Supporting Statement for the Assurance Identification/IRB Certification/Declarations of Exemption Form

A. Background

The Office for Human Research Protections is requesting a three-year extension of the Protection of Human Subjects: Assurance Identification/IRB Certification/Declaration of Exemption Form, OMB No. 0990-0263. The purpose of that Form is to provide a simplified procedure for institutions engaged in research conducted or supported by the Department of Health and Human Services (HHS) to satisfy the requirements of HHS regulations for the protection of human subjects at 45 CFR 46.103. The respondents for this collection are institutions engaged in research involving human subjects where the research is supported by HHS. Institutional use of the form is also relied upon by other federal departments and agencies that have codified or follow the Federal Policy for the Protection of Human Subjects (Common Rule) which is identical to 45 CFR part 46, subpart A.

B. Justification

1. Need and Legal Basis

Section 491(a) of Pub. L. 99-158 states that the Secretary of HHS shall by regulation require that each entity applying for HHS support (e.g., a grant, contract, or cooperative agreement) to conduct research involving human subjects submit to HHS assurances satisfactory to the Secretary that it has established an institutional review board (IRB) to review the research in order to protect the rights of the human subjects of such research. IRBs are boards, committees, or groups formally designated by an entity to review, approve, and have continuing oversight of research involving human subjects. The pertinent authorizing legislation is provided in Attachment 1.a., (42 U.S.C. 289).

Pursuant to the requirement of the Public Law, HHS has promulgated regulations under 45 CFR part 46. These regulations require that, before engaging in HHS-conducted or -supported research that is not exempt under 45 CFR 46.101(b), each institution must:

> (1) Hold an applicable OHRP-approved written assurance of compliance with the regulations [45 CFR 46.103(a)]; and
> (2) Certify to the awarding HHS agency that the application or proposal for research has been reviewed and approved by an IRB designated in the assurance [45 CFR 46.103(b) and (f)].

Since 1991, the Common Rule has implemented a common Federal policy for the protection of human subjects of research conducted, supported or regulated by the following Federal departments and agencies that have adopted the Common Rule:

> United States Department of Agriculture (7 CFR Part 1c)
> Department of Energy (10 CFR Part 745)

National Aeronautics and Space Administration (14 CFR Part 1230)
Department of Commerce (15 CFR Part 27)
Consumer Product Safety Commission (16 CFR Part 1028)
Agency for International Development (22 CFR Part 225)
Department of Housing and Urban Development (24 CFR Part 60)
Department of Justice (28 CFR Part 46)
Department of Defense (32 CFR Part 219)
Department of Education (34 CFR Part 97)
Department of Veterans Affairs (38 CFR Part 16)
Environmental Protection Agency (40 CFR Part 46)
Department of Health and Human Services (45 CFR Part 46)
National Science Foundation (45 CFR Part 690)
Department of Transportation (49 CFR Part 11).

In addition to departments and agencies which have codified the Common Rule, the Central Intelligence Agency is required by Executive Order 12333 and the Department of Homeland Security is required by statute to follow all subparts of 45 CFR part 46 in their human research programs.

Adoption of the common Federal Policy (56 FR 28003) by these departments and agencies implements a recommendation of the President's Commission for the Study of Ethical Problems in Medicine and Biomedical and Behavioral Research which was established on November 9, 1974, by Pub. L. 95-622. The Common Rule is based on HHS regulations at 45 CFR part 46, subpart A, the basic HHS Policy for the Protection of Human Subjects. The Common Rule and the HHS regulations are included in Attachments 1.b. and 1.c., respectively.

2. Information Users

Information obtained on the authority of Sections 103(b) and 103(f) from the holder of an acceptable assurance is used to ensure (1) that the institution/organization has established adequate administrative policies and procedures for protecting the rights and welfare of human subjects in research and (2) that it accepts this responsibility. Other reporting requirements are to assess whether the institution is following the established procedures; to ensure that no Federal funds are expended for unapproved human subjects research; and to determine if the approved status of an awarded grant should be reviewed, with the ultimate goal of maintaining or increasing human subjects protection.

3. Improved Information Technology

Institutions submitting a FWA will electronically submit all information for initial FWAs, or updates and renewals of existing FWAs, including the signature of the signatory official, via the internet using an interactive page on the OHRP website. OHRP has the technology that permits OHRP to accept electronic signatures of Signatory Officials for the FWA. This eliminates the need for submission of any paperwork, except for rare institutions that lack the ability to submit their FWAs electronically. Between January 1, 2014 and November 12, 2014, OHRP approved 3,824 FWAs, that were all submitted electronically. OHRP anticipates that all institutions will continue to submit FWA information via the internet

4. Duplication of Similar Information

The Common Rule and agency specific rules establish the only Federal standards for the conduct of federally-conducted or -sponsored research involving human subjects.

5. Small Businesses

Funding of research activities involving human subjects extends to small businesses. The committee that developed the Common Rule considered ways to reduce the burden on small businesses or organizations that receive Federal support and determined that it is not feasible to do so. However, organizations not having on file approved assurances for the proposed research (likely to be small organizations) do not have to certify IRB review until it is requested-generally only when an award is expected to be made.

