Cover Page - AMP SCZ® Observational Study

Accelerating Medicines Partnership® Schizophrenia Observational Study

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Content:

Clinical High Risk (CHR) Informed Consent forms for Psychosis-Risk Outcome Network (ProNET).

Research Study Center: __<Insert site name>_____

Coordinating Center: Northwell Health

Consent for Participation in a Research Study

Study Title: ProNET: Psychosis-Risk Outcomes Network

Principal Investigator: __<Insert site PI name>_____

Sponsor: National Institute of Mental Health (NIMH)

About this research
You are being asked to participate in a research study.

This consent form will give you information about the study to help you decide whether you want to participate. Please read this form, and ask any questions you have, before agreeing to be in the study.

Important Information
This information gives you an overview of the research. More information about these topics may be found in the pages that follow.

Why am I being asked to provide my consent?	This is a research study, which is different than personal medical care. Scientists do research to answer important questions. These answers might help change or improve the way we do things in the future.
Do I have to join this research study?	No. Taking part in this research study is voluntary. You may choose not to take part in the study or may choose to leave the study at any time. Your decisions will not result in any penalty or loss of benefits to which you are entitled.
Why is this research study being done?	The purpose of this research study is to collect information from individuals who are considered at Clinical High Risk (CHR) for possible development of psychosis. You are being asked to participate as an individual who may be at CHR for psychosis in this project because you have recently been experiencing changes in your mood, thinking, or behavior. Information will also be collected from individuals who are not considered CHR for psychosis "healthy controls". This information will be used to guide future treatments.
What will happen to me during the study?	You will participate in interviews and cognitive tasks, some of which may be recorded via audio or video; provide samples of your blood, saliva, and DNA; undergo brain scans such as MRI and EEG; provide

	blood pressure, heart rate and body temperature and complete questionnaires.
How long will I participate?	You may participate up to about 2 years.
Will taking part expose me to risks?	The risks are minimal. You may be exposed to discomfort and possibly loss of confidentiality.
Are there any benefits to participation?	Because the study involves only collection of information, there is no potential direct benefit to participation.
What are my alternatives to participation?	The alternative to participation is to not participate.

Please review the rest of this document for details about these topics and additional things you should know before making a decision about whether to participate in this research.

Introduction
You are being asked to join a research study. The purpose of a research study is to answer specific questions, sometimes about the safety of a drug or device and how well it works. Being in a research study is different from being a patient. When you are a patient, you and your doctor have freedom in making decisions about your healthcare. When you are in a research study, the researcher will follow the rules of the research study as closely as possible, while monitoring your health.

You do not have to be in this study to receive medical care. You should ask questions before you decide if you want to participate. You can also ask questions at any time during the study.

This consent form is written from the point of view of a research participant. If the parent or legal guardian of a minor or a legally authorized representative will be providing consent, the words "you" and "your" should be read as ("your child" or "the research participant").

Why is this research study being done?
The purpose of this research study is to collect information from individuals who are considered at CHR for possible development of mental illness including psychosis and from individuals who are not considered at risk for future difficulties “healthy controls”, in order to guide future treatments. You are being asked to participate in this project because you have recently been experiencing changes in your mood, thinking, or behavior which may indicate you are an individual who is at CHR for psychosis.

People at CHR for psychosis have a higher risk of developing a psychotic disorder than the general population because of particular symptoms and/or family history. Symptoms vary for

different individuals. These symptoms can include feeling low in mood, feeling paranoid, or seeing or hearing things that they know aren't there. Some people might worry that their thoughts are being heard, may not feel right in themselves, or might be having more difficulty than usual coping with work, school or relationships. Other people in the CHR group may not experience any of these symptoms, but have a family member with a psychotic disorder which may also increase their risk.

For some people, these early symptoms may become more severe over time. For others, the symptoms may stay the same over time, and for others the symptoms may decrease or go away entirely. At the moment we can't tell which direction a particular person might go in. Improving our knowledge about symptoms and risk factors, and the way that they change over time, is important. This information may help researchers and clinicians predict possible outcomes for individual patients and develop treatment plans that are suited to the individual patient.

Why is this research?
This is a research study because medical, psychiatric, and other information will be collected about you to learn more about individuals considered high risk for possible development of psychosis.

