STUDY INFORMATION

Study Title: Longitudinal neuroimaging and neurocognitive assessment of risk and protective factors across the schizophrenia spectrum

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SUMMARY OF THIS RESEARCH STUDY

A research study is when scientists try to answer a question about something that we don't know enough about. Participation in a research study may or may not directly help you or others. Participation is entirely voluntary. It is completely up to you whether or not you take part. You can change your mind at any time and it will not affect your ability to get medical care within the Mount Sinai Health System.

The purpose of this research study is to look at how brain structure and function differ across a continuum of individuals, from individuals without mental illness to those with schizophrenia spectrum disorders. Using non-invasive brain imaging and cognitive tests, the investigators seek to determine if there are factors associated with risk and resilience to schizophrenia spectrum disorders.

If you choose to participate, you will be asked to complete:

- Interviews
- Questionnaires
- Cognitive tests
- Medical evaluation
- MRI brain scans
- Urine tests
- Blood draws (please note your blood sample will be frozen and stored for use in future research)

Many of these procedures will be repeated at follow-up appointments at 9 months and 18 months from your baseline assessment. In total, your participation will take approximately 2 days over the course of 4 visits. You will be compensated for your time and transportation by check. Additionally, we will provide roundtrip car service to Mount Sinai for your MRI scan appointments. Car service will not be provided for other appointments.

Potential risks to you if you choose to participate are feeling distressed or bored during psychological interviews and tests, feeling anxious or claustrophobic while inside the MRI scanner, and feeling pain during the blood draws. You may benefit from participation in this research if you learn something about your health through the medical and psychiatric evaluations and MRI scan.

If you are interested in learning more about this study, please continue to read below.

PARTICIPATION IN THIS RESEARCH STUDY

This research study will be fully explained to you by a member of the study team. Feel free to ask questions before you make a decision about whether or not to participate. Any new information that develops during this research study that might make you change your mind about participating will be given to you promptly.

You may qualify to take part in this research study because you are medically and neurologically healthy, and fall into one of the following three categories:

1) You meet diagnostic criteria for schizophrenia or schizoaffective disorder, and your illness began within the past 2 years
2) You meet diagnostic criteria for schizotypal personality disorder
3) You are a healthy control, meaning you have no lifetime or current history of serious mental illness

Funds for conducting this research are provided by the National Institutes of Health (NIH).

LENGTH OF TIME AND NUMBER OF PEOPLE EXPECTED TO PARTICIPATE

Your participation in this research study is expected to last approximately 8 hours at the time of enrollment, 4 hours at the 9-month follow-up, and 6 hours at the 18-month follow-up.

The number of people expected to complete this research study at the Icahn School of Medicine at Mount Sinai is 240. We will likely enroll 500 people into the study.

DESCRIPTION OF WHAT'S INVOLVED

If you agree to participate in this research study, the following information describes what may be involved.

This study will take place at Mount Sinai Hospital. The majority of visits will take place at the Mt. Sinai Cognitive Psychophysiology Laboratory, located at 1399 Park Ave, 1-105C. The brain/magnetic resonance imaging (MRI) scans and blood draws will take place a 5-minute walk away, on the second floor of the Translational and Molecular Imaging Institute (TMII) on 102nd St. and Madison Ave.

- The study involves four visits: two visits at the time of enrollment (for a total of 8 hours), one visit 9 months later (4 hours), and one visit 18 months later (6 hours). We will work with you to find a convenient visit schedule. Visits will involve the following procedures:

Diagnostic Interview: This involves an interview during which you will be asked a wide range of questions about your mental health to determine whether you fall into one of our three categories of participants. This usually takes 2 hours.

Clinical Assessments: These interviews ask more targeted questions about your mental health. You will also be asked to complete questionnaires about your mental health. This usually takes 3 hours.

Audio Recording: We record part of the clinical assessments for the purposes of this study. The recording will consist only of your voice with no other identifying information.

