Implementation of Whole Genome Sequencing as Screening in a Diverse Cohort of Healthy Infants

Informed Consent Form

ClinicalTrials.gov ID NCT05161169

Last approval date: 09/22/2025

Boston Children's Hospital

RESEARCH CONSENT FORM

Use Plate or Print:

MRN#:

DOB:

Subject's Name:

Sex:

This section only to be edited by IRB office.

Protocol Title: Implementation of Whole Genome Sequencing as Screening in a Diverse Cohort of Healthy Infants

Principal Investigator:
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Robert C. Green, MD, MPH (Brigham and Women's Hospital)

This consent form gives you important information about a research study. A research study is a project that you and your family can choose to be part of. Scientists and community members help plan this project. It is designed to learn new scientific information and help improve healthcare.

Please read this consent form carefully and take your time making a decision. The first section gives you an overview of the key information you should know about the research study. More detailed information about these topics may be found in the pages that follow.

We want you to go through this consent form carefully, so you can decide if you want to take part in the study. Please ask questions about anything you do not understand or want more information on. You may want to talk to others like friends, family, or doctors before you decide.

Here are a few definitions that may help you better understand this study:

- **DNA** is a person's genetic material. Each person has unique DNA inherited from their parents.
- **Genes** are made of DNA. Genes determine features like eye color and hair color, and give instructions to help the body function**.**
- The **genome** is the entire set of genetic instructions. In humans, the genome consists of 3 billion letters of DNA.
- A **gene change** is a difference in the spelling of DNA. All people have differences in their unique DNA. Most are not harmful and do not affect you. Some changes can cause certain health risks.
- **Genome sequencing** is a lab test that can find most of the genetic changes in someone's DNA.

Summary of Important Information

We are asking you and your baby to take part in the research study "Implementation of Whole Genome Sequencing as Screening in a Diverse Cohort of Healthy Infants," also called "The BabySeq Project." Participation in this research study is voluntary. You may choose not to take part in this research study or may choose to leave the research study at any time. Your decision will not impact the clinical care you receive at Boston Children's Hospital.

In this research study, we want to learn more about using genome sequencing (DNA testing) as part of well-baby care. This may give clues about health risks now and in the future.

You are being asked to participate in this research study because your baby is seen for primary care in a clinic that is part of the study. Doctors in the clinic have learned about DNA testing to understand and use potential results. It is important to consider reasons why you would or would not want to take part in this research.

If you decide to join the study, the following things will happen:

- Over the next year, you will meet with our study team twice and complete 3 surveys.
- At the first meeting:
    - We will talk with you about the study and ask you to complete a survey.
    - We will ask questions about your relatives' health and any medical problems that seem to run in your family.
    - Half of the babies in the study will be randomly chosen to get genome sequencing. The other half will not get genome sequencing.
        - Each baby will have an equal, or fifty-fifty, chance to be in either group.
        - You will learn what group your baby is in after you complete the first survey.
    - If your baby is in the sequencing group, we will collect a few drops of blood from their foot using a "heel stick" or "finger stick" and we may also collect a saliva sample via a cheek swab.
- 3-4 months later:
    - You will meet with a doctor or genetic counselor from our study team.
    - We will share information about how your family history could affect the health of your baby.
    - If your baby had genome sequencing, we will also share those results with you and your doctor.
    - We will ask you to complete a survey about whether the study has affected medical care, your stress levels, or your family relationships.
- 6 months later:
    - We will ask you to complete another survey.

We would like to learn how genome sequencing affects babies as they grow up. So, we hope that your family will stay involved with the study over time.

- We may contact you at least once a year while the study is running. We will share updates on the research, and sometimes ask if you'd like to do another survey or interview.
- While your child is in the study, we will have access to information in their medical record. We may review this information regularly as part of the research.

There is minimal risk if you choose to take part in this study. The most important potential risks to know about are:

- You might learn genetic information that makes you worried or upset.
- It is possible that you will learn that your baby has a genetic risk factor that could affect them later in life.

The most important potential benefits to know about are:

- You might learn more about your baby's risk of developing health problems that run in your family and be able to address these early.
- You might learn about your baby's risk of developing health problems that wouldn't be expected or screened for otherwise. In some cases, this can help treat and/or help prevent future health problems.
- If we find that your baby has a genetic health risk, the baby's biological relatives may carry the same health risk.
    - These relatives (parents and siblings) can choose to also have genetic testing as part of the study.
    - If they get this information, it may be possible for them to screen for, treat, and/or help prevent future health problems.

