UNIVERSITY OF MICHIGAN
CONSENT TO BE PART OF A RESEARCH STUDY

INFORMATION ABOUT THIS FORM
You may be eligible to take part in a research study. This form gives you important information about the study. It describes the purpose of the study, and the risks and possible benefits of participating in the study.

Please take time to review this information carefully. After you have finished, you should talk to the researchers about the study and ask them any questions you have. You may also wish to talk to others (for example, your friends, family, or other doctors) about your participation in this study. If you decide to take part in the study, you will be asked to sign this form. Before you sign this form, be sure you understand what the study is about, including the risks and possible benefits to you.

1. GENERAL INFORMATION ABOUT THIS STUDY AND THE RESEARCHERS

1.1 Study title: Study to Promote Innovation in Rural Integrated Telepsychiatry (SPIRIT)

1.2 Company or agency sponsoring the study: Patient Centered Outcomes Research Institute (PCORI)

1.3 Names, degrees, and affiliations of the researchers conducting the study:
Principal Investigator: Paul Pfeiffer, M.D., Department of Psychiatry, University of Michigan
Principal Investigator: John Fortney, PhD, University of Washington
Study Coordinator: Karla Metzger, MSW, Department of Psychiatry, University of Michigan

Clinic Contacts:
Cherry Health: Dawn Keller, Site Manager, 616-438-1715
Upper Great Lakes Family Health Care: Donald Simila, CEO, (906) 483-1705
Health Delivery Inc. /Great Lakes Bay Area Health Center: Doug Saylor, CMO, dsaylor@healthdelivery.org
Family Medical Center: Audrey Smith, EVP, (313) 316-7733
Intercare: Judy Rayman, EVP, (269) 427-7937

2. PURPOSE OF THIS STUDY

2.1 Study purpose: This study is a multi-site partnership between University of Washington, University of Arkansas, and the University of Michigan. Two connected studies are covered in this consent form. In the first study, University of Michigan faculty and staff are comparing two approaches to improve clinical care of patients with mental health symptoms treated at participating Health Centers in Michigan including: Cherry Health, Intercare, Upper Great Lakes Family Health Care, Health Delivery, Inc. /Great Lakes Bay Area Health Center, and Family Medical Center of Michigan. In the second connected study, University of Washington faculty and staff are overseeing patient surveys to determine which of these two treatments are most effective.

Many Health Center patients with mental health symptoms do not have good access to mental health specialists. The purpose of these two connected studies is to identify the best way to help patients. We have identified two approaches to improving access to high quality care. Both approaches are likely effective, but we want to find out which approach is more effective.
1. **Referral Care:** The first treatment approach includes mental health specialists at the University of Michigan who take the lead in treating your mental health symptoms. These mental health specialists will communicate with you and other patients at the Health Center using a video camera and a microphone connected to a computer. This is called Referral Care because patients have been referred to the University of Michigan mental health specialists who take the lead on delivering the mental health treatment.

2. **Integrated Care:** The second treatment approach involves receiving treatment for your mental health symptoms from your primary care team. Mental health specialists from the University of Michigan will give recommendations to your primary care team who will deliver the treatment. This is called Integrated Care because the primary care team treats both mental health and physical health symptoms.

You will be asked to complete surveys at three time points in the study. All participants will be contacted by phone/email to complete surveys to see how well the treatment is meeting your needs and provide payment for your time in completing the surveys.

If you are randomized to Referral Care you can expect the following:

1. Study and clinic staff will work with you to schedule an appointment at your Federally Qualified Health Center (FQHC). At that visit, you will meet with a mental health specialist located at the University of Michigan through a video camera. These video camera sessions are not recorded. This first visit by video camera will last for approximately 50 minutes. At the first visit, the mental health specialist will ask you questions about your symptoms and what treatments you have tried in the past and enter this and other treatment information into a study computer and your clinic’s electronic medical record system. Then, you will work together to develop a mental health treatment plan that meets your needs and preferences.

2. You will continue to have video camera visits with University of Michigan mental health specialists for up to one year. The specialists will treat your mental health symptoms, while keeping your primary care team informed.

3. If you do not attend the video camera visits regularly during the first six months, you will be randomized (like the flip of a coin) again. Half of the participants will be able to schedule more visits by video camera. The other half will be able to receive treatment by telephone. You will be able to have telephone visits while you are at home or some other private location.

