100,000 Genomes Project

Personal Consultee Information Sheet

Invocation to become a Personal Consultee and outline of the role

We feel that your relative/friend is unable to decide for himself/herself whether to join the 100,000 Genomes Project, at the time that this decision needs to be made. An adult who is either temporarily or permanently unable to make a decision of this kind for themselves, is described as ‘lacking capacity’ under the Mental Capacity Act 2005.

This law protects the interests of adults aged 16 and over (in England and Wales) who are unable to make their own decisions, including as to whether they should take part in research.

As well as putting in place other protections for people who lack capacity and who take part in research, this law provides that a Consultee can be appointed to give researchers advice as to the likely wishes and feelings of an adult who lacks capacity about taking part in a proposed research project. The Consultee’s advice allows researchers to make the decision about whether or not that adult should take part in a specific approved research project (such as the 100,000 Genomes Project).

We’d like to invite you to become a Personal Consultee in regard to your relative/friend who lacks capacity. You must decide for yourself whether or not you want to take on the role. You may wish to seek independent advice before deciding. We will understand if you don’t want to take on this responsibility. Your relative/friend’s standard of care will not be affected if you tell us that you don’t want to take on the role of Personal Consultee. We will approach someone else to be a Consultee.

What is a Personal Consultee?

A Consultee role can either be personal or nominated. You are being invited to take on the Personal Consultee role. A person who lacks capacity can only have one Consultee at a time.

A **Personal Consultee** is someone unconnected with the 100,000 Genomes Project. They personally know the person who lacks capacity and they are able to advise on the person’s wishes or feelings. This could be the person’s friend, family member or a court appointee. They must not be someone who is paid to look after the person who lacks capacity.

A **Nominated Consultee** is also someone unconnected with the 100,000 Genomes Project. However, this Consultee does not have to personally know the person who lacks capacity, but they can ask other people close to the person who lacks capacity about the person’s wishes or feelings. A nominated Consultee may have a professional knowledge of the person who lacks capacity, such as their doctor or lawyer. They can be someone who is paid to look after the person who lacks capacity.

We will always take reasonable steps to identify a **Personal Consultee** in regards to the person who lacks capacity, in the first instance.

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1 The 100,000 Genomes Project is approved by the NRES Research Ethics Committee East of England – Cambridge South.
What would I need to do as a Personal Consultee?

- A Consultee needs to consider the broad aims of the proposed research and what the practicalities, risks and benefits of taking part will be for the person who lacks capacity, at the point the person is invited to join and afterwards.

- If you decide to take on the role of Personal Consultee, we will ask you to advise us whether you believe your relative/friend would want to join the 100,000 Genomes Project, if he or she had the capacity to make that decision. You are not being asked to give consent, only advice.

- You are not being asked to give us your own personal views on your friend/relative’s participation in the 100,000 Genomes Project, or about their participation in research in general. You must consider only your relative/friend’s past and present views and their interests, if you know about these.

- Please let us know of any advance decisions your relative/friend may have made about participating in research. These should take precedence.

- This advice from you, based on your opinion of the wishes and feelings of your relative/friend, will help their clinical team decide whether your relative/friend should join this Project. The final decision about your relative/friend joining will rest with the team.

- **If your advice as a Personal Consultee is that you believe your relative/friend would *not* want to join, he/she will *not* be included in the 100,000 Genomes Project.**

- The final decision about your relative/friend not joining rests with you. Your advice as a Consultee that your relative/friend would not wish to join will be recorded in your relative/friend’s medical notes. Based on this, for so long as your relative/friend lacks capacity, they will not be invited to join this Project again (so we wouldn’t approach you or anybody else again for advice about this as a Consultee).

- If you take on the role of Personal Consultee in respect of the person who lacks capacity, and your relative/friend joins as a participant, you could be asked to give your advice on other Project-related issues at any time for as long as the person both lacks capacity and remains a participant in this Project.

