UNIVERSITY OF MICHIGAN
CONSENT TO BE PART OF A RESEARCH STUDY

1. KEY INFORMATION ABOUT THE RESEARCHERS AND THIS STUDY

Study title: Effectiveness and Implementation of a Peer Mentorship Intervention (PREVAIL) to Reduce Suicide Attempts among High-Risk Adults, HUM00137787

Company or agency sponsoring the study: National Institutes of Health

Names, degrees, and affiliations of the principal investigator: Paul Pfeiffer, M.D., Associate Professor, University of Michigan Department of Psychiatry

1.1 Key Study Information

You may be eligible to take part in a research study. This form contains information that will help you decide whether to join the study. All information in this form is important. Take time to carefully review this information. After you finish, you should talk to the researchers about the study and ask them any questions you have. You may also wish to talk to others such as your friends, family, or other doctors about your possible participation in this study. If you decide to take part in the study, you will be asked to sign this form. Before you do, be sure you understand what the study is about.

2. PURPOSE OF THIS STUDY

2.1 Study purpose:

This study will test a peer support program for individuals at increased risk for suicide.

3. WHO MAY PARTICIPATE IN THE STUDY

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?

Patients can take place in this study if they are admitted to Michigan Medicine's inpatient psychiatry unit; are over the age of 18; are at increased risk for suicide at the time of admission; are fluent in English; and are able to be reached reliably by telephone. Patients will not be able to participate if they score poorly on a memory test, are already receiving peer support, are receiving electroconvulsive therapy (ECT), will be discharged to another inpatient or residential facility, live outside the state of Michigan, or if the attending psychiatrist thinks that peer support may be harmful to the patient or peer.

3.2 How many people are expected to take part in this study?

We anticipate recruiting up to 490 people to participate in the study. Participants are being recruited at the University of Michigan and at Henry Ford Health System.

4. INFORMATION ABOUT STUDY PARTICIPATION

4.1 What will happen to me in this study?

If you decide that you would like to participate in this study, you will be asked to complete an initial enrollment assessment consisting of a series of online survey questionnaires online. The survey questionnaires will ask questions including sensitive topics such as your mental health. This assessment will take approximately 90 minutes to complete and will occur at the inpatient psychiatry unit. Because we will need to contact you for a follow-up assessment in approximately 3 months, and again in 6 months, we will ask for your contact information. If research staff are unable to contact you for these follow-up assessments, we may make a home visit to attempt to reach you to schedule or complete these assessments. We will notify of the planned date and time of any home visit ahead of time by mailing a letter to your home. You may opt out of home visits now or later by informing a member of the study team.

After this assessment, you will be randomly assigned to one of two groups (assigned by chance in a process similar to "flipping a coin"):

1) A peer mentorship intervention in which a peer mentor will be making weekly follow-up contact with you in the community (in your home, at a local coffee shop, etc.) or by telephone for 3 months following hospital discharge. The peer mentor will provide support, as someone who has previously experienced mental health issues in the past. In addition to this, you will proceed with your usual mental health care.
2) You will receive a check-in message from the study team 24-72 hours after discharge. In addition to this, you will proceed with your usual mental health care.

All participants will have access to a list of mental health resources provided by study staff, if necessary.

If you are randomized to the part of the study working with a peer mentor, you will meet your peer mentor during your hospital stay.

If you are working with a peer mentor, sessions will be audio taped and reviewed by research staff for training purposes and to ensure that peer mentors are following protocol.

The sessions will be audio-recorded. You must agree to be audio-recorded to participate in the study.

If you are working with a peer mentor, we also would like permission to contact your other mental health care providers to inform them of your participation in this study. We will also contact your mental health care providers should the clinical need arise.

I agree to allow study staff members to contact my mental health care providers, if necessary.

Signature of Subject: _____

Date: _____

If you are working with a peer mentor, we also would like permission to obtain a copy of your suicide safety plan. We are requesting access to this so that the peer mentor will have it available in the event that they need to review the plan with you.

