

MEMORANDUM FOR: LTC Lorraine Babeu, Exemption Determination Official, HA/TMA, Falls Church, VA 22041

SUBJECT: Modification of Protocol

1. This is to request modification of the protocol listed below:

a. CDO Number: CDO-06-2006-CR3

b. Vendor Protocol Number: NHRC.2000.0007

c. Title: Prospective Studies of US Military Forces: The Millennium Cohort Study

d. Investigator: Dr. Tyler C. Smith

e. Government Project Manager: Dr. Tyler C. Smith

2. The following are the responses to the requested questions:

- Reasons for Modification:

The Millennium Cohort Study Survey Instrument has been slightly modified to assess identified gaps of military relevant information as well as sponsor driven initiatives.

Secondly, there has been a recent sponsor driven addition to the Millennium Cohort Study, the Millennium Cohort Family Study. Service member participants in the newly enrolled Panel 4 of the Millennium Cohort Study will be asked for permission to contact their spouse. We estimate that approximately 10,000 spouses will participate in the Family Cohort Study.

Please note, the Family Cohort questionnaire was designed to concurrently survey Millennium Cohort members and their spouses with measures consistent on both questionnaires. Additional items included in the Family Cohort survey assess interrelated health effects of military service and deployment on service members, spouses, and co-resident children from the spouse's perception.

Below is a brief list of similarities and slight differences between the Millennium Cohort and Family Cohort questionnaires.

Similar data collected on both questionnaires:

Demographics

Baseline general health

Mental and physical health

Physical exercise

Deployment data

Alcohol and tobacco

Reproductive health
Life events

Family Cohort questions not on Millennium Cohort questionnaire:

Military impact on family including deployment
Spousal relationship
Family environment
Social support
General child questions

-Describe exactly what you are going to be doing that is different from the original protocol

- Status of Data Collection: How many subjects have you obtained data on (include gender breakout).

To date, there are 151,597 consenting subjects in the Millennium Cohort Study.

The Millennium Cohort Family Study has been designed to enroll an estimated 10,000 spouses of military members from all services and components of the US armed forces. Based on over-sampling designed to include 25% military women in Panel 4, we estimate there to be approximately 75% female spouses surveyed in the family component of the Millennium Cohort Family Study.

- Adverse Events: There have been no untoward events, complications, or injuries.

- Preliminary Results: All preliminary results were included in the initial OMB submission. If approved by OMB, data collection for the revised Millennium Cohort Study questionnaire and the Millennium Cohort Family Study will begin in 2010.

- Publication Prospects: In recent decades, mental health and related outcomes for US military service members following deployment have been documented for multiple conflicts. Much less attention has been paid, however, to deployment-related outcomes for spouses and other family members of those deployed. Family member functioning can be degraded by separation and associated worries, and service member functioning can be degraded when concern over events at home reduces their ability to concentrate or to be attentive and vigilant. Additionally, war zone stress exposure has been shown to have substantial impact on service members after they return home, which can produce additional stressors for both the service member and their families when they are reunited.

Family relationships play an important role in the functioning and well-being of US military service members. It has been suggested that family relationships can be an important source of support that bolsters force readiness, or alternatively, a stressor that depletes service members' resources and reduces readiness. Few epidemiologic studies have examined the impact of war zone deployment on family members and family functioning. The Millennium Cohort Study is strategically positioned to complete this research. This research will also facilitate identification of specific interventions, such as

deployment-related stress, family member resilience, family support dynamics, service member and family well-being, and force readiness.

The primary Millennium Cohort Family Study objective is to compare the adjusted probabilities of new onset and persistent diseases and conditions among military spouses and children.

The secondary Millennium Cohort Family Study objective is to assess the importance of family support and other factors on positive and negative health outcomes.

3. Additionally, enclosed is a copy of the protocol modification approval from the primary IRB if applicable. If you any questions, please call Dr. Tyler C. Smith at 619-553-7593 or e-mail tyler.c.smith@med.navy.mil.

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