Partners HealthCare System
Research Consent Form

Subject Identification

Certificate of Confidentiality Template
Version Date: January 2019

Protocol Title: Treatment Engagement in Families with Substance Use and Psychosis: A Pilot Study

Principal Investigator: Julie M. McCarthy, PhD

Site Principal Investigator:

Description of Subject Population: Familes of and people diagnosed with schizophrenia, bipolar disorder, or related illnesses who use substances

PHASE 1 CONSENT FORM
About this consent form

Please read this form carefully. It tells you important information about a research study. A member of our research team will also talk to you about taking part in this research study. People who agree to take part in research studies are called "subjects." This term will be used throughout this consent form.

Partners HealthCare System is made up of Partners hospitals, health care providers, and researchers. In the rest of this consent form, we refer to the Partners system simply as "Partners."

If you decide to take part in this research study, you must sign this form to show that you want to take part. We will give you a signed copy of this form to keep.

Key Information

Taking part in this research study is up to you. You can decide not to take part. If you decide to take part now, you can change your mind and drop out later. Your decision won't change the medical care you get within Partners now or in the future.

The following key information is to help you decide whether or not to take part in this research study. We have included more details about the research in the Detailed Information section that follows the key information.

Why is this research study being done?

In this research study we want to learn more about how to improve treatment engagement and relationships in families of people with schizophrenia, bipolar disorder, and related illnesses who use substances. We are inviting people to be in this research study who have a family member in the McLean OnTrack program.

How long will you take part in this research study?

The study will take 3 in-person and/or virtual visit assessments at McLean Hospital (1st: 3 hours, 2nd and 3rd: 1 hour each), 6-8 therapy sessions (in-person and/or virtual visit), 1 virtual visit follow-up assessment (30 minutes), and you may be asked to complete an in-person or virtual focus group (30 minutes); times are approximate. Virtual visits refer to videoconferencing, telephone calls, and/or completing online surveys.

What will happen if you take part in this research study?

If you decide to join this research study, the following things will happen

a) Consent procedures
b) Clinical interview
c) Self-report questionnaires asking about preferences, daily life experiences (e.g., drug use), and symptoms (e.g., depression)
d) Intervention
e) Focus group

These procedures include activities/questionnaires using a computer, tablet, or pencil and paper, interviews, audio/video recording, and an intervention. If you have completed certain interviews, questionnaires, or tasks in the past month or year as part of another Schizophrenia and Bipolar Disorder Program study, you may not have to repeat them again for this study.

Why might you choose to take part in this study?

We cannot promise any benefits to you from taking part in this research study. However, possible benefits may include gaining additional support and coping skills. Others with family members who have psychosis may benefit in the future from what we learn in this study.

Why might you choose NOT to take part in this study?

Taking part in this research study has some risks and requirements that you should consider carefully.

Important risks and possible discomforts to know about include possible loss of confidentiality and feeling upset, bored, or stressed.

A detailed description of side effects, risks, and possible discomforts can be found later in this consent form in the section called "What are the risks and possible discomforts from being in this research study?"

What other treatments or procedures are available for your condition?

You do not have to take part in this study. Other treatments or procedures that are available to treat families of people with psychosis or substance use disorders include group, family, or individual therapy.

If you have questions or concerns about this research study, whom can you call?

You can call us with your questions or concerns. Our telephone numbers are listed below. Ask questions as often as you want.

Julie McCarthy, PhD is the person in charge of this research study. You can call her at **617-855-3521 M-F 9-5**. You can also call **Andrea Wood at 617-855-3497 M-F 9-5** with questions about this research study.

If you have questions about the scheduling of appointments or study visits, call **Andrea Wood at 617-855-3497.**

If you want to speak with someone **not** directly involved in this research study, please contact the Partners Human Research Committee office. You can call them at 857-282-1900.

You can talk to them about:

- Your rights as a research subject
- Your concerns about the research
- A complaint about the research
- Any pressure to take part in, or to continue in the research study

Detailed Information

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.

Why is this research study being done?

We want to learn more about how to improve treatment engagement and relationships in families of people with schizophrenia, bipolar disorder, and related illnesses who use substances. We also want to learn how to make interventions more accessible to families using technology.

