

100,000 Genomes Project



Consultee declaration form

Introduction

Following discussion, we feel that at the moment, your relative, friend, patient or client cannot decide for themselves whether to join the 100,000 Genomes Project. Someone who can't make this kind of decision at the time it is needed, is described as 'lacking capacity'.

In this information sheet, when we are talking about this person, we say 'the person who lacks capacity' or 'the person'.

We'd like to invite you to become a 'consultee' for this person. In other words, someone we consult about some decisions to do with the person's participation in the project. You do not have to take on this role and we will understand if you don't want to. You can stop being a consultee at any time. You don't need to give a reason. To stop being a consultee, tell the hospital staff running the project.

You will need to think about the aims of the project. You also need to think about the practicalities, risks and benefits of taking part for the person who lacks capacity. You need to consider their views and interests.

We'd like to ask your advice on whether you think the person would want to join the project. If you believe that they would want to join the 100,000 Genomes Project, we'd like to keep a record of your opinion using the form below.

Please let us know about any advance decisions the person may have already made about taking part in research. These should take priority.

If you decide that the person who lacks capacity would not want to take part, they will still receive the best available care.

The consultee declaration form below is similar to the consent form which we would have given to the person who lacks capacity, had they been able to make their own decision.

We have edited this form to address it to you as their potential consultee.

If you want to take on the role of consultee and tell us that, in your opinion, the person who lacks capacity would want to take part in the 100,000 Genomes Project, please fill in this form.

1 Taking part

I have read and understood the participant information sheet 'For Personal or Nominated Consultees of patients with a rare genetic disease' dated ____ / ____ / ____ (version ____). I have been able to ask questions and have had these answered.

I understand the following.

- **I can give you advice about whether my friend, relative, patient or client would want to join the project, or not.**
Their routine medical care or legal rights aren't affected if they don't take part.
- **I can tell you, at any time, if I think the person would want to be withdrawn from the project.**
I do not have to give a reason why. You will always follow my advice.
If the person withdraws, I understand that some research may have already taken place using their data and this can't be undone.

I agree the following.

- You can tell the person's GP and other healthcare professionals they have joined the project.
- Their samples and data can be used in the project at any time, including after their death (if this were to happen), unless I withdraw them from the project.
- You at Genomics England or the clinical team can contact me to:
 - ask my advice about the person who lacks capacity donating more information for the project;
 - ask my advice about them donating further samples if needed in the future;
 - invite me, or the person who lacks capacity, to join other research; and
 - send me general updates about the project.

Initial here to show you agree.	
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2 Samples

If my relative, friend, patient or client takes part, they will need to donate to the project:

- a sample of blood;
- other samples, such as saliva, if needed; and
- samples already collected as part of their medical care.

The samples can be used for:

- collecting DNA for whole genome sequencing; and
- studying blood to find out how the DNA is working.

I understand that there might be new ways of doing this in the future.

The samples or DNA could be sent to approved organisations outside the UK for processing or analysis.

Initial here to show you agree.

3

Data

I agree that the project can access and collect electronic copies of past and future health records for the person who lacks capacity.

- This includes personal information from all of their records from the NHS, their GP and other organisations. This includes information about any illnesses or stays in hospital – even ones that appear unrelated to their rare condition their family.
- The data is from different sets of records, including hospital or clinic records, medical notes, social care and local or national disease registries. It includes images from their NHS records, such as MRI scans, X-rays or photographs.
- To get this data, the project will need to send some details about the person who lacks capacity (for example, their NHS number and date of birth) to the organisations holding this information. This will allow them to find the health data they hold.
- The data may be used to study many different medical conditions, not just ones that affect them.
- It can be collected at any point in their life and will continue after their death, unless they have withdrawn from the project.
- Approved individuals from Genomics England, the NHS and other study monitors can look at this information at any time.

I understand that:

- all information you at Genomics England hold about the person who lacks capacity will be treated as confidential;
- the data, and information from the samples will only be used by researchers in a form that protects their identity;
- research organisations who are accessing the data and samples may include commercial (for-profit) companies;
- researchers won't be allowed to copy or remove any of their information; and
- neither I nor the person who lacks capacity will benefit financially if research data from the project (which includes their data) leads to new treatments or medical tests.

Initial here to show you agree.

4 Results

I agree that:

- tests can be run on the person's samples and health information to look for the cause of their rare genetic condition and to help their medical care; and
- the results can be reported to their clinical team and their clinical team can discuss these with me as appropriate.

I understand the following.

- Information generated by this project may benefit the person's family members, now or in the future. If relevant, the NHS will support me in sharing this with them.
- The person who lacks capacity may not get a diagnosis or information that will help with their medical care, now or in the future.
- The results may not be returned in time to be used in their medical care.

I understand that apart from the person's rare genetic condition and additional findings (if I have asked for these) no other information will be looked for or reported.

Initial here to show you agree.	
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5 Additional findings (optional)

I understand the following.

- I can tell you if I think the person without capacity would want certain other conditions that might affect them to be looked for in their samples ('additional findings').
- These conditions are not connected to their rare genetic condition.
- All the conditions can potentially be treated or prevented.
- The results might also be important to other members of their family.
- Even if the results seem to show that they don't have one of the conditions, they could still get it in the future.
- You may add to or change which conditions you look for. This means they might get other results in the future.
- I can change my mind about additional findings at any time.

Initial your choice.

I believe that the person without capacity would want additional findings to be looked for and given to the clinical team.	
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Or

I believe that the person without capacity would not want this information to be looked for and given to the clinical team.	
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For a consultee regarding either a patient with a rare genetic disease,
or an adult relative of a patient with a rare genetic disease.

Name of my relative, friend, patient
or client (BLOCK CAPITALS):

Date of birth:

(DD/MM/YY)

I have been consulted about this person's participation. I am willing to take the role of consultee.

Name of consultee
(BLOCK CAPITALS):

Signature:

Date:

(DD/MM/YY)

Consultee's relationship
to participant:

Please say if you are a 'personal'
or 'nominated' consultee:

Name of person taking consultee
declaration (BLOCK CAPITALS):

Signature:

Date:

(DD/MM/YY)

Name of interpreter if used
(BLOCK CAPITALS):

Signature:

Date:

(DD/MM/YY)

When you have filled in this form:

- 1 (the original) will be kept in the adult participant's 100,000 Genomes Project records.
- You will keep a copy.
- We at Genomics England will keep a copy.

Staff only (if this applies).
Adult participant's NHS number:

For administration use only (NHS GMC staff).