You will be actively involved in the study for about 1 year. The study will take about 2-3 hours of your time total. There is no cost for you to be in this study. You will receive $150 if you complete the whole study.

We are also asking your permission for your child to be in the study until they turn 18, if the study is still running. After the first year, we will send you updates on the study and occasionally review your child's medical record. We may ask you to do more surveys or interviews, but you can always say no. You can also leave the study at any time.

Why is this research study being done?

The goal of this research is to see if we should expand newborn screening to include genome sequencing for all babies.

All babies born in the United States currently have newborn screening using a heel stick to get a few drops of blood. Each U.S. state is recommended to screen for 61 conditions. States may screen for more or fewer conditions, depending on their specific program**.**

Many of these can be treated and treatment may help prevent more serious health problems in the future.

We could screen for thousands more health risks with genome sequencing. Early diagnosis of these conditions may help prevent serious health problems or even save the lives of babies carrying these risks. But, genome sequencing is not done very often because it is expensive, and doctors and scientists don't always know how to use all the information.

With this study, we hope to better understand the reactions of parents and doctors along with the actual medical benefits of genome sequencing in babies. We will also see how the test results are used in the baby's healthcare.

We are including families of diverse backgrounds so that everyone can benefit from testing.

Dr. Green, the PI of this study, has a financial interest in Nurture Genomics, a company developing a platform for parents interested in newborn genetic testing. In accordance with Mass General Brigham's conflict of interest policies, the Mass General Brigham Office for Interactions with Industry has reviewed Dr. Green's financial interest in the company and has determined that the interest creates no significant risk to the welfare of participants in this study or to the integrity of the research. If you would like more information about this, please contact the Mass General Brigham Office for Interactions with Industry at 857-282-2024 or PHSOIIRESEARCH@PARTNERS.ORG.

Who is leading the study, and where is it taking place?

Dr. Ingrid Holm is the principal investigator at Boston Children's Hospital (BCH). She is leading the study along with Dr. Robert Green at Brigham and Women's Hospital (BWH). Researchers in New York City, NY and Birmingham, AL are also part of the study. Other hospitals and cities might join the study in the future. The National Institutes of Health is funding the study.

How many people will take part in the study?

About 670 babies total will join this study with their parents and doctors. About 280 babies from Boston Children's Hospital will join.

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

We will review this consent form with you. If you choose to take part in this study, we will ask you to sign this consent form and give you a signed copy to keep.

During the first year, we will ask you to take part in 2 study visits, either in-person or by video, and to complete 3 surveys. We may also ask you to complete a survey or interview every year after you finish the main portion of the study (possibly until your child is 18 years old). We will still have access to your child's medical record to research how genome sequencing affects healthcare over time.

If the study is still running when your child turns 18 years old, we will ask them whether they would like to continue participating. If they would like to stay in the study as an adult, we will have them sign their own consent form.

Here are more details about what you will have to do if you are in this study:

Study Visit Timeline	Visit 1	Visit 2 (3 Months)	Visit 3 (9 Months)	Future
Consent	X			
Survey	X	X	X	X
Family history	X			
Sample collection *(sequencing group only)*	X			
Learning results		X		
Medical record review				X
Interview				X

Baseline study visit (Visit 1)
The first visit can be during one of your baby's regular visits with their doctor, or at another time that is convenient for you, either in-person or by video or phone.

For You, the Parent:
In a 30 to 60 minute visit with a research assistant, you will:

- Review this consent form.
- Answer questions about your family medical history.
- Complete a 30-minute survey online, in-person, or over the phone. The survey will ask you questions about:

- Your age, race, sex, job, and other information about your background
- Your thoughts and feelings about learning your baby's results
- Your levels of stress, anxiety, and depression
- Your feelings toward your baby and your other relationships (for example, a partner)

Since we are studying genome sequencing compared to regular well-baby care, your baby will be "randomized" into one of two study groups. Both groups will have a meeting with a genetic counselor to talk about your family history. One group will also get genome sequencing, and one group will not. You will have an equal chance of being in either group. Neither you nor the baby's doctor or research team can choose what group you will be in.

You will learn whether you have been randomized to the sequencing or non-sequencing (control group) after you fill out the first study survey.

