Supporting Statement for the Department of Health and Human Services (HHS) Subpart C Certification Form

Background

The Office for Human Research Protections (OHRP) is requesting a three-year extension, without changes, for the currently approved collection for the OMB No. 0990-0473, HHS Subpart C Certification Form. The current form is approved through October 31, 2026. The purpose of the form is to provide a simplified, standardized procedure for institutions to electronically submit subpart C research certifications to OHRP in order to meet the regulatory requirements for including prisoners in non-exempt human subjects research that is conducted or supported by HHS. The form also simplifies the internal process used by OHRP to review and record such certifications, resulting in faster processing while reducing unnecessary and burdensome staff time. Respondents for this collection are institutions or organizations operating Institutional Review Boards (IRBs) that have enrolled or are planning to enroll prisoners in human subjects research conducted or supported by HHS.

A. Justification

1. Need and Legal Basis

Section 491[289](a) of the PHS Act states that the Secretary of HHS shall by regulation require that each entity applying for 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 IRB to review research in order to protect the rights of the human subjects of such research. The Secretary of HHS has delegated this statutory authority to the Assistant Secretary of Health, and to OHRP. OHRP is responsible for interpreting and enforcing the HHS protection of human subjects regulations at 45 CFR 46[1].

Subpart C, 45 CFR part 46, provides "Additional Protections Pertaining to Biomedical and Behavioral Research Involving Prisoners as Subjects." Subpart C provides four permissible categories of HHS-conducted or –supported research in which prisoners may be involved (45 CFR 46.306(a)(2)); an epidemiological waiver was added later, and functions as a narrow fifth category of permissible research. In approving such research, an IRB reviewing research involving prisoners to which Subpart C applies must make seven findings, including the finding that the proposed research represents one of the permissible categories of research under section 46.306(a)(2) (45 CFR 46.305(a)). Pursuant to 45 CFR 46.305(c), an institution that

[1] The pre-2018 HHS Protection of Human Subjects Regulations (or pre-2018 Requirements), codified at subpart A, 45 CFR part 46 (as amended), were originally promulgated in 1991 (56 FR 28012, 28022) and amended on June 23, 2005 (70 FR 36325). The 2018 HHS Protection of Human Subjects Regulations (or 2018 Requirements), codified at subpart A, 45 CFR part 46 (as amended), were originally published on January 19, 2017 (82 FR 7149), and amended on January 22, 2018 (83 FR 2885) and June 19, 2018 (83 FR 28497).

intends to conduct HHS-supported research involving prisoners as subjects must certify to the Secretary (through OHRP) that the IRB has approved the research in accordance with section 46.305(a) Section 46.305(c) states that "The institution shall certify to the Secretary, in such form and manner as the Secretary may require, that the duties of the [IRB] under this section have been fulfilled."

2. Information Users

In order to standardize and facilitate the processing and recordation of such certifications, the Subpart C Certification Form requests the following information, for the following purposes:

(a) The name and address of the IRB of record institution, name(s) of institutions relying on the IRB of record, and the name, title or position, mailing address, phone number, and electronic mail address of the contact person for the institution or organization providing the certification information.

(Note: submitting the following information for the contact person is optional: title or position)

Purpose: OHRP will use this information to communicate with the IRB of record institution directly to ask questions and forward information and send electronic mail to that contact person. In cases in which the reviewing IRB is acting as the IRB of record on behalf of multiple institutions, clarity regarding to which institutions the certification applies.

(b) Relevant grant number, granting institution, and name and email address of granting institution's program officer.

Purpose: This information serves to specifically identify the study at issue, and provide contact information for future correspondence for questions or notification of final disposition.

(c) OHRP Assurance number

Purpose: OHRP collects this information to be able to contact the institutional official at the site(s) engaged in human subjects research, if necessary.

(d) IRB Registration number

Purpose: OHRP uses this information to identify the specific IRB which conducted the subpart C review.

(e) Study title, name of Principal Investigator(s), and brief summary of the

protocol

Purpose: OHRP uses this information to identify the research study, responsible investigator(s), and the research context.

(f) Dates of IRB approval under Subpart C

Purpose: The dates of initial and/or Subpart C review and verify IRB review and approval, as required by 45 CFR 46.111 and 46.305(a).

(g) IRB risk determination of minimal risk or greater than minimal risk

Purpose: the IRB risk determination of minimal risk or greater than minimal risk is necessary in order for OHRP to, if appropriate, revise the permissible 45 CFR 46.306(a)(2) category of research from the one designated by the reviewing IRB. Section 46.306(a)(2) allows four permissible categories of subpart C research. Sections 46.305(a)(2)(i) and (ii) apply only to minimal risk research, while sections 46.305(a)(2)(iii) and (iv) do not have a risk limit. In circumstances in which the IRB erroneously placed the research study in categories 46.306(a)(2)(iii) or (iv) and OHRP determines that the elements of those categories are not satisfied and that the study may be more appropriately categorized as 46.305(a)(2)(i) and (ii), OHRP may change the study's category determination. In order to do so, OHRP must know the IRB's determination of risk level to ensure the study does not exceed the limitations for the revised category.

(h) The applicable permissible category or categories of research, and a rationale as to why the research represents the specified category.

Purpose: In compliance with 45 CFR 46.305(a), the IRB must determine that the proposed research represents a permissible category of research under 45 CFR 46.306(a)(2), or satisfies criteria for the epidemiological waiver.

