# Study Application Form

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| 1. Study name |
| Click or tap here to enter text. |
| 2. Plain English study name(This will be included on the NIHR BioResource website) |
| Click or tap here to enter text. |
| 3. Contact details |
|  | Principal Investigator | Main Contact |
| Name | Click or tap here to enter text. | Click or tap here to enter text. |
| Phone | Click or tap here to enter text. | Click or tap here to enter text. |
| Email | Click or tap here to enter text. | Click or tap here to enter text. |
| Address | Click or tap here to enter text. | Click or tap here to enter text. |
| 4. Plain English summary of study, suitable for inclusion on NIHR BioResource website (200 word limit) |
| Please see Appendix 1 - Plain language summary guidelines. **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. |

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| 5. Study type |
| The BioResource supports two different types of study: **Samples** - use of samples already acquired and stored by the BioResource. **Recall** - invite volunteers to take part in a study under its own ethical approval separate to that of the BioResource.Which type of study applies to your application? Please note that you CAN request both samples and recall in a single application. |
| Pre-existing BioResource **Samples** [ ]  Number of samples requested: Click or tap here to enter text.(Please fill out sections 6, 8 and 9 onwards) | **Recall** of volunteers [ ]  Number of volunteers requested:Click or tap here to enter text.(Please fill out sections 6,7,8 and 10 onwards) |

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| 6. Genetic/Phenotype requirements |
| Please provide specific information relevant to your preferred genotypic recall/samples. Please provide Chromosome positions using hg38/GRCh38 and write the Chromosomal position or range as Chromosome:position e.g. 11:119338939.CDS protein numbers can be provided in addition to genomic coordinates |
| SNV [ ]  |

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| rsID number | Major homozygotes | Minor homozygotes | Heterozygotes | Chromosomal position | Variant e.g., C/T or delC |
|  |[ ] [ ] [ ]   |  |
|  |[ ] [ ] [ ]   |  |
|  |[ ] [ ] [ ]   |  |
|  |[ ] [ ] [ ]   |  |
|  |[ ] [ ] [ ]   |  |
| Haplotype [ ]  |
| Gene/Haplotype name | Chromosomal range | Alleles (imputation may be used) |
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| CNV [ ]  |
| Chromosomal rangeClick or tap here to enter text. |
| Recall by phenotypePlease provide detailsClick or tap here to enter text. |
| Please state details regarding how volunteers will be grouped and compared for recall This describes the different criteria for the different study groups. These should be compiled from the above information, please provide as much detail as possible. Click or tap here to enter text. |
| Frequency of group(s) in normal population and study population:Click or tap here to enter text. |
| Groups to be matched? Yes[ ]  No[ ]  |
| If yes:By genotypic gender [ ]  By age (< 5yr groups) [ ] Ethnicity [ ]  By age (5 – 10 yr groups) [ ] Other [ ] (please provide details)Click or tap here to enter text. |

