# STATEMENT OF INFORMED CONSENT

**TITLE OF STUDY:** A technology solution for peer-led Seeking Safety

**PRINCIPAL INVESTIGATOR:** Lisa M. Najavits, Ph.D. (24-hour contact: 617-299-1620)

**SPONSOR:** National Institutes on Health

# Introduction

You are being asked to participate in a research study titled, *A technology solution for peer-led Seeking Safety*, being conducted by Lisa M. Najavits, Ph.D. It is important that you read the following explanation of the proposed procedures. This form describes the purpose, procedures, benefits, risks, discomforts, and precautions of the study. It also describes the alternative procedures that are available to you and your right to withdraw from the study at any time. A member of the study staff will be available to you, if you choose, to read through the consent with you and discuss all the information, which can be done in person, via phone, or email depending on your preference. When you think you understand the study, you will be asked if you agree to take part and if you agree to take part, you will be asked to sign this consent form either electronically (e.g., via the internet, email, or text) or in hard copy. Once you sign it, we will provide you with a copy to keep, which will also be provided either electronically or in hard copy. You may also show this consent form to your family or trusted friends or your clinician or doctor before you sign it. You may want to discuss it with them to help you decide if you want to be part of the study.

# Purpose

The goal of this study is to obtain feedback about a new mobile app for adults age 18- 65 who have a substance abuse problem and trauma symptoms. The app is designed for tablets or smart phones to provide support using the peer-led *Seeking Safety* model, which focuses on teaching new coping skills to promote recovery. This study is funded by the National Institutes on Health. The entire study will last about one year. There are two phases to the study, and you can participate in one or both. The checkmark below indicates the part that you could participate in, if you are eligible and if you choose to. Both phases of the study have the goal of obtaining feedback so that we can develop the best possible mobile app.

We are recruiting up to 100 adults. You are eligible for this study if you: (1) are age 18-65; (2) have an alcohol or drug problem; (3) have trauma symptoms; and (4) are willing to complete the tasks described in the section below that has a checkmark next to it. Note that for phase 2 only, you would also need to (a) be willing to attend online peer-led Seeking Safety (“PSS”) sessions (in which you can choose not to reveal your identity, such as name, location, etc.); (b) have access to an Android smartphone or tablet so as to use the app; and (c) be currently under the care of a professional (e.g., therapist, psychiatrist) who is willing to provide confirmation (written or verbal) that it is safe for you to participate in PSS in this project.

 *Study phase 1:* Focus group. We will hold focus groups with up to six adults per group to identify app features they like best.

 *Study phase 2:* Using the app. In this phase of the study, you will have access to the app and can use it for 6 weeks. The app will include 6 free PSS sessions plus other content related to PSS. To be eligible for this study phase you need to have an Android phone so that you can try out the app. Our goal is to learn how helpful the app is.

# Procedures

 All procedures described below are for research only; they are not for clinical care (treatment).

 *Study phase 1:* Focus group. A member of our study team will conduct the focus groups online and will ask a series of questions to generate discussion. The focus groups will be audio-only (you will not be visible), and will be audio-recorded so that our team can listen to it later to identify important points discussed in the focus groups. The group would last up to 1.5 hours and you would participate in one group. You would also be asked to fill out an online measure to provide basic information about yourself (such as age, gender, how much you use a smartphone, etc.) During the online focus group you can choose not to reveal your identity by not revealing your full name, location, and other identifying details.

 *Study phase 2:* Using the app. If you participate in this phase of the study, you will given a unique login and password so that you can download the app onto your smartphone or tablet. You will be given access to the app for 6 weeks, which will include 6 free online (app-based) one-hour PSS group sessions led by a qualified peer, with up to 9 adults in the group. The app will also provide other features and content related to PSS that you can use. You will be sent a daily automated text reminder to look at the app. You will be asked to complete an online assessment prior to getting the app and after the 6 weeks of using it to see how much you like the materials to answer questions about the app, and to provide some basic information about you (such as age, gender, how much you use apps, etc.). This assessment will take about 20 minutes and will include the same measures you completed at the start of the study as well as some measures of satisfaction with the app. After the six weeks of using the app you will also be invited to participate in an individual feedback session by phone or online with one of our team to discuss what you liked and didn’t like about the app; that feedback session would take up to 1.5 hours and will be audio-recorded. Also your use of the app will also be automatically part of our database. This means that we will be able to identify how often you used the app and what parts of it you used. To be eligible for this phase of the study you need to have an Android smartphone or tablet so that you can use the app. You will also need to sign a Release of Information so that our study team can communicate with a treatment provider that you designate, in case of emergency or clinical concerns during your participation in this phase, and for this professional to verify (verbally or in writing), prior to you starting phase 2 of this project, that it’s safe for you to participate in PSS.

