

The NAFLD BioResource, part of the NIHR BioResource – A Research Study to Characterise Novel Clinical and Genetic Phenotypes, and Understand the Natural History of Non-Alcoholic Fatty Liver Disease (NAFLD)

PATIENT INFORMATION SHEET

The NAFLD BioResource has been established in collaboration with the NIHR BioResource in order to help in the fight against NAFLD and to support research in health-related conditions more generally. We would like to invite you to join the NAFLD BioResource. We are aiming to establish a group of around 7,500 participants with NAFLD from all over the UK and we would like to invite you to join the NAFLD BioResource.

We have provided some key definitions below. 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 NAFLD?

NAFLD stands for **Non-Alcoholic Fatty Liver Disease**, which is a common disorder and refers to a group of conditions where there is accumulation of excess fat in the liver of people who drink little or no alcohol. It is now the most common cause of liver disease in Western countries and affects approximately 30-40% of the UK population. We believe you have NAFLD, which is why we are inviting you to take part in this project.

What is the NIHR?

NIHR stands for the **National Institute for Health Research**, which is the research arm of the NHS. The NIHR is the nation's largest funder of health and care research.

What is the NIHR BioResource?

As mentioned above, the NIHR is one of the largest funder of health and care research. They have set-up a very large resource of patients and members of the general population called the NIHR BioResource. This BioResource includes participants who may have NAFLD, other illnesses or who have no illness. The NIHR BioResource includes the medical and lifestyle data provided by participants, along with biological samples provided by the participants for research purposes. The NIHR BioResource is formed of a number of BioResources around the country including the NAFLD BioResource.

A key requirement for joining the NIHR BioResource is that participants volunteer to give permission to the BioResource to access their medical records; another requirement is that they give their permission to be contacted and invited to participate in future medical research. Information and samples from this resource may also be made available to other scientists working in biomedical and healthcare research, and will support studies looking at how genes and other factors influence disease. This information will usually be de-personalised information, however we may also share

identifiable information for certain projects, but will always request permission from you before doing so.

What is the NAFLD BioResource?

The NAFLD BioResource is a small part of the NIHR BioResource, and therefore by agreeing to take part in the NAFLD BioResource, you will also be agreeing to take part in the NIHR BioResource (i.e. As the NAFLD BioResource is an integral part of the NIHR BioResource, participants joining the NAFLD BioResource will also be joining the NIHR BioResource). Where we refer to the 'BioResource' in this leaflet we mean both the NAFLD BioResource and the NIHR BioResource.

The NAFLD BioResource is focusing on participants who specifically have NAFLD. The aim is to help research into the causes of NAFLD and understand if there are any indicators or patterns that can be linked to NAFLD severity and treatment response. By doing this, we can begin to identify better treatments to reduce the effects of NAFLD, or potentially provide a cure.

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

TAKING PART

Why have I been invited to join the NAFLD BioResource?

The NAFLD BioResource is recruiting patients with non-alcoholic fatty liver disease from many hospitals, and as you have been diagnosed with non-alcoholic fatty liver disease, we are inviting you to join.

Do I have to join the NAFLD BioResource?

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 do decide to join, you will be free to withdraw at any time and without having to give a reason. Please note that by joining the NAFLD BioResource you will also be joining the main NIHR BioResource.

SAMPLES

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 (including email and mobile phone if available) which will be stored securely
- give some blood samples (approx. 20ml = 3-4 teaspoons)
- complete a health and lifestyle questionnaire (online or paper)
- Provide health information about you (including the BioResource accessing your medical or other health - related records, e.g. from GP, hospital records, NHS Digital or other central records) for collection, storage and analysis, even in the event of your incapacity or death.

- agree to be contacted in the future and invited to give more samples, or be involved in other research studies (you are under no obligation to do so)

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 (a substance formed as a product of metabolism). We will assess how these components affect risk and behaviour of NAFLD and other diseases, and how they influence response to treatment.

Researchers may seek access to your samples and related data, but your personal details will not be released to researchers without your consent and knowledge. Your samples will be kept in a secure location (Primarily samples are processed and held at the NIHR BioSample Centre in Milton Keynes, but alternative processing and archiving facilities may be used from time-to-time). Samples will continue to be stored in the event of your incapacity or death. If you withdraw from the BioResource you can choose that your centrally stored samples are destroyed.

