Cover Page - AMP SCZ® Observational Study

Accelerating Medicines Partnership® Schizophrenia Observational Study

Document Date: 11/17/2021

Content:

Clinical High Risk (CHR) – Self - Informed Consent forms for Trajectories and Predictors in the Clinical High Risk for Psychosis Population: Prediction Scientific Global Consortium (PRESCIENT).

Participant Information Sheet/Consent Form

UHR Participants - Self

Title	Trajectories and Predictors in the Clinical High Risk for Psychosis Population: Prediction Scientific Global Consortium
Short Title	PRESCIENT
Protocol Number	2021.166
Project Sponsor	Orygen
Coordinating Principal Investigator	Professor Barnaby Nelson
Site Principal Investigator	*[insert relevant PI]*
Location	*[insert site]*

1 Introduction

You have been invited to take part in this study, because you have been in contact with or have been referred to *[site]*. *[site]* is a service that provides specialised clinical care to young people with a range of mental health concerns including young people who may be at increased risk of developing psychosis. This is sometimes referred to as being at clinical high risk (CHR) or ultra high risk (UHR) for psychosis. This study aims to look at patterns in the development of symptoms over time in young people aged 12 to 30 who may be at a higher risk for developing psychosis.

What does ultra high risk for psychosis mean?

People at ultra high risk (UHR) 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, but can include feeling low in mood, feeling paranoid, or seeing or hearing things that they know aren't there. Some people might be having more difficulty than usual coping with work, school or relationships. Other people in the UHR group may not experience any of these symptoms, but have a family member with a psychotic disorder.

For some people, these early symptoms may get worse over time. For others, the symptoms may stay the same, and for others they 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 various symptoms and risk factors, and the way that they change over time, is important. This information will help researchers and clinicians make better predictions about possible outcomes for individual patients, and develop treatment plans that are suited to the individual.

We are also recruiting young people who are not experiencing any UHR symptoms in order to provide information on what the differences may be between a young person with UHR symptoms

and a young person with no UHR symptoms. By having young people without these symptoms, we are able to better identify differences between the two groups, which will ultimately help us target treatments (e.g. talking therapy or medications) more accurately.

Deciding whether to take part in this research study

This Participant Information Sheet and Consent Form tells you about the research study, and explains the assessments involved. Knowing what is involved will help you decide if you want to take part in the study or not.

Please read this information carefully. Ask questions about anything that you don't understand or want to know more about. Before deciding whether or not to take part, you might want to talk about it with a relative, friend or healthcare worker.

Participation in this study is voluntary. If you don't wish to take part, you don't have to. You will receive the best possible care whether you take part in the study or not.

If you decide you want to take part in the research study, you will be asked to sign the consent section. By signing it you are telling us that you:

- Understand what you have read
- Consent to take part in the research study
- Consent to the tests and research that are described
- Consent to the use of your personal and health information as described.

When we say 'personal information', it also means 'personal data', which is the phrase used in some countries to refer to this type of information.

You will be given a copy of this Participant Information and Consent Form to keep.

Once you have consented, a researcher will conduct a screening assessment to establish the level of symptoms you are experiencing. After this assessment, the study team will work out if you are eligible for the study or not. It is possible that you might consent to the study but then not be eligible to take part in it.

2 What is the purpose of this research?

For young people seeking mental health support, it's important for clinicians to be able to predict whether the problem will get better, stay the same, or get worse and to know what kinds of treatments would be most helpful. Making predictions about mental health concerns is difficult at the moment as there are still many things that we don't know about how mental health symptoms progress over time.

The purpose of this research is to examine a range of potential risk factors for psychosis and to create tools to more accurately predict outcomes for young people who may be at increased risk of psychosis. This can then be used to offer more suitable treatments to new patients and also to develop new, more effective treatments.

To do this, we will recruit up to 1,187 participants across Australia, Asia and Europe, and collect a wide range of information about their symptoms, experiences, behaviour, family history, thinking processes (neurocognition), and biology.

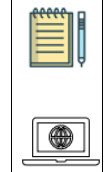
3 What does participation in this research involve?

Consent and the study assessments are presented as a graphic on the next page (Table 1). The assessments are then described in items 'A to I' below. The aims of the research study will be best achieved if you participate in *all* assessment components.

Table 1. Overview of Study Components and Time-points

KEY  **Consent**  **Clinical Interview (A, B, J)***  **Neurocognitive Tasks (C)**  **Brain Scan (D)**  **EEG Tasks (E),**

 **Speech Recording (F)****  **Fasting Blood Collection (G)**  **Fasting Saliva Sample (H)**  **Digital Assessments (I)**

Consent then Screen	Baseline (First assessment / starting point)	Month 1	Month 2	Month 3	Month 4	Month 5	Month 6	Month 7	Month 8	Month 9	Month 10	Month 11	Month 12	Month 18	Month 24
															
2 hours	9-10 hours	1.5 hours	7.5-8.5 hours	1.5 hours	20 mins	20 mins	2.5 hours	20 mins	20 mins	20 mins	20 mins	20 mins	3-3.5 hours	2 hours	3.5 hours
Digital Assessments															
	 Baseline to 12 months (daily) 														

*Note: If your symptoms increase in frequency or severity to the point that they meet criteria for psychosis, a Clinical Interview (J) will be completed at this time. This may occur at the same time or in addition to the time-points listed above. You will still complete other time-points as normal.

**Note: The speech recording involves the free speech interview as well as a 20 minute recording of a portion of the screening clinical interview and follow up assessments.

A) Screening Assessments: If you consent to the study, you will first be asked some general questions to determine whether you are eligible to participate. These questions relate to the presence of psychiatric symptoms, the history of these symptoms, as well as any relevant background information.

It is possible that you will not be eligible for the study following the completion of the screening assessments. If that is the case, your participation in this study will end and you will not go on to complete any other assessments–This will not affect your current treatment at *[site],* or your opportunity to take part in other studies being conducted at *[site].*

For the speech component of the study (see item F), we would also like to voice record a portion of the screening assessment and follow up assessments (approximately 20 minutes at each time point) in order to better understand thinking processes and also to make sure assessment instruments are being correctly rated.