Who will take part in this research?

We are asking you to take part in this research study because you have a family member in the McLean OnTrack program. About 28 families will take part in this research study, which is sponsored by the National Institutes of Health.

What will happen in this research study?

If you decide to join this research study, the following things will happen during the study visits:

a) Consent procedures
b) Clinical interview
c) Self-report questionnaires asking about preferences, daily life experiences (e.g., drug use), and symptoms (e.g., depression)
d) Intervention
e) Focus group

These procedures include activities/questionnaires using a computer, tablet, or pencil and paper, interviews, audio/video recording, and an intervention. If you have completed certain interviews, questionnaires, or tasks in the past month or year as part of another Schizophrenia and Bipolar Disorder Program study, you may not have to repeat them again for this study.

Clinical Interview
Trained study staff will interview you with standard questions. We may ask you about past and current medical health, psychiatric problems, daily life, and feedback about the intervention to make sure that we understand your history and experience correctly. You do not have to answer

any questions that make you feel uncomfortable during this evaluation. The interview may be audio/video recorded.

Intervention
You will complete 6-8 sessions of approximately 45 minute therapy. Topics include building motivation, self-care, communication, and understanding family interactions. The sessions will be in-person and/or virtual visits (video conferencing) and audio/video recorded. The audio/video recording will include identifiable information (e.g., face and potentially first names), but we will label the recordings with codes instead of your name. We will store the recordings indefinitely, and they will not be erased. The audio recording will be sent securely to trained coders who will review sessions for therapist quality assurance and training purposes. The coders will be external to Partners, but they will enter into appropriate privacy agreements with us. However, at any time, you may request (verbally or in writing) to have your audio/video recordings erased.

Focus Group
You may be asked to complete an in-person or virtual focus group to provide feedback about your experience to help improve the intervention. The group may be audio/video recorded.

Video conferencing: Study staff will provide you information on how to access the video conferencing platform. We will launch the video conferencing in a private and secure area. To protect your privacy we ask that you do not take screenshots, photographs, or recordings of any kind with any electronic equipment.

We would like to remind you that a video meeting is similar to us visiting you at home. We may learn more about your home and the people living with you than we would during a visit at the hospital. For example, we may learn information from you that must be reported to public health or public safety authorities. We are required by law to report known or suspected child or elder abuse. If we make such report, the public health and safety authorities can use the information as they see fit and may end up sharing it with other government agencies. Please ask the research staff if you have any questions about this prior to your video visit.

How may we use and share your samples and health information for other research?

The samples and information we collect in this study may help advance other research. If you join this study, we may remove all information that identifies you (for example your name, medical record number, and date of birth) and use these de-identified samples and data in other research. It won't be possible to link the information or samples back to you. Information and/or samples may be shared with investigators at our hospitals, at other academic institutions

or at for-profit, commercial entities. You will not be asked to provide additional informed consent for these uses.

A Global Unique Identifier (GUID) will be assigned to you during this study. This is done by entering personal information, such as date of birth, into a computer program that is stored at the investigator's institution. Your identifiable information will not be sent outside Partners in order to create the GUID. Once the GUID is created, only this subject number and not your personal identifiable information will be accessible to other investigators. This subject number may make it possible for a study doctor who used this unique subject number in another study that you took part in to identify you and combine information from this study and other studies together, using only the GUID.

Will you get the results of this research study?

You and your doctor should not expect to get information about the results of the research study or the results of your individual participation in the research study. We will study samples and information from many people. It could take many years before anyone knows whether the results have any meaning. There is a small chance that could find out something from the study that might be important to your health. If this happens, we may contact you to find out if you would like to learn more. However, even if we find something important to your health, we cannot guarantee that you will be contacted.

What are the risks and possible discomforts from being in this research study?

One potential risk is a breach of your confidentiality. This could lead your employer, insurance company, or others to find out that you participated in a research study. Steps we take to prevent this are described below in the Confidentiality section.

There is a risk that questions/interviews about your mental health and mood state may upset you psychologically. You are free to take a break from or stop answering these questions at any time.

What are the possible benefits from being in this research study?

