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

Background

The Office for Human Research Protections (OHRP) 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.

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

The collection of information is currently conducted by the traditional exchange of paper documents as well as electronically as part of the contract, grant, or cooperative agreement application process. Institutions submitting such applications can download the form from the OHRP Web site at http://www.hhs.gov/ohrp/humansubjects/assurance/OF310.rtf. This document is in rich text format, and can be filled in, saved, and printed by users for submittal with such applications.

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

A notice announcing a 60-day period for public comments on the information collection was published in the *Federal Register* on August 27, 2008, Volume No. 73, pg. no 50627. No public comments were submitted.

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 assurance is also available under the Freedom of Information Act, although portions may need to be redacted to comply with provisions relating to privacy and confidentiality.

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. Approximately 10,000 institutions receive such support. There are an estimated total of 70,000 health or human research studies supported each year, meaning an average of 7 certifications per institution annually, requiring an estimated one-half hour per certification at a labor rate of $22.85 per hour, for a total burden of 35,000 hours and $800,000 cost.

Estimated Annualized Burden in Hours for IRB Certification Burden

Form name	Number of Respondents	Number of responses per respondent	Average burden per response (in hours)	Total Burden hours
Protection of Human Subjects: Assurance Identification/IRB Certification/Declaration of Exemption	10,000	7	0.5	35,000

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 Exemption	35,000	$22.85	$800,000

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. Cost to the Federal Government

The estimated annual Federal cost of reviewing assurances and certifications is $1,992,000.

15. Program or Burden Changes

Burden estimates are unchanged based on experience since the 2005 clearance request.

16. Publication and Tabulation Dates

There are no plans to publish or tabulate the information.

17. Expiration Date

Display of OMB expiration date is appropriate.

18. Exceptions to Certification for Paperwork Reduction Act Submissions

No exception is requested.

C. 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 – Current 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

OMB No. 0990-0263

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

OMB No. 0990-0263
Approved for use through 11/30/2008

Protection of Human Subjects
Assurance Identification/IRB Certification/Declaration of Exemption
(Common Rule)

Policy: Research activities involving human subjects may not be conducted or supported by the Departments and Agencies adopting the Common Rule (56FR28003, June 18, 1991) unless the activities are exempt from or approved in accordance with the Common Rule. See section 101(b) of the Common Rule for exemptions. Institutions submitting applications or proposals for support must submit certification of appropriate Institutional Review Board (IRB) review and approval to the Department or Agency in accordance with the Common Rule.

Institutions must have an assurance of compliance that applies to the research to be conducted and should submit certification of IRB review and approval with each application or proposal unless otherwise advised by the Department or Agency.

1. Request Type	2. Type of Mechanism	3. Name of Federal Department or Agency and, if known, Application or Proposal Identification No.
[ ] ORIGINAL [ ] CONTINUATION [ ] EXEMPTION	[ ] GRANT [ ] CONTRACT [ ] FELLOWSHIP [ ] COOPERATIVE AGREEMENT [ ] OTHER:_____	
4. Title of Application or Activity		5. Name of Principal Investigator, Program Director, Fellow, or Other

6. Assurance Status of this Project *(Respond to one of the following)*

[ ] This Assurance, on file with Department of Health and Human Services, covers this activity:
Assurance Identification No._____, the expiration date_____ IRB Registration No. _____

[ ] This Assurance, on file with *(agency/dept)*_____, covers this activity.
Assurance No._____, the expiration date_____ IRB Registration/Identification No._____*(if applicable)*

[ ] No assurance has been filed for this institution. This institution declares that it will provide an Assurance and Certification of IRB review and approval upon request.

[ ] Exemption Status: Human subjects are involved, but this activity qualifies for exemption under Section 101(b), paragraph_____.

7. Certification of IRB Review (Respond to one of the following IF you have an Assurance on file)

[ ] This activity has been reviewed and approved by the IRB in accordance with the Common Rule and any other governing regulations.
by: [ ] Full IRB Review on (date of IRB meeting) _____ or [ ] Expedited Review on (date) _____
[ ] If less than one year approval, provide expiration date _____

[ ] This activity contains multiple projects, some of which have not been reviewed. The IRB has granted approval on condition that all projects covered by the Common Rule will be reviewed and approved before they are initiated and that appropriate further certification will be submitted.

8. Comments

9. The official signing below certifies that the information provided above is correct and that, as required, future reviews will be performed until study closure and certification will be provided.	10. Name and Address of Institution
11. Phone No. *(with area code)* 12. Fax No. *(with area code)* 13. Email:	
14. Name of Official	15. Title
16. Signature	17. Date

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