Official Title:	A 12-week Randomized, Double-blind, Placebo-controlled Trial Investigating the Effects of Levetiracetam in Early Psychosis
NCT Number:	NCT04317807
Study Number:	19-01820
Document Type:	Informed Consent Form
Date of the Document:	• March 19, 2024

Research Subject Informed Consent Form

Title of Study:	A 12-week randomized, double-blind, placebo-controlled trial investigating the effects of Levetiracetam in early psychosis i19-01820
Principal Investigator:	Donald C. Goff, MD Psychiatry NYU Langone Medical Center 1 Park Avenue, 8-212 646-754-4843
Emergency Contact:	Donald C. Goff, MD Psychiatry NYU Langone Medical Center 1 Park Avenue, 8-212 646-754-4843

1. About volunteering for this research study

You are being invited to take part in a research study. Your participation is voluntary which means you can choose whether or not you want to take part in this study.

People who agree to take part in research studies are called “subjects” or “research subjects”. These words are used throughout this consent form. Before you can make your decision, you will need to know what the study is about, the possible risks and benefits of being in this study, and what you will have to do in this study. You may also decide to discuss this study and this form with your family, friends, or doctor. If you have any questions about the study or about this form, please ask us. If you decide to take part in this study, you must sign this form. We will give you a copy of this form signed by you for you to keep.

Some of the people who may be able to take part in this study may not be able to give consent because they are under 18 years of age (a minor). Instead, we will ask their parent(s) or legal guardian to give consent. We will also ask the minor to agree (give their assent) to take part in the study. They will be given an Assent Form to sign. Throughout the consent form, “you” always refers to the “subject” or person who takes part in the study.

2. What is the purpose of this study?

The purpose of this study is to determine whether adding levetiracetam to usual medication treatment improves outcomes in early psychosis by protecting a part of the brain known as the hippocampus.

Levetiracetam is approved by the U.S. Food and Drug Administration (FDA) for use in epilepsy. The FDA has not approved levetiracetam for use in people with early psychosis. Therefore, it is considered investigational in this study.

Levetiracetam (brand name, Keppra) is a treatment for epilepsy and works by reducing excessive brain activity that causes epilepsy. We are testing the hypothesis that excessive brain activity may also contribute to psychosis and might be normalized by levetiracetam.

This research study will compare levetiracetam to placebo. Participants in the study will be randomly assigned to take either 500 mg of levetiracetam or placebo (sugar pill) 2 times a day for 12 weeks. After

12 weeks, the dose of the study medication will be gradually reduced and stopped over 9 days. The placebo pill looks just like the levetiracetam pill, but does not contain levetiracetam. This medication will be taken along with your currently prescribed antipsychotic medication(s). The research team will not determine which antipsychotic medication you will be prescribed.

You are being asked to participate in this study because you have been identified as someone experiencing early psychosis.

3. How long will I be in the study? How many other people will be in the study?

We plan to enroll a total of 28 participants. The study will last 14 weeks and will require 9 visits.

4. What will I be asked to do in the study?

If you choose to take part in this study, you will be asked to sign this consent form before any study procedures are performed.

At the first visit (Screening) we will check to see whether you are a good fit for the study; if you qualify for participation, you will return for the Baseline visit and be started on the study drug (placebo or levetiracetam), and return once weekly for 4 weeks to see how you are responding to the treatment. The screening visit may be combined with the first visit (baseline visit) or they may be completed separately.

After completing the first 4 weekly visits, you will be asked to come in for four more visits at weeks 6, 8, and 12. After the Week 12 visit, the study medicine will then be decreased and stopped over the next 9 days. After this, you will be asked to come in for one final visit. During these visits you will meet with a study psychiatrist or nurse practitioner, or with a member of the research team who will ask questions about how you are responding to treatment. If you are receiving treatment within the hospital on an inpatient unit, visits will be conducted on the unit according to the study schedule until you leave the hospital. After leaving the hospital the rest of the study visits will be conducted in the offices of the research staff.

