Genomics england

Genomic Research

and why it is important

V1.4

Contents

Introduction

We hope this document will help you to understand why agreeing to donate your samples, and health and genomic data is so important for you, your family, and for future generations. The more people take part, the more likely it is that we will all have improved health.

You will be asked if you want to donate your sample (blood / saliva / tissue, etc.), genome sequence and health data for research. If you agree, 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 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.

Why me?

As part of your care, or care of your relative, you have been offered a type of genomic testing through the NHS Genomic Medicine Service which involves whole genome sequencing. This means every letter of the 3 billion letters in your genome will be 'read' to create your unique genetic sequence. As well as being used for your clinical care, the data from your whole genome sequence is also useful for research. Below you will find answers to many questions that might help you to decide whether to donate your data.

Information related to your clinical care can be found here: **https://www.nhs.uk/conditions/genetic-and-genomic-testing/**

What does contributing to the National Genomic Research Library mean?

- Involvement may provide an opportunity for you to get answers which could lead to a diagnosis, access to a different treatment, or an opportunity to participate in clinical trials
- Involvement may help people with similar conditions to you as well as helping people with a variety of other conditions
- It could mean getting answers for you or others now or in the future
- You will be part of a new national approach working with the NHS to bring together health data to help patients get better care

Need to know

Getting the most accurate diagnosis for you involves comparing your data to that of thousands of other people. The more people that donate their data, the more likely you are to get an accurate diagnosis.

Important information discovered from this research is used by the NHS to get more accurate genomic testing for everyone.

What is the National Genomic Research Library?

- The National Genomic Research Library is a comprehensive resource that allows researchers to access samples, genomic data, and other associated health data
- The National Genomic Research Library is a partnership between NHS England and NHS Improvement and Genomics England. The offer to take part in research is an integral part of your clinical care
- Genomics England is a company set-up and owned by the Department of Health and Social Care. (Additional information about Genomics England is available: https://www.genomicsengland.co.uk/privacy-policy/) 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 GMS for patients in England
- Your individual information is important for your own health but researchers who use the National Genomic Research Library can learn more about everyone's health by looking for patterns in the data of thousands of patients
- Being able to compare all patient data in one place provides researchers with an opportunity to better understand diseases, develop new treatments and can lead to new diagnoses

Taking part

It's your decision whether or not you want to take part in the National Genomic Research Library. If you say 'no', it will not affect your care by the NHS and you will still get your genetic test.

What happens if I choose to take part?

- You will need to sign a form; the form has two simple questions and you need to agree to both of them
- If you agree, NHS England and NHS Improvement, on behalf of the Trusts that provided your genomic test, will allow Genomics England to access your personal data for inclusion in the National Genomic Research Library. (see https://www.england.nhs.uk/contact-us/privacy-notice/)
- Genomics England will then add your clinical test and health care data to the data of hundreds of thousands of other patients in the National Genomic Research Library
- 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)
- Genomics England makes sure that anyone who wants to use your data is fully approved. Every single study that researchers want to do has to be approved first by a Genomics England panel that includes patients whose data is also in the National Genomic Research Library
- Saying 'yes' to the National Genomic Research Library does not affect your involvement in any other research projects and you could be offered other research opportunities by your clinical team
- You do not have to decide to take part immediately, you can choose to participate at any point in the future by speaking to your healthcare professional

Will I be contacted in the future?

- From time-to-time you may be contacted by your clinical team (or occasionally by Genomics England) to give you more information:
  - If anything has been found which might be relevant to your health or that of your family
  - If there is an opportunity to involve you in a specific piece of research, or if you are eligible for a clinical trial
    - You may be contacted for additional research or trials related to your original test, or about different information that researchers are interested in
  - If there is general news about on the National Genomic Research Library
- If an additional or different sample is required for an approved research project, your clinical team or Genomics England might contact you
- The processes for re-contacting you will be managed by Genomics England together with the NHS
- You will never be contacted for marketing purposes
- Unfortunately, it won't be possible to let you know when your data has been accessed. This is because there are tens of millions of different bits of data in the Library and it isn't feasible to tell people every time a bit of their data has been used
- However, it is possible for you to see what type of research is being done in the National Genomic Research Library here: www.genomicsengland.co.uk/about-gecip/research
- We think it is very important that people see what has been achieved thanks to their data donation. Updates about new research are available on the Genomics England website for you to read and share

What happens to my sample(s)?

