
**Study ID #:** HSM 12-00875 **Form Version Date:** 10/24/19

## TITLE OF RESEARCH STUDY:

Title: Programming of Intergenerational Stress Mechanisms (PRISM Study)

## PRINCIPAL INVESTIGATOR (HEAD RESEARCHER) NAME AND CONTACT INFORMATION:

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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 to take part now and later change your mind. Whatever you decide is okay. It will not affect your 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 that might make you change your mind about 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. Genetic material (DNA) from your samples will be tested to determine which genes (the chemical structure that carries the information that determines your characteristics, such as height and eye color) and epigenetic changes (characteristics of the DNA molecule that don't affect the actual genetic code) are associated with environmental exposures during pregnancy. We will also test whether the genetic or epigenetic changes are related to your stress response (chemicals related to stress), your child's response to stress, and/or health outcomes in your child such as development of allergies or asthma.

The influence of the factors being studied (including stress, allergens and diet) begins during pregnancy, even before your child is born.

You may qualify to take part in this research study because you are pregnant.

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

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## LENGTH OF TIME AND NUMBER OF PEOPLE EXPECTED TO PARTICIPATE

Your participation in this research study is expected to last throughout your pregnancy and delivery, and until your child is about 30-36 months old. This means you could take part in this study for up to about 45 months (3 years and 9 months).

The number of people (both mothers and children) expected to take part in this research study at this site is 1500. The total number of people expected to take part in this research study is 2350.

## DESCRIPTION OF WHAT'S INVOLVED:

This form describes what you and your child will be asked to do if you agree to be in this research study.

Study staff will ask you to complete 3-4 visits while you are pregnant. After your child is born, we will see you and your child approximately every 6 months to a year until your child is about 3 years old. In addition, we will call you every 3-4 months after your child is born to ask more questions about how you and your child are doing.

All the activities are done for research purposes only. Visits will take place at the clinical or laboratory sites at Mount Sinai, at your home, or over the phone.

**Visit Summaries:** A short description of each visit is below. Questionnaires and samples are described in more detail after this section.

**Pregnancy visits:** 3-4 in total, including one at your home. You will complete questionnaires at each visit. We will collect urine, stool, and spot blood during your 2nd and 3rd trimesters; saliva, blood, hair, and dust once. From a subset of about 30 women, we will collect blood again late in pregnancy. From another subset of about 200 women, we will collect cervical cells once. From another subset of about 100 women, we will collect air from the home. Each visit will take about 45 minutes.

**Birth:** We will collect placenta, cord, and cord blood samples right after deliver and visit you in the hospital the next day to collect meconium (your child's first stool) from your baby**.**

**Child visits:** About every 6 months to a year. You will complete questionnaires at each visit. Other samples and activities will be:

- **1 month home visit:** We will collect breast milk from you, hair and stool from you and the baby, and nasal and cheek swabs and spot blood from your baby.
- **6 month lab visit:** We will ask you and your baby to complete tests measuring stress. We will watch how you interact with your infant, your parenting behaviors, and your infant's mood. During testing, we will place your infant in a car seat on a table 2 to 3 feet from you, and you will be seated facing your child at eye level. We will measure your and your infant's responses during testing by attaching 3 electrodes (sticky pads) and wearing a set of elastic bands with sensors built in that measure heart rate and rhythm as well breathing rate and volume (amount

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of air breathed in). We will set-up your system by asking you to do simple activities, such as breathing into and back out of a bag and breathing at different speeds.

You will complete a series of tests with your child in which you will play with your child for a few minutes. You will then hold a still face for a few minutes and not touch or talk to your child. You will then play with your child again. You will repeat this procedure of holding a still face and then playing with your child two times. The tests will be videotaped for later coding. We will remove the electrodes and bands at the end of these procedures. We will remove the equipment earlier if your infant appears unhappy or uncomfortable while wearing it, or if you ask us to remove the equipment from yourself or your infant at any time during testing.

During this visit, we will collect saliva from your infant before these tests start and every 15 minutes during testing, up to 5 times total. We will also collect hair, stool, nasal and cheek swabs from your child; and stool from you.

