

THE MOUNT SINAI HEALTH SYSTEM
PERMISSION FORM FOR A CHILD TO PARTICIPATE IN A RESEARCH STUDY
AND AUTHORIZATION FOR USE AND DISCLOSURE OF MEDICAL INFORMATION
Icahn School of Medicine at Mount Sinai

Page 1 of 15

Study ID #: HSM 12-00875

Form Version Date: 12/10/20

TITLE OF RESEARCH STUDY:

Title: Programming of Intergenerational Stress Mechanisms (PRISM Study), Phase 2

PRINCIPAL INVESTIGATOR (HEAD RESEARCHER) NAME AND CONTACT INFORMATION:

Name: Rosalind J. Wright, MD, MPH

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WHAT IS A RESEARCH STUDY?

A research study is when scientists try to answer a question about something that we don't know enough about. Participating may not help you or others.

People volunteer to be in a research study. The decision about whether or not to take part is totally up to you*. You can also agree for you and your child to take part now and later change your mind. Whatever you decide is okay. It will not affect your ability, or your child's ability, to get medical care within the Mount Sinai Health System.

Someone will explain this research study to you. Feel free to ask all the questions you want before you decide. Any new information that develops during this research study which might make you change your mind about you and your child's participating will be given to you promptly.

PURPOSE OF THIS RESEARCH STUDY:

The purpose of this study is to find out more about how stress and other factors in your environment, like allergens (substances that cause allergic reactions) and diet, affect the development of asthma, other allergic diseases in children, and other health outcomes. We want to understand the relationship between types of stress experienced by mothers and their children, and how these affect the health of their children later in life.

We want to better understand how stress-related changes in the immune system and stress hormones (chemicals related to stress) relate to the risk of developing allergic disorders including asthma, hay fever, and eczema in young children, and also to your child's growth and development.

You and your child may qualify to take part in this research study because he or she participated in the first part of the PRISM Study, starting at his or her birth until he or she was 3 years old.

Funds for conducting this research are provided by Mount Sinai and the National Institutes of Health.



Effective Date: 12/11/2020
End Date: 12/10/2021

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AND AUTHORIZATION FOR USE AND DISCLOSURE OF MEDICAL INFORMATION
Icahn School of Medicine at Mount Sinai

Page 2 of 15

Study ID #: HSM 12-00875

Form Version Date: 12/10/20

LENGTH OF TIME AND NUMBER OF PEOPLE EXPECTED TO PARTICIPATE

You and your child's participation in this research study is expected to last about 2 years, until your child is 5 years old.

The number of people expected to take part in this research study at Mount Sinai Hospital site is 1200—600 mothers and 600 children.

DESCRIPTION OF WHAT'S INVOLVED:

If you agree to your and your child's participation in this research study, the following information describes what may be involved.

All the activities are done for research purposes only. Visits will take place at your home, at our Mount Sinai lab at 5 East 98th Street, 10th floor, or over the phone.

42 Month Home Visit

You will be asked to complete some questionnaires and interviews. The questionnaires and interviews will ask you about several topics, including stressors you and your child may have experienced (for instance, violence, discrimination, trauma), emotions you may have experienced (for instance, depression or anxiety), emotional and behavioral difficulties your child may be having (for instance, anxiety, attention problems), and your relationship with your child. Some of the questions ask about sensitive material. You can refuse to answer any question you do not want to answer.

. We will ask to collect two blood samples from your child. One blood sample will be collected via venipuncture. For the venipuncture blood draw, we will insert a needle into a vein in your child's arm and withdraw up to 2 teaspoons of blood. The second sample will be collected via finger stick. The finger stick involves a quick prick of a finger by a sterile lancet (needle). The finger will then be massaged to collect the blood sample, and several blood drops will be collected on a blood (filter paper) sample card. We will use the blood samples to look at telomere length. Telomeres protect the ends of chromosomes from deteriorating and are important to the health of the body's cells. In addition, if you agree, portions of the blood samples will be stored indefinitely. These samples may be used to look for genetic or epigenetic (characteristics of the DNA molecule that do not affect the actual genetic code) characteristics related to stress responses. You may refuse to have your child's blood sample stored for future use. If you prefer or if we deem it in your child's best interest, we may draw one or both samples during the lab visit rather than the home visit. You may refuse to allow us to collect blood via venipuncture or finger stick. You may agree to one or both procedures. Any refusal will not affect your ability to participate in the study.

We will ask to collect a small amount of your child's hair (about the diameter of a pencil eraser). We will cut the hair close to your child's scalp in a spot that will be as unnoticeable as possible. We will use the hair to look at cortisol. Cortisol is a hormone in hair that is involved in the body's response to stress over days, weeks, or months. In addition, we may look at other markers that are identified through future research (for example, hormones other than cortisol). You may refuse to allow us to collect hair from your child. Such refusal will not affect your ability to participate in the study.