The screening assessment can be completed remotely (via video call) or in person (for example, in your home or at *[site]*). It will take approximately 2 hours to complete.

B) Baseline Clinical Interview: 'Baseline' refers to the starting point from which all other assessments are compared. The interview will consist of questions about your day-to-day life and activities, your mood, behaviour, emotions, and other experiences you may be having. We will also ask you questions about your schooling and employment, medical history, and drug and alcohol use. This interview will take between 3–4 hours and can be completed in person either in your home or at *[site],* or via video call. The interview can also be completed in smaller blocks of time on different days over 2-3 days if you'd prefer.

C) Neurocognitive Tasks: You will be asked to complete tasks that assess your 'thinking processes' - attention and memory, problem solving skills and the way you respond to different cues. Most of these assessments will be delivered via computer. The tasks will be completed at baseline, month 2, month 6, month 12 and month 24. They will take approximately 45mins-1 hour to complete at baseline and between 10 and 45 minutes at the other time points. *[English speaking sites: "Part C can be completed via video call or in person"; non-English speaking sites: Part C will need to be completed in person].*

D) Brain Imaging Scan: As part of the study, you will be asked to have MRI scans. These will be performed at *[scan site]* at baseline and month 2. The MRI session will take about 1.5 hours to complete. During this time, you will spend about 45 minutes actually in the scanner. MRI uses electromagnetic fields (radio waves), but no radiation. The scanner will be used to take pictures of the anatomy of your brain and its functioning over time.

Before the MRI scan, you will be asked questions to make sure it is safe for you to have the MRI. A Research Assistant will go through the procedure and safety requirements prior to scheduling the MRI. You will not be able to participate in the MRI if you have any metal objects on or in your body, such as braces or metal pins or screws. However, you may still participate in all other aspects of the study. We will ask you to lie on a table inside the MRI scanner and make sure you are in a comfortable position so you can keep still. The scanner is noisy and we can give you some earphones to reduce the noise. For roughly half of the time you are inside the MRI scanner you will be able to close your eyes and relax. For the remaining time you will be asked to relax and stay focused on a screen in front of you.

E) Electroencephalography (EEG) Tasks: You will be linked to an EEG machine so that electrical brain activity can be recorded while you complete some simple tasks. To do this, a cap containing several small detectors known as 'electrodes' will be placed on your head, and a gel will be applied under each electrode to ensure that the electrical activity of your brain is recordable by the electrodes. You will need to wash your hair either just before you come in for the EEG session, or the night before your EEG session. It is important that you don't use any type of hair product (e.g., gel, spray, cream,

foam or mousse) before the session as these substances can make EEG recordings difficult. EEG recordings will be completed at baseline and month 2. They will take place at *[EEG site].* We anticipate the EEG tasks, including the time spent setting up, will take approximately 1.5 to 2 hours.

F) Free Speech Interview: This component involves open-ended audiotaped conversations with a Research Assistant (at baseline andfollow up visits) about recent experiences and events in your life. These conversations last up to 20 minutes and can be completed via video call or in person.

As with the screening assessment, the purpose of this component is to better understand thinking processes by analysing speech patterns. We will also record video of the free speech interviews in order to analyse facial expressions and body movements. The recordings can be done either in person or via video call. If via video call, the researcher will arrange to meet with you via an online video platform and record the session. Before they start the recording, they will provide you with instructions on how to set up the laptop or phone and select the right settings so that the recording is clear.

The audio and video files will be stored on a secure computer, transcribed and reviewed, and any personal information about your health or information that can be used to identify you will be removed. These transcripts, which are completely anonymous (that is, have no names or identifying information other than a code number, to protect your identity) will then be analysed by computers for language and facial expression/body movement patterns and analysis of acoustic properties. After they've been analysed, they will be archived for potential future research at the NIMH Data Archive (NDA). See section 15 for more information.

G) Blood Sample: For this component, 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. The blood sample will be collected at *[pathology site]*, at your home, or *[site]*. On the morning of the blood test, we ask that you do not eat any food from the time you wake up until the blood test is completed. We encourage you to drink water before the blood test. Approximately 40ml (or 2.5 tablespoons) of your blood will be taken. At these time points, your vital signs including height, weight, blood pressure and temperature will also be assessed. This component will take approximately 20 minutes to complete.

H) Saliva Sample: We would like to collect fasting saliva samples at baseline and again at month 2. This involves depositing a small amount of saliva into a spit pot 3 times over a 2-hour period. Fasting, in this case, means no food or drink in the 4 hours prior to or during the 2-hour collection period. Saliva samples allow us measure levels of a stress hormone named cortisol. The saliva samples can be collected at your home, or at *[site]*.

I) Digital Assessments: This involves 3 parts.

For assessments 1 and 2 you will need to own a smartphone. You will be asked to download an app ('MindLAMP') on your smartphone.

1. **MindLAMP daily surveys:** This involves answering short (1-2 minute) surveys once a day (in the evening) on your smartphone using an app called 'MindLAMP' for a period of 12 months. The surveys contain questions regarding your current wellbeing, daily activities and context. You will also be prompted by the app to make short (2 minute) audio recordings (an 'audio diary') on a daily basis about your recent experiences, events and context. Once the MindLAMP 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 from the MindLAMP app can be uploaded to a secure Orygen data server based in Melbourne, Australia. The data transfer will only occur when your mobile phone is connected to a Wi-Fi network and will not affect your current data and voice plans from your mobile service provider. In the event that your MindLAMP 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 MindLAMP app.