- DNA is extracted from your sample and is then sequenced
- The sequence is used by the NHS to do the genomic test
- The actual DNA sample remains in the NHS
- A digital code representing your sequence is placed in the National Genomic Research Library and this is what researchers are able to use
- Sometimes all of your sample will be used when your DNA is sequenced. Sometimes there will be some material left over. If there is, it will be stored securely and may be used either for your further care or occasionally for research
- Genomics England may access surplus tissue (or other) samples stored in the NHS for research where it does not affect your care

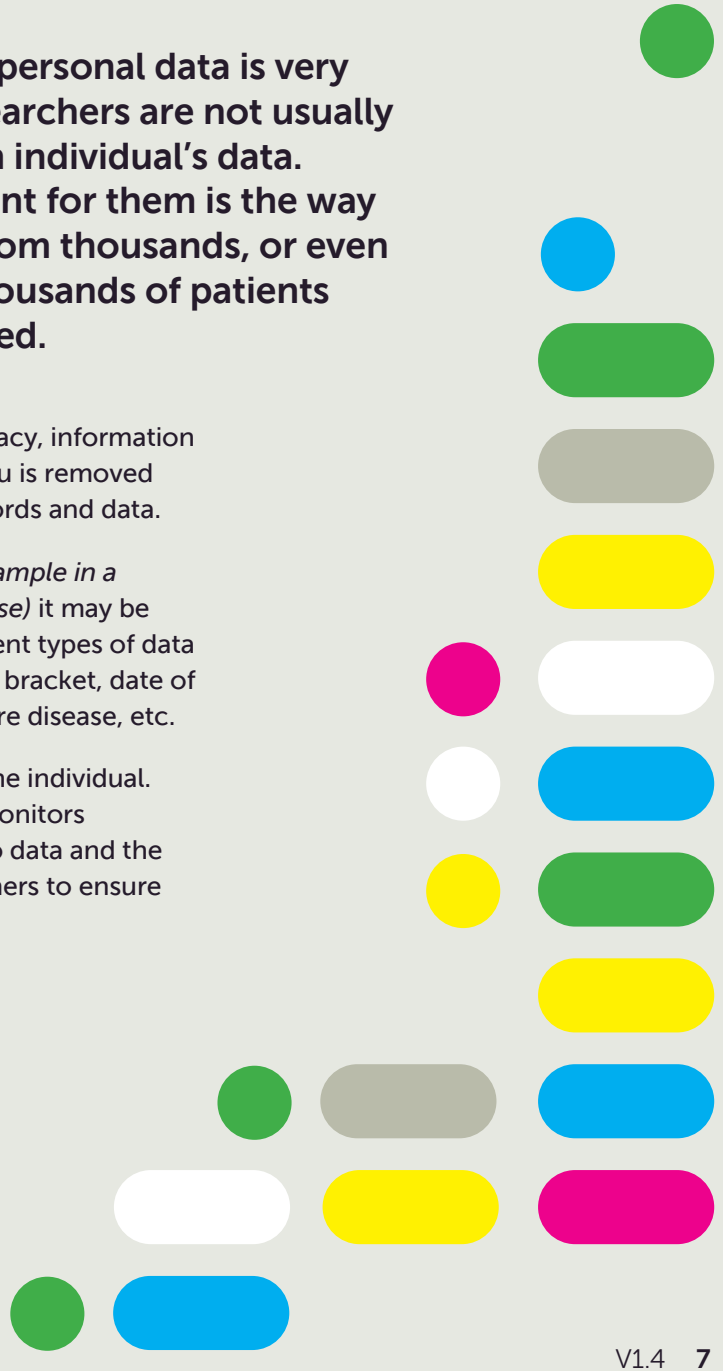
Data

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 patients can be compared.

To maintain your privacy, information that could identify you is removed from your health records and data.

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 can be used in the National Genomic Research Library?

- Genomics England always protects your data and controls who has access to it
- The National Genomic Research Library allows researchers to use the following de-identified information:
  - Your clinical test data
  - Electronic copies of all of your records from the NHS, your GP and other organisations (such as NHS Digital and Public Health England)
  - Information about any illnesses or stays in hospital – including information that you may not think are related to you or your family's diagnosis
  - Copies of hospital or clinic records, medical notes, social care, and local or national disease registries
  - Relevant images from your NHS records, such as MRI scans, X-rays or photographs
- Genomics England is constantly working to identify new sources of health data to include which is important for research
- Your original records remain within the NHS
- Where possible and appropriate, Genomics England will look to obtain and make available data from other research studies so that your data can be compared against more people
- Your records will continue to be updated throughout your lifetime, for as long as you give us permission to. This includes information added after your death, unless you have withdrawn from the Library

Need to know

"Why do you need my lifelong data?"

We need to know what happens to you next (health-wise). For instance, if you had a serious illness - did you get better or not? If some people who had that illness but got better quickly, there may be clues in their genome that tell us why.

This may allow development of better treatments or diagnostics for others.

Who has access to the data?