We cannot promise any benefits to you from taking part in this research study. However, possible benefits may include gaining additional support and coping skills. Others with family members who have psychosis may benefit in the future from what we learn in this study.

What other treatments or procedures are available for your condition?

You do not have to take part in this study. Other treatments or procedures that are available to treat families of people with psychosis or substance use disorders include group, family, or individual therapy.

Can you still get medical care within Partners if you don't take part in this research study, or if you stop taking part?

Yes. Your decision won't change the medical care you get within Partners now or in the future. There will be no penalty, and you won't lose any benefits you receive now or have a right to receive.

We will tell you if we learn new information that could make you change your mind about taking part in this research study.

What should you do if you want to stop taking part in the study?

If you take part in this research study, and want to drop out, you should tell us. We will make sure that you stop the study safely. We will also talk to you about follow-up care, if needed.

Also, it is possible that we will have to ask you to drop out of the study before you finish it. If this happens, we will tell you why. We will also help arrange other care for you, if needed.

Will you be paid to take part in this research study?

We will pay you $165 for completing all study procedures; compensation will be by check. You may receive up to an additional $40 for each of the three assessment visits if completed in-person for travel or other expenses documented with same-day receipts. If you do not complete the study, you will be compensated for the procedures that you did complete at a rate of $25/hour for the three assessment visits.

For internal auditing purposes, we collect your social security number because you are receiving payment for participation in this study. McLean Hospital is required to inform the IRS of any payments to you as a research subject in a given calendar year totaling $600 or more. If that

occurs, you will receive a 1099 form at the end of the year. No information identifying why you received payment is communicated to either the Hospital's accounting department or the government. This information is kept strictly confidential.

We may use your samples and information to develop a new product or medical test to be sold. The Sponsor, hospital, and researchers may benefit if this happens. There are no plans to pay you if your samples or information are used for this purpose.

What will you have to pay for if you take part in this research study?

There is no cost to you for your participation in this study.

What happens if you are injured as a result of taking part in this research study?

If you are injured as a direct result of taking part in this research study, we will assist you in obtaining the medical care needed to treat the injury. This means arranging for (but not paying for) transportation to an acute care center for treatment of the injury. McLean Hospital is a psychiatric care facility and does not provide general health care services.

The care provider may bill your insurance company or other third parties, if appropriate, for the care you get for the injury. We will try to have these costs paid for, but you may be responsible for some of them. For example, if the care is billed to your insurer, you will be responsible for payment of any deductibles and co-payments required by your insurer.

Injuries sometimes happen in research even when no one is at fault. There are no plans to pay you or give you other compensation for an injury, should one occur. However, you are not giving up any of your legal rights by signing this form.

If you think you have been injured or have experienced a medical problem as a result of taking part in this research study, tell the person in charge of this study as soon as possible. The researcher's name and phone number are listed in the beginning of this consent form.

If you take part in this research study, how will we protect your privacy?

Federal law requires Partners to protect the privacy of health information and related information that identifies you. We refer to this information as "identifiable information."

In this study, we may collect identifiable information about you from:

- Past, present, and future medical records
- Research procedures, including research office visits, tests, interviews, and questionnaires

Who may see, use, and share your identifiable information and why:

- Partners researchers and staff involved in this study
- The sponsor(s) of the study, and people or groups it hires to help perform this research or to audit the research
- Other researchers and medical centers that are part of this study
- The Partners ethics board or an ethics board outside Partners that oversees the research
- A group that oversees the data (study information) and safety of this study
- Non-research staff within Partners who need identifiable information to do their jobs, such as for treatment, payment (billing), or hospital operations (such as assessing the quality of care or research)
- People or groups that we hire to do certain work for us, such as data storage companies, accreditors, insurers, and lawyers
- Federal agencies (such as the U.S. Department of Health and Human Services (DHHS) and agencies within DHHS like the Food and Drug Administration, the National Institutes of Health, and the Office for Human Research Protections), state agencies, and foreign government bodies that oversee, evaluate, and audit research, which may include inspection of your records
- Public health and safety authorities, if we learn information that could mean harm to you or others (such as to make required reports about communicable diseases or about child or elder abuse)
- Other researchers within or outside Partners, for use in other research as allowed by law.