We will ask your child to complete one procedure. In this procedure, we will first spend time playing with your child for approximately 30 minutes. We will then ask your child to complete a matching task, for example matching animal figures to different colored balls. We will use a timer and tell you that if he/she completes the task in time, he/she will get a toy of his/her choice, but if he/she d



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PERMISSION FORM FOR A CHILD TO PARTICIPATE IN A RESEARCH STUDY
AND AUTHORIZATION FOR USE AND DISCLOSURE OF MEDICAL INFORMATION
Icahn School of Medicine at Mount Sinai

Page 3 of 15

Study ID #: HSM 12-00875

Form Version Date: 12/10/20

finish in time, he/she will get a sticker. Your child will be given three chances to attempt to complete the task. We will set the timer such that it will be difficult to complete the task on time. At the end of the procedure, we will tell your child that there was a problem with the timer setting and will give him/her a chance to try the task again without a time limit. We will also give your child the toy of his/her choice regardless of task performance. This task allows us to see how your child responds to a mild stressor. After the task, we will play with your child for about 1 hour. During this procedure, we will ask that you not be in the room with your child or that you be out of your child's line of sight so as to not distract the child. You may be completing questionnaires and interviews during this time. We will stop the procedure if your child becomes distressed. You can also stop the procedure or withdraw from the study at any time.

We will also collect saliva ("spit") from your child in 10-minute increments during the home visit. We will collect saliva up to 6 times. We will collect the saliva by using swabs that we will have your child mouth for approximately 1 minute. We will place the swab in your child's mouth while a staff member holds the other end so that your child will not be able to swallow it or choke on it. We will use the saliva we collect from the swabs to look at cortisol. Measuring cortisol at several time points within a short period of time will help us understand how children's biological responses help them manage stress. In addition, we may look at other markers that are identified through future research (for example, hormones other than cortisol). You may refuse to allow us to collect saliva from your child. Such refusal will not affect your ability to participate in the study.

At the end of the home visit, you will be asked to collect saliva from your child at home 4 times on 2 different days, for a total of 8 times, prior to the lab visit. You will be asked to fill out a short questionnaire on each of the days you collect saliva. You will be shown how to collect the saliva and will be given the materials needed to collect the saliva. If you cannot return the samples during your lab visit, study staff will arrange to pick up the saliva and questionnaire from you at your home or a place of your choosing. We will use the saliva we collect to look at cortisol and other stress markers. You may refuse to collect saliva at home. Such refusal will not affect your ability to participate in the study.

At the end of the home visit, you will also be asked to collect one sample of urine ("pee") from your child. You will be asked to fill out a short questionnaire on the day of collection. You will be shown how to collect the urine and will be given the materials needed to collect the urine. If you cannot return the sample during your lab visit, study staff will arrange to pick up the urine and questionnaire from you at your home or a place of your choosing. We will use the urine to look at markers of oxidative stress. Oxidative stress is a measure of the balance between chemicals that can damage cells and chemicals that can protect against cell damage. In addition, we may look at other markers that are identified through future research (for example, other markers of stress). You may refuse to collect urine at home. Such refusal will not affect your ability to participate in the study.

Every effort will be made to complete these questionnaires during your home visit. If it is not possible to complete the questionnaires during your home visit, we will try to finish them during the lab visit or ask if we can call you to finish the questionnaires over the phone or in person as soon as possible. We would like to finish the questionnaires within 1 week after your visit. The home visit will take approximately 2 ½ hours of your time. Home collection of saliva and urine will take approximately 30 minutes of your time. If for some reason we cannot come to your home to complete this visit, we will ask you to come to our lab at Mount Sinai to complete the procedures. This would be a separate visit from the one described below.



Effective Date: 12/11/2020
End Date: 12/10/2021

THE MOUNT SINAI HEALTH SYSTEM
PERMISSION FORM FOR A CHILD TO PARTICIPATE IN A RESEARCH STUDY
AND AUTHORIZATION FOR USE AND DISCLOSURE OF MEDICAL INFORMATION
Icahn School of Medicine at Mount Sinai

Page 4 of 15

Study ID #: HSM 12-00875

Form Version Date: 12/10/20

42 Month Lab Visit

Shortly before or after the home visit, we will ask you and your child to attend a lab visit at Mount Sinai Hospital. The research staff will do a lung function test with your child during which your child will breathe normally into a tube. We will also ask your child to complete two procedures. We will ask that you remain seated out of your child's sight or out of the testing room during the procedures so as to not distract your child. If out of the room, you will be able to watch your child in the observation room.

During the challenge procedure, we will ask your child to complete three short tasks while seated at a table. One task will ask your child to point to a series of pictures, repeat the name of a series of pictures, and then identify by name a series of pictures. In another task, we will put drops of water and drops of concentrated lemon or lime juice on your child's tongue and ask him/her to identify the liquid. In another task, we will show your child two 2-minute videos. One video will be a neutral (non-emotional) video. The other video will be a clip that your child might find to be scary. Before and after these tasks, your child will be read a short, neutral story. During these procedures, we will collect different measures from your child. We will use three ECG electrodes on your child's chest or back and two elastic bands to collect heart rate and breathing ("respiration") data. The electrodes are the same kind of electrodes that a doctor would use to examine your child's heartbeats. The electrodes have gel in the center and are surrounded by a sticky material that helps it stick to your child's skin. Special tape may also be used to keep the electrodes and bands in place. We may ask your child to complete a short breathing exercise (e.g., blowing into a bag or tube) to help us understand the respiration data. You may refuse to allow us to collect heart rate or respiration data from your child. Such refusal will not affect your ability to participate in the study.