You also have the option to participate in an optional brain scan performed at the Baseline and Week 12 visits to help us understand how the treatment is affecting your brain. Additionally, you could choose to take an optional cognitive assessment at the Baseline and Week 12 visits, as well as half way through (Week 6).

The visits and procedures are described in more detail below.

Visit 1: Screening (2 hours)

During the first study visit, called the Screening Visit, we will:

- Have the study doctor or the nurse practitioner examine you and collect information to see if you qualify to participate in this study.
- Review and record your medical and psychiatric history as well as the medications you are taking (including over-the-counter medications, vitamins, and supplements)
- Collect demographic information (age, gender, education level)
- Conduct a physical exam
- Collect urine specimens for clinical laboratory assessments and drug screen, as well as cannabis-use information
- Collect a blood sample for clinical laboratory assessments
- Measure your vital signs (blood pressure, heart rate, oral temperature)
- If you are assigned female at birth, we will test your urine for pregnancy

- Ask you to complete a series of questionnaires and interviews about your symptoms and how they affect your life.
- You will be asked if you have had any thoughts about hurting yourself or thoughts about trying to take your life. You will also be asked if you have engaged in self-injurious behaviors or have attempted to take your life.

Visit 2: Baseline (5 to 9 hours)
If you are eligible to continue in the study, during the baseline visit you will:

- Complete a series of questionnaires and interviews about your symptoms and how they affect your life.
- You have the option to complete cognitive testing which can also be delayed until later in the week.
- You have the option to complete a 30-minute brain imaging scan which measures blood flow and brain volume. The imaging can also be delayed until later in the week.
- Have a blood sample collected for biomarkers
- Receive study medication for the week.
- You will be observed for 3 hours after the administration of the first dose of levetiracetam.

Visit 3: Week 2 (1 hour)

- Complete a brief series of psychiatric questionnaires about your symptoms and meet with a study doctor or nurse practitioner to discuss any changes since your last study visit.
- Receive study medication for the week.

Visit 4: Week 3 (1 hour)

- Complete a brief series of psychiatric questionnaires about your symptoms and meet with a study doctor or nurse practitioner to discuss any changes since your last study visit.
- Receive study medication for the week.

Visit 5: Week 4 (1 hour)

- Complete a brief series of psychiatric questionnaires about your symptoms and meet with a study doctor or nurse practitioner to discuss any changes since your last study visit.
- Receive study medication for the next two weeks.

Visit 6: Week 6 (2-4 hours)

- Complete a longer series of questionnaires and interviews about your symptoms and how they affect your life.
- Obtain a blood sample for biomarkers and Levetiracetam levels
- Complete cognitive testing (optional)
- Receive study medication for the next two weeks.

Visit 7: Week 8 (1 hour)

- Complete a brief series of psychiatric questionnaires about your symptoms and meet with a study doctor or nurse practitioner to discuss any changes since your last study visit.
- Receive study medication for the next 4 weeks.

Visit 8: Week 12 (2-7 hours)

- Complete a longer series of questionnaires and interviews about your symptoms and how they affect your life.
- Obtain a blood sample for biomarkers and Levetiracetam levels
- Complete cognitive testing (optional)

- You may be asked to complete an optional 15-30-minute brain imaging scan to measure blood flow and brain volume.
- Receive a pill organizer containing decreasing doses of study drug to be taken over 9 days

Visit 9: Week 14 (1 hour)
Final check-in for safety after completion of final dose of medication—psychological and physical status will be reviewed.

Follow-up Phone Calls
After you complete the baseline visit, we will call you on the phone (if you are an outpatient) or will assess you in person (if you are in the hospital) daily for the following 5 days. The research team will ask if you have experienced any health problems or changes since you started the medication.
We will also reach out to you by phone during weeks 5, 7, 9, 10 and 11 to see if you have experienced any health problems or changes.

Medication Tapering
At the end of the study, we will slowly decrease the dose of medication over 9 days. This is to decrease the risk of seizure, which is associated with abruptly stopping this medication. The study staff will provide a pill organizer that contains pills arranged by each day to be taken over these 9 days and instructions for how to do so.

