

IBD BioResource, part of the NIHR BioResource

Version 8, 21/07/23

PATIENT INFORMATION SHEET

In the UK around 500,000 people live with Crohn's disease or ulcerative colitis (together known as inflammatory bowel disease or IBD). The IBD BioResource was set up to help in the fight against IBD. It is part of a bigger project, the NIHR BioResource which supports research in IBD and many other disease areas.

We would like to invite you to join the IBD BioResource. Please take some time to read the following information carefully and feel free to ask us if there is anything that is not clear or if you would simply like more information.

ABOUT IBD BIORESOURCE

What is the IBD BioResource?

The IBD BioResource aims to help research key questions in Crohn's and colitis. What causes Crohn's and colitis? What makes symptoms worse in one patient than another? Why do some treatments work for some patients and not others? What new treatments can be developed?

To help us answer these questions, we need to understand how genes and environmental factors, such as smoking and diet, affect the immune system which has stopped working properly for people with Crohn's and colitis.

Thousands of volunteers with Crohn's or colitis from all over the country have already agreed that blood samples and information about their health may be collected and stored in the IBD BioResource. The samples and information can then be analysed and compared with material from other volunteers in the NIHR BioResource (who may have other conditions or have no medical conditions) to help the research.

What is the NIHR BioResource?

The NIHR BioResource is the name for the collection of BioResources around the country together recruiting volunteers who are either 'healthy' or suffering from health conditions like IBD.

The health information and samples given to the IBD BioResource will be owned by NIHR BioResource and access to these may be given to authorised medical researchers and scientists working on IBD or other disease areas. By joining the IBD BioResource you are also joining the national NIHR BioResource, you cannot join one without the other

As part of the IBD BioResource, and based on analysis of your samples and information obtained from them, you may be contacted and invited to take part in future research studies. These may relate to Crohn's or colitis or you may be asked to join a study which is looking at a different health problem. If you are asked to take part in a

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ibd@bioresource.nihr.ac.uk

www.ibdbioresource.nihr.ac.uk

study, you can choose which ones you want to join - in all cases joining in will be entirely up to you.

BEING PART OF THE IBD BIORESOURCE

Why have I been invited to join the IBD BioResource?

The IBD BioResource is recruiting people with Crohn's disease or colitis from many hospitals around the UK, and as someone who has IBD or is under investigation for possible IBD we are inviting you to join in as well.

Do I have to join the IBD BioResource?

It is completely up to you whether or not you would like to join. If you decide not to, your decision will not affect the healthcare you receive in any way. If you do decide to join, you will be free to withdraw at any time and without having to give a reason.

What does joining involve?

If you agree to join, we will ask you to:

- Read, initial and sign the electronic or paper consent form
 - for electronic consent, we will email you a 'link' to follow and complete
- provide further details including your date of birth, NHS number and contact details (e.g. address and telephone number), and allow us to store them securely
- give some samples
- blood - up to 20ml = 4 teaspoons, may be collected with routine clinic bloods
 - if recently diagnosed or changing treatment or in stable remission, we may at future time point ask you to provide an additional 5-10ml blood sample and two stool samples to look for changes;
 - if you are having a colonoscopy as part of your medical care we may ask you if we can take up to 6 additional biopsies from up to 2 extra sites on top of the 16-24 that are usually done as part of the routine clinical assessment
- allow us to store and access samples for use in future research studies. This can include access to material already collected or collected in the future as part of your medical care (e.g. material from biopsies or surgeries) and other health related research studies. Samples obtained from people who (after investigation) turn out not to have IBD may still be used in research.
- fill in a health and lifestyle questionnaire (online or paper) and up to one update questionnaire per year. If you have been newly diagnosed, we will also ask you to complete a Patient Reported Outcome Measures (PROM) questionnaire at 6, 12, 24 and 36 months after joining to keep track of your symptoms and treatment(s). You may also be asked to complete an additional PROM at the time of future disease re-evaluation or treatment change; or when undergoing colonoscopy as part of your clinical care.
- allow us to collect, store and analyse health information about you. This involves accessing existing and future hospital records, GP records and centrally held health records (including but not limited to NHS Digital databases regarding hospital admissions, diagnoses, surgeries and cause of

death; Public Health England databases; prescribing databases; national cancer registries and IBD Registry; and data held at the Office for National Statistics such as COVID-19 data for example)

- consider taking part in the National Genomic Library to provide basic identifiers such as your name, date of birth, postcode and NHS Number to NHS Digital and other organisations so that they may collate your medical history records and provide the data to the Library (see the appendix for further details on the National Genomic Library)
- allow us to analyse your samples and data to identify things that affect health outcomes for example response to treatment (in other words whether IBD medicines work, risk of side effects from treatments, development of complications etc.)
- agree to provide further samples, either for other studies or if the initial sample provided was insufficient for certain types of testing. DNA will be isolated from these samples. You can decide at the time whether or not you would like to provide these additional samples, and are under no obligation to do so
- agree to be contacted in the future and invited to join in other research studies (you can choose whether or not to participate in any future studies at the time of being invited to them)

SAMPLES

What will happen to the samples I give?