6. Less Frequent Collection

The reporting of IRB approval is required with the submission of an application or proposal or at such later date as specified by the agency/department sponsoring the research. Institutions without an approved assurance covering the research shall certify within 30 days after receipt of a request for such a certification from the Common Rule department or agency that the application or proposal has been approved by the IRB. This is necessary to ensure that federally-supported research involving human subjects is subjected to the continuing IRB review and approval that is required at least once per year, as the obligation to protect human subjects is an ongoing responsibility and not a one-time effort. Changes in research protocols, new scientific or medical findings or innovations, as well as preliminary results or ongoing research, may change the degree of risks to the subjects; therefore, IRB review is required to be conducted at least annually. Reporting of the date of that review, and approval with the application describing those changes, notifies the funding department/agency of IRB approval of the changed protocol.

7. Special Circumstances

None.

8. Federal Register Notice/Outside Consultation

The 60-day Federal Register Notice published in the Federal Register on Monday, December 1, 2014, Vol. 79, No. 230, pg. # 71102. There were no public comments received.

9. Payment/Gift to Respondents

No payment or gifts are provided to respondents.

10. Confidentiality

The reporting of IRB review is a part of the grant or contract file and is available in many cases under the Freedom of Information Act. The information collected under the Assurance in the past was considered releasable under the Freedom of Information Act (FOIA). However, currently OHRP no longer requires public requesters to submit a FOIA request in order to obtain non-public Assurance information.

11. Sensitive Questions

No sensitive information is being collected on the form.

12. Burden Estimate (Total Hours and Wages)

Institutions seeking support for human subjects research are required by 45 CFR 46.103(f) to certify that the proposed research has been reviewed by an IRB. The estimate of the number of respondents is based upon the current number of institutions that have an OHRP-approved Federalwide Assurances (FWAs), 11,625, and projecting that the number may increase to 12,000. There are an estimated total of 25, 000 human research studies supported each year, an average of 2 certifications per institution annually (25,000/12,000 = 2.08), requiring an estimated one-half hour per certification, accounting for the estimated 12,000 (12,000 x 2 = 24 24,000; 24,000/.5 = 12,000 response burden hours. The burden estimate is similar to the previously approved burden.

The total burden dollars are estimated at 12,000 burden hours X $40/hour = $480,000.
The estimated burden dollars are identical to the previously approved burden.

Estimated Annualized Burden in Hours for IRB Certification Burden

Form name	Number of Respondents	Number of Responses per Respondent	Hours per Response	Response Burden Hours
Protection of Human Subjects: Assurance Identification/IRB Certification/Declaration of Exemption	12,000	2	30/60	12,000

Estimated Annualized Burden in Dollars for IRB Certification Burden

Form name	Total Burden Hours	Hourly Wage Rate	Total burden dollars
Protection of Human Subjects: Assurance Identification/IRB Certification/Declaration of	12,000	$40	$480,000

Exemption			

13. Capital Costs (Maintenance of Capital Costs

There are no direct capital costs to respondents other than the time to review the instructions and complete the form.

14. Annualized Cost to the Federal Government

The estimated annual Federal cost of reviewing assurances and certifications of IRB approval required under HHS regulations at 45 CFR 46.103 is $450,000.

15. Program or Burden Changes

The annual burden will remain the same, 12,000 hours.

16. Plans for Tabulation and Publication and Project Time Schedule

There are no plans to publish or tabulate the information.

17. Reason(s) Display of OMB Expiration Date is Inappropriate

Display of OMB expiration date is appropriate.

18. Exceptions to Certification for Paperwork Reduction Act Submissions

No exception is requested.

B. Justification of Information Employing Statistical Methods

Not applicable.

LIST OF ATTACHMENTS

Attachment 1 - Legal Authorities

a. 42 U.S.C. Section 289

b. 56 F.R. 28003 (Common Rule), in pertinent part

c. 45 CFR Part 46, Subpart A

Attachment 2 – Proposed Form OMB 0990-0263

Attachment 1.a. - Legal Authorities

42 U. S. C. Section 289

TITLE 42 – The Public Health and Welfare

CHAPTER 6A – PUBLIC HEALTH SERVICE

SUBCHAPTER III – NATIONAL RESEARCH INSTITUTES

Part H – General Provisions

INSTITUTIONAL REVIEW BOARDS; ETHICS GUIDANCE PROGRAM

Sec. 491. [289](a) The Secretary shall by regulation require that each entity which applies for a grant, contract, or cooperative agreement under this Act for any project or program which involves the conduct of biomedical or behavioral research involving human subjects submit in or with its application for such grant, contract, or cooperative agreement assurances satisfactory to the Secretary that it has established (in accordance with regulations which the Secretary shall prescribe) a board (to be known as an >Institutional Review Board=) to review biomedical and behavioral research involving human subjects conducted at or supported by such entity in order to protect the rights of the human subjects of such research.

(b)(1) The Secretary shall establish a program within the Department of Health and Human Services under which requests for clarification and guidance with respect to ethical issues raised in connection with biomedical and behavioral research involving human subjects are responded to promptly and appropriately.

(2) The Secretary shall establish a process for the prompt and appropriate response to information provided to the Director of NIH respecting incidences of violations of the rights of human subjects of research for which funds have been made available under this Act. The process shall include procedures for the receiving of reports of such information from recipients of funds under this Act and taking appropriate action with respect to such violations.

(*July 1, 1944, ch. 373, title IV, Sec. 491, as added Pub.L. 99-158, Sec. 2, Nov. 20, 1985, 99 Stat. 873.*)

Attachment 1.b. - Legal Authorities

56 FR 28003

Attachment 1.c. - Legal Authorities

45 CFR 46

Attachment 2

Proposed OMB No. 0990-0263

Protection of Human Subjects: Assurance Identification/Certification/ Declaration of Exemption