



North Carolina
Down Syndrome Alliance
empower • connect • support

Hello,

We are writing to ask for your help with a new research project. A team of researchers, led by clinicians from Harvard Medical School and Massachusetts General Hospital, have created a survey to study the medical support that parents receive around the time of the birth of their child with Down syndrome. If you choose to complete their brief questionnaire, your responses will help inform future research, policy, and advocacy that will affect the medical care that future parents receive.

North Carolina Down Syndrome Alliance has not shared your contact information with the researchers; instead, we have agreed to forward their message to you. Only if you choose to respond to the survey will the researchers obtain your contact information. Your participation is completely voluntary and deciding to not take part will not affect your relationship with North Carolina Down Syndrome Alliance. We invite you to participate in this effort.

The goal of this project is to understand how physicians deliver diagnoses of Down syndrome, how parents react to that news, and what strategies providers can adopt to best support parents' decision-making and well-being after a child's diagnosis. This study follows up on a previous study from 2003 with similar aims, whose results led to national legislation and guidelines for physicians.

If you are willing to take the survey, you may [click the link here](#). The survey should take about 15–20 minutes to complete. Below this email, we have also included some frequently asked questions that includes additional information about the study.

Thank you for your consideration of this project. If you have any questions regarding the study, please feel free to reach out to two members of the study research team: Jonathan Artal at jartal@mgh.harvard.edu, or Brian Skotko, M.D., M.P.P., the principal investigator, at bskotko@mgh.harvard.edu or (617) 643-3196.

Sincerely,

North Carolina Down Syndrome Alliance

Informational Q&A for Study Participants

What is the research study's goal? This research study will investigate whether, since 2003, there have been any improvements in the medical support that parents receive following a child's diagnosis of Down syndrome. We will investigate how physicians deliver the diagnosis and how parents respond to the news. Our primary aim is to identify strategies to improve medical support for parents whose children receive diagnoses of Down syndrome.

Who designed this study? This study was created by a team of researchers at Massachusetts General Hospital, which is sponsoring the study. The study's principal investigator is Brian Skotko, M.D., M.P.P., who chairs the hospital's Down Syndrome Program and is an Associate Professor of Pediatrics at Harvard Medical School.

What is involved? We are asking each parent to complete a brief online survey, which we expect to take 15–20 minutes per person. Not all questions will apply to you, but should you choose to complete the survey, you will be asked questions about diagnostic tests prior to the birth of your child, your family's decision to continue the pregnancy, and the support that you received from your medical staff before and after the birth of your child. At the end of the survey, you will have an opportunity to list your recommendations, if any, for how to improve the medical support that parents receive. The responses you provide in this survey will constitute the only data the study team will collect. At all times, your responses will remain confidential.

What happens if I do not complete the survey? Your participation is completely voluntary, and your refusal to participate will involve no consequences. Deciding not to participate will not affect medical care you receive at Massachusetts General Hospital or its affiliates, nor will it affect any benefits you have a right to receive. Similarly, deciding not to participate will not affect your membership in any Down syndrome organization with which we have partnered for this study.

What are the risks and possible discomforts? Some survey questions will address topics or events that might be sensitive in nature. While questions may evoke feelings of sadness or pain, you may choose not to respond to any question.

What are the benefits to me? While there are no direct benefits to you or remuneration for completing the survey, your responses will inform future research, policy, and advocacy that will affect the medical care that the Down syndrome community receives.

How is my privacy being protected? 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. During this study, identifiable information about you or your 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 health information only when we must, and we ask anyone who receives it from us to protect your privacy.

We will store all data we collect in a password-controlled folder behind hospital firewalls. We will aggregate all data so that it will be impossible to determine your identity from your responses. Your de-identified information will not be used or shared with other researchers and will not be used in clinical care. The risk of a confidentiality data breach is very small.

Who can I contact if I have questions about the study? If you have any questions regarding this survey, please do not hesitate to contact us. You may reach Jonathan Artal, a member of the research team, at jartal@mgh.harvard.edu, or Brian Skotko, M.D., M.P.P., the principal investigator, at bskotko@mgh.harvard.edu or (617) 643-3196. If you'd like to speak to someone not involved in this research about your rights as a research subject, or any concerns or complaints you may have about the research, contact the Partners Human Research Committee at (857) 282-1900.