



This is what Spectrum 10K has said about:

The inclusion of children in the study

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1. What is the consent procedure for including children in Spectrum 10K (including withdrawal and re-consent)?

For children up to the age of 16, a parent or a legal guardian will need to provide consent for the child to participate in Spectrum 10K.

For children 6 years of age or over, and who do not have a diagnosis of intellectual disability and can read and understand information appropriate for their age, we will additionally provide adapted information sheets. These documents will provide the child with information about the study in an easier read format and explain what is involved in taking part. Following research ethics guidelines, we will ask that the child completes an 'assent form' which asks 'yes' or 'no' questions to confirm they are happy to participate. This is not obligatory, but we recommend that this step is completed.

When the child turns 16 years of age during the study period, we will contact the parent/legal guardian to invite their child to provide their own consent to continue being part of Spectrum 10K. This would allow the 16-year-old to be invited to further studies.

Please note that this aspect of the study is currently being discussed with the HRA. The Spectrum 10K team will update consultees when more information becomes available.

2. What is meant by 'assent'?

Children who are under the age of 16 are not legally capable of providing consent. However, children who are able to read are able to provide 'assent' or agreement.



For any children who are at least 6 years old, who do not have a diagnosis of intellectual disability, and whose parents indicate that they are able to read and understand information appropriate for their age, we will seek their assent to participate in Spectrum 10K.

To do this, we will provide the child's parent with documents about Spectrum 10K that have been adapted to be easily read by children of the same age as their child. We will then request that the parent ask their child to read these documents and complete an 'assent form'. The assent form will contain simple 'yes or no' questions about whether they have understood the study and are happy to take part.

We will not register as participants children who indicate that they do not assent to taking part in Spectrum 10K, regardless of whether or not their parent has consented on their behalf. We will only register children if either:

- their parent consents on their behalf **and** the child provides assent, or
- their parent consents on their behalf **and** the child does not complete the assent form.

This procedure is in line with independent research ethics guidelines detailed in the following document: <https://www.hra.nhs.uk/planning-and-improving-research/policies-standards-legislation/research-involving-children/>

3. What will happen to DNA once a child becomes an adult?

Once a child turns 16 years of age, as is standard practice, their data (including DNA data) is stored and kept for the purpose of the study, as consented for by their parent(s).

Children who turn 16 have the option to withdraw themselves from Spectrum 10K. However, any data collected up to that point will be kept for archival purposes only. This means that their data, including DNA, cannot be used in future research, and is only stored to verify the validity of previous analysis.

4. Is it ethical to use DNA from children based on consent from their parents/carers, given that this cannot be retracted if the child decides later that they do not consent?

Whilst children under the age of 16 years cannot legally provide consent, children who can read can provide assent (agreement). An assent form is available for children in addition to a parent consent form.

Spectrum 10K has created easy-to-read, age-appropriate information sheets that provide an explanation of the study. Children can choose to be enrolled in the study only if they agree.



For children who are six and above, you can find these at:

[https://Spectrum 10K.org/information-sheets/](https://Spectrum10K.org/information-sheets/)).

For dependent adults who are able to read, there is an easy-to-read consent form.

For adults who lack the capacity to consent to participate in Spectrum 10K, a consultee is required and they can access a consultee information sheet and consultee declaration form.

These study procedures have been assessed by a specialist ethics committee with expertise in research studies involving adults who lack capacity to consent to participate in research studies.

When children turn 16, we will contact the parents to ask their child to consent in their own right if they have the capacity to consent. They can choose to withdraw from Spectrum 10K at this time. Our data maintenance plan will ensure that withdrawals from Spectrum 10K are possible for as long as the dataset is stored.

This plan is based on existing and long-running research studies that involve young people such as ALSPAC and Born in Bradford.