Suicide Prevention in Rural Veterans During High-risk Care Transition Scenarios

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**Due to clerical error and oversight, the consent form displays the study title to be "Randomized trial of VA Brief Intervention and Contact Program: VA-BIC". However, the actual study title is "Suicide Prevention in Rural Veterans During High-risk Care Transition Scenarios". These titles should be considered synonymous. Moreover, our local Institutional Review Board (Veteran's IRB of Northern New England) has approved the consent form despite the differing study titles.*

VA Research Consent and Authorization Form

Veteran's IRB of Northern New England (VINNE)
VA White River Junction, VA Maine Healthcare System, VA Manchester

Title of study: Randomized trial of VA Brief Intervention and Contact Program: VA-BIC
IRBNet #: 1439938
Researcher name: Brian Shiner, MD MPH

Key information

The purpose of the study is to evaluate a suicide prevention program, the VA Brief Intervention and Contact (VA-BIC) Program. The VA-BIC Program includes suicide prevention education, tailored to your unique needs, from a psychologist at the time you are discharged. Study personnel will regularly follow up with you for 3 months after you are discharged and help you stay connected to your treatment providers. This type of program has proven to decrease suicide risk in low-income countries, but is considered experimental within the United States Veteran population.

You are being asked to participate in this study because you are currently hospitalized in the inpatient mental health unit due to concerns about your possible risk of self-harm. Research studies include only people who choose to take part. The study team members will explain the study to you and will answer any questions you might have. You should take your time to make your decision.

If you choose to participate in this study, you will be assigned by chance (50/50, like a flip of a coin)to receive our VA-BIC Program along with your regular care OR to receive regular care only. If you are assigned to receive our VA-BIC program, the study psychologist will call or meet you in person 6 times periodically to check on you and help you stay connected to your treatment providers after you are discharged. All study participants will complete 3 study interviews which are described on page 3 of this form under "Study Assessments". You would be in this study for 3 months.

There are a few risks involved in taking part in this study. You may experience feelings of embarrassment, nervousness, boredom or discomfort when being asked to answer study questions about the problems that you might be struggling with.

We cannot promise any direct benefit to you for participating in this study. With your participation, we hope to find information that may help Veterans in the future. You do not have to participate in this study to receive mental health care at the VA. If you decide not to participate in this study, your other option is to receive regular care which is described on page 3 of this form under "Group B: Standard psychiatric hospital discharge care".

Introduction

You are being asked to be in this study because you are a Veteran who was admitted to the inpatient mental health unit in part due to concerns about your safety and you are currently working with your mental health care team on discharge plans, including the types of treatments and follow-up care you will receive after you leave the hospital. The purpose of this study is to assess whether our VA-BIC suicide prevention program decreases suicide risk after you are discharged from the VA inpatient mental health unit.

Your decision about being in this study will have no effect on the quality of your mental health care or medical care you receive. You do not have to take part in this study. If you decide to take part, you can stop being in the study at any time. You can say "no" to answering any of the questions you are asked during the study.

Please ask questions if there is any information about this study you do not understand. You may have a copy of this form to discuss with your doctors and family before making a decision about being in the study.

Will I personally benefit from being in this study?

You may not personally benefit from being in this research study. In this study, we hope to learn information that may help people in the future.

What does this study involve?

We expect up to 25 people to enter this study here at the White River Junction VA Medical Center. We expect people to be in this study for up to 3 months and participate in 3 or 10 study visits depending on which group you are assigned to. If you decide to join this study, you will be assigned by chance to one of the groups listed below.

Group A: VA-Brief Intervention and Contacts plus standard psychiatric hospital discharge care

For this group of people, the study activities include, in addition to receiving the standard care provided to all Veterans at the time of discharge from Ground East (please see the detailed description of standard psychiatric hospital discharge care listed for Group B):

- Brief education from the study psychologist on suicide prevention which is designed to address your unique situation. The education visit lasts approximately one hour and will occur prior to your discharge from Ground East.
- You will have a total of six contact visits (2 days, 2 weeks, 1 month, 6 weeks, 2 months, and 3 months after you are discharged) with the study psychologist. These

visits can be done over the phone, in-person or VA Video Connect. You can choose which one works best for you. Please note that while you have the choice to complete your visit over the phone or video, none of the visits even if they are in-person, over the phone, or via VA Video Connect will be recorded. At each of these follow-up study visits, you will be asked about how you have been doing since you were discharged and given advice on ways to feel better. These visits will last approximately 15-30 minutes.

