**Example Data Security & Privacy Protocol Language**

**Qualtrics Language**

**Participant Population**

***Describe your screening procedures, including how qualifying laboratory values will be obtained. If***

***you are collecting personal health information prior to enrollment (e.g., telephone screening), please***

***request a waiver of authorization for recruitment*.**

Potential participants will be screened via the Qualtrics survey platform. No PHI will be collected prior to

enrollment.

**Risks**

***Describe the planned procedures for protecting against and minimizing all potential risks. Include the***

***means for monitoring to detect hazards to the participant. Include steps to minimize risks to the confidentiality of identifiable information.***

The research team has a successful track record of safely implementing eHealth interventions, and we have developed a number of strategies to protect against the known risks of participation.

***DISCOMFORT ASSOCIATED WITH SURVEY QUESTIONS***. To minimize the risk of any discomfort

associated with answering questions related to psychological distress, we have selected only

psychometrically validated questionnaires that have been used in a number of previous studies with

Veterans with no known adverse consequences. Additionally, participants will be informed that they may discontinue their participation at any time with no impact to the care they receive at the VA. All participants will be informed that their participation is completely voluntary, confidential, and not accessible to anyone outside the research team. The data will only be used in aggregate and will be de-identified as soon as all participants have completed the study, making it impossible to link any identifying information (e.g., email address) with responses to the survey.

***PRIVACY-RELATED RISKS****.* In order to mitigate privacy risks that are inherent to using mobile phones or

websites, we will be implementing several strategies. First, prior to joining the study, potential participants will be directed to a study website (hosted on University/Affiliate's Qualtrics server) that will be protected using SSL certification to ensure the encryption of all information shared between the study website and potential participants. Accordingly, all responses related to the screening questions, consent process, and survey instruments will be encrypted prior to being uploaded to the study server. The following personal identifiers are necessary for the study: name, email address, phone number, and mailing address. Email addresses will be used only for the purpose of sending reminders to complete study surveys. Name and mailing address will be used to confirm identity (and minimize registration by potentially fraudulent users). Telephone numbers will be used to contact those who have not yet downloaded or used the app and to conduct the qualitative interview (with explicit permission from the participant), to confirm identity (and again minimize registration of fraudulent users), and in case of emergency. Participants will receive a unique invitation code that can be used to download and unlock the study app, and this unique code will be used to identify how users engage with the study app. App usage data will be fully de-identified. A linkage file that links the app usage data (using the unique invitation code) with personal identifiers (stored on the secure University/Affiliate’s Qualtrics survey) will be maintained on a research server maintained by Organization/Department, behind VA firewalls. The information that links PII with survey and app usage data will be stored only behind a VA firewall and will not be accessible outside of VA. Finally, all personal identifiers will be permanently removed from the dataset at the conclusion of the study, ensuring that the final dataset for analysis is fully de-identified.

***SAFETY-RELATED RISKS****.* The safety risks of this study are considered to be no greater than those of any mental health intervention trial, and there is no known evidence of technology-based self-management interventions for insomnia being associated with an increase in safety risks. All open-ended survey questions will be reviewed on an ongoing basis. The investigators will be reviewing survey responses on at least a weekly basis as new participants are enrolled. An attempt will be made to contact, by telephone, any participant who indicates distress that is severe enough to be potentially life-threatening.

**Privacy and Confidentiality**

**Privacy Protections**

***a) Describe how the conditions under which interactions will occur are adequate to protect the privacy interests of participants (e.g., privacy of physical setting for interviews or data collection, protections for follow-up interactions such as telephone, email and mail communications).***

All communications with participants will take place by telephone. Participants will be prompted using secure email prompts via the University Qualtrics platform to complete follow-up surveys. All participants will receive a phone number they can use to reach the study investigators for additional information about any aspect of the study, and telephone communications will take place discretely in offices assigned to the investigators at Organization/Department.