Cognitive Tests: This involves questions and computerized tests that look like games that help us assess your thinking process such as your reaction time, memory and vocabulary. This usually takes 2 hours.

MRI Scan: This study involves two brain/MRI scans using a magnetic resonance scanner. The MRI scan will take approximately 1 hour. Prior to an MRI scan you will have a medical evaluation. This includes urine toxicology and pregnancy (if female) tests.

Blood Draw and Urine Screen: You will provide us with a ~5 teaspoon blood sample at each visit to the MRI facilities. A nurse at the *Translational and Molecular Imaging Institute (TMII) w*ill perform the blood draws, which takes 10 minutes. The blood will be stored indefinitely for future research use and may be used for genetic research studies. On each MRI visit day, you will also provide a ~3 tablespoon urine sample that will be used to determine if you are using drugs of abuse.

COVID-19 Modifications:

During the COVID-19 pandemic, some of the study will be conducted remotely to minimize the amount of in-person visits. The initial remote visit consisting of interviews and assessments will be completed by trained research staff through online telehealth video platforms such as HIPAA-compliant Zoom.

When you do come in to the Mt. Sinai Cognitive Psychophysiology Laboratory for in-person appointments, there will be safety precautions in place. When arriving for your appointment at 1399 Park Avenue, you will be using a “virtual” waiting room. You will call 212-535-0847 to let us know you have arrived for your appointment and one of our research staff will meet you outside to escort you into the facility. Prior to entry, you will be assessed for respiratory symptoms and fever. If fever of 99.9F or greater and/or respiratory symptoms are present, you will be advised to seek medical treatment and be rescheduled. If none of these symptoms are present, you will be provided with a mask that you are required to wear during your appointment and will be asked to sanitize your hands upon entry into the facility. We ask that you do not touch any doors or handles while entering. If you must do so, you will be provided gloves that will be thrown away in hands-free garbage. While in the building for the baseline and follow-up testing sessions, we will use social distancing. You will complete the computerized tests in a spacious conference room. Clorox wipes will be used to wipe down the laptop computer, all testing materials, and the table and chair you will be seated in.

The frequency and duration of procedures is further outlined in the table below:

Time Point	Diagnostic Interview	Clinical Assessments	Cognitive Tests	MRI Scan	Urine Screen	Blood Draw	Total

Baseline	2 hours	3 hours	2 hours	1 hour	5 minutes	10 minutes	~8 hours
9 months	--	2 hours	2 hours	--		--	~4 hours
18 months	--	3 hours	2 hours	1 hour	5 minutes	10 minutes	~6 hours

A radiologist will read your MRI scan. There is a small likelihood that the scan will reveal a previously undiagnosed finding. In this case, you will be notified by our study physician and referred for appropriate follow-up care. In between each visit, one of the research assistants will contact you by phone or email to ensure that we have up to date contact details. Throughout the research study you will interact with research assistants, psychologists, MRI technicians, and medical staff. Your visits will be complete after 18 months, but please note that the material collected will be used indefinitely.

USE OF YOUR DATA AND/OR SPECIMENS

In the future, your identifiable information will be removed from the private information and/or samples that are collected as part of this research. After this removal, the information and/or samples will be used for future research studies or shared with other research teams for future research studies. You will not be informed of the details of specific research that is done with your medical information and biospecimens. That means that a research project might be done that you would not consent to if provided with the details of that research project. If you agree to take part in this study, your deidentified data will be used for future research studies at the Icahn School of Medicine at Mount Sinai and at other facilities. Deidentified information means that all personal identifiers (meaning personal information such as name, address, and phone number) are removed and replaced with a code number. In addition, we may contact you in the future to discuss the possibility of participating in other research studies.

To do more powerful research, it is helpful for researchers to combine data with other studies by putting it into one or more scientific databases, where it is stored along with information from other studies. A data repository is a large database where information from many studies is stored and managed. 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 will be placed into one or more scientific databases for future research. There are many different kinds of scientific databases; some are maintained by Icahn School of Medicine at Mount Sinai or another institution, some are maintained by the federal government (see next paragraph), and some are maintained by private companies. A researcher who wants to study the information must apply for permission to use 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.