For Your Baby:
If your baby is randomly assigned to the sequencing group, we will collect a sample to do whole genome sequencing. Some research studies just analyze a few genes linked to a specific health risk. In whole genome sequencing, all or most of your baby's genes are analyzed. In this study, we will be screening your baby for many health risks all at once.

There are different ways to collect a sample for whole genome sequencing. We will try to do this during one of your baby's regular appointments. We will tell you how we plan to collect the sample before you sign this form.

If your baby is 0-8 months old, we may collect a few drops of blood from their foot using a "heel stick". If your baby is over 8 months old, we may collect a few drops of blood from their hand using a "finger stick". We may also collect a saliva sample from your baby's mouth, or we might ask you to do this at home. If your baby is having a blood test for something else, we may try to collect blood for this research study at the same time. Or, we might use blood from your baby's umbilical cord or another leftover sample.

If your baby's first sample cannot be tested, we might ask if we can collect another sample.

Learning your baby's results (Visit 2 and post-disclosure survey)
About 3-4 months after enrolling, you will meet with a study genetic counselor or doctor to get your baby's results and answer any questions you may have. This may be done in-person or by video or phone and will take about 30 minutes to 1 hour.

Your baby's reports will include:

- Family history report with medical conditions in your family that could have a genetic link. This information can help you understand the risk for your baby and other family members to develop the same health problems. In some cases, knowing this information can help personalize medical care or lifestyle to reduce risk.
- Genome sequencing report (*if your baby is in the genome sequencing group*)

After this visit, we will ask you to complete a survey similar to the first survey. You may choose to do this survey either in-person, by phone, or online at your convenience. The survey will take about 20-30 minutes.

You will get a copy of your baby's results after this visit. The results will also be sent to your baby's doctor and put in your baby's medical record.

About 1 in 10 babies (10%) will have a genetic change that affects their health. If your baby has one of these changes, there is a chance their relatives have the same risk. In this case, the biological parents and siblings can choose to have genetic testing as part of the study.

If your baby develops health problems during the research study, doctors may ask the lab to see if your baby's gene changes could cause the specific health problems. If this extra test is ordered, you and your baby's doctor(s) will get a copy of these updated results, and we will place them in your baby's medical record.

If we cannot reach you to schedule a results disclsoure visit, we will send a final letter and email asking you to contact us. If we don't hear back after that, we will place the results in your baby's medical record for their doctor to review. You can still contact us at any time while the study is running to talk about the results.

6-month follow-up survey
6 months after learning your baby's results, we will ask you to complete a survey similar to the first two surveys either online, by phone, or by mail.

Yearly follow-up
Once per year (possibly until your child is 18 years old), we may contact you by phone, mail, or email to complete a follow-up survey or interview. These surveys/interviews will ask questions about how this study has affected your child and your family.

Throughout the study, the surveys and interviews will ask questions about potential anxiety and depression. If we are concerned about your responses, someone from the team may contact you. If you are already involved with a social worker or mental health provider, we may discuss our concerns with them. We do this to make sure you are okay.

Collecting information from your/your baby's medical record
As part of this research, we are learning how genome sequencing affects babies' healthcare. We will study things like how many times a baby goes to the doctor, or what medications they take.

We would like to learn how genome sequencing affects children's healthcare over time. So, the study staff may review your child's medical records at least once a year. We may collect data about test results, procedures, appointments, and doctors' notes. We will continue to collect this information until your baby turns 18, unless you leave the study. If the study is still running when your child turns 18, we will ask whether they would like to stay in the study. If they agree, we will ask them to sign their own consent form as an adult.

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

There are risks, discomforts, and inconveniences associated with any research study. Since tests to learn about a person's genome are new, there may be other risks that are currently unknown. The study researchers will carefully check for these risks. If there is any new information about the risks of taking part in this study, We will let you know.

- **We believe that the risks to your baby and your family as a result of taking part in this study are low.**
- **We think that the benefits of learning about how to use genome sequencing for infants outweigh these possible risks.**

If your baby is randomly selected for the control group that does not get genome sequencing, you may be disappointed.

