

APPENDIX D. POSTAPPROVAL DOCUMENTATION

INSTITUTIONAL REVIEW BOARD RECOMMENDATION

CONTINUING REVIEW

Date of Review: 20 July 2005

Protocol Number: NHRC.2000.0007

Research Protocol Title: Prospective Studies of U.S. Military Forces: The Millennium Cohort Study

Principal Investigator: CDR Margaret A. Ryan, MC, USN

Work Unit Title and Number: Deployment Health Research, 60002

Proposed Dates of Research: 01 Oct 2000 to 30 Sept 2022

No. of Previous Reviews: 9

The principal investigator submitted this continuing review application for a protocol that was previously classified as minimal risk. The objective of this research is to examine any trends in the health of U.S. military veterans over time. Toward that end, the health of a cohort of regular Active Duty, National Guard, and Reserve military personnel will be followed for 18 years via serial postal surveys. Participants are allowed to complete the questionnaire by paper-and-pencil or online at www.millenniumcohort.org. The first phase of enrollment ended in June 2003. The second phase of enrollment (Panel 2), and the re-survey of Panel 1 began in May 2004. The targeted sample size is 140,000. Surveys have been received from 101,352 consenting participants to date, and Panel 2 enrollment is ongoing. Analyses of baseline data are ongoing.

The Continuing Review submission reported several changes in support personnel. Expedited IRB approval to send email reminders to all individuals who began the survey online but failed to complete the process was granted in June 2005. No adverse events have occurred and the principal investigator indicated compliance with all relevant human subject protection regulations in the submission application.

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(a). This protocol is eligible for this type of review under OHRP expedited review category # 9. The Chair recommends continuation of this effort.

The next scheduled review is on or before 19 July 2006.

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


Signature & Date

DETERMINATION OF APPROVING AUTHORITY

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

Next review is required no later than: 19 July 2006

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 (DD/MM/YY)

M. Dukovich, CAPT, MSC, USN
Commanding Officer

M. Dukovich

20 July 05

15 July 2005

From: CDR Margaret Ryan, MC, USN, Principal Investigator
To: Chair, NHRC Institutional Review Board

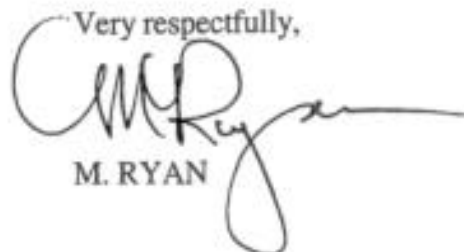
Subj: CONTINUING REVIEW OF PROTOCOL #2000-0007, "PROSPECTIVE STUDIES OF
U.S. MILITARY FORCES: THE MILLENNIUM COHORT STUDY"

Ref: (a) NAVHTHRESHCENINST 3900.2B

Encl: (1) Continuing review summary and updated protocol

1. Enclosure (1) is submitted to fulfill the requirement of reference (a) for the Institutional Review Board to review all work conducted under previously approved protocols at least annually.
2. Proposed modifications since the August 2004 review include administrative staff changes, and a change in on-line survey prompting for reminders to complete the survey. Proposed modifications are detailed on enclosure (1)
3. For questions, I may be contacted at 553-8097, ryan@nhrc.navy.mil. My alternative point of contact is Gia Gumbs at 553-8447, gumbs@nhrc.navy.mil

Very respectfully,



M. RYAN



Continuing Review Summary of Protocol Number NHRC 2000-0007
Title Prospective Studies of U.S. Military Forces: The Millennium Cohort Study
(Principal Investigator: CDR Margaret A.K. Ryan, MC, USN)

Background: In 1990 and 1991, the United States deployed approximately 700,000 troops to the Persian Gulf. Many individuals returned from the conflict with unexplained symptoms and illnesses. The patterns of symptoms and potential etiologic agents have been extensively studied in an attempt to identify the sources of illnesses and select effective courses of treatment. The lack of pre-deployment health data and deployment exposure data has been an important limitation to examining Gulf War Veteran morbidity questions. External review panels have recommended the development of systems for longitudinal tracking of health.

Objectives: The purpose of this study is to determine how the health of U.S. military veterans changes over time by analyzing the adjusted incidence of chronic disease within the cohort.

Research Methods: Regular active duty, National Guard, and Reserve military personnel will be followed via serial postal surveys with online completion options. Stratified random sampling will be used for cohorts in 2001, 2004, and 2007. These cohorts will be followed with repeat surveys at 3-year intervals through 2022. The surveys consist of standardized assessments of self-reported medical conditions and symptoms, general health and functional status, and psychiatric conditions. Supplemental medical and administrative data will be obtained from military and government databases.

Risks: The primary risks are those associated with inappropriate disclosure of sensitive information. The sensitive information certainly includes health data. Some career history data might also be considered sensitive.

Risk Mitigation: Standard NHRC procedures for constructing and maintaining electronic databases are being followed. These procedures include the assignment of a project-specific subject identification number (SID). Standard identifiers (e.g., SSN) will be used to match information from different databases, but only the SID will be included in the analytical database that merges different data sources. The procedures for protecting data transmitted during online completion of the questionnaire were reviewed and approved by qualified computer experts.

