Department of Veterans Affairs

# VA RESEARCH CONSENT FORM

**Subject Name:**

**Title of Study:** Online and Shared Decision-Making Interventions to Engage Service Men and Women in Post-Deployment Mental Health Care

**Principal Investigator:** Anne Sadler, Ph.D., R.N. **VAMC:** Iowa City, Iowa

## INFORMED CONSENT DOCUMENT

**Project Title:** Online and Shared Decision-Making Interventions to Engage Service Men and Women in Post-Deployment Mental Health Care

**Principal Investigator:** Anne Sadler, Ph.D., R.N.

**Research Team Contact:** Dr. Anne Sadler, 1-866-482-8387 (toll-free)

This consent form describes the research study to help you decide if you want to participate. This form provides important information about what you will be asked to do during the study, about the risks and benefits of the study, and about your rights as a research subject.

- If you have any questions about or do not understand something in this form, you should ask the research team for more information.
- You should discuss your participation with anyone you choose such as family or friends.
- Do not agree to participate in this study unless the research team has answered your questions and you decide that you want to be part of this study.

## WHY WAS I SELECTED FOR THIS STUDY PHASE?

We are inviting you to participate in this next phase of the research study because: 1) you are a Veteran who completed the online screening for the study, **"**Online and Shared Decision-Making Interventions to Engage Service Men and Women in Post-Deployment Mental Health Care**"**, 2) you had any positive mental health or readjustment screens, and 3) you agreed to consider participation in this next phase of the study.

SUBJECT'S IDENTIFICATION (I.D. plate or give name-last, first, middle)

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## WHY IS THIS SECOND STUDY PHASE IMPORTANT?

Too many Veterans do not access needed mental health care post-deployment or drop out of care early if they do. This study phase seeks to support Veterans in getting the information they need to understand their current emotional health symptoms and possible treatment options (with as few barriers as possible), and in using shared decision-making with their providers to make treatment choices according to their unique preferences and values.

This second study phase is a randomized clinical trial (RCT) to determine if Veterans who completed the online post-deployment screening solely ("usual care" group) have different care outcomes and satisfaction than Veterans who we assist with additional resources ("intervention" group). These additional resources include information about:

- Online VA and My Health*e*Vet enrollment,
- How to secure message a summary of your (already completed) screening results to the VA providers you wish to receive them, or if you are new to the VA, to your newly assigned provider.
- An informational video about shared decision-making.

## WHAT WILL MY PARTICIPATION INVOLVE?

If you volunteer to participate in this study, we will ask you to do the following things:

A) Sign and return the enclosed consent and HIPAA authorization forms, a form where you indicate which VA you prefer to attend and the provider that you would like to send your already completed screening results summary to (if you are enrolled in VA), and a form that includes your treatment priorities.

B) After we receive your completed forms, we will assign you to one of two groups.

- **For those assigned to the "usual care" group**, you will require no further follow up until approximately 6 months following your already completed online screening with WEB-ED. At that time, you may be invited to complete a telephone interview (see below).

- **For those assigned to the "intervention" group,** you will be emailed (through encrypted e-

mail) a summary of your screening results to secure message to your provider. You will receive (by postal and email) additional information regarding steps to take for VA and My Health*e*Vet enrollment, and a link to a brief (8 minute) shared-decision making educational video and three 1 page decision aids to support decision-making for often experienced post-deployment emotional health conditions.

**Your "intervention group" steps will include:**

- Enrolling in VA and My Health*e*Vet, if you are not already.
- Secure messaging a summary of your screening results summary to your provider.
- Reviewing the decision aids and watching the brief shared decision-making video.
- Scheduling an appointment to talk with your identified or new VA provider about your screening results and your treatment preferences (that can include choosing no treatment); and
- Using your shared decision-making and decision aids that we provided you by email in the appointment with your provider. **This appointment must be completed by March 10, 2023 (in person or tele-health) so we encourage you to make an appointment as soon as possible, if you do not have one already.**

Your VA provider will also be invited to participate. Their participation is also completely voluntary, so they may or may not view and use our provider-specific training and decision aid materials (for example, they may have had prior shared decision-making training). However, they will be aware of and expect your participation and information that you are receiving.