- For example, if further blood or saliva samples were needed, these would not be taken from your relative/friend without seeking your advice in advance (each time these were needed). Such samples would not be taken unless your advice is that your relative/friend would be content for this to happen. You are always free to advise that your relative/friend would not wish this to happen, if that is your opinion. You will also be informed by the clinical team if the Project changes from what is described in this information sheet, in a way that might affect your relative/friend.

- If as a Consultee, you come to believe that your relative/friend would want to stop being a participant in the Project, you should advise the clinical team that your relative/friend should be withdrawn. Your advice will always be carried out and your relative/friend will be withdrawn from the Project without delay.

- If you wish to stop being a Consultee, you can do this at any time by informing the clinical team of the person who lacks capacity. Your relative/friend can’t remain in the Project without having a Consultee, so they will also be removed from the Project once you stop being a Consultee. We will approach someone else to be a Consultee and to seek their advice on whether or not they believe your relative/friend would want to participate in this Project.
To help you decide about taking on the role of Consultee:

1. Please read this Personal Consultee Information Sheet (PCIS). It outlines how people who lack capacity to decide whether to join the 100,000 Genomes Project, at the time this decision needs to be made, can participate in this Project, and provides information about the Consultee role and the 100,000 Genomes Project. The PCIS is similar to the ‘Patient Information Sheet’ your relative/friend would have been offered if they had capacity, except that we have addressed it to you it to you as the potential Personal Consultee.

2. You will also be provided with a copy of the Personal Consultee Declaration Form (PCDF). If you decide to become a Personal Consultee, this form is where you should sign to confirm this and give us your advice if you think your relative/friend would have wished to join this Project had they been able to decide for themselves.

3. You will be asked to discuss the 100,000 Genomes Project with a healthcare professional involved. This is so that you can begin to form your opinion as to the likely wishes and feelings of the person who lacks capacity, with regard to joining the Project. Please ask any questions you may have.

4. If you are unsure about taking the role of Personal Consultee you may seek independent advice.

More information about being a Personal Consultee is available at these sources:


When you have decided, please then either:

- Tell us that you don’t wish to be a Personal Consultee. We will not ask you to sign anything if this is your decision. The clinical team will keep a record that you were asked and said no (so that you are not approached again about this role in future).

  OR

- Tell us that you agree to take on the Personal Consultee role **AND** give your opinion as either a) or b) as follows:

  a) Your advice is that your relative/friend **would not** want to become a participant in this Project. We will not ask you to sign anything if this is your decision and your advice. Your advice as a Consultee will be recorded in your relative/friend’s medical notes. So we won’t reapproach you or anybody else for advice about this in future. Based on your recorded advice, for so long as your relative/friend lacks capacity, they will not be invited to join this Project again.

  OR

  b) Your advice is that your relative/friend **would** want to become a participant in this Project. You will then need to sign the Personal Consultee Declaration form to let us know this in writing. We’ll then give you a copy to keep.
100,000 Genomes Project

Personal Consultee Information Sheet

This information sheet describes the Project and key points that your relative/friend would be asked to consider if he or she had capacity to consent for themselves.

1. INTRODUCTION

About the 100,000 Genomes Project

Genomics England is creating a lasting legacy for patients, the NHS and the UK economy through the sequencing of 100,000 genomes, all with the consent of participants. This is known as the 100,000 Genomes Project. The main goal of the Project is to transform the application of genetics to healthcare in the NHS. The Project is run by Genomics England, a company owned by the Department of Health.

Your genome

Your genome is all of the genetic information in your body’s instruction manual. Some of your genome is unique to you, but much of it you share with your relatives. Your genome is made of DNA, which is like a series of ‘letters’ that can be looked at using a technique called sequencing. Recent developments in science and technology mean it is now possible to sequence the whole genome.

What can sequencing a whole genome tell clinicians and researchers?