If you decide to withdraw from the study early, you will be asked to return for one final clinical assessment and to receive the medication supply that allows you to gradually reduce the dose.

Urine Drug Screen
During this study, we will test your urine for certain drugs, including illegal drugs, e.g., cocaine, barbiturates. If the test results show you have taken any of these drugs, it will be up to the study doctor or the psychiatric-mental health nurse practitioner to decide if you can continue to take part in the study. The results of the urine drug test will become part of your medical record. If your drug screen is positive for marijuana, you will be asked to abstain from smoking or consuming marijuana for 72 hours prior to the imaging scan.

Study Drug (Levetiracetam or Placebo)
If you complete this study, you will receive either levetiracetam (500 mg) or placebo. Two out of three or approximately 67% of participants will receive levetiracetam and one out of three or about 33% of participants will receive placebo. During the study, you, your doctor, and the study staff will not know whether you are receiving levetiracetam or placebo but if it becomes necessary for your safety your study doctor can learn which you are receiving.

MRI Scan
Participating in MRI imaging at the beginning and end of the study is optional. The MRI (which stands for magnetic resonance imaging) camera will take pictures of your brain. The brain imaging can last between 30-60 minutes and will measure the volume of your brain and blood flow. The MRI does not involve any radioactivity. Magnet waves are used to obtain pictures of internal parts of the body (in this case, the brain) by using a large magnet.

Before starting the test, you will be asked to remove any metal or magnetized objects (like keys or credit cards). You will then be asked to lie still on a table inside the MRI camera, which looks like a cylinder or a tunnel. Your head will be supported by foam cushions to reduce the motion. You will lie on a table that slides into the magnet so that your body is inside the camera from your head to your knees.

Once you are in the scanner you will not be able to see outside, but you will be able to hear us and we will hear you if you wish to say anything. The operator will watch you via a closed-circuit camera. You will hear a loud banging noise when the camera is taking pictures of your brain. You will be given foam earplugs to help reduce the noise. If you have metallic objects within your body, you are not eligible for this part of the study, since this would prevent you from entering the MRI. We will let you know if you are eligible to do the brain scan or not. The MRI scan will be done at the NYU Center for Biomedical Imaging (at 660 1st Avenue) or the NYU CBI (at Washington Square). You will be compensated for completing each of these MRI scans.

5. What are the possible risks or discomforts?

Risks of taking Levetiracetam

Side effects in Adults

The most common side effects seen in adults who take levetiracetam include:
- Drowsiness*
- Weakness* or fatigue
- Dizziness
- Infection

* Drowsiness and weakness may occur most frequently within the first 4 weeks of treatment

Additional side effects with levetiracetam are usually mild and include:
- Headache
- Mood and behavior changes such as:
  - Anger, hostility or irritability
  - Anxiety
  - Apathy or lack of interest or motivation
  - Agitation or aggression
  - Depression
  - Mood swings
- Memory loss or confusion
- Nausea or vomiting
- Abdominal pain
- Anorexia
- Pharyngitis (sore throat)
- Paresthesia (burning or prickling sensation)
- Problems with muscle coordination (problems walking and moving)

Uncommon but potentially serious side effects that occur in less than 1% of patients include:
- Suicidality
- Psychosis
- Leukopenia
- Serious dermatologic (skin) reactions

Side effects in Children

The most common side effects seen in children who take levetiracetam include:
- Drowsiness*
- Weakness* or fatigue

- Dizziness
- Infection
- Irritability
- Hostility
- Acting aggressive
- Decreased appetite
- Nasal congestion

* Drowsiness and weakness may occur most frequently within the first 4 weeks of treatment

Additional side effects with levetiracetam are usually mild and include:

- Headache
- Mood and behavior changes such as:
  - Anger
  - Anxiety
  - Apathy or lack of interest or motivation
  - Agitation or aggression
  - Depression
  - Mood swings
- Memory loss or confusion
- Nausea or vomiting
- Abdominal pain
- Anorexia
- Pharyngitis (sore throat)
- Paresthesia (burning or prickling sensation)
- Problems with muscle coordination (problems walking and moving)