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| 7. Volunteer Recall  |
| Please tick the location of the appointment |
| Face to face[ ]  and/or Online/from own home [ ]  |
| How many appointments/sessions will the volunteer be asked to attend? |
| Click or tap here to enter text. |
| For studies that require a blood sample: |
| Total blood volume required per volunteer (in ml): |
| Click or tap here to enter text. |
| Please give details of the collection tubes to be used and provide details for each visit if details differ per visit |
| Click or tap here to enter text. |
| If >50ml per volunteer is required, please provide clear justification for the amount requested |
| Click or tap here to enter text. |
| Please detail all other clinical interventions required (e.g., blood pressure, height, weight) |
| Click or tap here to enter text. |
| Will volunteer participation be conducted at one of our local BioResource Centres? |
| Yes [ ]  No [ ] If ‘Yes’ which Centre(s) if known: Click or tap here to enter text.If ‘No’ please provide further details on where study participation will take placeClick or tap here to enter text. |
| Please outline any payments volunteers will receive and when these will be made (if applicable). Researchers are responsible for all study travel expenses. You will be required to offer to reimburse travel and parking expenses for all volunteers in addition to any payment they receive. |
| Click or tap here to enter text. |
| 8. Data Required (pre-existing) |
| Please detail the pre-existing BioResource (including NIHRBR-RD) data that you require (if applicable) for example demographic, smoking status or medical conditions.  |
| Click or tap here to enter text. |
| 9. Samples Required (pre-existing) |
| Please detail specific requirements along with any criteria that should be applied to sample selection.  |
| Click or tap here to enter text. |
| Plasticware requirements (e.g., tubes or plates, specific brands or labelling, if plates require any blank wells) |
| Click or tap here to enter text. |
| As standard samples will be provided in FluidX individual tubes with 2D barcodes, please confirm that your lab can receive this tube format. |
| Click or tap here to enter text. |
| Batches (Are all samples required in 1 shipment or in batches, any requirements within batches such as duplicates or randomisation, for batches what is the preferred frequency of shipping?) |
| Click or tap here to enter text. |
| Freeze/Thaw cycles |
| [ ]  Samples must never have been freeze-thawed [ ]  Samples can be from aliquots that have been freeze-thawed |
| Shipping location/ requirements |
| Click or tap here to enter text. |
| Any other selection criteria/requests |
| Click or tap here to enter text. |
|  | Number of samples required | Volume per sample (µl) | Concentration (ng/µl) |
| DNA (from Blood)\* | Click or tap here to enter text. | Click or tap here to enter text. | Click or tap here to enter text. |
| DNA (from Saliva)\* | Click or tap here to enter text. | Click or tap here to enter text. | Click or tap here to enter text. |
| Plasma (EDTA) | Click or tap here to enter text. | Click or tap here to enter text. | N/A |
| Serum | Click or tap here to enter text. | Click or tap here to enter text. | N/A |
| \*Most sample collections have DNA derived from blood, but the Mental Health collection is a saliva-based cohort and some participants in other cohorts may have saliva-derived DNA. If DNA source is important for your downstream application, please specify above.Please note: Sample transport costs will be recharged to the research team; some plastic ware costs may also be rechargeable |

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| 10. Study Summary |
| Please provide an overview of the proposed study including the commitment required by each study participant (1 A4 side maximum).  |

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| 11. Scientific Justification |
|  Please give the scientific justification for the proposed study including sufficient evidence and reference to literature and any relevant previous results (2 A4 sides maximum). |

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| 12. Statistical Justification |
| Please provide an overview that explains the statistical justification and how these figures were arrived at including power calculations. If this is a pilot or there is no reasonably way to estimate the effect size please state this (1 A4 side maximum).  |

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| 13. Study Timeline |
| Please provide details of the anticipated timeline with potential study start & end dates. Whilst the BioResource will aim to start the study according to your timeline this cannot be guaranteed. |
| Click or tap here to enter text. |
| 14. Benefit to Patients  |
| Please provide a brief (up to 250 words) plain language outline of the likely future benefit to relevant patients. |
| Click or tap here to enter text. |
| 15. Equality, Diversity and Inclusion (EDI) |
| How have you considered 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. |
| 16. Ethics |
| Is there currently ethical approval in place for this study? |
| Yes [ ]  No [ ] If ‘yes’ please attach current copies of your Protocol, Patient Information Leaflet, Consent Form, IRAS form and letter of favourable opinion to this application.Please also confirm that PPI activity was undertaken in the process of gaining ethical approval Click or tap here to enter text. |
| Please note that studies that wish to use a local BioResource to facilitate their research appointments will need to have NHS REC and HRA approval. The site will need to be approved by the local NHS Trust’s R&D department. Approval from R&D is estimated to take 90 days from first submitting the local site pack to the time of the first enrolled volunteer. Responsibility for obtaining this approval will lie with the study team and NOT the BioResource. The BioResource may request that you make changes to your study documents to ensure that they are suitable for use within the BioResource and with our volunteers.  |