Also at this visit, we will look at your child's sucking by having him or her suck on a pacifier for about 5 minutes. This pacifier is attached to a machine that measures the pressure on the pacifier while your baby is sucking on it. This test can tell us a bit about the development of your baby's nervous system. For this test, we will use a silicone pacifier that is sold at various baby stores. Each baby will be tested with a new pacifier that is theirs to keep after the test is completed.

We will measure how long your baby watches objects, such as balls and cubes and/or pictures of patterns and faces on a computer screen. We do these tests to measure the baby's attention and memory, and their understanding of objects and things in the world.

These 2 procedures take about 50 minutes. If we cannot complete them at the 6 month visit, we will schedule another time for you and your baby to come to the lab to complete them.

This whole visit will take about 3 ½ hours.

Within 1 month before or after this visit, we will ask you collect saliva from your child at home 4 times a day on 2 different days. We will pick up the samples from your home or ask you to bring them in to the lab visit.

- **12-18 month visit:** We will do a series of play-based tasks with your child and measure your and your child's body. We will collect blood from your child's arm. If you or your child refuses, we will ask to collect spot blood. This visit will take about 2 hours and can be done in our lab or your home, whichever you prefer. If we cannot collect blood from your child's arm at this visit, we may try again a few months later, if you agree.
- **30 month home visit:** We will do a series of play-based tasks with your child and measure your and your child's body. We will collect blood from your child's arm. If you or your child refuses, we will ask to collect spot blood. We will also ask you to collect saliva from your child 4 times a day for 2 days. We will pick these samples up from you or ask you to bring them in to our lab at your next visit. We will collect oral and nasal swabs from your child and ask him or her to do a breathing test, which involves breathing into a facemask fitted over the nose and

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mouth. We will also collect a dust sample from your home. This visit will take about 2 ½ hours. If we cannot complete everything in one visit, we will schedule another visit, if you agree.

**Surveys/questionnaires**

At the first visit, we will ask information on sociodemographics (for example, what country you were born in and your race/ethnicity).

At every visit, you will answer questions about:

- how you are coping with many of life's daily stressors, such as challenges in parenting, emotions you have had, and your relationship with your child;
- your health and health behaviors, like diet and smoking;
- your child's health, development, behaviors, and emotions;
- where you live and the address of your child's school or day care, where he or she spends a lot of time.

Study staff will try to complete all questionnaires during your study visits. If it is not possible to complete them then, they will ask to call you to finish them over the phone or finish them at a later visit.

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.

**Sample Collection**

Study staff will collect samples (hair, urine, blood, saliva, stool, nasal swabs, cervical cells, dust, air) from you, your child, or your home (dust and air) so that they can look at markers of environmental factors, such as metals and chemicals, and markers of biological responses, such as changes in hormones, immune factors, or other proteins and molecules made in the body.

- Hair: We will cut a small amount of hair (about the diameter of a pencil eraser) close to your or your child's scalp from the back of the head in an area underneath so that it is not noticeable.
- Urine: We will give you instructions and collection kits to collect urine at home. We will contact you the day before by telephone to confirm your follow-up visit, and to remind you to collect the sample.
- Blood: We will collect blood from your and your child's arm. If possible, we will piggy back this on a scheduled clinical visit. We will collect about 5 teaspoons, or 25 ccs, during your 2nd trimester. In a subset of pregnant participants (about 30 in all), we will collect a blood sample (about 2 teaspoons or 10 ccs) at about 35-36 weeks, at the same time that you are having blood drawn for clinical care.

