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

Background

The Office for Human Research Protections (OHRP) is requesting approval of the Department of Health and Human Services (HHS) Subpart C Research Certification Form. This form will facilitate the collection of information relevant to an institutional request for OHRP authorization of research involving prisoners; the information in the form will be entered into OHRP's prisoner research database, and will be used by OHRP to draft a response certification letter back to the institution. This is a new information collection request.

The Subpart C Research Certification Form will provide institutions with a simplified, standardized procedure for submitting subpart C research certification requests to OHRP in order to obtain authorization to include prisoners in human subjects research. The form will also simplify the internal process used by OHRP to review and record such certifications in the prisoner research database, which is then used to draft the OHRP response certification letter back to the institution, resulting in faster processing while reducing unnecessary and burdensome staff time.

The respondents for this collection are institutions or organizations operating Institutional Review Boards (IRBs) that have approved enrollment, or are planning to approve enrollment, of prisoners in human subjects research conducted or supported by HHS.

A. Justification

1. Need and Legal Basis

   Section 491(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 and welfare 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 part 46.

   45 CFR part 46, subpart C, 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 permissibly may be involved (see 45 CFR 46.306(a)(2)) and a later-added epidemiological waiver which functions as a narrow fifth category of permissible research. An IRB reviewing proposed research under 45 CFR 46.306(a)(2) involving prisoners 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). Pursuant to 45 CFR 46.305(c), an institution that intends to conduct HHS-supported research involving prisoners as subjects must certify to the Secretary (through OHRP) that the IRB has made the seven findings required under 45 CFR 46.305(a); 45 CFR 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."

Under OHRP's current practice, the institution must send OHRP a certification request letter, which must include the name and address of the institution, specific identification of the research protocol, and relevant materials for review. After reviewing the materials, OHRP determines whether the research conforms to a permissible category of research, and issues a letter concurring or non-concurring with the institution's cited provision. The concurrence from OHRP authorizes the inclusion of prisoner-subjects in human subjects research, and allows the release of HHS funding for such research.

In order to review a certification request regarding research subject to subpart C, and under its authority at 45 CFR 46.115(b), OHRP requires the responsible institution to submit to OHRP a copy of the research proposal so that OHRP can determine whether the proposed research involves one of the categories of research permissible under 45 CFR 46.306(a)(2). For purposes of certification, the term "research proposal" includes:

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

2. Information to be collected

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

(a) The name of institution, and name, title or position, mailing address, phone number, and electronic mail address of the contact person 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 institution directly to ask questions, forward information, and send electronic mail to the institution through that contact person.

(b) Relevant grant number, granting institution, and name 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) IRB Registration number

Purpose: OHRP uses this information to identify the specific IRB which performed the subpart C review. OHRP posts a list of registered IRBs on its website, including the name and location of each IRB and the name and location of the organization operating the IRB.

(d) OHRP Assurance number

Purpose: OHRP collects this information to be able to contact the institutional official at the site engaged in human subjects research, if necessary. Institutions that only serve as an IRB will not have this number.

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

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

(f) Dates of IRB approval under Subpart C

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

(g) 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.

(h) 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 part 46.305(a)(2)-(7).

Purpose: This certification is required by 45 CFR 46.305(c).

(i) Names of institutions (and associated institutional Assurance numbers) relying on the reviewing IRB as the IRB of record for the subpart C review and certification of this study.

Purpose: In cases in which the certifying IRB is acting as the IRB of record on behalf of multiple institutions, this provides clarity regarding which institutions have fulfilled the certification requirement.

3. Improved Information Technology

OHRP's current practice is to require that subpart C certifications be submitted electronically. This practice will be continued, and the subpart C certification will be submitted to subpartc@hhs.gov. If an institution or organization lacks the ability to submit a subpart C certification electronically, it should contact OHRP and may send its certification information in writing to OHRP.

4. Duplication of Similar Information

There is no duplication of similar information relevant to this information collection. OHRP is the only entity overseeing application of 45 CFR part 46 to HHS-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 OHRP 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 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

   Public Comments were solicited for a 60-day period in the Federal Register published on September 13, 2019 (84 FR178, p. 48359) on this proposed collection. No comments were 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 database information. The information from the form in the database is not affirmatively made public due to policy considerations; it will only be made public to the extent required by the FOIA in response to a FOIA request.

    The Subpart C Certification Form does not collect information that is subject to the Privacy Act; all information collected is about institutions (entities). Although the names and contact information described in 2(a), (b), and (e) identify particular individuals, each individual is merely serving as an institution's point of contact or Principal Investigator. The described purposes for which such names and contact information are used concern or affect only the institutions.

11. Sensitive Questions

    No sensitive information is being collected by 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 2018, 100 percent of the respondents submitted their certification information electronically.

    The burden is estimated to average one hour per Subpart C Certification Form. If on average 80 previous respondents submit certifications each year, the total annual burden hours are projected to be 80 hours.

Estimated Annualized Burden Table

Type of Respondent	No. of Respondents	No. Responses per Respondent	Average Burden per Response (in hours)	Total Burden Hours
Subpart C Certification Forrm	40	2	1	80
Total				**80**

The estimate of the hours per response assumes that all respondents will complete the Subpart C Certification Form and email it to subpartc@hhs.gov. The time estimate includes an estimate of the time needed to (i) read and understand the instructions for completing the IRB Registration Form; (ii) collect the information to complete the form; and (iii) enter the information requested on the IRB Registration Form. Based on OHRP's experience in processing current subpart C certifications, most of the respondents will be administrative staff persons within organizations and institutions. The hourly wage is estimated to be $17.41 and the total burden cost is estimated to be $1,392.80.

Total Estimated Annualized Burden Table

Type of Respondent	No. of Respondents	No. Responses per Respondents	Hourly Wage Rate	Total Burden Dollars
Subpart C Certification Form	40	2	$17.41	$1,392.80

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 for reviewing and accepting Subpart C Certification Forms is $42,914.00.

15. Program or Burden Changes

This is the initial request, therefore there are no changes to note.

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. Section 289 of the Public Health Service Act
- b. Title 45 Code of Federal Regulations Part 46, Subpart C

Attachment 2- Subpart C Research Certification Form