**100,000 Genomes Project**

**Personal Consultee Declaration Form**

**Introduction**

We feel that your relative/friend is unable to decide for himself/herself at this time whether to join the 100,000 Genomes Project. We would like to invite you to consider becoming a Personal Consultee for your relative/friend who lacks capacity in relation to this.

We'd like to ask your opinion on whether or not your relative/friend would want to take part, to help decide if they should 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.

We ask you to consider what you know of your relative/friend's wishes and feelings and to consider their interests. Please let us know of any advance decisions they may have made about participating in research. These should take precedence.

After reading the information below, if you wish to take on the role of a Personal Consultee and wish to advise us that your relative/friend would want to become a participant in this Project, we will ask you to read and sign this Personal Consultee Declaration Form.

If you decide that your relative/friend would not wish to take part it will not affect the standard of care they receive in any way. If you are unsure about taking on the role of consultee you may seek independent advice. We will understand if you do not want to take on this responsibility.

The following Personal Consultee Declaration Form is similar to the Consent Form which would have been provided to your relative/friend regarding their own consent to join the Project, had they been able to consider their participation on their own behalf. We have edited this form to address it to you as a potential Personal Consultee for your relative/friend.
**100,000 Genomes Project**

**Personal Consultee Declaration Form**

After reading this form, if you wish to take on the role of Personal Consultee and advise us that in your opinion your relative/friend would want to take part in the 100,000 Genomes Project (if he or she had capacity to consider this for him or herself), please *initial* every box, *tick* the appropriate option in box 10, and *sign* at the end of this form.

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<th>Name of my relative/friend (BLOCK CAPITALS)</th>
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I [name of consultee] have been consulted about [name of potential participant]’s participation in the 100,000 Genomes Project
For a Personal Consultee regarding a patient with a rare genetic disease, or an adult relative of a patient with a rare genetic disease

1. I have read and understood the information sheet ‘For a Personal Consultee regarding a patient with a rare genetic disease, or an adult relative of a patient with a rare genetic disease’ (dated _________ (version______) for the 100,000 Genomes Project. I have had the opportunity to ask questions and have had these answered satisfactorily.
   I have been informed about the role of a Personal Consultee and I am willing to take on this role in relation to my relative/friend named in this Consultee Declaration Form, who has been deemed to lack mental capacity to give consent to join the Project at this time.
   I understand that my advice concerning the participation of my relative/friend in the 100,000 Genomes Project is voluntary. If at any time I decide to stop being the Personal Consultee, I don’t need to give any reason and my present or future medical care or legal rights will not be affected.
   In my opinion my relative/friend would be happy to take part in the 100,000 Genomes Project.

   Initial here to indicate your agreement

2. **Sample collection**
   I understand that the following will happen if my relative/friend takes part:
   To join the 100,000 Genomes Project, the person who lacks capacity will need to give a blood sample, and/or samples already collected as part of his or her medical care will be used. I also understand that saliva will be collected if necessary.
   I agree to being asked to give my advice when my relative/friend is requested to provide further samples for the purposes of the Project. I understand that I do not have to give this advice, and I am free to advise that my relative/friend would not have wanted the samples to be taken.
   I understand that any samples my relative/friend provides and related details about them will be stored securely by Genomics England.

   Initial here to indicate your agreement

3. **Use of samples**
   I understand that the donated sample(s) of my relative/friend will be used to collect DNA for whole genome sequencing, and for studies looking at proteins or other components of his or her cells.
   I understand that their samples or DNA could be sent to approved organisations outside the UK for secure processing or analysis.
   I understand that future research on the samples of my relative/friend may use new tests or techniques that are not yet known.

   Initial here to indicate your agreement
4 Use of health data
The 100,000 Genomes Project allows medical researchers, healthcare teams and commercial organisations to access samples and information collected from my relative/friend by the Project.

My advice is that my relative/friend would want the Project to be able to access, collect, store and analyse information from their medical notes, health records and personal information (from my relative/friend’s GP or hospital or social care records, or other sources such as local or national disease registries) to be used alongside their samples for scientific or medical purposes and research relating to medical condition(s) affecting them or other people.