I agree to release a copy of my suicide safety plan to study staff so that my peer mentor will be able to review it with me, if necessary.

Signature of Subject: _____

Date: _____

As a subject participating in this research study, you have certain responsibilities that may apply to this study, such as participating in sessions with a peer mentor, and reporting any adverse reactions you may have during the study.

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

If you choose to participate, you will be asked to complete a baseline survey, approximately 90 minutes. You will also be asked to complete another survey in three months, and again in six months, which should each take approximately 90 minutes. If you are randomized to the part of the study working with a peer mentor, you will be asked to speak with your peer over a 3-month period. Each of these meetings with your peer will typically be about 60 minutes in length, but this can vary depending on what you determine and agree upon with your peer.

4.3 When will my participation in the study be over?

Your participation in this study will be completed once the six-month survey is complete.

If you are working with a peer mentor, you may also be contacted by research staff after your participation in this study ends and be invited to participate in an interview about your experience with the PREVAIL intervention. Participation in this interview is voluntary.

In addition to the time above, we will collect information from your medical records for up to 4 years after your participation. The entire study is expected to last about 4 years.

4.4 What will happen with my information and/or biospecimens used in this study?

Data from this study will be submitted to the National Institute of Mental Health Data Archive (NDA). NDA is a data repository run by the National Institute of Mental Health (NIMH) that allows researchers studying mental illness to collect and share deidentified information with each other. A data repository is a large database where information from many studies is stored and managed. Deidentified information means that all personal information about research participants such as name, address, and phone number is removed and replaced with a code number. With an easier way to share, researchers hope to learn new and important things about mental illnesses more quickly than before.

You may decide now or later that you do not want to share your information using NDA. If so, contact the researchers who conducted this study, and they will tell NDA, which can stop sharing the research information. However, NDA cannot take back information that was shared before you changed your mind. If you would like more information about NDA, this is available on-line at http://data-archive.nimh.gov.

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 STUDY 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:

The most common risks of this study (occurring in more than 10% of patients) is tiredness or emotional discomfort or stress when completing study assessments.

Rarely (less than 1% of patients), participants assigned to the peer mentorship intervention may experience increased emotional distress and/or suicidal thoughts or behaviors because of uncomfortable or negative interactions with a peer mentor.

Tiredness or emotional discomfort or stress when completing study assessments is expected to be temporary. You may refuse to answer any questions in the assessment that make you uncomfortable or that you choose not to answer.

The researchers will try to minimize the risk of increased emotional distress and/or suicidal thoughts or behaviors because of uncomfortable or negative interactions with a peer mentor by ensuring that all research staff, including peer mentors, have been trained to manage emotional distress and/or suicidal crisis situations. All participants in this study will be asked about their thoughts of suicide during baseline, and at 3 and 6-month study assessments. If you are assigned to the peer mentorship intervention, your peer mentor will also ask you about thoughts of suicide at every session. If you report that you are having thoughts of suicide, and/or that you may act on these thoughts, research staff may intervene to connect you with additional support. Research staff may connect you with a study clinician, the National Suicide Crisis Line, or emergency medical services. If staff are concerned that you might harm yourself and cannot reach you by phone or are unable to conduct a complete risk assessment, they may call your emergency contact(s). If staff are unable to reach you or your emergency contact(s), they may activate police to conduct a wellness check. Research staff may also notify your outpatient treatment provider(s) and/or a study clinician of your thoughts of suicide.

Additionally, there may be a risk of loss to confidentiality or privacy. See Section 9 of this document for more information on how the study team will protect your confidentiality and privacy.

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 this study, can I also participate in other studies?

Being in more than one research study at the same time, or even at different times, 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?

You may not receive any personal benefits from being in this study. However, others may benefit from the knowledge gained from 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. ALTERNATIVES TO PARTICIPATING IN THE STUDY

6.1 If I decide not to take part in this study, what other options do I have?

If you decide not to take part in the study, there will be no penalty to you. Your standard medical treatment does not depend on your participation in this study. Participation is completely voluntary. There may be other ways to treat your mental health condition. There may be other programs for suicide prevention available to you. Ask the researchers or your health care providers about other options you may have.

