

## Liggins Institute: Suggested Reconsent Standard Operating Procedures (SOP) for Children Reaching 16 Years of Age

### Scope

Reconsent is required for children turning 16 within studies in which their parents/guardians have previously provided consent. This includes long-term follow up studies. Participants reaching 16 years of age are to be asked to give their own consent for ongoing participation and use of their data. In studies in which multiple data sources are used (e.g. data linkage studies from multiple administrative data sources), reconsent must be sought for each data source.

### Reconsent has two key aspects:

1. Consent to collection of additional data after age 16 years (ongoing participation).
2. Consent to use data already acquired under the parental consent including data regarding the participant at ages up to 16 years.

Participants can choose to consent to either of the above aspects, both or none. If they consent to none, the participant should be considered to have withdrawn. Withdrawal will mean that subsequent use of that individual's data is not allowed.

### Records

1. At the time of reconsent, participant responses will be added to the study database – linked to the participant ID – under a reconsent tab.
2. Upon receipt of non-consent:
  - a. All data for the individual will be locked within the database.
  - b. Any researchers currently using the study data will be notified of the reconsent result and advised to review the updated list of consents and amend their datasets accordingly by removing all these participants data from the dataset.

### The approach to data for specific reconsent scenarios is covered in the table below:

Scenario	Approach
A. The participant agrees to continued participation and has agreed to use of <16yo data. If multiple data sources are used (e.g. data linkage studies), participant consents to all data sources that the parent consented to or the participant consents to use of additional datasets compared with parental form.	Data are used as collected. If data collection is ongoing/planned from those sources that the participant has now consented to, participant is included in data collection.
B. The participant agrees to continued participation and has agreed to use of some <16yo data. Participant does not consent to some data sources which were agreed to previously by their parent/guardian.	Data from sources that the participant has consented to are used as collected. Data are removed for those sources for which the participant did not consent in the reconsent form and are not collected if data collection is ongoing/planned from those sources.
C. The participant agrees to continued participation but declines use of <16yo data	Data are removed from existing datasets. If data collection is ongoing/planned, participant is still included in data collection.

D. The participant agrees to continued participation but does not answer the question on the consent form regarding <16yo data.	Consent from parent still applies. Data are used as collected. No changes needed.
E. The participant declines continued participation but agrees to use of <16yo data (declined).	Data in existing datasets are used as collected. If data collection is ongoing/planned, participant is excluded from data collection.
F. The participant declines continued participation but does not answer the question on the consent form regarding <16yo data (declined).	Aim to clarify with participant. If unable to clarify, data from all sources will be removed as for Scenario G.
G. The participant declines continued participation and declines use of <16yo data (withdrawn).	All data are removed from existing datasets. If data collection is ongoing/planned, participant is excluded from data collection.

**In the case of withdrawals or change in consent status:**

Data are assumed to be locked at the point of completion of analyses specified in the agreed statistical analysis plan and no further withdrawals can be made for the data in these analyses.

Withdrawals of data can still be made for analyses that are in progress. This will involve exclusion of data from ongoing and future analyses and if specifically requested removal of their data from raw data and intermediate datasets with the exception of any analysis dataset that is maintained for archival and data sharing purposes after completion of each statistical analysis plan and subsequent publications.

Removal of data in the case of withdrawal or change in consent status should be completed as soon as possible and no later than 1 month from the time of completing the reconsent.

The primary investigator will be notified that participant data has been removed from the source records.

A register of removed data will be stored with source data and will be notified as part of any data-sharing agreements.

**Timeline of reconsent process:**

The reconsent process described above for participants turning 16 years old should continue whilst data are being used for ongoing analyses and will cease once all planned analyses have been completed.

**Version :** 1  
**Date:** 13/03/2025  
**Adopted:** 08/05/2025  
**Signed:**   
**For review:** 13/03/2027