Uncommon but potentially serious side effects that occur in less than 1% of patients include:

- Suicidality
- Psychosis
- Leukopenia
  Serious dermatologic (skin) reactions

There are no known risks or interactions with combining levetiracetam and antipsychotic medications

<u>Other Levetiracetam Risks</u>

- Call Dr. Goff or other research staff right away if you have any of these symptoms:
  - Serious mood and behavior changes, including anger or suicidal thoughts, or a skin reaction.
- Stopping levetiracetam abruptly (without gradually decreasing the dose) may cause seizures
- There may be other risks of levetiracetam that are currently unknown.
  As with any drug, an allergic reaction can occur. Allergic reactions can be mild or more serious, and can even result in death. Common symptoms of an allergic reaction are rash, itching, skin problems, swelling of the face and throat, or trouble breathing. If you think you are having an allergic reaction, call the study doctor or psychiatric-mental health nurse practitioner right away. If you are having trouble breathing, call 911 immediately.

Risks of taking Levetiracetam with Marijuana:
There are no known interactions between the components of marijuana including tetrahydrocannabinol (THC), cannabidiol (CBD) or other phytocannabinoids and levetiracetam. For participants experiencing psychotic symptoms, the use of marijuana may make symptoms worse.

Subjects who are identified with a mild cannabis use disorder, will be notified and referred for appropriate care by the study team.

Risks of Magnetic Fields:
MRI uses a strong magnetic field to create images of the body. Because of the strong magnetic field, there are risks. These risks are detailed in this section.

One possible risk is burns to the skin. There is a risk of burns from devices that conduct electrical energy. These devices can include metallic objects, pulse oximeters, EKG leads, or skin tattoos. These devices can be either in or on the patient in order for a skin burn to occur. The FDA has found that 70% of all reported injuries from MRIs were burns to the skin.

To reduce this risk, all patients who are scanned in this study must complete thorough screening to ensure that no conductive materials are present in or on the patient's body (including, metal implants, pacemaker, or other metal items). ~~Individuals with tattoos will be excluded from imaging if tattoos cover more than 5% of the body surface, if a tattoo is greater than 20 cm, or if the tattoo is located on the face, neck or genitals.~~ Individuals with a contraindication to MRI may participate in the trial but will be excluded from the elective MRI component. Additionally, the power limits of the magnet will be adjusted as necessary.

Another possible risk is that a metal object could be pulled into the scanner and hit you. You could be physically injured as a result.

To reduce this risk, everyone near the magnet will remove all metal from their clothing or pockets when in the scanning environment. The door to the scan room will remain closed during the exam for your safety.

There are no known risks or adverse effects resulting directly from exposure to MRI. However, subjects who have a pacemaker or metal objects in their body such as shrapnel or metal in the eye should not have the scan performed. If you have any question about metal implants or metal fragments in the body, you should inform the technologist or investigators before entering the magnet room.

Fear of Confined Spaces: Some people may feel confined and experience anxiety in the MRI scanner. If you are unable to tolerate being in the scanner, we can stop the scan immediately at any time.

Noise Levels: The MRI scanner produces tapping sounds during operation, which may reach very loud levels. To minimize any discomfort from this noise, you will be given disposable earplugs to reduce the noise levels but will still allow voice communication with the scanner operator.

MRI system failure (quench): In extremely rare cases, a magnet can lose its magnetism, in which case cooling fluids may be released noisily through escape valves and may collect in gas form in the scan room. The gas is not harmful in itself as long as fresh air is available. In this very rare event, you will immediately be brought out of the magnet room.

Neurostimulation and heating: Some subjects may experience muscle twitches or tingling sensations and/or a slight increase in body temperature during some types of scan activity. These are very unlikely under current MRI guidelines.

Risks of Blood Draws
You may have a bruise (a black and blue mark) or pain where we take the blood samples. There is also a small risk of infection, lightheadedness, and/or fainting.