2. **Passive sensing:** MindLAMP automatically ('passively') collects data stored in your phone from your phone's GPS and accelerometer sensors. There is nothing that you need to do for this data to be captured. GPS stands for global positioning system. It allows the phone to know where you are physically located and stores this data. GPS is usually accurate to within 3 metres, which means this app will collect data on where you are (location). The accelerometer sensor measures physical acceleration (whether the phone is in motion or not). For the purpose of this study, this passive sensing data will be turned into measures like how much time you may spend at home each day and how long you may be asleep for. However, the 'raw' (unprocessed) passive sensing data will be transferred to the NIMH Data Archive (NDA) along with other data, to be made available to other researchers if they apply to access it, as described later in this document. This data is important for the study because it can help us understand how different environments and activities impact people's mental health.

3. **Activity monitor:** You will also be asked to wear an activity monitor (like a fitbit) the size of a wristwatch during the same 12-month period. The watch will collect information about your physical activity levels that will be used to analyse your sleeping pattern and movement intensity. 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 want to participate in one or more of these, please indicate this in the consent section at the end of the form.

You will be asked at the baseline time point to participate in an orientation session conducted by a Research Assistant. The Research Assistant will explain to you how to download and use the smartphone apps before going through a demonstration. You will also be shown how to use and wear the activity monitor. This demonstration may be conducted in person, or remotely via phone call or video chat. The watch will be replaced every 4 four weeks. Where safe to do so, the watch exchange will be done in person, or alternatively via postage or contactless drop off/pick up. The orientation for Part I (digital assessments) can be completed with the Research Assistant in person or remotely. There will be a need to meet in person to swap for a new watch every now and then but all other aspects of Part I will be completed remotely. Each time you return a watch, you will receive one entry into a $100 raffle to be drawn at the end of the study.

If you take part in all components (parts B to I) the baseline assessment should take approximately 9-10 hours to complete. This can be done over multiple sessions, so as not to be too tiring or burdensome. The same goes for the month 2 time-point at which all of the components are repeated. The Research Assistant will check in with you regularly to ask if you would like to take a break or continue with the remaining items on another day.

J) Monthly Follow-up Assessments until month 12, plus at month 18 and month 24: We will ask you to complete a clinical interview (similar to part B) every month for 12 months and again at month 18 and month 24. If your symptoms increase in frequency or severity to the point that they meet criteria for psychosis, a clinical interview will be completed at this time. These interviews will be shorter than the baseline interview, taking between 20 minutes and 2 hours to complete, depending on the month of follow up. We will ask some of the same questions, covering the period since we last saw you. Interviews can be completed in person either in your home or at *[site]*, or remotely (via phone or video call). As mentioned above, we would also like to audio record a portion of the follow up assessments (approximately 20 minutes). The study team will send you text messages every now and then as reminders of upcoming appointments. Please let the Research Assistant know if you would prefer an alternative form of contact.

K) Permission to Access your Medical Records: In order to collect information required for this study we will be asking for your permission to access your medical records held at *[site].* Only

information associated with this study will be collected. The information collected includes your medical history relevant to the study, information related to your symptoms, any medications you've been taking, and whether or not your family has a history of psychiatric disorders and other medical disorders. Young people are sometimes classified in UHR because someone in their family has been diagnosed with a psychiatric disorder. Therefore, evidence of a family history of psychiatric disorders will be obtained from your medical record and from the information you provide during the initial interview. We will collect the following information should any of your family members have a psychiatric disorder: how they are related to you, what their diagnosis is, how the diagnosis was verified and any other important information you provide that gives the researchers an understanding of the extent of the family member's psychiatric disorder. This information will be collected from you directly or from your medical record. Your family members' medical records will not be accessed unless they are also participating in the study.

If you withdraw from the study or we are unable to recontact you, we may access state-wide Government databases, such as the Client Management Interface (CMI*)/[alternative site system if applicable],* to find out if you have had further contact with mental health services and to acquire information about your health after you end your participation in the study. This information will only be accessed by the study team up to 26 months from your baseline assessment. The Client Management Interface (CMI) is the local client information system used by each public mental health service.

L) Permission to contact a friend/family member and pharmacist: We would like you to nominate at least one friend or relative who we may contact to obtain information about your health and treatment or your latest contact details if we are unable to contact you. We would also like your permission to contact your pharmacist to obtain details of your medications, if required. You can decide not to provide these details if you would prefer us not to contact a friend/family member or pharmacist.

M) Treating Doctor / Psychiatrist / General Practitioner (GP): In order to participate in this study, we ask that you engage with a doctor, including a Psychiatrist or a GP, for the duration of the study if you are not already. We also ask that you provide their details so that the study team can advise them of your participation in the study and liaise with them to ensure that you are well-supported throughout the study.

[Section M is a requirement for Orygen Clinical Trials Unit and can be deleted by sites as required].

N) Reimbursements:

There are no costs associated with participating in the research project. As an acknowledgement of the time and effort involved in participating in the study, you will be reimbursed the following amounts for each component completed *[AUD - adjust for local currency]:*

- $60 for the baseline clinical interview (B)
- $40 for each follow up clinical assessment time-point (J)
- $40 for each neurocognitive assessment (C)
- $50 for each MRI (D)
- $50 for each EEG assessment (E)
- $30 for each free speech interview (F)
- $30 for each blood test (G)
- $30 for a saliva sample time-point which includes 3x samples over 2 hours (H)
- Up to $150 (depending on how much you complete) for the digital assessment component (I)

Participants who complete all assessment components and time points (excluding the digital assessment component) will receive a 'completion payment' of $100 in order to reimburse them for their extensive time commitment. This will be provided at the end of the study along with the month 24 follow up clinical assessment payment.

The total reimbursement for completing all components at the baseline time-point $290. The total reimbursement for completing the entire study (all components at all time-points) is $1,450. Taxi vouchers can also be provided if required.

4 What do I have to do?

Participation in this study means that you will be asked to participate in the assessments described above and follow instructions about the assessments provided by the research staff. You are also responsible for letting the research staff know if you no longer want to participate in the study, if you have been hospitalised during the study, if you become pregnant, or if your contact information changes.

Please also let the research staff know if you are currently participating in any other studies or join any other studies while you are taking part in this one.

Participation in this research will not result in restriction of your diet, lifestyle or treatment options.

