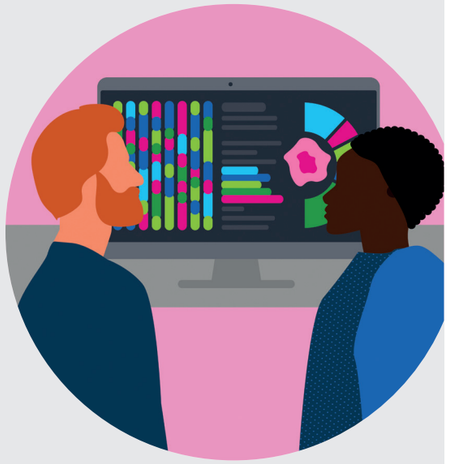
National Genomic Research Library Participant

Information Sheet

Genomics England

Introduction

You have been asked if you want to donate your sample (blood / saliva / tissue, etc.), genome sequence and health data for research, and we hope this document will answer some of your questions.



A genome is the body's 'instruction manual' and contains all the information needed to make you, run you and repair you. It is unique to you and you inherit it from your parents.

It is made of DNA and is written in DNA's special code.

Each one of the 3 billion letters in a genome can be read using a technique called whole genome sequencing.

If you say yes, your samples will be stored securely, and your data will be added to the National Genomic Research Library. This is a secure national database of de-identified genomic and health data managed by Genomics England.

Approved researchers can use the samples and data in a form that does not identify you to study diseases and look for new treatments. Their research might help you and others now or in the future.

Who are we?

Genomics England is a company set-up and owned by the Department of Health and Social Care.

> "Originally tasked with sequencing 100,000 genomes from NHS patients with rare diseases or cancer, Genomics England has supported NHS England and NHS Improvement to implement the NHS Genomic Medicine Service for patients in England.

Additional information about Genomics England is available:

www.genomicsengland.co.uk/privacy-policy

What is the National Genomic Research Library?

The National Genomic Research Library is a database that contains (with their consent) the de-identified health data and genetic sequences of tens of thousands of individuals and allows approved researchers to see and use that data for approved research. Researchers use the data to make discoveries and help develop new treatments and medicines. You can find out more about Genomics England and our mission on our website.

Being able to compare all participant health data and genomic sequences in one place provides researchers with an opportunity to better understand diseases, develop new treatments and can lead to new diagnoses that will benefit society as a whole.

Why me?

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 we have, the better the outcomes for everyone. Below you will find answers to many questions that might help you to decide whether to donate your data.

What do I need to do?

You will need to sign a form and give a small blood sample for your DNA to be sequenced or give permission for an existing DNA sample from you to be sequenced.

Your sequenced DNA and your health data will be added to the National Genomic Research Library for researchers to use. Before giving researchers access, Genomics England 'de-identifies' your data. This means removing anything that might identify you personally (like your name, date of-birth, NHS number and other personal details).

We will store any of your remaining DNA sample and use it for future ethically approved medical research. Access to your sample will be subject to UK regulations and approval from Genomics England's independent Access Review Committee.

It is your decision whether you want to take part in the National Genomic Research Library. If you say 'no', it will not affect your continued participation in any other research projects you are involved with.

What about data

When you agree to take part in the Library, we provide basic identifiers such as your name, date of birth, post code and NHS Number to NHS Digital and other organisations so that they may collate your medical history records and return this data to us.

Although your personal data is very important, researchers are not usually interested in an individual's data. What's important for them is the way that the data from thousands, or even hundreds of thousands of participants can be compared.

To maintain your privacy, information that could identify you is removed from your health records and data, meaning that researchers cannot see this information.

In some cases (for example in a particularly rare disease) it may be possible to link different types of data together, such as age bracket, date of diagnosis, name of rare disease, etc. This could point to one individual. Genomics England monitors requests for access to data and the behaviour of researchers to ensure this isn't abused.

What data will be used in the National Genomic Research Library?

Genomics England will access a copy of your health records, but the original will stay with e.g. the NHS. But if you agree, electronic copies of your health records will be deposited in the National Genomic Research Library, along with your DNA data. 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, 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)

Who has access to my data?

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.

How is my data protected?

Data security is Genomics England's most important concern. We use industry-standard tools and techniques to prevent unauthorised access and regularly undertake security tests. Genomics England protect your data and control who has access to it.

This information will only be used for healthcare research by researchers who have been approved by our independent Access Review Committee.

Your information will never be used for insurance or marketing purposes.In rare cases if there was a risk of you being identified because of research, we would contact you again and get your permission first.

The General Data Protection Regulation (UK GDPR), along with the UK Data Protection Act 2018, governs how we process (or use) your personal data.

Under UK GDPR we are required to inform you of the lawful basis on which we process your data.

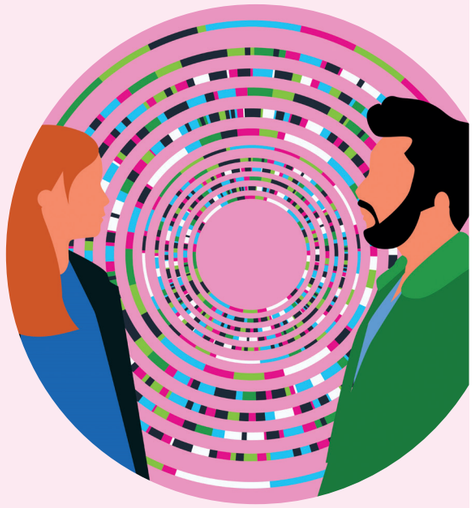
Our Article 6 lawful basis is Legitimate Interests Our Article 9 lawful basis is Research and Article 89 because our National Genomic Research Library has been approved by a Research Ethics Committee.

