PARTICIPANT INFORMATION SHEET

Improving Black Health Outcomes (IBHO)
NIHR BioResource

Version 2.0, 19 Nov 2024

⌛ Reading time: 20 minutes

This is a detailed document outlining why we are inviting you to join the National Institute for Health and Care Research (NIHR) BioResource through a research project called **I**mproving **B**lack **H**ealth **O**utcomes (IBHO), known as the IBHO BioResource. We understand your time is valuable, however, we would encourage you to take the time to read all the information before deciding whether you would like to get involved.

Please feel free to ask if you have questions or would like more information. You can also visit: www.bioresource.nihr.ac.uk/ibho

Taking part in research is completely voluntary and your decision will not in any way affect your healthcare. You can also withdraw from taking part at any time. More information on this can be found in this document in Section 1 & 2.

Contents:

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

Section 1

Why am I being asked to join the IBHO BioResource?

We are inviting people from Black communities, with and without health conditions, to join the IBHO BioResource.

For the IBHO BioResource, Black communities refers to individuals who are from the following ethnic backgrounds: Black African, Black Caribbean, Black African-Caribbean, Black British, Black Welsh, Black Irish, Black Scottish, Dual or Mixed Black heritage, and/or Black 'other'.
We recognise that individuals who are not from Black communities may also live with a health condition of interest to the IBHO BioResource, such as Sickle Cell. To help us better understand these conditions, we are inviting patients **of any ethnicity** with certain health conditions to join our programme. Your contribution will help us improve understanding, treatment and ultimately outcomes for all individuals affected.

What is the aim of the IBHO BioResource?

Health research studies have rarely focused on the specific health needs and experiences of people from Black communities. This can be problematic since the findings might not always apply to everyone equally. As a result, people from Black communities have often not benefitted from advances in health research. By creating the IBHO BioResource we hope to change this, so that in future, when researchers find something important, for example, a gene that relates to a health condition, we can be sure that this is true for Black communities too.

The IBHO BioResource will be a resource to support health research. We will create this resource by collecting information from your sample (e.g., genetic data), information from health records (e.g., use of medication), personal information (e.g., age, gender), and lifestyle (e.g., diet, smoking), and social factors (e.g., housing, employment).

Why is the IBHO BioResource important?

The IBHO BioResource will enable research into a range of health conditions. These include:

- conditions that are common in UK-based Black communities such as diabetes,
- conditions that almost exclusively affect Black people such as sickle cell disorder,
- conditions that are not well researched in UK-based Black communities such as anxiety, depression, and skin problems.

We aim to improve our understanding of:

a) how and why some health conditions occur in Black communities,

b) what are the best assessments to accurately identify these conditions in Black people, and, most importantly,

c) how we can use the research findings to improve and/or develop interventions and treatments that are tailored to the specific needs and health experiences of Black communities.

Do I have to join the IBHO BioResource?

No. Your decision is voluntary, and it is completely up to you to decide whether you wish to take part. 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, without having to give a reason.

Section 2

Who manages and funds the IBHO BioResource?

The IBHO BioResource forms part of the NIHR BioResource Research Tissue Bank.

The IBHO BioResource is a collaboration between the NIHR Maudsley BioResource Centre at King’s College London, led by Professor Gerome Breen and Dr Juliana Onwumere (IBHO project Co-Principal Investigators), the NIHR BioResource, which is led by Professor John Bradley (Chief Investigator) and Dr Nathalie Kingston (Director), and Genomics England, led by Professor Matt Brown (Chief Scientific Officer) and Dr Sara Trompeter (Clinical lead for Sickle Cell, Diverse Data).

The NIHR BioResource and NIHR Maudsley BioResource Centre is funded by the National Institute for Health and Care Research (NIHR). Genomics England is funded by the Department of Health and Social Care (DHSC).

Research such as this must be approved by a research ethics committee. The NIHR BioResource has been approved by Cambridge Central Research Ethics Committee.

What is the NIHR BioResource Research Tissue Bank?

The NIHR BioResource is a panel of hundreds of thousands of volunteers, with and without health conditions, who wish to participate in health research. 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. Invitations are based on data gathered from samples and information volunteers have provided. Information and samples that the BioResource holds may also be made available to researchers working in biomedical and healthcare research.

What is Genomics England’s National Genomic Research Library?

The National Genomic Research Library (the ‘Library’) is a secure national database of de-identified genetic and health data from people in the UK, managed by Genomics England. We are inviting you to join the ‘Library’, to help us learn more about genes and health, so we can improve healthcare for everyone in the future.