5 Where will I need to go to complete the various components for this study?

The table below shows where each of the parts in this study can take place. For the parts that can be done remotely or in your home, the Research Assistant will discuss the options and help you to pick what is best for you based on your preference and the timing of each of the components.

Table 2. Assessment Component Locations

Parts that can be completed in person, over the phone, or via video call	Parts that can be completed via video call but not over the phone	Parts that will need to be completed in person but the researcher can either come to your home or you can attend the relevant clinic	Parts that will need to be completed onsite at a relevant medical facility
Part J (monthly follow up interviews only). Consent, Parts A and B (screening and baseline interviews) will need to be done via video call or in person	Parts A and B	Part I will mostly be completed online but you will just need to meet with the researcher every now and then to swap for a newly charged watch	

KEY

Consent | Clinical Interview (A, B, J) | Neurocognitive Tasks (C)

Brain Scan (D) | EEG Tasks (E), | Speech Recording (F) | Fasting Blood Collection (G)

Fasting Saliva Sample (H) | Digital Assessments (I)

6 Other relevant information about the research project

[International sites to adjust this section for their local IRB submission].

It is expected that up to 1,187 participants will take part in this research project over a two-year recruitment period. These participants will be recruited from the community and from Orygen, and its associated networks in Melbourne, Victoria; from headspace and headspace Youth Early Psychosis Programs in South Australia and Western Australia; as well as mental health centres and communities in Europe and Asia.

7 Do I have to take part in this research project?

Participation in any research project is voluntary. If you do not wish to take part, you do not have to. If you decide to take part and later change your mind, you are free to withdraw from the project at any stage. If you do decide to take part, you will be given this Participant Information and Consent Form to sign and you will be given a copy to keep. Your decision whether or not to take part, or to take part and then withdraw, will not affect your routine treatment, your relationship with those treating you or your relationship with *[site].*

8 What are the alternatives to participating?

You do not have to participate in this research project to receive treatment from *[site].* You can continue with your current treatment as usual if you choose not to participate or if you choose to consent and later withdraw from the project. You can discuss the option to participate with your clinician or with your local doctor.

9 What are the possible benefits of taking part?

This research study may help us to understand the different courses of symptoms in young people who may be at risk of developing psychosis, to predict these different courses early on, and to match treatments to each course of symptoms.

The results of this research project will be used for research purposes and will not provide you with any direct benefit nor are they intended to be used as part of clinical examinations. Results will not be used to help diagnose, treat or manage a particular condition. While we do not expect your MRI scan, EEG or blood samples to indicate any abnormalities that may be of clinical significance, there is a small chance that this could occur. If it does, your treating team will be informed. They, or an appropriately qualified (medically trained) study team member, will contact you to let you know that a potential clinically relevant finding has been identified and ask you if you would like to know about the results. If you do, the clinical team and/or study team will discuss the results with you and will assist you to organise any follow up assessments that may be required.

10 What are the possible risks and disadvantages of taking part?

The physical risks involved in participating in this study are very low. Should you feel distressed when being interviewed, we ask that you let the interviewer know. The interview materials and the types of questions asked in this project have been used in projects in the past and no adverse effects have been reported. You can choose not to answer any questions or participate in any part of the project that makes you feel uncomfortable. If you feel uncomfortable or distressed during any of the procedures in this study, you can request to stop at any time. The research team will be able to

arrange counselling or other appropriate support for you. Any counselling or support will be provided by staff who are not members of the research team. Please also see section 19, “Clinical/mental health support contact person”.

The EEG procedure is painless and safe and there are no known health risks. It is possible that you may feel mild discomfort when the cap containing the electrodes is put on your head, because it is a little tight, like a swimming cap. The gel used to enhance EEG recordings is a colourless, odourless and hypoallergenic substance. The gel is administered to the scalp with a blunt tip, plastic syringe. You may experience some slight discomfort when the tip rests on your scalp and are encouraged to inform the technician of any discomfort throughout the session.

An MRI does not produce or expose you to any radiation. However, as the imaging machine produces a magnetic field (like a ‘giant magnet’) it is important that you do not take metal objects into the scanner. You must tell the researcher if you have metal implanted in your body, if you have been involved in an accident in which metal may have got into your body, or if you are pregnant. Prior to the scan at *[site]* you will be asked to fill out a medical history form which the radiographers will discuss with you, to make sure there is no reason for you not to have the scan.

MRI is considered a safe procedure when performed at an experienced centre with appropriate guidelines. The space inside the MRI scanner is small and can be quite noisy. Feelings of mild anxiety or claustrophobia are normal in the first few minutes. If these feelings persist or become distressing, testing will stop until you have recovered.

The risks of the blood sample collection are the same as those of ordinary blood tests. When your blood is drawn there may be some small discomfort, pain and/or bruising. Infection, swelling, excess bleeding, clotting or fainting are also possible, although less common. If this happens, it can be easily treated. There is no known risk associated with saliva collection.

A risk associated with audio and video recordings and use of watch and app data includes potential data breaches. This risk is low and will be mitigated through the use of coded files, restricted logins and secure data transfers.

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.

11 What if new information arises during this research project?

During the research project, new information about the risks and benefits of the project may become known to researchers. If this occurs, you will be told about this new information and the researchers will discuss whether this new information affects you.

12 What if I withdraw from this research project?

You are free to withdraw from this research project at any point during the study. If you decide to withdraw from the project, please notify a member of the research team. This can be done in person (for example, at an appointment), or via a phone call or text message. This notice will allow a research staff member or supervisor to further discuss with you any concerns linked to withdrawing from the research project. Your decision to withdraw from the research project will not affect your clinical care.

If you withdraw during the research project, the study team will not contact you to collect any additional personal information but may seek information from your medical records regarding your contact with health services (see items J and K above). Information that was already collected during

the research project will be retained to ensure that the results of the study can be measured accurately and to comply with applicable laws. You should be aware that data collected up to the time you withdraw will form part of the research project results. If you do not want the research team to do this, you must let them know at the time of withdrawal.