Learning more about genomes can identify the cause of disease and may help to improve treatments. When the genome sequences of patients with the same condition are compared, it is possible to see patterns. These patterns can be put together with health information about everyone taking part. Once this is done we may be able to link particular patterns with whether people become ill and how severe their illness is likely to be. Sometimes these patterns can also give clues as to the best treatments for a patient, or may reveal information that could be important to other family members.

Why is the 100,000 Genomes Project being done in the NHS?

Fast, low-cost, whole genome sequencing is now affordable for the NHS. Using whole genome sequencing for the benefit of patients is called ‘genomic medicine’. Although genomic medicine is already happening in the NHS on a small scale, we want to develop the evidence that may expand its use across healthcare.

What is the 100,000 Genomes Project planning to do?

This Project will sequence 100,000 whole genomes, half in people with rare genetic diseases and half in patients with cancer. The results will be linked with patients’ medical records and stored securely. By combining this information and allowing authorised researchers to access it, the Project aims to:

- Provide a diagnosis for some patients with rare diseases.
- Learn how to adapt cancer treatment by looking at the genome of the tumour.
- Make new discoveries that will help us understand why some people get ill and others don’t.
- Develop a genomic medicine service for the NHS.
- Support clinicians and researchers in hospitals, universities and companies of all sizes to develop new medicines, therapies and diagnostic tests.
2. TAKING PART

Why has my relative/friend been invited to join the 100,000 Genomes Project?
Your relative/friend has been invited to join the 100,000 Genomes Project because they have a suspected (or already diagnosed) cancer of a type that is included in the Project. Many changes occur in the genome of cancer cells, which allow the cancer to develop. Comparing the genome of your relative/friend’s healthy cells to the genome of their cancer cells can give clues about how the cancer grows and spreads, and may help us understand how best to treat it.

What am I being invited to do as the Personal Consultee for my relative/friend?
After the Project has been explained, you will have time to consider, in consultation with others where appropriate, whether you think your relative/friend would want to take part in the Project. If you advise us that your relative/friend would want to join the Project, you will then be asked to:

- Read and fill in a Consultee Declaration Form.
- Provide your contact details to the Project. All contact details are confidential to the clinical team and the 100,000 Genomes Project team and will not be shared with anyone else.

You can ask the clinical team questions about the Project at any stage.

What will be needed from my relative/friend if they join this Project?

- Your relative/friend will need to have a blood test (up to 3 tablespoons of blood); occasionally other samples such as saliva might also be requested.
- Your relative/friend will need to give the Project a piece of their tumour collected during their normal cancer care.
- Your relative/friend’s personal details, contact details and health information will be provided to the Project. More information about what information will be collected and how this will be used is given in section 4.
- Your relative/friend’s GP and other doctors involved in their care may be informed that they are taking part.

3. SAMPLES

What will happen to my relative/friend’s samples after they have donated them to the 100,000 Genomes Project?
This relates to points 2 and 3 on the Personal Consultee Declaration Form.

- DNA will be extracted from your relative/friend’s blood and tumour samples for whole genome sequencing. This is most likely to take place in England, but it could occasionally be done overseas.
- We will also take blood samples to allow us to do other tests to understand how genes work. In future, we may be able to do new tests on the samples (tests that are yet to be developed).
- Your relative/friend’s DNA and other samples will be stored by Genomics England in a secure ‘bank’ called a bio-repository. This is located in the UK.
- Instead of your relative/friend’s name being used to label your sample(s), they will be labelled with a unique code number before they are sent to the bio-repository. This means your relative/friend cannot be directly identified from the sample(s).
- Your relative/friend’s samples could be used up soon and then their clinical team may ask you to advise on whether you think your relative/friend would be willing to give more at that time. Alternatively, your relative/friend’s samples could remain stored for many years.
- There may be certain circumstances where your relative/friend’s DNA will not be sequenced. If this happens, their clinical team will explain why.
4. ACCESS TO MY RELATIVE/FRIEND’S DATA AND CONFIDENTIALITY

What information are you asking my relative/friend to donate to the Project?

This relates to point 4 on the Personal Consultee Declaration Form.

