



RESEARCH CONSENT FORM

Children's Hospital Boston

Use Plate or Print:

Protocol Title: Longitudinal Down Syndrome Study

MRN#:

DOB:

Principal Investigator:
Brian Skotko, MD, MPP

Subject's Name:

Gender:

Principal Investigator: Brian Skotko, M.D., M.P.P.

Protocol Title: Longitudinal Down Syndrome Study (LDSS)

Why is this research study being conducted; What is its purpose?

Due to medical advances, people with Down syndrome are living longer than ever before. In fact, increased life expectancy has nearly doubled in the past 25 years. Yet, researchers and clinicians know very little about the conditions that co-occur with Down syndrome. We would like to change that by studying all of the tests and results that we would ordinarily have ordered as part of your son's or daughter's visit to the Down Syndrome Program at Children's Hospital Boston. By systematically studying the conditions that co-occur with Down syndrome, we aim to improve delivery of evidenced-based medical care to people with Down syndrome.

The data from this longitudinal study might also generate new hypotheses regarding how certain co-occurring conditions come to be (such as diabetes and Alzheimer's disease). The data might also enable researchers to develop novel treatment for these conditions in people with Down syndrome and the general population.

Who is conducting this research study, and where is it being conducted?

The LDSS is a multicenter, observational, U.S.-based study of the clinical course of Down syndrome and associated secondary conditions. One of the sites participating in the study is the Down Syndrome Program at Children's Hospital Boston. All of the healthcare professionals associated with our Down Syndrome Program are involved in this research study. Other sites include Down syndrome clinics at other universities around the country.

How are individuals selected for this research study? How many will participate?

All current patients, of all ages, in the Down Syndrome Program at Children's Hospital Boston are invited to participate. There is no limit to the number of patients who can participate in this study

What do I have to do if I am in this research study?

If you (or your son or daughter) participates in this study, no additional work is needed on your part after you sign the consent and/or assent form. By participating in this study, you are giving us permission to systematically analyze the medical information and test results that we would ordinarily be collecting from your visit (or your son's or daughter's visit) to the Down Syndrome Program. We might also be sharing de-identified information (that is, we would remove all names and identifying associations with the information) with our national collaborations so that we achieve important understandings about Down syndrome and co-occurring conditions.

What are the risks of this research study? What could go wrong?

There are no significant risks beyond that which would already be occurring with your clinical visit to the Down Syndrome Program. Children's Hospital Boston takes all precautions and securities to ensure that your (or your son's or daughter's) medical information remains private. However, a breach of information is always possible. Although the risks associated with this research study are minimal and adverse events are not anticipated, all participants will be under the care and supervision of experienced medical staff at the Down Syndrome Program of Children's Hospital



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What are the benefits of this research study?

Although we do not anticipate any direct benefits to participants in the study, we hope that the things we learn from this study will help us take better care of you and others with Down syndrome.

Are there costs associated with this research study? Will I receive any payments?

There are no costs or payments associated with this research study.

What will happen with the information obtained as part of this research study? What about confidentiality?

The results of this research study may be published, but volunteers' names or identities will not be revealed. Records will remain confidential. In order that confidentiality can be maintained, the principal investigators will keep all paper records locked in cabinets, and all electronic data will be de-identified. Electronic data will be entered into a national Down syndrome registry so that we can collaborate with other Down syndrome clinics around the country to better understand Down syndrome and co-occurring conditions. No identifying information will be shared in the national registry.

Information collected during this research study may be shared with:

De-identified information collected from this research might be shared with other medical centers/institutions/investigators outside of Children's Hospital Boston participating in the research.

If I do not want to take part in this research study, what are the other choices?

Participation in the Longitudinal Down Syndrome Study is completely voluntary. Deciding not to be part of the study will not change your regular medical care in any way. Additionally, participants can withdraw from the study at anytime, again, with no change in their regular medical care.

What are my rights as a research participant?

Participation in this study is completely voluntary, and refusal to participate or withdraw will in no way affect the medical care patients receive at Children's Hospital Boston. Participants will be informed of any specific research findings that are unique and relevant to their health.

What information do I need to know about the Health Insurance Portability and Accountability Act (HIPAA)?

During this research, information about your or your child's health will be collected. In general, under federal law, information about patients is private, but there are exceptions and you should know who will have access to this information and might see it. Researchers may be collecting information about you or your child from medical records. They may also learn things from procedures that are part of the research itself such as tests, office visits, questionnaires and interviews.

The following people will be able to see this information:

- As HIPAA permits, medical and research staff at Children's Hospital, including people listed on your informed consent
- Medical staff who are directly involved in your care that is related to the research or arise from it
- People who oversee, advise or conduct research at Children's Hospital, and people who oversee or evaluate research and care, including the Committee on Clinical Investigation, staff working on quality improvement, and other clinicians and administrative staff of Children's Hospital



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- People from agencies and organizations that provide independent accreditation and oversight of research
- Sponsors or others involved in funding the research
- Federal agencies that oversee or review research information
- Government agencies and sponsors
- If some law or court requires us to share the information, we would have to follow that law or final ruling

You/your child should be aware that the federal privacy rule does not cover all of these possible uses. This means that once some of the above mentioned users receive your/your child's health information they do not have to follow the same rules. Other laws may or may not protect sharing of private health information. If you have a question about this you may contact the Children's Hospital Privacy Officer at 617-355-5502

There is no set time for destroying this information and no time limit for its use. Researchers continue to analyze data for many years and it is not possible to know when they will be done.

You or your child do not have to sign this form. If the form is not signed, however, you won't be able to participate in the study. Not signing will not affect your care or your child's care at Children's Hospital in any way now or in the future. Also, there will be no penalty or loss of benefits if you choose not to sign and participate.

You or your child also have the right to withdraw from this study at any time. You have the right to end your permission for Children's Hospital to use or share the protected information about you or your child that was collected as part of the research.

Researchers may also continue to use information already collected to protect the integrity of the study. This means that your withdrawal won't make the whole study useless. Once you remove your permission and you or your child is no longer in the study, no more private health information will be collected. If you wish to withdraw you will need to do so in writing. Your investigator will have a form for you to use. If you or your child decide to share private information with anyone not involved in the study, the federal law designed to protect privacy may no longer apply to this information.

Although there are some legal limitations, you or your child have the right to get protected information resulting from this research that relates to your treatment or to payments. This information is available after the study analysis is done. To request the information, please contact the Hospital's Privacy Officer at 617-355-5502. If you have questions, please be sure to ask for answers.

Research at Children's Hospital: Children's Hospital has recently developed a web-based, interactive educational program for parents called "A Parent's Guide to Medical Research." To find out more about research at Children's Hospital, please visit the program at: www.researchchildren.org

Children's Hospital is interested in hearing your comments, answering your questions and responding to any concerns regarding clinical research at Children's hospital. If you would like further information about the type of clinical research performed at the hospital or have suggestions, questions or concerns regarding clinical research you may send an email to cci@childrens.harvard.edu or call 617 355-7052 between the hours of 8:30 and 5:00.

CONSENT/AUTHORIZATION:

If the child to be involved in this research study is a foster child or a ward of the state please notify the researcher or their staff who is obtaining your consent.

I understand that I may use the following contact information to reach the appropriate person/office to address any questions or concerns I may have about this study. I know:

I can call ...	At ...	If I have questions or concerns about ...
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