The second procedure, the cognitive procedure, will consist of a series of tasks mostly completed on a computer. In one task, your child will be asked to remember associations between animals and colors on a computer screen and then to indicate which color corresponds to which animal. In another task, your child will be presented with a series of fish and shark pictures on a computer screen and asked to press a button when he/she sees a fish and to not press the button when he/she sees a shark. In another task, your child will be presented with a row of five fish pointing in different directions and asked to press a button corresponding to the direction the middle fish is pointing. In another, non-computerized task, we will ask your child to turn around while we wrap a gift. We will then leave your child alone in the room with the gift, asking your child not to touch the gift. Your child will then be allowed to unwrap and keep the gift.

If your child becomes upset during any portion of the lab visit, we will stop the procedure and allow you to comfort your child. We will take breaks as needed.

We will also measure your and your child's height and weight, waist and hip circumference, and blood pressure. We will collect a sample from the inside of your child's mouth using a nylon brush against each cheek. During this visit we will also ask you to complete a questionnaire that will update us on any breathing symptoms that may have happened to your child.

The lab visit will take approximately 2 ½ - 3 hours of your time. We may schedule a visit to come to your home and/or speak on the phone after the lab visit to complete any study activities that we could not complete in the initial home visit and lab visit. We will try to complete all study activities before you leave the lab. We will try to schedule any follow-up visits within two weeks of your lab visit.

When your child is about 4 years old, we will measure how long he or she watches objects, such as balls and cubes and/or pictures of patterns and faces on a computer screen. We do these to measure the baby's attention and memory, and their understanding of objects and things in the



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End Date: 12/10/2021

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PERMISSION FORM FOR A CHILD TO PARTICIPATE IN A RESEARCH STUDY
AND AUTHORIZATION FOR USE AND DISCLOSURE OF MEDICAL INFORMATION
Icahn School of Medicine at Mount Sinai

Page 5 of 15

Study ID #: HSM 12-00875

Form Version Date: 12/10/20

At either one of the 42 month visits, we will collect cheek and nasal swabs from your child and stool from you and your child. We will insert small brushes into your child's mouth and each nostril to collect the swabs. We will give you collection kits for the stool. If you cannot provide the stool samples at the visit, you can mail the samples to our lab using a prepaid mailer or our staff can pick them up from you.

5-Year Home Visit

The 5-year home visit will include the same activities as described for the 42 month home visit. These include the following procedures: (1) maternal questionnaires and interviews; (2) collection of your child's blood via venipuncture and finger stick; (3) obtaining a sample of your child's hair; (4) the matching task; (5) saliva collection up to 6 times. We will also ask your child to complete some cognitive tasks, such as making designs with blocks and answering questions about how two things are alike. We will also ask you to collect your child's saliva again 4 times per day over 2 days, and we will ask you to collect one sample of your child's urine. We will ask you to return the saliva and urine samples, with their corresponding questionnaires, during your child's laboratory visit. If you are unable to return the samples during the lab visit, we will ask to make arrangements to get them from you at another time. You may refuse any procedure, and your refusal will not affect your ability to participate in the study.

The home visit will take approximately 2 1/2 hours of your time. Home collection of saliva and urine will take approximately 30 minutes of your time. If for some reason we cannot come to your home to complete this visit, we will ask you to come to our lab at Mount Sinai to complete the procedures. This would be a separate visit from the one described below.

5-Year Lab Visit

The 5-year lab visit will include the same tasks as the 42-month lab visit as described above, including the challenge procedure and the cognitive procedure. As during the 42-month visit, we will collect heart rate and respiration data during the challenge procedure.

In addition to these procedures, we will conduct two additional tasks. During one task, we will show your child pairs of emotional faces (happy/neutral, angry/neutral, neutral/neutral) on a computer. After each pair, we will then show a marker in the location of one of the faces and ask your child to press a button where the marker appeared. In the other task, we will tell your child he/she will earn a toy if he/she can complete a puzzle in 5 minutes without looking at it. The puzzle will be under a cloth. Your child will receive a toy at the end of the task whether or not he/she finishes the puzzle.

In addition, during some of the cognitive procedure tasks, we may record your child's brain activity using a small cap that is made of stretchy material. Each cap has many sponges on it, and inside each sponge is a small recording sensor. We soak the caps in a warm salt water solution so that the sponges get soft before we put the cap on your child's head. As your brain is working, it is constantly giving off small electrical signals, which travel out to the scalp where we can pick them up with the special sensors. We will ask your child to wear the cap while sitting quietly and opening and closing his/her eyes to obtain a baseline reading. We will then ask your child to complete some of the cognitive procedure tasks while wearing the cap. If your child refuses to wear the cap, we will conduct the cognitive tasks without the cap.