**Key point**
Participants’ past medical records, as well as current and future information about their condition (health data) can be collected by the 100,000 Genomes Project. This information can be studied now and after their death.

You are being asked to advise whether you feel that your relative/friend would have wanted to:

- Allow information about their current condition to be sent by their clinical team to the 100,000 Genomes Project.
- Allow the Project to obtain health-related information and past medical records that span their lifetime, including current and past illnesses or stays in hospital. This could include medical records held by the NHS, their GP, and other bodies like local and national disease registries. (Registries are collections of information about patients with a particular condition.)
- Allow the Project to continue to access their health records electronically into the future, so we can update the medical records that we hold on your relative/friend over the rest of their life. This will include receiving information from their clinical team charting the course of their illness. The data we keep for the Project will be in the form of electronic copies and not your relative/friend’s original records which will remain in the NHS.
- Allow researchers to view (but not take away) any digital images that are collected from your relative/friend’s health records, such as MRI scans and photographs.
- Allow their data to continue to be studied throughout their lifetime as well as after his or her death, to collect as much useful information as possible, for the benefit of future healthcare and research.

What will happen to my relative/friend’s data after I have shared it with the Project?

This relates to points 4 and 5 on the Personal Consultee Declaration Form.

**Key point**
The 100,000 Genomes Project links your relative/friend’s genome sequence with their medical records and information about their condition. Researchers will only have access to this data if they are approved by an Advisory Committee to Genomics England. All the information is held securely, and will only be used for scientific and healthcare purposes.

- Your relative/friend’s healthcare information will be linked to their sequence data and stored to be compared with many thousands of other sets of information donated by other participants.
- Their data may be used to study many different medical conditions, not just the cancer that led to them being asked to take part, or future conditions that they might go on to develop.

Who will have access to my relative/friend’s data?

This relates to point 6 on the Personal Consultee Declaration Form.

- To get the most value for healthcare from the information from your relative/friend, this needs to be accessible worldwide, in a form which protects their identity.
- Genomics England will put the names of all the companies or organisations that have been approved to access data and for what purpose, on the 100,000 Genomes Project website: www.genomicsengland.co.uk.
- Access to any of the data held by Genomics England for marketing or insurance purposes will not be allowed.
Access for commercial researchers and organisations

This relates to points 6 and 7 on the Personal Consultee Declaration Form.

Key point
You are agreeing that approved researchers from for-profit companies can have access to this data under specific conditions and rules.

- Not-for-profit organisations will be able to access your relative/friend’s data, such as research charities, universities or hospitals.
- For-profit (commercial) companies will also be able to access your relative/friend’s data, such as drug companies, or companies making diagnostic tests or developing faster ways to analyse large amounts of data.
- This is to enable new medicines, treatments and diagnostic tests to be developed as quickly as possible.
- Companies will have to pay to access the data we hold, although access may cost them less if they make their results available to all other researchers. If any financial profits are made by Genomics England, these will go back to the NHS.
- You or your relative/friend will not benefit financially if a product or test is successful because of your relative/friend’s participation in the Project.

As their Personal Consultee, can I access my relative/friend’s data?

- Genomics England owns the data from this Project. We protect it on your relative/friend’s behalf and decide who gets access to it.
- You can ask for a copy of your relative/friend’s data, although there will be a charge for providing this.

How will you keep my relative/friend’s information secure and confidential?

- Your relative/friend’s data is stored in a controlled access database in the UK, and its security level meets national and international data standards.
- Their name and other personal details will be available to their clinical team and the Project team, who need these to analyse their individual results and provide a report. Their name and personal details will not be included in the data which is provided to researchers.
- Researchers looking at your relative/friend’s data will be tracked by Genomics England to check that they are following the laws and ethical guidelines that apply to biomedical research.
- Although researchers can look at your relative/friend’s data and ask questions about it, they can only take away the answers to their questions (their results). They can’t copy or take away any of your relative/friend’s individual data.
- Revealing your relative/friend’s data on purpose in a way that identifies him or her would be a legal breach against the permitted use of samples and data from the Project and is against good research practice. Any individual or institution that misused data in this way could face criminal charges or substantial fines, and would be barred from accessing our Project again. Major research funders in the UK have said that they will withdraw funding from any researcher that did this.