How many people will take part in this study?
This research study hopes to enroll 1,430 individuals (1,040 CHR and 390 healthy control) at 26 sites, 17 in the United States and 9 outside the United States.

How long will you be in this study?
If you choose to take part in this study, the study procedures will last for approximately 2 years.

What will happen in this research study?
If you agree to participate in the study you will be asked to thoroughly review this consent form and provide informed consent. After you provide informed consent you will complete a screening visit to see if you qualify for the study. During the screening visit we may determine that you do not qualify for the study. If this happens, we will inform you and give you the option to continue completing the visit or to stop the visit. Continuing the visit will help us better understand the characteristics of those participants who do not qualify for the study. This visit will take about 2-3 hours.

If you qualify for the study, you will be asked to attend 15 additional visits. The first additional visit (month 0) will last about 8-9 hours and can be split over a few days. For the remaining visits:

- 3 visits (months 1, 3, and 6) will last about 2-3 hours,
- 7 visits (months 4, 5, 7, 8, 9, 10, and 11)will last less than 1 hour
- 1 visit (month 2) will last about 6 hours and can be split over a few days
- 1 visit (month 12) will last about 3 to 4 hours
- 1 visit (month 18) will last about 2 hours
- 1 visit (month 24) will last about 4 hours

If your symptoms significantly worsen we may ask you to come back for an unscheduled study visit.

This visit will last about 2.75 hours.

At each visit you will be asked to complete questionnaires, participate in interviews, and at some visits take tests on a computer or tablet that measure memory, attention and ability to plan and solve problems. Some of the study procedures may be recorded via audio and/or video.

Digital Assessments
As part of this study you will also be asked to participate in 2 different digital optional assessments.

The first optional digital assessment is a smartphone app. If you do not have a smartphone, one will be provided to you for the duration of the study. You will be asked to download an application onto your smartphone. This app includes two different parts. The first part of the app is daily audio recordings (audio diaries) and daily surveys. For the daily audio diaries and surveys, you will be asked to make a short (2 minute) audio diary about your recent experiences, events and context and respond to a brief survey every day for your first year in the study. The questions in the survey will take about 2 minutes to answer. You will be paid $2 for each day you complete the audio diary and survey.

The second part of the app is called passive sensing. This app will track information such as physical activity and sleep, your physical location, how much the other apps on the phone are used, and the amount of time the phone is spent unlocked. Information that collects your smartphone's physical location is personally identifiable and sensitive information that could be used to identify you and the exact locations you visit. For example, the app will record when you are at home, school, or doctors' appointments and the frequency at which you visit these locations. However, individuals who have access to your data will have to promise not to use the locations collected to try to identify or contact any individuals who have participated in the study. It is very rare for someone to break that promise, and doing so could result in denial of further access to NDA data and in other actions. Even so, there is a small possibility that in the future an unauthorized attempt to identify you as a participant in the study could succeed. Safeguards will be put in place to minimize this risk.

Once the app is installed, you must leave it running in the background on your phone. Your phone must also be connected to Wi-Fi at least once a day, so that the data can be uploaded to the secure cloud server. In the event that your app is not properly functioning, you may be contacted by phone to troubleshoot the issue. There are no other expectations for you to interact with the app.

In order to participate in the smartphone app you must agree to participate in the daily audio diaries and surveys. The passive sensing part of the app, including collecting your physical location, is optional.

The second optional digital assessment is called an activity monitor. You will be asked to wear a device on your wrist, like a watch, to track how active you are. You would be asked to wear this device for a year. The watch is intended to be worn continuously, like a fitbit. If necessary, it can be taken off every now and then.

If you do not wish to participate in one or more of the Optional Digital Assessment components, please indicate this below.

I would like to opt out of:

i. Only the physical location part of the passive sensing ☐

ii. The passive sensing part of the smartphone app (includes physical location) ☐

iii. The smartphone app entirely ☐

iv. The wrist device ☐

At two visits you will also be asked to complete an MRI, EEG, submit blood and saliva samples and provide vital signs.

MRI

MRI (Magnetic Resonance Imaging) machines use a strong magnet to make pictures of the inside of your body. During the scanning, you will lie on a long narrow cushioned platform for about 1 hour while the machine gathers data. You will not feel anything while the data is being collected. You will hear tapping noises that are from the MRI scanner.