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| 17. Confirmation of Conduct for Researchers Please read and sign the following.  |
| Further to the NIHR BioResource granting approval for my study I can confirm that:1. I have/will obtain the necessary ethical permissions from the relevant RECs for the above named study, where applicable.
2. I will follow all research governance guidelines when conducting this study. If applicable, I will notify the NIHR BioResource of any minor or substantial amendments in relation to this study. I understand that failure to do so may result in the early termination of this recall study.
3. Where COVID-19 research activity is undertaken via the NIHR BioResource Research Tissue Bank ethics, I will ensure all relevant members of the research team are included on the delegation log and have undergone appropriate training in line with the tasks they undertake and as per the NIHR BioResource requirements. I will also ensure compliance with any Human Tissue Authority requirements. I agree to provide the BioResource with information on sample storage/processing as required.
4. Publications
	1. I agree to acknowledge the NIHR BioResource in all publications and literature relating to this application. Suitable wording is provided in the “Publications Policy” given in Appendix 2.
	2. I agree to abide by the terms outlined in the NIHR BioResource ”Publications Policy” as set out in Appendix 2.
	3. I will inform the NIHR BioResource of all publications relating to this study. Please send publication details to publications@bioresource.nihr.ac.uk
	4. I agree that if I lodge data in a (managed-access) repository as a condition of publication, then the NIHR BioResource will be appointed to manage the access, and will provide the NIHR BioResource with a copy of the results.
5. I agree that if the NIHR BioResource requests a copy of any genotype and/or phenotype data which has been generated as a result of this study, such data will be promptly shared, at no cost, with the NIHR BioResource.
6. I agree to use the data and/samples provided and generated, according to the consent obtained from participants. Data and samples can only be used for the approved purpose and project described in the application; use for a new purpose or project will require a new application and approval.
7. I agree not to redistribute the data, or any subset or derivative that could be used to identify the research participant other than in accordance with clause 4 above.
8. Following completion of the study, prior to and as a condition of the NIHR BioResource supplying any genotype information, I will destroy any personal identification information and will hold results identified by the NIHR BioResource Study Specific ID only. I also agree:
	1. To maintain all appropriate procedures to ensure that all data is only used for the purposes outlined in the application and is kept secure and not disclosed to any third party.
	2. To 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, I understand my 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.
	3. To acknowledge 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 I will be the Data Controller and Data Processor for the above research proposal.
	4. Not to 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, including in publications.
	5. Not to 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, or it is freely available without restriction, without specific permission being sought for this purpose from the relevant access committees.
9. I accept that the majority of NIHR BioResource recall studies are based on selecting participants, their samples or data on the basis of data already held. The NIHR BioResource makes every effort to ensure that its data and sample holding accurately represents the participants who have joined. However, there is still a small chance that errors may have been made during sample-handling and/or data-extraction processes. Researchers are therefore advised to check by a method of their choice any particular aspect of the data provided by the NIHR BioResource, if it is critical to their research. If in the course of subsequent data analyses we discover any errors, these will be notified to the relevant researchers.
10. I accept that approval for this application will terminate immediately upon any breach of the above conditions.

Name of Principal Investigator (PRINT) Click or tap here to enter text.Date Click or tap to enter a date. |

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| Signature  |  |

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| Appendix 1 – Plain language summary guidelines |
| The study name, PI name, institution 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 of the research is, who is conducting the research (organisations rather than individual names), what will happen to the data generated, 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/),](http://www.readabilityformulas.com/%29) 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.Please note: Unsuitable study summaries may delay the approval and/or start of your study.  |

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| Appendix 2 - Publications Policy |
| 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 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.ukThis 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.Press and Social MediaNIHR BioResource should be acknowledged for its role in the research detailed in this application in any communications that relate to the research. Please contact the NIHR BioResource in advance of any press or media activity relating to the research to allow us to support the dissemination of the story. Twitter activity must where possible include the NIHR BioResource handle @NIHRBioResource and on LinkedIn via the company name NIHR BioResource. |