

Consent form

This document outlines what you are agreeing to when you consent to joining the Generation Study. It is important that you understand how the study works before consenting. You can do this by reading the Participant Information Sheet (version 5.0) and the study website at www.generationstudy.co.uk. Your study team will help explain the study and answer any questions you have.

Please confirm that you understand the following:

01 About the study

This study is for research. It is optional and separate from your baby's standard NHS care. They will still be offered the newborn blood spot test, which the NHS recommends. Like any medical research, there are benefits and risks to joining.

Your baby's other parent should be involved in your decision. If you are in contact with them, you have discussed this with them. They are happy for your baby to join the study.

02 Conditions we test for

Genomics England will test for certain gene changes in your baby. These changes can cause 200+ genetic conditions that can be treated in the NHS during childhood.

03 Collecting the sample

An NHS practitioner will collect a blood sample from your baby. Genomics England will use this sample to sequence your baby's DNA. You can decide to not have the sample collected. This means your baby will not join the study.

04 Getting results

You will be contacted with the result of the test. There is no exact timeframe for this. If a condition is not suspected, you will be informed by email or letter. If a condition is suspected, an NHS specialist will get in touch to arrange next steps.

The result is not a diagnosis and must be confirmed by further tests. This process can have uncertainties, such as an unclear or incorrect result. The NHS specialist will share information about your baby back to Genomics England, to help understand the accuracy of the test.

05 Data and access

Genomics England will securely store the samples and data. This includes your baby's samples and DNA sequence, updates from their healthcare record, and your antenatal data. The antenatal and health data are collected from NHS England and other organisations listed at www.genomicsengland.co.uk/privacy-policy/.

Data and samples will be used for healthcare research. Approved researchers will access it so that they can work on new treatments. They could be from charities, universities, and private healthcare companies, such as pharmaceutical companies.

06 Ongoing contact

Genomics England will contact you during the study. They will share updates and tell you about more chances to take part in research.

07 Withdrawing from the study

You can stop taking part in the study at any time and you don't need to tell us why. If the data has already been stored, or is already involved in research, it cannot be deleted.

The study will go on for 16 years. When your child is around 16, Genomics England will ask them if they'd like to continue themselves.

Please confirm that you understand the information in the Participant Information Sheet (version 5.0) and the statements above and agree to your and your baby's participation in the study.