The lab visit will take approximately 2.5 hours of your time. We may schedule a visit to come home and/or speak on the phone after the lab visit to complete any study activities we co



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PERMISSION FORM FOR A CHILD TO PARTICIPATE IN A RESEARCH STUDY
AND AUTHORIZATION FOR USE AND DISCLOSURE OF MEDICAL INFORMATION
Icahn School of Medicine at Mount Sinai

Page 6 of 15

Study ID #: HSM 12-00875

Form Version Date: 12/10/20

complete in the initial home visit and lab visit. We will try to complete all study activities before you leave the lab. We will try to schedule any follow-up visits within two weeks of your lab visit. You may refuse any procedure, and your refusal will not affect your ability to participate in the study.

We may use an application called Twilio to send you appointment reminders or questionnaire links by text or email. In order to protect your privacy, your phone number/email address as well as all the content of the messages will be completely erased from the server of the third party service that sends the messages. In that way, the data collected from each form will only be stored on our secure firewalled internal server.

Video Recording

We will video record the home and lab procedures at 42 months and 5 years so that we can score ("code") the videos at a later time. The types of things we code from the videos are your child's behaviors and emotions. In addition to the purposes of this research, we may want to use the videos for teaching purposes. We will only use the videos to write articles about the study and/or to give talks about the study to academic audiences. We will not use your or your child's name when we show the video, but people who know you or your child may be able to tell who you or your child are. We will say what the study is about when we show the video, so people viewing the video may also learn things about your or your child's life that you usually do not tell others. The video will not be part of your or your child's medical record, but it will belong to the hospital. We will keep the video as long as it might be useful to us. We can decide to destroy the video at any time. You may agree to have the videos used for the purposes of research only and not for teaching/public presentations.

You do not have to agree to let us take videos of you and your child. Your decision (either yes or no) will not affect the care you or your child may receive at any of the hospitals associated with this study. It may affect which parts of the study you and your child can participate in. While you and your child are being videotaped, you can ask us to stop, and you do not have to give us a reason for stopping. You can also ask us to stop using the video for research and/or teaching purposes. If you or your child would like us to stop using the video at any time, you can call Dr. Rosalind Wright at (212) 241-4947.

Can we videotape you and your child? Please initial your choice:

I agree to have my child and I videotaped: _____ Yes _____ No

If you checked Yes, where can we show the video of you and your child? Please initial your choice:

Research Staff (includes non-Mount Sinai Health System research staff)

_____ Yes _____ No

Hospital staff in Mount Sinai Health System

_____ Yes _____ No

Public presentations to community groups

_____ Yes _____ No

National academic/medical conferences

_____ Yes _____ No



Effective Date: 12/11/2020
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PERMISSION FORM FOR A CHILD TO PARTICIPATE IN A RESEARCH STUDY
AND AUTHORIZATION FOR USE AND DISCLOSURE OF MEDICAL INFORMATION
Icahn School of Medicine at Mount Sinai

Page 7 of 15

Study ID #: HSM 12-00875

Form Version Date: 12/10/20

Storage of Samples and Data

Your child's samples and data will be kept for as long as the researchers need them. When your child reaches the age of 18, the researchers will contact him/her and ask if he/she agrees to have his or her samples and data stored for as long as they need them. If your child agrees, he/she will be asked to give written consent at that time. If your child does not agree, then the rest of his/her remaining samples will be destroyed and no more testing of the samples will be done. If the researchers cannot contact your child because your child has moved or for any other reason, then the following will be done: all links to your child's identity will be removed from the remaining samples, and these nameless samples will continue to be used.

Scientific Databases

To do more powerful research, it is helpful for researchers to share information they get from studying human samples. They do this by putting it into one or more scientific databases, where it is stored along with information from other studies. Researchers can then study the combined information to learn even more about health and disease. If you agree to take part in this study, some of your child's genetic and health information might be placed into one or more scientific databases. There are many different kinds of scientific databases; some are maintained by the study site, some are maintained by the federal government, and some are maintained by private companies. For example, the National Institutes of Health (an agency of the federal government) maintains a database called "dbGaP." A researcher who wants to study the information must apply to the database. Different databases may have different ways of reviewing such requests. Researchers with an approved study may be able to see and use your child's information, along with that from many other people. Your child's name and other information that could directly identify them such as address or social security number) will never be placed into a scientific database. However, because your child's genetic information is unique to them, there is a small chance that someone could trace it back to them. The risk of this happening is very small, but may grow in the future. Researchers will always have a duty to protect your privacy and to keep your information confidential.

Future Use of Data or Samples

It is possible that the researchers will use your child's data or samples in the future for purposes related to this study or for unrelated uses. If the data or samples are shared with researchers who are not involved in this study, any links to your child's identity will be removed.

RESPONSIBILITIES FOR PARTICIPATING IN THIS RESEARCH:

If you decide that you and your child will take part in this research study, you would be responsible for the following things: attendance at study visits, completion of study questionnaires, collection of study samples.

