RESEARCH INFORMED CONSENT FORM

STUDY TITLE: Optimizing Psychological Health and Preventing Clinical Problems: Testing the Effectiveness of an Evidence-Based Toolkit for Integrated Operational Support (IOS) (IRB-FY2023-7921)

INVESTIGATOR(S): Amy M. Smith Slep, Ph.D. and Richard E. Heyman, Ph.D.

FUNDING SPONSOR: This project is funded by a grant from the Department of Defense Health Program, Peer Reviewed Medical Research Program Lifestyle and Behavioral Health Interventions Research Award to New York University, in support of the investigators' work on this study.

INVITATION TO BE A PART OF A RESEARCH STUDY

You are invited to participate in a research study. This form has information to help you decide whether or not you wish to participate—please review it carefully. Your participation is voluntary. Please ask any questions you have about the study or about this form before deciding to participate.

PURPOSE OF THE STUDY

The purpose of this project is to test how training in and delivery of EB *Toolkit* intervention resources affects SMs psychological and behavioral health.

DESCRIPTION OF STUDY PROCEDURES

If you agree to participate in this research, you will be asked to do the following things:

- Read and sign this consent form
- Attend a video-conferencing orientation meeting where the research team and a DAF MH advisory council will explain the project and answer your questions.
- Complete weekly electronic count tracking of the number of SMs you've had sessions with the number of sessions you've used an EBI Toolkit resource for, and the number of EBI tools completed in their entirety. This tracker will include 2 questions to respond to each time you choose to initiate an EBI with a new client.
- Participate in a structured *Toolkit* intervention deliberate-practice-based training program for 10 weeks for improved evidence-based intervention competence and delivery.
    1. You will attend an initial seminar providing you with specific information about this training, research evidence, and tenets of deliberate practice, and have a coach (a clinical psychologist or licensed MSW with expertise in the EBI toolkit) assigned to you.
    2. For a ten-week period, you will meet weekly with this coach to review session notes, engage in practice exercises, and work toward mastering important skills and competencies across each of the component tools.
    3. You will have up to 3 sessions with Toolkit sessions a patient actor recorded and rated by your supervisor to provide you with detailed structured feedback and guide continued progress.
    4. You will also be assigned weekly homework to practice tools by going through the motions of each tool you are using that week as though you were the SM client. You will bring your reflections on these self-administered

sessions and any other homework to your weekly meetings with your toolkit coach.

5. During these meetings, you will identify strengths and points for improvement, role-play specific skills, and come up with a weekly targeted learning plan.

RISKS OR DISCOMFORTS

This study involves the following risks or discomforts:

Participants will incur no more than minimal risk as all DAF-embedded BH technicians will have the opportunity for deeper training as part of this project, no sensitive (only procedural) information is being collected, and all study procedures are consistent with the role and duties of their position. There is some risk of discomfort in receiving evaluative feedback from Toolkit coaches. However, this is consistent with the role of a BH technician and standard best practice across all types of MH providers.

Please tell the researchers if you believe you are harmed from your participation in the study.

BENEFITS

It is hoped that this study will contribute to knowledge about how to assist DAF in determining best practice strategies for increasing the dissemination of BH-training structures in interventions. By participating in the study, you are assisting the Investigators and DAF-embedded IOS leadership to determine whether the training in *Toolkit* affects service member outcomes in indicators of behavioral health (sleep, stress management, mood, and psychological well-being).

There are no direct benefits to you for participating in this project. However, it is possible that participation in the training intervention may help you develop your skillset and competence in the delivery of EBI resources to SMs.

VOLUNTARY PARTICIPATION

Participating in this study is completely voluntary. You may choose not to take part in the study or to stop participating at any time, for any reason, without penalty or negative consequences.

- You have the right to change your mind and leave the study at any time without giving any reason and without penalty.
- Any new information that may make you change your mind about being in this study will be given to you.
- You can keep a copy of this consent form to refer back to at any point during the duration of the project.
- You do not lose any of your legal rights by participating in this study.
- Participation in this study has no bearing on your military standing.

PRIVACY & DATA CONFIDENTIALITY

In this study, you may be asked to provide information that could be used to identify you personally. This information will be kept confidential. Only researchers and others that will keep the information confidential (e.g., regulatory agencies or oversight groups) may access information that could personally identify you. We want to ensure that your data is truly confidential. To help you understand how we are going to do this, we are taking the following steps:

1. All electronic consent documents will be stored on REDCap. Only IRB-certified members of the research team have access. We will ensure data confidentiality by using ID numbers. Identifying information will only be collected for consent and recontact

purposes and will be maintained separately from data using the procedures outlined above.

2. Your weekly tracking data will be input directly into REDCap identified only by a participant number you will be assigned. Only a preferred means of contact (e.g., cell phone number for texting automated reminders with links to input weekly tracking data).
3. The mock session data recorded to capture your strengths, areas for improvement, fidelity, and criterion competence across specific Toolkit interventions will be saved in a password-protected folder accessible only by the study team in NYU's HIPAA-compliant version of Dropbox for Business.
4. The single REDCap file linking your name to your participant number will be deleted after the completion of the study.

Future Use of Data

Information about you collected for this study may be shared with other researchers, used for other research studies, or placed in a data repository. These studies may be similar to this study or completely different. We will not ask you for additional permission before sharing the information.

ACCESS TO YOUR STUDY INFORMATION

We will not give you access to the information that is collected about you in this study.

CONTACT INFORMATION

You are encouraged to ask questions at any time during this study. For information about the study, contact Drs. Slep or Heyman at (212) 998-9815. Representatives of the DOD are authorized to review research records. If you have questions about your rights as a research participant or if you believe you have been harmed from the research, please contact the NYU Human Research Protection Program at (212)998-4808 or ask.humansubjects@nyu.edu.

AGREEMENT TO PARTICIPATE

By signing this document, you are agreeing to participate in this study. Make sure you understand what the study involves before you sign. If you have any questions about the study after you agree to participate, you can contact the research team using the information provided above. You may keep a copy of this form.

Name of Participant (print) _____

_____ _____

Signature of Participant Date