# Study Application Form

Prior to submitting an application, please email the BioResource, nbr@bioresource.nihr.ac.uk, to arrange a discussion regarding your requirements and feasibility. Completed application forms must be submitted to nbr@bioresource.nihr.ac.uk. All applications will be review by our Scientific Advisory Board and our participant representative group.

Further information and advice on completing your application can be found on [our website](https://bioresource.nihr.ac.uk/using-our-bioresource/).

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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 (300 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. Provision of stored samples is covered under the BioResource’s research tissue bank ethics. Separate ethical approval is not required. **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 and Phenotype requirements |
| **6.a Does your request require recall or samples by genotype, or are you requesting genetic information as part of your request? (If no please skip to section 6b.)**  |
| Yes [ ]  No [ ] If yes, 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. |
| Frequency of genes in normal population and study population:Click or tap here to enter text. |
| **6.b Does your request require recall or samples by phenotype?** |
| Yes [ ]  No [ ] If yes, please provide information about the phenotypic requirements. If relevant please include the type of patients you would like, whether diagnosis needs to be via a particular test and whether clinical confirmation of diagnosis is required (as opposed to self-declaration). If you have specific clinical information you require, please discuss this with the BioResource before submitting an application. Click or tap here to enter text. |
| **6.c Comparison groups**Will your samples/recall be split into comparison groups for analysis?  |
| Yes [ ]  No [ ] If yes, please provide more details and use the options below to indicate whether the groups need to be matched. (e.g., patients need to be matched with controls of the same age and gender). Click or tap here to enter text. |
| Groups to be matched? Yes[ ]  No[ ] 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 (recall requests only) |
| 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 may receive and when these will be made (if applicable). Researchers are responsible for all study travel expenses. You will, in addition to any inconvenience payments, be required to offer to reimburse travel and parking expenses for all volunteers. |
| Click or tap here to enter text. |
| 8. Data Required (pre-existing) |
| Please indicate which, if any, pre-existing data you require and include details of the data required in the text bow below (if you are unsure what data is available please email nbr@bioresource.nihr.ac.uk to discuss your requirements before you submit your application). Please note that only data that has been requested and approved in your application will be provided.  |
| Clinical data (only available for patient groups) [ ] Health and lifestyle data [ ] Genetic data [ ] Click or tap here to enter text. |
| 9. Pre-existing Samples Required (samples requests only) |
| 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.OWN section |
| 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.  |
| 17. Public and Patient Involvement |
| Have you undertaken any PPI activities as part of the design of this research or part of the ethical approval process?  |
| Yes [ ]  No [ ]  |
| Please include details of the PPI activities you have undertaken, if you have not undertaken any PPI activities, please provide justification for this, including any future plans for PPI involvement with your research.  |
| Click or tap here to enter text. |

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| 18. Publication 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/> **Notification of Publication**All manuscripts that make use of data, samples or recall from the NIHR BioResource must be reviewed by the BioResource publications committee prior to submission. The committee will require a minimum of 1 week to provide comment on manuscripts prior to submission. Please send all manuscripts to publications@bioresource.nihr.ac.uk. Once a manuscript has been published, please notify us using the same email address. **Acknowledgement:** Authors who use NIHR BioResource Data, samples or volunteer recall **must** acknowledge the NIHR BioResource and its stakeholders using the wording which is currently found on the NIHR BioResource website: <https://bioresource.nihr.ac.uk/researchers/researchers/acknowledgement/>  When appropriate, authors should also refer to NIHR BioResource grant numbers (general or study-specific) which can be provided upon request.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. A list of NIHR BioResource authors is maintained and can be shared with the corresponding author for inclusion in the paper.**Open Access**It is NIHR policy that all publications involving use of Data/Samples/Volunteer recall that have been obtained through NIHR funded research should use Open Access and the Recipient should provide the Open Access. Please see the web pages below for further information.[https://www.journalslibrary.nihr.ac.uk/journals/#Open%20Access](https://www.journalslibrary.nihr.ac.uk/journals/%23Open%20Access)<https://www.nihr.ac.uk/documents/nihr-open-access-policy-for-publications-submitted-on-or-after-1-june-2022/28999>  https://www.nihr.ac.uk/documents/nihr-open-access-publications-funding-guidance/30210 If your project does not have funding to cover open access publication, please contact us for advice.**Open Data**While aggregate data may be published openly, we usually state that “Data is available on request”, and that data is made available through a managed-access process, described here: https://bioresource.nihr.ac.uk/using-our-bioresource/academic-and-clinical-researchers/apply-for-bioresource-data/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 release and Social Media**NIHR BioResource should be acknowledged in any papers and in any communications that relate to research that makes use of data, samples or volunteer recall from the NIHR BioResource. 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 (comms@bioresource.nihr.ac.uk). Twitter activity, where possible, must include the NIHR BioResource handle @NIHRBioResource and on LinkedIn via the company name NIHR BioResource.If your study relates to the Rare Disease RNA Phenotyping project, please refer to the Rare Diseases RNA Phenotyping publications policy.[ ]  I confirm that I have read and understood the Publication Policy of the NIHR BioResource. I agree to abide by this policy and understand that if I do not then I may be restricted from accessing the BioResource in future.  |

