If you are using Epic for this study, fax a copy of the signed consent form to 410-367-7382

Patient I.D. plate

RESEARCH PARTICIPANT INFORMED CONSENT AND PRIVACY AUTHORIZATION FORM

Protocol Title: **RCT for Texting for Relapse Prevention (T4RP) in Schizophrenia**

Patient RCT Consent

Application No.: **IRB001035033**

Sponsor: **National Institutes of Health**

Principal Investigator: **Dr. Bernadette Cullen (Goggins)**
Meyer 144, 600 North Wolfe St.
Baltimore, MD 21287
Office Phone: 410-955-5748; Office Fax: 410-955-5795

1. What you should know about this study:

- You are being asked to join a research study. This consent form explains the research study and your part in it. Please read it carefully and take as much time as you need. Ask your study doctor or the study team to explain any words or information that you do not understand.
- You are a volunteer. If you join the study, you can change your mind later. There will be no penalty or loss of benefits if you decide to quit the study.
- During the study, we will tell you if we learn any new information that might affect whether you wish to continue to participate.
- If we think your participation in this study may affect your clinical care, information about your study participation will be included in your medical record, which is used throughout Johns Hopkins. Doctors outside of Johns Hopkins may not have access to this information. You can ask the research team to send this information to any of your doctors.
- When Johns Hopkins is used in this consent form, it includes The Johns Hopkins University, The Johns Hopkins Hospital, Johns Hopkins Bayview Medical Center, Howard County General Hospital, Johns Hopkins Community Physicians, Suburban Hospital, Sibley Memorial Hospital and All Children's Hospital.
- A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.
- If you would like to review the information for this study, or a summary of the results, ask the study team doctor for the ClinicalTrials.gov study registration number.

2. Why is this research being done?

This research is being done to see if using text messaging can help identify early warning symptoms of relapse in schizophrenia and schizoaffective disorder.

We want to learn more from you about the early symptoms of your illness and if you know when you are having an early sign of your illness. We want to see if sending text messages asking about your early symptoms is helpful.

The use of text messaging software in this research study is investigational. The word "investigational" means that "X" is not approved for marketing by the Food and Drug Administration (FDA).

People who have been diagnosed with schizophrenia or schizoaffective disorder, who use text-messaging and who have a provider enrolled in the study may join.

Providers who treat people with schizophrenia or schizoaffective disorder will also be involved in the study. Administrators who work in the clinic will also be taking part.

How many people will be in this study?

There will be about 40 people with schizophrenia or schizoaffective disorder involved in this part of the study and 5 to 15 providers.

3. What will happen if you join this study?

If you agree to be in this study, we will ask you to meet with an interviewer for about 2 hours at 3 different visits which are 3 months apart. During these visits you will:

- Complete a number of surveys. An interviewer will read the questions to you and ask for your responses. The surveys ask questions about symptoms of depression, mania and schizophrenia and also asks about your medication. You will also fill out some surveys yourself about your memory and how you feel you are managing and living with your illness – the interviewer will be able to help you with these if you want.

- At the end of the first interview you may be asked to take part in another part of the study where you will receive text messages asking about your symptoms. You will be randomly assigned (by chance, like flipping a coin) to receive study text messages or continue your usual care.

- If you are asked to take part in the text message group you will get text messages every day asking you about symptoms you have told us happen when your illness is coming back. You will also get messages about why it is good to take your medications and messages which are inspirational quotes. You will get 2 to 3 messages a day and you will be expected to text back an answer for the messages about your symptoms. If you are having problems with symptoms you will get a text with suggestions on what you could do to help yourself. If your text replies show that you are getting a lot of symptoms then your provider will be contacted and they will call you within 24 hours to talk about a plan that could help you. These text messages will go on for 6 months.

- At the end of the 6 months you will attend a group discussion with other people who have been in the study and an interviewer to talk about what you thought of the text message study. The focus group will be audio-recorded. If you do not wish to be recorded you can meet one on one with the interviewer and they will ask you the same questions as will be asked in the group and they will write down your answers.

- We will begin the focus group by asking the participants to agree to the importance of keeping information discussed in the focus group confidential. In addition, we will ask each participant to verbally agree to keep everything discussed in the room confidential, and will remind them at the end of the group not to discuss the material outside.

Audio recordings:

- These recordings will be used for the purposes of this research and will not be published for any other reason.

Future Contact

We would like your permission for the research team members at Johns Hopkins to review your medical records in the department to see whether you might be eligible to join other research studies. This is called "screening". If you agree, then we might contact you in the future and tell you about a research study. At that time, you could decide whether or not you are interested in participating in a particular study.

Please check one box:

YES ☐ _____
Signature of Participant

NO ☐ _____
Signature of Participant

How long will you be in the study?

You will be in this study for 6 months.