You can choose not to join the ‘Library’ and still join the IBHO BioResource. If you choose to opt-in, the IBHO team may share your sample and data with Genomics England depending on the analysis that will be done (e.g., whole genome sequencing). The NIHR BioResource will also share a copy of your signed consent form with Genomics England.

Section 3

What will happen if I agree to take part in the IBHO BioResource?

1. If you are interested in participating, you will be asked to read and sign the consent form at the end of this document, and you will be given a copy to keep.
2. After providing your written permission to take part, you will be asked to complete a questionnaire that will ask some questions about yourself and your health experiences. You can choose to complete it either by yourself or with a member of the healthcare or research team using a paper format or online. This will take approximately 20 minutes.
3. To facilitate this important health research, we also request consent to link to your health and social care records. Using these linkages, we can investigate how health experiences and treatment can affect your healthcare and other areas of your life, such as education and employment.
4. You will be asked to provide a blood or saliva sample, depending on your preference. This will involve taking blood from you via a needle in your arm like during a blood test or swabbing the inside of your cheek/spitting into a tube. If you have previously donated a sample, for example as part of our Rare Diseases study, we may be able to use this sample.
5. We will offer you a £15 voucher and cover travel costs incurred outside of routine clinical appointments up to the value of £22.50 for joining the IBHO BioResource.
6. As a participant of the IBHO BioResource, and based on the information you provide, you may receive invitations to other studies you can take part in, and you can decide whether to do so. You will be invited to a maximum of eight studies per year (four face-to-face and four online).

   Participation in further studies will always be optional and voluntary. If applicable, we can contribute towards your travel costs to take part in further studies.

   Some studies may not require any further input from you as the data or samples you provided previously will be enough.

What are the potential benefits of taking part in IBHO?

There are no immediate benefits to taking part in the IBHO BioResource. However, some people welcome the opportunity to be involved in a new project and contributing to new knowledge that might lead to better future healthcare for individuals.

We will keep participants who opt in on the Data Collection Sheet up to date with progress via a yearly newsletter.

What are the potential disadvantages/risks?
Some of the study questionnaires include sensitive questions about health conditions, experiences of using health services, and other topics. You do not have to complete any questions that you do not wish to answer, and you can always approach a member of the clinical or IBHO BioResource team for further clarification if anything is unclear.

Providing a saliva sample involves spitting into a tube that some people find unpleasant.

Giving a blood sample can sometimes cause discomfort, and a small bruise may develop. Only trained staff will collect samples and will be happy to answer any questions, respond to any concerns you might have and provide reassurance.

What will happen to the samples I give?
We will extract DNA (**d**eoxyribo**n**ucleic **a**cid) from your blood or saliva sample in various ways to study your genetic makeup. This can include methods such as whole genome sequencing of your DNA. For specific projects, we will also test other parts of your blood, such as cells, RNA (**r**ibo**n**ucleic **a**cid), proteins and metabolites.

Your samples will be labelled with a unique number before being transferred to the laboratory for testing, so that laboratory staff will not know your name or any personal information. Your samples will be kept in a secure location.

Why are you collecting my genetic data (DNA)?
Genes are made up of DNA. The genetic code of your DNA can provide a picture about risks of disease development, and can, together with lifestyle data, help us research and understand potential changes that affect health risks.

Can I know the results obtained from my samples?
The BioResource does not provide a report or feedback on any genetic or laboratory results obtained from your sample, as it is taken for research purposes only.

Will any of the results obtained with my sample predict the risk of disease?
The BioResource supports studies that may discover genetic links to certain diseases. While it is unlikely that the sample of a single person can predict disease risk, looking at data and samples in large numbers helps us find patterns and trends. It may be years before these discoveries can be used to predict the risk of disease or the risk of a complication from a known disease.

If you are contacted to take part in a future study, this does not mean that your health is at risk. Genetic differences between individuals can either protect against or increase the risk of developing a disease. We are a long way from fully understanding the complete picture of how genes and environmental factors (e.g., lifestyle) affect the risk of disease.

Some of the studies the IBHO BioResource may invite you to take part in could reveal unexpected/previously unknown health conditions or future health risks. You will be able to decide if you want to be invited to these types of studies.

What happens if an invention is made using my sample?
Your samples and related information are donated as a gift for research. If an invention is made from the research undertaken with your sample or data, you will not receive any compensation, recognition or payment for your valuable contribution. Any researchers who publish studies that use IBHO BioResource and/or 'Library' data are required to thank IBHO participants for their contribution. The BioResource and/or the 'Library' will not share your sample to make a profit.

Will my details be kept confidential and secure?
Yes. Best ethical and legal practices will be followed to ensure that all information collected about you will be handled safely and securely.

