

# IMID (Immune-Mediated Inflammatory Diseases) BioResource, part of the National Institute for Health and Care Research BioResource

Version 5.0 03/03/2023

## PATIENT INFORMATION SHEET

\*If you require this information to be translated into another language or in a different format, please speak to a member of the BioResource team

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. You can visit <https://bioresource.nihr.ac.uk/centres-programmes/imid-bioresource/> which explains how to join the IMID BioResource.

### What is the National Institute for Health and Care Research?

The National Institute for Health and Care Research is the research arm of the NHS. It is the nation's largest funder of health and care research.

### What is the IMID BioResource?

The IMID BioResource is a component part of the National Institute for Health and Care Research (NIHR) BioResource. It aims to help research into the causes of Immune-Mediated Inflammatory Diseases and understand determinants of IMID severity and treatment response. By understanding which genes and environmental factors are involved, and their impact on the immune system, we can investigate why some people get immune-mediated inflammatory diseases, 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 IMID.

The IMID BioResource is a collaboration managed by a partnership across 3 Biomedical Research Centres (BRCs) - Manchester, Newcastle and Leeds and co-ordinated from Manchester BRC.

We are establishing a panel of thousands of volunteers with IMID from all over the country; this will form the IMID BioResource, which is fully integrated with the NIHR BioResource.

**What is the NIHR BioResource?**

The NIHR BioResource comprises a number of BioResources, including the IMID BioResource. The National Institute for Health and Care BioResource consists of a panel of hundreds of thousands of volunteers who wish to participate in health research. The NIHR BioResource also includes people who have other illnesses, some of which are related to IMID, and people who have no illness. The National Coordinating Centre is in Cambridge with several BioResource centres around the country. Volunteers joining the BioResource are asked to donate a small blood or saliva sample and give consent to be invited to participate in health related research studies on the basis of data gathered from samples and information they have provided. Information and samples that the BioResource holds may also be made available to researchers working in biomedical and healthcare research. This extends the value of the BioResource enormously.

The NIHR BioResource and the IMID 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 IMID BioResource as this is an integral part of the NIHR BioResource).

**Where we refer to the 'BioResource' in this leaflet we mean both the IMID BioResource and the NIHR BioResource.**

**Why am I being asked to join the IMID BioResource?**

The IMID BioResource is recruiting patients with immune-mediated inflammatory diseases (IMIDs) from many hospitals, and as you have an IMID we are inviting you to join. If you do not have an IMID but have certain symptoms, or are a relative of a patient with an IMID, you may also have been asked to take part.

**Do I have to join the IMID BioResource?**

No. It is completely up to you whether or not you wish to join. If you decide not to join, your decision will not affect the healthcare you receive in any way. If you join, you will be free to withdraw at any time and without having to give a reason.

**What will I need to do if I take part?**

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

- read and sign a study consent form
- provide your name, date of birth, NHS number and contact details which will be stored securely
- donate a small sample of blood ( up to a maximum of 50ml = 10 teaspoons can be taken, but routinely this will be approx. 20ml = 3-4 teaspoons) or saliva

IMID@manchester.ac.uk

<https://bioresource.nihr.ac.uk/using-our-bioresource/our-cohorts/common-diseases/>

IRAS number 263004 PIS/CF Version 5 03/03/2023

sample where blood samples are not possible to obtain. In the future you may be invited to provide further samples

- complete a questionnaire about your health and lifestyle
  - allow us to collect, store and analyse health information about you (including the BioResource accessing your medical records, other health related records, (for example , NHS Digital or other central records)
  - agree to be contacted in the future about research studies, including clinical trials, which we believe you are suitable for based on the information we hold.
- For all BioResource subjects, this contact may relate to both IMID-focused studies and other research not related to IMID. You will be provided with information about any study you are eligible for, and you can decide whether you would like to take part. You are under no obligation to do so. We will monitor how often you are approached. The BioResource are happy to contribute towards any travel costs. Some research will not need any further input from you as the samples and data you provide will be enough; Agree to be contacted by the BioResource about updates, newsletters, invitations to open events, etc. You can choose not to receive these if you prefer.

### **What are the disadvantages/ risks?**

Qualified, experienced staff will collect blood samples. Blood sampling can sometimes cause minor discomfort, and there is a possibility that a small bruise may develop.

