STATEMENT OF INFORMED CONSENT

TITLE OF STUDY: A technology solution for peer-led Seeking Safety, phase 2

PRINCIPAL INVESTIGATOR: Lisa M. Najavits, PhD (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, phase 2,* being conducted by Lisa M. Najavits, PhD. 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 is available for you to ask questions and/or read through the consent with you and discuss all the information; you can contact our study team via email or phone (see the section at the end of this document titled, *"Whom to contact if you have questions about the study*" for our contact information). When you think you understand the study, you will then be asked if you agree to take part. If you agree, you will be asked to sign this consent form electronically by typing your name. Once you sign it, you can download a copy electronically by printing it from your computer screen or by contacting us for a copy that we can email to you. You may 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 ages 18- 65 who have a substance abuse problem and trauma symptoms. The app is designed for mobile phones to provide support while participating in the Peer-Led *Seeking Safety* (PLSS) model, which focuses on teaching new coping skills to promote recovery. We are recruiting up to 350 adults. This study is funded by the National Institutes on Health and will last about two years. But if you are eligible and decide to participate, your involvement in this study would be much shorter. There are two parts 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.

You may be eligible for this study if you: (1) are age 18-65; (2) have a substance abuse problem (alcohol and/or drugs) and/or are in a substance abuse program; (3) have trauma problems; (4) have access to a mobile phone to use our app during the study; and (4) are willing to complete the tasks described in the sections below that have a checkmark next to them. Note that for Study Part B only, you would also need to be willing to attend telephone peer-led Seeking Safety ("PSS") sessions (in which you can choose not to reveal your identity, such as name, location, etc.)

Procedures

___*Study part A:* Initial feedback interviews. A member of our study team will conduct an individual interview with you either by phone or online and will ask a series of questions to obtain your feedback about possible features of the new app. If conducted online, we will use a platform such as Zoom.com or Uberconference.com that allows you to see our screen so that we can show you images and other material related to the app development. The feedback interview will be audio-recorded so that our team can listen to it later to identify important points that came up. The interview would last about an hour. You would also be asked to fill out a measure to provide basic information about yourself (such as age, gender, how much you use a smartphone, etc.) The measure would be filled out online.

___*Study part B:* Using the app and telephone Peer-Led Seeking Safety (PLSS) sessions. In this phase of the study, you will have access to the app and can use it for 12 weeks. The app will offer content and support related to PLSS. During this time there will be 12 free weekly one-hour telephone group PLSS sessions led by a qualified peer, with up to 9 adults in the group.

To be eligible for this study phase you need to have a mobile phone so that you can use out the app. Our goals

is to learn how helpful the PLSS sessions and the app are.

(1) First, you would first go through an assessment that will include various measures that ask about your substance use and related problems, and other areas relevant to this project. Some of the measures will be based on interview (which may be done by phone or in person), and other measures will be ones where you can write in your answers, which will all be done online. The entire assessment is estimated to take about 1 hour.

(2) Second, if you are found to be eligible for this project based on the assessment in the paragraph above, you will be assigned by chance (randomly) to one of the following two study conditions and you will have a 50% chance of being assigned to each group: (i) the *enhanced PLSS app condition* (you would be given an enhanced phone app, which is designed to provide a very appealing, interesting way to support the PLSS sessions); or (2) the *basic app condition* (you would be given a basic phone app that provides PLSS information). Whichever study condition you are assigned to, you will receive a unique login and password so that you can download the app onto your smartphone. All participants will be given access to their app (enhanced or basic) for 6 months and only 6 months (the initial12 weeks while the PLSS sessions are occurring and for 3 months after that as well). You will also be sent automated text reminders to use the app at random times as well as times that you identify.

(3) After your 12 weeks access to the app and PLSS phone sessions you will be asked to complete an assessment that is like the one you did in the section "1" above except that it is estimated to take about a half hour. You will also be asked how much you liked the app and to answer questions about it. 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.

(4) Finally, 3 months later (timed from the 12-week asessment listed in #3 above), you would be asked to complete an assessment that is like the one you did at 12 weeks (estimated to take about a half hour).