If you are randomized to Integrated Care, you can expect the following:

1. The mental health specialists located at the University of Michigan will work with your primary care provider to find the best treatment for you. You and your primary care team will be in charge of treating your mental health symptoms.

2. Study and clinic staff will work with you to schedule an appointment at your Health Center. At the first consult visit, you will meet with a mental health specialist located at the University of Michigan through video camera. This video camera visit will last approximately 50 minutes. The mental health specialist will ask you questions about your symptoms and what treatments you
have tried in the past. They will enter this and other treatment information into a study computer and your clinic’s electronic medical record system. Then they will recommend a treatment plan to your primary care team that meets your needs and preferences.

3. A care manager from your Health Center will also be a part of your primary care team. The care manager will contact you every couple of weeks by phone. The care manager will give you information about your symptoms, describe your treatment options, and answer your questions. The care manager will also ask how much your symptoms are bothering you and how your treatment is going. The care manager will share important information with your primary care provider and the mental health specialist at the University of Michigan. The care manager will also enter this information into a study computer and your clinic’s electronic medical record system.

4. If the treatment is not working, the University of Michigan mental health specialist will give new recommendations to your primary care providers.

The treatments that you will be offered are medications and counseling. You will be free to choose just medications or just counseling, or both. You can also choose to receive no treatment at all. All medications and counseling programs have been proven to be effective and/or are used routinely to treat patients. This study is NOT testing experimental drugs, devices, or therapies.

### 3. INFORMATION ABOUT STUDY PARTICIPANTS (SUBJECTS)

Taking part in this study is completely **voluntary**. You do not have to participate if you don’t want to. You may also leave the study at any time. If you leave the study before it is finished, there will be no penalty to you, and you will not lose any benefits to which you are otherwise entitled.

#### 3.1 Who can take part in this study?

You can take part in the study if you are:

1. Age 18 or older
2. Currently receiving care at a Health Center participating in the study
3. Currently experiencing some mental health symptoms and screen positive on standardized mental health symptom scales.

You cannot take part in the study if you:

1. Are not English or Spanish speaking
2. Are currently being prescribed medications by a mental health specialist.

#### 3.2 How many people (subjects) are expected to take part in this study?

A total of 1,000 study participants will be enrolled across 3 states. University of Michigan and their partner Health Centers within Michigan are expected to enroll 400 subjects.

500 study participants across all states will be randomly selected to receive Referral Care and 500 will be randomly selected to receive Integrated Care. By “randomly” we mean like the flip of a coin.
4. INFORMATION ABOUT STUDY PARTICIPATION

4.1 What will happen to me in this study?

You will be asked to complete surveys at three time points in the study. All participants will be contacted by phone, mail or email to complete surveys to see how well the treatment is meeting your needs and payment will be provided for your time in completing the surveys. All study participants will be asked to complete a survey when you start the study and complete follow-up surveys at 6 and 12 months after you start the study. Surveys will be completed using the phone or Internet. Surveys are overseen by University of Washington.

We may also contact you in the future to take part in an optional interview by phone or in person about your treatment experience. Therefore, we will invite about 50 patients to participate in interviews. During these interviews, we will ask you what you liked and didn’t like about the treatment you received. The interviews will last for up to one hour.

If you do not want to be invited to participate in these interviews, check this box □

After the study is over, we may want to contact you again to see if you want to participate in another research study.

If you do not want to be contacted about future research studies, check this box □

4.2 How much of my time will be needed to take part in this study?

Each survey overseen by the University of Washington will take about one hour to complete for a total of three hours.

The interview would last about one hour.

4.3 When will my participation in the study be over?

Your participation in the study will end after 1 year.

4.4 What will happen with my information used in this study?

Your collected information may be shared with the study sponsor, Patient Centered Outcomes Research Institute (PCORI). With appropriate permissions, your collected information may also be shared with other researchers. Your identifiable private information may be stripped of identifiers and used for future research studies or distributed to another researcher for future research studies without additional informed consent.
5. INFORMATION ABOUT RISKS AND BENEFITS

5.1 What risks will I face by taking part in the study? What will the researchers do to protect me against these risks?

The known or expected risks are:

**Treatment:** All medications and counseling programs have been proven to be effective and/or are used in routine care. However, many patients experience side effects from medications. Also, counseling can be uncomfortable because it can involve disclosing personal information. These risks are the same as the risks for usual care by your primary care team or mental health specialist. Remember that this study is NOT testing experimental drugs, devices, or therapies.