Since the MRI scanner is a magnet, metal objects will be attracted to the scanner. It is very important that you tell the researcher about any metal objects, devices or implants that are in or on your body before you enter the scanner room. All metal objects must be removed before entering the magnet room. In some cases, having those devices may mean that you should not have an MRI scan.

Facial and ear features that are collected as part of the MRI could be used to identify you, but individuals who have access to your data will have to agree not to try to identify any individuals who have participated in the study.

EEG

EEG (Electroencephalogram) evaluates the electrical activity in the brain because brain cells communicate with each other through electrical impulses that can be measured on the surface of scalp. Measurements will be taken from small recording disks attached to the surface of your scalp with an elastic cap and water-soluble gel, and from recording sensors (i.e., small, metal disks) taped to your forehead, cheeks, and nose. All of these sensors will be removed at the end of the study.

Fitting the elastic cap and filling the sensors with gel will take approximately 15 minutes. After the elastic cap is fitted, you will then be ready to perform the actual experiment. The testing

phase of the experiment will last approximately 90 minutes. You will be given breaks at regular intervals.

Blood and Saliva Samples
You will provide samples of your blood. Less than 50 mL (a little more than 3 tablespoons) of blood will be collected. You will be asked to provide a fasting blood sample at baseline and month 2. A fasting sample means that the sample is taken when you haven't had any food or drink other than water for at least 4 hours prior to the collection. On the morning of the blood test, we ask that you do not consume any food from the time you wake up until the blood test is completed. We encourage you to drink water before the blood test.

Blood and saliva samples that are collected will be sent to the National Institute of Mental Health (NIMH) Repository and Genomics Resource (NRGR). Blood samples will be identified by a number only, and no identifying information will be included with any of the samples. At the NRGR, genetic material (DNA) will be extracted from blood samples and stored for future research use. A portion of the DNA will be used for genetic analyses. We will also store whole blood and the liquid portion of your blood (plasma and serum) at the NRGR for future research.

If you agree to be recontacted, an additional blood sample may be taken later so that NRGR can extract cells from your blood to start cell lines that grow indefinitely that will be stored at NRGR for future research use.

__ I would like to opt out of being recontacted about an additional blood sample

The genetic testing involved in this study is to determine some of the genetic variants in your DNA.

The purpose of the genetic tests in this study is to create a risk score from different combinations of genetic variants that might predict whether you develop different symptoms in the future. Genetic testing of your sample is for research purposes only. No genetic results will be returned to you or your physician, even if they have potential implications for your health or medical condition, or that of your family members. No genetic results will be placed in your medical record. Genetic counseling, which is available for established genetic tests, is not offered through participation in this research study, although you may seek genetic counseling from other sources.

Your samples will be stored in locked freezers within locked rooms. However, storage cannot be guaranteed, since there is always the possibility of a storage problem, (i.e. refrigeration failure, etc.).

Samples of your saliva will be analyzed for the levels of a stress hormone (cortisol).

<u>Vital Signs Measurement</u>
Your height and weight, blood pressure, heart rate, and body temperature will be measured.

Procedure	Visit 1	Visit 2	Visit 3	Visit 4	Visit 5	Visit 6	Visit 7	Visit 8	Visit 9
Time	**Week -3 to -1**	**Month 0**	**Month 1**	**Month 2**	**Month 3**	**Month 4**	**Month 5**	**Month 6**	**Month 7**
Consent form									
Interview/ Questionnaires									
Cognitive tasks									
MRI *									
EEG*									
Blood and saliva samples*									
Vital Signs									
Phone app and survey									
Wrist activity tracker									

Procedure	Visit10	Visit11	Visit12	Visit13	Visit14	Visit15	Visit16	Extra visit (if needed)
	Month 8	**Month 9**	**Month 10**	**Month 11**	**Month 12**	**Month 18**	**Month 24**	
Interview/ Questionnaires								
Cognitive tasks								
Phone app survey								
Wrist activity tacker								

* These procedures must be completed at the clinic. All other procedures may be completed by phone or video conference instead of the clinic. You and your study team will decide where it is best to complete the visits.

Possible Risks, Discomforts, and Inconveniences
There are risks, discomforts, and inconveniences associated with any research study. These deserve careful thought. You should talk with the Protocol Director if you have any questions.

