

100,000 Genomes Project



Consent form

If you agree for your child to take part in the 100,000 Genomes Project, please:

- initial boxes 1, 2, 3 and 4;
- initial your choices for returning additional findings in box 5; and
- sign your name at the end of this form.

Introduction

At least one person with legal parental responsibility for your child needs to fill in this form to agree for your child to join the 100,000 Genomes Project.

If you aren't sure who has 'legal parental responsibility' for your child, your healthcare professional can explain.

Please read the information sheet 'For parents of participating children' and discuss this with a healthcare professional and your child.

Only you can choose if you want your child to join. If you don't want them to join, you don't have to say why. If they don't join, they will still receive the best available care.

A healthcare professional will explain the project to your child. They will receive their own information sheet and they can ask any questions. You can be with them while this happens.

Your child can show they agree to join the project by signing an 'assent form' if they want to. Their other parent can also sign this consent form if they want to, but this isn't needed.

If you agree that your child joins the project, once they are old enough and able to give permission (consent) themselves, we will ask them to agree on their own behalf to stay in the project. At that time they will make their own decision.

Taking part, samples and data

1 Taking part

I have legal parental responsibility for the child named below. I authorise this consent form on behalf of my child, and I agree for my child to take part in the 100,000 Genomes Project.

I have read and understood the information sheet 'For parents of participating children' dated ____/____/____ (version ____). I have been able to ask questions and have these answered.

I understand the following.

- **Only I can decide if I want my child to join the project, or not.**
My child's routine medical care or legal rights will not be affected if they don't take part.
- **If my child joins the project, I can choose to withdraw them at any time.**
I do not need to give a reason why.
If I withdraw my child, I understand that some research may have already taken place using their data and this can't be undone.

I agree to the following.

- You can tell my child's GP and other healthcare professionals that my child has joined the project.
- You can use my child's samples and data 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 and the clinical team can contact me to:
 - ask my child to donate more information for the project;
 - ask my child to donate further samples if needed in the future;
 - invite my child to join other research; and
 - send me general updates about the project.

If I am asked, I can say yes or no. It is my choice.

Initial here to show you agree.	
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2 Samples

I agree that my child can 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.

My child's samples can be used for:

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

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

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 my child's past and future health records.

- This includes personal information from all of my child's 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 the rare condition in my 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 my child's NHS records, such as MRI scans, X-rays or photographs.
- To get this data, the project will need to send some details about my child (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 about my child.
- The data may be used to study many different medical conditions, not just ones that affect my child.
- It can be collected at any point in my child's 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 about my child held by the project will be treated as confidential;
- my child's data, and information from their samples will only be used by researchers in a form that protects my child's identity;
- research organisations accessing my child's data and samples may include commercial (for-profit) companies;
- researchers won't be allowed to copy or remove any of my child's information; and
- my child will not benefit financially if research using data from the project (which includes my child's data) leads to new treatments or medical tests.

Initial here to show you agree.

4 Results

I agree that:

- tests can be run on my child'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 my child's clinical team for them to discuss with me.

I understand the following.

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

I understand that apart from my child's rare 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 choose if I want certain other conditions that might affect my child to be looked for in their samples ('additional findings').
- These conditions are not connected to my child's rare disease.
- All the conditions can potentially be treated or prevented.
- The results might also be important to other members of my family.
- Even if the results seem to show that my child does not have one of the conditions, they may still get it in the future.
- We may add to or change which conditions we look for. This means my child might get other results in the future.
- I can change my mind at any time about receiving additional findings for my child.

Initial your choice.

Yes, I want additional findings to be looked for and given to my child's clinical team.	
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Or

No, I do not want this information to be looked for and given to my child's clinical team.	
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Full name of parent
(BLOCK CAPITALS):

Your signature:

Date:

(DD/MM/YY)

Full name of the other parent
(optional) (BLOCK CAPITALS):

Signature:

Date:

(DD/MM/YY)

Name of your child (participant)
(BLOCK CAPITALS):

Date of birth:

(DD/MM/YY)

Date:

(DD/MM/YY)

Name of person receiving consent (BLOCK CAPITALS):	
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Signature:	
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Date:	(DD/MM/YY)
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Name of interpreter if used (BLOCK CAPITALS):	
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Signature:	
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Date:	(DD/MM/YY)
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When you have filled this in:

- 1 (the original) will be kept in the child's 100,000 Genomes Project records.
- You will keep one copy.
- The other parent can keep one copy (if this applies).
- We at Genomics England will keep a copy.