**Surveys:** Answering survey questions takes time and you may find this inconvenient. We will do our best to schedule the survey at a time that fits your schedule. Some of the survey questions may also make you feel uncomfortable. An example of such a question is “In the past month, how much were you bothered by having strong negative feelings such as fear, horror, anger, guilt, or shame?”

**Confidentiality:** Another risk of participating in this study is possible loss of confidentiality if a person not connected to the study is able to see your survey answers. This is very unlikely, but we cannot guarantee that it will not happen.

The researchers will try to minimize the risks of the research study by:

**Treatment:** Your mental health and primary care providers will help you deal with problems from treatment with medication and counseling as they normally would.

**Surveys:** Research staff will attempt to minimize any discomfort you may have when completing surveys. If you become upset by the surveys, you can talk to research staff or your usual doctors and primary care team.

**Confidentiality:** Survey data will be stored on a secure computer at the University of Washington. Only trained staff will have access to this survey. When the results of this study are reported, your data will be combined with the data of other study participants. You will not be personally identified in any way. For example, we will report the percent of patients saying “very satisfied” to a survey question about satisfaction with treatment rather than your personal level of satisfaction. Your visits with the study mental health specialists are part of the medical record and have all of the same protections as your usual medical records.

As with any research study, there may be additional risks that are unknown or unexpected.

5.2 What happens if I get hurt, become sick, or have other problems as a result of this research?

The researchers have taken steps to minimize the risks of this study. Even so, you may still have problems or side effects, even when the researchers are careful to avoid them. Please tell the researchers listed in Section 10 about any injuries, side effects, or other problems that you have during this study. You should also tell your regular doctors.
5.3 If I take part in these two connected studies, can I also participate in other studies?

*Being in more than one distinct research study at the same time may increase the risks to you. It may also affect the results of the studies.* You should not take part in more than one study without approval from the researchers involved in each study.

5.4 How could I benefit if I take part in this study? How could others benefit?

Many patients do not have good access to specialty mental health services. This study will determine if referring to mental health specialty care or integrating primary and mental health care is the best approach to improving access to effective mental health treatment. Both the referral care approach and the integrated care approach are designed to improve access to effective mental health care. You may not receive any personal benefits from being in this study as there is no guarantee that your health will improve if you take part of this study.

5.5 Will the researchers tell me if they learn of new information that could change my willingness to stay in this study?

Yes, the researchers will tell you if they learn of important new information that may change your willingness to stay in this study. If new information is provided to you after you have joined the study, it is possible that you may be asked to sign a new consent form that includes the new information.

6. OTHER OPTIONS

6.1 If I decide not to take part in this study, what other options do I have? If you do not take part in this study, you can stick with the treatment you are currently receiving at our clinic. Or you can go see a mental health specialist that is not part of the study. You or your insurance company may be charged for treatment delivered by providers who are not part of the study.

7. ENDING THE STUDY

7.1 If I want to stop participating in the study, what should I do?

You are free to leave the study at any time. If you leave the study before it is finished, there will be no penalty to you. You will not lose any benefits to which you may otherwise be entitled. If you choose to tell the researchers why you are leaving the study, your reasons for leaving may be kept as part of the study record. If you decide to leave the study before it is finished, please tell one of the persons listed in Section 10 “Contact Information” (below).

7.2 Could there be any harm to me if I decide to leave the study before it is finished? You may discontinue participation in the study with no harm to you. The mental health specialists and your primary care team will work together to make a smooth transition back to your usual care.

7.3 Could the researchers take me out of the study even if I want to continue to participate?

Yes. There are reasons why the researchers may need to end your participation in the study. An example is:

✓ The study is suspended or canceled.

8. FINANCIAL INFORMATION

8.1 Who will pay for the costs of the study? Will I or my health plan be billed for any costs of the study?

The study will pay for research-related items or services that are provided only because you are in the study. If you are not sure what these are, see Section 4.1 above or ask the researchers for a list. If you get a bill you think is wrong, call the researchers’ number listed in section 10.1.
If you have insurance, treatment by a mental health specialist over video camera will be billed to your insurance company. Treatment by phone will not be billed to your insurance company. If you have insurance which does not cover this type of treatment, the study will pay for your treatment. If treatment is billed, your insurance company may require you to pay a co-payment. Likewise, if you normally have to make co-payments for your medications, you will also be asked to make the same co-payments for any medications prescribed to you or recommended for you by the mental health specialists.