My opinion is that my relative/friend would have been content that this access to their information could be at any point during their life and that it will continue after my relative/friend’s death, unless they have been withdrawn from the Project.

I understand that researchers won’t be allowed to copy or remove any information.
I understand that the notes and records or the samples that my relative/friend has given may be looked at by approved individuals from Genomics England or from the NHS Trust and other study monitors at any time.

Initial here to indicate your agreement

5 Confidentiality
I understand that all information about my relative/friend held by the Project will be treated as confidential. I understand that information from my relative/friend’s samples, records or other information they give to the Project will only be accessible to researchers other than their clinical team in a form that protects their identity.
I understand that my relative/friend’s GP and other healthcare professionals may be informed of their participation in the Project.

Initial here to indicate your agreement

6 Access for commercial companies
I understand that the research organisations accessing the data could include commercial (for-profit) companies.

Initial here to indicate your agreement

7 Financial implications
I understand that neither I nor my relative/friend 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
8 Future contact
I agree to be contacted by my relative/friend’s clinical team, or directly by the Project team so that they can invite my relative/friend, or myself as the Personal Consultee, to participate in future research studies.
I understand that this research may be about this Project or other ethically approved research studies, including clinical trials or research about my experience of the Project.
I understand that I will be provided with full information about these studies when and if I am contacted, and that agreeing to be contacted does not mean that I or my relative/friend have to take part.

Initial here to indicate your agreement

9 Main findings (these will be returned to everyone who takes part in the Project)
I understand that the Project will run tests on my relative/friend’s samples and health information relating to the cause or management of the rare genetic disease that was the reason they were invited to join the Project. (Main findings are also sometimes called ‘primary’ or ‘pertinent’ findings).
I understand that these results will be reported to my relative/friend’s clinical team and agree that their clinical team can discuss these results with me as appropriate.
I understand that the results may not be able to provide a diagnosis for my relative/friend or their family member, or to provide information to help with their clinical care.
I understand that the results may not be returned in a time frame which will allow them to be used in the care of my relative/friend or members of their family.

Initial here to indicate your agreement
10 **Health-related additional findings (optional):**

I understand that I can advise whether or not my relative/friend would want the Project to **look in his/her genome for additional genetic results, beyond any main findings.** (Additional Findings are also sometimes called ‘secondary’ findings).

I understand that if I advise them to, the Project will look for findings that are likely to benefit my relative/friend because they may be offered screening or treatment as a result. However, I understand that there is still uncertainty about such findings and my relative/friend may not benefit from receiving them.

I understand that if no additional findings are found, my relative/friend may still be at risk of the conditions they can cause.

I understand that I can change my mind about whether I think my relative/friend would wish to receive these results at any time by informing their clinical team.

Tick your choice (✓)

Yes, I advise that my relative/friend would want this information to be looked for and fed back to his or her clinical team

OR

No, I advise that my relative/friend would not want this information to be looked for and fed back to his or her clinical team

Initial here to confirm your choice

11 **Other findings**

I understand that any other results of genetic or other analysis of the samples from my relative/friend (which are not related to the main or additional findings above) will not routinely be fed back.

Initial here to indicate your agreement

12 **Family members**

I understand that information generated by this Project may be of benefit to family members of my relative/friend now or in the future. I understand that the clinical team will give advice about what information would be helpful to pass on, and discuss with me the best way of doing this if this is the case.

Initial here to indicate your agreement
**13 Withdrawing from the Project**

I understand that I can advise at any time that my relative/friend should be withdrawn from the Project because I believe that is what they would want at that time. My advice will always be followed.  
I understand that if my relative/friend is withdrawn, his or her routine medical care will not be affected.  
I understand that if my relative/friend is withdrawn from the Project, it will not be possible to remove their data from research that has already taken place.

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<th>Personal Consultee’s relationship to participant:</th>
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<th>Name of person taking consultee declaration (BLOCK CAPITALS)</th>
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When completed:
1 (original) to be kept in the adult participant’s 100,000 Genomes Project records.
1 copy for Personal Consultee.
1 copy to be sent to Genomics England.

Staff only (as applicable)

Adult participant NHS no: 

INSERT LOCAL CONTACT DETAILS/ LABEL HERE