Potential risks for this study are listed below:

Blood Draws
There are no major risks of having blood drawn. It can be uncomfortable and can sometimes cause a bruise. In rare cases, it can cause fainting. Only trained staff will draw your blood.

Genetic Testing
You should be aware that there might be social and economic burden associated with collecting genetic information. Our testing might find an inherited gene, which puts you or a relative at risk for a genetic disorder in the future. However we will not return any genetics results to you. We will do our best to keep all information confidential.

Magnetic Resonance Imaging (MRI)
The magnetic resonance imaging (MRI) machine is a powerful magnet. This magnet may cause any metal in your body to move. If you know of any metal in your body, you will need to tell the researcher right away. Otherwise, there are no known risks of MRI. Some people with claustrophobia (fear of closed spaces) may find the MRI scanner too confining. In that case, you can ask to be removed from the scanner and this will be done immediately. The MRI scanner makes a loud beeping sound. We may ask you to wear protective earplugs during scanning.

EEG
The EEG to be used in this study measures brain electrical activity passively. There is a potential for developing a headache from participating in the EEG evaluation, due to wearing the cap on your head. This headache is related to the tightness of the cap, and is not related to the measurement of the surface electrical activity on your scalp. There is also a very low risk of developing an allergic reaction to the electrode conductive gel, which contains chemicals similar to human sweat.

Telephone Assessment and Data Collection
When using Internet-connected or smartphone technology to store and transmit data there is always some degree of risk related to information breaches and privacy concerns. Your data will have all identifiers removed when possible and it will be treated as if it were protected health information. In some circumstances, it will not be totally possible to remove identifiers though; for example your smartphone location data will be collected, which could be used to derive personal information about you. For this reason, all efforts to minimize the risk of data breach will be undertaken, including maintaining all data in a highly secure environment and encrypted in transit. Additionally, for study purposes you will be given a unique study ID to associate with

data collected from your phone. Only researchers working on this study will have access to a key that can link your name with your study ID.

Wrist Device
The risk associated with the Axivity AX3 device are expected to be minimal and could include a rash or psychological stress from wearing a device. The device collects no personal or health information so any data breach would not compromise personal or health data.

Pregnancy
Pregnancy is not an exclusion criterion, and you are able to participate in this project if you are pregnant or if you become pregnant during the project. It is important that you let the research team at your study site know if you are pregnant or if you become pregnant during the study so they can discuss any relevant risks or considerations you need to be aware of.

Incidental Findings
Although the imaging you will have in this study is being undertaken for research purposes only, it is possible that doctors may notice something that could be important to your health. Although not likely, it is possible that the doctors may notice something that may be very serious and could immediately affect your life. If so, we will contact you to explain what was observed. If you so desire, we will also talk with your private physician. If you do not have a private physician, we will refer you to an appropriate clinic for follow-up. It will be your choice whether to proceed with additional tests and/or treatments to evaluate what we observed, and you or your insurer will be responsible for these costs.

The genetics you will have done in this study is also being undertaken for research purposes only. There may be incidental findings, such as discovery of a gene mutation that may affect your health. No genetics results will be returned as part of this study

Interviews/Questionnaires
During the clinical interviews or neurocognitive tests you may become tired or upset about the questions. If this happens, you should tell the interviewer/study personnel and he/she will stop the examination. Depending upon how you feel, you may then 1) take a rest period and resume later, 2) reschedule the appointment or 3) decide not to finish the exam/session.

Collection of Sensitive Information
Some of the questions we will ask you are personal. You may feel embarrassed or stressed. You may ask to see the questions before deciding whether or not to take part in this study.

Unknown Side Effects
As with any medical and psychiatric questioning and procedures, there might be side effects that are unknown at this time. You will be closely watched for side effects. You should report any unusual events to the study staff.

What are the benefits of this research study?
This research will not benefit you directly. However, information we learn about this disease or condition may help patients in the future.

Will I receive my results?
We may learn things about you from the study activities which could be important to your health or to your treatment. If this happens, this information will be provided to you. You may need to meet with professionals with expertise to help you learn more about your research results. The study team/study will not cover the costs of any follow-up consultations or actions.