Group B: Standard psychiatric hospital discharge care

For this group of people, the study activities include the standard care provided to all Veterans at the time of discharge from Ground East. As part of standard psychiatric hospital discharge care, your treatment team will work with you and your outpatient providers to determine the best treatments for your particular mental health condition. The treatment team will ask you to complete a safety plan. The treatment team will arrange for you to meet with a mental health provider(s) as an outpatient for a set number of times after discharge. Finally, if you are assigned to the High Risk for Suicide List by the inpatient treatment team (or your outpatient providers), the Suicide Prevention Coordinator will ensure that a pop-up flag is placed in your medical record to make providers aware of your mental health needs.

Study Assessments:

(To be completed by all participants in Groups A & B)

Visit 1: Baseline assessment on Ground East before you are discharged (approximately 60 minutes)

- The study member will conduct a brief diagnostic interview with you to determine your current mental health diagnoses.
- The study member will ask you to complete 5 short surveys which ask about how you are feeling, self-harming thoughts and behaviors, level of support and your feelings about treatment.
- The research team will look in your medical chart to collect information on your age, gender and race.

Visit 2 & 3: Follow-up study assessments at 1month and 3 months after discharge (approximately 30 minutes)

- The study member will ask you to complete 5 short surveys which ask about how you are feeling, self-harming thoughts and behaviors, level of support and your feelings about treatment since your last study visit.

- The study member will ask you about treatments you received after discharge outside of the VA and look in your medical record at treatments you received after discharge within the VA system.

You and the researcher will not be able to control the group to which you are assigned. You will be notified of your group upon assignment. If you are assigned to Group A, the psychologist doing your contact visits will know that you are in Group A. However, the person who conducts the follow-up assessment interviews will not know what group you are in. This is on purpose and we will ask that you please do not tell your interviewer what group you are in.

What are my other choices if I decide not to be in this study?

Instead of being in this study you could choose one of the options listed below.

- The usual plan of medical care for people with your condition, which is standard psychiatric hospital discharge care. Standard psychiatric hospital discharge care on Ground East is outlined under the description of Group B above.
- You could also decide to enroll in other research studies aimed at evaluating suicide prevention strategies after psychiatric hospitalization. We are not aware of any such research studies currently being tested at the White River Junction VA Medical Center, but such studies may exist at other VA facilities or in the private sector. You do not have to join this study to receive medical care.

Can I continue with my current mental healthcare treatment during the study?

Yes, while participating in this study, you can continue to participate in the mental healthcare treatment that you and your healthcare providers have decided is the best treatment plan for you.

If I decide to be in this study, what activities are done only for research purposes?

If you join this study, the activities listed below will be done only for research purposes.

- Participation in baseline and follow-up assessments listed above (under "What does this study involve")
- If assigned to Group A, brief suicide prevention education and 6 study intervention contact visits as described above (under "What does this study involve")

Are there risks and discomforts involved in this study?

There could be risks and discomforts involved in this study however, the risks associated with participating in this study are small. We will ask you questions about how you are feeling as well as about self-harming thoughts and behaviors. We will also discuss ways to manage your symptoms. Sometimes people can feel embarrassed, nervous, bored or generally uncomfortable

when they are asked to answer these types of questions or talk about the problems that they might be struggling with. If any of the questions make you feel uncomfortable, you should feel free to mention this to the interviewer and have this concern addressed. You can also refuse to answer a question. If you need to take a break, let the interviewer know.

