**Application for Access to NIHR BioResource Data**

**Prior to submitting your application, please contact the data access team via email at** **dac@bioresource.nihr.ac.uk** **to discuss your requirements. Please note your application will be reviewed by all Data Access Committee members, including patient/public representatives**

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| **Project Application Title**Please provide a title of not more than 30 words, in plain, simple language. Your project title will be posted, for example, to the NIHR BioResource website, following approval of your application. *Click or tap here to enter text.* |
| If the NIHR BioResource has previously supported any of your studies, please provide the name and DAA/NBR/CBR reference number, applicable results, and any publications arising from those studies.Click or tap here to enter text.  |
| **Did you preliminary discussed your application with NIHR Bioresource staff?**[ ] Yes [ ] No*If yes, please specify staff name*: Click or tap here to enter text. |

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| **SECTION 1: APPLICANTS(S)** |
| **1. Lead Applicant** |
| Name: | Click or tap here to enter text. |
| Job title: *Please list job title relevant to application* | Click or tap here to enter text. |
| ORCID ID: | Click or tap here to enter text. |
| Organisational email:*Do not use personal email address* | Click or tap here to enter text. |
| Organisation: | Click or tap here to enter text. |
| Department: | Click or tap here to enter text. |
| Postal Address: | Click or tap here to enter text. |
| Name of Consortium, if applicable.*Co-applicants working at different institutions need to complete an Additional Applicant form and submit alongside lead applicant’s application.* | Click or tap here to enter text. |
| **2. Co-Applicant(s)** |
| **Name:** | Click or tap here to enter text. |
| Job title:*Please list job title relevant to application* | Click or tap here to enter text. |
| ORCID ID: | Click or tap here to enter text. |
| Organisational email:*Do not use personal email address* | Click or tap here to enter text. |
| Organisation: | Click or tap here to enter text. |
| Department: | Click or tap here to enter text. |
| Postal Address: | Click or tap here to enter text. |
| **Name:** | Click or tap here to enter text. |
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| Department: | Click or tap here to enter text. |
| Postal Address: | Click or tap here to enter text. |
| **Name:** | Click or tap here to enter text. |
| Job title:*Please list job title relevant to application* | Click or tap here to enter text. |
| ORCID ID: | Click or tap here to enter text. |
| Organisational email:*Do not use personal email address* | Click or tap here to enter text. |
| Organisation: | Click or tap here to enter text. |
| Department: | Click or tap here to enter text. |
| Postal Address: | Click or tap here to enter text. |
| *Add additional rows, if necessary*Click or tap here to enter text. |
| [ ]  **Please tick box to confirm a CV has been submitted for each of the above Lead & Co-Applicants.** *Please note your application will not be reviewed if CVs are not submitted.*[ ]  **A short (max 5) recent and relevant publication list MUST be provided for the applicant, Co-Applicants, and PhD supervisor/line manager where PhD students have applied.**  |
| **3.** Where PhD supervisor/line manager are listed as Co-Applicants, please indicate what level of access to the Data both the PhD student and supervisor/line manager will individually require. Please provide assurances that PhD students will have the adequate supervision necessary to carry out the data analysis. Please note the BioResource will not provide bioinformatics training.Click or tap here to enter text. |
| **4. About your experience and expertise** Please describe relevant experience and expertise, and that of your co-applicants in analysing data, and how this will be applied to the proposed study. The NIHR BioResource needs assurance of competence in handling of datasets of this size and nature.Click or tap here to enter text. |