Are there any costs for being in this research study?
This research study is funded through an award from the National Institutes of Health, National Institute of Mental Health and is part of the Accelerating Medicines Partnership(R) program. All study related visits and procedures will be given to you at no cost. Neither you nor your insurance company will be billed for your participation in this research.

Will you receive any payments for participating in this research study?
You will be paid $30 per hour for your time for being in this study. If you do not complete the entire study, you will be paid for the number of hours that you have completed. You will also receive $2 per visit for completion of one of the questions on the app. If you decided to participate in the daily questions on the app, you will be reimbursed $2 for every day you answer the questions. Payment will be made <insert site payment information>.

Since the total amount of payment is more than $600 in a year, <insert site name> needs to report this income to the IRS. We will issue you a 1099 form as your payment will be considered taxable income. You will need to provide your social security number for this purpose. You will be responsible for reporting this income when you file your tax return.

Will my biospecimens be used to create a marketable product? And if so, will I receive payment?
Your specimens may be used to create a marketable product. If this research produces a marketable product, there are no plans for you to receive any money.

What happens if you are injured while participating in this study?
If you are hurt from being in the study, you will receive medical care and treatment as needed from <insert site name>. However, you will be responsible for the costs of such medical treatment, directly or through your medical insurance or other forms of medical coverage. No money will be given to you.

What are your rights as a research participant?
Your participation in this project is voluntary. The quality of your medical care will be the same, whether you join, refuse to join, or decide to leave the study.

If you do not join the study you will not be penalized or lose benefits to which you are entitled. If you join the study, you may withdraw at any time without prejudice to your future care at <insert site name>. Follow-up examinations may be needed to assure your well-being.

Could you be taken off the study before it is over?

It is also possible that your participation in this study may end without your consent. This decision may be made by a researcher, study sponsor or the Institutional Review Board (IRB- the committee that oversees research at this institution).

Reasons for withdrawal may include:

- failure to follow instructions,
- failure to show up for study visits,
- it is not in your best interest to continue on this study, or
- the study is stopped.

If you withdraw from this study or if you are withdrawn from the study, any data (or samples) already collected will continue to be used. However, no new data will be collected.

What happens if new information is learned?
You will be told of any new findings that may change your decision to continue to participate. Your consent to continue to take part in this study may be obtained again.

What will happen with the information we collect as part of this research study?
All results of your assessments (e.g., all of the responses to questions or tasks, scores, MRI results, biological samples, genetic information, DNA, audio, video, digital momentary assessments via mobile devices, or physiological measures) will be associated with a unique participant code that contains no explicit information about your identity (pseudo-anonymized). Pseudo-anonymized study data means that all personal information about you (such as name, address, birthdate and phone number) is removed and replaced with a code number.

The unique participant code that will be assigned to you will allow researchers to see if you have been involved in more than one research study or database for patients with a psychotic illness. If you have participated in more than one study or database, this unique code will help connect information across studies. This participant code will also allow your pseudo-anonymized data to be combined with data from other research studies to increase the likelihood of meaningful analysis. Only this participant code and not your personal identifiable information will be accessible to other investigators. This unique participant code may make it possible for a study doctor who used this unique code in another study that you took part in to identify you.

Creating the participant code will be done at your local site and will not require you to share your name outside the site. Only the local site research team will have your address and phone number. <Insert site name> will keep address and phone number in a securely protected database for as long as the study continues, and then it will be destroyed. Only authorized people at the site level, who have agreed to protect your identity, will have access to this information.

All other data elements will be entered from <insert site name> into a secure database and associated with your unique participant code at Yale University (lead site), which will meet all regulatory requirements for this study in compliance with regulations at your site.

Pseudo-anonymized data will be sent to a secure server controlled by the National Institute of Mental Health (NIMH) and will be accessible by the Data Processing Analysis and Coordinating

Center (DPACC) which is also based in the USA. After the DPACC review, pseudo-anonymized data will be deposited in the NIMH Data Archive (NDA) and the NRGR, which are data repositories maintained or sponsored by the NIMH. Access to these data in NDA and NRGR will be controlled by the NIMH and not by the ProNET study team or by your local study staff. The NDA and NRGR intend to share the study data with other investigators who request access to the data and who meet their requirements. This would include pseudo-anonymized data and could also include the results of genetic analyses, MRI data, or location data that could be used to identify you. The NDA and NRGR have safeguards in place that require all investigators granted access to study data to agree not to try to identify any individuals who have participated in the study. However, there is a small possibility that in the future an unauthorized attempt to identify you as a participant could succeed. Study findings may ultimately have significant therapeutic or commercial value. By agreeing to participate in this study, you agree to such future uses.

