| --- | --- |
| Name of Organisation | *Click here to enter text.* |
| Address | *Click here to enter text.* |
| Name of Consortium, (if applicable) | *Click here to enter text.* |

**2 Applicants (Registered Users):**

Primary Applicant

|  |  |
| --- | --- |
| Name: | *Click here to enter text.* |
| Affiliation: | *Click here to enter text.* |
| Address : | *Click here to enter text.* |
| Email : | *Click here to enter text.* |

Co-Applicants

|  |  |
| --- | --- |
| Name: | *Click here to enter text.* |
| Affiliation: | *Click here to enter text.* |
| Address : | *Click here to enter text.* |
| Email : | *Click here to enter text.* |

|  |  |
| --- | --- |
| Name: | *Click here to enter text.* |
| Affiliation: | *Click here to enter text.* |
| Address : | *Click here to enter text.* |
| Email : | *Click here to enter text.* |
| Please check this box if there are more than two Co-Applicants and complete the Addendum | |

**3 The Study**

|  |
| --- |
| **BioResource Study No (if known):** |
| *Click here to enter text.* |
| **Study Name** (in plain English and **in less than 30 words**. Please note that this Study Name and description will be included on the NIHR BioResource website if the Application is approved). |
| *Click here to enter text.* |

**4 About The Data**

|  |
| --- |
| **Data Requested**  Please indicate the diseases you require data on: |
| *Click here to enter text.* |
| Please indicate, by checking the appropriate boxes, below the control data you require:  Whole Genome Sequencing/Whole Exome Sequencing  Phenotypic Data/Clinical Data  Metabolomic Data  Genotype Array Data  Other Data (please specify)  *Click here to enter text.* |
| **Data Access**  Please indicate, by checking the appropriate box below, how you wish to access the Data. Please also note the restrictions on using the Data contained in Clause 5 of Schedule 1.  We wish to view and analyse Data at the University of Cambridge’s High Performance Computing Service  We wish to download and/or copy Data  We wish to access Rare Disease Data via Gene Docs |
| Where PhD supervisors are listed as Co-Applicants, please indicate what level of access to the Data each of them will require: |
| *Click here to enter text.* |
| **Please provide any additional information** (max 750 words) |
| *Click here to enter text.* |

**5 Project Summary**

|  |
| --- |
| Please also provide a **summary of your project in not more than 300 words in plain language**, which we will add to the NIHR BioResource website after the Application has been approved. |
| *Click here to enter text.* |

**6 Patient Benefit**

|  |
| --- |
| Please describe in no more than two sentences the anticipated patient benefit or impact. |
| *Click here to enter text.* |

**7 About The Research**

|  |  |
| --- | --- |
| Please provide a **clear** description of the project and its specific aims in no more than 750 words. This should include specific details of **what you plan to do with the data** and include key references and, where applicable, the **Ethics Reference Number**. | |
| *Click here to enter text.* | |
| **Ethics Reference Number (if known)** | *Click here to enter text.* |

**8 About Your Experience and Expertise**

|  |
| --- |
| Please describe your experience and expertise, and that of your collaborators in analysing data, and how this will be applied to the proposed study. A short publication list **MUST** be provided for the applicant, co-applicants and PhD supervisors where PhD students have applied. The NIHR BioResource needs assurance of competence in handling and secure storage of datasets of this size and nature. |
| *Click here to enter text.* |

The NIHR BioResource for Translational Research in Common and Rare Diseases complies with the requirements of the General Data Protection Regulation 2016/679 with regard to the collection, storage, processing and disclosure of personal information and is committed to upholding the core Data Protection Principles as more widely described at <https://bioresource.nihr.ac.uk/gdpr/>

The Data Access Agreement appended as Schedule 1 governs the terms under which access will be granted to the Data held by the NIHR BioResource to the Registered Users. In signing this Application, the Recipient and Registered Users agree to be bound by the terms and conditions for the access set out in the Data Access Agreement.

Information collected will be used for the purposes of maintaining the Agreement, and may be used for statistical reporting.

For the sake of clarity, the terms of access set out here apply to both the Registered Users as well as the Recipient.

**9 Organisation and Applicant Signatures**

**AGREED AND ACCEPTED by the Recipient and its Registered Users through their authorised signatories**

**For and on behalf of the Organisation (Recipient)** (Note: this should be someone who is authorised to sign legal contracts on behalf of your Organisation. It should not be someone listed in the Applicants.)

|  |  |
| --- | --- |
| **Name of Organisation** | *Click here to enter text.* |
| **Signed By:** | *Click here to sign* |
| **Print Name:** | *Click here to enter text.* |
| **Title** | *Click here to enter text.* |
| **Date:** | *Click here to enter text.* |

**For and on behalf of Applicants (Registered Users):**

**Applicants (Registered Users) confirm that the contents of the application above are correct and acknowledge the contents of the Data Access Agreement that is appended to this Application and agree to comply with the obligations therein.**

Please note that all Applicants and Registered Users need to sign.