If your baby is randomly selected for the genome sequencing group, the potential risks to you and your baby are:

Risks to your baby:

- **Risks related to privacy:** Your child's privacy is very important to us, and we will use many safety measures to protect it. But, since your child's genetic information is unique, there is a small chance that someone could trace it back to them.
- **Risks related to insurance and discrimination.** Some people worry that risk information could affect a baby's future. There is a federal law called the Genetic Information Nondiscrimination Act (GINA). This law makes it illegal for most jobs to discriminate based on DNA. The law also prevents health insurance companies from discriminating based on DNA. But, GINA does not apply to life insurance, disability insurance, or long-term care insurance. These companies can use genetic information. Some state laws have extra protections against this type of discrimination. For more information about GINA, please see http://www.eeoc.gov/laws/types/genetic.cfm.
  Risks related to learning genetic information: It is possible that when your baby gets older, they will learn genetic information from this study that they did not want to know about.
- **Risks of a heel stick or finger stick sample:** may cause a small amount of pain, or a temporary bruise or "black and blue mark" on your baby's heel or finger. Very rarely, the heel or finger may become red and swollen, or infected. If this happens, you should contact your baby's doctor.

Risks to you:

- **Risks related to learning genetic information:** Some people may feel anxious about their child having a genetic risk. When you learn your baby's results from a study genetic counselor or doctor, you can talk about feelings you have. Throughout the study, you can also talk with a genetic counselor or social worker. While very unlikely, you could learn that your baby carries a genetic change that may cause them to develop a serious illness that has no cure or effective treatment. Most genetic disorders do not have any cures, but many have treatments.

- **Economic risks:** Some babies may need more medical tests to follow up on results found through genome sequencing. If this happens, you may be responsible for some of the costs.
- **Risks associated with genomic testing:** We know that some changes in the genome cause specific diseases. But, we are still learning about the genome and how certain changes affect a person's health. We may find changes in your baby's genome but not know for sure what they mean for their health. There may be certain types of gene changes that this test cannot find. There are also conditions we cannot predict based on genetic changes. In the future, your baby could develop conditions that are not found by this test.

What are the benefits of this study?

If you and your baby take part in the study (both groups):
You might learn more about your baby's risk of developing health problems. In some cases, this can help make future health problems less serious. You might learn more about how your family's medical history can impact your health risks. In some cases, this information could help screen for, treat, and/or help prevent future health problems.

If your baby is in the genome sequencing group:
You might learn about a genetic change that could put your baby or other children at risk. In some cases, genetic information can help guide treatment. In other cases, doctors might recommend medical care or lifestyle changes. Genetic information could help you plan for future financial and/or family decisions. Some genetic changes are related to treatable conditions later in life. This could benefit your baby and other relatives. Doctors might recommend screening or other options to lower risk.

By taking part in this study, you can help advance research and improve healthcare.

Will I receive my study results?

All babies in this study will get a family history report. A doctor or genetic counselor will talk to you about this report and any recommendations. During this research we may learn information from the study results which could be important for your baby's health or medical care. This information will be shared with you and your baby's doctor. The information we may share is about inherited risks for health problems.

If your baby is in group that will receive genomic sequencing, a study doctor or genetic counselor will talk to you about the genetic results. You and your baby's doctor will both get a copy of the results.

Your baby's genome sequencing results can include different types of information.

- Some gene changes may help you plan for and/or treat health problems that could develop in childhood.
    - Some of these health problems have a treatment available. Some may have a treatment being developed. Some might not have any treatments.
- Some gene changes may help you plan for and/or treat health problems that could develop in adulthood.

- For example, some gene changes can increase the risk of certain cancers. These changes would be reported if there are screening or prevention steps available.
- Gene changes will NOT be reported if the health problem is expected to start in adulthood, but there is no treatment available. For example, you would not learn about a risk to develop Alzheimer's disease.
- We use recommendations from the American College of Medical Genetics and Genomics to decide what to report.

- Some gene conditions require two changes in a gene to cause a health problem, one from each parent. A single gene change should not affect your baby's health. We will still tell you about these changes because if you are hoping to have more children you might be able to use this information.

This study is only looking for genetic information that could affect the baby's health. You will not learn other results from the study, like who the baby's biological parents are or what the baby's genetic ancestry is.

Will my information be used for research in the future?

The BabySeq study team will do research using your baby's data. Only our study team will be able to see "identifiable" information about your baby, like their name and date of birth. Your baby's identifiable information, including a copy of this consent form, will be stored at BCH as well as the study coordinating site at BWH. We only use information about your baby that is needed for the study.