How will information about you be protected?
Every effort will be taken to protect your identity in this study. We protect your privacy by assigning a participant code to and omitting your name as much as possible from all computer and paper documents on which information is recorded as part of the study. We will keep personal identifying information needed to contact you to arrange study appointments separate from all information collected as part of this study, in a password protected computer file.

Researchers will always have a duty to protect your privacy and to keep your information confidential. Some information collected in this study contains information that could be used to try to identify you.

- As your genetic information is unique to you, there is a small chance that someone could trace it back to you. Researchers that use your genetic information agree to not try to identify any study participant based on their genetic information and to store the genetic information securely, so the risk of this happening is very small, but could change in future. However, you may be concerned that someone could get access to your genetic information and that it could be misused; for example, to make it harder for you to get or keep a job or insurance. There are laws that make illegal for an employer or health insurance company to discriminate against an individual based on their genetic information.
- Data that collects your physical location could be used to identify where you live or visit.
- Facial features that are present on your MRI could be used to identify you

All researchers who have access to data have to agree to not try to identify you and will also be required to have their institution's approval to view the data. Access to location data will specifically require approval from their institution's ethics board.

Participants will not be identified in any report or publication about this study. Although every effort will be made to keep research records private, there may be times when federal or state law requires the disclosure of such records, including personal information. This is very unlikely, but if disclosure is ever required, **<insert site>** will take steps allowable by law to protect the privacy of personal information.

Most research with your data is not expected to yield new information that would be meaningful to share with you personally. There are no plans to re-contact you or other subjects with information about research results.

What information will be collected and used for this study?
If you agree to be in this study, we will collect health information that identifies you. We may collect the results of tests, questionnaires and interviews. We may also collect information from your medical record. We will only collect information that is needed for the research. This information has been described in this consent form. If you sign this consent form, you are giving us permission to collect, use and share your health information. This permission is called authorization. If you do not want to provide authorization, then you cannot participate in this research study.

Who else will see your information?
Study records that identify you will be kept private. You will not be identified in study records or publications disclosed outside **<insert site name>**, except as detailed below.

Investigators will share information that may contain personal information about you from this research study with investigators who are managing the ProNET study at:

- Yale University
- Northwell Health,
- University of California at Los Angeles,
- University of Calgary,
- King's College London,
- Beth Israel Deaconess Medical Center,
- Emory University,
- University of California at San Francisco,
- University of North Carolina and
- NIMH-funded Data Processing Analysis and Coordinator Center (DPACC) at Harvard University/Brigham and Women's Hospital and NIMH-funded PRESCIENT research network for quality control purposes in analyses of audio and video files.

Pseudo-anonymized data from the project will be shared from Yale University databases with

- Investigators affiliated with the ProNET study,
- Investigators from ProNET sites not listed above,
- NIMH-funded Data Processing Analysis and Coordinator Center (DPACC) at Harvard University/Brigham and Women's Hospital, and
- NIMH Data Archive (NDA).

The following reviewers may access your study and medical records to make sure that this study is being done properly:

- The DPACC data monitoring team
- Representatives from federal and state government oversight agencies such as NIMH
- Representatives from Northwell Health's Human Research Protection Program (the group of people that oversee research at this institution).

We will do our best to protect the privacy of your records and we will require anyone who has access to your records to use best practices to protect your privacy. However, although unlikely, it is still possible that once information is shared with people listed on this form, it could be released to others. If this happens, your information may no longer be protected by the federal law.

In the future, we may publish results of this study in scientific journals and may present it at scientific meetings. If we do we will not identify you.

If the researchers learn about potential serious harm to you or someone else or other public health concerns, it will be shared with the appropriate authorities.

Will you be able to access your records?
If your research records are used for decisions related to your clinical care, then you have the right to review this information and request changes. This is limited to information about your treatment and does not include information related to procedures or tests that are for research purposes only. You may access this information only after the study analysis is complete. You have the right to know who has and who will see your records. To request this information, please call the Human Research Protection Program at 516-465-1910.