COSTS OR PAYMENTS THAT MAY RESULT FROM PARTICIPATION:

If you and your child take part in this research study, we will pay you up to \$485 for your time and effort as follows:

- \$50 for the 42 month home visit,
- \$125 for the 42 month lab visit, as well as a round trip metrocard,



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End Date: 12/10/2021

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PERMISSION FORM FOR A CHILD TO PARTICIPATE IN A RESEARCH STUDY
AND AUTHORIZATION FOR USE AND DISCLOSURE OF MEDICAL INFORMATION
Icahn School of Medicine at Mount Sinai

Page 8 of 15

Study ID #: HSM 12-00875

Form Version Date: 12/10/20

- \$50 and a small toy for the lung function testing,
- \$10 for the cheek swab
- \$50 for the 5 year home visit,
- \$75 for the 5 year lab visit,
- \$10 for completing each of the following:
 - child home saliva collection at 42 months,
 - child home urine collection at 42 months,
 - child spot blood collection at 42 months,
 - child venous blood collection at 42 months,
 - child home saliva collection at 5 years,
 - child home urine collection at 5 years,
 - child spot blood collection at 5 years,
 - child venous blood collection at 5 years.
- \$15 for the cheek and nasal swabs at 42 months
- \$15 each for the stool collections from you and your child.

You will be paid cash at the end of each visit you complete. These payments are for both your and your child's participation. You and your child will not receive separate payments, however throughout the visits, your child will receive small gifts after completing the study tasks.

Tax law may require the Mount Sinai Finance Department to report the amount of payment you receive from Mount Sinai to the Internal Revenue Service (IRS) or other agencies, as applicable. Generally this reporting would take place if you receive payments that equal \$600 or more from Mount Sinai in a calendar year. You would be responsible for the payment of any tax that may be due.

POSSIBLE BENEFITS:

You and your child are not expected to get any benefit from taking part in this research study. Others may not benefit either. However, possible benefits to others include increased knowledge of how allergic and other health conditions develop in childhood.

REASONABLY FORESEEABLE RISKS AND DISCOMFORTS:

Physical risks: The risks of a blood draw include pain, bruising, and the slight possibility of infection at the place where the needle goes in. Some people feel dizzy or may faint during or after a blood draw. Your child may experience some discomfort when the heart rate electrodes are removed. To lessen this risk, methods that reduce skin irritation will be used. There are no risks related to recording your child's brain activity, but if your child refuses to wear the cap, we can continue without it. Your child might feel some discomfort during the mouth swab. We will stop the procedure if you or your child wish us to.



Effective Date: 12/11/2020
End Date: 12/10/2021

THE MOUNT SINAI HEALTH SYSTEM
PERMISSION FORM FOR A CHILD TO PARTICIPATE IN A RESEARCH STUDY
AND AUTHORIZATION FOR USE AND DISCLOSURE OF MEDICAL INFORMATION
Icahn School of Medicine at Mount Sinai

Page 9 of 15

Study ID #: HSM 12-00875

Form Version Date: 12/10/20

Psychological risks: Your child may become bored or distressed when completing the home or lab tasks. Each of the tasks was designed for young children. The tasks should not be more upsetting than situations your child may typically experience. If your child becomes very upset, the study will be stopped and you will be allowed to comfort your child. You may also end the procedure or withdraw from the study at any time. You may experience psychological discomfort or distress when answering questions about emotional symptoms or stressors. You may refuse to answer any question you do not want to answer. If you become upset during any of the procedures, the assessment will be stopped. You can also stop the study at any time by saying that you want to stop. You can withdraw from the study at any time. Stopping or withdrawing from the study will not affect any care you may receive at any of the hospitals associated with this study. If you become very upset during the study, you will be referred for evaluation at your community clinic or the nearest emergency room. If you need continued treatment, you will be referred to an appropriate mental health professional in your community.

Privacy risks: There always exists the potential for loss of private information; however, there are procedures in place to minimize this risk. All of your answers to our questions and all of the information we gather about you and your child will be confidential and will be made available only to the study staff. As described in the confidentiality section, we will make every effort to keep information about your and your child's identity and links to your and your child's individual information private, and in locked cabinets only accessible to the study staff for purposes of contacting you for follow-up and analysis. Even with these precautions, we still cannot guarantee absolute confidentiality unless information is collected anonymously.

To further help us protect your and your child's privacy, we have obtained a Certificate of Confidentiality from the Department of Health and Human Services. With this Certificate, we cannot be forced (for example, by court subpoena) to disclose information that may identify you or your child in any federal, state, or local civil, criminal, administrative, legislative, or other proceedings. Disclosure will be necessary, however, if the Department of Health and Human Studies requests we do so for audit or program evaluation purposes.

You should understand that a Certificate of Confidentiality does not prevent you or a member of your family from voluntarily releasing information about yourself or your involvement in this research. However, if an insurer or an employer learns about your participation, and obtains your consent to receive research information, then we may not use the Certificate of Confidentiality to withhold this information. This means that you and your family must also actively protect your own privacy.

Finally, you should understand that there are certain limits to confidentiality. If, during your participation in this study, the researcher has reasonable cause to believe that previously unreported abuse is occurring, he/she must comply with state law by filing a child abuse report with the Department of Children and Families. If, during the completion of this study, the researchers have reason to believe that you are at risk for being suicidal or otherwise harming yourself or someone else, we are required to take the necessary actions. This may include notifying you, your therapist(s) if applicable, or other individuals. If this were to occur, the researchers would not be able to assure confidentiality.



