APPENDIX D. POSTAPPROVAL DOCUMENTATION

INSTITUTIONAL REVIEW BOARD RECOMMENDATION

CONTINUING REVIEW

Date of Review: 15 October 2010 Protocol Number: NHRC.2007.0011

Protocol Title: Status of Transitioning Military Personnel

Principal Investigator: Laurel Hourani, PhD, RTI International
NHRC Co-Principal Investigator: Gerald Larson, PhD

Approximate Dates of the Research: 01 March 2007 to 30 September 2011

No. of Previous Reviews: 7

The NHRC co-principal investigator submitted this protocol for continuing review. This research is be performed by RTI International and will also be approved by their IRB. The goal of this proposal is to characterize the direct impact of combat exposure on mental health outcomes among Sailors and Marines in transition from active duty to civilian life and to examine the interrelationships between combat exposure, a variety of moderators, and subsequent psychological resilience, mental health symptoms, and substance abuse. A baseline survey has been administered to volunteers taking part in Transition Assistance Program (TAP) sessions for service members planning to leave the service. A subgroup of participants will be asked to participate in a follow up via US mail or web-based survey approximately six months after separation. Survey data will be combined with existing data from personnel and medical databases. Data collection for the initial phase of the survey has concluded. A total of 3,755 personnel completed the initial baseline survey, of which 1,191 participants completed the follow-up questionnaire. The baseline data collection for the continuation study concluded in April 2010 and the follow up survey for this round is set to begin in the fall of 2010. Follow-up materials (survey, cover letter, etc.) for the second wave of participants must be submitted for review before the follow-up begins.

No adverse events have been reported. The Principal Investigator indicated compliance with all relevant human subject protection regulations. The Chair reviewed this continuing review under the expedited review authority subdelegated by the Naval Health Research Center Commanding Officer and permitted under 32 CFR § 219.110(b)(1). This protocol is eligible for this type of review under Federal Register expedited review categories # 5 and # 7. The criteria for the approval of research continue to be met under 32 CFR § 219.111.The Chair recommends continuation of this effort.

The next scheduled review is on or before 14 October 2011.

Christopher G. Blood, J.D., M.A.
Chair, NHRC IRB

11/2/10
Signature & Date

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DETERMINATION OF APPROVING AUTHORITY

1. I concur with the recommendation of the IRB, and I approve continuation of this research.

   Next review is required no later than: 14 October 2011.

2. I concur with the recommendations of the IRB, but I require additional modifications or restrictions prior to providing continuing approval (Attach modifications or restrictions required).

   Next review is required no later than:

3. I disagree with the recommendations of the IRB and recommend (Attach statement regarding recommendations and reasons).

Signature	Date (MM/DD/YY)
GREGORY C. UTZ, CAPT, MC, USN Commanding Officer	30Nov2010

10/29/10

From: Laurel Hourani, Ph.D., RTI International
Jerry Larson, Ph.D., Naval Health Research Center
To: Chair, Institutional Review Board, Naval Health Research Center, San Diego, CA

Subj: CONTINUING REVIEW OF PROTOCOL #NHRC.2007.0011, Status of Transitioning Military Personnel

Ref: (a) NAVHLTHRSCHCENINST 3900.2E

Encl: (1) Continuing Review Summary for Protocol #2007.0011

1. Enclosure (1) is submitted to fulfill the reference (a) requirement for the Institutional Review Board (IRB) to review all work conducted under previously approved research protocols at least annually.

2. Point of contact for further information is Dr. Laurel Hourani or Dr. Jerry Larson.

Laurel Hourani 10/28/10
Dr. Laurel Hourani
PI Signature and Date

Jerry Larson 10-27-2010
Dr. Jerry Larson
PI Signature and Date

APPROVED
DATE 11/03/10
INT JD
EXP 10/14/11
NAVAL HEALTH RESEARCH CENTER SAN DIEGO

Continuing Review Summary of Protocol Number NHRC.2007.0011
Status of Transitioning Military Personnel
Principal Investigators: Dr. Laurel Hourani (RTI) and Dr. Jerry Larson (NHRC)

Background: Studies from both the United States and other parts of the world have identified significant mental health outcomes associated with deployment stressors, especially when combat operations are involved (Hoge et al., 2004; Litz et al., 1997; Jordan et al., 1991). Among 303,905 soldiers and Marines returning from Iraq between May 1, 2003, and April 30, 2004, 19% screened positive for a mental health disorder, 35% sought mental health care within a year, and nearly 17% left military service within a year of returning home (Hoge et al., 2006). Those who screened positive for a mental health concern were significantly more likely to have left military service (21%) than those who screened negative for a mental health problem (16%). A recent study found that service members are more than two times as likely to report mental health concerns 3 to 4 months after returning from deployment compared with reporting immediately on return (Bliese, Wright, Adler, & Thomas, 2004). Moreover, although acute anxiety symptoms often dissipate within weeks of a traumatic exposure, post-traumatic stress disorder (PTSD), the most severe disorder resulting from traumatic exposure, is usually not diagnosed until months after the initial exposure. Because about 200,000 servicemen and women are discharged per year (Brothers, 2006), the implication of the above findings is that a considerable proportion of Service members transitioning into civilian life will have significant mental health concerns that may not become evident until after separation.