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| **SECTION 2: THE STUDY** |
| **1. Type of Research***(Tick all that apply)*[ ] University [ ] Industry[ ] Other (e.g., Charity; Healthcare provider; National body; Sanger)  Please provide details:Click or tap here to enter text. |
| **2. Plain, simple language summary**Please provide a summary of your project in not more than **300 words**, in plain and simple language (please refer to the data access agreement for guidelines). Your summary will be posted to the NIHR BioResource website (https://bioresource.nihr.ac.uk/studies/), following approval of your application. *Please note: This section is important and will influence the application approval, a poor-quality plain language summary will be returned and delay the approvals process*Click or tap here to enter text. |
| **3. Study Description** Please provide a **clear** description of your study and its specific aims in no more than 750 words. This should include specific details of **why you need access to the data you have asked for,** **what you plan to do with it and** the minimum amount of data you need. Please add key references and, where applicable, complete the Ethics section below. Click or tap here to enter text. |
|  **4. Participant group(s)/disease cohorts** List participant group(s)/disease [cohorts](https://bioresource.nihr.ac.uk/using-our-bioresource/our-cohorts/) you require data on: (Please note that not all **datasets** are  available for all participants. Additionally, ethical constraints on data access/release may apply for some  cohorts).Click or tap here to enter text. |
|  **5. Specify the number of participants you require data on: ­­**Click or tap here to enter text. |
|  **6. What is minimum number of data records you require for statistical justification?**Click or tap here to enter text. |
|  **7. How will the data requested be used to achieve the project objectives?**  *Please include the power calculation behind the participant sample number.*Click or tap here to enter text. |
|  **8. Please describe in no more than 200 words how the study will benefit patients, health and/or social care,**  **including expected measurable benefits. Please visit NIHR website for** [**patient and public involvement**](https://www.nihr.ac.uk/documents/ppi-patient-and-public-involvement-resources-for-applicants-to-nihr-research-programmes/23437) **guidance.** Following approval of your application**,** your summary will be posted to public websites, for example, the [Health Data Research Innovation Gateway](https://www.healthdatagateway.org/) (HDRUK). Click or tap here to enter text. |
| **9. Patient and Public Involvement (PPI): Please describe the inputs that patients and the public have had in reviewing, shaping or designing this research.** Please see the [UK Standards for Patient Involvement in Research.](https://sites.google.com/nihr.ac.uk/pi-standards/home)(If you consider this research to be at a stage where PPI is not yet needed, please explain this.)Click or tap here to enter text. |
|  **10. How have you considered Equality, Diversity, and Inclusion (EDI) in your proposal? Please provide a** **short overview of your considerations and how these have been implemented where possible.** *Please refer to the* [*NIHR INCLUDE framework*](https://www.nihr.ac.uk/documents/improving-inclusion-of-under-served-groups-in-clinical-research-guidance-from-include-project/25435) *for information on how EDI should be considered and embedded in research.* Click or tap here to enter text. |
|  **11. How will you disseminate study findings?** *(Please refer to* Schedule 2 *of the Data Access Agreement)*Click or tap here to enter text. |
|  **12. Please tick** [ ]  **I/We, the applicant(s), declare that I/we have sufficient funds to carry out and publish**  **this study.**  Please provide funders name:Click or tap here to enter text. |
|  **13. Is there commercial interest in this project?** [ ]  Yes [ ]  No*If yes, please specify.* Click or tap here to enter text. |
|  **14. Study Timeline** Anticipated Start Date: Click or tap to enter a date. Anticipated End Date: Click or tap to enter a date. |
|  **15. Does your study require ethical approval?** [ ]  Yes [ ]  No *If yes, please provide details below.*Click or tap here to enter text. |
|  Research Ethics Committee Name | Click or tap here to enter text. |
|  Research Ethics Reference Number | Click or tap here to enter text. |
|  Please tick to confirm that you have enclosed a copy of the research ethics approval letter alongside this  application [ ]   |

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| **SECTION 3: DATA**  |
|  **1. Please indicate, by checking the appropriate boxes below, the data you require.** Clinical Data: [ ]  Case Report Forms; [ ]  NHS Trust Data [ ]  Demographic Data[ ]  Genotype Array Data[ ]  EGA (European Genome-Phenome Archive) data: please specify dataset ID(s):Haplotype Data: [ ]  ApoE; [ ]  HLA; [ ]  Blood groupsSequencing Data: [ ]  WES; [ ]  WGS; [ ]  RNA-SeqSelf-Reported Data: [ ]  Health & Lifestyle Questionnaire Data[ ]  Metabolomic Data [ ]  Other Data (please specify) Click or tap here to enter text. **Not all these data types are available for all themes.** |
|  **2. Please indicate, by checking the appropriate boxes below, which demographic data you require:** [ ]  Identifiers to link to existing patient cohort or previous study.  *Please specify:*Click or tap here to enter text. [ ]  Age  *Data are standardly provided as 5-year age bands.* [ ]  Biological sex  *Either gender* ***or*** *biological sex will be released. If your study requires* ***both****, please provide justification and explain how you will mitigate the potential*  *disclosure risk associated with the small number of cases where gender does not match biological sex.*[ ]  Gender [ ]  Ethnicity [ ]  Other Click or tap here to enter text.  |
| **3. Do you anticipate any risks to individual privacy, and if so, what steps have you made in your proposal**  **to mitigate these?**Click or tap here to enter text. |
|  **4. Data Access** Please note we have different data access methods which are listed below in order of increasing complexity (to be ticked by NIHR Staff):[ ] download[ ] copy bespoke data[ ] view and analyse data at the University of Cambridge’s High-Performance Computing (HPC) service[ ] Please note that some data sets can only be shared using a dedicated Secure Data Environment (SDE)We will contact you with further information on which data access method applies to your requested dataset.Complex requests may take longer to fulfil, exact delivery dates will be discussed upon approval. Please note the restrictions on using the Data contained in Clause 5 of Schedule 1 of the Data Access Agreement.Please note: if further data is requested following approval, an amendment will need to be submitted. If the data request is deemed minor, appropriate, and relevant to the original application, consideration for approval will be given by Data Access Committee Chair(s). |
|  **5. Data download: If the data access team has advised that your request coul be fulfilled via a download please complete this section.** Please provide your reasons for needing to download the data. Click or tap here to enter text. Local data security & governanceWhat is the name of the entity that will be providing the infrastructure on which the data is hosted e.g., University, Hospital, or IT Services Provider (if outsourced)?Click or tap here to enter text.What Information Security / Information Governance accreditations does this organisation hold? Please provide an accessible Web link, valid certificate, or other documentary evidence. Click or tap here to enter text.Please provide a copy of or a link to a document-controlled version of an Information Security Policy for the relevant organisation. Please provide a link, valid certificate, or other documentary evidenceClick or tap here to enter text.Please provide a copy of or a link to a document-controlled version of an Information Governance Policy for the relevant organisation. Please provide a link, valid certificate, or other documentary evidenceClick or tap here to enter text.Please provide the contact details of the above-named institutions Data Protection Officer (DPO) or legal equivalent:Click or tap here to enter text.

