

Supporting Statement for HHS/OASH Consultation Process, Institutional Review Board (IRB) Records

Background

The Office for Human Research Protections (OHRP) is requesting reinstatement of the Office of Management and Budget (OMB) information collection request, OMB No. 0990-0481, For HHS/OASH Consultation Process, Institutional Review Board (IRB) Records, with no changes, for a three-year period. The previous information collection was approved by OMB on February 14, 2022, and expired on February 28, 2025. The purpose of the collection is for OHRP to receive IRB records when an IRB or an institution requests an HHS consultation process, for proposed research that is not otherwise approvable by an IRB involving, respectively: (1) pregnant women, human fetuses or neonates; (2) prisoners; or, (3) children, as subjects. OHRP uses this information to determine whether or not an HHS consultation process should be performed.

A. Justification

1. Need and legal basis

The Department of Health and Human Services (HHS) Protection of Human Subjects regulations at 45 CFR part 46 include three subparts that have provisions that, in the event IRBs are unable to approve certain categories of research, permit IRBs or institutions to refer such proposed research to HHS for further consideration as to whether the research may be conducted (referred to in this supporting statement as “HHS consultation process”). The Secretary of HHS¹ may determine that such research can be conducted or supported by HHS, after consulting with experts and meeting other procedural requirements.

The provisions in the above-referenced subparts are:

(1) 45 CFR part 46, subpart B (Additional Protections for Pregnant Women, Human Fetuses and Neonates Involved in Research), §46. 207 – Research not otherwise approvable which presents an opportunity to understand, prevent, or alleviate a serious

¹ The Secretary’s authority has been delegated to the Assistant Secretary for Health (ASH), and to the Director, OHRP, 44 FR 46318 (August 7, 1979); see 67 FR 10216 (March 6, 2002).

problem affecting the health or welfare of pregnant women, fetuses, or neonates.²

(2) 45 CFR part 46, subpart C (Additional Protections Pertaining to Biomedical and Behavioral Research Involving Prisoners as Subjects), §46.306 (iii) and (iv) – Permitted research involving prisoners,

- §46.306 (iii), Research on conditions particularly affecting prisoners as a class (for example, vaccine trials and other research on hepatitis which is much more prevalent in prisons than elsewhere; and research on social and psychological problems such as alcoholism, drug addiction, and sexual assaults) provided that the study may proceed only after the Secretary has consulted with appropriate experts including experts in penology, medicine, and ethics, and published notice, in the Federal Register, of his intent to approve such research;
- §46.306 (iv) Research on practices, both innovative and accepted, which have the intent and reasonable probability of improving the health or well-being of the subject. In cases in which those studies require the assignment of prisoners in a manner consistent with protocols approved by the IRB to control groups which may not benefit from the research, the study may proceed only after the Secretary has consulted with appropriate experts, including experts in penology, medicine, and ethics, and published notice, in the Federal Register, of the intent to approve such research.

² The Secretary will conduct or support research that the IRB does not believe meets the requirements of §46.204 or §46.205 only if:

(a) The IRB finds that the research presents a reasonable opportunity to further the understanding, prevention, or alleviation of a serious problem affecting the health or welfare of pregnant women, fetuses or neonates; and

(b) The Secretary, after consultation with a panel of experts in pertinent disciplines (for example: science, medicine, ethics, law) and following opportunity for public review and comment, including a public meeting announced in the FEDERAL REGISTER, has determined either:

(1) That the research in fact satisfies the conditions of §46.204, as applicable; or

(2) The following:

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) The research presents a reasonable opportunity to further the understanding, prevention, or alleviation of a serious problem affecting the health or welfare of pregnant women, fetuses or neonates;

(ii) The research will be conducted in accord with sound ethical principles; and

(iii) Informed consent will be obtained in accord with the informed consent provisions of subpart A and other applicable subparts of this part.

(3) 45 CFR part 46, subpart D (Additional Protections for Children Involved as Subjects in Research), §46.407 – Research not otherwise approvable which presents an opportunity to understand, prevent, or alleviate a serious affecting the health or welfare of children.³

In order for OHRP, on behalf of the Secretary of HHS, to determine if a consultation process should be performed, the referring institution or IRB must submit information supporting its request.

2. Purpose and Use of the Information

If an IRB has determined that a research protocol meets the conditions to refer it to OHRP to be considered under an HHS consultation process, the IRB or its institution may submit the research protocol and supporting information to OHRP. The information that must be submitted to OHRP is the research protocol, the informed consent, parental permission or child assent documentation (if relevant), and other relevant IRB records (e.g., IRB minutes).

OHRP uses this information to determine whether or not an HHS consultation process should be performed.