# Voluntary nature of this study

Your participation in this study is voluntary. Your refusal to participate or your withdrawal from the study will involve no penalty or loss of benefits to which you are entitled. Throughout the study, you can refuse to answer any questions that make you feel uncomfortable or you choose not to answer. You may stop your participation at any time without affecting your ongoing medical care in any way.

# Discomforts or inconveniences of the study

Foreseeable inconveniences/discomfort includes answering questions that may feel sensitive to some people.

# Risks of the study

Participation in this study may involve some added risks or discomforts. These include:

1. It may be uncomfortable to provide your feedback and opinions to a member of our study team whom you have not met before. However, you can skip any questions that make you uncomfortable.
2. It may be uncomfortable to participate in PSS online sessions with a peer leader and group members that you don’t know. However, all sessions are voluntary, and you can choose not to reveal your identity (as long as you don’t reveal your full name or other identifying details), and you can say as little as you choose to. Also, PSS is designed to help you with coping skills to aid your recovery.
3. Loss of confidentiality is possible. A number of steps will be taken to minimize risk related to loss of confidentiality. To minimize that risk, we will use only a confidential participant identification number to identify you, keep all study files locked, retain strict control over all of the information that we collect from all participants, including the audio recordings, the surveys you complete, and information from the phone app such as how much you used it. We will make sure that only study staff has access to information about you. To prevent disclosure of information that is not related to the study, we will only verify with one of your treatment professionals that you designate that you are eligible for this study.
4. If you report any major distress or upset while participating in any aspect of this study, this will trigger us to contact your treatment professional with this information so that s/he can help provide clinical assistance to you. However, it is unlikely that the app or related study tasks would be distressing or upsetting.

In addition to the risks listed above, you may experience a previously unknown risk or side effect, but we consider this unlikely as this project is designed to create a calming phone app. Also, the assessments we will conduct are widely used and rarely if ever have negative impact.

# Expected benefits of the study

You may or may not benefit from participation in this study.

# Confidentiality

If you agree to join this study, the study team will ask you for some personal health information needed for the study. Personal health information is any information that could be used to identify you and, for participants in this study, also includes your name, address, date of birth, and information on substance abuse and mental health symptoms.

The survey information and app usage information that is collected for the study will be kept on a password-protected computer indefinitely. All audio recordings will be digital and will be coded using only your study identification number (no names or other identifying information); and will be stored on the study’s password-protected computer at Treatment Innovations. These digital recordings will not be destroyed; they will be kept indefinitely.

All surveys and data will be handled by the study team. For all participants, your name will not be publicly disclosed at any time and you will not be identifiable in any publications or presentation that may arise from this research.

If you decide to leave the study, the information about you that was collected before you left the study will still be used. No new information will be collected without your permission. None of your research records and the information you provide in any way will be used for any purpose other than that which is described in this consent form.

While all efforts will be made to protect your privacy, you should understand that there are ethical and legal limits to confidentiality, and that there are some circumstances under which information that may identify you may be released. In particular, this may occur if you indicate, or the research staff has reason to believe, that you express a clear and credible threat or intention to do serious harm to yourself or to some other identifiable person. Under federal law and our professional ethics codes, the research staff would have an obligation to take all reasonable steps to protect both you and the intended victim. This usually involves notifying the other person but may involve notifying the police or others who could intervene to prevent harm from being done. In all cases, only the minimal necessary information would be released. A similar situation would exist if, during the research, you indicate that a child or elder in your care is being abused and/or neglected. There is a mandatory reporting law whereby the research staff would be required by state law to report admitted or suspected child or elder abuse and/or neglect to the Department of Social Services. Finally, if a court of law chose to subpoena (request) the records from this study, we would be required to release them; however, this is an extremely unlikely event.

The study team places a high value on the privacy of its research participants and the confidentiality of the data collected in all of its research projects. In order to strictly protect your confidentiality, all of your records will be kept in a locked file, under a code number rather than your name; the records will be strictly maintained according to current legal requirements. All electronic information, including audio- and video-recordings, will be kept in a database using a code number rather than your name. Nothing shared will be traceable to participants as individuals. Only authorized personnel will have access to your electronic and other records; such authorized personnel will include the New England Independent Review Board, which provides oversight on the ethics of research for this project.

# Costs

There are no costs for participating in this study.

# Payment

If you participate in study phase 1 you will be paid $25. If you participate in study phase 2, you will be paid up to $45 ($10 if you complete the first assessment, $10 if you complete the second assessment 6 weeks later, and $25 if you complete the feedback interview after the second assessment). For phase 2 you will receive all payments only at the end of your participation. All payments will be either by check or an electronic gift card (such as from amazon.com) sent to your email. You can choose which method of payment you prefer. Thus, the total you can receive in this study is $25 if you participate in phase 1 only or $70 if you participate in both phases 1 and 2.