Data from this study will be submitted to the National Institute of Mental Health Data Archive (NDA). NDA is a data repository that allows researchers studying mental illness to collect and share deidentified information with each other. During and after the study, the researchers will send

deidentified information (i.e., without personal identifiers) about your health and behavior to the NDA using a study specific electronic portal. Other researchers nationwide can then file an application with the NIMH to obtain access to your deidentified (i.e., without personal identifiers) study data for research purposes. Data stored in the NDA repository can be used for any future unspecified research including non-medical topics.

You may decide later that you do not want to share your information. If so, contact the researchers who conducted this study, and they will stop using this information and also tell NDA to stop sharing the research information. However, information that was shared before you changed your mind cannot be taken back. If you would like more information about NDA, this is available on-line at https://nda.nih.gov/.

YOUR RESPONSIBILITIES IF YOU TAKE PART IN THIS RESEARCH

If you decide to take part in this research study you will be responsible for the following things:

1) Attending 3-4 visits over an 18-month period and allowing contact during this time
2) Answering questions about your personal health and doing cognitive tests at each visit
3) Having two brain/MRI scans, 18 months apart
4) Having two blood draws, 18 months apart
5) Agree for deidentified data (i.e. data that can be used to identify you such as name, date of birth, address, phone number that has been removed) to be used for future research and to be deposited in the National Institute of Mental Health Data Archive.
6) Having access to a computer, wifi, and a private quiet space for the initial telehealth visit during Covid-19 procedures

COSTS OR PAYMENTS THAT MAY RESULT FROM PARTICIPATION

If you agree to take part in this research study, we will pay you for your time and effort, up to $300 for your initial visit, $100 after your 9-month visit, and $250 after your 18-month visit. In addition, if you complete all 3 study timepoints you will be eligible to earn an additional $100. Payments will be provided by check after the completion of each time point (i.e. three separate checks: one for the baseline, 9-month, and 18-month visit). You will only be paid for procedures that you complete, the details of which are outlined below:

Time Point	Diagnostic Interview	Clinical Assessments	Cognitive Tests	MRI Scan/ Urine Screen	Blood Draw	Total
Baseline visit	$50	$75	$50	$100	$25	$300
9-month visit	Review	$50	$50	--	--	$100

18-month visit	Review	$75	$50	$100	$25	$250
Completion bonus (all visits and assessments)	--	--	--	--	--	$100

Please note we will share your personal information with the Mount Sinai Finance Department so they can write your checks. Checks require some time to be prepared and will be given to you once processed and available. 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 will be responsible for the payment of any tax that may be due.

POSSIBLE BENEFITS

It is important to know that you may not get any benefit from taking part in this research. However, possible benefits may be that brain-imaging procedures reveal a previously undiagnosed condition. You will be notified and referred for appropriate follow-up care if clinically indicated and in collaboration with the study physician. You may also receive a copy of your MRI report. Additionally, your clinical assessment may reveal a previously-undiagnosed psychiatric condition. Lastly, your participation may benefit future individuals with schizophrenia spectrum disorders, e.g., informing treatment strategies.

REASONABLY FORESEEABLE RISKS AND DISCOMFORTS

Risks of clinical assessments: During clinical interviews and surveys, you will be asked personal questions. Participants sometimes find this uncomfortable, and occasionally become emotionally distressed. You may stop and/or postpone the assessment if needed. The audio recording will consist only of your voice with no other identifying information; however, you could be identified by your voice in the audio recording. The data from your assessment that is contained in a research folder will be entered into an electronic database. The electronic database will be password protected and stored on Mt. Sinai computers on the Mt. Sinai network.