Will taking part affect my relative/friend’s insurance?

- Any medical treatment your relative/friend has may need to be disclosed to an insurer that asks about it. However, under an agreement between the Department of Health and the Association of British Insurers, the results of your relative/friend’s whole genome sequencing carried out in the 100,000 Genomes Project are not disclosable to insurers.
• You (or anyone else on behalf of your relative/friend) do not therefore have to tell an insurer that your relative/friend is part of the 100,000 Genomes Project, and they won’t have access to the results.

5. FUTURE CONTACT

As a Consultee, what might you contact me about in the future?

This relates to point 8 on the Personal Consultee Declaration Form.

Key point

You may be contacted in the future by the clinical team, or by Genomics England, to ask you for additional health information about your relative/friend, or to advise whether you think they would wish to take part in future research.

• In the future you be contacted by the clinical team, or directly by Genomics England, to advise whether your relative/friend would wish to take part in further research. This might include clinical trials of new medicines. You could also be invited to join research as a Personal Consultee. For example, this could be research about your views on aspects of the Project.
• If you feel your relative/friend wouldn’t want to take part in research when you are contacted then they don’t have to. Similarly, as a Consultee if you don’t want to take part in any research suggested to you, then you don’t have to.

6. RESULTS

What information will I receive about my relative/friend’s main condition?

This relates to points 9 and 12 on the Personal Consultee Declaration Form.

Key point

The clinical team will be given the results of whole genome sequencing. They will pass this on to you in an appropriate way.

There could be no findings that explain your relative/friend’s cancer. The results might not come back in time to influence their care.

Your relative/friend’s ‘main condition’ is how we describe the cancer that was the reason they were invited to join this Project.

• After your relative/friend’s genome is sequenced, the results will be sent to their clinical team who will check them and discuss them with you as appropriate.
• In time, findings will be returned within a couple of weeks as the technology and our understanding of the results develops. At first this will take longer, so the clinical team may not receive some or all of the findings until after your relative/friend’s treatment has been completed.
• The results may provide information that helps guide your relative/friend’s treatment, but alternatively it is also possible that there will be no information to report.
• In addition to information about your relative/friend’s current cancer, the results might include genetic changes in your relative/friend’s healthy cells which could have caused their cancer to develop. If this happens, these results could increase their chance of developing another cancer in future.
• If your relative/friend has a genetic change in their healthy cells, other people in their family could be tested for this to see whether they have an increased chance of developing cancer. If this happens, the clinical team will give advice about what information would be helpful to pass on, and discuss with you
the best way of doing this.

- If your relative/friend or their family members are found to have a change in their healthy cells, they may be offered extra screening or treatment to reduce the chance of developing cancer in the future.
- You will not be told personally about the results of research that has included your relative/friend’s data, unless the result is important for their individual diagnosis or treatment. Details of all the studies using the Project’s databases will be published and made available on the Genomics England website.

**What other results can the 100,000 Genomes Project look for?**

This relates to point 10 in the Personal Consultee Declaration Form.

**Key point**

As well as looking for the cause of your relative/friend’s cancer, we are able to look for a limited number of ‘additional findings’ in their genome. These are findings that could be relevant for your relative/friend’s future health.

As their Personal Consultee, you will be asked to advise whether your relative/friend would want us to look for these ‘additional findings’.

Your relative/friend’s genome sequence contains information which might be relevant for their health, as well as other types of information such as how they are related to members of their family or their eye colour. It also contains a lot of information we cannot fully understand.

When your relative/friend’s genome sequence is analysed in this Project, we can look for information which might be relevant for their future health, or the health of other members of their family. We call these ‘additional findings’ (because they are different to the main condition) and you can advise whether we look for these.