4. What are the risks or discomforts of the study

- During the individual interviews there may be questions that could make you feel uncomfortable. You may get tired or bored when we are asking you questions or you are completing questionnaires. If there are questions that you do not want to answer, you do not have to answer them.
- If you are getting text messages you may feel uncomfortable or annoyed by the texts. You do not have to text back if you do not want to.
- If you are receiving study text messages, it is possible that you could lose your privacy if someone sees the messages on your phone. We can help you set your phone so that others cannot use it and/or so that the text messages do not automatically appear on your screen.
- If you are getting text messages it is possible that your provider may not be contacted or respond if you are having a problem. We will follow up with your provider if they are not responding. If you are in crisis there will be a simple text that you can send that will give you information on what to do.
- This study involves Johns Hopkins and the Center for Innovative Public Health Research (CiPHR). CiPHR is the place where the text messages will be sent from so the researchers at that site will have

access to your name and telephone number so that they can send you the text messages. The Principal Investigator at CiPHR will also have access to any of the information that you provide to us in the study as she is involved in analyzing the data.

- If you are receiving study text messages it is important to know that your phone company can store any of your text messages for at least 90 days and it is possible that you could lose your privacy if they looked at your messages.

5. Are there benefits to being in the study?

For those who are getting text messages it is possible that if you experience symptoms of your illness during the study the text messages may be helpful to you and stop your illness getting worse. There may, however, be no direct benefit to you from being in this study.

If you take part in this study, you may help others in the future. The information we gather from you may help us make a program that helps people with schizophrenia or schizoaffective disorder.

6. What are your options if you do not want to be in the study?

If you decide not to join this study you will continue to receive the same care that you have been receiving at the program.

You do not have to join this study. If you do not join, your care at Johns Hopkins will not be affected.

7. Will it cost you anything to be in this study?

If you in the text messaging group your telephone carrier may charge you for getting or sending texts. We will give you $10 a month for 6 months to help with this.

8. Will you be paid if you join this study?

You will get $40 for each study interview that you do and if you are in the text messaging group you will get $10 a month for 6 months to help with the cost of text messaging.

You may be required to provide your social security number to be paid for taking part in this study. Federal tax law requires that you report your research payments when you file your taxes. If your total payments from Johns Hopkins exceed $600 per year, Johns Hopkins will report these payments to the Internal Revenue Service and you will receive a 1099-MISC form from us.

9. Can you leave the study early?

- You can agree to be in the study now and change your mind later.
- If you wish to stop, please tell us right away.
- Leaving this study early will not stop you from getting regular medical care.

If you leave the study early, Johns Hopkins may use or give out your health information that it has already collected if the information is needed for this study or any follow-up activities.

10. Why might we take you out of the study early?

- You may be taken out of the study if you are admitted to hospital for the whole time the study is happening.
- There may be other reasons to take you out of the study that we do not know at this time.

If you are taken out of the study early, Johns Hopkins may use or give out your health information that it has already collected if the information is needed for this study or any follow-up activities.

11. How will your privacy be protected?

We have rules to protect information about you. Federal and state laws and the federal medical Privacy Rule also protect your privacy. By signing this form you provide your permission, called your "authorization," for the use and disclosure of information protected by the Privacy Rule.

The research team working on the study will collect information about you. This includes things learned from the procedures described in this consent form. They may also collect other information including your name, address, date of birth, and information from your medical records (which may include information about HIV status, drug, alcohol or STD treatment, genetic test results, or mental health treatment).

The research team at Johns Hopkins and at the Center for Innovative Public Health Research (CiPHR) will know your identity and that you are in the research study. Other people at Johns Hopkins, particularly your doctors, may also see or give out your information. We make this information available to your doctors for your safety.

People outside of Johns Hopkins may need to see or receive your information for this study. Examples include government agencies (such as the Food and Drug Administration), safety monitors, other sites in the study and companies that sponsor the study.

If you are in a cancer study that receives federal funding, the National Cancer Institute (NCI) now requires that we report identifiable information (such as, zip code) about your participation. You may contact the NCI if you have questions about how this information is used.

We cannot do this study without your authorization to use and give out your information. You do not have to give us this authorization. If you do not, then you may not join this study.

We will use and disclose your information only as described in this form and in our Notice of Privacy Practices; however, people outside Johns Hopkins who receive your information may not be covered by this promise or by the federal Privacy Rule. We try to make sure that everyone who needs to see your information keeps it confidential – but we cannot guarantee that your information will not be re-disclosed.

The use and disclosure of your information has no time limit. You may revoke (cancel) your permission to use and disclose your information at any time by notifying the Principal Investigator of this study by phone or in writing. If you contact the Principal Investigator by phone, you must follow-up with a written request that includes the study number and your contact information. The Principal Investigator's name, address, phone and fax information are on page one of this consent form.

If you do cancel your authorization to use and disclose your information, your part in this study will end and no further information about you will be collected. Your revocation (cancellation) would not affect information already collected in the study, or information we disclosed before you wrote to the Principal Investigator to cancel your authorization.

