camh
Centre for Addiction and Mental Health

INFORMED CONSENT FORM

Name of Study: Testing the Feasibility and Outcomes of a Digital Health Support for Individuals with Schizophrenia Spectrum Mental Illnesses

Responsible Investigators: Sean Kidd 416-535-8501 ext. 36295, Centre for Addition and Mental Health (CAMH); Kwame McKenzie, CAMH; Aristotle Voineskos, CAMH

Purpose: This study is being done to gather information that might be helpful in developing a mobile phone application for people with schizophrenia other illnesses that involve psychosis.

The reason that we are doing this is to develop a mobile technology specifically for people with schizophrenia that might assist with coping efforts, reduce social isolation, and promote connections with community resources. This project is taking place only at CAMH and the stage that you are being asked to participate in involves 30 people.

Participation in this project involves:

a) At the beginning and end of a three week period you would complete questionnaires on topics related to your mental health and use of cellphone technology, including the app being tested. The first meeting would be slightly longer to allow time for uploading the app onto your phone and orienting me to how to use it - taking approximately 2.5 hours. The second meeting would be 60-90 minutes.
b) Using the mobile app for a three week period.
c) Having 2 brief phone call check ins during the three weeks about the app and your use of it (15 minutes per call).You will receive a text message or phone call to remind you about our appointment times if you agree to it.

Eligibility: To take part in this study you must be 18 years of age or older, have a diagnosis of schizophrenia spectrum illness, and use a smartphone cell phone equipped with an Android or iOS operating system regularly, and have a talk and data plan. You will also be able to speak and read English.

Confidentiality: All information that identifies you will be kept confidential and stored and locked in a secure place that only the study personnel will have access to. In addition, electronic files will be stored on a secure hospital or institutional network and will be password protected. The investigators will dispose of your paper and computer-based records after the research obligations for the study have been met. Confidentiality will be respected and no information that discloses your identity will be released or published without consent, unless required by law. The information you provide will not affect the usual care that you receive.

There are three exceptions to our confidentiality policy. In any of the following situations, we are obligated by law to contact authorities: 1) if there is a serious possibility that you may harm yourself or others, 2) if you have been involved in any form of child abuse or neglect, 3) if you have been the victim of abuse by a healthcare worker.

The study team may also request information from your physician or review your health records to determine eligibility and/or obtain additional clinically relevant information for research purposes.

As part of the Research Services Quality Assurance role, this study may be monitored and/or audited by a member of the Quality Assurance Team. Your research records and CAMH records may be reviewed, during which confidentiality will be maintained as per CAMH policies and to the extent permitted by law.

As a part of continuing review of the research, your study records may be assessed on behalf of the Research Ethics Board. A person from the research ethics team may contact you (if your contact information is available) to ask you questions about the research study and your consent to participate. The person assessing your file or contacting you must maintain their confidentiality to the extent permitted by law.

In addition, research data gathered as part of this study may be shared and provided to other investigators affiliated with Slaight Family Centre for Youth in Transition (SFCYT) for the purpose of data sharing. If you are enrolled in multiple studies with Slaight affiliated PIs, your research data will be shared across studies to reduce participant burden and avoid duplication of procedures. Only investigators/research team affiliated with the Slaight Centre will have access to secured files and / or research data and will be well-informed regarding the protection of participants' rights to confidentiality.

Furthermore, investigators collaborating with SFCYT (or other secondary investigators) will have access to the research data collected during the study for the purposes conducting secondary analyses about mental illnesses, such as autism spectrum disorder, depressive disorders, psychotic disorders, bipolar disorders, anxiety disorders, sleep disorders, or dementia (e.g. Alzheimer's disease).

Risks: We do not anticipate there being any physical discomfort related to you participating in this study. While psychological risk is expected to be minimal, some aspects of the surveys may be distressing to some participants. All participants are encouraged to discuss any such distress with the trained research staff who can provide information about supports that might be helpful.

Compensation: You will receive $100.00 to compensate you for your time. This will include $30 for the initial assessment, $25 for the assessment at the end of the three weeks, $10 for each of the two brief phone check ins, and $25 in compensation for the potential of cellular data overage during the trial.

Benefits: Participation in this study is intended to assist with coping with schizophrenia but does not guarantee that the use of this app will prove helpful to you in any way. However, your participation may assist in the development of interventions that could be accessed by other persons with mental illness.

Voluntary Participation: **Your participation in this study is voluntary.** You may choose to withdraw from the study at any time. If your participation ends early for any reason, you will receive full compensation for participating as described above. Your choice to not participate or your choice to withdraw **will not** affect any treatment needs that you might have at the Centre for Addiction and Mental Health now or in the future.

Additional Information: If you have questions about the study that are not answered in these Information Sheets, please ask them. In addition, if you have questions in the future you may contact the study investigators at the telephone numbers given on the first page. Dr. Robert Levitan, Chair, Research Ethics Board, Centre for Addiction and Mental Health, may be contacted by research subjects to discuss their rights.
Dr. Robert Levitan may be reached by telephone at 416-535-8501 extension 34020.

AGREEMENT TO PARTICIPATE

I, _____, have read (or had read to me) the Informed Consent Form for the study named 'Testing the Feasibility and Outcomes of a Digital Health Support for Individuals with Schizophrenia Spectrum Mental Illnesses.'

- My role in the study is as a research volunteer to help the investigators understand how best to develop such a mobile application.
- My questions, if any, have been answered to my satisfaction.
- By signing this consent form I do not waive any of my rights.
- I agree to voluntarily participate in this research and give my consent freely.
- I understand that the project will be conducted in accordance with the Informed Consent Form, a copy of which I have retained for my records.
- I understand I can withdraw from the project at any time, without penalty, and do not have to give any reason for withdrawal.

I consent to:

1. At the beginning and end of a three week period complete questionnaires on topics related to my mental health and use of cellphone technology, including the app being tested. The first meeting would be slightly longer to allow time for uploading the app onto my phone and orienting me to how to use it- taking approximately 2.5 hours. The second meeting would be 60-90 minutes.
2. Using the mobile app for a three week period.
3. Having 2 brief phone call check ins during the three weeks about the app and my use of it (15 minutes per call).

Dr. Robert Levitan, Chair, Research Ethics Board, Centre for Addiction and Mental Health, may be contacted by research subjects to discuss their rights. **Dr. Robert Levitan may be reached by telephone at 416-535-8501 extension 34020.**

I agree to participate.

Research Volunteer:	**Person Obtaining Consent/Witness:**
Signature: _____	Signature: _____
Date: _____	Date: _____
Name: _____	Name: _____
(Please Print)	(Please Print)

I have been given a copy of this form to keep.