Participants Name: _____ **Date:** _____

Social Security Number:_____ **VAMC: Bedford, MA**

Principal Investigator: Eric G. Smith, MD, PhD, MPH

Title of Study: The "AIM Study": Investigating whether Actigraphy and Ideation Measurement Can Promote Patient Safety

Sponsor of the Study: VA Clinical Research and Development Service

1. Purpose of study and how long it will last:

You are invited to take part in a research project looking at whether measuring someone's movements or responses to certain questions can help predict suicidal thoughts or actions. The main part of the project will occur during this hospitalization. For a limited number of participants, there will be 1 phone call after your inpatient treatment ends.

2. Description of the study including procedures to be used:

This project has two parts: The first part will occur while you are receiving inpatient treatment at the Bedford VA Hospital. The first part involves wearing a watch-like device on your wrist and answering questions or doing tasks to measure your mood and other mental health symptoms, and your suicidal thoughts. We will also look at your VA medical record for information about risk factors for suicide or suicidal actions and the medications you are taking. Your participation is voluntary and will last for up to as long as you are hospitalized on this unit of the Bedford VAMC. In the second phase, we may call you around 12 months after you have left the hospital. We will discuss how you are doing and if you had had suicidal thoughts or made suicidal acts.

We will also look at your medical record to see if you have been back to a mental health hospital or attended outpatient visits, or have had thoughts or taken actions to harm yourself. This project hopes to enroll between 115 and 300 participants.

Part 1 will involve the following questions and activities, typically completed as follows:

1) Initial Session: You will be asked to answer questions about your recent and current suicidal thinking and actions, mood, other physical and mental health symptoms, and your sense of yourself. You will also be asked to do a task on a computer that has you press keys when presented with various words. Some of these words will relate to death or, less often, suicide**.** We will also explain the Actigraph device to you and attach it to your wrist. It is estimated this session will take up to 90 minutes.
2) The Next Day: You will be asked to answer questions about your recent suicidal thinking and actions, and some physical and mental health symptoms, questions about your past suicidal thinking and behavior and mental health symptoms, and about family history of suicidal behavior. It is estimated that this session will take 15-25 minutes.
3) All Following Days: You will be asked to answer questions about your recent suicidal thinking and actions, some physical or mental health symptoms and sometimes about mood. These sessions with take up to 15 minutes.

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If you are discharged to another program on the Bedford VA campus and we have not administered assessments on that day, we might approach you at that program to see if you would be willing to go to a private setting and complete those assessments with us.

4) While wearing the Actigraph device, we will ask you to press the button each time you are having thoughts of suicide. You do not need to press it if you are having thoughts about being dead or wishes to be dead but not thoughts of suicide. If you want privacy when pressing the button, you can go to your room, or, if occupied, go to the end of the hall to press the button. If you forget or are not able to press the button when you are having suicidal thoughts, that is not a problem. The next time we visit you, we will ask you if you were unable to press the button at any time you were having suicidal thoughts.
5) If you remove the device, you will be immediately withdrawn from the study.

Part 2 is estimated to require up to 20 minutes, and will involve:
We may try to talk to you at least once by phone after you leave the unit, around 12 months after discharge. If we try to talk to you, we will make up to 6 attempts to reach you since it is important to the project for us to get information from you about how things have been going. Prior to discharge, we will ask you if you are willing to provide us with a contact phone number for someone you know who can give us your current phone number if it changes after discharge. If you agree to this (and you do not have to agree to be in the study), we would then also call that person or person(s) (up to twice) if we are unable to reach you at any phone number you provided or the phone numbers listed for you in your VA medical record after 6 attempts or receiving information that that phone number is out of service or belongs to someone else. We then would attempt to reach you (up to 6 times) at the new contact number they provide. During the phone call, we would ask you about your suicidal thoughts or actions since leaving the hospital, and if you have needed to return to the hospital and why. We may call you earlier than 12 months if you are discharged and leave without receiving your gift cards and/or your copy of this document, or if you leave while still wearing the Actigraph device. We will also examine your VA patient record to see what information it has about suicidal actions, thoughts, and care you have received (including hospitalizations) since leaving the hospital.

3. Description of any procedures that may result in discomfort or inconvenience:

It is possible that you may become tired or bored answering the questions or that you may find the Actigraph uncomfortable. It is also possible that when we call when it is not convenient. We will try to schedule a time to talk that works well for you.

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4. Expected risks of study:

The Actiwatch device may cause some unknown risk of skin irritation, even though this is a nickel-free, non-latex product. Please inform Nursing or Study Staff if you notice any irritation or need the device removed. Try to minimize the soap that gets under the device when showering.

There is a chance that you will find some of the questions upsetting, or that the questions cause you to dwell on thoughts of suicide more than you would otherwise. If this is the case, please let your treatment team know. (Or, if you are no longer on the unit, one of your outpatient treaters). Depending on your answers to questions while you are on the inpatient unit, we may notify your inpatient treatment team if we feel it is important to maintain your safety or would help them to better treat you. Depending on your answers to the questions when we call you on the phone, we may transfer your call to the Veterans Crisis Line hotline, or notify your outpatient treater or Suicide Prevention Coordinator if we feel it is important to maintain your safety or it would help them to better treat you.

Participation in research may involve a loss of privacy. While on the unit, other patients or staff who know about the study may be able to tell you are taking part in a study focused on suicidal thoughts by seeing the Actigraph on your wrist. Also, since the unit is small, there is a chance your responses may be overheard by others. We have tried to minimize these risks by having you write responses to as many questions as possible, and meeting with you alone or in out-of-the-way locations.