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

Information about you will not be used or shared for any purpose other than for research. We do not share any data with insurance companies. We also do not share data with governmental organisations, unless they have a research purpose.

An explanation of how the BioResource complies with the Data Protection Act 2018 and UK General Data Protection Regulation (UK GDPR) can be found at the end of this document.

Data linkage for health and social care records
For data linkage for important information about your health, and where necessary education and social records, the IBHO BioResource or 'Library' team will securely link your data directly with the database managers at, for example, the NHS or Office for National Statistics. Only individuals with approved qualifications, including on data security can do this linkage. This will be via secure transfer that meets NHS and/or Government data security standards.

How will researchers use data within the IBHO BioResource and/or the 'Library'?
IBHO BioResource

Researchers must apply, and receive approval, to access your samples or data. Researchers can only request data that is relevant and specific to their project. Research applications are discussed by our Data Access Committee or Steering Committee, who use a set of principles to decide whether the application is acceptable. This is referred to as ‘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.

Data may be accessed in several ways, for example, by logging in to secure data analysis environments or by downloading it from the BioResource. Researchers are legally bound to keep your data secure by accepting the terms of an agreement, this includes not attempting to identify you.

Researchers can publish the results of their studies in reports or publications which are available on the internet and in journal articles. Under no circumstances will information that identifies you or any other participant be disclosed.

Published studies are available to view on the NIHR BioResource website https://bioresource.nihr.ac.uk/studies/.

National Genomic Research Library

As in the BioResource, researchers can apply to use samples and data from the ‘Library’ in a format that does not identify you, to study diseases and look for new treatments. Researchers may come from all over the world, and they may work for not-for-profit organisations, such as research charities, universities, or hospitals, and commercial companies such as drug or technology companies. They will only have access to your de-identified (pseudonymised) data in the National Genomic Research Library, and only if their application to access your data is approved by Genomics England.

Your samples and data will be kept securely. Your data cannot be taken out of the ‘Library’ and any results of research cannot be used to re-identify you.

What if I no longer wish to be a member of the IBHO BioResource and/or the National Genomic Research Library?

You are free to withdraw from the IBHO BioResource and/or the National Genomic Research Library at any time, without giving a reason. If you would like to withdraw, simply contact the IBHO BioResource team by email or phone.

If you choose to withdraw, there are two options:

1. **Full withdrawal:** 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.
2. **Partial withdrawal:** 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, but we will not contact you about future research.

Your personal information will be retained in an archive so that a record remains of your initial 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.

Contact information
If you require further information before deciding to join the IBHO BioResource, or have any queries, please feel free to contact the BioResource team on Kimberley Benjamin 0121 371 8535 or email us on Kimberley.Benjamin@uhb.nhs.uk

General Data Protection Regulation (UK GDPR)
Here, we explain how we comply with the Data protection Act 2018 and UK General Data Protection Regulation (UK GDPR). Please also read our Privacy Notice: https://bioresource.nihr.ac.uk/media/04nhduml/privacy-notice-v2.pdf, which explains what we do with the information we hold about you, how you can request access to this personal data, and your other data rights.

Cambridge University Hospitals NHS Foundation Trust (CUH) is the organisation responsible for managing the NIHR BioResource Research Tissue Bank, including the IBHO BioResource.

We will be using information from you, and your healthcare, social care and education (if required) records in order to support research studies, and CUH will act as the data controller for the information we hold. We are responsible for looking after your information and using it properly.

We will keep identifiable information about you for 10 years after the programme has finished, and we may approach you to extend this.

How will we use information about you?
The IBHO BioResource and/or Genomics England asks to use information from you, from your medical records, including from your GP, hospital records and other health-related central records. The NIHR BioResource will also ask to access your social care and, if required, your education records.

This information will include your:

- Full name;
- NHS/CHI 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, medical history, medication etc;
- Social care and education information, e.g., level of education;
- Genetic information that will be generated from your blood or saliva samples or provided by, for example, NHS health-related central records, disease registries etc.

- Electronic copies of all your past and future records from the NHS, your GP and other organisations (such as NHS England and other Public Health bodies);
- Information about any illnesses or stays in an NHS hospital;
- Copies of hospital or clinic records, medical notes, social care, and other local or national disease registries;
- Relevant images from your NHS or other records, such as MRI scans, X-rays, or medical 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).

Information about you, but not your personal identifiable information, will be sent to approved researchers in other countries worldwide. They will not be able to see your name, NHS/CHI number, date of birth or contact details (which are your “personal identifiable information”). Your data will be de-identified and have a code number instead.
They must follow our rules about keeping your information safe (see the section about ‘Managed access’).