### **What will happen to the samples I give?**

Your samples will be kept in a secure processing/storage facility approved by the NIHR BioResource. We want to know how genes influence health, disease and treatment response. Genes are made up of DNA (deoxyribonucleic acid). We extract a sample of your DNA from your blood or saliva sample and study your genetic makeup. We may also 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 IMID and other diseases, and how they influence response to treatment.

Researchers may seek to access your samples and related data, but your personal details will not be released to researchers without your knowledge.

### **Will the details about me be kept confidential?**

Yes. Best ethical and legal practices will be followed to ensure that all information collected will be handled safely and securely. Your personal details will never be released to researchers without your consent.

Your samples will be labelled with a unique number before being transferred to the laboratory for testing. Information from genetic and other tests will be linked to this unique number. 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). Your samples and data can only be accessed by researchers once they've been de-personalised (i.e. with all identifying information removed).

Researchers can apply to access your samples or data, and they have to explain how they will use it, e.g. the research question they wish to answer. This is referred to as 'managed access'. Data may be accessed in a number of ways, for example, by logging in to secure data analysis environments or by downloading from the BioResource. Researchers will be reminded of their obligation to keep your data safe and secure by accepting the terms of a data transfer/ access agreement. Researchers who analyse the information should not be able to identify you, and promise not to try to do so as a condition of data access.

'Managed access' requests could come from researchers from the public and charitable sector (Universities, Research Institutes) or from commercial and pharmaceutical companies. These can be based either in the UK or overseas.

The BioResource will request further details about you from public bodies, like the NHS (via NHS Digital or other registries) and the UK Health Security Agency. To do this, identifiable information, like your name, NHS number and date of birth, will be sent securely to these agencies, so that they can find you in their databases.

Researchers can share the results of their studies in reports or publications which are published on the internet and in press articles, etc. Under no circumstances will information that identifies you personally be disclosed in any of these documents.

Information from tests will not be used or made available for any purpose other than for research and improvements in health care.

An explanation of how the BioResource complies with the General Data Protection Regulation (GDPR) can be found at the end of this information leaflet.

Your original signed consent form will be stored in a secure locked area at the NHS site where you took part in the study. Copies of your consent form and data collection form will be sent to the University of Manchester where they will be scanned and securely uploaded onto the databases of Manchester University NHS Foundation

Trust and of the National Institute for Health and Care Research BioResource. The paper copies will then be shredded

### **The National Genomics 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.

## Your Invitation to future studies

The BioResource supports many different research studies, from surveys to studies requiring further samples to be taken and even trials of new therapies. NIHR BioResource may contact you and invite you to take part in these 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 IMID. You will be provided with full information regarding each study and will be free to decide whether or not to participate at the time.

Some research will not require any further input from you as the sample and data generated from your sample and the information you provided/ granted us access to when you joined can be used for research purposes.

If you are contacted to take part in a future study, this does not mean that your health is at risk. All individuals carry risk and protective DNA variants in their genes, and we are a long way from understanding how they balance each other and what combination of markers interacting with other factors such as age, gender, smoking and drinking habits, etc. cause disease.

## RESULTS

### Can I know the results obtained from my study samples?

The IMID BioResource and the NIHR BioResource teams do not feedback on any genetic or laboratory results obtained from your sample as it is taken for research purposes only.

### What happens if an invention is made using my sample?

Your donated samples and related information are given as a gift, which may help researchers in the public and commercial sector make an invention that could improve the future healthcare of patients and blood/ organ donors, such as a new product to diagnose or treat a condition. If an invention results from the research undertaken with your sample, you will not receive any compensation, recognition or payment.

The BioResource will not share your sample to make a profit. Published studies are available to view on the NIHR BioResource website

<https://bioresource.nihr.ac.uk/studies/>

## WITHDRAWAL PROCESS

Please note that by withdrawing from the IMID BioResource you will also be withdrawn from the NIHR BioResource and vice versa.

If you choose to withdraw, you have two options:

1. You can allow us to continue accessing your healthcare records (and any required social and educational records) from central NHS records, your hospital, your GP, school and/or research done with your sample. This is a 'no further contact' withdrawal.

