[Trust Logo]

IBD BioResource, part of the NIHR BioResource

Version 6, 22/01/19

PATIENT INFORMATION SHEET

In the UK more than 300,000 people live with Crohn's disease or ulcerative colitis (together known as inflammatory bowel disease or IBD). The IBD BioResource, part of the NIHR BioResource, has been established in collaboration with the NIHR BioResource to help in the fight against IBD and to support research in other disease areas. We would like to invite you to join the IBD BioResource. Please take the 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.

What is the IBD BioResource?

The IBD BioResource is part of the NIHR BioResource. It aims to help research into the causes of Crohn's and colitis, understand determinants of IBD severity and treatment response, and facilitate development of new treatments. By understanding which genes and environmental factors are involved, and their impact on the immune system, we can investigate why some people get Crohn's or colitis, why some of the existing treatments work in some patients but not in others, how better treatments might be developed and whether it might be possible to prevent or cure IBD.

We are establishing a panel of thousands of volunteers with IBD from all over the country; this will form the IBD BioResource, which is fully integrated with the NIHR BioResource. The latter also includes people who have other illnesses, some of which are related to IBD, and people who have no illness.

What is the NIHR BioResource?

The NIHR BioResource comprises of a number of BioResources around the country including the IBD BioResource. Information and samples from this resource may also be made available to our own and other scientists working in biomedical and healthcare research. The NIHR BioResource and the IBD BioResource are working collaboratively in supporting studies looking at how genes and other factors influence disease; for this reason, it is not possible to only join one part of the BioResource (i.e. you cannot just join the IBD BioResource as this is an integral part of the NIHR BioResource).

All volunteers donate a blood sample and consent to be contacted and invited to participate in future medical research, based on analysis of their samples and information they have supplied. For all BioResource subjects, this contact may relate to both IBD-focused studies and other research not related to IBD. Participation in any such future studies is entirely voluntary: you decide at the time.

TAKING PART

Why have I been invited to join the IBD BioResource?
The IBD BioResource is recruiting patients with Crohn's disease or colitis from many hospitals, and as you have IBD so we are inviting you to join.

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 join, 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.

SAMPLES AND DATA

What does joining involve?

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

- read and sign a consent form
- provide your name, date of birth, NHS number and contact details, and allow us to store them
- give some blood samples (approx. 20ml = 3-4 teaspoons)
- complete a health and lifestyle questionnaire (online or paper) and up to one update questionnaire per year
- allow us to collect, store and analyse health information about you (including accessing your medical or other health related records)
- agree to be contacted in the future and invited to be involved 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 influence disease and treatment response. Genes are made up of DNA. Therefore, we will isolate, analyse and store a sample of your DNA from your donated blood sample. This may include determining the sequence of part or all of your DNA code. We may also isolate and test other components of your blood such as cells, RNA, protein and metabolites. We will assess how these components impact immune function, affect risk and behaviour of IBD and other diseases, and how they influence response to treatment.

Researchers may access your samples and related data, but your personal details will never be released to researchers without your knowledge. Your samples will be kept in a secure location.

What happens if an invention is made using my sample?

Your donated samples and related information are given as an absolute gift, i.e. without receiving a payment and without conditions. The BioResource is operating on a non-commercial basis, meaning 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, a fee may be charged to cover the BioResource operational costs.

In the future, your sample may help researchers in the public and commercial sector to make an invention, for example, develop a new product to diagnose or treat a disease. If an invention results from the research undertaken with your sample, you will not receive any compensation, recognition or payment. BioResource partners in the public sector may work together with commercial companies to develop inventions for the benefit of patients, and we hope that such products are brought into use to improve healthcare in the future.

DATA

How will the data we collect be used and stored?

Anonymous data about you (i.e. with all identifying information removed) may be stored in an electronic archive and made available to researchers. This data may include part of or all of your DNA code, or the results of other tests performed with your samples and other information from the research database that does not identify you personally.

Researchers will have to make a request to access this data and explain how they will use it, e.g. which research question they are trying to answer. This type of system is referred to as ‘managed access’. Genuine researchers will be given access to the data for their research via data transfers/access agreements and they will be obliged to keep your data safe as defined within these agreements.

‘Managed access’ requests could come from researchers who are working in the public and charitable sector (Universities, Research Institutes) or in commercial companies, either in the UK or overseas.

Researchers share the results of their studies by means of reports or publications, which includes placing information/data on the internet, in press articles, in project leaflets and through other media. Under no circumstances will information that identifies you personally be disclosed in any of these documents.

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.

Your rights to access, change or move your information are limited, as we need to manage your information in specific ways in order for the research to be reliable and accurate. If you withdraw from the study, we will keep the information about you that we have already obtained. To safeguard your rights, we will use the minimum personally-identifiable information possible.