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- Spot Blood: We will also collect blood by pricking your finger and your child's heel or finger with a needle. We will then massage the finger or heel so that a few blood drops (less than 100 microliters, or 0.02 teaspoons) fall onto a blood filter paper sample card.
- Saliva: We will collect saliva from you and your child to test for stress hormones. We will ask you to drool into tubes we give you for this purpose. We will ask you for 5 samples a day (less than ½ of a teaspoon per sample) over 3 typical weekdays. Your child will chew or suck on a piece of cotton with Kool-Aid crystals on it, then the saliva will be squeezed out of it into small tubes. We will ask you to complete a diary that asks about your or your child's mood, activities, and sleep along with the saliva collections. We will show you how to collect the saliva when we give you the collection kit and give you written instructions.
- Stool: We will give you collection kits for you to collect stool from yourself and your baby. The samples will either be collected during a scheduled visit or at another time. If not at a visit, you can mail them back to us with a prepaid label, or our staff can pick them up from you. We will also ask you to complete a diary about your diet and medications.
- Birth samples: Immediately after you give birth, we will collect about four teaspoons of blood from the umbilical cord. After your placenta (the afterbirth) has been removed, a sample of the umbilical cord (about 2.5 inches) and four to six small pieces of the placenta will be taken. The placenta (including the cord and its contents) is usually discarded by the hospital.
- Breast milk: If you breast feed your baby, we will ask you to collect about 3 ounces of breast milk. We will give you a kit and instructions for collection. We will pick up the breast milk from you after the collection.
- Nasal and cheek swabs: We will collect cells from your child's mouth and nose. We will insert a small brush into your child's mouth and rub it against the cheek for 10 seconds. We will also insert two brushes, one at a time, into each of your child's nostrils and rub them against the inside of the nostril.
- Dust: Using a small vacuum cleaner, we will collect dust specimens from the bed(s) in which you and your child sleep and the bedroom floor, to look for substances which may cause allergies or asthma. We will also ask you some questions about the respiratory health of the members of your family and characteristics about your home. We will collect more dust using a dry cloth.
- Body measurements: Study staff will measure your child's height and weight, waist and hip circumference, skinfold thickness, and blood pressure. Using a special scale, we will measure your child's body mass. We will do the same body measurements on you.

**Medical Record Review:** We will also look at the medical records from the year before you became pregnant, during your pregnancy, and your child's birth. We will collect information that includes: your health before you became pregnant, including the results of basic laboratory tests results, vital signs, and environmental exposures; the outcomes of previous pregnancies; weight gain during this pregnancy; ultrasound results related to the baby's growth; how many weeks pregnant you were at

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the time of delivery; the baby's birth weight, length, head circumference, and health; and any complications of pregnancy (for example, gestational diabetes or high blood pressure). So that we can reach you for study visits, we will sometimes check your medical record to see if your contact information has changed. If there is a new address, phone number, or email address in your medical record, we will record it in our files.

**Storage of Samples and Data**

Your 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 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 information, along with that from many other people. Your name and other information that could directly identify you (such as address or social security number) will never be placed into a scientific database. However, because your genetic information is unique to you, there is a small chance that someone could trace it back to you. 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 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 identity will be removed.

**Videotaping**

At the lab visits, we will videotape you and your child. We will only use the videotapes for research purposes. 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

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video at any time. 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 can participate in. While you and/or 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 videotape. If you would like us to stop using the video at any time, you can call Dr. Wright.

Please initial "yes" or "no":

- ❑ I agree to have my child and me videotaped.
  Yes_____ No_____

## YOUR RESPONSIBILITIES IF YOU TAKE PART IN THIS RESEARCH:

If you decide to take part in this research study, we will ask you to complete study surveys and allow study staff to collect study samples.

## COSTS OR PAYMENTS THAT MAY RESULT FROM PARTICIPATION:

If you agree to take part in this research study, we will pay you a total of $340 for your time and effort if you complete all of the study visits and procedures up to and including your child's birth, and $570 if you and your child complete all the study visits and procedures after birth. If you do not complete all of the visits and procedures, we will still pay you for those visits you do complete. Your child will also receive toys or other gifts (for example, books, stuffed animals, stickers, play stethoscopes) for their participation.

<u>Pregnancy and birth (total up to $340)</u>

- $30 for each of 2 clinic visits
- $40 for the prenatal home visit, including dust collection
- $15 for each sample collection
  - Prenatal blood, if not piggy-backed on a clinical blood draw. We will also include your name in a raffle with other subjects for a chance to win $150.
  - 2nd trimester spot blood
  - 2nd trimester urine
  - 2nd trimester stool
  - Each of 3 days of saliva collection ($45 in all). We will also include your name in a raffle with other subjects for a chance to win $150.
  - Hair
  - 3rd trimester spot blood

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- 3rd trimester urine
- 3rd trimester stool

- $75 for birth samples

Child visits (total up to $570)