Effective Date: 12/11/2020
End Date: 12/10/2021

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PERMISSION FORM FOR A CHILD TO PARTICIPATE IN A RESEARCH STUDY
AND AUTHORIZATION FOR USE AND DISCLOSURE OF MEDICAL INFORMATION
Icahn School of Medicine at Mount Sinai

Page 10 of 15

Study ID #: HSM 12-00875

Form Version Date: 12/10/20

OTHER POSSIBLE OPTIONS TO CONSIDER:

You may decide not to take part in this research study without any penalty. The choice is totally up to you.

IN CASE OF INJURY DURING THIS RESEARCH STUDY:

If you believe that you or your child has suffered an injury related to this research as a participant in this study, you should contact the Principal Investigator.

ENDING PARTICIPATION IN THE RESEARCH STUDY:

You may decide to stop your or your child's participation in this research study at any time without any penalty. This will not affect your or your child's ability to receive medical care at any of the Mount Sinai Health System hospitals or to receive any benefits to which you, or your child, are otherwise entitled.

If you decide to stop your or your child's participation in the research study, please contact the Principal Investigator or the research staff.

If you decide to stop your or your child's participation in the research study, already collected information may not be removed from the research study database and will continue to be used to complete the research analysis. You may be asked whether the investigator can collect information from your child's routine medical care. If you agree, this data will be handled the same as research data. You may request in writing to the Principal Investigator at the address on the first page that samples we have already collected from you be withdrawn or destroyed.

You may also withdraw your permission for the use and disclosure of any of your or your child's protected information for research, but you must do so in writing to the Principal Investigator at the address on the first page. Even if you withdraw your authorization, the Principal Investigator for the research study may still use the information that was already collected if that information is necessary to complete the research study. Your or your child's health information may still be used or shared after you withdraw your authorization if you or your child has an adverse event (a bad effect) from participating in the research study.

If you agreed to the optional collection and retention of your child's specimen(s) for future research, you still will retain the right to have the specimen(s) destroyed at any time by contacting the Principal Investigator at the address listed on page 1 of this form. If you decide to have your child's specimen(s) destroyed, any data or analysis that was done before your request will not be removed from the study; however, all of your child's remaining specimen(s) will be destroyed, and no additional analysis will be done with your child's specimen(s). Your child may still participate in the main study even if you decide to have your child's optional specimen(s) destroyed.

Withdrawal without your permission: The study doctor, the sponsor or the institution may stop your or your child's involvement in this research study at any time without your permission. This may be because the research study is being stopped, the instructions of the study team have not been followed, the investigator believes it is in your or your child's best interest, or for any other reason. If specimens or data have been stored as part of the research study, they too can be destroyed without your permission.



Effective Date: 12/11/2020
End Date: 12/10/2021

THE MOUNT SINAI HEALTH SYSTEM
PERMISSION FORM FOR A CHILD TO PARTICIPATE IN A RESEARCH STUDY
AND AUTHORIZATION FOR USE AND DISCLOSURE OF MEDICAL INFORMATION
Icahn School of Medicine at Mount Sinai

Page 11 of 15

Study ID #: HSM 12-00875

Form Version Date: 12/10/20

CONTACT PERSON(S):

If you have any questions, concerns, or complaints at any time about this research, or you think the research has hurt you or your child, please contact the office of the research team and/or the Principal Investigator at phone number (212) 241-5287.

This research has been reviewed and approved by an Institutional Review Board. You may reach a representative of the Program for the Protection of Human Subjects at the Icahn School of Medicine at Mount Sinai at telephone number (212) 824-8200 during standard work hours for any of the reasons listed below. This office will direct your call to the right person within the Mount Sinai Health System:

- Your questions, concerns, or complaints are not being answered by the research team.
- You cannot reach the research team.
- You are not comfortable talking to the research team.
- You have questions about rights of research subjects.
- You want to get information or provide input about this research.

DISCLOSURE OF FINANCIAL INTERESTS:

Sometimes, physicians/researchers receive payments for consulting or similar work performed for industry. Effective September 2014 Mount Sinai reviews only payments to an individual totaling more than \$5,000 a year per entity when determining potential conflicts of interest. If you have questions regarding industry relationships, we encourage you to talk your physician/researcher or visit our website at <http://icahn.mssm.edu/> where Mount Sinai publicly discloses the industry relationships of our faculty.

MAINTAINING CONFIDENTIALITY – HIPAA AUTHORIZATION:

As you take part in this research project it will be necessary for the research team and others to use and share some of your or your child's private protected health information. Consistent with the federal Health Insurance Portability and Accountability Act (HIPAA), we are asking your permission to receive, use and share that information.

What protected health information is collected and used in this study, and might also be disclosed (shared) with others?

As part of this research project, the research team at the hospital(s) involved in the research will collect your name, address, telephone numbers, email address, birth date, your child's name, address, and birth date.

During the study the researchers will gather information by: completing the tests, procedures, questionnaires and interviews explained in the description section of this consent

Why is your or your child's protected health information being used?