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| 19. Confirmation of Conduct for Researchers Please read and sign the following.  |
| Please read and sign the following. 1. I have/will obtain the necessary ethical permissions from the relevant RECs for the above named

study, where applicable.1. 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. Iunderstand that failure to do so may result in the early termination of this recall study.1. 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 thedelegation log and have undergone appropriate training in line with the tasks they undertake andas per the NIHR BioResource requirements. I will also ensure compliance with any Human TissueAuthority requirements. I agree to provide the BioResource with information on samplestorage/processing as required.1. 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 this document.
	2. I agree to abide by the terms outlined in the NIHR BioResource ”Publications Policy” as set out in this document
	3. I will inform the NIHR BioResource in writing of all publications relating to this study prior to their submission to a journal. I will provide a minimum of one week to allow the NIHR BioResource to review the publication prior to its submission. I will information the NIHR BioResource of any accepted publications. 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.
2. 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.
3. 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.
4. 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.
5. I 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 my employer 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 for linkage being obtained for this purpose from the relevant access committees.
6. 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 and I will promptly notify the NIHR BioResource if I discover any errors. If, in the course of subsequent data analyses, the NIHR BioResource discovers any errors, these will be notified to the relevant researchers.
7. 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 |
| Provision of a plain-language summary (PLS) is a condition of ethical approval for access to NIHR (National Institute for Health Research) BioResource resources. A well written PLS is an essential part of the application and approval process. **One of the main reasons that approval of applications is delayed is a poor PLS that does not meet the requirements below** Following application approval, the study title, lead applicant name, institution and PLS **will be published on the NIHR BioResource website** where it is available to study participants, the public, media, other researchers, and funders. **What is a plain language summary?**The plain language summary is a stand-alone summary of the proposed research project. It should not simply be copied from other project descriptions but needs to be written afresh. The PLS should use plain English suitable for a reading age of 12. You may want to consider using a readability checker such as [https://readable.io/.](https://readable.io/) In the PLS you should minimise the use of technical terms and jargon. Any technical or scientific terms including acronyms used should be clearly explained. Examples of jargon are clinical and methodological terms, as well as words that can have different meanings in science than in common use (e.g. local, blind, control). Consider using a plain language glossary such as [https://www.lib.umich.edu/taubman-health-sciences-library/plain-language-medical-dictionary.](https://www.lib.umich.edu/taubman-health-sciences-library/plain-language-medical-dictionary) The PLS should clearly convey the key questions and purpose of the project. The goal of writing in plain language is to enable readers to understand the content the first time they read it.You must make sure the plain language summary is consistent with the scientific project description submitted for approval.**What should the summary include?** The summary should clearly state what the specific purpose of the research is, who is conducting the research (organizations 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. Your summary needs to contain the following sections:1. Problem – set out the problem, explain why the research is necessary
2. Methods – explain in simplistic terms what methods you will use
3. Relevance of requested data/samples/recall of volunteers – describe how NIHR BioResource contributes to the work
4. Benefit to patients and impact – describe the impact that the research could have to the patients and public