You or your health plan will pay for all the things you would have paid for even if you were not in the study, like:

- Health care given during the study that is part of your regular care
- Items or services needed to give you study drugs or devices
- Monitoring for side effects or other problems
- Deductibles or co-pays for these items or services.

If you do not have a health plan, or if you think your health plan may not cover these costs during the study, please talk to the researchers listed in Section 10 below or call your health plan’s medical reviewer.

By signing this form, you do not give up your right to seek payment if you are harmed as a result of being in this study.

**8.2 Will I be paid or given anything for taking part in this study?** The University of Washington will compensate you $30 for each survey you complete following the initial appointment, 6 months later and 1 year later. For the two follow-up telephone surveys we will also include a $5 bill in the reminder letter. Total compensation for the study is $100.

**8.3 Who could profit or financially benefit from the study results?**
The University of Michigan will not receive profit/financial benefit from the study results.

Research can lead to new discoveries, such as new tests, drugs, or devices. Researchers, their organizations, and other entities, including companies, may potentially benefit from the use of the data or discoveries. You will not have rights to these discoveries or any proceeds from them.

### 9. CONFIDENTIALITY OF SUBJECT RECORDS AND AUTHORIZATION TO RELEASE YOUR PROTECTED HEALTH INFORMATION

The information below describes how your privacy and the confidentiality of your research records will be protected in this study.

**9.1 How will the researchers protect my privacy?**

We will store your responses to the survey questions and the review of your medical records in a data file at the University of Washington. This data will not contain any identifying information about you (like name, address). The data files may be shared with other researchers. The data file will contain your study number. We will maintain a separate file for 5 years that contains your study number and your identifying information. The separate file containing your identifying information will only be available
to the UM study team, the Institutional Review Board at the University of Washington, the Institutional Review Board at the University of Michigan, and the federal Office for Human Research Protection. The Institutional Review Board and the Office for Human Research Projection sometimes review study records to make sure studies are being done safely and legally. If a review of this study takes place, your records may be examined. These reviewers will protect your privacy. The study records will not be used to put you at legal risk of harm.

All of the information you provide will remain strictly confidential. However, if we learn that you intend to harm others, we must report that to the authorities. If you report that you intend to harm yourself, we will connect you with professionals trained in suicide prevention. We will also work with your providers to make sure you are safe.

9.2 What information about me could be seen by the researchers or by other people? Why? Who might see it?

Signing this form gives the researchers your permission to obtain, use, and share information about you for this study, and is required in order for you to take part in the study. Information about you may be obtained from any hospital, doctor, and other health care provider involved in your care, including:
- Hospital/doctor's office records, including test results (X-rays, blood tests, urine tests, etc.)
- Mental health care records (except psychotherapy notes not kept with your medical records)
- Alcohol/substance abuse treatment records
- HIV/AIDS status
- Sexually transmitted disease or other communicable disease status
- All records relating to your condition, the treatment you have received, and your response to the treatment
- Billing information
- Demographic information
- Personal information
- Other information

There are many reasons why information about you may be used or seen by the researchers or others during or after this study. Examples include:

- The researchers may need the information to make sure you can take part in the study.
- The researchers may need the information to check your test results or look for side effects.
- University, and/or other government officials may need the information to make sure that the study is done in a safe and proper manner.
- Study sponsors or funders, or safety monitors or committees, may need the information to:
  - Make sure the study is done safely and properly
  - Learn more about side effects
  - Analyze the results of the study
- Insurance companies or other organizations may need the information in order to pay your medical bills or other costs of your participation in the study.
- The researchers may need to use the information to create a databank of information about your condition or its treatment.
- Information about your study participation may be included in your regular medical record.
• If you receive any payments for taking part in this study, the University of Washington accounting department may need your name, address, payment amount, and related information to mail you a check.
• Federal or State law may require the study team to give information to government agencies. For example, to prevent harm to you or others, or for public health reasons.

The results of this study could be published in an article, but would not include any information that would let others know who you are.

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.