3. Use of Improved Information Technology and Burden Reduction

³ HHS will conduct or support research that the IRB does not believe meets the requirements of §46.404, §46.405, or §46.406 only if:

(a) the IRB finds that the research presents a reasonable opportunity to further the understanding, prevention, or alleviation of a serious problem affecting the health or welfare of children; and

(b) the Secretary, after consultation with a panel of experts in pertinent disciplines (for example: science, medicine, education, ethics, law) and following opportunity for public review and comment, has determined either:

(1) that the research in fact satisfies the conditions of §46.404, §46.405, or §46.406, as applicable, or (2) the following:

(i) the research presents a reasonable opportunity to further the understanding, prevention, or alleviation of a serious problem affecting the health or welfare of children;

(ii) the research will be conducted in accordance with sound ethical principles;

(iii) adequate provisions are made for soliciting the assent of children and the permission of their parents or guardians, as set forth in §46.408.

This information collection imposes no technological or standard format requirements for respondents. We encourage automated technology if possible.

4. Efforts to Identify Duplication and Use of Similar Information

There is no duplication resulting from the information collection.

5. Impact on Small Businesses or Other Small Entities

Support of research activities involving human subjects extends to small businesses. The collection of information requested will not have a significant economic impact on the small businesses.

6. Consequences if Information is Collected Less Frequently

Without this information collection, OHRP would not be able to determine whether or not an HHS consultation process should be performed.

7. Special Circumstances Relating to the Guidelines of 5 CFR 1320.5

There are no special circumstances for this collection of information.

8. Consultation Outside of Agency

Public comments for this information collection were solicited for a 60-day period in the *Federal Register* published on January 6, 2025 (90 FR 658). No comments were submitted.

9. Explanation of Any Payment or Gift to Respondents

No payments or gifts will be provided to respondents of this information collection.

10. Assurance of Confidentiality Provided to Respondents

Collected information will be kept private to the extent required by law.

11. Justification for Sensitive Questions

No sensitive information is being collected.

12. Estimates of Annualized Burden Hours and Costs

12 a. Annualized Reporting Burden Estimate

As of November 27, 2024, a total of 5,205 active IRBs that indicate they review HHS-conducted or supported research are registered with OHRP. The expectation is that OHRP may receive up to ten referrals a year that involve 1) pregnant women, human fetuses and neonates; (2) prisoners; or, (3) children, as subjects that are not otherwise approvable by an IRB. We assume that each respondent would need an hour to submit the required information. If there is an average of 10 respondents per year, the total annual burden hours are projected to be 10 hours.

Estimated Annualized Burden Hours

45 CFR part 46 - HHS Consultation Process Provision	Respondent Type	No. of Respondents	No. of Respondents	Average Burden per Response (in hours)	Total Burden Hours
subpart B, §46.207	IRBs	3	1	1	3
subpart C, §46.306 (iii) and (iv)	IRBs	3	1	1	3
subpart D, §46.407	IRBs	4	1	1	4
TOTAL					10

12b. Annualized Cost Burden Estimate

Estimated Annualized Respondents Costs

45 CFR part 46 - HHS Consultation Process Provision	Respondent Type	Total Burden Hours	Hourly Wage Rate	Total Respondent Costs
subpart B, §46.207	IRBs	3	\$53.87	\$161.61

subpart C, §46.306 (iii) and (iv)	IRBs	3	\$53.87	\$161.61
subpart D, §46.407	IRBs	4	\$53.87	\$215.48
TOTAL				\$538.70

OHRP estimates an average respondent hourly wage rate of \$53.87 per hour (for institutional officials, administrators, administrative staff). This is based on the 2024 OPM hourly pay tables and is equivalent to a GS 12, step 5. The total annual cost for providing information for the process is estimated to be 10 burden hours X 53.87/hour = \$538.70.

13. Capital Costs (Maintenance of Capital Costs)

There are no direct capital costs to respondents.

14. Annualized Cost to the Federal Government

The estimated annual cost to the Federal government for reviewing collected information for each set of IRB records that are submitted is \$9,981.00.

15. Program or Burden Changes

There are no adjustments or changes to the burden hour calculations with this request for renewal.

16. Publication and Tabulation Dates

When OHRP determines that an HHS consultation process will be performed, the collected information (e.g., research protocol and supporting materials) will be posted for public review and comment.

17. Reasons Display of OMB Expiration Date is Inappropriate

The program agrees to show the approval date.

18. Exceptions to Certification for Paperwork Reduction Act Submissions

There are no exceptions to the certification.

ATTACHMENT

Attachment 1 - Legal Authority

a. 45 CFR part 46

<https://www.ecfr.gov/current/title-45/subtitle-A/subchapter-A/part-46?toc=1>

Attachment 1 - Legal Authority

a. 45 CFR part 46

Access here: <https://www.ecfr.gov/cgi-bin/retrieveECFR?gp=&SID=83cd09e1c0f5c6937cd9d7513160fc3f&pitd=20180719&n=pt45.1.46&r=PART&ty=HTML>