Certificate of Confidentiality

A federal Certificate of Confidentiality (Certificate) has been issued for this research to add special protection for information and specimens that may identify you. With a Certificate, unless you give permission (such as in this form) and except as described above, the researchers are not allowed to share your identifiable information or identifiable specimens, including for a court order or subpoena.

Certain information from the research will be put into your medical record and will not be covered by the Certificate. This includes records of medical tests or procedures done at the hospitals and clinics, and information that treating health care providers may need to care for you. Please ask your study doctor if you have any questions about what information will be included in your medical record. Other researchers receiving your identifiable information or specimens are expected to comply with the privacy protections of the Certificate. The Certificate does not stop you from voluntarily releasing information about yourself or your participation in this study.

Even with these measures to protect your privacy, once your identifiable information is shared outside Partners, we cannot control all the ways that others use or share it and cannot promise that it will remain completely private.

Because research is an ongoing process, we cannot give you an exact date when we will either destroy or stop using or sharing your identifiable information. Your permission to use and share your identifiable information does not expire.

The results of this research may be published in a medical book or journal, or used to teach others. However, your name or other identifiable information **will not** be used for these purposes without your specific permission.

Your Privacy Rights

You have the right **not** to sign this form that allows us to use and share your identifiable information for research; however, if you don't sign it, you can't take part in this research study.

You have the right to withdraw your permission for us to use or share your identifiable information for this research study. If you want to withdraw your permission, you must notify the person in charge of this research study in writing. Once permission is withdrawn, you cannot continue to take part in the study.

If you withdraw your permission, we will not be able to take back information that has already been used or shared with others, and such information may continue to be used for certain purposes, such as to comply with the law or maintain the reliability of the study.

You have the right to see and get a copy of your identifiable information that is used or shared for treatment or for payment. To ask for this information, please contact the person in charge of this research study. You may only get such information after the research is finished.

Informed Consent and Authorization

Statement of Person Giving Informed Consent and Authorization

- I have read this consent form.
- This research study has been explained to me, including risks and possible benefits (if any), other possible treatments or procedures, and other important things about the study.
- I have had the opportunity to ask questions.
- I understand the information given to me.

Signature of Subject:

I give my consent to take part in this research study and agree to allow my identifiable information to be used and shared as described above.

_____	_____	_____
Subject	Date	Time (optional)

_____
Printed Name

Signature of Study Doctor or Person Obtaining Consent:

Statement of Study Doctor or Person Obtaining Consent

- I have explained the research to the study subject.
- I have answered all questions about this research study to the best of my ability.

_____	_____	_____
Study Doctor or Person Obtaining Consent	Date	Time (optional)

_____
Printed Name

Clinic Coordination

I give my permission for the research study staff to inform the McLean OnTrack program (or other first episode psychosis clinic: _____) that I am participating in this research study and to provide updates for coordination of care purposes.

☐ Yes ☐ No Initials_____

Contact Name:_____Phone:_____

Follow-up Studies

We may wish to contact you in the future to see if you are interested in participating in another research study. Giving your permission for the research team to contact you does not obligate you to participate in future research – you always have the right to decline. You may also withdraw permission to be contacted at any time by contacting us.

Someone may contact me in the future by telephone or email to ask me to participate in more research.

☐ Yes ☐ No Initials_____

Email Preference

The Partners standard is to send email securely. If you prefer, we can send you "unencrypted" email that is not secure and could result in the unauthorized use or disclosure of your information. If you want to receive communications by unencrypted email despite these risks, Partners HealthCare will not be held responsible. Your preference to receive unencrypted email will apply to: emails sent to you from research staff in this study only. If you wish to communicate with other research staff at Partners regarding additional studies, your preference will have to be documented with each research group.

For email communication, I prefer:

☐ Unencrypted email ☐ Encrypted email Initials_____

Alternate Contact

By providing the name of an alternative contact person below, you give us permission to contact this person in case we have trouble contacting you directly. If we contact them, we will share that we are trying to contact you about your interest in participating in another research study and ask to verify your current contact information.

Alternative Contact Person_____ Phone _____

Consent Form Version Date: 06/06/2022