SUPPORTING STATEMENT FOR PAPERWORK REDUCTION ACT SUBMISSION

A. JUSTIFICATION

1. Needs and Use

Federal Government institutions wishing to conduct, sponsor, or support research on human subjects must first submit for approval to duly designated authorities an Assurance that they will comply with established guidelines in such research. Such Assurances are granted by components of DoD and by the Department of Health and Human Services (HHS). New DoD guidance now requires principal and co-principal investigators individually and explicitly to acknowledge that they understand and accept responsibility for protecting the rights and welfare of human research subjects. All principal and co-principal investigators engaged in research supported or conducted under the purview of the Under Secretary of Defense for Personnel and Readiness (USD(P&R)) must read and sign a document that attests to their commitment to abide by the provisions of: a) *The Belmont Report: Ethical Principles and Guidelines for the Protection of Human Subjects of Research*; b) the US Department of Defense (DoD) regulations for the protection of human subjects at Title 32, Code of Federal Regulations, Part 219 (32 CFR 219) and DoD Directive 3216.02; c) the Assurance of the engaged institution; relevant institutional policies and procedures where appropriate; and other Federal, State, or local regulations where appropriate.

2. Purpose and users of the information

This collection instrument is for use by the Component Designated Official Office (CDOO) within the Office of the USD(P&R) to document human research project team leaders' commitment to the body of regulations designed to protect the wellbeing and privacy of human research subjects whether the research is clinical or behavioral/social.

3. Information Collection Techniques

The CDOO will distribute the document as an e-mail attachment. After signing the document and entering contact information, the principal and co-principal investigators will scan the document and return it to the CDOO as a Portable Document Format (.pdf) attachment to an e-mail. In a few cases where the investigators do not have access to scanning equipment, the documents will be mailed to the CDOO. The electronic documents will be kept on file and a database will be annotated to indicate individual compliance. Once this requirement is fully implemented, investigators will not be permitted to conduct human subject research until their commitment document is on file with the CDOO.

4. Duplication and Similar Information

There is no duplication of data collection. This is the first time human research principal and co-principal investigators are required to individually commit to complying with human research guidance.

5. Small Business

This collection of information does not involve small businesses or other small entities.

6. Less Frequent Collections

Individuals are requested to provide one response as a result of conducting human subject research under the purview of the USD(P&R). If they remain engaged in such research under USD(P&R) after three years, they will be asked to reaffirm their commitment to ethical human research in a short, digitally signed e-mail.

7. Special Circumstances

There are no special circumstances that require the collection to be conducted in a manner inconsistent with the guidelines in 5 CFR 1320.5 (d) (2)

8. Federal Register Notice/Consultations

The Federal Register Notice for this collection of information was published on May 7, 2008 (73 FR 25685-25686). No public comments were received.

9. Payment/Gift to Respondents

None

10. Confidentiality

The researcher responsibility acknowledgement document contains no sensitive information, and confidentiality is not an issue. The information will not be published or further disseminated.

11. Sensitive Questions

There are no questions of sensitive nature asked in the document.

12. Burden Estimated (hours)

The total annual hour burden for the respondents of 293 hours is based on a response the first year of all approximately 585 principal and co-principal investigators currently engaged in human research. The burden is further based on an estimate of

one half hour to read, sign, fill out, scan, and transmit the two-page document. Subsequently, only newly assigned investigators will be required to execute the document (approximately 20 annually).

13. Cost to Respondents

None

14. Cost of Federal Government

None

15. Change in Burden

This is a new collection.

16. Publication/Tabulation

The document is not a survey, and no statistical treatment will be required. Individual investigator compliance with the requirement will be posted to a database, but data on individual compliance will not be published.

17. Expiration Date

DoD is not seeking an exception to displaying the expiration date of this information collection.

18. There are no exceptions to the certification statement in Item 19 of OMB Form 83-1.

B. COLLECTION OF INFORMATION EMPLOYING STATISTICAL METHODS

As noted above, this information collection is not a survey, and no statistical methods will be employed. There will be no sampling, and all lead investigators will be required to submit the signed document.