IMID@manchester.ac.uk

<https://bioresource.nihr.ac.uk/using-our-bioresource/our-cohorts/common-diseases/>

IRAS number 263004 PIS/CF Version 5 03/03/2023

2. You can ask us to stop further use of your data and to destroy your remaining samples. Any research that has used your data or sample(s) cannot be undone. This is 'no further use' withdrawal.

Your personal information will be retained in an archive so that a record remains of your initial study consent and the withdrawal process.

If the BioResource is unable to confirm your decision, your sample(s) and data will be retained for future use, and you will not be contacted again.

### **Who funds and sponsors the IMID BioResource?**

The IMID BioResource is funded by the National Institute for Health Research (NIHR). The sponsor of the IMID BioResource is Manchester University NHS Foundation Trust. This study has been reviewed and approved by North West - Greater Manchester Central Research Ethics Committee.

Please remember, by joining the IMID BioResource you will be also joining the main National Institute for Health and Care Research BioResource. The NIHR BioResource is a Research Tissue Bank and is also funded by the NIHR; the establishment responsible for its management is Cambridge University Hospitals NHS Foundation Trust. The NIHR BioResource has been reviewed and approved by the East of England – Cambridge Central Research Ethics Committee.

### **What if something goes wrong?**

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

Telephone: 0191 223 1382 or 0191 223 1454 Email: [patient.relations@nuth.nhs.uk](mailto:patient.relations@nuth.nhs.uk)

Address:

Patient Relations Department

The Newcastle upon Tyne Hospitals NHS Foundation Trust

The Freeman Hospital

Newcastle upon Tyne

NE7 7DN

If you remain unhappy and wish to complain formally, you can do this by contacting [\[Research.GetInvolved@mft.nhs.uk\]](mailto:Research.GetInvolved@mft.nhs.uk)

### **Further information**

If you require further information before deciding to join the IMID BioResource or have any queries about anything concerning the IMID BioResource/ NIHR BioResource, please feel free to contact your local IMID team on 0919 2085001 or [newcastlebioresource@ncl.ac.uk](mailto:newcastlebioresource@ncl.ac.uk), or you can contact the central IMID BioResource team on 0800 090 2459 or e-mail us on [IMID@manchester.ac.uk](mailto:IMID@manchester.ac.uk)

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IRAS number 263004 PIS/CF Version 5 03/03/2023

Thank you for reading this information sheet and for considering joining the IMID BioResource, part of the NIHR BioResource.



## General Data Protection Regulations (GDPR)

From May 25<sup>th</sup> 2018 there are new data regulations governing the UK and the EU that should ensure more transparency in what research is being done with samples and information you are providing, We need to be clear on the following points:

Manchester University NHS Foundation Trust (MFT) is the sponsor for the IMID BioResource. Cambridge University Hospitals NHS Foundation Trust (CUH) is responsible for the managing the National Institute for Health and Care Research BioResource - Research Tissue Bank (RTB). Both are based in the United Kingdom and will act as the data controllers for the IMID data.

We will be using information from you and your health care records in order to undertake this study. This means that we are responsible for looking after your information and using it properly.

The Cambridge University Hospitals NHS Foundation Trust and Manchester University 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?

The NIHR BioResource, will need to use information from you, 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 or provided by e.g. NHS health-related central records, disease registries etc.

People will use this information to do the 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, will be sent to other countries worldwide. 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?

- 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.
- If you choose to stop taking part in the study you have two options as outlined in the 'Withdrawal process' section. Further information on leaving the BioResource can be found here: [insert link];
- You may request a copy of the information we hold about you. We need to manage your records in specific ways for the research to be reliable. This means that 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).

### 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/](http://www.hra.nhs.uk/information-about-patients/)
- our privacy notices available from <https://research.cmft.nhs.uk/getting-involved/gdpr-and-research>, <<https://bioresource.nihr.ac.uk/about-us/gdpr/>>, which include the sponsors' Data Protection Officer contact details
- by asking one of the research team
- by sending an email to [Rheumatology.Research@mft.nhs.uk](mailto:Rheumatology.Research@mft.nhs.uk) or <[nbr@bioresource.nihr.ac.uk](mailto:nbr@bioresource.nihr.ac.uk)>
- by ringing us on the IMID team phone number <0800 090 2233>