13 Could this research project be stopped unexpectedly?

This research project may be stopped unexpectedly for a variety of reasons. These may include reasons such as:

- Decisions made by the investigators
- Loss of funding

14 What happens when the research project ends?

Once the study is complete and the results are known, a written plain language summary of the overall results of the study will be posted on the Orygen website and sent to you upon request. To obtain this please record your email address at the end of this document. You may also contact one of the investigators listed in Section 19.

15 What will happen to information about me?

We will rely on your explicit consent as the lawful basis on which we will collect, use and share your personal information. In some countries this is known as 'processing your personal data'.

By signing the consent form you consent to the relevant research staff collecting and using personal information about you for the research project in the way described. Your personal information will remain confidential, be securely stored and will only be used for the purposes stated in this document

How is my privacy protected?

First, your identity and contact details (your name, date of birth, address, email address and phone number) are removed from the other records, and replaced with a unique code. The code is your 'participant number'. Your other data, health records and samples, including images (i.e. MRI and EEG), will then be identified only by your participant number. This is known as 'coded data'.

The research team at *[site]* will have the link between your identity and contact details and your participant number. The principal investigator of this project, and local study team, will keep the identity and contact details that matches your participant number in a securely protected database. The participant number can be used to single out and combine your data from different records, without re-identifying you.

Your participant number will allow researchers to see if you have been involved in more than one research study or database. For example, if you have participated in more than one study or database, this participant number will help connect information across studies. This participant number will also allow your coded data to be combined with data from other research studies to increase the likelihood of meaningful analysis. Only this participant number will be accessible to other investigators. This participant number may make it possible for a study team member to re-identify you if the same participant number was used for another study that you took part in.

We aim to keep all the information that we collect in the assessments strictly confidential. However, there are some exceptions to this: 1) information from the assessments may be communicated to your treating doctor/case manager/clinician to ensure that you receive the best care possible; 2) if we are concerned about risk to yourself or to someone else, we may need to discuss this with your

treating doctor/case manager/clinician at the service where you receive treatment; 3) if during the interview you provide information around current or past trauma or abuse and we believe someone may be at risk. In some cases, we may contact services responsible for monitoring risk to children under the age of 17 years. Mandatory reporting laws for *[site/country/state]* require *[include relevant site-specific mandatory reporting laws]*. In cases where abuse is reported, information gathered by researchers is passed on to your clinical team and the appropriate clinical procedures normally used within their clinical service are implemented. We will try to the best of our ability to discuss this with you first.

Test Samples / Biospecimens

By participating in this study, you consent to the collection, storage and use of blood and saliva test samples/biospecimens.

Blood samples will be collected by a trained staff member at two separate study time points (baseline and month 2). Some of your blood will be transferred to an appropriate pathology service for immediate testing. These initial research analytical samples will be destroyed upon analysis according to the standard operating procedures of the pathology service. Other blood samples will be stored in an -80 Celsius freezer prior to being transferred to *[add if international or interstate: "Melbourne, Australia for central storage before being sent to"]* an external contracted collaborator for analysis purposes. Saliva will require self-collection at baseline and month 2 and you will be provided with the containers and verbal instructions for how to do this.

Analysis of biospecimens including blood and saliva usually takes place toward the end of the study so your samples will be stored in a secure facility until an appropriate point in time. All samples obtained for the purpose of this research project will be shipped to the Florey Institute of Neuroscience and Mental Health in Melbourne, Australia for central storage. The Florey Institute will store the samples and arrange shipment to the respective laboratories for analysis. Saliva samples will be analysed at a to be determined lab. Blood samples will be sent to a laboratory/ies (location to be determined) for analysis.

Following the completion of analyses for the current study, your remaining genetic (DNA) and other biological samples will be shipped to the NIMH Repository and Genomics Resource (NRGR) which is a central location called a 'repository' or 'bank' located in the United States. Your identity and contact details will not be provided to the repository, only your participant ID. Samples are stored in the repository indefinitely and made available to other researchers upon approved application to conduct research in the future. All requests for access to data and biospecimens from the NRGR made to the NIH in the United States will be reviewed by an NIH Data Access Committee. The study team will not be involved in the process and as such, your samples may be used for research outside the scope of this project. It is important to note that further consent for these additional research activities will not be sought directly from you. *[Sites to add if needed for local IRB submission: "The blood and saliva samples will not be used for restricted human biomedical research involving human-animal combinations."]*

Genetic Research and Privacy

Genetic material or your genetic code (DNA) will be extracted from your blood samples in order to perform genomic analyses. We may extract the whole DNA sequence or just parts of your DNA The genetic research undertaken with your DNA sample will only involve the study of genes of research interest. The genes investigated will not be diagnostic nor have any relevance for your current or future health. Your samples might be used to help with current research into genetics and other further genetic studies, and include types of questions which have not even been thought of yet, because knowledge of genetics and how genetic make-up relates to a person's physical and mental health is progressing at such a fast rate.

The type of genetic testing being conducted in this study is not designed to provide information about your future health, future treatment or risk of having children with a genetic disorder. It is also not designed to provide information that may be relevant to the health of family members who are not part of the project. We also do not expect that it will have any consequences for your future insurance or employment. We will not provide you with any individual results from analysis of the research samples you provide us. While we do not expect to find any clinically significant results in one of your samples, there is a small chance this could occur. If it does, the research team will be contacted so they can link your sample code with your personal details and make contact with you and your clinical team. Your clinical team or a medical study team member will then contact you to ask if you would like to know about the results. If you would, they will discuss the findings with you and advise on any follow up required.

If you choose not to give us access to your genetic material, that is your right and that will not affect your relationship with *[site]* or your treating clinicians. If you give permission, but later choose to withdraw that permission, you can contact the research team at any time and request that your genetic material be destroyed and not included in future research (contact your relevant study contact or the researcher listed in section 19 at the end of this form to do this). You are free to change your mind at any time. In that case, *[site]* will instruct that your samples immediately be destroyed permanently and completely according to the storage facility's Standard Operating Procedure for destruction of genetic material. Data generated and shared prior to your request to destroy the samples will be retained.