Objectives: The objective of this longitudinal research study is to characterize the direct impact of combat exposure on mental health outcomes among Marines and Sailors in transition from active duty to civilian life and to examine the interrelationships between combat exposure, a variety of moderators, and subsequent psychological resilience, mental health symptoms and substance abuse. This study will examine a number of specific hypotheses regarding the effects of individual risk and protective factors on mental health outcomes.

Research Methods: A baseline paper-and-pencil questionnaire was administered to Marines and Sailors during TAP classes at selected installations. A total of 3,755 military personnel participated in this phase of the study. The questionnaire assessed the following content areas: (1) demographics; (2) deployment experiences; (3) psychological distress (including PTSD, depression, and anxiety); (4) substance abuse; (5) experiences with seeking and receiving mental health care; (6) family issues and social support; and (7) resilience. Participants were asked to provide their names and SSNs on the questionnaire, which allowed the researchers to link participants' survey responses with medical and personnel data. A dual mode (paper-and-pencil and web) follow-up survey was administered to baseline participants and 1,191 completed follow-up questionnaires were obtained. Questionnaire content for the follow-up survey assessed the same content areas as the baseline survey. We initiated baseline data collection for a continuation study for the USMC and surveyed 2,889 Marines per the approved protocol. A dual mode follow-up with these respondents is planned for Fall, 2010.

Risks: There are two possible but unlikely risks associated with study participation: (1) discomfort in answering the survey questions, and (2) inadvertent disclosure of medical and personal information.

Risk Mitigation: The risk of discomfort is mitigated by telling participants that participation is voluntary, they have the right to skip individual questions, and to discontinue the survey at any time. If respondents feel some psychological distress during the survey, installation-specific referral cards with mental health resource phone numbers are available for respondents desiring to seek help. During the baseline surveys, no respondents showed distress or requested additional referral information. The risk of inadvertent disclosure has been and will continue to be mitigated as follows. All project staff have been trained in confidentiality procedures. RTI administers the baseline survey onsite at selected installations via a paper-and-pencil questionnaire; dual mode follow-up surveys are administered via paper-and-pencil and web. Onsite surveys are secured at all times by RTI study staff, and web surveys include a logout button on each screen so respondents can immediately close the survey should they encounter any privacy concerns while completing the survey. All survey data are stored in a Microsoft SQL Server database utilizing a relational table structure. All identifying information is kept behind the RTI firewall in a separate table from questionnaire data, which also is kept behind the firewall. The questionnaire data are linked to identifying data only by a unique RTI-assigned ID and only when necessary to combine questionnaire data with data from other sources (CHAMPS and PDHRA) as authorized by participants during the consent process. All data are kept

completely confidential and only the selected RTI and NHRC project researchers will ever have access to the data. All paper questionnaires are and will continue to be kept in locked cabinets; computerized data are and will continue to be securely maintained within the RTI computer environment; access to data is available only to selected study staff. In addition, once participant survey data have been collected and matched with medical and personnel data (CHAMPS and PDHRA data), all identifying information will be removed from participants' data files.

Risk Classification: The study was originally classified as minimal risk.

Comments: Data collection for the initial baseline survey concluded on December 19th, 2007 and a follow up survey was completed in July 2009. A total of 3,755 personnel completed the baseline survey and 1,191 completed the follow-up questionnaire. The baseline data collection for the continuation study concluded on April 26th, 2010 and the follow up survey for this round is set to begin in the fall of 2010. The follow-up survey has been submitted to the Office of Management and Budget (OMB). We have completed the initial 60-day public comment period through the Federal Register. No comments were received by OMB for that period. We are now going through the second 30-day period for the public to comment.

CONTINUING REVIEW FOR IRB PROTOCOL NUMBER NHRC.2007.0011

1. PROTOCOL NUMBER: NHRC.2007.0011

2. PROTOCOL TITLE: Status of Transitioning Military Personnel

3. WORK UNIT TITLE AND NUMBER: 60814, Psychological Health Tracking

4. PRINCIPAL INVESTIGATOR(S): Dr. Laurel Hourani (RTI) and Dr. Jerry Larson (NHRC)

5. UPDATE OF RESEARCH BACKGROUND

The research literature relevant to this project appearing in print since the last IRB review of this protocol has been surveyed. The research issues addressed in this research protocol have not been resolved. No additional risks or benefits have been identified from the review of the recent literature. Based on this review, the utility of the research and the risk-benefit ratio have not changed.

6. CHANGES SINCE LAST REVIEW

Incentive for follow-up changed from $25 to $10 based on an incentive sub-study conducted during the first round follow-up as request by OMB.

7. SUBJECTS

During the initial fielding, we obtained completed surveys from 3,755 baseline respondents and 1,191 follow up participants. The number of completed surveys for the baseline phase of the continuation study was 2,889 Marines.

8. ADVERSE EVENTS

There have been no untoward events, complications, or injuries.

9. MEDICAL CARE

It has not been necessary to provide medical care to any study participants.

