**NIHR BioResource Data Access Application (DAA)**

Please submit this form containing the original signature and the CV of all the applicants by email to: [dac@bioresource.nihr.ac.uk](mailto:dac@bioresource.nihr.ac.uk). When submitting this form please include all pages.

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| **DAA reference number (DAAn)** | *to be filled by BioResource staff* |
| Has the BioResource previously supported any of your studies? If so, please provide the name and DAA/NBR/CBR reference number | *Click or tap here to enter text.* |

**Review**

Following an initial feasibility assessment your application will be reviewed by the BioResource Data Access Committee and National Participant Advisory Group**.**

**Data protection**

The NIHR BioResource for Translational Research 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 [General Data Protection Regulation (GDPR)](https://bioresource.nihr.ac.uk/about-us/governance-and-ethics/gdpr/) webpage. webpage.

**Data access agreement**

Your application will be reviewed by the NIHR BioResource Data Access Committee. Once approval of the application is notified to you, the organisation for each applicant will be required to sign a data access agreement before data is made available to you. This agreement is publicly available at: [Data Access Agreement doc](https://nihr-bioresource-www-cms.azurewebsites.net/media/aisovgxl/3_data_access_agreement_template.docx)

**Costs**

The BioResource may charge applications for the provisions of data. Please ensure you have a preliminary discussion with the BioResource on costings prior to submitting an application via the dac@bioresource.nihr.ac.uk email.

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| 1. **THE APPLICANTS** | |
| **Lead Applicant** | |
| **Full name** |  |
| **Job title** |  |
| **Organisation** |  |
| **Email** |  |
| PhD/MSc students should be named as co-applicants, and we ask that the supervisor is the lead-applicant named on this form. | |
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| **ADDITIONAL APPLICANT(S):**  Please list **all** other individuals that require access to the data as additional co-applicants. Please add additional line if required | |
| **Full name** |  |
| **Job title** |  |
| **Organisation** |  |
| **Email** |  |
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| 1. **About your experience and expertise** |
| Please describe the relevant experience and expertise of all 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.  Where PhD supervisor/line manager are listed as Co-Applicants, please provide assurances that PhD students will have the adequate supervision necessary to carry out the data analysis.  Please note that the BioResource does not offer support in data analysis; the BioResource can advise on the provided data types and the background of the data. |
| *Click or tap here to enter text.* |

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| 1. **THE STUDY** | |
| **3.1 Type of Research (tick all that apply)** | |
| Academia/Research institute  Industry  Other (including charity, health care provider, national body, patient group). Please provide details:  *Click or tap here to enter text.* | |
| **3.2 Plain English study title (max 70 characters)** | |
| Any acronyms should be explained in full. Take care to translate medical terms into plain English. The study name should be understandable by anyone with a reading age of 9 which is the national average reading age. The study name should reflect a reasonable understanding of nature and question of the research in lay terms | |
| *Click or tap here to enter text.* | |
| **3.3 Plain language summary of your study** | |
| Your summary will be posted to the [NIHR BioResource website](https://bioresource.nihr.ac.uk/studies/) following approval of your application and it will be submitted to the Health Research Authority in the Annual Progress Report to the Research Ethics Committee. **The summary must be suitable for a reading age of 9 which is the National average reading age.**   * Please provide a lay summary of your project in not more than 300 words. * Please ensure to avoid or explain medical or technical terms. * Please give a succinct lay understanding of the specific research question, context of the research, summary benefits/unmet needs fulfilled by the study, summary of method/approach of the research, in lay terms ([online guidance](https://bioresource.nihr.ac.uk/media/isgbwuag/v1-plain-language-guidance-for-daa-applications.pdf))   Please note that if your summary is not suitable for a lay audience your study application will not be approved**.** | |
| *Click or tap here to enter text.* | |
| **3.4 Scientific study title** |
| *Click or tap here to enter text.* |
| **3.5 Study Description** | |
| * Please provide a clear description of your study in no more than 500 words, including the background and current knowledge of the field * Please indicate the research question your study is planning to answer and the research hypothesis. * Please include specific details of why you need access to the data you are asking for and what you plan to do with it. * Reference key publications, where applicable (excluded from word limit). | |
| *Click or tap here to enter text.* | |
| **3.6 Study methodology** | |
| * Please describe your methodology and study population including number of participants. * Please describe how the data requested will be used to achieve the project objectives. * Where applicable, please describe the minimum amount of data you require for statistical justification and the power calculation behind the participant sample number. | |
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| **3.7 Patient benefit** | |
| * Please describe in plain language and in no more than 300 words the intended benefits to patients' health and general quality of life, as well as any wider health economic and/or socioeconomic benefits that may result from this research study, as well as any intended benefits if further research is anticipated. * Where possible please explain why these benefits are anticipated and with what confidence. * All Data Access Applications will be reviewed by the BioResource National Participant Advisory Group (NPAG)   Please note that if your study does not clearly indicate patient benefits your application will not be approved. Following approval of your application, this section may be posted to public websites, including NIHR BioResource studies webpage. | |
| *Click or tap here to enter text.* | |
| **3.8 Patient and Public Involvement and Engagement (PPIE)** | |
| * Please describe in no more than 300 words the input 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 patients and the public have not yet been involved in shaping this study, please describe how you anticipate they will be involved in the future and why they haven’t yet been consulted. * Please describe how will patients and the public be made aware of this research and its outcomes | |
| *Click or tap here to enter text.* | |
| **3.9 Equality, Diversity and Inclusion (EDI)** | |
| * Please provide in no more than 300 words a short overview on how Equality, Diversity & Inclusion will be analysed and actively prioritised within your research. * Please consider typical standards of equality, diversity and inclusion such as ethnicity, age, sex, gender, disability etc as well as broader inclusion for example: geographical diversity, socio economic diversity, educational diversity and those typically excluded in research.   How will the data be assessed for representativeness? 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 could be considered and embedded in research. | |
| *Click or tap here to enter text.* | |
| **3.10 Is there a commercial interest in this project or is there an industry collaborator?** | |
| If yes, please specify and describe the commercial benefit you envision as a result of accessing this data (e.g. a new product or service being developed, cost reduction, market expansion etc.). If there is an industry collaborator, please provide details below | |
| Yes  No  *Click or tap here to enter text.* | |
| **3.11 Is this project funded by industry in anyway (including in kind contributions)?** | |
| If yes, please specify the funder name | |
| Yes  No  *Click or tap here to enter text.* | |
| **3.12 Is there a study timeline?** | |
| If your research timeframe is limited to grant funding or any other defined time periods, please let us know. Please note that we cannot guarantee delivery to set timelines.  If yes, please specify start and end date (for example grant period, PhD/fellowship period). | |
| Yes  No  Click or tap here to enter text. | |
| **3.13 How will you disseminate the study findings?** | |
| * Please indicate to which audience and in what format you plan to disseminate the study findings * Please indicate both academic and patient-related dissemination if applicable * All dissemination should adhere to the guidelines on how to acknowledge [BioResource](https://bioresource.nihr.ac.uk/using-our-bioresource/acknowledging-the-bioresource/) (https://bioresource.nihr.ac.uk/using-our-bioresource/acknowledging-the-bioresource/) | |
| *Click or tap here to enter text.* | |
| **3.14 What is the potential impact of your study in a health or social care context?** | |
| * Please include which aspects of your research findings would benefit external stakeholders (outside academia or commercial parties), including the public/patients/healthcare workers/policy makers * Please include economic, social and/or cultural impact | |
| *Click or tap here to enter text.* | |

