

Guidance for participating young people currently on child consent who have turned 16 or deemed Gillick competent.

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1 Document History and Control

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1.1 Version History

Version	Date	Description
1.0	26/05/ 2017	Transfer content from existing word document into formal layout.
1.1	26/072018	Updated by Alice Tuff-Lacey to reflect project completion work
1.2	31/07/2018	Comments and edits from Fiona Maleady-Crowe
1.3	31/07/2018	Clean version
1.4	13/08/2018	Updated with agreed text circulated by email and points raised by GMC's on Gillick competence.
1.5	14/08/2018	Incorporated Fiona's comments
1.6	14/08/2018	Clean version

2 Background

This document contains guidance on consenting young participants whose parent/s (or the authority with legal parental responsibility) consented for them to take part in the 100,000 Genomes Project, and who have now reached the age of 16 or over.

16 year olds (or younger children) with capacity to consent in their own right to continue in the project as an adult participant, need to be given the opportunity to do so. They will also be able to decide for themselves about other aspects of participation for example: whether or not they want additional findings (health-related and carrier testing).

NHS GMCs have been provided with a list of participants who have/will have reached the age of 16 by 2nd January 2019, and have not signed an adult consent form or who have not had a consultee who has completed the relevant declaration form. The list should be have been circulated by early August and please contact the service desk if you have not received it.

NHS GMCs should follow the guidance outlined in this document in Section 3. NHS GMCs have expressed concerns about the long term plan for re-consenting child participants when they turn 16+. In line with the current protocol our understanding is that while we can return the first report to those on a child consent who are now over 16, we cannot

undertake reanalysis until they have completed an adult consent form. We appreciate the challenges this presents and we are taking further advice from colleagues in the Ethics Advisory Committee to determine whether a long-term ethical, and pragmatic solution is possible.

If you are in contact with a child participant who is now of age, you should take the opportunity to discuss reconsenting, for example if results are being returned. It is not expected that NHS GMCs assess Gillick competence of all the participants on child consent. This option has been included as guidance for the event where a clinician deems a child Gillick competent but they did not want to consent to adult participation.

We are reviewing how Genomics England can support NHS GMCs on this issue. In the meantime in order to support contact of young people, we have provided a draft template of a letter to send to young people which you can amend to accommodate local circumstances. Please let us know by contacting Alice Tuff-Lacey (alice.tuff-lacey@genomicsengland.co.uk) if you have any suggested feedback to this letter and we can incorporate this centrally.

3 Guidance

If a relevant participant is in contact, for example for review or to feedback results, NHS GMCs should inform the participant that signing an adult consent form is needed for them to continue in the project as an adult. Consent should be sought using the adult consent materials. Adult consent is not required before results can be returned.

3.1 If the young person wishes to participate in the Project as an adult

Once completed, the new adult consent form should be uploaded in line with the standard process.

3.2 If the young person expresses that s/he does not wish to participate in the Project as an adult, or it is not possible to confirm their wishes

If the participant does not wish to consent to continue in the Project as an adult - at age 16 or on attaining Gillick competence, whichever is sooner, or it has not been possible to confirm their wishes after a period of time that the clinician considers appropriate, then this should be recorded in their medical notes. Genomics England should be informed of this via the interim “no consent to adult participation” (NCAP) which is available here:

<https://www.genomicsengland.co.uk/information-for-gmc-staff/recruitment-materials/>.

If a young person responds asking to be withdrawn from future participation, please complete the NCAP form in line with the “Participating young people who turn 16” guidance.

However, if you contact young people and receive no response, please **DO NOT** complete an NCAP form yet. Guidance will be issued pending confirmation of the future plan for the 100,000 Genomes Project, and for research participation within the new NHS Genomic Medicine Service following further discussion with our Ethics Advisory Committee.

The completion of the NCAP form requires a clinician's signature. When the NHS GMC have filled in this form:

- 1) The original form should be kept in the participant's 100,000 Genomes Project records.
- 2) For OpenClinica users, the withdrawal form tab and for XML users, the withdrawal XML should be populated using the following guidance:
 - a. In name and version of consent form, "no consent to adult participation" should be selected.
 - b. In the withdrawal option, "partial withdrawal" should be selected.
 - c. All other data points in the withdrawal section should be filled in according to the data model requirements.
 - d. A copy **must** be uploaded to the Genomics England sFTP server, via the UPLOAD button.

Completion of this form means that no further data will be collected prospectively or stored. Genomics England have taken advice with regard to the diagnostic main condition results (and any additional findings) that were consented for originally by the individuals' parents and these will continue to be analysed and returned to the NHS GMCs as part of routine clinical care. They will not be re-analysed unless the young person consents to adult participation.

Note: The consent that the participant's parents gave in relation to the research use of childhood samples and data (i.e. that was collected during their Project participation as a child on parental consent), will remain in place unless a full withdrawal form is completed by the parents or the participant transfers to adult consent and then completes a full withdrawal. This is regardless of whether the young person participates as an adult in the Project. This should be explained to the young person when they are considering whether to consent as an adult participant.

4 What to do if young person does not have capacity to consent once they are an adult

If the participant is not considered to have capacity to consent to take part in the 100,000 Genomes Project as an adult, the standard process for adults lacking capacity should be adopted. A personal or nominated consultee should be appointed and asked to give advice

(in their view) as to whether or not the young person would want to continue to participate in their own right now they are an adult.