**Confidentiality Protections**

***b) Specify PHI (Protected Health Information). PHI is health information linked to HIPAA identifiers***

***(see above). List BOTH health information AND HIPAA identifiers. If you are using STARR, use the***

***Data Privacy Attestation to ensure that your request will match your IRB-approved protocol. Be***

***consistent with information entered in section 15a.***

The only identifiers that will be obtained will be name, phone number, email address, and mailing address, all of which will be obtained using the University Qualtrics secure platform. Email address will be used solely for prompting participants to complete follow-up surveys. Name and mailing address will be used to mail gift cards to participants at the completion of key study procedures, and the accompanying letter will be brief and will not contain any sensitive information.

***Describe how data or specimens will be labeled (e.g. name, medical record number, study number,***

***linked coding system) or de-identified. If you are de-identifying data or specimens, who will be***

***responsible for the de-identification?***

The primary key for all data sources will be a unique subject identifier. Data will be periodically downloaded from the secure Stanford Qualtrics platform and stored behind the VA firewall. Once

downloaded and stored on VA servers, all identifiers will be removed and stored in a separate "linkage" file that contains the unique subject identifier and all personal identifiers: email address, phone number, name, mailing address.

***e) Indicate who will have access to the data or specimens (e.g., research team, sponsors, consultants) and describe levels of access control (e.g., restricted access for certain persons or groups, access to linked data or specimens).***

Only research team members will have access to data.

***f) If data or specimens will be coded, describe the method in which they will be coded so that study***

***participants' identities cannot be readily ascertained from the code.***

Sequential numbers will be assigned that have no connection to the participant.

***If data or specimens will be coded, indicate who will maintain the key to the code and describe how it will be protected against unauthorized access.***

All participants will be assigned a code number. Information to connect participants with ID numbers will be kept in a locked cabinet in a locked office. At the end of the study, the key will be given to a custodian who will not share it with the study team (Federal government agencies cannot destroy any research records.)

**Consent Background**

**What steps are you taking to minimize the possibility of coercion and undue influence? vi) If consent relates to children and if you have a reason for only one parent signing, provide that**

**rationale for IRB consideration.**

Consent administered online as part of standard online survey methodology. Participants provided with

basic information about the study and eligibility criteria and are then offered the option to evaluate whether they are eligible to get started.

**b) What is the Procedure to assess understanding of the information contained in the consent? How will the information be provided to participants if they do not understand English or if they have a hearing impairment? See /hrpp/Chapter12.html#ch12\_2 HRPP Chapter12.2 for guidance.**

Participants will be self-reporting their preferences and no identifying information will be collected.

**c) What steps are you taking to determine that potential participants are competent to participate in the decision-making process? If your study may enroll adults who are unable to consent, describe (i) how you will assess the capacity to consent, (ii) what provisions will be taken if the participant regains the capacity to consent,(iii) who will be used as a legally authorized representative, and (iv) what**

**provisions will be made for the assent of the participant.**

Participants will be self-reporting their preferences and no identifying information will be collected.

***Additional VA questions:***

***i) List the people to whom you have formally delegated responsibility to obtain informed consent, and***

***state whether they have the appropriate training to perform this activity.***

All study personnel listed on the protocol who have completed current CITI training.

***If consent relates to children and if you have a reason for only one parent signing, provide that***

***rationale for IRB consideration.***

Participants will provide consent online using the University Qualtrics survey platform. Participants will be provided with information about the study and will have the option to contact a study representative by telephone and will have the luxury of reading/printing the consent form at the time and place of their choosing. All relevant information will be provided in the consent form and in more informal information pages viewed by participants on the study website prior to seeing the consent form. Potential participants will not be coerced in any way.

**21 CFR 56.109(c)(1). For research that is subject to FDA regulation, presents no more than minimal risk of harm to participants and involves no procedures for which written consent is normally required outside of the research context.**

**Rationale for above selection:**

This study presents only minimal risk to participants and could not reasonably be carried out without

completing the consent process via the study website. Personal information will only be collected on

a secure University Qualtrics website approved for this use and will be maintained separately from all

sensitive information obtained from use of the mobile apps.