Risks of Questionnaires
During the psychiatric interviews and evaluations, and while you are completing the questionnaires you may become bored, tired or frustrated. Some questions may also be embarrassing or upsetting to you. You can skip any questions you don't want to answer. You do not need to give any information that you do not wish to discuss. You can stop the interview at any time.

Risk of Losing Confidentiality
A risk of taking part in this study is a loss of confidentiality of your private information, such as your psychiatric diagnosis. Every effort will be made to protect your confidentiality throughout the study.

You will be assigned a study identification code that will be used for all study documents instead of your name. Your name will not appear on records from this study and you will not be identified in any presentations that are given of the results of this study. Study documents collected in this study will be kept in a locked cabinet. Only research staff who are directly involved in this study will have access to that file.

We will write in your medical record that you are participating in the study and we will record the medication that you receive. Your answers to the questions asked during interviews with researchers will not appear in your medical record. This information will be kept confidential and will be labeled with a code and not with your name.

Not sharing information about your participation in this study with others will minimize these risks. Although every effort will be made to keep your participation confidential, the investigators cannot guarantee absolute confidentiality. If you tell your family doctor that you have participated in this study, or if you tell your doctor about any specific aspects relating to your participation, this information may then become part of your medical record with this doctor. Insurance companies routinely have access to such records. We will not release information about you or your family to your doctor unless you authorize us to do so.

Communicating with the Research Team:
Researchers may need to communicate with you about information relevant to the research study. The research team will usually contact you for these purposes by phone, but if you have given the researchers your email address and mobile/cell phone number and permission to send a text message, the research team may contact you that way. When the research team sends email messages that include identifiable health information, they will use encrypted messaging (e.g. SendSafe). When the research team uses texting over mobile/cell phones there is no way to encrypt the message. This means that information you send or receive by text message is unencrypted and could be intercepted or viewed by an unintended recipient, or by your mobile/cell phone provider or carrier. Therefore, text messages carry security and privacy risks.

Below are some important points about texting in this research study.

- Text messages are not encrypted, and therefore are unsecure and may result in a breach of your confidentiality.
- You will be responsible for all fees charged by your carrier's service plan for text messaging. This research study and NYULH/Bellevue will not cover the cost related to any increased charges, data usage against plan limits or changes to data fees from the research texts
- Text messages will only be read during regular business hours. However, if you have a scheduled visit outside of business hours, you may receive a text in relation to this visit outside of regular business hours.
- Text messaging should not be used in case of an emergency. If you experience a medical emergency, call 911 or go to the nearest hospital emergency department.
- You may decide to not send or receive text messages with staff associated with this research study at any time. You can do this in person or by sending the research number a text message that says "Stop Research Text."
- Your agreement applies to this research study only. Agreeing to other texts from NYULH/Bellevue, for example appointment reminders, is a separate process. Opting out of other texts from NYULH/Bellevue is a separate process as well.

Please make sure to keep the research team updated if your mobile/cell phone number changes during the study.

☐ Yes, I agree to receive texts from this research group.
Cell phone number:_____
☐ No, I do not agree to receive texts from this research group.

_____
Subject Initials

6. Can I be in the study if I am pregnant or breastfeeding?

Because taking part in this study may harm an embryo, fetus, or breastfeeding baby, you should not become pregnant, breastfeed a baby, or father a child while participating in this study. Other risks may not yet be known.

If you are currently pregnant, you will not be able participate in the study. You should not become pregnant while you are participating in this study. If you are able to become pregnant, you will be required to use a medically accepted method of birth control while you participate in the study:

- Hormonal methods like birth control pills, patches, vaginal rings or implants
- Barrier methods such as condoms or a diaphragm used with spermicide (a foam, cream or gel that kills sperm)
- Intrauterine device (IUD)
- Abstinence (no sex)

If you become or you think you have become pregnant during the study, you must tell the principal investigator right away and must tell your obstetrician or other health care provider caring for you during your pregnancy that you took part in this study. If you become pregnant, you will have to stop taking part in the study for safety reasons. The principal investigator may ask you to provide information about the outcome of your pregnancy and the health of your baby.