- Those who have access to the National Genomic Research Library will be researchers who are trying to better understand diseases and how to treat them
- 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
- The NHS does not usually develop or test medicines itself, instead working in partnership with commercial companies to do this so that patients benefit as quickly as possible from new discoveries
- Information about the research groups, projects and companies Genomics England works with is available on the website: https://www.genomicsengland.co.uk/about-gecip/research/
- The National Genomic Research Library brings together lots of data from different sources, so Genomics England will always make your data available to the NHS if they need it for your clinical care

What will the data be used for?

- Research must be in line with the acceptable uses as detailed in the Research Ethics Committee (https://www.hra.nhs.uk/) approved Protocol (https://www.genomicsengland.co.uk/national-genomic-research-library/)
- Helping to find new treatments and possibly cures for a wide range of health conditions
- Researchers might use the data in the National Genomic Research Library to try and find new, faster ways to analyse large amounts of data
- Researchers may publish the results of their research in scientific journals. They may also present their results at scientific meetings. It is important for scientists and doctors to share results to help research advance as quickly as possible. You will not be identified when they do this
- New drugs and diagnostic tests will be developed by the NHS, universities and companies across the world using this data
- Researchers will be able to find opportunities for you, and others like you, to take part in clinical trials or other relevant research projects

What will the data NOT be used for?

- Genomics England will not allow access to any data for insurance purposes
- Genomics England will not allow access to any data for marketing purposes
- No speculative searches of the National Genomic Research Library will be allowed by anybody. The Department of Health and Social Care has had confirmation from the Home Office and the Association of Chief Police Officers that they will not seek access to Genomics England's data without presentation of a court order
- For further details of unacceptable uses, please see the list as detailed in the Research Ethics Committee approved Protocol (https://www.genomicsengland.co.uk/national-genomic-research-library/)

How is the data stored?

- All patient data is held in secure facilities based in the UK
- Apart from in very rare situations, all of the data stays within the secure, monitored environment where it can be analysed by researchers; In this way, Genomics England considers the National Genomic Research Library to be a reading library – not a lending library
- In rare situations where there is a clear potential benefit to patients, a copy of requested data might be provided to approved researchers for study. Any request will be reviewed by a number of committees (https://www.genomicsengland.co.uk/understanding-genomics/data/current-research/) and the copy will be destroyed after the research is completed
- If you want information about how Genomics England processes your data see here: https://www.genomicsengland.co.uk/privacy-policy/
- In some cases, it may be possible for Genomics England to provide the data we hold about you. For more information see here: https://www.genomicsengland.co.uk/privacy-policy/

How securely is data protected?

- Genomics England continuously reviews the latest best practice for secure storage
- Data security is Genomics England's most important concern. It uses industry-standard tools and techniques to prevent unauthorised access and regularly undertakes security tests
- The National Genomic Research Library has to meet laws and standards to protect your data
- All requests by researchers to access data is reviewed in two stages by a committee; this 'air-lock' process protects the security and integrity of the data
- The same approval processes are in place for all researchers:
  - Research applications are reviewed by an independent Access Review Committee (https://www.genomicsengland.co.uk/about-genomics-england/the-board/access-review-committee/); this is overseen by Genomics England and NHS England and NHS Improvement. This includes patients who have their own genomes and data in the dataset
  - Researchers have to have their identities checked and confirmed
  - The researcher's organisation is required to sign legal documentation
  - Only when approved are Researchers given secure access to the National Genomic Research Library
- All research activity is monitored by Genomics England
- Maintaining your data security and protecting your privacy is very important to Genomics England. Any researcher who attempts to re-identify your data (and thus "identify" you) is highly likely to be found out.
  - Penalties are in place for any organisation or individual who breaches or attempts to breach your confidentiality.
  - Penalties include: Removal of access (including access by the organisation the individual is contracted to), the reporting of the offending activity to the Information Commissioner's Office (ICO) which may result in significant fines or even imprisonment
- Of course, even with the best data security, unauthorised access or 'hacking' will always be a possibility, as has occurred from time to time for data such as credit card details and email accounts

Making the choice for others

What if my child has a test?

- As a parent or guardian, you will need to decide on behalf of your child if you want them to take part in the National Genomic Research Library
- If you don't want them to, they won't be included
- At least one person with legal parental responsibility needs to complete the 'record of discussion' form
- Where appropriate, your child can be involved in making the decision to take part by completing a young person's assent form which will be provided by one of your healthcare team

What if I'm asked to provide make the choice on behalf of someone else?