How long will your health information be kept?
There is no limit on the length of time we will keep your information for this research because it may be analyzed for many years. We will keep it as long as it is useful, unless you decide you no longer want to take part or we close the study. You are allowing access to this information indefinitely.

Can you change your mind?
If you change your mind about being in the study, you may withdraw at any time. If you want us to stop collecting your health information, you need to send a letter to the researcher at the following address:

<Insert PI Name>
<Insert PI Address>

Your letter needs to say that you have changed your mind and do not want the researcher to collect and share your health information. You may also need to leave the research study if we cannot collect any more health information. We may still use the information we have already collected or is being analyzed at the time of your request. We need to know what happens to everyone who starts a research study, not just those people who stay in it. If you do not want your data that was already collected to continue to be used, you need to include this in your letter. Once the researchers have been notified, your data would be removed or remaining samples would be destroyed. If you do not make such a request, the samples already collected may be stored forever. The researchers may choose to destroy the samples at any time.

Certificate of Confidentiality

To help us protect your privacy, this research is covered by Certificates of Confidentiality from the US Department of Health and Human Services (DHHS). The Certificates of Confidentiality mean that researchers and the NIMH Data Archive cannot be forced to identify you, even under a court subpoena. The Certificate does not mean the Secretary of DHHS approves or disapproves of the project. It adds special protection for the research information about you. You should know, however, that researchers may provide information to appropriate individuals or agencies if harm to you, harm to others or child abuse becomes a concern. A Certificate of Confidentiality does not prevent you or a member of your family from voluntarily releasing information about yourself or your involvement in this research. However, if an insurer, employer or other person learns about your participation and gets your consent to receive research information, then the researchers will have to provide your information. In addition, the NIMH Data Archive will redact individual-level information from responses to Freedom of Information Act requests. Data associated with specimens in the NIMH Repository and Genomics Resource is pseudo-anonymized and does not contain any information that is personally identifying.

Will my information be used for research in the future?
During and after the study, data from this study will be submitted to the National Institute of Mental Health Data Archive (NDA) at the National Institutes of Health (NIH). The NDA is a large database where pseudo-anonymized study data from many National Institute of Mental Health (NIMH) studies is stored and managed. Sharing your pseudo-anonymized study data helps researchers learn new and important things about mental health and substance use more quickly than before.

During and after the study, the study researchers will send pseudo-anonymized study data about your health and behavior to the NDA. Other researchers across the world can then request your pseudo-anonymized study data for other research. Access to your data in the NDA will be controlled by the NIMH and not by the ProNET study team or by your local study staff. Every researcher (and institutions to which they belong) who requests your pseudo-anonymized study data must promise to keep your data safe and promise not to try to learn your identity. For data about your location, the researchers would be required to have approval from their ethics board before viewing the data. Experts at the NIH who know how to keep your data safe will review each request carefully to reduce risks to your privacy. Sharing your study data does have some risks, although these risks are rare. Your study data could be accidentally shared with an unauthorized person who may attempt to learn your identity. The study researchers will make every attempt to protect your identity.

You may not benefit directly from allowing your study data to be shared with NDA. The study data provided to NDA may help researchers around the world learn more about mental health and substance use and how to help others who have problems with mental health and substance use. NIMH will also report to Congress and on its website about the different studies using NDA data. You will not be contacted directly about the study data you contributed to NDA.

If you decide any time after today that you do not want your data to be added to the NDA, call or email the study staff who conducted this study, and they will tell the NDA to stop sharing your study data. Once your data is part of the NDA, the study researchers cannot take back the study

data that was shared before they were notified that you changed your mind. If you would like more information about NDA, this is available on-line at http://nda.nih.gov.

Biological samples not used for planned analyses will be stored indefinitely for as yet undetermined analyses. This is because we want to help scientists learn more about the causes of human diseases such as mental illnesses. For the samples stored in the NRGR your data will become part of a larger effort to gather health information and biological materials from persons with many different mental illnesses, so your study information, blood and genetic samples will be stored with the samples from people who participate in other research studies. NIMH will make these resources available to other scientists who want to do research that has been reviewed and approved by an NIH and NIMH data access committee. Your participation in this project involves you giving broad consent. This means that you allow your samples to be used for a variety of future research, but which cannot be specified at the present time. These databases are restricted and can only be accessed by approved researchers.

