

IRB 17-36 Mod8: Additional Items to Support Option 20 Research Project

Overview

Background: The purpose of IRB 17-36 is to evaluate the effectiveness of the Tailored Adaptive Personality Assessment System (TAPAS), and to help develop and evaluate measures for selecting new Soldiers into the Army and helping them choose the MOS in which they will be most successful. Participants complete an assessment battery that includes measures of Soldiers' attitudes, interests, performance, Army experiences, and job knowledge. The approved protocol also includes collection of peer and supervisor ratings and longitudinal administrative data.

Addition of Option 20 research questions: ARI has been asked to investigate the impacts of living and working in Alaska on effectiveness, quality of life, cohesion, leadership, recruiting and retention. ARI is also investigating potential differences between Soldiers who elect Alaska as their first duty station (i.e., Option 20) and Soldiers who are assigned to Alaska (i.e., Non-Option 20). Focus group data were collected from Soldiers in Alaska under HRPP 22-31. Based on information gathered in that project, questions were added to the IRB 17-36 protocol in Mod7 in order to compare the experiences of Soldiers in Alaska to the experiences of Soldiers stationed elsewhere. The overall purpose of IRB 17-36 has not changed, as these new questions will also contribute to the development and evaluation of measures for selection and assignment.

Investigators: The PI of the overall 17-36 project remains Dr. Cristina Kirkendall. The Option 20 portion of the research is led by IRB 17-36 co-investigator Dr. Krystal Roach.

Purpose of the current mod: The questions added in the current mod (IRB 17-36 Mod8) will be administered only to Soldiers in Alaska to gain a deeper understanding of the experiences that are specific to being stationed in Alaska and the differences between Option 20 and Non-Option 20 Soldiers. Notably, based on a tasking from the Vice Chief of Staff of the Army, the assessment battery for these participants will include items from the Columbia Suicide Severity Rating Scale (C-SSRS), which have been utilized in an epidemiological study.

Purpose of this document: The approved procedures for IRB 17-36 include the collection of personally identifiable information (PII) in order to combine data from various sources and track Soldiers over time. Researchers will thus have access to data that could potentially identify Soldiers at risk for suicide. The rest of this document explains how we will adapt the approved 17-36 procedures to deal with this sensitive situation. All procedures described in this document apply only to 17-36 data collected in Alaska, not to any other 17-36 data collections.

Expertise: Because ARI research psychologists are not trained clinicians, outside expertise was sought from both mental health experts and lawyers to ensure that this plan deals appropriately with any mental health, legal, and regulatory issues that could arise from the collection and handling of responses to questions about suicide. In addition to the clinical and legal guidance sought by the IRB as part of the review process, this plan was developed in consultation with CPT Michael Able, a behavioral health (BH) clinician in Alaska who is serving as the clinical POC for this project. CPT Able has also offered to connect us with BH officers under his oversight as needed (see details below).

Planned Procedures – Option 20

- 1. What will prospective subjects be told about circumstances in which confidentiality might be breached?**
 - See the introductory script at the end of this document and the Informed Consent Form (in a separate document).
- 2. When and how will the responses be reviewed?**
 - Responses will be reviewed by a member of the research team as soon as possible after every data collection (no later than the end of each calendar day on which data are collected). Data collections are approximately 1½ hours in duration and approximately three to four data collections occur daily.
- 3. Who will inform someone if the need arises?**
 - Dr. Roach will inform someone if the need arises (see Question 5 for details regarding what responses will trigger notification). If Dr. Roach is not available, a member of the project team or the SARU Unit Chief, Dr. Tonia Heffner, will inform someone.
- 4. Who will be informed, and what will you do if you are not able to reach that person in a timely manner?**
 - The Soldier’s Company Commander will be informed. The Company Commander will receive an initial email informing them of the study. They will be informed that they may be contacted if their Soldier expresses suicidal ideation and that they need to acknowledge that they received the email. (See email templates in Encl C.)
 - Company Commanders were selected for notification due to their position as the level of commander with the most contact with Soldiers. In addition, this plan is consistent with AR 600-92, Section 1-33.d, which states that Commanders of companies, detachments, and equivalent units are responsible for ensuring that Soldiers “are encouraged to seek assistance if they are experiencing challenges or have been identified with suicide-risk symptoms.”
 - Participants will be told in the Informed Consent Form that their Company Commander will be notified if any of their responses during the assessment indicate that they may be thinking about harming themselves or others.
 - To ensure that the correct commander is identified for each participant, the spreadsheet on which participants sign in at the start of each session will request that participants provide the name of their company and commander.
 - If we do not receive a response from the Company Commander within the requested time frame, we will contact CPT Able by phone or email and ask him to connect us with the BH specialist for the appropriate Battalion. Either CPT Able or a member of the research team will call the BH specialist and request that they reach out to the Company Commander. The BH specialist will not be given information about any particular research participant, but instead will simply be asked to ensure that the Company Commander is aware of the email from the research team and responds in a timely manner. If we do not receive a response after the BH specialist reaches out to

