

APPENDIX D. POSTAPPROVAL DOCUMENTATION

INSTITUTIONAL REVIEW BOARD RECOMMENDATION

**PROTOCOL MODIFICATION**

Date of Review: 3 January 2013 Protocol Number: NHRC.2000.0007  
Research Protocol Title: Prospective Studies of U.S. Military Forces: The Millennium Cohort Study  
Principal Investigator: Nancy F. Crum-Cianflone, MD, MPH

The principal investigator submitted a modification request 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. service members and their families 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 surveys administered at three-year intervals. Survey data is then merged with DoD medical and personnel records. Subject enrollment is ongoing.

The modification submission requested 1) update the web page to reflect that active duties members are asked to provide contact information for their spouses, rather than seeking service members' explicit authorization for spouses to participate in a separate survey study; 2) two new questions have been added to the Family Survey for the 2014 survey administration; and 3) a post card to Family Cohort participants was submitted for stamping.

The Chair reviewed this modification under the expedited review authority subdelegated by the Naval Health Research Center Commanding Officer and permitted under 32 CFR § 219.110. This protocol is eligible for this type of review under 32 CFR § 219.110(b)(2). The Chair recommends approval of these modifications.

The current IRB approval period expires on 27 March 2013.

Christopher G. Blood, JD, MA  
Chair, NHRC IRB

  
Signature & Date

\*\*\*\*\*

**DETERMINATION OF APPROVING AUTHORITY**

SW

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

Next review is required no later than: 27 March 2013

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

Gregory C. Utz      3 Jan 2013

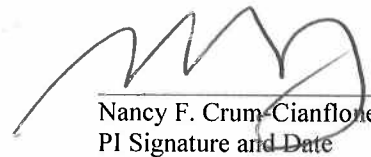
HUMAN USE PROTOCOL ROUTING SLIP - MODIFICATION				
FROM (Principal Investigator): Nancy F. Crum-Cianflone, MD, MPH		(PI SIGNATURE)		
In accordance with NAVHLTHRSCHCENINST 3900.2F, I am submitting the attached human use protocol for consideration.				
TITLE OF PROTOCOL: Prospective Studies of U.S. Military Forces: The Millennium Cohort Study ABBREVIATED TITLE: The Millennium Cohort Study				
PROPOSED DATES OF RESEARCH: 2000/10/01 to 2022/09/30				
SUBMISSION (CHECK ONE): <input type="checkbox"/> INITIAL SUBMISSION <input checked="" type="checkbox"/> MODIFICATION OF PREVIOUS SUBMISSION <input type="checkbox"/> CONTINUING/ANNUAL REVIEW				
PROTOCOL OBJECTIVE (Brief sentence or two):				
COMMENTS (e.g., issues, special considerations):				
DoD PROTOCOL NUMBER: #NHRC.2000-0007				
Note: You must obtain signatures 1-3 before you submit the protocol to the IRB.		DATE RECEIVED	DATE APPROVED	INITIALS
1	PROGRAM MANAGER	12/4/12	12/4/12	NFC
2	PROGRAM IRB MEMBER			
3	DIRECTOR OF SCIENCE AND TECHNOLOGY			
4	IRB ADMINISTRATOR	DEC 04 2012		WJG
5	COMMANDING OFFICER			

28 November 2012

From: Nancy F. Crum-Cianflone, MD, MPH, Principal Investigator  
To: Chair, Institutional Review Board, Naval Health Research Center, San Diego, CA  
Subj: MODIFICATION TO PROTOCOL #NHRC.2000-0007, "Prospective Studies of U.S. Military Forces:  
The Millennium Cohort Study"

Ref: (a) NAVHLTHRSCHCENINST 3900.2F

1. This modification request is submitted to fulfill the reference (a) requirement for the Principal Investigator to seek approval for any changes that the PI wishes to incorporate to an approved protocol.
2. I certify that all study personnel have been informed of and accept the proposed changes.
3. For questions, I may be contacted at 553-7335, nancy.crum@med.navy.mil. My alternative point of contact is Kari Sausedo at 553-8125, kari.sausedo@med.navy.mil.

 12/4/12  
Nancy F. Crum-Cianflone  
PI Signature and Date

**MODIFICATION OF IRB PROTOCOL**

1. **PROTOCOL NUMBER:** NHRC.2000-0007
2. **PROTOCOL TITLE:** Prospective Studies of U.S. Military Forces: The Millennium Cohort Study
3. **WORK UNIT TITLE AND NUMBER:** Deployment Health Research, 60002
4. **PRINCIPAL INVESTIGATOR:** Nancy F. Crum-Cianflone, MD, MPH
5. **RISK LEVEL:** Minimal Risk
6. **CURRENT STUDY STATUS:** Ongoing
7. **CHANGES SINCE LAST REVIEW:** We respectfully request the following modifications to the protocol:
  - In order to update the web page on the Millennium Cohort web survey after the removal of the referral process (previously approved), we request permission to update the referral web page so that it no longer asks for secondary consent from service members. This page will only ask the New Enrollee for their spouse's contact information. A PDF of the web page is attached for review.
  - The following questions were added to the 2014 Family Study Follow-Up Survey (approved June 8, 2012) :
    - To best understand the dynamics of health care utilization and the needs of service members and their families, are you willing to allow us to link your survey data to DoD medical records of any children you may have that are under the age of five years old?
    - A great deal has been learned from this study, and as a consequence we've been asked to consider other research possibilities. If other related research studies become available, is it ok to contact you to let you know about these opportunities? This question is consistent with language on the Millennium Cohort Study.The 2014 Family Follow-Up Survey is attached.
  - A Welcome to the Family Study winter card will be sent to those subjects who have completed the Family Study. A PDF of the card is attached for review.

  
PI Signature and Date 12/4/12