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

Background

The Office for Human Research Protections (OHRP) is requesting a 3-year extension of the Protection of Human Subjects: Assurance Identification/IRB/Institutional Review Board Certification/Declaration of Exemption Form, OMB No. 0990-0263. The purpose of the 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 for assurance identification, and IRB certification, and declaration of exempt status. 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 (the Common Rule, which is codified for HHS at 45 CFR part 46, subpart A).

A. Justification

In this supporting statement, the term "pre-2018 Common Rule (or pre-2018 Requirements)" refers to subpart A of 45 CFR part 46 (i.e., the Common Rule) as published in the 2016 edition of the Code of Federal Regulations. The pre-2018 Requirements were originally promulgated in 1991 and subsequently amended on June 23, 2005 (70 FR 36325).

The term "2018 Common Rule (or 2018 Requirements)" refers to the revised Common Rule as published in the July 19, 2018 edition of the Code of Federal Regulations. The 2018 Requirements were originally published on January 19, 2017 (82 FR 7149) and further amended on January 22, 2018 (83 FR 2885) and June 19, 2018 (83 FR 28497).

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 an assurance satisfactory to the Secretary that it has established an 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 conduct 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) (pre-2018 Requirements)

and 45 CFR 46.103 (2018 Requirements) or waived under 45 CFR 46.101(i), each institution must:

> (1) Hold an applicable OHRP-approved written assurance of compliance with the regulations [45 CFR 46.103(a)]; and either
> (2) Certify to the awarding HHS agency that the application or proposal for research has been reviewed and approved by an IRB [45 CFR 46.103(b) and (f) in the pre-2018 Requirements], or
> (3) Certify to the awarding HHS agency that each proposed research study has been reviewed and approved by an IRB [45 CFR 46.103(a) and (d) in the 2018 Requirements].

Pre-2018 Requirements

Common Rule Department or Agency Signatories:

Number	Department or Agency	CFR Citation
1	Department of Agriculture	7 CFR Part 1c
2	Department of Energy	10 CFR Part 745
3	National Aeronautics and Space Administration	14 CFR Part 1230
4	Department of Commerce	15 CFR Part 27
5	Agency for International Development	22 CFR Part 225
6	Department of Housing and Urban Development	24 CFR Part 60
7	Department of Justice	28 CFR Part 60
8	Department of Defense	32 CFR Part 219
9	Department of Education	34 CFR Partm97
10	Department of Veterans Affairs	38 CFR Part 16
11	Environmental Protection Agency	40 CFR Part 26
12	Department of Health and Human Services	45 CFR Part 46
13	National Science Foundation	45 CFR Part 690
14	Department of Transportation	49 CFR Part 11
15	Consumer Product Safety Commission	16 CFR Part 1028

Common Rule Department or Agency Executive Order or Statutory Mandate:

Number	Department or Agency	EO/Statutory Mandate
1	Department of Homeland Security	Pub. L. 108-458, title VIII, section 8306
2	Social Security Administration	Pub. L. 103-296, Section 106
3	Office of the Director of National Intelligence	Executive Order 12333
4	Central Intelligence Agency	Executive Order 12333

2018 Requirements

Common Rule Department or Agency Signatories[1]:

[1] Department of Justice intends to become an official signatory.

Number	Department or Agency	CFR Citation
1	Department of Homeland Security	6 CFR Part 46
2	Department of Agriculture	7 CFR Part 1c
3	Department of Energy	10 CFR Part 745
4	National Aeronautics and Space Administration	14 CFR Part 1230
5	Department of Commerce	15 CFR Part 27
6	Social Security Administration	20 CFR Part 431
7	Agency for International Development	22 CFR Part 225
8	Department of Housing and Urban Development	24 CFR Part 60
9	Department of Labor	29 CFR Part 21
10	Department of Defense	32 CFR Part 219
11	Department of Education	34 CFR Part 97
12	Department of Veterans Affairs	38 CFR Part 16
13	Environmental Protection Agency	40 CFR Part 26
14	Department of Health and Human Services	45 CFR Part 46
15	National Science Foundation	45 CFR Part 690
16	Department of Transportation	49 CFR Part 11
17	Consumer Product Safety Commission	16 CFR Part 1028

Common Rule Department or Agency Via Executive Order:

Number	Department or Agency	EO/Statutory Mandate
1	Office of the Director of National Intelligence	Executive Order 12333
2	Central Intelligence Agency	Executive Order 12333

2. Information Users

Information obtained on the authority of 45 CFR 46.103(b) and (f) of the pre-2018 Requirements and the authority of 45 CFR 46.103(a) and (d) of the 2018 Requirements is provided by the holder of an acceptable assurance as affirmation that (1) the institution/organization has established adequate administrative policies and procedures for protecting the rights and welfare of human subjects in research and (2) it accepts this responsibility.