Risk Classification: This study was classified as minimal risk.

Comments: The first phase of enrollment (Panel 1) ended in June 2003. The second phase of enrollment (Panel 2), and the re-survey of Panel 1 began in May 2004 and is ongoing.

CONTINUING REVIEW FOR IRB PROTOCOL NUMBER 2000-0007

1. **WORK UNIT TITLE:** Deployment Health Research
2. **WORK UNIT NUMBER:** 60002
3. **PROTOCOL TITLE:** Prospective Studies of U.S. Military Forces: The Millennium Cohort Study
4. **PROTOCOL NUMBER:** NHRC.2000-0007
5. **PRINCIPAL INVESTIGATOR(S):** (CAPT Gregory C. Gray, MC, USN (ret): 01Oct00 through 31May01)
CDR Margaret A.K. Ryan, MC, USN: 01Jun01 to present

6. **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.

Reviewed literature includes:

Eisen SA, Kang HK, Murphy FM, Blanchard MS, Reda DJ, Henderson WG, Toomey R, Jackson LW, Alpern R, Parks BJ, Klimas N, Hall C, Pak HS, Hunter J, Karlinsky J, Battistone MJ, Lyons MJ; Gulf War Study Participating Investigators. Gulf War veterans' health: medical evaluation of a U.S. cohort. *Ann Intern Med.* 2005 Jun 7;142(11):881-90.

Kress AM, Hartzel MC, Peterson MR. Burden of disease associated with overweight and obesity among U.S. military retirees and their dependents, aged 38-64, 2003. *Prev Med.* 2005 Jul;41(1):63-9. Epub 2004 Nov 19.

Cunradi CB, Moore R, Killoran M, Ames G. Survey nonresponse bias among young adults: the role of alcohol, tobacco, and drugs. *Subst Use Misuse.* 2005;40(2):171-85.

Iversen A, Nikolaou V, Greenberg N, Unwin C, Hull L, Hotopf M, Dandeker C, Ross J, Wessely S. What happens to British veterans when they leave the armed forces? *Eur J Public Health.* 2005 Apr;15(2):175-84. Epub 2005 Mar 8.

Hoge CW, Toboni HE, Messer SC, Bell N, Amoroso P, Orman DT. The occupational burden of mental disorders in the U.S. military: psychiatric hospitalizations, involuntary separations, and disability. *Am J Psychiatry.* 2005 Mar;162(3):585-91.

7. **CHANGES SINCE LAST REVIEW**

Respectfully request the following changes with this review:

- This protocol has undergone a change of staff. Ms. Janette Astiazaran, Mr. Tom Corbeil, Ms. Doris Diehn, and Ms. Wendy Goldfinger no longer work for the Department of Defense Center for Deployment Health Research. Ms. Katharine Chapman, Ms. Angelee Ferber, Ms. Isabel Gomez, Ms. Cynthia Leard, and Ms. Christina Spooner have been added as new key support personnel.
- As of 13 June 2005, subjects who begin the survey online will no longer be asked, "Would you like to receive an email reminder?" Due to coding/script challenges, investigators have been unable to determine who specifically requested a reminder and who closed their browser without responding to the prompt. Per discussion with the IRB Chair and email approval dated 01 June 2005, email reminders will now be sent to all individuals who began the survey online but fail to complete/submit.

8. SUBJECTS

The targeted sample size of this study is 140,000. We have received surveys from 101,352 consenting participants to date, and Panel 2 enrollment is ongoing.

9. ADVERSE EVENTS

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

10. MEDICAL CARE

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

11. INFORMED CONSENT

Informed consent has been obtained from all study participants by providing them with a copy of the IRB approved consent form. Participants can ask questions via a toll-free number and email (info@millenniumcohort.org).

12. RESEARCH AND SAFETY PROCEDURES

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

13. FINDINGS TO DATE

Analyses of baseline data are ongoing. However, recent publications include:

Smith TC, Smith B, Cobeil TE, Riddle JR, Ryan MAK, for the Millennium Cohort Team. Self-reported mental health among US military personnel, prior and subsequent to the terrorist attacks of September 11, 2001. *J Occup Environ Med*, 2004;46:775-782

14. COMPLIANCE WITH REGULATIONS

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

15. PERSONNEL QUALIFICATIONS

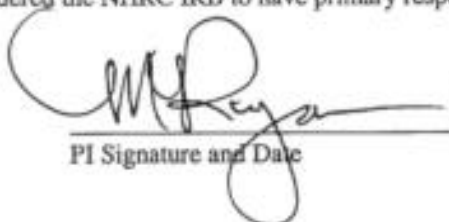
All personnel are appropriately trained and qualified for their work on the project.

16. MAINTENANCE OF RECORDS

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

17. COLLABORATING INSTITUTIONS

This protocol is a collaborative undertaking with researchers at Uniformed Services University of the Health Sciences (USUHS), United States Army Research Institute of Environmental Medicine (USARIEM), and the Seattle VA Puget Sound Health Care System. Institutional Review Boards at USUHS, USARIEM, and Seattle VA Puget Sound Health Care System have considered the NHRC IRB to have primary responsibility for protocol review.

 15 July 2005
PI Signature and Date

