

## 100,000 Genomes Project

# Consent form for a child participant

### Introduction

At least one person with legal responsibility for your child needs to complete this form to allow your child to join the 100,000 Genomes Project. Please read the Information Sheet for parents of participating children, and discuss this with a healthcare professional, and with your child (as appropriate to his or her age).

**It is your choice whether your child joins or not.** If you do not wish for your child to take part it will not affect the standard of care they receive in any way.

If you decide that your child should join the 100,000 Genomes Project, please:

1. **Read, initial and sign** the Consent Form on page 2.
2. We'll then give you a copy to keep.

There will be an opportunity for your child to have the Project explained by a healthcare professional (appropriately to their age) and to ask any questions they would like. You can be with your child while this happens.

Your child can show their agreement to taking part by signing an Assent Form, if they want to.

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

If your child's other parent would like to sign this Consent Form they can do so, but their signature is not required in order to allow your child to join the Project.

After your child reaches 16 years old, or gains the capacity to decide for him or herself, whichever is sooner, if they would like to remain in the Project they are considered to be an adult for the purposes of giving consent. Accordingly, we will ask them to give their consent in their own right to remain in the Project at that point. If consent is given by your child to stay in the Project, this would then replace your parental consent. If your child does not give consent to stay in the Project at that time, they will leave the Project. If, by the age of 16, your child does not gain this capacity to decide as an adult, other arrangements will be put in place to enable them to remain in the Project, if at that time it is advised that they should remain in the Project and that this is in their best interests. If this advice is not given then they will leave the Project.

Please *initial* each box and sign this form at the end.

**A** I, the undersigned, have legal parental responsibility for the child named below. I authorise this Consent Form on behalf of my child.

Initial here to indicate your agreement

**B** I have read and understood the Information Sheet for parents of participating children dated \_\_\_/\_\_\_/\_\_\_ (version \_\_\_). I have had the opportunity to consider this information, ask questions and I have had these answered satisfactorily.

Initial here to indicate your agreement

**C** I agree for my child to take part in the 100,000 Genomes Project (Protocol v2.0).

Initial here to indicate your agreement

### More specifically:

**1** I understand that my child's participation in the 100,000 Genomes Project is my decision. If I refuse, or later want to withdraw my child, I don't need to give any reason and my child's present or future medical care or legal rights will not be affected.

Initial here to indicate your agreement

**2** I understand that the 100,000 Genomes Project allows medical researchers, healthcare teams and commercial organisations to access samples from my child and health and related information collected from my child's records.

Initial here to indicate your agreement

**3** I agree that my child can give a sample of blood and/or for samples already collected as part of their medical care to be used, and if essential, saliva to be collected, and for details about my child and any samples they provide to be stored securely by Genomics England.

Initial here to indicate your agreement

**4** I agree that my child's donated sample(s) can be used to collect DNA for whole genome sequencing, or for studies looking at proteins or other components of their cells. I understand that their samples may be processed in other ways that have approval from the 100,000 Genomes Project. I understand that their samples or DNA could be sent for secure processing or analysis outside of the UK by approved organisations. I understand that future research on their samples may use new tests or techniques that are not yet known.

Initial here to indicate your agreement

**5** I agree that the Project can have access to my child's health records and personal information to be used alongside their samples for scientific or medical purposes and research relating to medical condition(s) affecting my child, or other people. I understand that information from records about participants in the Project can be collected at any point in the future. Information will continue to be collected even after their death, if they have not withdrawn from the Project at that point.

Initial here to indicate your agreement

**6** I agree that my child's samples, DNA sequence, and information from their health records and any other information we give to the Project can be collected and stored securely by the Project as a resource for use by approved researchers from around the world, for future scientific or medical purposes during my child's life and after their death. I understand that researchers won't be allowed to copy or remove any of my child's information.

Initial here to indicate your agreement

**7** I agree that the 100,000 Genomes Project can collect, store and analyse information from my child's medical notes and health records from my child's GP or hospital or social care records, or other sources such as local or national disease registries. I agree that these notes and records or the samples my child gives may be looked at by approved individuals from Genomics England or from the NHS and other study monitors at any time.

Initial here to indicate your agreement

**8** I understand that all information about my child held by the Project will be treated as confidential. I understand that information from the samples, records or other information my child gives to the Project will only be accessible to researchers in a form which protects my child's identity.

Initial here to indicate your agreement

**9** I understand that these research organisations could include commercial (for-profit) companies.

Initial here to indicate your agreement

**10** I understand that neither my child nor I will benefit financially if research undertaken through the 100,000 Genomes Project leads to new treatments or medical tests.