## WHAT IF I HAVE QUESTIONS OR GET STUCK ON ONE OF THE STEPS?

Please note that our study team is available to you at our toll-free number to assist you with any questions or any step along the way. For example, we can step in to secure message your screening results summary to your provider if necessary.

**Participants in both study groups may be among the 75 Veterans invited to complete a telephone interview that will occur up to 6 months after their initial online screening and that will take about 25 minutes.** For

this phone interview, the study coordinator or a trained study interviewer will ask you brief questions about your assessment of the online processes, educational materials, your perceptions of and satisfaction with your interface with a VA provider and subsequent mental health care engagement (or not). The interviewer will also ask you about factors that might influence your willingness or reluctance to seek VA health care. This call will not be recorded and only your study identification number will be used for documenting your answers. The study coordinator or a trained study interviewer will answer any further questions you may have or provide you with any additional information about VA resources following this telephone interview if you would like them to.

**We will also perform a chart review** that will focus on what happened in your care interface with your provider following study participation for people in each study group to compare if there are differences in care engagement and satisfaction. We will also review VA care that you have received (or not) post-deployment through up to 6 months after your initial on-line screening. We will specifically look at your provider's documentation about your treatment preferences and decision-making, health care visits, medications for mental health, mental health assessment and counseling, and substance use treatment (if any).

## HOW MANY PEOPLE WILL PARTICIPATE?

Approximately 1,400 will take part in the randomized clinical trial phase of the study that includes a chart review approximately 6 months following WEB-ED completion. Approximately 75 of the Veterans participating in the clinical trial will be asked to complete telephone interviews conducted by investigators through the Iowa City VA Health Care System.

## HOW LONG WILL I BE IN THIS STUDY?

If you agree to take part in this study, your participation will last from the time you return your consents and HIPAA authorization forms (that allow us to access your electronic medical record for chart review purposes from the time we receive the form) to 6 months after your already completed online screenings. You may also be invited to complete a 25-minute telephone interview approximately 6 months after completion of online screening.

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## WHAT ARE THE RISKS OF THIS STUDY?

You may experience one or more of the risks indicated below from being in this study. In addition to these, there may be other unknown risks, or risks that we did not anticipate, associated with being in this study.

There is a risk of loss of confidentiality of data. If you find that you are distressed after your participation, VA resources are available to you 24 hours a day via toll-free numbers that we will provide to you in study materials. On every web site page, we provide information for the VA suicide hotline, Veterans Emotional Crisis Hotline, and other key VA contacts to assist you in connecting with needed resources as well as OEF/OIF/OND transition patient advocates so you can have any needed help in engaging with VA care. Contact numbers for the principal investigator and research coordinator will also be included.

## WHAT ARE THE BENEFITS OF THIS STUDY?

We don't know if you will benefit from being in this study. However, we hope that, in the future, other Veterans might benefit from this study because this information will be used to understand how best to provide important information to Veterans and to facilitate their access to VA mental health care that is patient-centered, that is according to their preferences, priorities, and values.

## WILL IT COST ME ANYTHING TO BE IN THIS STUDY?

You will not have any costs for being in this research study.

## WILL I BE PAID FOR PARTICIPATING?

We are not allowed to pay you to engage in VA care that you are entitled to and seek as a result of participating with this study. However, you will receive **$50.00 for the return of a consent form and the enclosed HIPAA form that indicates you will participate in the study in either research group** that you are assigned to. **You will receive an additional $75.00 if you are assigned to the intervention group and complete all the study steps, including attending an appointment with your VA provider**. This appointment must be completed by March 1, 2023 (in person or by telehealth) so we encourage you to make an appointment as soon as possible, if you do not have one already. Lastly, you will receive an additional $**40.00 upon completion of the study interview if**

**you are invited and chose to participate.** These payments are to reimburse your time and effort to help us improve care for Veterans.

We will need your social security number as well as your bank information in order to pay you. If you do not want your social security number to be used in this way, please call the study coordinator and let her know (contact information is listed below). However, without using your social security number and bank information, we will not be able to pay you. You may still participate in the study if you decline payment. You can provide this information in a form that you can return with your consent documents, or you can call our toll-free number to personally communicate this information to a member of our study team.