A risk of genetic research is a potential loss of privacy. We take careful measures to protect your privacy and confidentiality. However, it is possible that someone could obtain unauthorized access or break into the system that stores information about you. If your genomic information is linked back to your personal details, someone might use this information to learn something about your health. There also may be other privacy risks that we have not foreseen. Every precaution will be taken to minimise this risk, including use of special ID codes, passwords, and restricting access to research databases.

Should any information unexpectedly become available, we will assist you in seeking appropriate counselling and follow-up. However, it is not expected that you will experience any consequences of consenting to provide researchers with use of this genetic material.

Data Transfers and Storage

During this study, all of the personal information collected about you will be kept strictly confidential. Hard copy study records will be kept in secure storage by *[site].* Electronic copies of personal information will be stored on secure servers and will be password protected and accessed only by researchers involved in this project. As mentioned above, your data will be identified only by a unique code (your participant number). Data transfers will comply with local data security standards and industry best practices.

Data from the MindLAMP app and watch will be uploaded to a secure data server based in Melbourne, Australia, only when your phone is connected to a Wi-Fi network. Therefore, it will not affect your current data and voice plans from your mobile service provider. All transactions with the servers are encrypted. Your phone/watch data will not be shared with clinicians. No one will be monitoring this data during its actual collection. For the purpose of the study this data will be analysed using computer programs. The analysis will look at roaming, movement and sleep patterns rather than specific activities.

This study has received funding from the National Institute of Health (NIH) in the USA, and as part of this funding, data from the study will be submitted to the National Institute of Mental Health (NIMH) Data Archive (NDA) based in the USA. During and after the study, the researchers will transfer your coded data from Orygen/University of Melbourne servers to a secure server at the NIMH NDA (NDA Staging Environment). The NIMH NDA Staging Environment will only be accessible by the Data

Processing Analysis and Coordinating Center (DPACC), which is another organisation based in the USA. The DPACC will only access your coded data and will not access the link between your coded data and personal identifying information. The DPACC will, however, have access to the dates on which you completed the various assessments. The DPACC will conduct data monitoring and quality control checks on the data in the NDA Staging Environment. In rare circumstances, the DPACC may also require access to some of your coded data on Orygen/University of Melbourne servers for QC and monitoring purposes, prior to it being sent to the NDA Staging Environment. After the DPACC review, your coded data will be transferred to the NIMH NDA Collaboration Space.

Researchers and organisations involved in this project will have access to the data in the NDA Collaboration Space for monitoring and data analysis. Access to the NDA Collaboration Space will be controlled by the NIMH and not by the PRESCIENT study team or by your local study staff.

Your audio and video recorded interviews will be coded (i.e., your personal details will be removed) before they are transferred to the NIMH NDA. A professional transcription service called TranscribeMe, based in the USA, will listen to your audiotaped interview and make a transcription of it (that is, they will write down everything that is said). Computer software called OpenFace will be used to extract information about facial expressions from the video recording. Acoustic properties will be extracted by OpenSmile. The study team will then check that these transcripts and information from the videos do not accidentally contain anything that might identify you. If the transcript does unexpectedly contain identifying information, the study team will manually code it. Only the coded data derived from audio and video-recordings will be transferred to the NIMH NDA. The original audio and video recordings will be stored indefinitely on secure servers at [site name]. The 'raw' (unprocessed) passive sensing data, including location data, will be transferred to the NIMH NDA.

Every six months the NIMH NDA will make the study data available to the general research community (NDA Curated Releases). This will include your coded data as well as the raw passive sensing (location) data. By sharing this data broadly with other qualified researchers we hope to learn new and important things about mental illnesses more quickly than we did before. The reason for making 'raw' (unprocessed) physical location data available to the general research community is that this data may be particularly useful for helping us understand how different environments and activities impact people's mental health. Experts at the NIMH who know how to protect health and science information will look at every request to access the data carefully to minimize risks to your privacy. For example, all researchers who have access to or request data have to agree to not try to identify you and will also be required to have their institution's approval to review the data that could potentially be used to identify you. Access to your physical location data will specifically require the institution's ethics committee approval. 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.

By agreeing to participate in this study, you agree to the NIMH NDA making your coded data and location data (if you consent to this component) available to the general research community for future research purposes and that the data will be retained for as long as it will be informative to research.

You may not benefit directly from allowing your study data to be shared with NIMH NDA. The information provided to NDA may help researchers around the world treat future children and adults at risk of mental illnesses so that they have better outcomes. NIMH will also report to Congress (parliament of the USA) and on its website about the different studies using NDA data. You will not be contacted directly by NIMH or the DPACC about the study data you contributed.

If you consent to participate in this study, your data and samples will be sent to the NDA and NRGR. If you later choose to withdraw your consent, you can contact the research team at any time and request that your study data and/or samples not be shared with NDA and/or NRGR (contact your relevant study contact or the researcher in section 19 towards the end of this form). Once the

researchers have been notified, your data will be removed and remaining samples destroyed. However, NDA and NRGR cannot take back information or samples that were shared before you changed your mind.

If you would like more information about NDA, this is available on-line at the NIMH Data Archive web page (currently http://data-archive.nimh.nih.gov). For more information about the NRGR biorepository, you can visit their web page (currently https://nimh.isi.edu/).

Cloud Storage

Your study data may be stored in the Cloud. "In the Cloud" refers to servers in a data centre that are managed by a third party and accessible through the Internet. Your data will be coded with a unique code before it is encrypted and stored on a secure Cloud server to prevent improper access. This data will be part of a broader Orygen database.