**Primary Applicant**

|  |  |
| --- | --- |
| **Signed By:** | *Click here to sign* |
| **Print Name:** | *Click here to enter text.* |
| **Title** | *Click here to enter text.* |
| **Date:** | *Click here to enter text.* |
| **Co-Applicants** | Please check this box if there are more than two Co-Applicants and complete the Addendum |
| **Signed By:** | *Click here to sign* |
| **Print Name:** | *Click here to enter text.* |
| **Title** | *Click here to enter text.* |
| **Date:** | *Click here to enter text.* |

|  |  |
| --- | --- |
| **Signed By:** | *Click here to sign* |
| **Print Name:** | *Click here to enter text.* |
| **Title** | *Click here to enter text.* |
| **Date:** | *Click here to enter text.* |

WHEN SUBMITTING THIS DOCUMENT, PLEASE INCLUDE ALL PAGES OF THIS DOCUMENT INCLUDING THE ADDENDUM IF COMPLETED AND THE DATA ACCESS AGREEMENT (Schedule 1)

Please submit forms containing the original signatures by email to:

[dac@bioresource.nihr.ac.uk](mailto:dac@bioresource.nihr.ac.uk)

**10 NIHR BioResource Approval**

By signing below through its authorised signatory, the NIHR BioResource agrees to grant access to the Recipient and its Registered Users as identified above.

|  |  |
| --- | --- |
| **Signed By:** | *Click here to sign*  **For and on behalf of the NIHR BioResource** |
| **Print Name:** | *Click here to enter text.* |
| **Title** | *Click here to enter text.* |
| **Date:** | *Click here to enter text.* |

**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:

# Definitions:

***Data*** means all and any Participant-related data held by NIHR BioResource and includes Personal Data.

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

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

***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 GDPR.

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

***Recipient*** is the organisation which has signed this Agreement.

***Registered User*** means a Researcher (or individual conducting research under the supervision of a Researcher) 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 studybeing carried out by the Researcherto discover new information or reach a new understanding in improving health, care and services. Details of the Researchers’ research interests are included in the Application.

***Researcher(s)*** shall mean an individual or individuals carrying out Research who are seeking access to Data.

# Purpose

The Recipient agrees to use Data only for the Research, according to the consent obtained from Participants. The Data can only be used for the approved purpose and 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.

# Confidentiality

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

# Data Protection

* 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 GDPR as amended from time to time, or equivalent national provisions no less onerous than those contained in 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.
  2. The Recipient acknowledges that the 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 and Data Processor 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:

* + 1. lead to the identification of any Participant, where the Data has been provided pseudo-anonymised; or
    2. 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 archive data available for the data sets provided, 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.

# Access and Governance

* 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 is 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 results of analysis will be available for download as long as they do not contain Personal Data.
  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.
  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 at the end of 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.
  4. The Recipient shall not transfer, copy or in any other way disclose the Data, in whole or part, or any identifiable 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 5.1 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. The NIHR BioResource reserves the right to request and inspect data security and management documentation to ensure the adequacy of data protection measures.

# Errors

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

# 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.

# Intellectual Property

* 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.
  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.
  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.
  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.

# Publications

* 1. The Recipient agrees to acknowledge in any work based in whole or part on the Data, the published paper from which the Data derives, the version 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.
  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.
  3. The Recipient agrees to abide by the terms outlined in the NIHR BioResource ”Publications Policy” as set out in Schedule 2.
  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.

# Termination of Agreement

* 1. This Agreement will terminate immediately upon any breach of the provisions of this Agreement by the Recipient or its Registered Users.
  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.
  3. Either party shall have the right to terminate this Agreement with immediate effect upon giving written notice of termination to the other party.
  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.

# Legal statement

* 1. The Recipient acknowledges that the NIHR BioResource and all other parties involved in the creation, funding or protection of the Data:
     1. make no warranty or representation, express or implied as to the accuracy, quality or comprehensiveness of the Data; and
     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.
  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.

# 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.

**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/about-us/who-we-are/our-policies/nihr-open-access-policy.htm>

Authors who use NIHR BioResource Data must acknowledge the NIHR BioResource using the wording which is then current on the NIHR BioResource website:

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

The author shall also ensure that the icons used in the heading of this Agreement are used in presentations, posters and reports.

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.

To submit a manuscript to the Publications Committee please contact:

[**publications@bioresource.nihr.ac.uk**](mailto:publications@bioresource.nihr.ac.uk)

Please notify us of any new publications at:

[**publications@bioresource.nihr.ac.uk**](mailto:publications@bioresource.nihr.ac.uk)

If a journal requires access to the Data in the publication, please contact us immediately at:

[**publications@bioresource.nihr.ac.uk**](mailto:publications@bioresource.nihr.ac.uk)

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.

**ADDENDUM**

Please complete this Addendum to add additional Co-Applicants and PhD student supervisors.

**Registered Users confirm that the contents of the application above are correct and acknowledge the contents of the Data Access Agreement that is appended to the Application and agree to comply with the obligations therein.**

Co-Applicants

|  |  |
| --- | --- |
| Name: | *Click here to enter text.* |
| Affiliation: | *Click here to enter text.* |
| Address : | *Click here to enter text.* |
| Email : | *Click here to enter text.* |
| Signed By: | *Click here to sign* |
| Title | *Click here to enter text.* |
| Date: | *Click here to enter text.* |

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