Your personal contact information, and that of your child, is important to be able to contact you the study. Your and your child's health information and the results of any tests and procedure collected as part of this research study will be used for the purpose of this study as explained



Effective Date: 12/11/2020
End Date: 12/10/2021

THE MOUNT SINAI HEALTH SYSTEM
PERMISSION FORM FOR A CHILD TO PARTICIPATE IN A RESEARCH STUDY
AND AUTHORIZATION FOR USE AND DISCLOSURE OF MEDICAL INFORMATION
Icahn School of Medicine at Mount Sinai

Page 12 of 15

Study ID #: HSM 12-00875

Form Version Date: 12/10/20

in this consent form. The results of this study could be published or presented at scientific meetings, lectures, or other events, but would not include any information that would let others know who you or your child are, unless you give separate permission to do so.

The research team and other authorized members of The Mount Sinai Health System ("Mount Sinai") workforce may use and share your and your child's information to ensure that the research meets legal, institutional or accreditation requirements. For example, the School's Program for the Protection of Human Subjects is responsible for overseeing research on human subjects, and may need to see your and your child's information. If any payments for taking part in this study, the Mount Sinai Finance Department may need names, addresses, social security numbers, payment amounts, and related information for tax reporting purposes. If the research team uncovers abuse, neglect, or reportable diseases, this information may be disclosed to appropriate authorities.

Who, outside Mount Sinai, might receive your or your child's protected health information?

As part of the study, the Principal Investigator, study team and others in the Mount Sinai workforce may disclose your or your child's protected health information, including the results of the research study tests and procedures, to the following people or organizations: (It is possible that there may be changes to the list during this research study; you may request an up-to-date list at any time by contacting the Principal Investigator.)

- Other collaborating research center(s) and their associated research/clinical staff who are working with the investigators on this project: Beth Israel Deaconess Medical Center
- The sponsoring government agency and/or their representative who need to confirm the accuracy of the results submitted to the government or the use of government funds: National Institutes of Health
- The United States Department of Health and Human Services and the Office of Human Research Protection.

In almost all disclosures outside of Mount Sinai, you and your child will not be identified by name, address, or any other direct personal identifier. Some records and information disclosed may be identified with a unique code number. The Principal Investigator will ensure that the key to the code will be kept in a locked file, or will be securely stored electronically. The code will not be used to link the information back to you without your permission, unless the Institutional Review Board allows it after determining that there would be minimal risk to your privacy. The Certificate of Confidentiality obtained from the Department of Health and Human Services will not be used to prevent disclosure to local authorities of child abuse and neglect, or harm to self or others. It is possible that a sponsor or their representatives, a data coordinating office, or a contract research organization, will come to inspect your records. Even if those records are identifiable when inspected, the information leaving the institution will be stripped of direct identifiers. Additionally, the Office for Human Research Protections (OHRP) of the Department of Health and Human Services as well as the Food and Drug Administration (FDA) will be granted direct access to your child's medical records for verification of the research procedures and data. They are authorized to remove information with identifiers if necessary to complete their task. By signing this document you are authorizing this access. We may publish the results of this research. However, we will keep your name and other identifying information confidential.]

For how long will Mount Sinai be able to use or disclose your and your child's protected health information? Your authorization for use of your and your child's protected health information specific study does not expire.

Will you be able to access your and your child's records?



Effective Date: 12/11/2020
End Date: 12/10/2021

THE MOUNT SINAI HEALTH SYSTEM
PERMISSION FORM FOR A CHILD TO PARTICIPATE IN A RESEARCH STUDY
AND AUTHORIZATION FOR USE AND DISCLOSURE OF MEDICAL INFORMATION
Icahn School of Medicine at Mount Sinai

Page 13 of 15

Study ID #: HSM 12-00875

Form Version Date: 12/10/20

During participation in this study, you will have access to your and your child's medical record and any study information that is part of that record. The investigator is not required to release research information that is not part of your or your child's medical record to you.

Do you need to give us permission to obtain, use or share to you or your child health information?

NO! If you decide not to let us obtain, use or share your and your child's health information you should not sign this form, and you and your child will not be allowed to volunteer in the research study. If you do not sign, it will not affect treatment, payment or enrollment in any health plans or affect eligibility for benefits.

Can you change your mind?

You may withdraw your permission for the use and disclosure of any of your and your child's protected information for research, but you must do so in writing to the Principal Investigator at the address on the first page. Even if you withdraw your permission, the Principal Investigator for the research study may still use you and your child's protected information that was already collected if that information is necessary to complete the study. Your and your child's health information may still be used or shared after you withdraw your authorization should you or your child have an adverse event (a bad effect) from being in the study. If you withdraw your permission to use your and your child's protected health information for research that means you and your child will also be withdrawn from the research study, but standard medical care and any other benefits to which you and your child is entitled will not be affected. You can also tell us you want to withdraw your and your child from the research study at any time without canceling the Authorization to use your child's data.

It is important for you to understand that once information is disclosed to others outside Mount Sinai, the information may be re-disclosed and will no longer be covered by the federal privacy protection regulations. However, even if information will no longer be protected by federal regulations, where possible, Mount Sinai has entered into agreements with those who will receive the information to continue to protect confidentiality.

