Cover Letter

Official title: Developing a Down Syndrome Health Instrument

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Online consent form in REDCap

Consent Information for Participation in a Research Study

Title of the study
Developing a Down Syndrome Health Instrument (DHI)

Principal Investigator
Stephanie Santoro, MD

Sponsor of the research
National Institutes of Health (NICHD)

Purpose of the research
We are trying to learn about parents' views of the health of their son or daughter with Down syndrome. This information will help us to create a survey to measure health.

How did you obtain my name and contact information?
We obtained your name and contact information from the eligibility screening questionnaire you completed online.

Why am I being asked to participate and how many people will participate?
According to the information that you have submitted at our study recruitment website, you are eligible to participate in our study. We are planning to enroll 700 parents/caregivers of people with Down syndrome from around the country to take part in this research study.

About this consent form

Please read this form carefully. It tells you important information about this research study. People who agree to take part in research studies are called "subjects". This term will be used throughout this consent form.

MGB (formerly "Partners") HealthCare System is made up of MGB (formerly "Partners") hospitals, health care providers, and researchers. In the rest of this consent form, we refer to the MGB (formerly "Partners") system simply as "MGB".

If you have any questions about the research or about this form, please contact us directly at 617-643-8912 or researchdownsyndrome@mgh.harvard.edu. You may also contact the MGB Human Research Committee Office at 617-424-4100. Taking part in this research is up to you. If you decide to take part in this research study, you must check the box at the bottom of this form to show that you want him/her to take part. If you want to keep a copy of this form, you can save it to your computer.

Why is this research study being done?

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 how we define health in individuals with Down syndrome. We would like to change that by studying the views of individuals who are the primary caregivers / parents of individuals with Down syndrome. This will guide our understanding of what 'health' encompasses and what factors it could relate to. We will also ask the primary care physicians/pediatricians and teachers of individuals with Down syndrome a few questions for validation.

How long will I take part in this research study?

Participation in this study will consist of an electronic (or paper-and-pencil if you prefer) survey comprised of approximately 70 questions which should take approximately 30 minutes. This survey will be administered twice, with the second survey being completed 2 weeks after the first. This repeat survey can be done electronically at home, or it can be mailed to you with return postage.

When you complete the first survey, there are a few additional surveys that will be completed once. These should take less than 15 minutes. There is an additional Activity Log that you fill out once which tracks your child's activities during a day.

What will happen in this research study?

In addition to completing this survey, 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 son's or daughter's visit to the Down Syndrome Program. The purpose of accessing this information is to compare views of health with measurable medical features (e.g. if we were studying views of sleep, we might want to compare that to concrete numbers like your child's sleep study results). At the end of the survey, you will be

asked to provide the name and contact information (email and phone number) of your child with Down syndrome's pediatrician/ primary care physician and teacher. With your consent, our research team will use this information to contact them and ask them to complete a shortened, but similar survey about aspects of health.

What are the risks and possible discomforts from being in this research study?

The greatest discomfort is the time required to complete the surveys (approximately 45 minutes). You can work on the surveys at your convenience, completed at more than one sitting. There are no significant risks beyond that which would already be occurring with your clinical visit to the Down Syndrome Program. Massachusetts General Hospital 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 Massachusetts General Hospital.

What are the possible benefits from being in 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 learn more about health, and ultimately to take better care of patients with Down syndrome.

What other treatments or procedures are available for my child's condition?

Participation in the Health Survey is completely voluntary. Deciding not to be part of the study will not change your child's regular medical care in any way. Additionally, participants can withdraw from the study at any time, again, with no change in their child's regular medical care.

Can my child still get medical care within MGB if s/he doesn't take part in this research study, or if s/he stops taking part?

Yes. Your decision won't change the medical care your child gets within MGB now or in the future. There will be no penalty, and you won't lose any benefits your child receives now or has a right to receive.

What should I do if I want to stop taking part in this study?

If you decide to take part in the research study, you can change your mind and drop out later. We will tell you if we learn new information that could make you change your mind about your involvement in this research study.