The samples collected are part of the NIHR BioResource; continuous funding for its maintenance will be sought. Alternatively, at the end of the research and funding, the NIHR BioResource will seek adoption of the sample collection by another national tissue bank; in this case you would be informed well in advance of any transfer of samples and/or data and asked to agree with this, otherwise your samples and/or data will be destroyed.

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 operate 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 operational costs of the BioResource.

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. The 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 AND COMMUNICATION

How will the data we collect be used and/stored?

The personal data you provide will be stored securely by both the NAFLD BioResource and NIHR BioResource. Both meet rigorous NHS security standards. Access to this data is restricted to trained

Page 3 of 9 https://bioresource.nihr.ac.uk/centres-programmes/naflid-bioresource/ uhb-tr.naflidbioresource@nhs.net	Version 2.0 (04 February 2021) IRAS: 259099
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staff whose role requires it, e.g. to contact you for recall studies or to send newsletters and questionnaires.

You will be asked during recruitment about your preferred method of contact e.g. email, post or phone.

Please note that when using email to contact the BioResource, you understand that the BioResource can not guarantee or take responsibility for the security of the information transmitted via email. By contacting the BioResource by email, you accept this risk.

De-personalised data about you (i.e. data still held for one person at a time, but with all obvious identifying information removed) will be stored separately in secure electronic archives and made available to approved researchers. This data may include part of or all of your DNA code (genetics), or the results of other tests performed with your samples and other information from the research database. None of this will identify you personally.

Researchers will have to make a written 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. Approved researchers will be given access to the data for their research via data transfers/access legal agreements and they will be obliged to keep your data safe as defined within these agreements. Part of the legal agreement is that they will make no effort to identify anyone from the limited data they can access.

'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. We will list all approved researchers on NIHR BioResource website, with summaries of their proposed research.

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/information.

General Data Protection Regulation (GDPR)

From May 25th 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:

The Cambridge University Hospitals NHS Foundation Trust is responsible for managing the NIHR BioResource - Research Tissue Bank. The University Hospitals Birmingham NHS Foundation Trust is the sponsor for the NAFLD BioResource. Both are based in the United Kingdom and will act as the data controllers for the NAFLD data. This means that we are responsible for looking after your information and using it properly. The Cambridge University Hospitals NHS Foundation Trust and University Hospitals Birmingham NHS Foundation Trust will keep identifiable information about you 10 years after the study has finished; this is until 2032 in the first instance, and we may approach you to extend this.

How will we use information about you?

We, the NAFLD BioResource and the NIHR BioResource, will need to use information from you, 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 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 by asking us to stop further contact with you, we would like to continue collecting information about your health from central NHS records, your hospital, your GP and/or research done with your sample. This is called ‘no further contact’ withdrawal. If you do not want this to happen, tell us and we will stop using your information and destroy your remaining sample, as well as stopping further contact with you. This is called ‘no further use’ withdrawal.
- 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 for example).

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/
- You can find out more about how the NAFLD BioResource will we use your information at URL: <https://www.uhb.nhs.uk/privacy-notice> or by contacting: uhb-tr.nafldbioresource@nhs.net
- You can find out more about how the NIHR BioResource – Research Tissue Bank will use your information at URL: <https://bioresource.nihr.ac.uk/gdpr> or by contacting: nbr@bioresource.nihr.ac.uk

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. The BioResource 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 NAFLD. 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, data generated from your sample, and 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.

How often will I be contacted?

We closely monitor how many times you are approached to be invited to future studies. We will ensure we do not invite you to more than eight studies per year (with a maximum of 4 face-to-face). Your participation in future studies is completely your choice. We greatly appreciate the effort made by volunteers and are happy to refund travel/parking costs incurred by participating in studies.

Further to contacting you about taking part in future studies, we may 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

Page 6 of 9 https://bioresource.nihr.ac.uk/centres-programmes/naflid-bioresource/uhb-tr.nafldbioresource@nhs.net	Version 2.0 (04 February 2021) IRAS: 259099
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(rather than personal data) before being transferred to the laboratory for testing and storage. Any information from genetic and other tests will be linked to this unique number and stored separately from your personal details. Information from these tests will not be used or made available for any purpose other than for research and improvements in healthcare. Access to your personal details will only be available to necessary members of the NAFLD and NIHR BioResource teams. You will not be identified personally in any report or publication, including information about BioResource studies which will be released on the Internet.

BENEFITS AND RISKS OF JOINING

What are the benefits of joining the NAFLD BioResource?