the Company Commander, a member of the Option 20 research team will go to the Commander's office.

5. What will you look for in the responses to know that a commander needs to be informed?

- CPT Able advised that the safest course of action is to inform the Company Commander if the Soldier responds "Yes" to either or both of the following questions:
 - Since arriving at this duty station, have you wished you were dead or wished you could go to sleep and not wake up?
 - Since arriving at this duty station, have you actually had any thoughts of killing yourself?

6. What guidance will be available for on-site researchers in terms of dealing with any issues that may arise on the spot?

- The on-site researchers will be provided with the following information:
 - CPT Able has offered to connect us with BH officers under his oversight.
 - In the event that ARI research psychologists encounter a participant in signs of distress, we will follow the following protocol: ARI will contact CPT Able, a member of CPT Able's team, or the brigade behavioral health (BH) officer identified by CPT Able. The person will be informed of the situation and the need for immediate intervention. The POC will be responsible for mobilizing the appropriate local resources to address the issue.
 - If a Soldier requires an escort, the POC will facilitate this.
 - After the situation is under control, the ARI researcher will notify Dr. Tonia Heffner (SARU Chief) of the situation if she did not witness the event. The post POC will also be informed if they did not witness the event.
- ARI will **not**:
 - Provide counseling to the Soldier (e.g., discussing symptoms). ARI personnel are not trained clinicians, so this is not appropriate intervention.
 - Try to convince the Soldier they know how they feel.
 - Try to analyze the Soldier's motives, criticize or argue with the Soldier, offer alternative perspectives or solution, or debate the morality of self-destruction.
 - Instead, ARI researchers will use the script below as a guide (to be adapted as needed to the particular situation and the responses of the Soldier in distress).

Script after Soldier Expresses to us about Suicidal Ideation

ARI Researcher: Thank you for sharing that with me. I am a research psychologist and not a trained clinician, so I would like to connect you with resources. If you wait right here, I can reach out to someone to come meet you here.

If Soldier Leaves or Expresses that they are not interested

Record Soldier's name and contact commander because the Soldier expressed suicidal ideation to us.

Introductory Script for Data Collection Sessions

Because all of the assessment materials are online, the approved protocol for IRB 17-36 does not include an introductory script or talking points. Participants report to a computer lab to learn about the project. They read the Informed Consent Form online, and if they choose to complete the assessment, they are provided with a link.

Due to the sensitive nature of the questions that will be added to the assessment for Soldiers in Alaska, a brief script will be added to these data collections:

- After providing Soldiers with the link, the Option 20 Team is able to inform participants:
 - “There are some items on this assessment that ask about your mental and physical health and whether you have had thoughts about suicide. If any of your responses indicate that you may be thinking about harming yourself or others, we are required to inform your company commander. Additional information will be provided in the Informed Consent Form that you will see online before deciding whether to complete the assessment. Paper copies of the consent form are available for you to take with you today, along with a page of mental health resources with phone numbers you can call if you want to speak with someone confidentially.”

As noted above in the script, a list of mental health resources (including Military OneSource and two suicide hotlines) will be available in hard copy for participants to take with them after the session.

Documentation and Communication with the IRB

The research team will document all instances in which a company commander is notified, including the name of the commander, the number of Soldiers about whom the commander was notified, the dates of all correspondence sent and received, and any follow-up actions that were taken (e.g., contacting a BH specialist in attempt to reach a company commander). All documentation will be provided to the ARI IRB upon request.

A member of the research team will notify the ARI IRB promptly if any of the following occurs:

- Subject complaint(s)
- Breach in confidentiality (other than the planned procedures for notifying company commanders in the event that a Soldier endorses suicidal ideation)
- Deviation(s) from the approved protocol
- Unanticipated problem(s) involving risks to subjects or others