<u>Note to Men</u>
Because the effect of participating in this study on sperm is unknown, you will be required to use a

medically accepted method of birth control while you participate in the study using one of the methods described above.

If your partner becomes or thinks she may have become pregnant during the time you are in the study, you must tell the principal investigator right away.

7. What if new information becomes available?

During the course of this study, we may find more information that could be important to you. This includes information that might cause you to change your mind about being in the study. We will notify you as soon as possible if such information becomes available.

Results of your scans

While MRI scans are sometimes done for clinical purposes, the kind of MRI scan you may have as part of this study is for research purposes only. This means that the scans are not designed to provide clinical information that might be helpful to you or your doctor and they may not show problems that would normally be found in an MRI ordered to evaluate a specific medical problem. It is likely that the MRI scan will not have the quality of those done for clinical purposes.

However, within a month of the MRI, the scan will be read by a neuroradiologist for evidence of any obvious irregularities requiring your follow-up. You, or a physician whom you may designate, will be informed only when significant abnormalities are detected. If you wish, we can also inform you if there were no obvious findings. Given the nature of the scan, the absence of a finding does not mean that one is not present.

8. What are the possible benefits of the study?

If you receive levetiracetam, it is possible that your psychosis will improve while you are taking it. However, it's also possible you won't benefit from taking part in this study. Others with early psychosis may benefit in the future from what we learn in this study.

9. What other choices do I have if I do not participate?

You do not have to take part in this research study to be treated for early psychosis. If you decide not to participate, the clinician who referred you will discuss the options for treatment with you.

If you decide not to participate in this study, your decision won't change the medical care you get now or in the future. There will be no penalty and you will not lose benefits you receive now or have a right to receive.

Students who elect to participate in this study can choose to/not to participate or withdraw at any time without any impact on their grades or academic standing.

10. Will I be paid for being in this study?

You may be compensated up to $495.00 if you complete all study visits including the optional procedures. If you do not complete the study, we will pay you for each of the visits you complete. You will be paid:

- $25 for Screening (Visit 1)
- $75 for Baseline (Visit 2)
- $25 for Weeks 2,3,4,8
- $50 for Week 6
- $85 for Week 12
- $15 for Follow-Up visit after tapering regimen

Optional assessments:

- $35 per MRI (add-on to Baseline and Week 12)
- $25 per MCCB assessment completed (add-on to Baseline, Week 6 and Week 12)

You will not receive remuneration for the follow-up phone call.

Participants who request to withdraw from the study early will be asked to return for two additional study visits. These visits will consist of the content of the Week 12 visit and the Follow-Up visit. Participants completing those two additional visits will be paid in accordance with the amounts listed for the Week 12 and follow-up visits above.

As is required by the laws that apply to NYU Langone, in order for you to receive a payment (i.e., check, Clincard or bank gift card), you need to give the study staff either your Social Security number or your Alien Registration number and will be asked to complete an IRS W9. If you do not have either of these numbers or are not willing to complete the IRS, you may be in the study but will not receive any payment.

11. Will I have to pay for anything?

NYU is providing the study drug at no cost. Study funds will pay for study-related procedures and study visits that are done only for research. Charges for any ongoing or routine medical care you receive outside of this study will be billed to you or to your insurance company in the usual way. This includes your antipsychotic medication. You will be responsible for any deductibles or co-payments required by your insurer for your routine medical care.

12. What happens if I am injured from being in the study?

For medical emergencies contact 911. If you think you have been injured as a result of taking part in this research study, tell the principal investigator as soon as possible. The principal investigator's name and phone number are listed at the top of page 1 of this consent form.

We will offer you the care needed to treat any injury that directly results from taking part in this research study. We reserve the right to bill your insurance company or other third parties, if appropriate, for the care you get for the injury. We will try to have these costs paid for, but you may be responsible for some of them. For example, if the care is billed to your insurer, you will be responsible for payment of any deductibles and co-payments required by your insurer.