(i) Certification that the research has been approved by an IRB that has adhered to all responsibilities prescribed for IRBs under subpart C, that the research under review represents one of the categories of permissible research under 45 CFR 46.306(a)(2) or falls within the epidemiological waiver, and that the IRB has made the determinations required by 45 CFR 46.305(a)(2)-(7).

Purpose: This certification is required by 45 CFR 46.305(c), and by the terms of the epidemiological waiver.

3. Improved Information Technology

OHRP use information technology to allow for electronic completion and submission of the collected information on the Subpart C Certification form that is automatically transferred to a database. If an institution is unable to submit the information electronically, it can contact OHRP by phone, 240-453-8141 or email, subpartc@hhs.gov, to discuss an alternative submission process.

To send a subpart C certification request to OHRP, the institution must complete and submit the Subpart C Certification form, https://oash.force.com/ohrpwebforms/s/prisoner-web-form in conjunction with a copy of the research proposal. The term "research proposal" includes:

- the IRB-approved protocol, including consent forms;
- any IRB application forms required by the IRB; and
- any other information requested or required by the IRB to be considered during IRB review.

Note: If an IRB considers the grant application during its review of the study, only submit portions of the grant application relevant to subpart C review.

4. Duplication of Similar Information

There is no duplication of similar information relevant to this information collection. OHRP is the only entity exercising regulatory oversight of the Subpart C certification requirement for SuHHS-conducted or -supported research involving prisoners.

5. Small Businesses

The information collection through the Subpart C Certification Form is simple and straightforward and represents the minimum amount of information necessary to satisfy the Subpart C certification requirements. The information collection will not have a significant economic impact on a substantial number of small entities.

6. Less Frequent Collection

The Subpart C Certification Form must be submitted prior to any HHS-conducted or -supported non-exempt human subjects research interaction or intervention with prisoners. The certification must be resubmitted only if there is a change in the IRB-approved category of permissible research (45 CFR 46.305(a)).

7. Special Circumstances

None.

8. Federal Register Notice/Outside Consultation

A notice announcing a 60-day period for public comments on this information collection was published in the *Federal Register* (91 FR 40543) on July 2, 2026. The comment period ended on August 31, 2026. There were no comments submitted.

9. Payment/Gift to Respondent

No payments or gifts are provided to the respondents.

10. Confidentiality

The public is required to submit a Freedom of Information Act (FOIA) request to request non-public Subpart C Certification Form information.

11. Sensitive Questions

No sensitive information is being collected on the Subpart C Certification form.

12. Burden Estimate (Total Hours & Wages)

The estimate of the number of respondents is based upon the current number of institutions certifying HHS-conducted or -supported subpart C human subjects research to OHRP. In 2025, OHRP received fifty-one certifications from thirty-eight institutions or organizations and one hundred percent of the respondents submitted their certification information electronically. We project that annually, forty institutions will submit certifications. Most respondents will submit the form twice annually, however some respondents may submit the form 3 times annually. Consistent with 5 CFR 1320.5(a)(1)(iv)(5), therefore, we believe this estimate represents the total annual reporting and recordkeeping burden that will result from the collection of information.

The burden is estimated to average one hour per Subpart C Certification Form and the total annual burden hours are projected to be eighty-five.

12a. Estimated Annualized Burden Hours

Form name	Respondents	Number of Respondents	Number of Responses per Respondent	Average Burden per Response (in hours)	Total Burden hours
Subpart C Certification Form	Institutions or Organizations operating Institutional Review Boards (IRBs)	40	2.13	1.0	85
Total					85

We expect that respondents will be research staff persons (to include IRB administrators and Human Protection Administrators), at organizations and institutions. The hourly wage is estimated to be an average $55.80 and the total estimated annualized burden cost is estimated to be $2,681.25

12b. Estimated Annualized Burden Costs

Form Name	Number of Respondents	Burden Hours	Hourly Wage	Total Respondent Costs
Subpart C Certification Form	40	85	$55.80	$4,743.00
Total				**$4,743.00**

The total annualized cost for completing the HHS Subpart C Certification form is $14,229.

OHRP estimates an average submitter's hourly wage rate of $55.80 per hour (for institutional officials, administrators, administrative staff). This is based on the 2026 OPM hourly pay tables and is equivalent to a GS 12, step 5. The total annual costs for completing and submitting certification information electronically is estimated to be 85 burden hours X $55.80/hour = $4,743 plus a 200% fully loaded rate of $9,486 accounting for benefits, etc.

(85 burden hours X 55.80/hour) = $4,743 plus a 200% fully loaded rate of $9,486 that accounts for benefits, etc.

$4,743 + $9,486= **$14,229**

13. Capital Costs (Maintenance of Capital Costs)

There are no direct capital costs to respondents other than the time to review the instructions and to complete the Subpart C Certification Form.

14. Cost to Federal Government

The estimated annual Federal costs is $137,701: $54,701 for reviewing and accepting Subpart C certifications and $87,000 for operating the database.

15. Program or Burden Changes

The burden calculation has been adjusted to account for the number of institutions that submitted for certifications, average responses per institution annually, and the time required to complete a certification. We estimate that an average of forty

institutions will submit certifications: thirty-five of the institutions will submit two certifications (35 x 2= 70); five of the forty institutions will submit three certifications (5 x 3= 15); and that each certification will require 1 hour to complete, accounting for the estimated 85 response burden hours. This represents an increase in annual burden hours of 20 hours compared to the previously approved burden. The change accounts for agency adjustments based on data on the number of institutions that submitted certifications.

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. 45 CFR 46 (pre-2018 Requirements)
c. 45 CFR 46 (2018 Requirements)

Attachment 2 – Subpart C Certification Form