# Research-Related Injury

As mentioned above, the assessments we will conduct are widely used and rarely if ever have negative impact. Also, the app is designed to be supportive and helpful. Nevertheless, every effort will be made to prevent any adverse reactions from occurring in the study. If you should experience any adverse reactions or injuries directly resulting from this research, we will do everything we can to manage the situation, in a timely manner, with the best possible care. If, during your assessment or an online PSS session, you have an adverse reaction (for example, becoming so upset that you are not safe), a trained clinician from our study team will intervene to protect your safety. This may include: communicating with the treatment professional you have listed for us to contact at the start of this study, arranging transport to a local emergency room for evaluation, and/or talking with you to help you decide on the best plan of action. Please be aware, however, that there are no plans to provide medical care or financial compensation for any research-related or non-research-related medical injuries or adverse reactions.

In summary, if you become ill, injured or harmed during or as a result of taking part in this study, you will be referred to care. However, you will be responsible for the cost of this care. Signing this consent form does not waive your legal rights nor does it relieve the investigators, sponsors or involved institutions from their legal and professional responsibilities. You do not give up any of your legal rights by signing this consent form.

# Alternatives to participating in this study

As this is not a treatment study, your alternative is to not participate. This study is designed to obtain your opinions and feedback about a new phone app. If you choose not to participate in this study, you would simply not be providing your opinions and feedback. Your choice of whether or not to participate in this study will not alter any of the treatment you are receiving.

**New Findings**

You will be told of any significant new findings that come to light during the course of this study and that may relate to your wanting to stay in the study.

# Right to refuse or withdraw

You can ask any questions during the survey or interview at any time, and can refuse to answer any questions that make you feel uncomfortable. Your participation in this study is voluntary and you may decide to withdraw your consent and discontinue participation in this project at any time. However, once you provide any study data or taped interviews, you will not have the option to withdraw these.

# Possible removal from the study

Your participation in this study can be ended by the study team for any of the following reasons (even if you want to remain in the study):

* 1. If you are unable to keep your scheduled appointment(s) to participate;.
	2. If the investigator decides that you should no longer be in the study;
	3. If you appear to be intoxicated at your scheduled appointments or in PSS online sessions;
	4. If you represent a clear threat to study staff or others;
	5. If the study is cancelled by the sponsor or the New England Institutional Review Board.
	6. If new information shows that the study is no longer in your best interest;
	7. If you do not complete the required study assessments;
	8. If we are unable to reach you.

# Conflict of interest

Dr. Najavits, the study investigator for this research, is developing the app for this project which, if successful, may be sold in the future to individuals and/or treatment programs. She is also the developer of the Seeking Safety model, for which she received royalties for the Seeking Safety book. She could thus potentially benefit financially from this project if it is successful. She is director and owner of Treatment Innovations, a limited liability company that received the grant from the National Institutes of Health, this study’s sponsor.

# Whom to contact in case of emergency

If you experience an adverse reaction or a research-related injury during the course of the study, you should immediately contact the study Principal Investigator, Dr. Lisa Najavits at 617-299-1620 (office and cell number) at any time, including after hours. You can also call the study team at 617- 299-1670 or 617-299-1640. You can also seek immediate care from a resource that is available 24/7 such as an emergency room, doctor on call, or other service. You can also seek care from clinical staff at the SSTAR, your doctor or any other health professionals you choose throughout the course of the study.

# Whom to contact if you have questions about the study

Should you have any questions about the research in general, you may contact Dr. Najavits at 617-299-1620 (office and cell number) or the study team at 617-299-1610 or 617-299-1640 or 617-299-1670, or email the study team at <info@seekingsafety.org>. If you have questions about your rights as a research subject, or other concerns about the research, you can contact the New England IRB at 1-800-232-9570.

# VOLUNTEER'S STATEMENT

I have been given a chance to ask questions about this research study. These questions have been answered to my satisfaction. I may contact Dr. Najavits if I have any more questions about taking part in this study. Dr. Najavits and the company she is employed by are being paid by the sponsor for my participation in this study.

I understand that my participation in this research project is voluntary. I know that I may quit the study at any time without harming my future medical care and/or my employment or losing any benefits to which I might be entitled. I also understand that the investigator in charge of this study may decide at any time that I should no longer participate in this study.

If I have any questions, complaints or concerns about this study or questions about research subjects’ rights, I can contact:

 New England Independent Review Board

 Telephone: 1-800-232-9570

 INFO@NEIRB.com

By signing this form, I have not waived any of my legal rights.

I have read and understand the above information. I agree to participate in this study. I understand that I will be given a copy of this signed and dated form for my own records.

Study Participant (signature) Date

Print Participant’s Name

Person who explained this study (signature) Date

# At some future point after the study, we may want to contact you to see if you might be interested in a later follow-up study. Please initial here if you are willing for us to contact you after your involvement in the study .