We want to know how genes and things in the environment like diet, infections etc. influence both disease and 'response' to treatments. Genes are made up of DNA which we can find in your cells. When you give us a blood or stool sample, we separate out the DNA, analyse it and store both it and the data safely. The analysis may include identifying all the genes in your DNA by 'sequencing'.

We may also look for other things in your samples for example:

- different types of cells such as those involved in the immune system
- RNA – a molecule that works with your DNA to make other important molecules for your body
- Proteins such as antibodies and molecules that send signals between cells
- metabolites (molecules that form from chemical reactions in your body).
- Indicators to find out how the immune system might defend against bacteria, fungi and viruses

This will help us understand the impact of these substances on your immune system, on how your IBD behaves and how well your treatment works.

DATA

How will the data we collect be used and stored?

Data about you (e.g. personal details and health information) will be stored in secure electronic databases. Any information from genetic and other tests or analyses will be stored separately from your personal details. Access to your personal details will only be available to authorised members of the BioResource (for example, to invite you to take part in other research studies).

ACCESS TO SAMPLES AND DATA

Once de-personalised (i.e., with all identifying information removed), your samples and data can be accessed by approved researchers wishing to study the causes of Crohn's and colitis, responses to treatments etc. Data may include part of, or all of your DNA code, or the results of other tests carried out with your samples and other information from the research database. None of this will identify you personally.

These studies may involve:

- access to data only (e.g., genetic information)
- access to data and samples (e.g., medication history and stored DNA)
- Recall studies (e.g., where the BioResource may contact you to request new samples, complete questionnaires or invite you to take part in clinical trials)

Before external researchers are allowed to access samples and/or data from the IBD BioResource, the following steps must be satisfied:

- Researchers requesting access to samples and/or data need to justify what research question they are trying to answer and have approval from an independent research ethics committee.
- Researchers' applications are then considered by an expert NIHR BioResource committee to check that research questions will produce scientific advances or benefit to patients or both. This type of system is called 'managed access'
- Once approved, researchers will be given access to data for their research through data access agreements which requires them to keep your data safe as defined within these agreements and by the law. See GDPR section in the appendix for more details

For recall studies and to preserve confidentiality, patients meeting inclusion criteria **will only be contacted by the BioResource team** with an email or letter of invitation and a patient information leaflet. Researchers themselves are never given your contact details.

'Managed access' requests could come from researchers who are working in the public and charitable sector (Universities, Research Institutes) or from commercial companies such as those developing new treatments, either in the UK or overseas. We will never allow your data to be used for marketing or by insurance companies.

What happens if an invention is made using my sample?

Your sample may help researchers in the public or the commercial sectors invent a new product which can be used to diagnose or treat diseases including IBD for the benefit of patients. We hope that such products will improve healthcare in the future.

When you donate your samples and related information, they are given as an absolute gift – that is they are given without you receiving a payment and without conditions. If an invention comes from research using your sample you will not receive any compensation, recognition or payment.

The BioResource is operating on a non-commercial basis. It does not sell your samples to make a profit and will not allow anyone else who is working with the sample to do so either. However, if samples are made available to other research institutions

or to commercial companies for research purposes, a fee may be charged to cover the BioResource operational costs.

How often will I be contacted?

We closely monitor how many times you are approached for future studies and restrict the number of contacts and invitations. We greatly appreciate the effort made by volunteers and are happy to refund travel/parking costs incurred by participating in these further studies. We would also like to send you occasional newsletters, to inform you about the progress we are making with research, or to tell you about any changes to the way the BioResource operates.

Will my details be kept confidential?

Yes. Best ethical and legal practice will be followed to ensure that all information collected about you will be handled in confidence. Your samples will be labelled with a unique sample study number (rather than personal data) before being transferred to the laboratory for testing.

Only staff employed in the NIHR BioResource have access to both your personal identifiable data and data extracted from your health records (for example, what treatments you have had or what other conditions you may have). These staff are bound by the terms of 'Good Clinical Practice' which is - the international ethical, scientific and practical standard to which all clinical research is conducted¹. Researchers do not get access to information that identifies you.

Results of research analyses done on your samples **will not be used** or made available for any purpose other than for research. Researchers may share the results of their studies in reports or publications, which includes placing the results of research on the internet, in press articles, in medical research journals, in project leaflets and through other media. Under no circumstances will any information that identifies you personally be disclosed in any of these types of media.