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”.

7.2 Could there be any harm to me if I decide to leave the study before it is finished?

There will be no harm to you if you decide to leave the study before it is completed. If you decide to leave the study before it is finished, the researchers will ask you to complete a brief exit interview. This interview is voluntary and would take about five minutes to complete.

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

Yes. There are many reasons why the researchers may need to end your participation in the study. Some examples are:

- The researcher believes that it is not in your best interest to stay in the study.
- You become ineligible to participate.
- Your condition changes and you need treatment that is not allowed while you are taking part in the study.
- You do not follow instructions from the researchers.
- 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 researcher's telephone number listed in Section 10.1.

The study team has given you instructions about this research study. It is important that you follow these instructions carefully. If you get sick, have a medical complication, or are injured as a result of your being in the study, call Dr. Paul Pfeiffer immediately, at (734) 845-3645. The doctor will either treat you or send you to another doctor for treatment. You will get free medical care at the UMHS for any complication, injury, or illness caused by the study drug, device, or procedure. The UMHS and the study doctor are responsible for determining whether your condition was the result of your participation in the study. The UMHS will pay for your treatment only if the need for treatment has been caused by the study drug, device or procedure. This means that you or your health plan must pay for any treatment that is part of your usual medical care or that is related to a medical condition you had before participating in the study. It is not the general policy of the federal funding agencies to compensate or provide medical treatment for human subjects in federally funded studies.

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 as 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?

All compensation will be in the form of gift cards. You will be given $10 for completion of the initial baseline measures and $35 each for completion of the 3-month and 6-month measures after you complete each assessment. Therefore, your maximum compensation for this study is $80.

8.3 Who could profit or financially benefit from the study results?

This research is funded by the National Institutes of Health (NIH). No person or organization has a financial interest in the outcome of the study, and no person or organization will financially 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 the confidentiality of your research records will be protected in this study, and any sub-studies described in this document.

9.1 How will the researchers protect my information?

Research records that include your name and/or any identifying information about you will be stored in a locked cabinet that is separated from any data collected from you during study assessments or from your medical record.

Research records that include data collected from you during study assessments or from medical records or audio recordings of peer mentor sessions will be kept in separate research files that do not include names, registration numbers, or other information that is likely to allow someone other than the researchers to link the information to you.

You will be completing survey measures in Qualtrics, a web-based survey research tool. Qualtrics has SAS 70 Certification and meets HIPAA privacy standards. The Qualtrics website is password protected and hosted on a secure server. Confidentiality will be protected by restricting access to the Qualtrics research data to authorized study personnel only. No identifiable information about you will be stored in Qualtrics. Instead, you will be assigned a unique study ID number that will only identify you to study staff. Audio recordings of participants' sessions with their peer mentor will be stored using encryption.

If you are randomized to the peer mentorship arm of the study, research staff may send a text message to your selected peer mentor that contains limited information about you. This message would include only the minimum necessary information for your peer to contact you and arrange your first meeting, such as your first name, phone number, expected discharge date, and unique study ID number. These texts would be sent between passcode-protected study smart phones.

This research is covered by a Certificate of Confidentiality from the National Institutes of Health. The researchers with this Certificate may not disclose or use information or documents that may identify you in any federal, state, or local civil, criminal, administrative, legislative, or other action, suit, or proceeding, or be used as evidence, for example, if there is a court subpoena, unless you have

consented for this use. Information or documents protected by this Certificate cannot be disclosed to anyone else who is not connected with the research except, if there is a federal, state, or local law that requires disclosure (such as to report child abuse or communicable diseases but not for federal, state, or local civil, criminal, administrative, legislative, or other proceedings, see below); if you have consented to the disclosure, including for your medical treatment; or if it is used for other scientific research, as allowed by federal regulations protecting research subjects.