- Information from your relative/friend’s genome which is relevant to their main condition will routinely be provided to the clinical team, as described above.
- Information about health-related additional findings will only be looked for and provided to the clinical team if you advise us that your relative/friend would want this in the Personal Consultee Declaration Form.
- Any other information in your relative/friend’s genome which is not relevant to the main condition and is not an additional finding will not be looked for or provided to the clinical team.

If you advise us to look for health-related additional findings in your relative/friend’s genome, all of the diseases we will look for can either be treated, or screening can be offered aiming to pick them up at an early stage.

Although we know that treatment or screening can be useful in these diseases, there are some people who will receive an additional finding, but who will never go on to develop the disease. As the Project continues, we hope to understand better who will benefit from treatment or screening.

If your relative/friend is found to have an additional finding, they may be given extra treatment or screening as a result. They might not be given any treatment or screening straight away, for example if the disease is known to cause problems in older people, and they are too young to benefit from any treatment or screening.

Even if no additional findings are reported in your relative/friend’s genome, there is still a small chance that he or she could develop one of the diseases we have looked for. This is because we do not yet know whether genome sequencing will pick up all important genetic changes. We should know more about this by the end of the Project.

The diseases we will look for are uncommon, and the chance of your relative/friend having one of them is not high.
As we learn more about how to use genome sequence information over the life of the Project, the additional findings which we will look for will be regularly updated. If this new information shows that your relative/friend has an additional finding in the future, this information will be provided to your clinical team to discuss with you. Part of the purpose of offering information about additional findings is to help us decide whether we should look for these as part of NHS standard clinical care.

**Can I change my advice about additional findings in the future?**

- You can change your advice about whether your relative/friend would want to receive health-related additional findings at any time by filling in an Opt-in or Opt-out form, which you can get from your clinical team or from the Genomics England website [www.genomicsengland.co.uk](http://www.genomicsengland.co.uk).

**What will happen after the initial reports are sent to my relative/friend’s clinical team?**

- If you advise us to look for additional findings, these results these may be returned separately from the main results.
- After the clinical team receive these reports, all your relative/friend’s information will continue to be held on the Project’s research databases, and will be added to as new records become available.
- If more information about your relative/friend’s genome becomes available after more research has been done, the clinical team will be told about this. This means there could be further reports in the future, as well as initial reports on the main results, and the additional findings (if you advise us to look for these).

**What are the benefits of my relative/friend joining the 100,000 Genomes Project?**

- Your relative/friend might benefit in terms of their healthcare personally but they might not benefit at all.
- Other patients may benefit from the knowledge generated by this Project.

**What are the risks to my relative/friend in joining the 100,000 Genomes Project?**

- **Being identified as someone taking part in the Project:** We will always do everything we can to stop this happening. There are penalties in place, but there is still a remote risk that this could happen.
- **Giving blood samples:** There is a small risk of bruising, inflammation or fainting but no more than with any other blood sample. Experienced staff will collect the blood.
- **Future risks:** There might be new ways in the future to link information back to your relative/friend directly, but we will keep up with these developments in order to protect his or her data.

### 7. LEAVING THE 100,000 GENOMES PROJECT

**How can I withdraw my relative/friend from the Project?**

This relates to **point 13** on the Personal Consultee Declaration Form.

**Key point**

You can withdraw your relative/friend from the 100,000 Genomes Project at any time in the future, by advising the clinical team that you believe this is what your relative/friend would want.
As their Personal Consultee, if you believe your relative/friend would want to leave the Project, ask the clinical team for a Withdrawal form, complete the form and return it to them. There are two options for withdrawal, as below. More information about these options is available from your clinical team or in the withdrawal form.

1) **No further contact, but continue to include my relative/friend’s samples and information in the Project**
   
   **OR**

2) **No further contact and no further use of my relative/friend’s samples or information.**

**The clinical team will be happy to answer any questions you have. Please share this leaflet with your family and friends if you want to. Thank you for considering becoming a Personal Consultee.**