An explanation of how the BioResource complies with the General Data Protection Regulation (GDPR) can be found in the appendix.

BENEFITS AND RISKS OF JOINING

What are the benefits of joining the IBD BioResource?

There will be no direct benefit to you. However, by joining the IBD BioResource you will be helping to improve our understanding of the links between genes and environmental factors that cause IBD and other diseases. Our goal is to improve treatment and the long-term prevention of IBD and other diseases.

What are the risks of joining the IBD BioResource? Joining the IBD BioResource will involve donating small amounts of biological samples. Qualified staff will collect this usually at the time of clinic bloods being taken, but blood sampling can sometimes cause discomfort and may cause a small bruise.

¹ <https://www.nihr.ac.uk/health-and-care-professionals/learning-and-support/good-clinical-practice.htm>.

Biopsy samples will only be taken at the time of colonoscopies, which are done as part of your routine clinical care. The biopsies are tiny (each less than 2mm). You will not feel the biopsies being taken and such sampling is not associated with significant risk. For those newly diagnosed, a stool sample will need to be collected and posted from home at the time of joining and at 6 months after joining the BioResource. This may add some inconvenience to your day.

GENETIC FEEDBACK

We do not routinely feedback any research results from your sample, however you do have the option to be told if you are at an increased risk of certain genetic conditions which could be prevented or treated early by the NHS. Details of this option will be on the IBD BioResource consent form. You can see the list of rare genetic conditions which the option covers at [Genomics England](#)

If it is found that you are at increased risk of such conditions, and you choose to be informed about this, your consultant will be made aware and a further sample would be taken for analysis within an accredited NHS diagnostics laboratory to confirm any such finding. A health professional or genetic counsellor would then feedback to you on the final results.

As more genetic findings are identified, we will investigate their association with patterns of IBD and IBD treatment responses; this may include asking clinicians whether genetic information is useful to inform decisions regarding choice of treatment. In addition, in some cases we might find that your IBD or treatment response (including risk of side effects) appears to be due to a genetic abnormality in just one gene ('monogenic IBD'). If this happens and might affect treatment options we will feed the information back to your consultant for formal testing through an NHS accredited diagnostics lab.

Important Points:

IBD BioResource gives the option to participants to get feedback on a limited number of rare genetics conditions, these can be found on the [genomics England](#)

If you are concerned that you are at risk of a genetic disease, please discuss this with your clinical care team. The genetic results from this research study will take a significant length of time to be analysed and requesting feedback on incidental findings should not be used in place of genetic testing.

WITHDRAWAL PROCESS

What if I no longer want to be a member of the IBD BioResource?

Volunteers are free to withdraw from the IBD BioResource at any time without giving a reason. Please note:

- You will be asked to specify whether you would like us to destroy the sample(s) you have donated, which are stored at the central archive.
- It will not be possible to destroy samples already prepared or already distributed for testing.
- Your personal information will be retained in an archive so that by withdrawing from the **IBD BioResource** you will also be withdrawing from the NIHR BioResource and vice versa.
- Pre-existing data and data that has already been distributed to other researchers cannot be destroyed.
- Once you confirm your decision to withdraw through your local IBD team or by contacting us at ibd@bioresource.nihr.ac.uk, there are 2 options to choose from: Option 1: **'No further contact' withdrawal** and Option 2: **'No further use' withdrawal**

For further details on the withdrawal options, please refer to the GDPR section in the appendix. If the IBD BioResource is unable to confirm your preferences regarding withdrawal options, **it will be considered as a 'no further contact' withdrawal by default.**

FUNDING & SPONSORSHIP

Who funds and sponsors the IBD BioResource?

The IBD BioResource is funded by the National Institute for Health Research (NIHR), the Medical Research Council, the Wellcome Trust, Open Targets, Crohn's and Colitis UK and the Helmsley Charitable Trust. We also receive grant support from industry partners. This study has been reviewed and approved by East of England - Cambridge Central Research Ethics Committee. Cambridge University NHS Foundation Trust is the establishment responsible for the management of the NIHR BioResource – Research Tissue Bank.

What if something goes wrong?

If you have a concern about any aspect of this study, you should ask to speak to the local IBD team [[insert local details](#)] who will do their best to answer your questions [[contact number](#)]. You can also contact the NHS Patient Advice and Liaison Service staff (PALS), [[insert local details](#)] who may be able to resolve your concerns.

FUTHER INFORMATION

If you need more information before deciding or have any queries about anything concerning the IBD BioResource/NIHR BioResource, please feel free to contact your local IBD team on [[insert local details](#)] or you can contact the central IBD BioResource team on 0800 090 2277 or e-mail us on ibd@bioresource.nihr.ac.uk

Thank you for considering joining the IBD BioResource, part of the NIHR BioResource.