The Certificate cannot be used to refuse a request for information from personnel of the United States federal or state government agency sponsoring the project that is needed for auditing or program evaluation by the National Institutes of Health (NIH) which is funding this project or for information that must be disclosed in order to meet the requirements of the federal Food and Drug Administration (FDA). You should understand that a Certificate of Confidentiality does not prevent you from voluntarily releasing information about yourself or your involvement in this research. If you want your research information released to an insurer, medical care provider, or any other person not connected with the research, you must provide consent to allow the researchers to release it.

The Certificate of Confidentiality will not be used to prevent disclosure as required by federal, state, or local law of child or elder abuse or neglect, or of actual or potential harm to self or others.
The Certificate of Confidentiality will not be used to prevent disclosure for any purpose you have consented to in this informed consent document.

If you tell us or we learn something that makes us believe that a child or a vulnerable adult (i.e., mentally or physically impaired or of advanced age) may have been or may be physically harmed, we may be required to report that information to the appropriate agencies.

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.

9.2 What protected health information (PHI) 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.

Medical information and billing records are protected by the privacy regulations of the federal Health Insurance Portability and Accountability Act of 1996 (HIPAA). This type of information is called protected health information (PHI). PHI about you may be obtained from any hospital, doctor, and other health care provider involved in your care, including:

- Mental health care records (except psychotherapy notes not kept with your medical records)
- Alcohol/substance abuse treatment records
- All records relating to your condition, the treatment you have received, and your response to the treatment
- Demographic information
- Personal identifiers

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 look for side effects.
- University, Food and Drug Administration (FDA) and/or other government officials, auditors, and/or the IRB 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 UMHS medical record.
- If you receive any payments for taking part in this study, the University of Michigan accounting department may need your name, address, Social Security number, payment amount, and related information for tax reporting purposes.
- 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.

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

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 the University of Michigan Health System, it is protected by the Health System's privacy policies. For more information about these policies, ask for a copy of the University of Michigan "Notice of Privacy Practices". This information is also available on the web at http://www.uofmhealth.org/patient+and+visitor+guide/hipaa. 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 to use my PHI 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). If you withdraw your permission, you may no longer be eligible to participate in this study.

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

Principal Investigator: Paul Pfeiffer, M.D.
Mailing Address: 2800 Plymouth Rd., NCRC, Building 16, Ann Arbor, MI 48109
Telephone: 734-845-3645

Study Coordinator: Jennifer Jagusch
Mailing Address: 2800 Plymouth Rd., NCRC, Building 16, Ann Arbor, MI 48109
Telephone: 734-222-7437

You may also express a question or 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 (For International Studies, include the appropriate calling codes.)
Fax: 734-763-1234
e-mail: irbmed@umich.edu

If you are concerned about a possible violation of your privacy or concerned about a study you may contact the University of Michigan Health System Compliance Help Line at 1-866-990-0111.

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.)*

You will receive a copy of the signed and dated informed consent.

12. SIGNATURES

Sig-A

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 [NAME OF STUDY TEAM MEMBER OBTAINING CONSENT] _____. 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 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.

Print Legal Name: _____

Signature: _____

Date of Signature (mm/dd/yy): _____

Date of Birth (mm/dd/yy): _____

Sig-B

Consent to audio recording solely for purposes of this research

This study involves audio recording of sessions with your peer mentor. If you do not agree to be recorded, you CANNOT take part in the study.

_____ Yes, I agree to be audio recorded.

_____ No, I do not agree to be audio recorded.

Print Legal Name: _____

Signature: _____

Date of Signature (mm/dd/yy): _____

Sig-D

Consent/Assent to Collect for Unspecified Future Research

This project involves the option to allow the study team to keep your identifiable data for use in future research. I understand that it is my choice whether or not to allow future use of my data. 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.

_____ Yes, I agree to let the study team keep my data for future research.

_____ No, I do not agree to let the study team keep my data for future research.

Print Legal Name: _____

Signature: _____

Date of Signature (mm/dd/yy): _____

Sig-G

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.

Printed Legal Name: _____

Title: _____

Signature: _____

Date of Signature (mm/dd/yy): _____