An important part of learning more about genetics and health is sharing data with other researchers. This is a rule for studies funded by the National Institutes of Health (NIH), like this one. When we share your baby's data outside of our study team, this information will be "de-identified." That means we remove your baby's name, date of birth, medical record number, and other details linking it to your baby. The de-identified data will be shared as a computer file. The data has a research code number that other researchers cannot link back to you or your child.

The de-identified data may be shared with:

- Other researchers, hospitals, and businesses that work directly with the research team or who are approved by Boston Children's Hospital.
- Large databases so the research community can analyze data from many studies.
  - These databases are managed by NIH, other hospitals, or research laboratories.
  - These databases include de-identified information from many thousands of people.
  - Other qualified researchers can use this de-identified data to do more studies. These researchers need approval to access the data.

The de-identified data might be combined with other researcher's data. This can help scientists understand why diseases develop or how to treat them. Doctors might learn how to develop new medicines. The data will be available for research on many health conditions.

We will do everything we can to protect your child's privacy before sharing data with other researchers. But, there is a very small chance that your child could be re-identified. For example, since your child's genetic

information is unique, there is a small chance that someone could trace it back to them. We follow all data protection laws to minimize this risk.

This is an important part of the study. Sharing genetic data can lead to scientific advances and new treatments in the future. If you don't want your baby's genetic data to be shared, you can choose not to join this study.

Are there costs associated with this study?

There is no cost for you to take part in this study. The study will pay for:

- your baby's cheek swab or blood draw
- genome sequencing and other testing performed under this study
- the study doctor/genetic counselor to review your baby's reports with you
- genetic testing for your baby's biological relatives (parents and siblings). This testing is optional. If we find a genetic health risk for your baby, they can choose to learn if they have the same risk

A doctor might recommend extra medical care based on what you learn from this study. For example, a doctor might recommend a new appointment based on your family history information. Or, a doctor might recommend more testing to follow up on your baby's genetic information.

You or your health insurer will have to pay for any medical care you receive outside of this study. You will be responsible for any payments required by your health insurance company. This may include deductibles or copayments.

If you have any questions about these costs, please ask someone from the study. We can have you talk to Patient Financial Services for more information.

Will I receive any payments?

You will be paid with an electronic gift card after completing each survey. You will get $50 after the first study meeting and survey, $50 after the second meeting and survey, and $50 after the third survey. This will add up to $150 if you complete the whole study over one year. If you leave the study early or we have to take you out of the study, you will keep the gift cards you already got.

If your baby is in the sequencing group, we might ask you to spend extra time or come in for a separate appointment to complete the sample collection. If this happens, we will offer you an additional $25 to help cover any costs like transportation or time away from work.

We may also contact you for a follow-up survey/interview after your third study survey. Currently, we do not have money to pay you for these surveys/interviews. If we get more funding in the future we will give you gift cards for your time.

There is a small chance that in the future, samples or data from this study could be used to develop new treatments or other inventions. If this has commercial value, you will not get a part of the profits. The hospital makes sure that the potential for profit does not harm people in the study.

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

This research is voluntary (your choice). If you do not join, your baby will keep getting regular health care from their doctor.

Are there other things I should know about?

Storage of samples, reports, and genome sequencing data

- The genome sequencing is done at a clinical (medical) testing lab. If your baby is in the genome sequencing group, the lab is required to store some information after the study ends.
    - The samples and genetic data will be stored for at least two years after the study ends.
    - The genetic testing report will be stored for at least 25 years after the study ends.
- The lab saves a copy of this information because it can be important for your family over time.
- This rule is the same for all clinical testing labs in the U.S.

Why would I be taken off the study early?

We might ask you to stop the study before you finish taking part. This could happen if:

- You and the baby's other parent/guardian disagree about taking part in the study.
- The study staff is concerned that you are anxious, depressed, or upset about the study. This could be due to survey responses, conversations with the study staff, or conversations with a mental health provider.

Who may see, use or share your health information?

A copy of this consent form may be placed in your baby's medical record.

Results from this study will become part of your baby's medical record. Medical records are permanent, so information cannot be changed or deleted. Hospital staff can see medical records to do their jobs. They are required by law and hospital policies to maintain confidentiality. Information that can identify you or your baby will not be shared with anyone outside of the hospital or research study. This may change if you give written permission, or if sharing is required by law.

Other information that is collected for the study will be stored in secure files only available to our study team. You can see this information if you request it. We will only share this information with others if it is required by law.

If you and your baby stop the study, we will not collect any more information about you. However, de-identified data that has already been collected will still be used in the research.