Appendix

Transparency Statement under General Data Protection Regulation (GDPR)

The Cambridge University Hospitals NHS Foundation Trust is the sponsor for the Research Tissue Bank and the IBD BioResource study based in the United Kingdom. We will be using information from you and your medical records in order to undertake this study and will act as the data controller for this study. This means that we are responsible for looking after your information and using it properly. University of Cambridge and the Cambridge University Hospitals NHS Foundation Trust will keep identifiable information about you for 10 years after the study has finished, and we may approach you to extend this.

How will we use information about you?

We, the IBD BioResource and NIHR BioResource, will use information from you and from your medical records, including from your GP, hospital records and other health-related central records for this research project.

This information will include your:

- Full name
- NHS number
- Date of birth
- Contact details including address, phone number and email address
- Name and contact details of your GP
- Health-related information e.g. on your lifestyle, disease history, medication etc.
- Genetic information that will be generated from your blood or saliva samples
- Medical information provided by e.g. NHS health-related central records, disease registries etc.

People will use this information for research or to check your records to make sure that the research is being done properly. People who do not need to know who you are will not be able to see your name, NHS number, date of birth or contact details (which are your “personal identifiable information”). Your data will have a code number instead. We will keep all information about you safe and secure. Some of your information, but not your personal identifiable information, may be shared with researchers and service providers within and outside the UK (for example some of the genetic analysis is done overseas). They must follow our rules about keeping your information safe. Once we have finished the study, we will keep some of the data so we can check the results. We will write our reports in a way that no-one can work out that you took part in the study.

What are your choices about how your information is used?

We need to manage your records in specific ways for the research to be reliable. We will be able to let you see the data we hold about you. We will be able to change some of the information we hold about you (for example your contact details and contact preferences) if you ask us to; however, we won't be able to let you change other data we hold about you (such as your genetic information for example). You can stop being

part of the study at any time, without giving a reason, but we will keep information about you that we already have. There are then two options:

1. ‘no further contact’ withdrawal: with this option we will stop further contact with you, but we would like to continue collecting information about your health from central NHS records, your hospital, your GP; and continue to use data from your existing samples for research.
2. ‘no further use’ withdrawal: If you do not want any more data to be collected, or your data to be used further tell us and we will stop using your information and destroy your remaining sample, as well as stopping further contact with you.

Where can you find out more about how your information is used?

You can find out more about how we use your information

- at www.hra.nhs.uk/information-about-patients/
- our privacy notice available from [NIHR BioResource](#) which includes the sponsor’s Data Protection Officer contact details
- by asking one of the research team
- by sending an email to ibd@bioresource.nihr.ac.uk or nbr@bioresource.nihr.ac.uk
- by ringing us on [0800 090 2277] or [0800 090 2233].

The National Genomic Research Library

The National Genomic Research Library is a secure national database of de-identified genomic and health data that is managed by Genomics England, which is a company set-up by the Department of Health and Social Care. Approved researchers can use the samples and data in a form that does not identify you to study diseases and look for new treatments. Adding your personal health and genomic data to the Library helps by adding to others’ data to make the Library a rich source of data for researchers. Everyone is unique and the more the Library holds, the better the outcomes for everyone.

If you agree to take part in the Library, we will provide basic identifiers such as your name, date of birth, postcode and NHS Number to NHS Digital and other organisations so that they may collate your medical history records and provide the data to the Library. All identifying information is removed before researchers are able to use it. Your data will be kept in secure systems. Your data cannot be removed from the Library and any results of research that are taken out cannot be used to re-identify you.

Your data may include:

- Electronic copies of all your past and future records from the NHS, your GP and other organisations (such as NHS Digital and Public Health bodies);
- Information about any illnesses or stays in hospital;

- Copies of hospital or clinic records, medical notes, social care, and local or national disease registries, and data from other research studies;
- Relevant images from your NHS records, such as MRI scans, X-rays, or photographs;
- Data from other research registries and studies that may be relevant (but only where you have given them your permission to share that information).

Only researchers who are trying to better understand diseases and how to treat them will have access to the National Genomic Research Library. Researchers may come from all over the world, pooling international data and research gives the best chance of new discoveries. Approved researchers may work for not-for-profit organisations, such as research charities, universities, or hospitals, and for-profit (commercial) companies such as drug or technology companies. They will only have access to your de-identified genomic and health data in the National Genomic Research Library if they apply and are approved by Genomics England.

You can leave the Library at any time without giving a reason. You will need to sign a withdrawal form to record your decision. The form can be requested from [Genomics England](#).