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| Name of Data Protection Officer (DPO) or equivalent officer responsible for organisational data security: | Click or tap here to enter text. |
| Email: | Click or tap here to enter text. |
| Postal address: | Click or tap here to enter text. |

For more information, please see Schedule 1 of the Data Access Agreement.[ ]  We agree to undertake to destroy/archive downloaded data on completion of this project, if requested, and in accordance with UK Data Service (https://ukdataservice.ac.uk/learning-hub/research-data-management/store-your-data/disposal/). |
|  **6. Data Protection**The NIHR BioResource for Translational Research in Common and Rare Diseases (the NIHR BioResource)  complies with the requirements of the UK General Data Protection Regulation (UK GDPR) regarding 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 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. |

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| **SECTION 4: APPLICANT CHECKLIST** |
| **Please tick boxes to confirm that you have provided the following information:**[ ]  The entire form is complete[ ]  CVs and publications provided[ ]  Organisational email addresses provided, relevant to the project.  For example: If you are applying for data under the auspices of a commercial company, do not provide your academic email address. [ ]  Data Protection Officer contact details provided [ ]  Ethics Approval letter, if applicable[ ]  Document-controlled version of an Information Security Policy[ ]  Data Access Agreement viewed and accepted  |

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| **SECTION 5: LEAD APPLICANT SIGNATURE**  |
| **For and on behalf of Applicants:** **Applicants 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. Co-Applicants should add their signature to section 6, below, along with their details. |
| **Print Name:** | Click or tap here to enter text. |

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| **Signed By:** |

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| **Date:** | Click or tap to enter a date. |
| WHEN SUBMITTING THIS DOCUMENT, PLEASE INCLUDE ALL PAGES OF THIS DOCUMENTPlease submit forms containing the original signatures by email to: dac@bioresource.nihr.ac.uk |

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| **SECTION 6: CO-APPLICANT SIGNATURES****If more than 4 co-applicants, please complete** [**APPENDIX 1**](#APPENDIX_1) |
| **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. Supervisor/line manager of students are considered to be co-applicants.**  |
| **Name:** | Click or tap here to enter text. |
| Affiliation: | Click or tap here to enter text. |

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| **Name:** | Click or tap here to enter text. |
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| **SECTION 7: ORGANISATIONAL SIGNATURE** |
| AGREED AND ACCEPTED by the Recipient and its Registered Users through their authorised signatoriesFor and on behalf of the Organisation (Recipient) **Note: An authorised signature must be a person who is authorised to sign legally binding contracts on behalf of your Organisation. It should not be someone listed as an applicant.**  |
| **Name of Organisation:** | Click or tap here to enter text. |

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| **Signed By:** |  |

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| **Print Name:** | Click or tap here to enter text. |
| **Title:** | Click or tap here to enter text. |
| **Date:** | Click or tap to enter a date. |

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| **SECTION 8: NIHR BIORESOURCE SIGNATURE** |
| By signing below through its authorised signatory, the NIHR BioResource agrees to grant access to the Recipient and its Registered Users as identified in this form.  |

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| **Signed By:** |  |
|  | **For and on behalf of the NIHR BioResource** |

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| **Print Name:** | Click or tap here to enter text. |
| **Title:** | Click or tap here to enter text. |
| **Date:** | Click or tap to enter a date. |

**APPENDIX 1: Co-Applicants**

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| **Name:** | Click or tap here to enter text. |
| Affiliation: | Click or tap here to enter text. |

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