___*Study part C:* Final feedback interviews. This will be conducted exactly the same as described in Study Part A above.

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. You can also attend any treatments, self-help or other supports that you choose to during this study.

Discomforts or inconveniences of the study
Foreseeable inconveniences/discomfort include 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 can be uncomfortable to provide your feedback and opinions to a member of our study team whom you have not met before. Also some of the questions in our assessments will ask about personal and/or sensitive information about you such as emotional problems you may be experiencing. However you can skip any questions that make you uncomfortable.
2. It may be uncomfortable to participate in PLSS 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). Also, PLSS 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 and unique initials to identify you; and will 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 our study team has access to information about you.

4. Although unlikely, if you report any major distress or upset while participating in any aspect of this study, this will trigger us to contact your clinician and/or program with this information (if you have a clinician and/or program and you have given us written permission to contact them) so that they can help provide clinical assistance to you. You can and should also contact emergency medical services at any point if you feel unsafe or extremely distressed, such as by calling 911 or going to a local emergency room.

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 positive phone app experience. 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. The phone apps that we are developing are designed to help you learn to cope better, but you may or may not experience benefit from them.

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 clients in this study, also includes your name, address, date of birth, and information on your mental health diagnoses.

The survey information and app usage information that is collected for the study will be kept on a password-protected computer indefinitely. Also you are encouraged to put a password on your phone. 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.

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 and unique initials rather than your name; the records will be strictly maintained according to current legal requirements. All electronic information, including audio 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.

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.

Costs
There are no costs for participating in this study.

Payment
If you participate in the feedback interview (study parts A and/or C), you will be paid $25 for each. If you participate in the app usage research (study part B), you will be paid $30 for each of the three assessments (baseline, 12 weeks, and 3 month followup). All payments will be electronic gift card for amazon.com sent to your smartphone or email. Payments will be sent immediately after your participation for the feedback interview (study parts A and/or C), and at the end of your participation (3 month followup) for the app usage research (study part B).

The total you can receive in this study is $140 ($25 each for parts A and C; and $90 for part B).

Research-Related Injury
As mentioned above, the assessments we will conduct are widely used and rarely if ever have negative impact. Also, the phone apps in this study are designed to create a positive experience. Nevertheless, every effort will be made to prevent any adverse reactions from occurring in the study. If you 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 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: arranging transport to a local emergency room for evaluation, contacting your individual counselor or psychopharmacologist, 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. If you choose not to participate in this study, you would simply not be providing your opinions and feedback and would not use the phone app or PLSS telephone sessions provided by this study. Your choice of whether or not to participate in this study will not alter any treatment you are receiving elsewhere. You can learn about coping skills using other methods than we provide in this study, for example, by searching the Web for the term "coping skills" or by searching for mobile apps with that term.

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 to participate.
2. If the investigator decides that you should no longer be in the study.
3. If you are intoxicated at the time of your scheduled appointments.
4. If you represent a clear threat to study staff or others.
5. If the study is cancelled by the sponsor or the Solutions 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 you are unable to download the study app.
9. If we are unable to reach you.

Conflict of interest

Dr. Najavits, the study investigator for this research, is developing the phone apps for this project, which if successful may be sold in the future to individuals and/or treatment programs. 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 617-299-1610, 617-299-1630, 617-299-1640, 617-299-1670 or 617-299-1690. 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 fromyour 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, concerns or complaints about the research in general, you may contact Dr. Najavits at 617-299-1620 (office and cell number) or a member of the study team at 617-299-1610, 617-299-1630, 617-299-1640, 617-299-1670 or 617-299-1690, or email the study team at info@treatment-innovations.org. If you have questions about your rights as a research subject, or other questions, concerns or complaints about the research, you can contact the Solutions IRB at participants@solutionosirb.com (email) or 855-226-4472 (phone).

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 about my rights as a research subject in this study I may contact:

Solutions Institutional Review Board
Telephone: 855-226-4472
Email: participants@solutionosirb.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 able to download this form for my own records or can request it at any time by emailing info@treatment-innovations.org or calling or texting 6170299-1610.

_____ _____

Study Participant (typed name on electronic system) Date

_____

Print Participant's Name

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 ____.