9.3 What happens to information about me after the study is over or if I cancel my permission?

As a rule, the researchers will not continue to use or disclose information about you, but will keep it secure until it is destroyed. Sometimes, it may be necessary for information about you to continue to be used or disclosed, even after you have canceled your permission or the study is over.

Examples of reasons for this include:
• To avoid losing study results that have already included your information
• To provide limited information for research, education, or other activities (This information would not include your name, social security number, or anything else that could let others know who you are.)
• To help University and government officials make sure that the study was conducted properly

As long as your information is kept within your primary care office’s records, it is protected by your Health Clinic’s privacy policies. For more information about these policies, ask for a copy of your clinic’s “Notice of Privacy Practices”. Note that once your information has been shared with others as described under Question 9.2, it may no longer be protected by the privacy regulations of the federal Health Insurance Portability and Accountability Act of 1996 (HIPAA).

9.4 When does my permission expire?
Your permission expires at the end of the study, unless you cancel it sooner. You may cancel your permission at any time by writing to the researchers listed in Section 10 “Contact Information” (below).

10. CONTACT INFORMATION

10.1 Who can I contact about this study?
Please contact the researchers listed below to:
• Obtain more information about the study
• Ask a question about the study procedures or treatments
• Talk about study-related costs to you or your health plan
• Report an illness, injury, or other problem (you may also need to tell your regular doctors)
• Leave the study before it is finished
• Express a concern about the study

If you have any questions about your eligibility, this consent form or the clinical care you are being provided as a part of this study, please contact:
University of Michigan Principal Investigator: Paul Pfeiffer, MD, MS  
Mailing Address: 2800 Plymouth Rd  
NCRC, Bldg, 16, Room 226W  
Ann Arbor, MI 48109  
Telephone: (734) 845-3645

Project Manager: Karla Metzger, LMSW  
Mailing Address: 2800 Plymouth Road  
NCRC Bldg. 16 2nd Floor  
Ann Arbor MI 48109-2800  
Telephone: (734) 232-0533

If you have any questions about surveys, please contact:

UW Principal Investigator: John Fortney, PhD  
Mailing Address: Department of Psychiatry and Behavioral Sciences  
1959 NE Pacific St.  
Seattle, WA 98195-6560  
Telephone: (206) 686-6955

You may also express a concern about a study by contacting the Institutional Review Board listed below.  
University of Michigan Medical School Institutional Review Board (IRBMED)  
2800 Plymouth Road  
Building 520, Room 3214  
Ann Arbor, MI 48109-2800  
Telephone: 734-763-4768  
Fax: 734-763-1234  
e-mail: irbmed@umich.edu

When you call or write about a concern, please provide as much information as possible, including the name of the researcher, the IRBMED number (at the top of this form), and details about the problem. This will help University officials to look into your concern. When reporting a concern, you do not have to give your name unless you want to.

11. RECORD OF INFORMATION PROVIDED

11.1 What documents will be given to me?  
Your signature in the next section means that you have received copies of all of the following documents:
- This "Consent to be Part of a Research Study" document.  
  (Note: In addition to the copy you receive, copies of this document will be stored in a separate confidential research file and may be entered into your regular University of Michigan medical record.)  
- Other (specify): _______
## 12. SIGNATURES

**Consent to Participate in the Research Study**

I understand the information printed on this form. I have discussed this study, its risks and potential benefits, and my other choices with _______________________. My questions so far have been answered. I understand that if I have more questions or concerns about the study or my participation as a research subject, I may contact one of the people listed in Section 10 (above). I understand that if I will receive a copy of this form at the time I sign it and later upon request. I understand that if my ability to consent or assent for myself changes, either I or my legal representative may be asked to re-consent prior to my continued participation in this study.

- **Legal Name:** ________________________________________________________________________
- **Signature:** _________________________________________________________________________
- **Date of Signature (mm/dd/yy):** ________________________

**Principal Investigator or Designee**

I have provided this participant and/or his/her legally authorized representative(s) with information about this study that I believe to be accurate and complete. The participant and/or his/her legally authorized representative(s) indicated that he or she understands the nature of the study, including risks and benefits of participating.

- **Legal Name:** ________________________________________________________________________
- **Title:** ______________________________________________________________________________
- **Signature:** _________________________________________________________________________
- **Date of Signature (mm/dd/yy):** ________________________