12. What if there is a Certificate of Confidentiality for this study?

NIMH has given us a Certificate of Confidentiality for this study. This Certificate provides some additional protection for research information that identifies you. The Certificate allows us, in some circumstances, to refuse to give out information that could identify you as a research subject without your consent, when such information is sought in a federal, state, or local court or public agency action. Still, we may disclose identifying information about you if, for example, you need medical help.

We may also disclose identifiable information about you as described in Section 12 of this form or in other cases. For example, the government may see your information if it audits us, and the research team will voluntarily comply with reporting requirements to the appropriate local or state authorities:

- if they suspect abuse, neglect or abandonment of a child or vulnerable or dependent adult;
- if certain diseases are present; and
- if the team learns that you plan to harm someone. In this case, the team also may warn the person who is at risk.

Even with this Certificate in place, you and your family members must continue to protect your own privacy. If you voluntarily give your written consent for an insurer, employer, or lawyer to receive information about your participation in the research, then we may not use the Certificate to withhold this information.

This Certificate does not mean the government approves or disapproves of this research project.

13. What other things should you know about this research study?

a. What is the Institutional Review Board (IRB) and how does it protect you?

The Johns Hopkins Medicine IRB is made up of:

- Doctors
- Nurses
- Ethicists
- Non-scientists
- and people from the local community.

The IRB reviews human research studies. It protects the rights and welfare of the people taking part in those studies. You may contact the IRB if you have questions about your rights as a participant or if you think you have not been treated fairly. The IRB office number is 410-955-3008. You may also call this number for other questions, concerns or complaints about the research.

When the Johns Hopkins School of Medicine Institutional Review Board (IRB) reviews a study at another site, that site (institution) is solely responsible for the safe conduct of the study and for following the protocol approved by the Johns Hopkins IRB.

b. What do you do if you have questions about the study?

Call the principal investigator, Dr. Cullen at 410-955-5748. If you wish, you may contact the principal investigator by letter or by fax. The address and fax number are on page one of this consent form. If you cannot reach the principal investigator or wish to talk to someone else, call the IRB office at 410-955-3008.

c. What happens to Data that are collected in the study?

Johns Hopkins and our research partners work to understand and cure diseases. The data you provide are important to this effort. For this study the Center for Innovative Public Health Research (CiPHR) is the partner involved. This center will be setting up the text message system that we will use and we will be sharing your data with them so that we can do the study. CiPHR follows all the same privacy and security rules that Johns Hopkins does.

If you join this study, you should understand that you will not own your data, and should researchers use it to create a new product or idea, you will not benefit financially.

The researchers of this study will send the study data, including information about you, to the National Institutes of Mental Health Data Archive (NIMH DR). NIMH DR is a computer system run by the National Institutes of Health that allows researchers studying schizophrenia/ schizoaffective disorder (SAD) to share information with each other and improve research on schizophrenia and SAD.

Any information that may identify you, such as your name, address, and phone number, will be replaced with a code number. For other researchers to access this study's data, they must first file an application with the National Institutes of Health. Experts at the National Institutes of Health who know how to protect research information will look at every request carefully.

You may not benefit directly from allowing your information to be shared with NIMH DR. The information provided to NIMH DR might help researchers around the world to treat adults with schizophrenia and SAD. NIMH DR will report to Congress and on its website about the different studies that researchers are conducting using NIMH DR data; however, NIMH DR will not be able to contact you individually about specific studies.

You may decide now or later that you do not want to share your information using NIMH DR. If so, contact the researchers who conducted this study so that your information can be removed. However, NIMH DR cannot take back information that was shared before you changed your mind. If you would like more information about NIMH DR, this is available on-line at http://ndar.nih.gov

14. What does your signature on this consent form mean?

Your signature on this form means that: You understand the information given to you in this form, you accept the provisions in the form and you agree to join the study. You will not give up any legal rights by signing this consent form.

WE WILL GIVE YOU A COPY OF THIS SIGNED AND DATED CONSENT FORM

Signature of Participant	(Print Name)	Date/Time

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

NOTE: A COPY OF THE SIGNED, DATED CONSENT FORM MUST BE KEPT BY THE PRINCIPAL INVESTIGATOR; A COPY MUST BE GIVEN TO THE PARTICIPANT; IF YOU ARE USING EPIC FOR THIS STUDY A COPY MUST BE FAXED TO 410-367-7382; IF YOU ARE NOT USING EPIC A COPY MUST BE PLACED IN THE PARTICIPANT'S MEDICAL RECORD (UNLESS NO MEDICAL RECORD EXISTS OR WILL BE CREATED).

ONLY CONSENT FORMS THAT INCLUDE THE JOHNS HOPKINS MEDICINE LOGO CAN BE USED TO OBTAIN THE CONSENT OF RESEARCH PARTICIPANTS.