Your rights are further explained in our Privacy Notice.

Genomics England have appointed a Data Protection Officer who can be contacted by emailing: dataprotection@genomicsengland.co.uk

Can I withdraw from the study at any point?

Yes, you can leave the Library at any time without giving reason.



You will need to sign a withdrawal form to record your decision. The form can be requested the Genomics England website, or through the study that you enrolled with.

There are two options to consider when withdrawing from the National Genomic Research Library:

1. Partial withdrawal

- This option is for situations where you would be content for your data to continue to be used for research but want no further contact.
- Genomics England will update our records to ensure you are no longer contacted.
- Genomics England will continue to update and store information from your health and other records for use in approved research.

2. Full withdrawal

- This option is for situations where you no longer wish for your data to be used for research and want no further contact.

Genomics England will not:

- Contact you directly
- Continue to update and store information from your health and other records
- Allow new research access to information that is held about you
- Use your information for purposes other auditing

Genomics England will not:

- Remove data from research that is underway or has already been done; or
- Remove all records related to you from our databases
- An audit record is needed to confirm that you were once part of the National Genomic Research Library and then withdrew; this information includes your first name, surname, date of birth, address and contact details

What if I joined as part of a specific study?

The study you also enrolled in may have offered to provide you with information on any findings they make. They can only do that if they can identify you from their work in the Library.

Genomics England will only identify you under instruction from your research study.

This is done under very strict conditions and any information will only be given to researchers that you have that unique relationship with, never to anyone else.
We always check to make sure you have provided consent for them to do this via their consent form and other information provided to you at the time you joined their research.

Will you contact me again?

We may contact you again for further information or to tell you about other research opportunities or if you are eligible for a clinical trial. We may need to get in touch if there is other information that researchers are interested in.

How can I get more information?

If you would like more information about the study, you can contact us at Genomics England at:
info@genomicsengland.co.uk

You can find out more about how Genomics England uses your data here:

- www.genomicsengland.co.uk/understanding-genomics/data/faqs
- www.youtube.com/channel/UCFVzGiIYp-nRxsOTjjNUqOg

You can read the Genomics England privacy policy here:
www.genomicsengland.co.uk/privacy-policy

Genomics England

Genomics England

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www.genomicsengland.co.uk

Participation in the National Genomic Research Library

First name	**Reference No.** (or postcode if not known)
Last name	**Date of birth** D D M M Y Y Y Y

One form is required for each person being offered the opportunity to take part

All the statements below remain relevant even if you are providing consent on behalf of somebody else, for example your child

You have been invited to contribute to the National Genomic Research Library, managed by Genomics England.

Genomics England was set up in 2013 by the Department of Health and Social Care to work with the NHS to build a library of human genomes for researchers to study. Combining data from many different people helps researchers to better understand disease and spot patterns in the data.

Taking part in research may benefit you or others, now or in the future. Approved researchers can use the samples and data to study diseases and look for new treatments. Please read the following statements. Feel free to ask any questions before making a decision.

Statements overleaf on page 2 of 4

Participation in the National Genomic Research Library

By saying 'yes' to research, I confirm that I have read the accompanying participant information sheet and understand that:

DNA, sample and health data use

1. My sample and / or DNA sequence can be stored and used for future research.
2. Researchers may include national or international scientists, healthcare companies and NHS staff. To access the data, these researchers must all be approved by an independent committee of experts, including health professionals, clinical academics, and patients. There will be no access to the data by personal insurers and marketing companies.
3. Different aspects of my health data will be collected from the NHS and other organisations a list of which will be updated from time to time www.genomicsengland.co.uk/understanding-genomics/data. The collection and analysis of my health data for research will continue across my entire lifetime and beyond.

Security

4. Any data stored by Genomics England will always be stored securely. Genomics England will take all reasonable steps to ensure that I cannot be personally identified.

Re-contact

5. Genomics England can contact me if the data reveals any clinical trials or other research that I might benefit from.

Withdrawal

6. I can change my mind about taking part at any time.

More information regarding research in the National Genomic Research Library can be found at:
www.genomicsengland.co.uk. For any further questions, my healthcare professional can provide information.

Please use page three to indicate your choices.

This document is subject to version control and is regularly updated. Please confirm you are using the current version by contacting Genomics England Limited.

First name	**Reference No.** (or postcode if not known)
Last name	Date of birth D D M M Y Y Y Y

Please provide confirmation of your choices

I confirm that I have read PIS V2.0 and had the opportunity to discuss information about the Library, and my choices are circled below

A. I agree that my data and sample may contribute to the National Genomic Research Library

YES | NO

Participant name	Signature	Date
.....	.....	D D M M Y Y Y Y

If you are signing this form on behalf of someone else (children, adults without capacity or deceased patients) then please sign below

Parent/Guardian/ Consultee name* *Please amend as appropriate*	Signature	Date
.....	.....	D D M M Y Y Y Y

Participation in the National Genomic Research Library

Administration use only

To be completed by the person recording the participant's choices

Participant Category

- ☐ Adult (signed by themselves)
- ☐ Adult lacking capacity (signed by consultee)
- ☐ Child (signed by parent or guardian)
- ☐ Deceased (signed on behalf of deceased individual)

Researcher name	Signature	Date
.....	.....	D D M M Y Y Y Y

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