The study staff may collect information about your baby's medical care and costs of care. The cost data may include billing records from the hospital, and information from your health insurance company.

We will not tell your insurance company if your baby has genome sequencing. We will not share the genetic results with the insurance company. But, they may be able to see this information if they review your baby's

medical records. As described above, the Genetic Information Nondiscrimination Act (GINA) is a federal law. GINA makes it illegal for health insurance companies to use this information to harm your baby.

Certificate of Confidentiality

This study has a Certificate of Confidentiality from NIH.

This adds special protection for your baby's samples and research information. our study team may not share information that may identify you or your baby, even if there is a court order or subpoena. We will not share this information unless you give permission.

There are only a few ways that our study team may share information about you/your baby, if:

- required by law (to report child abuse, infectious diseases, or harm to self or others)
- you have agreed to sharing (such as for you or your baby's medical treatment)
- it is used for other research (as allowed by law)
- a government agency sponsoring the project wants to audit the research

The Certificate does not apply to:

- information in your baby's medical record
- other types of information-sharing that you are agreeing to as part of this study
- you personally sharing information about you or your baby participating in the study
- you giving written permission for someone else to receive study information

Clinical Trial Registration

A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. law. This web site will not include information that can identify you. At most, it will include a summary of the results. You can search this web site at any time.

Future Contact

Next, we are asking if we can contact you in the future about other research projects. You can say no to any of these without affecting your baby's medical care or participation in BabySeq.

Research staff may contact you to:

1. Donate additional samples
2. Ask if you are interested in joining other research studies

Would you like us to contact you about opportunities to participate in future research?

☐ Yes

☐ No

We might also contact you about opportunities to speak with the media. This could be for TV, magazine, radio, etc. Sometimes reporters are interested in sharing information about BabySeq.

Would you like us to contact you about opportunities to speak with the media?

☐ Yes

☐ No

If you answered Yes to either question, please list your contact information below

Name:_____

Address:_____

Phone: _____

Email:_____

Email and Text Messages

The Boston Children's Hospital standard is to send emails securely by encryption. If you prefer, we can send you regular non-encrypted emails. Unencrypted emails are sent directly to and can be opened from your personal email account.

We would also like to offer you the option of receiving study information and updates via SMS text message. Text messages are sent directly to the personal phone number you have provided. Text messages are sent from study-related Boston Children's Hospital phone numbers. There is a potential risk of loss of confidentiality when using unencrypted e-mail and text messaging, as both are hosted by a third-party. Please be aware that these communications can be intercepted in transmission or misdirected.

You acknowledge that you have been informed and understand that we cannot guarantee that regular non-encrypted email or text messages will be confidential. Please check below if you wish to receive non-encrypted emails or text messages.

_____ ☐ I wish to receive regular non-encrypted emails from the study team.

_____ ☐ I wish to receive text messages from the study team.

If, at any point, you no longer wish to receive unencrypted emails from us, you may indicate this by sending an email to babyseq@childrens.harvard.edu, and we will return to communicating via encrypted email. If you no longer wish to receive text messages from us, you may also reply STOP to a study text message and we will no longer send study text messages.

What should you know about HIPAA and confidentiality?

Your baby's health information is protected by a specific U.S. law. This law is called the Health Information Portability and Accountability Act (HIPAA).

In general, anyone who is involved with the study is allowed to see data that includes information about you. For example, the following people might see information about you:

- The study staff
- Staff involved with your baby's care related to the study
- Other researchers and centers that are a part of this study
- People at the hospitals who oversee research and care. This includes the ethics board and quality improvement program
- People from agencies and organizations that provide accreditation and oversight of research
- People that oversee the study information. This may include data coordinating centers and others
- Sponsors or others who fund the study, including the government or private sponsors
- Federal and state agencies that oversee or review research information. This may include the Food and Drug Administration, the Department of Health and Human Services, and the NIH. This may also include public health and safety authorities.
- Groups that provide services related to research at the hospital, like a laboratory
- Your health insurer, for parts of study-related care that are considered billable

Our study team may have to share information about you or your baby, as required by law. Some people or groups who get your baby's health information might not have to follow the same privacy rules. Once information is shared outside of Boston Children's Hospital, we cannot promise that it will remain private.