10. INFORMED CONSENT

During the baseline phases of the study, informed consent was obtained from all participants by providing them with a copy of the consent form approved by the IRB, giving them time to read it, and answering any questions they had about the protocol. No additional written consent will be obtained during the follow-up study.

11. RESEARCH AND SAFETY PROCEDURES

All research and safety procedures have faithfully conformed to the descriptions in the protocol as approved by the IRB.

12. FINDINGS TO DATE

Analyses of baseline and follow-up data from the initial baseline and follow-up have been completed. Findings from the initial baseline indicated that overall, prevalence rates ranged from 5% for suicidal ideation among Navy TAP attendees to 52.5% for substance abuse among Marines. Excluding substance abuse, high rates of any mental health symptoms were found among both transitioning Sailors and Marines with Marine Corps rates significantly higher than those for the Navy (55% and 40%, respectively). Rates for depression in transitioning

Marines were three times as high as the rates noted by Hoge and colleagues (14.7% vs. 49.2%), and rates for anxiety were twice as high (31% vs. 15.7%). For the follow-up, results showed a drop in the overall prevalence of anxiety and depression for both Sailors and Marines from baseline to follow-up, but also numerous new cases in both categories (between 9% and 31%). The percentage of participants reporting new posttraumatic stress disorder (PTSD) symptoms at the time of follow-up exceeded the percentage reporting symptom reduction between baseline and follow-up. The strongest risk factors for anxiety and depression at time of follow-up were self-reported stressors, baseline anxiety or depression symptoms, and risk-taking behaviors. With the exception of social support, protective factors, including resilience scores, accounted for a relatively minor amount of the variance compared with risk factors.

Data collection for the baseline for the continuation study has been completed. Data have been prepared for analysis, but analysis has not progressed to the point of having results to report at this time.

13. COMPLIANCE WITH REGULATIONS

To the best of my knowledge, this project has been conducted in compliance with all of the requirements of NAVHLTHRSCHCENINST 3900.2E and the related instructions and regulations cited therein.

14. PERSONNEL QUALIFICATIONS

All personnel are appropriately trained and qualified for their work on the project.

15. MAINTENANCE OF RECORDS

All IRB-relevant records are properly kept and securely stored as described in the protocol approved by the IRB.

16. CONFLICT OF INTEREST

No persons involved in the design, conduct, or reporting of research has a financial or other interest that could reasonably appear to be affected by the carrying out or the results of the research.

17. COLLABORATING INSTITUTIONS

This protocol is a collaborative undertaking with researchers at RTI International. Review of this project was last conducted and approved by RTI's IRB on January 21, 2010; documentation of that review is attached. Current RTI IRB approval for this project expires on February 5, 2011.

Laurel Hourani 10/28/10

Dr. Laurel Hourani
PI Signature and Date

10-28-2010

Dr. Jerry Larson
PI Signature and Date

RTI

IRB ID Number: 11722

Office of Research Protection and Ethics
Institutional Review Board Notice of Approval
Federalwide Assurance No. 3331

Title of Study: Mental Health Resilience Trajectories among Active Duty and Separated Military Personnel
RTI Project Number 0209522.006 **RTI Proposal Number (if no Project Number)**
Project Leader: Laurel Hourani
Project Team Member Contact (if different from Project Leader): Russ Peeler
Source of Funding for this Study: Naval Health Research Center
Date Submitted to IRB: January 21, 2010

Level of Review *(check one)*:
Full ☐, **IRB Meeting Date:**
Expedited ☒, **category:** 9: Cont. Rev. minimal risk research

Type of Review *(check one)*:
- ☐ Preliminary review (Do not involve human subjects or data until pretest or full study is approved.)
- ☐ Pretest/Pilot Test
- ☐ Full Implementation
- ☐ Amendment, describe:
- ☐ Add study site(s):
- ☒ Renewal
- ☐ Study Closure

IRB Approval of Special Conditions *(check all that apply)*:
- ☐ Waiver of Signed Informed Consent/Parental Permission
- ☐ Participation of Pregnant Women (Worksheet B submitted by project team)
- ☐ Participation of Prisoners (Worksheet C submitted by project team
- ☐ Participation of Prisoners in DHHS-funded studies (OHRP acknowledgement received)
- ☐ Participation of Minors (Worksheet D submitted by project team)
- ☐ IRB Agreement of Nonsignificant Risk Device Study Determination

Please note the following requirements:
- If unexpected problems or adverse events occur, the project team must notify the IRB.
- If there are changes in study procedures or protocol or any data collection materials (brochures, letters, questionnaires, etc.) the project team must notify the IRB before they are implemented.
- The project team is required to apply for continuing review as long as the study is active, which includes participation of human subjects or possession of human data or specimens.

Expiration Date of IRB Approval: February 5, 2011
(No human subjects research can occur after this date without continuing review and approval.)

Juesta M. Caddell — 1/21/2010

Signature - IRB Member or Chair — **Date of IRB Approval**

Juesta Caddell, PhD
Name - IRB Member or Chair (print or type)

☒ Copy sent to project leader
☒ Entered into MIS

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