If you decide any time after today that you no longer want your samples to be stored in the NRGR, you should call or email the study staff who conducted this study, and they will have your sample removed. Analyses that have already been completed before your sample was removed will not be redone.

You will not be contacted in the future about the biological sample you provided.

Does the investigator of this study receive money if you take part?
The investigators on this study receive money to conduct the study, but do not financially benefit from your participation. The money they receive is to pay them back for the costs of conducting the research study. Funding for this research study is provided by NIMH. If your doctor is an investigator for this study s/he is interested in both your healthcare and the conduct of this research. You do not have to take part in a research study conducted by your doctor. Your information and biospecimens will not be sold.

Who can answer your questions about this study?
If you have any questions about the study, you may call <insert site PI> at <insert phone number>. If you have questions about side effects or injury caused by research, you should call <insert site PI> at <insert phone number>. If you need emergency care, dial 911 or go to the nearest Emergency Room. If you have questions about your rights as a research participant, or concerns about being in the study, or would like to offer input, you may contact the Office of the Institutional Review Board (the committee that oversees research at this institution) at (516)465-1910. A signed copy of this consent form will be given to you.

[Signature Page Follows]

Summation/Signature

You have read the above description of the research study. You have been told of the risks and benefits involved and all your questions have been answered to your satisfaction. A member of the research team will answer any future questions you may have. You voluntarily agree to join this study and know that you can withdraw from the study at any time without penalty. By signing this form, you have not given up any of your legal rights.

_____ _____
Signature of Participant Date

Participant's Name: _____

_____
Printed Name of Parent or Legal Guardian
(complete if participant is under 18 y.o.)

_____ _____
Signature of Parent or Legal Guardian Date

Investigator's Statement
In addition to advising the above participant of other forms of treatment and therapy which are appropriate, I have offered an opportunity for further explanation of the risks and discomforts which are, or may be associated with this study and to answer any further questions relating to it.

_____ _____
Person obtaining consent signature **Date**

_____
Person obtaining consent printed name

Research Study Center: __<Insert site name>_____

Coordinating Center: Northwell Health

Assent to be in a Research Study

Title:_**ProNET: Psychosis-Risk Outcomes Network**

1. My name is <insert name>.

2. We are asking you to take part in a research study because we are trying to learn more about individuals who are considered at risk for possible development of mental problems.

3. If you decide to be in this study, you will:
   - Answer questions in person and on the computer;
   - Download an app to your smartphone that will track physical activity and sleep, location, how much the other apps on the phone are used, and the amount of time the phone is spent unlocked, among other metrics. The app will also ask a few questions before each study visit to assess functioning;
   - Provide some blood and saliva samples
   - Some of the blood samples collected will be sent to the NRGR. Genetic material (DNA) will be extracted from blood samples and stored, and cells from your blood could be used to start cell lines that grow indefinitely. These cell lines would provide additional DNA and other biologic material for future research.
   - Complete scans of your brain while lying down in two different tests called EEG and MRI;
   - You can continue in the study for about 2 years during about 15 different visits

4. Sometimes things that don't feel good happen in research studies. Some things that could happen may hurt you, make you feel yucky, or make you feel upset. Some of the things might happen to you or they might not. Or things might happen that we don't know about yet.

5. You will be paid $30 per hour for being in this study. You will also receive $2 during each visit that you complete some questions called an EMA survey.

6. Please talk to your parents about this before you decide whether or not to be in this research study. We will also ask your parents to give their permission for you to be in this study. But even if your parents say "yes," you can still decide not to be in this research study.

7. If you don't want to be in this study, you don't have to.

8. You may stop being in this any time. Remember, being in this study is up to you and no one will be upset if you don't want to take part in this study or even if you change your mind later and want to stop.

9. You can ask any questions that you have about the study. If you have a question later that you didn't think of now, you can call me at <insert phone number> or ask me next time.

10. Putting your name at the bottom means that you have decided to be in this study. You and your parents will be given a copy of this form after you have signed it.

_____	_____	_____
Name of Subject	Sign your name here ↑	Date

_____	_____	_____
Person Obtaining Consent Printed Name	Person Obtaining Consent Signature	Date