- $40 for the one month home visit
- $100 for the 6 month lab visit
- $15 for the 6 month attention task
- $10 and a pacifier for the 6 month sucking test
- $40 for the 12-18 month visit
- $50 for the 30 month visit, including dust collection
- $15 for each sample collected
  - Meconium, and a pack of diapers
  - 1 month child cheek and nasal swabs
  - 1 month adult stool
  - 1 month child stool, and a pack of diapers
  - 1 month adult hair
  - 1 month child hair
  - 1 month child spot blood
  - Breast milk. We will also include your name in a raffle with other subjects for a chance to win $150.
  - 6 month cheek and nasal swabs
  - 6 month adult stool
  - 6 month child stool, and a pack of diapers
  - 6 month hair
  - Each of 3 days (1 in lab, 2 at home) of child saliva collection at 6 months ($45 in all)
  - Blood from your child's arm at 12-18 months
  - Spot blood at 12-18 months
  - Blood from your child's arm at 30 months
  - Spot blood at 30 months
  - Each of 2 days of child saliva collection at 30 months ($30 in all)

Payments will be made in cash at the end of each study visit. If it is necessary to mail you payment for study participation, we will mail you a gift card in the amount due to you.

*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*

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*from Mount Sinai in a calendar year. You would be responsible for the payment of any tax that may be due.*

## POSSIBLE BENEFITS:

You 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. For this reason, we always collect blood samples when you or your child is sitting down.

The nasal swab may tickle or slightly irritate your child's nose. There is a possibility that you or your child will become physically uncomfortable wearing the bands during the 6 month visit. If you or your child are too uncomfortable to continue, you may remove the bands. Your child should feel no difference between sucking on the pacifier while it is attached to the machine versus a regular pacifier. The machine is grounded, so there is no danger of the baby getting an electric shock.

*Psychological risks:* Answering the questionnaires may be upsetting, as it may involve remembering and disclosing sensitive information about personal experiences. After the interview when we ask you questions about such experiences, we will give you a listing of available community legal and social service resources that you may find useful for yourself and/or your child if either of you have been victimized by violence in your community.

Your child may become upset and may cry when you hold a still face. You may find it upsetting to see your child upset. We will stop the procedure if your child becomes distressed. You can also stop the procedure or withdraw from the study at any time.

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 your child will be confidential and will be available only to the study staff. Information about your and your child's identity and links to your and your child's individual information will be kept in locked cabinets or securely stored electronically, only accessible to the study staff who will need to contact you for follow-up and analysis. Even with these precautions, we still cannot guarantee absolute confidentiality.

Your name and other information that could directly identify you (such as address or social security number) will never be placed into a scientific database. However, because your genetic information is unique to you, there is a small chance that someone could trace it back to you. The risk of this happening is very small, but may grow in the future. Since the database includes genetic information,

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a break in security may also pose a potential risk to blood relatives as well as yourself. For example, it could be used to make it harder for you (or a relative) to get or keep a job or insurance. If your private information was misused, it is possible you would also experience other harms, such as stress, anxiety, stigmatization, or embarrassment from revealing information about your family relationships, ethnic heritage, or health conditions.

Group Risks: Although we will not give researchers your name, we will give them basic information such as your race, ethnic group, and sex. This information helps researchers learn whether the factors that lead to health problems are the same in different groups of people. It is possible that such findings could one day help people of the same race, ethnic group, or sex as you. However, they could also be used to support harmful stereotypes or even promote discrimination.

There is a Federal law called the Genetic Information Nondiscrimination Act (GINA). In general, this law makes it illegal for health insurance companies, group health plans, and most large employers to discriminate against you based on your genetic information. However, it does not protect you against discrimination by companies that sell life insurance, disability insurance, or long-term care insurance.

## 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 have 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 stop taking part in this research study at any time without any penalty. This will not affect your ability to receive medical care at any of the Mount Sinai Health System hospitals or to receive any benefits to which you are otherwise entitled.

If you decide to stop being in the research study, please contact the Principal Investigator or the research staff.

If you stop being 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 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.