If and when the IBHO BioResource finishes, we will keep some of the data so we can check the results. We will write our reports in a way that ensures 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 as explained in the 'Withdrawal process’ section above.
- You may request a copy of the information we hold about you;
- You can request changes in some of the information we hold about you (for example, your contact details and contact preferences); however, we won’t be able to 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

- On the Health Research Authority website http://www.hra.nhs.uk/patientdataandresearch
- The NIHR BioResource privacy notice, available from https://bioresource.nihr.ac.uk/media/04nhduml/privacy-notice-v2.pdf which includes the contact details of the Data Protection Officer at CUH;
- Genomics England's privacy notice available from https://www.genomicsengland.co.uk/privacy-policy
- By asking one of the IBHO BioResource research team;
- By sending us an email at [insert email address];
- By calling us on Freephone [Insert phone number].

Thank you for reading this information sheet and for considering joining the IBHO BioResource

[for localisation to an NHS Trust site, fill in the information as appropriate below:]

If you would like independent advice please contact:

Patients Advice and Liaat University Hospitals Birmingham NHS Trust by phone on 0121 424 0808, by email on pals@uhb.nhs.uk

Principal Investigator

Dr Paul Clift, Consultant Cardiologist, (secretary) 0121 371 4731

Core Research Team, Kimberley Benjamin contact number 0121 371 8535, email Kimberley.Benjamin@uhb.nhs.uk, office hours 07:00 to 15:00

Attach barcode here

PARTICIPANT CONSENT FORM

The IBHO BioResource, part of the NIHR BioResource Research Tissue Bank

Please initial box

1. I confirm that I have read (or had read to me) the information sheet version 2.0, dated 19/NOV/2024. I have had the opportunity to consider the information, ask questions and have these answered satisfactorily. ☐

2. I understand that my participation is voluntary and that I am free to withdraw at any time, without giving any reason, and without my medical care or legal rights being affected. ☐

3. I agree that the IBHO BioResource may access my medical, health, social care, and educational (if required) records held by public bodies, and to analyse and store this information long-term. I understand that this may include the provision of information about my health status. I understand that in order to access these records, identifiable personal details – like name, NHS number, date of birth will be sent to these public bodies. ☐

4. I agree to give blood or saliva for health-related research, or for any other previously donated sample to be used. I understand that my samples and data may be shared to support future research, including commercial studies. I understand my samples will be tested, and that this may include the reading of my entire genetic code. I understand my samples will be stored long-term. ☐

5. I agree to provide personal and contact details. I agree to provide information for example, through the completion of questionnaires. I agree to be contacted by the BioResource to invite me to participate in other research studies. ☐

6. I understand that relevant sections of my medical/health related, social care and education (if required) records and data collected during the study may be looked at by approved individuals for auditing and monitoring purposes. I give permission for this. ☐

7. I understand my samples and de-personalised data may be shared with researchers through a ‘managed access’ process. ☐

8. I understand that my samples are taken for research, and the BioResource will not feed back any genetic or other test results. ☐

9. **I agree to join the IBHO BioResource, which is part of the NIHR BioResource Research Tissue Bank.** ☐

OPTIONAL CONSENT TO THE NATIONAL GENOMIC RESEARCH LIBRARY

Please put your initials in the box

Please initial box

This section gives you the choice to **opt-in** to the National Genomic Research Library.

10. I understand that my sample and data may be held in the National Genomic Research Library, managed by Genomics England. I am happy for Genomics England to obtain additional data from the NHS and other public registries. I give my permission for approved researchers to access my data for research. I understand I can withdraw from the National Genomic Research Library at any time. I agree for my sample and data to be held by the National Genomic Research Library. ☐

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Participant: First Name and Surname (BLOCK CAPITALS)	Date of Birth	Signature	Date
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Person receiving consent: First Name and Surname (BLOCK CAPITALS)		Signature	Date

WITNESS/TRANSLATOR STATEMENT: If participant is not able to read the text and/or sign for themselves but has capacity to give consent OR if the Participant Information Sheet and Consent Form has been translated.
Witness/translator [to delete either as appropriate]:
I witnessed accurate reading of the consent form to the potential participant, who could ask any questions and received satisfactory answers
or
I was present during the meeting between [insert name] and the participant. I translated for the participant the Participant Information Sheet and the Consent Form.

I confirm that they gave their consent freely.

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Witness/translator: First Name and Surname (BLOCK CAPITALS)	Signature	Date

FOR WITNESS AND/OR TRANSLATOR USE ONLY

When completed: 1 for participant; 1 (original) for researcher site file; [1 to be kept in medical notes]