



Billing Code: 5001-06

DEPARTMENT OF DEFENSE

Office of the Secretary

[Docket ID: DoD-2013-HA-0175]

Proposed Collection; Comment Request

AGENCY: Office of the Assistant Secretary of Defense for Health Affairs, DoD.

ACTION: Notice.

In compliance with Section 3506(c)(2)(A) of the *Paperwork Reduction Act of 1995*, the Office of the Assistant Secretary of Defense for Health Affairs announces a proposed public information collection and seeks public comment on the provisions thereof.

Comments are invited on: (a) whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed information collection; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the information collection on respondents, including through the use of automated collection techniques or other forms of information technology.

DATES: Consideration will be given to all comments received by [insert date 60 days from publication of this notice in the Federal Register].

ADDRESSES: You may submit comments, identified by docket number and title, by any of the following methods:

- Federal eRulemaking Portal: <http://www.regulations.gov>. Follow the instructions for submitting comments.

- Mail: Federal Docket Management System Office, 4800 Mark Center Drive, East Tower, Suite 02G09, Alexandria, VA 22350-3100.

Instructions: All submissions received must include the agency name, docket number and title for this Federal Register document. The general policy for comments and other submissions from members of the public is to make these submissions available for public viewing on the Internet at <http://www.regulations.gov> as they are received without change, including any personal identifiers or contact information.

FOR FURTHER INFORMATION CONTACT: To request more information on this proposed information collection or to obtain a copy of the proposal and associated collection instruments, please write to the Office of the Assistant Secretary of Defense for Health Affairs, Force Health Protection and Readiness, ATTN: CAPT John Eckert, 7700 Arlington Boulevard, Suite 5101 (CODE: FHP&R), Falls Church, VA 22042-5101, or call (703) 681-8356.

TITLE; ASSOCIATED FORM; AND OMB NUMBER: Researcher Responsibilities Form, OMB Number 0720-0042.

NEEDS AND USES: The information collection requirement is necessary to document researcher's understanding and acceptance of the regulatory and ethical responsibilities pertaining to including humans as subjects in research. Principal and associate investigators must have the proposed, signed form on file before they may engage in research conducted or supported by entities under the purview of the Under Secretary of Defense for Personnel and Readiness (USD(P&R)).

AFFECTED PUBLIC: Federal Government, For-profit Businesses, Not-for-profit Businesses.

ANNUAL BURDEN HOURS: 44.5

NUMBER OF RESPONDENTS: 89

RESPONSES PER RESPONDENT: 1

AVERAGE BURDEN PER RESPONSE: 30 minutes

FREQUENCY: On occasion; original document submitted one time per researcher.

Once their document is on file, a researcher may reaffirm their commitment every three years electronically if they remain engaged in human subject research.

SUPPLEMENTARY INFORMATION:

Summary of Information Collection

Federal Government institutions wishing to conduct 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). DoD guidance requires principal and associate 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 associate investigators engaged in research supported or conducted under the purview of the 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 Instruction 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. The Office of the Assistant Secretary of Defense for Health Affairs announces the intent to renew its Researcher Responsibility Form for this purpose and seeks public comment on the provisions thereof. Respondents are professionals who have been designated as principal or associate investigators. When preparing to initiate work on their first human subject research protocol, each principal investigator and associate investigator must assure they have the proposed Researcher Responsibilities form on file with the OUSD(P&R) Component office. This may require new forms from approximately 90 investigators. The form is two pages in length including statements agreed to and half a page for respondent signature and contact information. Respondents generally will be required to scan the form and forward it electronically. The form will be filed electronically and form completion will be logged into a database. After three years, if a researcher still is engaged in research with OUSD(P&R), he/she will be asked to reaffirm his/her commitment electronically. This information collection does not involve sensitive personal information and requires no special confidentiality measures.

Dated: August 15, 2013.

Aaron Siegel,
Alternate OSD Federal Register
Liaison Officer,
Department of Defense.

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