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| 1. **Requested de-identified data** |
| **4.1 Data types** |
| Please indicate which **data type** you would like to request per cohort by ticking in the relevant box. Data is not available for a particular cohort where the box is greyed out. |

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| |  |  |  |  |  |  |  |  | | --- | --- | --- | --- | --- | --- | --- | --- | | Cohort/ Data type | GA | WES | WGS | RNA-seq | Meta | HLQ | CRF | | COVID-19 |  |  |  |  |  |  |  | | General Population |  |  |  |  |  |  |  | | IBD |  |  |  |  |  |  |  | | IMID |  |  |  |  |  |  |  | | Mental Health |  |  |  |  |  |  |  | | NAFLD/MASLD |  |  |  |  |  |  |  | | Rare Diseases |  |  |  |  |  |  |  | | DCYPHR |  |  |  |  |  |  |  | | Diversity\* |  |  |  |  |  |  |  |   GA= Genotype Array; WES= whole exome sequencing; WGS= whole-genome sequencing; Meta= metabolome; HLQ = Health & Lifestyle Questionnaire; CRF = Clinical Report Form  \* the Diversity data is a cross-cutting cohort covering several patient groups and healthy volunteers, the available data can be discussed as per requirements.  Please refer to the **data holdings table** published on the BioResource data access webpage for details of number of participants per cohort: <https://bioresource.nihr.ac.uk/using-our-bioresource/apply-for-bioresource-data-access/> |
| **4.2 Please indicate which demographic data you request** |
| Age (provided as 5-year age bands)  Gender (self-declared; not available for all cohorts)  Ethnicity (self-declared; not available for all cohorts)  Other *Click or tap here to enter text.*  Please note that the BioResource is committed to contribute to the implementation of the NIHR framework ([Improving inclusion of under-served groups in clinical research: Guidance from INCLUDE project | NIHR](https://www.nihr.ac.uk/documents/improving-inclusion-of-under-served-groups-in-clinical-research-guidance-from-include-project/25435#nihrinclude-ethnicity-framework)). We strongly encourage Data Access Applications to request ethnicity data to be included as part of their research. When requested, and where available, the BioResource will provide self-declared ethnicity information. |

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| **4.3 Please indicate which other data you request** |
| Identifiers to link to existing patient cohort or previous study:  *Click or tap here to enter text.*  EGA (European Genome-Phenome Archive) data; please specify dataset ID(s):  *Click or tap here to enter text.*  Other Data (please specify and describe which not listed data you would like to request)  *Click or tap here to enter text.* |
| **4.4 Are you planning to meta-analyse or federate this data with other datasets?** |
| If yes, please specify the plan of the name of the consortium |
| Yes  No  *Click or tap here to enter text.* |
| **4.5 Do you anticipate any risks to individual privacy?** |
| If yes, please specify which steps have you made to mitigate this: |
| Yes  No  *Click or tap here to enter text.* |

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| 1. **Funding and ethical approval** |

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| **5.1 Funding (please tick to confirm)** |
| I, the lead applicant, declare that I/we have sufficient funds to carry out and publish this study.  Please provide funder’s name: Click or tap here to enter text. |
| **5.2 Has your study obtained additional ethical approval?** |
| Sharing of data held by the BioResource may be covered by the BioResource ethical approval. Please specify whether you believe additional ethical approval is required.  If yes, please provide details including the REC reference number. We will also require a copy of the research ethics favourable opinion letter alongside this application. |
| Yes  No  Please specify:*Click or tap here to enter text.* |

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| 1. **LEAD APPLICANT SIGNATURE** | |
| As the lead applicant you are responsible for ensuring that the information in this application form is correct. | |
| Print Name: | Click or tap here to enter text. |
| Signature |  |
| Date | Click or tap to enter a date. |