If you take part in this research study, and you want to drop out, you should tell us. It is possible that we will have to ask you to drop out before you finish the study. If this happens, we will tell you why.

Will I be paid to take part in this research study?

Yes, you will receive a small reimbursement associated with this study.

Parents will receive $25; pediatricians / primary care physicians and teachers will receive $10.

Each participant will only be compensated once – there is no additional compensation for completing the survey multiple times.

If responses are found to be fraudulent, no compensation will be given.

What will I have to pay for if I take part in this research study?

There are no costs associated with participation in this study.

What happens if my child is injured as a result of taking part in this research study?

This is not anticipated in a survey of parents, but if so, we will offer your child the care needed to treat any injury that directly results from taking part in this research study. We reserve the right to bill your insurance company or other third parties, if appropriate, for the care your child gets for the injury. We will try to have these costs paid for, but you may be responsible for some of them. For example, if the care is billed to your insurer, you will be responsible for

payment of any deductibles and co-payments required by your insurer. Injuries sometimes happen in research even when no one is at fault. There are no plans to pay you or give you other compensation for an injury, should one occur. However, you are not giving up any of your legal rights by signing this form.

If you think your child has been injured or has experienced a medical problem as a result to taking part in this research study, tell the person in charge of this study as soon as possible. The researcher's name and phone number are listed in the next section of this consent form.

If I have questions or concerns about this research study, whom can I call?

You can call us with your questions or concerns. Our telephone numbers are listed below. Ask questions as often as you want.

- Dr. Stephanie Santoro is in charge of this research study. You can call 617-726-2000 and have her paged Mo-Fri 9a-5p. Her direct email is: ssantoro3@mgh.harvard.edu.
- If you have questions about the scheduling of appointments or study visits, call Dr. Stephanie Santoro at the same number at (617) 643-8912.
- If you want to speak with someone not directly involved in this research study, please contact the MGB Human Research Committee office. You can call them at 617-424-4100.

You can talk to them about:

- Your rights as a research subject
- Your concerns about the research
- A complaint about the research

Also, if you feel pressured to take part in this research study, or to continue with it, they want to know and can help.

Email Considerations:

The MGB standard is to send email securely. This requires you to initially set up and activate an account with a password. You can then use the password to access secure emails sent to you from MGB HealthCare. If you prefer, we can send you "unencrypted" email that is not secure and could result in the unauthorized use or disclosure of your information. If you want to receive communications by unencrypted email despite these risks, MGB HealthCare will not be held responsible. Your preference to receive unencrypted email will apply to emails sent from this research group/study only."

How will you protect my and my child's privacy?

During this research, identifiable information about your health will be collected. In the rest of this section, we refer to this information simply as "health information". In general, under federal law, health information is private. However, there are exceptions to this rule and you should know who may be able to see, use, and share your health information for research and why they may need to do so.

All survey data will be collected through REDCap (Research Electronic Data Capture), a secure, National Institutes of Health (NIH)-funded, and Health Insurance Portability and Accountability Act (HIPAA)-compliant web-based application hosted by MGB HealthCare Research Computing. All data collected for this study will be stored in a secure (password-protected) confidential hard drive within the MGB computer system, behind the MGB firewall. Access to these files will be strictly limited to the Principal Investigator and authorized members of the research staff. No information will be published in any manner that would personally identify you or your child/dependent and only coded (de-identified) data will be shared among collaborators.

We will be communicating with you during the course of this study by e-mail. Throughout the study, you will need to keep the study staff informed of any changes in your e-mail address. All study communications will be made using your preferred e-mail address.

E-mail sent over the Internet is not secure unless both parties are using an encryption technology. Without encryption, it is possible for other individuals (beyond the intended recipient of the email) to access and read the e-mail, and this could result in the unauthorized use or disclosure of your information, for which MGB HealthCare will not be held responsible. Our study does not have the technological capability to send e-mail using encryption technology. By proceeding with this consent, you are agreeing and indicating a preference to proceed with standard, unencrypted e-mail despite these risks.