There will be no direct benefit to you but you will be making a contribution to science and there may be a benefit to the future development of healthcare provision in NAFLD and other diseases. The goal is to improve treatment and long term prevention of NAFLD and other diseases.

What are the risks of joining the NAFLD BioResource?

Joining the NAFLD BioResource will involve donating a small blood sample. Qualified staff will collect this, but blood sampling can sometimes cause discomfort and may cause a bruise. The study is indemnified by University Hospitals Birmingham NHS Foundation Trust who are the sponsors.

RESULTS

Clinical Results

All blood samples taken for the NAFLD BioResource are for research purposes only. Therefore the BioResource team will not routinely feedback any genetic or biochemical results obtained from your research sample directly to you or your GP.

Since your blood samples for the NAFLD BioResource are taken by your local clinical care team usually at the time of your usual hospital clinic visit, they will be taken after any clinical samples needed for your health care. Your local care team will be responsible for feedback of any results obtained from your clinical samples that are part of your usual health care to you and your GP, as per their local processes.

Publications/Research Results

We encourage all results from trials and studies based on the NAFLD BioResource to be published on platforms which are accessible to the general public. We encourage that a plain language summary is included in these publications. Where formal clinical trials are concerned, we encourage these will be uploaded to the EU Clinical Trials Register in a timely manner at each stage and we encourage these uploads to include full results including the lay summary. We encourage the investigators to inform participants of these publications and where the results can be found.

WITHDRAWAL PROCESS

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

Page 7 of 9 https://bioresource.nihr.ac.uk/centres-programmes/naflid-bioresource/ uhb-tr.naflidbioresource@nhs.net	Version 2.0 (04 February 2021) IRAS: 259099
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Participants are free to withdraw from the BioResource at any time without giving a reason. Please note that by withdrawing from the NAFLD BioResource you will also be withdrawn from the NIHR BioResource and vice versa. Please contact us for a withdrawal form or complete the online form on our website. You can also withdraw by calling us. If you choose to withdraw:

- You will be asked to specify whether you would like us to destroy the sample(s) you have donated and which are stored by the BioResource or not.
- 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, by choosing 'no further use' withdrawal, no further data will be retrieved from your health-related records and no new data from laboratory measurements will be added to the research database. Already existing data will not be used in further analysis wherever possible.
- Already 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 decision of whether you want to withdraw from further contact only, or also from further use of your samples and data, 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 NAFLD BioResource?

The NAFLD BioResource is funded by the National Institute for Health Research (NIHR). The sponsor of the NAFLD BioResource is University Hospitals Birmingham NHS Foundation Trust. This study has been reviewed and approved by Yorkshire and the Humber – Leeds West.

Please remember, by joining the NAFLD BioResource, you will also be joining the main NIHR BioResource (NIHR BioResource – Research Tissue Bank). The NIHR BioResource – Research Tissue Bank is also funded by the NIHR but the establishment responsible for its management (sponsor) is the Cambridge University Hospitals NHS Foundation Trust. The NIHR BioResource has been reviewed and approved by the East of England – Cambridge Central Research Ethics Committee (17/EE/0025).

Further information

If you require more information before deciding or have any queries about anything concerning the NAFLD BioResource/NIHR BioResource, please feel free to contact your local NAFLD team on newcastlebioresource@ncl.ac.uk or you can contact the central NAFLD BioResource team on 0121 371 4028 or e-mail us on uhb-tr.nafldbiorresource@nhs.net.

WHAT IF SOMETHING GOES WRONG?

Page 8 of 9 https://bioresource.nihr.ac.uk/centres-programmes/nafl-d-biorresource/uhb-tr.nafldbiorresource@nhs.net	Version 2.0 (04 February 2021) IRAS: 259099
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We think it is unlikely that you will be harmed in this study. However, if you are harmed by taking part in this study, owing to someone's negligence, then you may have grounds for legal action under the NHS Indemnity Scheme. If you suffer harm which is not the result of negligence, there are no special compensation arrangements.

Regardless of this, if you wish to complain, or have any concerns about the way you have been approached or treated during the course of this study, you should contact the study organisers as listed in the Further Information section above.

You can also contact the Patient Advice and Liaison Service (PALS) at the hospital you attend for your clinic visit [\[insert local PALS details if applicable\]](#).

If you remain unhappy and wish to complain formally to the NAFLD BioResource, you can do this by contacting uhb-tr.nafldbioresource@nhs.net.

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