3. Improved Information Technology

Institutions submitting a Federalwide Assurance (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's technology permits it to accept electronic signatures, eliminating the need for submission of paperwork, except for the rare instance in which an institution lacks the ability to submit the FWA electronically. Between January 1, 2020 and November 16, 2020, OHRP approved 3,003 FWAs, and all were submitted electronically. OHRP anticipates that nearly all institutions will continue to submit FWA information via the internet.

4. Duplication of Similar Information

The Assurance Identification/IRB Certification/Declaration of Exemption Form does not duplicate any other information collection effort that OHRP is aware of.

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 that do not already have approved assurances that would apply to proposed research (likely to be small organizations) do not have to certify IRB review until it is requested, and generally only when an award is expected to be made.

6. Less Frequent Collection

Reporting of IRB approval is required with the submission of an application or proposal, or proposed research study, 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, or proposed research study, has been approved by an 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 (unless the research does not require continuing review as permitted for some research in 45 CFR 46.109(f)(1) of the 2018 Requirements). The obligation to protect human subjects is an ongoing responsibility and not a one-time effort. In general, continuing review is required because 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. Reporting the date of continuing review and approval with the application describing those changes notifies the funding department/agency of IRB approval of the altered protocol.

7. Special Circumstances

None.

8. *Federal Register* Notice/Outside Consultation

Public comments were solicited for a 60-day comment period in the *Federal Register* (86 FR 4100) on January 15, 2021. No 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. In the past, the information collected under an assurance was considered releasable under the Freedom of Information Act (FOIA). However, 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 collected on the form.

12. Estimates of Annualized Burden Hours and Costs

12 a. Annualized Hour Burden Estimate

Specific burden estimates for the Protection of Human Subjects: Assurance Identification/IRB Certification/Declaration of Exemption Form are provided below.

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	14,000	2	0.5	14,000

Institutions seeking support for human subjects research are required by 45 CFR 46.103(f) of the Pre-2018 Requirements and 45 CFR 46.103(d) of the 2018 Requirements to certify that each application or proposal, or proposed research study, has been reviewed and approved by an IRB. The estimate of the number of respondents is based on the current number of institutions with an active OHRP-approved FWA; 13,687 (as of 11/16/2020), and projecting that the number may increase to 14,000. We estimate that there will be an average of 2 certifications per institution annually (14,000 x 2 = 28,000) and that each certification will require 30 minutes to complete, accounting for the estimated 14,000 response burden hours. This represents no change in annual burden hours compared to the previously approved burden.

12 b. Annualized Cost Burden Estimate

OHRP staff estimates an average submitter's hourly wage rate of $40 per hour. The total

annual costs for reading and understanding instructions and entering the information on the form are estimated to be $560,000 (14,000 burden hours x $40/hour = $560,000). The estimated burden dollars did not change compared to the previously approved burden.

Total Estimated Annualized Burden Table

Form name	Total Burden Hours	Hourly Wage Rate	Total Burden Dollars
Protection of Human Subjects: Assurance Identification/IRB Certification/Declaration of Exemption	14,000	$40/hour	$560,000

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 certifications of IRB approval required under HHS regulations at 45 CFR 46.103 is $467,000.

15. Program or Burden Changes

The annual burden will be $560,000, which will be no change compared to the prior information collection request.

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. Certification 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), i.e., Pre-2018 Requirements

c. 45 CFR Part 46, Subpart A (i.e., 2018 Requirements)

Attachment 2 – Protection of Human Subjects: Assurance Identification/IRB Certification/Declaration of Exemption 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 (i.e., Pre-2018Requirements)

Attachment 1.c. - Legal Authorities

45 CFR 46 (i.e., 2018 Requirements)

An official version of the 2018 Requirements in 45 CFR 46 of the July 19, 2018 edition of the e-Code of Federal Regulations can be accessed at: https://www.ecfr.gov/cgi-bin/retrieveECFR?gp=&SID=83cd09e1c0f5c6937cd9d7513160fc3f&pitd=20180719&n=pt45.1.46&r=PART&ty=HTML

Attachment 2

Proposed OMB No. 0990-0263

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