If as part of this research project your or your child's medical records are being reviewed, or your or your child's medical history is being taken, it is possible that HIV-related information may be revealed to the researchers. If that is the case, the following information concerns you. If this research does not involve any review of medical records or questions about your child's medical history or conditions, then the following section may be ignored.

Notice Concerning HIV-Related Information

If you are authorizing the release of HIV-related information, you should be aware that the recipient(s) is (are) prohibited from re-disclosing any HIV-related information without your authorization unless permitted to do so under federal or state law. You also have a right to request a list of people who may receive or use your child's HIV-related information without authorization. If you or your child experience discrimination because of the release or disclosure of HIV-related information, you may contact the New York State Division of Human Rights at (888) 392-3644 or the New York City Commission on Human Rights at (212) 306-5070. These agencies are responsible for protecting your rights.

Certificate of Confidentiality: To further protect your and your child's privacy, the researcher obtained a Certificate of Confidentiality from the Department of Health and Human Service. Certificate does not mean that the Department of Health and Human Services approves research. Rather, it is intended to ensure that your and your child's identity as participants



Effective Date: 12/11/2020
End Date: 12/10/2021

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PERMISSION FORM FOR A CHILD TO PARTICIPATE IN A RESEARCH STUDY
AND AUTHORIZATION FOR USE AND DISCLOSURE OF MEDICAL INFORMATION
Icahn School of Medicine at Mount Sinai**

Page 14 of 15

Study ID #: HSM 12-00875

Form Version Date: 12/10/20

research study will not have to be disclosed as a result from a subpoena, for the purpose of identifying you in any federal, state, or local civil, criminal, administrative, legislative, or other proceedings other than to the FDA or OHRP as identified above. The research staff will not share any of your or your child's research information with anyone who is not a member of the research team, including any family members or friends, other than to those identified above. However, you should know that if we learn that your child or someone else is threatened with serious harm, such as a child or an elderly person being abused, the investigators may notify the appropriate authorities if necessary to protect your child or others. A Certificate of Confidentiality does not prevent you, your child, or a member of your family from voluntarily releasing information about your child or his/her involvement in this research. This means that you, your child and your family must also actively protect your child's privacy. If an insurer or employer learns about your child's research participation, and you agree that they can have your child's research information, then the researchers may not use the Certificate of Confidentiality to keep this information from them.



Effective Date: 12/11/2020
End Date: 12/10/2021

THE MOUNT SINAI HEALTH SYSTEM
PERMISSION FORM FOR A CHILD TO PARTICIPATE IN A RESEARCH STUDY
AND AUTHORIZATION FOR USE AND DISCLOSURE OF MEDICAL INFORMATION
Icahn School of Medicine at Mount Sinai

Page 15 of 15

Study ID #: HSM 12-00875

Form Version Date: 12/10/20

Signature Block for Research Involving Children

Your signature documents your permission for the child named below to take part in this research and to the use and disclosure of this child's protected health information. A signed and dated copy will be given to you.

<hr/> <div style="text-align: center;">Printed name of child</div>	<hr/> <div style="text-align: center;">Date</div>
<hr/> <div style="text-align: center;">Signature of parent or guardian</div>	<hr/>
<hr/> <div style="text-align: center;">Printed name of parent or guardian</div>	<div><input type="checkbox"/> Parent <input type="checkbox"/> Guardian (May provide permission only if legally authorized to consent to the child's general medical care.)</div>
<hr/> <div style="text-align: center;">Signature of second parent</div>	<hr/> <div style="text-align: center;">Date</div>
<hr/> <div style="text-align: center;">Printed name of second parent</div>	<hr/> <div style="text-align: center;">Time</div>

Note on Second Parent: If the IRB determined both parents must give permission unless an exception below applies, and if documented permission of the second parent of this child is not obtained, indicate the reason: (select one)

- | | |
|---|---|
| <input type="checkbox"/> Second parent is deceased | <input type="checkbox"/> Second parent is not reasonably available |
| <input type="checkbox"/> Second parent is unknown | <input type="checkbox"/> Only one parent has legal responsibility for the care and custody of the child |
| <input type="checkbox"/> Second parent is incompetent | |

Person Explaining Study and Obtaining Consent

<hr/> <div style="text-align: center;">Signature of person obtaining consent</div>	<hr/> <div style="text-align: center;">Date</div>
<hr/> <div style="text-align: center;">Printed name of person obtaining consent</div>	<hr/> <div style="text-align: center;">Time</div>

If a witness is required to observe the consent process, document below:

My signature below documents that the information in the consent document and any other written information was accurately explained to, and apparently understood by, the parent(s)/guardian, and that permission was freely given.

<hr/> <div style="text-align: center;">Signature of witness to consent process</div>	<hr/> <div style="text-align: center;">Date</div>
<hr/> <div style="text-align: center;">Printed name of person witnessing consent process</div>	<hr/> <div style="text-align: center;">Time</div>



Effective Date: 12/11/2020
End Date: 12/10/2021