Your Privacy Rights

We are required by the Health Insurance Portability and Accountability Act (HIPAA) to protect the privacy of health information obtained for research. This is an abbreviated notice, and does not describe all details of this requirement (see MGB Privacy Notice). During this study, identifiable information about you or your child/dependent or your child/dependent's health will be collected and shared with the researchers conducting the research. In general, under federal law, identifiable health information is private. However, there are exceptions to this rule. In some cases, others may see your identifiable health information for purposes of research oversight, quality control, public health and safety, or law enforcement. We share your or your child/dependent's health information only when we must, and we ask anyone who receives it from us to protect your privacy.*

**MGB HealthCare Notice for Use and Sharing of Protected Health Information*
http://www.partners.org/Assets/Documents/Notices/Partners_Privacy_Policy_English.pdf

In this study, we may collect health information about your child from:

- Past, present, and future medical records
- Research procedures, including research office visits, tests, interviews, and questionnaires

Who may see, use, and share your identifiable health information and why they may need to do so:

- MGB research staff involved in this study
- The sponsor(s) of this study, and the people or groups its hires to help perform this research
- Other researchers and medical centers that are part of this study and their ethics boards
- A group that oversees the data (study information) and safety of this research
- Non-research staff within MGB who need this information to do their jobs (such as for treatment, payment (billing), or health care operations)
- The MGB ethics board that oversees the research and the MGB research quality improvement programs
- People from organizations that provide independent accreditation and oversight of hospitals and research
- People or groups that we hire to do work for us, such as data storage companies, insurers, and lawyers
- Federal and state agencies (such as the Food and Drug Administration, the Department of Health and Human Services, the National Institutes of Health, and other US or foreign government bodies that oversee or review research)
- Public health and safety authorities (for example, if we learn information that could mean harm to you or others, we may need to report this, as required by law)
- Other: N/A

Some people or groups who get your health information might not have to follow the same privacy rules that we follow. We share your health information only when we must, and we ask anyone who receives it from us to protect your privacy. However, once your information is shared outside of MGB, we cannot promise that it will remain private.

Because research is an ongoing process, we cannot give you an exact date when we will either destroy or stop using or sharing your health information.

The results of this research study may be published in a medical book or journal or used to teach others. However, your name or other identifying information **will not** be used for these purposes without your specific permission.

Your Privacy Rights

You have the right **not** to sign this form that allows us to use and hare your health information for research; however, if you don't sign it, you can't take part in this research study.

You have the right to withdraw your permission for us to use or share your health information for this research study. If you want to withdraw your permission, you must notify the person in charge of this research study in writing. Once permission is withdrawn, you cannot continue to take part in this study.

If you withdraw your permission, we will not be able to take back information that has already been used or shared with others.

You have the right to see and get a copy of your health information that is used or shared for treatment or for payment. To ask for this information, please contact the person in charge of this research study. You may only get such information after the research is finished.

Informed Consent And Authorization (online)

Please check the following required boxes indicating that you understand the information that was provided above.

☐ I understand that I will be asked to complete a series of questionnaires at 2 time points during this study: (1) at initial time after completing this Consent Form, (2) about 2-4 weeks after the first Survey.

☐ I understand that I will be compensated after completion of the survey or questionnaire. I understand that my compensation will be in the form of an electronic gift card from Amazon.com or other national retailers.

☐ I understand that I will agree to have the research team contact my child's pediatrician / primary care physician and teacher. I understand that I will provide the contact information to the pediatrician / primary care physician and teacher to the best of my knowledge.

☐ I understand the need to keep the study staff informed if my e-mail changes during the course of this study. I understand that all important study communications will be made using my preferred e-mail address. I understand that the study communications will not be encrypted.

Please indicate your consent to participate in this research by checking the appropriate box below.

❍ YES, I AGREE TO PARTICIPATE IN THIS RESEARCH
❍ NO, I DO NOT WISH TO PARTICIPATE IN THIS RESEARCH

If yes:

Your first name

Your last name

Your e-mail address

Your e-mail address (repeated to ensure accuracy)

Your mailing address

Your phone number

Your child's pediatrician / PCP contact info:

Name
Email
Address
Phone Number

Your child's teacher contact info:

Name
Email
Address
Phone Number