Initial here to indicate your agreement

**11** If, based on results obtained from my child's samples and/or information about me, my child might be eligible to participate in future research studies, I agree to be contacted by my clinical team in order to invite my child to participate. This may be about this Project or other ethically approved research studies. I will be provided with full information about these studies, when and if I am contacted. I understand that agreeing to be contacted does not oblige my child to participate.

Initial here to indicate your agreement

**12** I agree to my child being asked to provide further samples or health information by their clinical care team for the purposes of the Project. I understand that I am not obliged to give this permission. I also agree to be contacted directly up to four times in any year by the Project (not via my child's doctor), for additional information about my child's health or lifestyle. I understand that this does not oblige my child to participate.

Initial here to indicate your agreement

## Return of results

**13** I understand that it is not possible to guarantee that any genetic results of significance for my child will be found now or in the future.

Initial here to indicate your agreement

**14** Main genetic findings (*non-optional*): I give consent for the Project to run tests on my child's samples and health information relating to the cause or management of the rare genetic disease that led my child to be invited to join the Project (sometimes called their 'primary' or 'pertinent' findings). I agree that these results can be reported to my child's extended clinical care team. I agree that my child's clinical care team can discuss these results with me. I also understand that the results may **not** be able to provide a diagnosis or to provide information to influence my child's clinical care, assuming that these results can be returned in a relevant time frame, which may not be possible.

Initial here to indicate your agreement

**15** Additional genetic findings (*optional*): I understand that I can choose whether or not I want the Project to use my child's samples and health information to **look for additional genetic results, beyond his or her main findings** (sometimes called their 'secondary' findings). My child's results would relate to his or her risk of developing certain serious or possibly life-threatening and rare medical conditions which would eventuate before adulthood (considered here as under the age of 18) and which can be cured, made less severe, or prevented via standard NHS treatment. I understand that these investigations will not be carried out in respect of conditions likely to eventuate when my child is an adult, whilst he or she is aged under 18. The Project has agreed with the NHS a limited list of the medical conditions to be looked for under this criteria in respect of child participants in this Project. This list will be updated and may change over time according to new medical evidence. The person taking my consent has a list available of which genetic conditions will currently be looked for under these criteria. These conditions will be fully explained to me, along with the implications for my child of a positive test, and the support that will be available to me if I then choose that my child should have these tests. If I allow the Project to look for these additional findings in respect of my child, a health professional will discuss these results with me after they have been confirmed in the NHS.

Tick your choice (ü)

<input type="checkbox"/>	<b>Yes, I want this information to be looked for and fed back to my clinical team</b>
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OR

<input type="checkbox"/>	<b>No, I do not want this information to be looked for and fed back to my clinical team</b>
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Initial here to confirm your choice

**16** Incidental findings: I understand and agree that any **other** results of genetic or other analysis of my child's samples (separate to the main findings and, if consented for, the additional findings described above) will **not** be fed back to me.

Initial here to indicate your agreement

**17** I understand that information generated by this Project may be of benefit to my child's family members now or in future. I understand that normal clinical practice will be applied in the use and sharing of this information with other members of my child's family and their medical teams, based on my child's relative/s' potential benefit from receiving this information.

Initial here to indicate your agreement

**18** I understand that I am free to withdraw my permission for my child's samples and information to be used at any time in the future. I don't need to give a reason and my child's medical care will not be affected. I understand that if I join my child to the Project and then withdraw them, it will not be possible to remove my child's data from research that may already have taken place.

Initial here to indicate your agreement

**Full name of parent with parental responsibility (BLOCK CAPITALS)**

**Signature**

**Date**

 DD / MM / YY

**Full name of additional parent (if wished) (BLOCK CAPITALS)**

**Signature**

**Date**

 DD / MM / YY

**Name of child (participant) (BLOCK CAPITALS)**

**Date of birth**

 DD / MM / YY

**Signature**

**Date**

 DD / MM / YY

**Name of child's (participant) clinician (BLOCK CAPITALS)**

**Signature**

**Date**

 DD / MM / YY

**When completed:**

- 1 (original) to be kept in the child participant's 100,000 Genomes Project records.
- 1 copy for parent completing this form.
- 1 copy for additional parent (if applicable).
- 1 copy to be sent to Genomics England.

<b>Insert local contact details here</b>	
<b>Phone number:</b>	01223 254634 /254630
<b>Email address:</b>	eegmc@nhs.net
<b>Hospital address:</b>	Cambridge University Hospitals NHS Foundation Trust Hills Road Cambridge CB2 0QQ