

What is the purpose of the study?

Babies and children with Down's syndrome often have more health problems than other children. We aim to find out more about this by collecting as much information about their health as we can.

Who is doing the study?

The study is being done by researchers and doctors and nurses involved in the care of babies and children with Down's syndrome.

Why was my child chosen?

We are interested in all babies and children with Down's syndrome. Some babies may join the study as newborns and other babies and children may join when they are older.

Why should I help?

Information collected about your child could lead to a greater understanding of the health of babies and children with Down's syndrome.

What does the study involve?

The study has several parts but if there is any part you would prefer your child not to be involved in, you can indicate this on the consent form and your wishes will be respected. For babies joining the study as newborns, we would like your permission to have

access to a blood sample taken shortly after your baby's birth. In most cases we will be able to use one that has already been taken. If a suitable sample is not available, we would like your permission to take another.

If you agree to participate we will write to you with more information about the next stage of the study. This will include:

- ✿ Sending you a short questionnaire before your child's first birthday and then once a year after that.
- ✿ Looking at medical records.
- ✿ Collecting blood samples from your child when they are having routine tests.
- ✿ Collecting buccal (mouth) swabs from you and your child.

Why do you need blood samples from my child?

Children with Down's syndrome are known to be at increased risk of a number of conditions affecting their blood. These may be minor or more serious ones like leukaemia. At present we do not know much about what causes these conditions or about factors influencing their development. By looking at children's blood over several years we hope to find out more.

How will you collect the blood samples?

Most children with Down's syndrome have routine blood tests to monitor their thyroid function. In many regions these are done yearly, though the frequency varies in different parts of the country.

When your child is due to have this blood test, we will send you a small tube to take to the clinic along with instructions.

What happens to my child's blood samples?

These will be stored and will be used for research purposes only.

What happens if you find a serious change in my child's blood sample?

If we see a serious abnormality in a test result that needs to be followed up, we will contact your doctor so that your child can receive the best care possible.

Why do you need buccal (mouth) swabs?

From cheek cells in your mouth we can get DNA which we will be able to store for research.

Why do you need to look at medical records?

We need accurate information about the health of you and your child.

Will the information I provide be kept confidential?

Yes. All information you provide is confidential and kept in accordance with the Data Protection Act.

No one outside the research team will be able to trace or identify you or your child. The samples and information collected will be used for research purposes only.

Does my child have to take part?

It is up to you to decide whether or not you would like your child to take part. If you take part, you are free to withdraw at any time. Your decision will not affect the standard of care your child receives or the relationship with your child's doctors.

What should I do now?

If you wish to take part, you will be asked to read and sign a consent form. You will be given a copy to keep.

What if I change my mind?

You can join or withdraw from the study at anytime. If you wish to do either of these, please contact us using the contact details below.

Standard NHS indemnity arrangements apply to this research.

For more information please call the freephone number, visit our website or email the address below:

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Website: www.cdss.org.uk

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PARENT/GUARDIAN INFORMATION LEAFLET

This is an invitation to take part in a research study. Please take time to read the leaflet carefully and discuss it with other people if you wish. It is important that you understand why the research is being done and what it will involve before you decide whether or not to take part. Please contact us if there is anything that is not clear, or if you would like more information - our contact details are on the back page.