You can find out more about how we use your information at URL: http://www.ibdbioresource.nihr.ac.uk/ or by contacting: ibd@bioresource.nihr.ac.uk

If you are recruited by a hospital outside Cambridge, the below will apply to you:

[Insert Trust name] will use your name, NHS number and contact details including address, phone number and email address (where available) to contact you about the research study, and make sure that relevant information about the study is recorded for your care, and to oversee the quality of the study. Individuals from the NIHR BioResource and regulatory organisations may look at your medical and research records to check the accuracy of the research study. The NHS site will pass these details to NIHR BioResource along with the information collected from you and your medical records.

The only people in NIHR BioResource who will have access to information that identifies you will be people who need to contact you to send newsletters, invite you to events such as open days, or invite you to further studies, or audit the data collection process. The people who analyse the information will not attempt to identify you and will not be given your name, NHS number or contact details.

The NIHR BioResource will collect information about you for research from medical records, health registries and sometimes we will ask you to complete questionnaires. This information will include your name, NHS number, contact details and health information, which is regarded as a special category of information. We will use this information to try to expedite research into Crohn's disease and ulcerative colitis and help develop new and better therapies. Where this information could identify you, the information will be held securely with strict arrangements about who can access the information. The information will only be used for the purpose of health research, or to contact you about future opportunities to participate in research. It will not be used to make decisions about future services available to you, such as insurance. Where a study requires you to be identified (e.g. for recall) your data will only be accessed for projects that have been independently reviewed by an ethics committee.

Future studies

In the future, a number of studies will be carried out based on the IBD BioResource panel. We may contact you and invite you to take part on the basis of genetic/biochemical results obtained from your sample and other information you give to us or obtained from your medical records. These studies may or may not be related to IBD. You will be provided with full information regarding each study and will be free to decide whether or not to participate at the time.

The BioResource supports many different research studies from surveys to studies requiring further samples to be taken and even trials of new therapies.

Some research will not require any further input from you as the samples and data generated from the BioResource, combined with anonymised information you provided / granted access to when you joined, may be sufficient.

How often will I be contacted?

We closely monitor how many times you are approached for future studies and restrict invitations. We greatly appreciate the effort made by volunteers and are happy to refund travel/parking costs incurred by participating in studies. We will also contact you from time to time with information about the progress of the research through newsletters etc.

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. Any information from genetic and other tests will be stored separately from your personal details. Information from these tests will not be used or made available for any purpose other than for research. Access to your personal details will only be available to necessary members of the IBD and NIHR BioResource teams. You will not be identified personally in any report or publication.

BENEFITS AND RISKS OF JOINING

What are the benefits of joining the IBD BioResource?

There will be no direct benefit to you. By joining the IBD BioResource you will be helping improve understanding of the links between genes and environmental factors that cause IBD and other diseases, and the determinants of treatment response. The goal is to improve treatment and long term prevention of IBD and other diseases.

What are the risks of joining the IBD BioResource?

Joining the IBD BioResource will involve donating a small blood sample. Qualified staff will collect this, but blood sampling can sometimes cause discomfort and may cause a small bruise. The study is indemnified by Cambridge University Hospital NHS Trust.

RESULTS

IBD BioResource

The IBD BioResource will not routinely feedback any genetic or biochemical research results obtained from your sample. 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 to the above, you will have a choice on the consent form to indicate if you would want to be informed in the rare event that you were found to be at increased risk of a genetic disease. This information may also be uncovered in the course of the research and might be relevant to your future health (for example, identifying an increased risk of a condition that might be prevented or treated early by the NHS).

The updated list of the rare genetic conditions for which the option of this feedback is available on the Genomics England website at: www.genomicsengland.co.uk/information-for-participants/findings/ (in ‘Additional or secondary findings’ section, expand the information box “if a participant agrees, we look for changes in the following genes”). If the genetic analysis indicates that you might be at increased risk of such conditions, and you choose to be informed about this, the provisional result of the research analysis will be handed back by the IBD BioResource team to your consultant or GP for discussion with you. A further sample would be taken for analysis within an accredited NHS diagnostics laboratory to confirm any “additional or secondary finding” A health professional or genetic counsellor would then feedback to you on the final results.

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 website: www.genomicsengland.co.uk/information-for-participants/findings/

If you are concerned that you are at risk of a genetic disease, please discuss this with your GP or 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 BioResource at any time without giving a reason. If you choose to withdraw:

- 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 a record remains of your initial consent and the withdrawal process.
- Should you wish, no further data will be retrieved from your health-related records and no new data from laboratory measurements will be added to the research databases; pre-existing data will not be used in further analysis wherever possible.
- Pre-existing data and data that has already been distributed to other researchers cannot be destroyed.
- Once confirmation of your decision to withdraw is received, you will not be contacted again by the BioResource.
- If the BioResource is unable to confirm your preferences regarding withdrawal, your sample(s) and data will be retained for future use, but you will not be contacted again.

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 and Crohn's and Colitis UK. This study has been reviewed and approved by East of England - Cambridge Central Research Ethics Committee.

Further information

If you require 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.