

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 to the currently approved information collection request, 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 institutions engaged in research conducted or supported by the Department of Health and Human Services (HHS) and other Common Rule signatory departments and agencies a simplified method of collecting information for IRB certification to satisfy the requirements of the Common Rule provisions at section 103, pursuant to 42 U.S.C. 289.

The form also allows institutions engaged in human subjects research supported or conducted by a Common Rule department or agency to provide identification of their assurance status, and if applicable, declaration of exempt status. The respondents for this collection are institutions engaged in research involving human subjects where the research is supported or conducted by HHS; the form can also be used by institutions engaged in research supported or conducted by other Common Rule departments or agencies. That is, 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, can also rely on use of this form if they choose to adopt this process.

Updates to the currently approved collection primarily include edits to the form's frontmatter to accurately describe the policy and purpose statements. There are two non-substantive changes to the information that the form collects. In section 6 of the form, instructions are added that if additional assurances apply to the project, a description can be provided in the comments in section 8. These instructions are added to clarify how the form can be used for cooperative research projects for which more than one Federalwide Assurance (FWA) applies. In section 7 of the form, the text has been modified to clarify that the expiration date of IRB approval only needs to be provided if applicable. The reason for the proposed change is that many research projects have no expiration.

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, as published in the 2016 edition of the Code of Federal Regulations for HHS. The pre-2018 Requirements were originally promulgated in 1991 and subsequently amended on June 23, 2005 (70 FR 36325). Tables of adoption by other Federal departments and agencies appear later in this section.

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 at section 46.103 of both the pre-2018 and 2018 Requirements require that, unless waived under 45 CFR 46.101(i), before engaging in nonexempt HHS-conducted or -supported research, each institution must provide written assurance satisfactory to the department or agency head that it will comply with the regulations and certify to the supporting department or agency that the research has been reviewed and approved by an IRB.

This information collection facilitates the required certification of IRB approval by HHS and other Common Rule departments and agencies that choose to adopt this process. It allows responding institutions to provide information regarding their assurance of compliance. Where the human subjects research is exempt, it further allows responding institutions to inform the supporting or conducting department or agency of the exemption. Including IRB certification or exempt status and assurance information in one form is intended to make it easier for institutions to provide relevant details to the supporting department or agency.

Two non-substantive changes to the information collection are intended to clarify 1) how the form can be used to collect information on multiple assurances when applicable, such as in the case of collaborative research, and 2) that not all projects will have an expiration date to report.

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 Part 97
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 Signatories¹:

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
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¹ Department of Justice intends to become an official signatory.

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 engaged in research requiring IRB certification submit such certification, per the pre-2018 and 2018 Requirements, as prescribed by the Federal department or agency supporting the research. This form provides Federal departments and agencies a simplified way to collect pertinent details of the IRB certification, for example, as part of award management activities. This information collection involves the use of a fillable, electronic form that institutions can download, file, and distribute as the department or agency prescribes.

4. Duplication of Similar Information

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

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. The form provides institutions, including small businesses, that are engaged in research conducted or supported by HHS or other Common Rule signatory departments and agencies a simplified method of collecting and submitting information about their IRB certification or exempt status, and their assurance of compliance, to the supporting department or agency. Including IRB certification or exempt status and assurance information in one form is intended to make it easier for institutions to provide relevant details to the supporting department or agency.

6. Less Frequent Collection

Reporting of IRB certification of nonexempt, HHS-supported or conducted research is required under both the pre-2018 and 2018 Requirements, unless waived. Engaged institutions also must be covered by an assurance of compliance. The form is a simplified method for institutions to document and submit this information, or declaration of

exemption when applicable, to the supporting department or agency.

7. Special Circumstances

None.

8. Federal Register Notice/Outside Consultation

Public comments were solicited for a 60-day period in the *Federal Register* published on April 1, 2024 (89 FR 22413). No comments were submitted.

9. Payment/Gift to Respondents

No payment or gifts are provided to respondents.

10. Confidentiality

The reporting of IRB certification or exempt declaration is a part of the grant or contract file and is available in many cases under the Freedom of Information Act. This information collection allows Federal departments or agencies, or their components, to obtain information pertinent to the Common Rule. Those departments/agencies/components are responsible for managing these records.

Information about Federalwide assurances is also maintained by OHRP; OHRP no longer requires public requesters to submit a Freedom of Information Act request 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	13,000	2	0.5	13,000

Certification/Declaration of Exemption				
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The estimate of the number of respondents is based on the current number of institutions with an active OHRP-approved FWA; 12,700 (as of 12/31/2023), and projecting that the number may increase to 13,000. We estimate that there will be an average of 2 certifications per institution annually (13,000 x 2 = 26,000) and that each form, including certification or declaration of exemption and assurance information, will require 30 minutes to complete, accounting for the estimated 13,000 response burden hours. This represents a 1,000 hour decrease in annual burden hours compared to the previously approved burden. The decrease is because there are 1,000 fewer institutions with an active OHRP-approved FWA compared to the prior approved information collection request.

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 \$520,000 (13,000 burden hours x \$40/hour = \$520,000). The estimated burden dollars decreased by \$40,000 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	13,000	\$40/hour	\$520,000

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 the forms, including certifications of IRB approval or exempt status and assurance information, required under HHS regulations at 45 CFR 46.103 is \$467,000.

15. Program or Burden Changes

The burden calculation has been adjusted to account for changes to the overall number of institutions that hold an active FWA with OHRP. We estimate that there will be an average of 2 certifications per institution annually (13,000 x 2 = 26,000) and that each form, including certification or declaration of exemption and assurance information, will require 30 minutes to complete, accounting for the estimated 13,000 response burden hours. This represents a 1,000 hour decrease in annual burden hours compared to the previously approved burden. The decrease is because there are 1,000 fewer institutions with an active OHRP-approved FWA compared to the prior approved 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**