Other important information you should know

- **Withdrawal from the study:** You can choose to stop being in this study at any time by notifying a member of the research team. If you decide to stop, it will not affect the quality of your mental health care. It is possible the study may be terminated early, thereby ending your participation. It is also possible the researchers may choose to terminate your participation in the study without your consent if they feel it is in your best interest.
- **New Information:** We will tell you about new scientific findings related to this research as they become known. You can then decide again if you want to continue being in this study.
- **Funding:** The Office of Rural Health, VA Rural Health Resource Center- Eastern Region is the sponsor of this research and funds this research. This research is also supported by the VA National Center for Patient Safety Center of Inquiry Program.
- **Research results**: If imminent suicidal risk is identified from the research procedures, you will be informed.

How will my privacy and the confidentiality of the information collected for the study be protected?

This study uses the same practices as a medical clinic to protect your privacy, such as using non-public spaces for physical exams and interviews.

Your de-identified data will not be distributed for future research studies. However, it could be used in the future by this study team for additional analyses. Please see Page 7, "**How is the confidentiality of study information protected?",** for details on how your information will be stored and protected.

During your time in the study, you will not have access to your research data. You may request your study data once your time in the study is completed. At any time, you may exercise your rights to request access to your medical records.

Health Information Portability and Accountability Act (HIPAA)
There are rules to protect your private health information. Federal and state laws and the federal medical law, known as the HIPAA Privacy Rule, also protect your privacy. By signing this form, you provide your permission called your 'authorization,' for the use and disclosure of information protected by the HIPAA Privacy Rule.

The research team working on the study will collect information about you. This includes things learned from the procedures described in this consent form. They may also collect other information including your name, address, date of birth, and information from your medical records such as medical history, medications, drug or alcohol treatment, or mental health treatment.

The research team may also need to disclose your health information and the information it collects to others as part of the study progress. Others may include the:

- Office of Rural Health, Rural Health Resource Center- Eastern Region (the study funder)
- The Data Safety Monitoring Board, comprised of VA research investigators at White River Junction VA Medical Center
- The Veterans Institutional Review Board of Northern New England (VINNE) and the Research & Development Committee at the Veterans Affairs Medical Center at White River Junction, VT
- Central VA/VHA offices: Office of Research Oversight (ORO), the Office of Research and Development (ORD), Office of Inspector General, and Office of General Counsel (GAO)
- The Office of Human Research Protection in the U.S. Department of Health and Human Services (OHRP)

Your health information disclosed pursuant to this authorization may no longer be protected by Federal laws or regulations and may be subject to re-disclosure by the recipient.

You can revoke this authorization, in writing, at any time. To revoke your authorization, you must write to the Release of Information Office at this facility (802-295-9363 X5068/6408) or you can ask a member of the research team to give you a form to revoke the authorization. Your request will be valid when the Release of Information Office receives it. If you revoke this authorization, you will not be able to continue to participate in the study. This will not affect your rights as a VHA patient to treatment or benefit outside of the study. If you revoke this authorization, **Dr. Brian Shiner** and his research team can continue to use information about you that was collected before receipt of the revocation. The research team will not collect information about you after you revoke the authorization.

Treatment, payment or enrollment/eligibility for benefits cannot be conditioned on you signing this authorization. This authorization will expire at the end of the research study unless revoked prior to that time.

How is the confidentiality of study information protected?
The rules of VA Record Control Schedule apply to the information collected and created for this research. We also have made careful plans to protect the identities of the people who are in the study and the confidentiality of the information collected about them for this study.

Efforts will be made to protect the identities of the participants and the confidentiality of the research data used in this study, such as:

- Any written research materials will be kept on the WRJ VA Medical Center Grounds in a locked cabinet located in a locked building.
- Data will also be stored on a local, secure computer research server. To gain access to the server, the investigator must use a password protected computer. The computer is located in a locked building on the WRJ VA Medical Center Groups.

If you give the research team information about sexual, physical, or other abuse of a child or older person, the research team will report it to authorities. If you make a threat of violence to yourself or others, the study team will evaluate you and take steps to provide appropriate treatment and protection.

Once the research data is no longer being actively collected or analyzed, the research data will be kept (stored as described above) for a minimum of 6 years after study completion in compliance with the VA Records Retention Policy.

Certificate of Confidentiality
This research will be covered by a Certificate of Confidentiality from the National Institutes of Health. This means that the researchers cannot release or use information, documents, or samples that may identify you in any action or suit unless you say it is okay. They also cannot provide them as evidence unless you have agreed. This protection includes federal, state, or local civil, criminal, administrative, legislative, or other proceedings. An example would be a court subpoena.