Risks of cognitive assessments: Sometimes participants find cognitive testing to be boring or tedious and may become distressed. There are breaks during the testing session to minimize these potential risks. You may stop and/or postpone the assessment if needed.

Risks of MRI scans: No short-term risks have been reported for MRI; longer-term risks are under evaluation. There are no known risks to pregnancy by having an MRI, but we are being overly cautious and excluding women who are pregnant. If you think you are pregnant you should not have the MRI scan. No sedation will be used for the MRI. Because MRI uses harmless radio waves and magnetization

instead of x-rays, it is considered safer than other radiological techniques that do use x-rays. It may be uncomfortable to lie motionless in the scanner and some people may feel anxious because of this. Some people may have a claustrophobic reaction in the MRI scanner. You will be accompanied to the MRI scan by the study's clinical research assistant, who is specially trained to provide support and reassurance to reduce anxiety. The assistant will talk to you via the intercom to provide reassurance. If you cannot tolerate the MRI, it will be discontinued immediately. Lastly, because the scanner uses a large magnet, there are medical risks if you have metal in your body or a heart pacemaker, so you will be screened to determine whether it is safe for you to enter the MRI environment.

Risks of blood draw: 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.

Risk of loss of private information: The risk of loss of private information always exists, but there are procedures and safeguards in place to minimize the risk.

Legal risk: You may interact with a professional who is a mandatory reporter of child abuse and neglect, so there is a risk of being reported for child abuse or neglect if you disclose this information.

Risks of Data Sharing:

Group Risks: Although we will not give other 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.

Privacy Risks: Your name and other information that could directly identify you (such as address, date of birth 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. Because the database may include genetic information, 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.

Insurance Risks: 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 employers of over 15 people 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 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, Dr. Erin Hazlett.

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 decide you don't want your data to be used for research anymore, you must contact the Principal Investigator in writing (Erin Hazlett, PhD, Department of Psychiatry, One Gustave L. Levy Place, Box 1230 New York, NY 20019) and ask to have your data removed from future use. If any data have already been shared without your identity, it won't be possible to retrieve them because no one will know who you are. Data that have already been used will not be affected by your decision. Any data that are still linked to your identity by a code the researcher has will be withdrawn so that no future sharing of your data will take place.

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 data and specimens have been stored as part of the research study, they too can be destroyed without your consent.

CONTACT INFORMATION

If you have any questions, concerns, or complaints at any time about this research, or you think the research has harmed you, please contact the office of the research team and/or the Principal Investigator, Dr. Erin Hazlett at phone number (212) 241-0442 or at the VA Hospital: (718) 584-9000 x3701 or x5869.

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.

DISCLOSURE OF FINANCIAL INTERESTS

Sometimes, 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 be shared with others?

As part of this research project, the research team at the hospital(s) involved in the research will collect your name, date of birth, SSN, address, telephone number, and email. The medical records number will be recorded only if you receive medical care at the Mount Sinai Campus. During the study the researchers will gather information by:

- Taking a medical history (includes current and past medications or therapies, illnesses, conditions or symptoms, family medical history, allergies, etc.)
- Completing the tests, procedures, questionnaires and interviews explained in the description section of this consent.
- Reviewing mental health records but only if held on the EPIC system at the Mount Sinai Health System; the aim of reviewing your records is to confirm and supplement information supplied during the interviews with regards to psychiatric care and medication.

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 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).

- 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 Institute of Health (NIH)
- The United States Department of Health and Human Services and the Office of Human Research Protection.

In 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 unless disclosure of the direct identifier is required by law. 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. 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.

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.

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.

If you have not already received it, you will also be given The Hospital's Notice of Privacy Practices that contains more information about how The Hospital uses and discloses your protected health information.

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.

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.

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.

ADULT PARTICIPANT:

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.

_____	_____	_____
Signature of Subject	Printed Name of Subject	Date

PERSON EXPLAINING STUDY AND OBTAINING CONSENT:

_____	_____	_____
Signature of Consent Delegate	Printed Name of Consent Delegate	Date