

DEPARTMENT OF VETERANS AFFAIRS
VA San Diego Healthcare System
Mail Code 151
3350 La Jolla Village Dr.
San Diego, CA 92161
Human Research Protection Program
Institutional Review Board

Date: January 21, 2016

From: VA San Diego Healthcare System IRB

Re: H130026
Validation of the Peritraumatic Behavior Questionnaire–Observer Rated, an Instrument for
Embedded Medical Personnel to Assess In-Theater Risk for Combat PTSD in Marines
Submission Reference Number: 010313

To: Dewleen Baker

The above-referenced project was reviewed and approved on 01/21/2016 by the VA San Diego Healthcare System Institutional Review Board in accordance with the requirements of the Code of Federal Regulations on the Protection of Human Subjects (45 CFR 46 and 21 CFR 50 and 56), including its relevant Subparts.

This study was reviewed through the expedited review procedure as authorized by 45 CFR 46.110 and 21 CFR 56.110 and VHA Handbook 1200.05 falls under the following research category (categories):

Category 5: Research involving materials (data, documents, records, or specimens) that have been previously collected for any purpose, including previous research, or that have been or that will be collected solely for non-research purposes (such as for medical treatment or diagnosis).

The IRB determined that the research currently presents minimal risk to human subjects in that the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examination or tests.

Because continuing review occurs annually and the IRB performed continuing review within 30 days before the IRB approval period expires, the IRB retained the anniversary date as the date by which the continuing review must occur.

Date of IRB review and approval: 01/21/2016

Date of expiration of IRB approval: 02/20/2017

On behalf of the Institutional Review Board,



William Penny, MD
VASDHS IRB Chair
(858) 642-6320

cc R&D Committee

VASDHS Human Research Protections Program

General Approval Information

All continuing VASDHS research must also maintain approval by the VA Research and Development Committee.

The information below does not encompass all human subjects study requirements but is intended to highlight those of highest significance.

Consent Documents and HIPAA Authorizations

Approved and stamped Informed Consent Forms and stamped HIPAA Authorizations will be available in the OnRamp system when required. Whether through initial application or amendment, the appropriate versions are those stamped with the corresponding date of IRB approval documented in the approval letter from the IRB. Waivers will be documented in the approval letter where appropriate, such as waiver of documented consent or waiver of authorization for use of protected health information (PHI).

Duration of IRB approval

The IRB may grant approval for up to 365 days (see 38 CFR 16.109(d) and 21 CFR 56.109(d)). However, for some studies the committee may grant approval for a shorter period or a specific number of subjects to allow for more frequent monitoring. The approval letter or related documentation will indicate this information. When continuing review occurs annually and the IRB performs continuing review within 30 days before the IRB approval period expires, the IRB may retain the anniversary date as the date by which the continuing review must occur.

Continuing Review

Because IRB review of research studies must be completed at least annually, investigators should plan ahead to meet required continuing review dates. Please submit complete continuing review documentation at least 45 days prior to the expiration date to guard against a lapse in IRB approval. The continuing review application must be received before the continuing review process can begin. Continuing review is required even if no changes are made, the only study activity is participant follow-up, or the only study activity is data analysis.

Continuing Review Notifications

As a courtesy, automated continuing review reminders will be sent out prior to the expiration date. As these are automated messages, some software programs (such as spam blockers or anti-virus software) may block receipt of these messages. PIs must not rely upon notification but should have internal mechanisms which track continuing review submission timelines. It is the PI's responsibility to initiate a continuing review application, allowing sufficient time for the review and re-approval process to be completed before the current approval expires.

What happens if there is a lapse in IRB approval?

If the IRB has not reviewed and approved a research study by the study expiration date, all research activities must stop. This includes all research-related interventions or interactions with currently enrolled subjects, recruitment and informed consent procedures; and collection and/or analysis of data/information. An exception is that research-related interventions or interactions with enrolled subjects may continue if the IRB determines that stopping the research would jeopardize the rights or welfare of the current subjects. See VA Handbook 1200.05, Investigator Responsibilities, http://www1.va.gov/vhapublications/ViewPublication.asp?pub_ID=2531.

Amendment/revision of an IRB approved study

IRB approval is required before implementing any changes in the approved research plan, consent documents, recruitment materials, or other study-related documents, except when necessary to eliminate immediate hazard(s) to the subject(s). Changes made for safety reasons must be reported to the IRB within 5 working days.

Adverse Events and Unanticipated Problems Reporting

All local serious adverse events and all unexpected problems possibly related to the research must be reported to the IRB within 5 working days. All deaths, whether or not they are directly related to study procedures, must be reported. Local adverse events that are not serious or not related to the research may be reported in tabular form at annual review. An IRB Reports submission form must be submitted along with any supplemental information appropriate to the review.

Changes in Financial Interest or Conflict of Interest (COI) disclosure

Any changes in the financial relationship between the study sponsor and any of the investigators on the study and/or any new potential conflicts of interest must be reported immediately to the Independent Review Committee and submitted as an IRB Protocol Amendment form. If these changes affect the conduct of the study or result in a change in the required wording of the approved consent form, then these changes must be included in the an amendment request.

CPRS Research Note

A "Research/Informed Consent" progress note must be entered in CPRS for consented subjects if 1) the study is a clinical trial or treatment study, or 2) the study requires the use of clinical facilities [e.g., the clinical lab service] for research purposes, or 3) the study includes a significant risk of adverse events. The signed informed consent document, HIPAA authorization, and Consent for Use of Picture/Voice (if applicable) must also be scanned into CPRS.

Studies Involving Non-Veteran Subjects

Non-Veteran subjects may only be enrolled if specifically approved by the IRB. If non-veteran subjects consent to participate and a CPRS Research/Informed Consent progress note is required, the subjects must be given a copy of the VA's Notice of Privacy Practices and sign the Acknowledgement form. The Acknowledgement must be scanned into CPRS along with the Informed Consent Form and HIPAA Authorization. These forms may be found under the help (?) link of the OnRamp system.

MCM 11-24 Suicidality Assessment compliance

Per MCM 11-24, Protocol for Responding to Research Participants Requiring Clinical Assessment of Suicidality form should be completed for all protocols in category B or C. For protocols in these categories, if the form has not already been submitted it should be submitted as an amendment through the OnRAMP system.

Devices Requiring Inventory or Inspection

For devices that may be used with subjects, please contact Valarie Westberg and Clinical Engineering to verify if the devices require inventory and/or safety inspection prior to use with human subjects.

VA Research Appointments

Only those personnel who have currently approved appointments through VA Research Staffing Section and are current in all training requirements may participate in VASDHS research