Injuries sometimes happen in research even when no one is at fault. There are no plans for the NYU School of Medicine or Medical Center to pay you or give you other compensation for the injury. You do not give up your legal rights by signing this form

13. When is the study over? Can I leave the Study before it ends?

This study is expected to end after all participants have completed all visits, and all information has been collected. This study may also be stopped or your participation ended at any time by your physician, the study sponsor, or the Food and Drug Administration (FDA) without your consent because:

- The principal investigator feels it is necessary for your health or safety. Such an action would not require your consent, but you will be informed if such a decision is made and the reason for this decision.
- You are unable to attend the required study visits.
- You have not followed study instructions.

- The study sponsor, the principal investigator, the Food and Drug Administration (FDA) or other body responsible for monitoring the safety of the study has decided to stop the study.

If you decide to participate, you are free to leave the study at any time. Leaving the study will not interfere with your future care, payment for your health care or your eligibility for health care benefits. It is important for you to know that there is increased risk of seizures with rapid withdrawal of levetiracetam. If you decide to withdraw from the study before it ends (and more than 7 days after starting the medication), you will be asked to return for 2 additional visits. The first will consist of a clinical assessment, and you will be given a 9-day tapering regimen. The second visit (scheduled within 3 days of completing the tapering regimen) will consist of an abbreviated assessment and a study termination form.

14. How will you protect my confidentiality?

Your medical information is protected health information, or “PHI”, and is protected by federal and state laws, such as the Health Insurance Portability and Accountability Act, or HIPAA. This includes information in your research record as well as information in your medical record at NYU Langone Health. In compliance with NYU Langone Health policies and procedures and with HIPAA, only those individuals with a job purpose can access this information.

Medical information created by this research study may become part of your medical record. We may include your research information in your medical record for several reasons, including for the billing of services provided in connection with the study, to securely document any medical services you receive, and so that other members of the NYU Langone Health community who may treat you have access to important information about your health.

You have a right to access information in your medical record. In some cases, when necessary to protect the integrity of the research, you will not be allowed to see or copy certain information relating to the study while the study is in progress, but you will have the right to see and copy the information once the study is over in accordance with NYU Langone Health policies and applicable law.

Certificate of Confidentiality
This research is covered by a Certificate of Confidentiality from the National Institutes of Health. The researchers with this Certificate may not disclose or use information, documents, or biospecimens that may identify you in any federal, state, or local civil, criminal, administrative, legislative, or other action, suit, or proceeding, or be used as evidence, for example, if there is a court subpoena, unless you have consented for this use. Information, documents, or biospecimens protected by this Certificate cannot be disclosed to anyone else who is not connected with the research except, if there is a federal, state, or local law that requires disclosure (such as to report child abuse or communicable diseases but not for federal, state, or local civil, criminal, administrative, legislative, or other proceedings, see below); if you have consented to the disclosure, including for your medical treatment; or if it is used for other scientific research, as allowed by federal regulations protecting research subjects. The Certificate of Confidentiality will not be used to prevent disclosure as required by federal, state, or local law of child abuse or neglect, or harm to self or others.

The Certificate cannot be used to refuse a request for information from personnel of the United States federal or state government agency sponsoring the project that is needed for auditing or program evaluation by the NIH which is funding this project or for information that must be disclosed in order to meet the requirements of the federal Food and Drug Administration (FDA). You should understand that a Certificate of Confidentiality does not prevent you from voluntarily releasing information about yourself or

your involvement in this research. If you want your research information released to an insurer, medical care provider, or any other person not connected with the research, you must provide consent to allow the researchers to release it.

15. HIPAA Authorization

As noted in the Confidentiality section above, federal law requires us, and our affiliated researchers, health care providers, and physician network to protect the privacy of information that identifies you and relates to your past, present, and future physical and mental health conditions. We are asking for your permission (authorization) to use and share your health information with others in connection with this study, in other words, for purposes of this research, including conducting and overseeing the study.

Your treatment outside of this study, payment for your health care, and your health care benefits will not be affected even if you do not authorize the use and disclosure of your information for this study.

What information may be used or shared with others in connection with this study?
All information in your research record for this study may be used and shared with those individuals listed in this section. Additionally, information in your medical record that the research team believes may be important to the study may be accessed by those listed here. This includes, for example, results from your physical examinations, laboratory tests, procedures, questionnaires, and diaries.