Your research records will be kept as confidential as possible. Only a code number will identify your research records, except for a master list linking names and last four numbers of social security numbers to records, which will be kept separately from the research data.
The code number will not be based on any information that could be used to identify you (for example, social security number, initials, birth date, etc.)

All research information will be kept in locked files at all times. Your identity will not be revealed in any reports or publications resulting from this study. Only authorized persons will have access to the information gathered in this study. Federal Agencies such as the Office for Human Research Protection (OHRP), Government Accountability Office (GAO) and Food and Drug Administration (FDA) may have access to the records.

The Department of Veterans Affairs (VA) requires some information to be recorded in the VA

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electronic medical record for all Veteran and non-Veteran research subjects. Therefore, if you participate in this study, a note of your participation will be entered into your medical record. Federal laws and regulation that protect privacy of medical records will apply to your VA record.

If you agree to allow us to contact someone you specifically identified for us if we are unable to reach you at your contact numbers, when we call them we will only identify ourselves as employees of the Bedford VA who are trying to reach you. We will not mention what the call concerns; however, it is possible our call will prompt them to ask you questions about why we are calling. We will only call them after multiple unsuccessful attempts to reach you at the phone number you provide or that or listed in CPRS (or after learning these are no longer your number). You do not have to provide someone else's phone number if we need help contacting you to be in the study,

5. Expected direct benefits of study:

It is possible that participating in this project will help you be more aware of your thoughts or actions in the past, or help you practice being more aware of your suicidal thinking when it occurs. It is also possible that the information we gather from you may, in some cases, help your inpatient treatment team take better care of you. However, we can't guarantee that you will personally experience benefits from participating in this study. Others may benefit from the information we find in this study.

6. Alternative diagnostic procedures:

The questions we ask may be more detailed than those asked by your treatment team. However, these questions do not replace the procedures usually used on the inpatient unit. Data from the wrist Actigraph or computer test will not be used for diagnosis.

You may choose to withdraw from this study at any time. There will be no consequences if you do so and no impact on your VA care. We will also notify you while you are on the unit or during our phone calls if there are significant new findings that may affecting your willingness to continue in the study. Although not expected, if the researchers become concerned that somehow being in the study is harming you, we may stop your participation, even if you do not agree. If you or we stop your involvement in the study, no additional data will be obtained, but the data already obtained might be used. Since your data is most useful if we have at least 2 days of data after the initial visit, if you need to withdraw before then we might approach you if you are

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admitted in the future to see if you would like to participate again.

7. Use of research results/Confidentiality:

Your information will be kept confidential, except when we think that some of your responses might enhance your ongoing care. In that case, we may notify your treatment team about your responses. This may or may not affect your inpatient treatment and length of stay on the unit.

The questionnaires will be kept in a locked office in Building 70 and in a locked file cabinet that only authorized persons will be able to access. Data from these questionnaires, your medical record will be coded and kept on a secure, password-protected VA computer server. The Actigraphy data will also be kept on a secure, password-protected VA computer server. All data will be retained in accordance with the VA record control schedule.

If results of this study are reported in medical journals or at meetings, you will not be identified by name, by recognizable photograph, or by any other means without your specific consent. Your medical records will be maintained according to VA requirements. The Food and Drug Administration may inspect the records. A description of this study will be available on http://www.ClinicalTrials.gov. This website will not include information that can identify you. At most, the website will include a summary of the results. You can search this website at any time.

8. Special Circumstances:

You will be paid with gift cards to CVS Stores to compensate you for the time you spend on this project. You will be paid $25 after completion of the initial visit, and $25 after completion of all the follow-up sessions while you are on the unit. These gift cards will be placed with your belongings to be received by you upon discharge, or will be mailed to you at home. If for some reason you are determined to be ineligible for the study, we will give you a $10 gift card to compensate you for the time you provided to us already.

9. **Future Use of Data.**

As of now, VA research data is retained after research. This data will stored in secure VA computer drives, or in locked files in Building 70. Only authorized persons will have access to this data. Once the study is complete, the data will not be used again.

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RESEARCH PARTICIPANTS' RIGHTS: I have read, or have had read to me all of the above. The Research Coordinator or Principal Investigator has explained the study to me and answered all of my questions. I have been told of the risks or discomfort and possible benefits of the study. I have been told of other choices of treatment available to me.

I understand that I do not have to take part in this study, and my refusal to participate will involve no penalty or loss of rights to which I am entitled. I may withdraw from this study at any time without penalty or loss of VA or other benefits to which I am entitled.

The results of this study may be published, but my records will not be revealed unless required by law.

A Veteran-participant does not have to pay for care received as a participant in a VA research project except in accordance with federal law. Certain Veterans have to pay co-payments for medical care and services provided by VA. In case there are medical problems or questions, I have been told I can call: **Dr. Smith at 781-687-2766 during the day, or by paging him by calling 781-687-3355 and entering in the numbers 033, then enter your phone number and the pound sign (#). When it says to speak you can just hang up. VA Medical Facilities shall provide, or arrange for, necessary medical treatment to a research subject injured as a result of participation in a research project. This does not apply to treatment for injuries due to non-compliance by the subject with the study procedures. If I have any questions, concerns, or complaints regarding my rights as a research subject I may call Joseph Squicciarini at 781-687-2926. No money has been set aside for compensation in case of injury as a result of participating in this study however I understand that I would still have the right to file any legal action.**

I understand my rights as a research subject, and I voluntarily consent to participate in this study. I understand what the study is about and how and why it is being done. I will receive a signed copy of this consent form.

_____ _____

Participant's Signature **Date**

_____ _____ _____

Signature of Investigator **Signature of the person obtaining consent** **Date**