How data will travel to other countries

For participants in the European Union, when you agree to participate in this study, you are agreeing to the transfer of your personal information to Australia and then on to the USA. Neither Australia nor the USA are recognised by the European Union as having laws protecting privacy which are equivalent to the laws which exist in the European Union (the General Data Protection Regulation (GDPR)). However, by virtue of running this study, Orygen is itself regulated by the GDPR, as well as by the Australian privacy laws (the *Privacy Act 1988*) which offers enforceable rights to privacy. In addition, only coded information (and your location data) will be transferred from Orygen to the NIMH in the USA.

Data Sharing

At times, a participant may choose to participate in more than one research project. In such cases, we ask that the data collected as part of one research project may be shared with other research projects. As many of the same measures are used across different projects, the purpose of sharing data is to prevent unnecessary repetition of assessments and ensure that participation in both projects is as simple as possible for the participant.

Health Records

Information about you may be obtained from your health records held at this site, *[insert relevant site]* or for the purpose of this research. By signing the consent form, you agree to the study team accessing health records from *[site]* if they are relevant to your participation in this research study.

Information about your participation in this research project will be recorded in your health record. Your health records and any information obtained during the research project are subject to inspection (for the purpose of verifying the procedures and the data) by the relevant authorities such as the Therapeutic Goods Administration (TGA) and authorised representatives of the Sponsor, Orygen, by *[institution relevant to this Participant Information and Consent Sheet]*), or as required by law. Authorised representatives from DPACC and other researchers who request access to data from the NDA will not have access to your health records. By signing the Consent Form, you authorise release of, or access to, this confidential information to the relevant study personnel and regulatory authorities as noted above. Your information will only be used for the purpose of this research project and it will only be disclosed with your permission, except as required by law.

Freedom of Information

In accordance with relevant privacy and confidentiality laws, you have the right to request access to your information collected and stored by the research team. You also have the right to request that

any information with which you disagree be corrected. *[For sites in which this is relevant, add line: You can also request for your data and test samples to be deleted or destroyed provided they have not already been used in analyses. Data entered into the secure database cannot be permanently deleted (an audit trail is retained) but it will not be included in analyses if you let us know prior to analyses taking place].* You can contact the study team member named at the end of this document if you would like to access your information or if you would like to know more about your rights about your information.

Publication

It is anticipated that the results of this research project will be published and/or presented in a variety of forums. In any publication and/or presentation, information will be provided in such a way that you cannot be identified, except with your permission.

A research study team member or a representative of the Orygen communications team may contact you asking for your thoughts on the research project or your lived experience of mental health. You are free to say no to their requests, or to provide comments anonymously (i.e., your name will not be used in any media releases). Your comments may be used to promote the research study's findings on social media, in a news article or other communications materials. If you do not wish to be contacted for communications purposes, please let a member of the study team know.

Future Research

All data collected from you may be kept indefinitely. The researchers may choose to destroy the samples at any time. Your data may also be used for future research which has not yet been identified, and which may or may not be related to this current research or other research projects you have participated in. Please see 'Data Transfer and Storage' section above (p.11-12) for potential future use of your data. Access to your data and/or samples from the NIMH NDA for studies will need to be approved by the NDA, which has clear guidelines for data use. Access to your location data from the NIMH NDA for future research studies will also require approval from the applicant institution's local ethics committee.

16 Complaints and compensation

[This section to be adjusted by international sites for their local IRB submissions]

If you suffer any injuries or complications as a result of this research project, you should contact the study team as soon as possible and they will be assisted with arranging appropriate medical treatment. If you are eligible for Medicare, you can receive any medical treatment required to treat the injury or complication, free of charge, as a public patient in any Australian public hospital.

In the event of loss or injury resulting from study participation, the parties involved in this study agree to be bound by the Medicines Australia Guidelines for Compensation for Injury Resulting from Participating in a Clinical Trial. A copy of these guidelines is available from the study staff or can be accessed online at the Medicines Australia website.

17 Who is organising and funding the research?

This research has been initiated by the study Principal Investigator, Professor Barnaby Nelson. The sponsor for the study is Orygen which is a youth mental health organisation.

This research has been funded through an award from the United States National Institute of Health (NIH), National Institute of Mental Health and is part of the Accelerating Medicines Partnership®

program (https://www.nimh.nih.gov/research/research-funded-by-nimh/research-initiatives/accelerating-medicines-partnershipr-program-schizophrenia-ampr-scz).

No member of the research team will receive a personal financial benefit from your involvement in this research project (other than their ordinary wages).

You will not benefit financially from your involvement in this research project even if, for example, your data (or knowledge acquired from analysis of your data) prove to be of commercial value to Orygen or *[site].*

In addition, if knowledge acquired through this research leads to discoveries that are of commercial value to Orygen or *[site]*, there will be no financial benefit to you or your family from these discoveries.

18 Who has reviewed the research project?

[This section to be adjusted by interstate and international sites for their local IRB submissions]

All research in Australia involving humans is reviewed by an independent group of people called a Human Research Ethics Committee (HREC). The ethical aspects of this research project have been approved by the HREC of Melbourne Health.

This project will be carried out according to the National Statement on Ethical Conduct in Human Research (2007). This statement has been developed to protect the interests of people who agree to participate in human research studies.

19 Further information and who to contact

The person you may need to contact will depend on the nature of your query.

Coordinating Principal Investigator

Name	Professor Barnaby Nelson
Position	Coordinating Principal Investigator
Telephone	+61421 204 818
Email	Barnaby.nelson@orygen.org.au

Site Principal Investigator

Name	
Position	
Telephone	
Email	

If you want any further information concerning this project, or for matters relating to research at the site at which you are participating, the details of the complaints person are:

Information and Complaints contact person

Name	
Position	
Telephone	
Email	

If you have any medical problems which may be related to your involvement in the project (for example, any side effects), you can contact the principal study doctor/clinician:

Clinical /mental health support contact person

Name	
Position	
Telephone	
Email	

In case of emergency, please call *[000; or local country emergency number]*. If you require out-of-hours contact, you can call *[the 24-hour Orygen clinical team (Youth Assessment Team) on 1800 888 320; or local crisis support team].*

If you have any complaints about any aspect of the project, the way it is being conducted or any questions about being a research participant in general, then you may contact:

Reviewing HREC approving this research and HREC Executive Officer details

Reviewing HREC name	*Melbourne Health HREC*
HREC Executive Officer	*Manager HREC*
Telephone	*(03) 9342 8530*
Email	*Research@mh.org.au*

Data Protection Officer details

Data Protection Officer name	
Telephone	
Email	

Consent Form – UHR Participants (Self)

Title	Trajectories and Predictors in the Clinical High Risk for Psychosis Population: Prediction Scientific Global Consortium
Short Title	PRESCIENT
Protocol Number	2021.166
Project Sponsor	Orygen
Coordinating Principal Investigator	Professor Barnaby Nelson
Site Principal Investigator	*[insert relevant PI]*
Location	*[insert relevant location]*

Consent Agreement:

- I have read the Participant Information Sheet or someone has read it to me in a language that I understand.
- I understand the purposes, procedures and risks of the research described in the project.
- I understand that the study team will keep my identity and contact details (my name, date of birth, address, email address and phone number) that links to my unique code (my participant number) in a securely protected database. I understand that my identity and contact details will be retained even after the study finishes so that I may be contacted about this study or future research.
- I understand that the rest of the information collected about me will be 'coded data', which means that my participant number will be attached to that information, but my identity and contact details will not.
- I understand that my coded data will be transferred to the NIMH and stored in the NIMH Data Archive (NDA) in the United States and may be made available to other researchers for future research projects unconnected to this study upon application and approval by an NIH data use committee. Researchers that seek to access my location data will also need to receive Human Research Ethics Committee approval, and that the study team for this study have no involvement in that process.
- I understand that my biospecimen samples (including blood and saliva) and associated data will be sent to to be determined labs for storage and analyses (see page 13).
- I have agreed to provide biological samples and their use has been explained and accepted by me, including the generation of genetic information by sequencing my genome.
- I understand that at the completion of the study, my remaining samples will be sent to the NIMH Repository and Genomics Resource (NRGR), a biorepository in the United States, to be stored and shared with other researchers for future research projects unconnected to this study upon application and approval by an NIH data use committee and that the study team for this study have no involvement in that process.
- I give permission for my doctors, other health professionals, hospitals or laboratories outside of *[site]* to release information to *[site]* concerning my condition and treatment for the purposes of this project. I understand that such information will remain confidential.

- I understand that the study team may access state-wide Government databases to find out if I have had further contact with mental health services and to acquire information about my health after my participation in the study.
- I provide permission for my data to be shared between research projects conducted at *[site].* I understand that I can withdraw my consent for this to occur at any time without affecting my participation in either study or my future health care.
- I have had an opportunity to ask questions and I am satisfied with the answers I have received.
- I freely agree to participate in this research project as described and understand that I am free to withdraw at any time during the project without affecting my future health care.
- I understand that I will be given a signed copy of this document to keep.

1a) I acknowledge that by consenting to participate in this study, I consent to the collection, storage and use of my data for the following assessments which will form part of the data for this project and transferred to the NIMH in the United States for inclusion in a data repository where it will be available for other current or future projects: Clinical interviews and assessments (A, B, J), Neurocognitive Assessment (C), MRI (D), EEG (E), Free Speech Interview (F), Blood Collection (G), Saliva Sample (H)

Initial _____ Date _____

1b) I understand that by consenting to participate in this study, genetic/genomic analyses will be performed on my blood samples.

Initial _____ Date _____

1c) I acknowledge that by consenting to participate in this study, I consent to the collection, storage and use of my data for one or more of the Digital Assessment (I) components which will form part of the data for this project and other current or future projects, unless I opt out below.

Initial _____ Date _____

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

I would like to <u>opt out</u> of:

i. MindLAMP smartphone app entirely ☐
ii. Daily surveys part of smartphone app ☐
iii. Passive sensing part of smartphone app ☐
iv. Activity watch ☐

2) Contact for Future Research and Feedback:

I consent to being contacted again in the future so I can be invited to participate in future research projects	Yes ☐	No ☐
I consent to being contacted again in the future regarding any opportunities to provide a young person's perspective about this study or research more generally	Yes ☐	No ☐

3) Results:

I would like a summary of the study results to be sent to my email after the project has finished.

Initials: _____ Date: _____ Email: _____

4) Permission for study team to contact a nominated friend/family member:

We would like you to nominate at least one friend or relative who we may contact to obtain information about your health or your latest contact details if we are unable to contact you.

I provide consent for the study team to contact the friend/family member nominated below to obtain information about my health if they are unable to contact me.	Yes ☐	No ☐

Name of nominated friend/family member: _____

Phone number of nominated friend/family member: _____

5) Permission for study team to contact my Treating Doctor/Psychiatrist/General Practitioner (GP)

I provide consent for the study team to contact my Treating Doctor / Psychiatrist / GP in order to advise them of my participation in the study and to facilitate care.	Yes ☐	No ☐

Name of Treating Doctor / GP: _____

Phone number of Treating Doctor / GP: _____

6) Permission for study team to contact my Treating Pharmacist

I provide consent for the study team to contact my Pharmacist in order to obtain details of my medications.	Yes ☐	No ☐

Name of Pharmacist: _____

Phone number of Pharmacist: _____

7) Declaration by Participant – for participants who have read the information

Name of Participant (please print) _____

Signature _____ Date _____

8) Declaration by Witness – if participant or researcher requests a witness

Witness to the informed consent process

Name (please print) _____

Signature _____ Date _____

*Witness is not to be the investigator, a member of the study team or their delegate. In the event that an interpreter is used, the interpreter may not act as a witness to the consent process. Witness must be 18 years or older. Witnesses must date their own signature.

9) Declaration by Researcher†

I have given a verbal explanation of the research project, its procedures and risks and I believe that the participant has understood that explanation.

Name of Researcher†
(please print) _____

Signature _____ Date _____

† A member of the research team must provide the explanation of, and information concerning, the research project.
Note: All parties signing the consent section must date their own signature.