Who may use and share information in connection with this study?
The following individuals may use, share, or receive your information for this research study:

- The research team, including the Principal Investigator, study coordinators, and personnel responsible for the support or oversight of the study
- The study sponsor: National Institute of Mental Health
- Governmental agencies responsible for research oversight (e.g., the Food and Drug Administration or FDA).
- Health care providers, including your doctors and others who provide services to you in connection with this study, and laboratories or other individuals who analyze your health information in connection with this study.
- Other study sites involved in the research

Your information may be re-disclosed or used for other purposes if the person who receives your information is not required by law to protect the privacy of the information.

What if I do not want to give permission to use and share my information for this study?
Signing this form is voluntary. You do not have to give us permission to use and share your information, but if you do not, you will not be able to participate in this study.

Can I change my mind and withdraw permission to use or share my information?
Yes, you may withdraw or take back your permission to use and share your health information at any time for this research study. If you withdraw your permission, we will not be able to take back information that has already been used or shared with others. To withdraw your permission, send a written notice to the principal investigator for the study noted at the top of page 1 of this form. If you withdraw your permission, you will not be able to stay in this study.

How long may my information be used or shared?
Your permission to use or share your personal health information for this study will never expire unless you withdraw it.

16. Optional permission for future use

NYULMC would also like to store, use, and share your health information from this study in research databases or registries for future research conducted by NYULMC or its research partners. Such health information may include biological samples from the study. To give this additional permission, check the box below and write your initials where indicated. You may still participate in this study even if you do not give us this additional permission.

NYULMC will continue to protect the confidentiality and privacy of this information as required by law and our institutional polices. If you give this additional permission, you will continue to have the rights described in this form. You have the right to take back this additional permission at any time.

☐ Checking this box indicates my permission to store, use, and share my health information from this study in research databases or registries for future research conducted by NYULMC or its research partners.

_____
Subject Initials

17. The Institutional Review Board (IRB) and how it protects you

The IRB reviews all human research studies – including this study. The IRB follows Federal Government rules and guidelines designed to protect the rights and welfare of the people taking part in the research studies. The IRB also reviews research to make sure the risks for all studies are as small as possible. The NYU IRB Office number is (212)263-4110. The NYU School of Medicine's IRB is made up of doctors, nurses, non-scientists, and people from the community.

18. Who can I call with questions, or if I'm concerned about my rights as a research subject?

If you have questions, concerns or complaints regarding your participation in this research study or if you have any questions about your rights as a research subject, you should speak with the Principal Investigator listed on top of the page 1 of this consent form. If a member of the research team cannot be reached or you want to talk to someone other than those working on the study, you may contact the Institutional Review Board (IRB) at (212) 263-4110.

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

When you sign this form, you are agreeing to take part in this research study as described to you. This means that you have read the consent form, your questions have been answered, and you have decided to volunteer.

Name of Subject (Print)	Signature of Subject	Date

Name of Person Obtaining Consent (Print)	Signature of Person Obtaining Consent	Date

Signature of Parent(s)/Guardian for Child

I give my consent for my child to take part in this research study and agree to allow his/her health information to be used and shared as described above.

Name of Parent (Print)	Signature of Parent	Date

Witness to Consent of Non-English Speaking Subjects

Statement of Witness

As someone who understands both English and the language spoken by the subject, I represent that the English version of the consent form was presented orally to the subject in the subject's own language, and that the subject was given the opportunity to ask questions.

Name of Witness (Print)	Signature of Witness	Date

Witness to Consent of a Subject Who Cannot Read or Write

Statement of Witness

I represent that the consent form was presented orally to the subject in the subject's own language, that the subject was given the opportunity to ask questions, and that the subject has indicated his/her consent and authorization for participation by (check box that applies).

☐ Subject making his/her own "X" above in the subject signature line

☐ Subject showed approval for participation in another way; describe:

Name of Witness (Print)	Signature of Witness	Date