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You may also withdraw your permission for the use and disclosure of any of your 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 the information that was already collected if that information is necessary to complete the research study. Your health information may still be used or shared after you withdraw your authorization if you have an adverse event (a bad effect) from participating in the research study.

If you agreed to the optional collection and retention of your 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 specimen(s) destroyed, any data or analysis that was done before your request will not be removed from the study; however, all of your remaining specimen(s) will be destroyed, and no additional analysis will be done with your specimen(s). You may still participate in the main study even if you decide to have your optional specimen(s) destroyed.

Withdrawal without your consent: The study doctor, the sponsor or the institution may stop your involvement in this research study at any time without your consent. 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 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 consent.

## 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, 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 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 your rights as a research subject.
- You want to get information or provide input about this research.

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## 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 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, admission and discharge dates for the birth of your child, medical records number.

The researchers will also get information from your medical record from The Mount Sinai Hospital, your private doctor, and your child's private doctor.

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 protected health information being used?

Your personal contact information is important to be able to contact you during the study. Your health information and the results of any tests and procedures being collected as part of this research study will be used for the purpose of this study as explained earlier 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 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 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 information. If you receive any payments for taking part in this study, the Mount Sinai Finance Department may need your name, address, social security number, payment amount, and related information for tax

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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 protected health information?

As part of the study, the Principal Investigator, study team and others in the Mount Sinai workforce may disclose your 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: University of Chicago, Beth Israel Deaconess Medical Center, University of Cincinnati
- 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: the 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 will not be identified by name, social security number, address, telephone number, 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 of Human Subjects Protection (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 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 protected health information?

Your authorization for use of your protected health information for this specific study does not expire.

*Throughout this document “child” refers to a minor under applicable state law and “you” refers to any individual who may legally act on the minor’s behalf (e.g. parent or legal guardian)

Will you be able to access your records?

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

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

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

Can you change your mind?

You may withdraw your permission for the use and disclosure of any of your 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 your protected information that was already collected if that information is necessary to complete the study. Your health information may still be used or shared after you withdraw your authorization if you should have an adverse event (a bad effect) from being in the study. If you withdraw your permission to use your protected health information for research that means you will also be withdrawn from the research study, but standard medical care and any other benefits to which you are entitled will not be affected. You can also tell us you want to withdraw from the research study at any time without canceling the Authorization to use your 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 your information will no longer be protected by federal regulations, where possible, Mount Sinai has entered into agreements with those who will receive your information to continue to protect your confidentiality.

Genetic Information

Any further disclosure of genetic test results to persons or organizations not named on the informed consent shall only be done with your informed consent. Your family members will not be contacted for clinical, research, or other purposes without your consent. Information about you derived from genetic tests will not be released to anyone else without your explicit written consent.

If as part of this research project your medical records are being reviewed, or a 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 medical history or conditions, then the following section may be ignored.

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## 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 HIV-related information without authorization. If you 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 privacy, the researchers have obtained a Certificate of Confidentiality from the Department of Health and Human Services. This Certificate does not mean that the Department of Health and Human Services approves of this research. Rather, it is intended to ensure that your identity as a participant in this 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 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 you 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 you or others. 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. This means that you and your family must also actively protect your own privacy. If an insurer or employer learns about your research participation, and you agree that they can have your research information, then the researchers may not use the Certificate of Confidentiality to keep this information from them.

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**Study ID #:** HSM 12-00875 **Form Version Date:** 10/24/19

## Signature Block for Capable Adult

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

**DO NOT SIGN THIS FORM AFTER THIS DATE →** **12/10/2020**

| | |
|---|---|
| Signature of subject | Date |
| Printed name of subject | |

## Person Explaining Study and Obtaining Consent

| | |
|---|---|
| Signature of person obtaining consent | Date |
| Printed name of person obtaining consent | |

***Witness Section: For use when a witness is required to observe the consent process,, document below (for example, subject is illiterate or visually impaired, or this accompanies a short form consent):***

*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 subject, and that consent was freely given by the subject.*

| | |
|---|---|
| *Signature of witness to consent process* | *Date* |
| *Printed name of person witnessing consent process* | |

*Throughout this document "child" refers to a minor under applicable state law and "you" refers to any individual who may legally act on the minor's behalf (e.g. parent or legal guardian)