**What should I include in the 4 sections?** **Problem.** Evoke the problem first. There are some questions which help to do this: What is the essence of the problem and what are the consequences of the problem? Which research question are you trying to answer to solve the problem? Why is it important? **Methods.** What is the method, in plain language? **Relevance of requested data.** How will the participants’ data or samples be used to investigate the research question?**Benefit to patients and impact.** What are the potential benefits or implications of your proposed research? This may include short term outcomes or longer-term impact. This section is also important to show Bioresource volunteers their valuable role in participation in health research.**Example of a good plain language summary***Changes in our DNA, called “mutations”, cause some people to get autoimmune diseases such as Inflammatory Bowel diseases (IBD). Exactly which mutations are responsible and how they lead to diseases is unknown. We are studying a region of DNA that has been linked to Crohn’s disease and ulcerative colitis, to types of IBD. Which genetic region controls inflammation in Crohn’s disease and ulcerative colitis? Which exact mutation is responsible for it? To answer these questions may help us find better treatments.**To answer these questions, we would like to do two experiments. First, we will introduce a previously selected mutation into blood cells from healthy people who do not carry it. We expect this will cause a nearby disease gene to turn on. Second, we will see whether patients with this mutation get worse inflammation than those without it. We hope to learn what goes wrong to cause these diseases.**The NIHR BioResource, we can select participants for this study based on their genetic make-up and their disease. NIHR Bioresource offers a unique opportunity to study the link between genetics and Inflammatory Bowel disease in a large group of individuals from the general population and patients.**The proposed research has the potential to improve treatment options for IBD patients.***Who is the plain language summary for?** * The NIHR BioResource Data Access Committee (DAC) and/or NIHR BioResource Steering Committee. The summary explains the project for the Committee members. Our committees have a diverse range of expertise and may not be familiar with your area of research.
* The funders of the NIHR BioResource. The funders want to know the scope and potential impact of the work that is being proposed.
* The Research Ethics Committee. The NIHR BioResource provides an annual summary of all research done, as a condition of being permitted to release samples and data as a Research Tissue Bank.
* Researchers. The PLS for approved projects can be viewed online by other researchers. The research themes and broad methodology show what areas of research are already under investigation.
* NIHR BioResource participants. Participants can see how they have contributed to current knowledge. They need to understand what questions are being researched, how they have contributed to this, and the potential benefits of the work – without getting bogged down in technicalities.

**Tips for writing in plain language** * Limit sentences to one key point.
* Use short paragraphs.
* Be careful with words or phrases with dual or nuanced meanings (e.g. drugs; diet).
* Avoid technical words, jargon or words that are long or have many syllables. Consider those who do not have English as a first language.
* Avoid unnecessary technical details if you can make the same point in plain language.
* If you must use technical vocabulary, provide a short definition of your term when it is first introduced and do not use too many technical words together in one sentence.
* Do not include citations to research literature.
* Consider introducing an acronym or shorter term for repeated use.
* Write for an international audience. Avoid words or terms that are region-specific (A&E versus ER).
* Use the active voice (For example, use “previous research showed that…” rather than “it was shown in previous research that…”).
* Keep it concise (within the word limit of 300 words).

**Sources** The NIHR BioResource gratefully acknowledges the work of METADAC study participant members and the METADAC Secretariat to generate these guidelines, which have been adapted here. The guidelines are based on (but not limited to) the following resources: * METADAC guidelines - <https://cpb-eu-w2.wpmucdn.com/blogs.bristol.ac.uk/dist/7/314/files/2017/06/v1.0-Plain-language-guidance-for-METADAC-applications.pdf>
* Cochrane Reviews Guidance [-](http://editorial-unit.cochrane.org/sites/editorial-unit.cochrane.org/files/public/uploads/PLSBooklet2.pdf)[guidance-writing-cochrane-plain-language-summary.pdf](https://training.cochrane.org/guidance-writing-cochrane-plain-language-summary.pdf)
* National Institute for Health Research (INVOLVE)[-http://www.invo.org.uk/resource-centre/plainhttp://www.invo.org.uk/resource-centre/plain-english-summaries/english-summaries/](http://www.invo.org.uk/resource-centre/plain-english-summaries/)
* The Plain Language Campaign -<http://www.plainenglish.co.uk/free-guides.html>
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