There are some important things that you need to know. The Certificate DOES NOT stop reporting that federal, state or local laws require such as abuse or threats of harm as mentioned above. The Certificate CANNOT BE USED to stop a sponsoring United States federal or state

government agency from checking records or evaluating programs. Researchers may release information about you when you say it is okay. For example, you may give them permission to release information to insurers, medical providers or any other persons not connected with the research. The Certificate of Confidentiality does not stop you from willingly releasing information about your involvement in this research. It also does not prevent you from requesting access to your own information upon study completion.

Who can I call with questions or concerns about this study?

You should call the study project lead, Dr. Natalie Riblet, with questions or concerns about this study. You can reach her at *(802) 299-8682* during normal business hours. If Dr. Riblet is not available, other staff members are available during normal business hours to answer your questions or listen to your concerns. After business hours, you can talk to the White River Junction VA Medical Center mental health doctor on-call at *(802) 295-9363* or call the Veterans Crisis Line at **1-800-273-8255** and **Press 1** to talk to someone if you are experiencing an acute crisis.

If you have questions, concerns, complaints, or suggestions about human research at the VA Medical Center, you can call the office for the Veteran's Institutional Review Board of Northern New England (VINNE) at (802) 295-9363, extension 5052, during normal business hours.

Will there be costs to me if I decide to be in this study?

There is no cost to you or your health insurance plan for the study related-visits described earlier in this form under "If I decide to be in this study, what activities will be done only for research purposes?" Any other medical services that you may receive during this study are standard care for your condition. You or your health insurance plan may be billed for this medical care or your VA benefits may cover these costs with co-payments from you like those for other medical services.

Will I be paid to participate in this study?

Yes. You will be reimbursed a total of **$300** for your time and effort. The payment will be provided to you as a direct deposit into your bank account. We listed the schedule of payments below.

- Baseline Assessment Visit: **$50**
- Follow-up Assessment Visit at 1 month: **$100**
- Follow-up Assessment Visit at 3 months: **$150**

You will receive each payment after completing the study visit.

Your name, address, and social security number, and bank information will be given to the VA Fiscal Department so they can make your study payments to your bank account via direct deposit.

What happens if I get sick or hurt from participating in this study?

VA Policy: If you have an injury or illness as a result of being in this study, the VA will provide emergency treatment and medical care at no cost to you. No additional payments by the VA are planned. By signing this form, you do not lose any of your legal rights or release the VA Medical Center from its duty to provide proper medical care.

If you believe you have injury, illness, or a bad reaction related to the study activities, please let the researcher know as soon as possible. You can call the researcher, Dr. Natalie Riblet, at *(802) 299-8682* during the day or the on-call VA doctor at *(802) 295-9363* after business hours. If you receive emergency medical care in a private hospital because you are unable to come to the VA Medical Center, please have a family member or friend let the researcher know. The VA Medical Center can then work with the private hospital to support your medical care.

More information about medical care and payments for medical services in the event of a study related injury or illness is available from the VA Medical Center's Business Office at *(802) 295-9363* extension *5748*. You may also call the VA Medical Center's Patient Advocate at *(802) 295-9363* extension *6293*.

Your rights and responsibilities

I have read, or someone read to me, the information about this study in this form. The researcher has explained the study to me and answered my questions. I have been told about the possible risks, discomforts, and benefits of the study. I have also been told about the other choices that are available to me instead of being in this study.

If I decide to join this study, I am aware that I am expected to make reasonable efforts to follow the instructions of the researcher and study staff. If I have any health problems while in the study, I agree to report them right away to the researcher.

I am also aware I do not have to join this study. If I decide not to be in the study or change my mind and decide to leave it after joining it, no penalty or loss of my VA or other benefits will happen. My decisions about this study will have no effect on my current or future medical care at the VA.

My signature on this form means that I agree to take part in this study. I will be given a copy of this form after I sign it for my own records.

_____	_____	_____
Signature of study participant	Date	Time

Initials of study participant after receiving a copy of this consent form _____