You will receive an electronic deposit within 4-6 weeks after you have completed the interview to reimburse your participation time and effort.

## WHO IS FUNDING THIS STUDY?

The Department of Veterans Affairs (VA) is funding this research study. This means that the Iowa City VAHCS is receiving payments from the VA to support the activities that are required to conduct the study. No one on the research team will receive a direct payment or increase in salary from the VA for conducting this study.

## WHAT ABOUT CONFIDENTIALITY?

We will keep your participation in this research study confidential to the extent permitted by law. However, it is possible that other people such as those indicated below may become aware of your participation in this study and may inspect and copy records pertaining to this research. Some of these records could contain information that personally identifies you.

- federal government regulatory agencies,
- Iowa City VA Health Care System
- auditing departments of the University of Iowa, and
- the University of Iowa Institutional Review Board (a committee that reviews and approves research studies)
- the VA, the sponsor of the study.

Your study data is further secured using network permissions assigned under the direction of the Principal Investigator, Dr. Sadler. This ensures that only study personnel with the approval of Dr. Sadler (in accordance with our Institutional Review Board requirements) have access to identifiable information. Database security will be maintained by following a confidential system of user identifiers, passwords, and numerous other established standard security measures.

Information linking your study number with your personal information and answers will be kept in locked files and databases accessible only to study researchers within the VA. Any paper documents containing confidential information will be kept in the secured office space in a locked research facility and in locked filing cabinets. All study personnel will complete CITI Human Subjects Training and VA confidentiality certifications before starting work.

## IS BEING IN THIS STUDY VOLUNTARY?

Taking part in this research study is completely voluntary. You may choose not to take part at all. If you decide to be in this study, you may stop participating at any time. If you decide not to be in this study, or if you stop participating at any time, you won't be penalized or lose any benefits for which you otherwise qualify.

## WHAT IF I DECIDE TO DROP OUT OF THE STUDY?

If you decide to leave this study early, there will be no consequences to you for early withdrawal.

## WHAT IF I HAVE QUESTIONS?

We encourage you to ask questions. If you have any questions about the research study itself, please contact: Dr. Anne Sadler at 1-866-482-8387 (Iowa City VA Health Care System). If you experience a research related injury, please contact: Dr. Anne Sadler at 1-866-482-8387.

If you have questions, concerns, or complaints about your rights as a research subject or about research related injury, please contact the Human Subjects Office, 105 Hardin Library for the Health Sciences, 600 Newton Road,

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University of Iowa, Iowa City, IA 52242-1098, (319) 335-6564. A copy of the VA brochure "Volunteering in Research" is available here: http://www.research.va.gov/programs/pride/veterans/Volunteering-in-Research.pdf. General information about being a research subject can be found by clicking "Info for Public" on the Human Subjects Office web site, http://research.uiowa.edu/hso. To offer input about your experiences as a research subject or to speak to someone other than the research staff, call the Human Subjects Office at the number above.

## RESEARCH SUBJECT'S RIGHTS

I have read or have had read to me all of the above. Anne Sadler, Ph.D., R.N. has explained the study to me and answered all of my questions. I have been told of the risks or discomforts and possible benefits of the study. I have been told of other choices of treatment available to me.

**I have been told 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 VA Health Care System is available to provide necessary medical treatment for any injury resulting from participation in this research study. I have been told that I will not be required to pay for care received as a subject in this study except in accordance with federal law (Title 38 United States Code 1710(f) and 1710(g)) and that certain Veterans are required to pay co-payments for medical care and services provided by the VA. This Informed Consent Document is not a contract. It is a written explanation of what will happen during the study if you decide to participate. You are not waiving any legal rights by signing this Informed Consent Document. Your signature indicates that this research study has been explained to you, that your questions have been answered, and that you agree to take part in this study. You will receive a copy of this form.

Subject's Signature _____ Date _____

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**Check the method by which consent is being obtained:**

□ Consent is being obtained by mail without a discussion between a research team member and the subject. (Research team member does not sign this document)

□ Consent is being obtained in person or by mail after a discussion between a research team member and the subject. (Research team member signs below.)



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