CONSULTEES

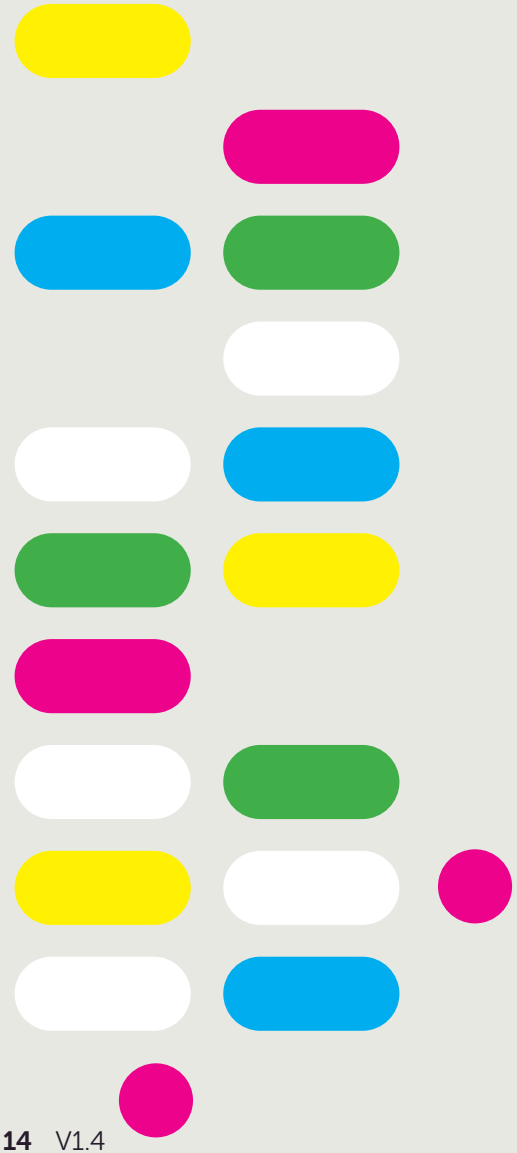
- If you have been asked to be a 'Consultee', this means you are making a decision for somebody who is considered to be unable to decide for themselves
- You should consider their likely views and interests and set aside your own personal views about participating in research
- One of your healthcare team will ask you to sign a consultee declaration form; this document provides more information about the responsibilities of the role

DECEASED RELATIVES

- Sometimes, your healthcare team might ask for permission to collect a sample from a relative shortly after their death. This may be to help understand more about your relative's health conditions, for the benefit of other family members, or other patients with the same condition
- You might be asked to decide if the data from a deceased relative can be included in the National Genomic Research Library

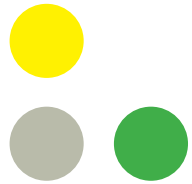
Withdrawal

Your data can help researchers for many years – or for as long as you wish to take part.



If you change your mind however and want to withdraw from the National Genomic Research Library, you are free to do so at any time. You don't need to give a reason. This applies if you are a parent wanting to withdraw your child, or a consultee wanting to withdraw on behalf of somebody else.

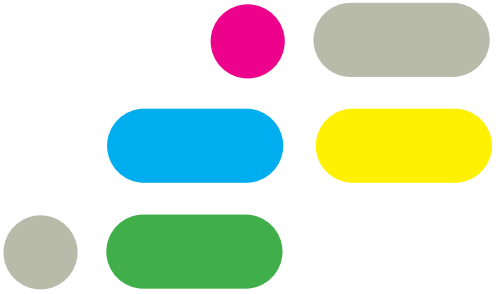
A withdrawal form will be required to record this decision. The form can be requested from your healthcare professional or downloaded from the Genomics England website: https://www.genomicsengland.co.uk/taking-part/patient-information-sheets-and-consent-forms/.



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 their 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 cannot:**
  - 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

Useful links

- Further resources may be informative and/or supportive:
  - https://www.nhs.uk/conditions/genetics/
  - https://www.geneticalliance.org.uk
  - https://www.macmillan.org.uk
  - https://www.genomicsengland.co.uk/nhs-gms/research-information/
- Please refer to the following resources for further information:
  - https://www.genomicseducation.hee.nhs.uk/news/new-guide-for-clinicians-feeding-back-genomic-results/
- Genomics England
  - https://www.genomicsengland.co.uk/understanding-genomics/data/faqs/
  - https://www.youtube.com/channel/UCFVzGiIYp-nRxsOTjjNUqOg
- Insurance and genetic testing:
  - https://www.abi.org.uk/globalassets/files/publications/public/genetics/code-on-genetic-testing-and-insurance_embargoed.pdf
  - https://www.gov.uk/government/publications/code-on-genetic-testing-and-insurance-consumer-guide
- Understanding Patient Data
  - http://understandingpatientdata.org.uk/case-studies
- How your data is looked after in the NHS
  - https://digital.nhs.uk/about-nhs-digital/our-work/keeping-patient-data-safe/how-we-look-after-your-health-and-care-information

Questions about NGRL?

For more information, please contact us by email or telephone:

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