If you decide to share private information with anyone else, federal laws might not apply. Other laws may or may not protect sharing of private health information. If you have a question about this, you may contact the BCH Privacy Officer at (857) 218-4680. This office can help you understand privacy and confidentiality.

Research is ongoing and researchers use data for many years. So, we cannot give you an exact time when we will destroy your information.

We will create a "code" for the research information we collect about your baby. Identifying information will be kept separately from your baby's de-identified data.

The results of this research may be published in a medical book or journal. Results might be used to teach others. Your baby's name or identifying information will not be shared unless you give permission.

Your privacy rights

If you want to take part in this research study, you must sign this form.

If you do not sign this form, it will not affect your care at any study hospital now or in the future. You will not be penalized or lose benefits. You/your child can withdraw from the study at any time. You can end your permission to use or share information that was collected as part of the study at any time. But, you cannot get back information that was already shared with others. Once you remove your permission, no more private health information about you/your baby will be collected. If you wish to remove your/your baby's health information, please contact our study team.

You may have the right to find out if information collected for this study was shared with others. You may not be allowed to review the information until after the study is completed. When the study is over, you will have the right to access the information again. To request the information, please contact the Hospital's Privacy Officer at (857) 218-4680.

Other information that may help you:

Boston Children's Hospital is interested in hearing your comments, answering your questions, and responding to any concerns regarding the research. If you have questions or concerns, you may email IRB@childrens.harvard.edu or call (617) 355-7052 between the hours of 8:30 and 5:00, Monday through Friday.

Contact Information

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

I can call:	At:	If I have questions or concerns about:
Investigator: **Dr. Ingrid Holm (BCH)** **Dr. Robert Green (BWH)**	Phone: **617-919-2338** Phone: **617-264-5834**	▪ General questions about the study. ▪ Study-related injuries or emergencies. ▪ Any study-related concerns or complaints.
Study Contact: **Bethany Zettler (BWH/BCH)**	Phone: **617-264-5884**	▪ General questions about the study. ▪ Any study-related concerns or complaints.
Institutional Review Board: **BCH Office of Clinical Investigations**	Phone: **617-355-7052**	▪ Rights of a study participant. ▪ Use of protected health information. ▪ Compensation in event of a study-related injury. ▪ Any study-related concerns or complaints. ▪ If investigator/study contact cannot be reached.

		▪ If I want to speak with someone other than the Investigator, Study Contact or study staff.
(BWH) Mass General Brigham Human Research Committee	Phone: **857-282-1900**	▪ Rights of a study participant. ▪ Any study-related concerns or complaints.

Documentation of Informed Consent and Authorization

- ■ I have read this consent form and was given enough time to decide to take part in the study.
- ■ The study has been clearly and fully explained to me, including possible risks and benefits.
- ■ All my questions were answered.
- ■ I understand taking part in the study is my choice and I can stop taking part at any time.
- ■ I am signing this consent form before taking part in any study activities.
- ■ I give permission for taking part in the study and for the use of my/my child's protected health information as described above (HIPAA).

Parent/Legal Guardian Permission for Child Participation

■ _____ _____ _____

Date (MM/DD/YEAR) Signature of **Parent/Legal Guardian #1** Relationship to child

Adult Participant

■ _____ _____

Date (MM/DD/YEAR) Signature of **Adult Participant** *(18+ years)*

Research Investigator or Associate's Statement & Signature

- ■ I have fully explained the research described above, including the possible risks and benefits, to all involved parties (participant/parents/legal guardian as applicable).
- ■ I have answered and will answer all questions to the best of my ability.
- ■ I will inform all involved parties of any changes (if applicable) to the research procedures or the risks and benefits during or after the course of the research.
- ■ I have provided a copy of the consent form signed by the participant/parent/guardian and a copy of the hospital's privacy notification (if requested).

■ _____ _____

Date (MM/DD/YEAR) Signature of **Research Investigator or Associate**

Witness Statement & Signature

A witness must be present for the entire consent process in the following situations (please check the appropriate box)

☐ The individual cannot read and this consent document was read to the participant or legal representative, **or**

☐ The individual has certain communication impairments that limit the participant's ability to clearly express consent **or**

☐ Situations where the IRB requests a witness be present: please specify _____

I confirm that the information in this consent form was accurately explained to the participant, parent or legally authorized representative, the individual appeared to understand the information and had the opportunity to ask questions, and that informed consent was given freely.

■ _____ _____

Date (MM/DD/YEAR) Signature of **Witness**