Supporting Statement for the Department of Health and Human Services (HHS) Institutional Review Board (IRB) Registration Form

Background

The Office for Human Research Protections (OHRP) and the Food and Drug Administration (FDA) are requesting reinstatement with change for the Office of Management and Budget (OMB) No. 0990-0279, Department of Health and Human Services (HHS) Institutional Review Board (IRB) Registration Form. The previous information collection was approved by OMB on June 27, 2022, and expired on June 30, 2025. The reinstatement with change request involves implementing a burden reducing change in the 2018 Requirements at 45 CFR 46.103, eliminating the requirement to provide a list of IRB members to HHS. This change is anticipated to result in a shorter, simplified IRB registration process for respondents.

The form was modified in 2009 to be consistent with IRB registration requirements that were adopted in July 2009 by the Office for Human Research Protections (OHRP) and the Food and Drug Administration (FDA), respectively. At that time, OMB recommended that the information collection request required by OHRP's and FDA's IRB registration requirements be combined because the information would be submitted using the same form. A similar mechanism has been used since then and is proposed to continue with this revision request for OMB form No. 0990-0279.

The purpose of the form is to provide a simplified procedure for: (1) IRBs to satisfy the requirements for IRB registration at 45 CFR part 46, subpart E; and (2) IRBs in the United States (US) to satisfy the FDA requirements for IRB registration at 21 CFR 56.106.

Institutions engaged in nonexempt human subjects research conducted or supported by HHS, or another Common Rule department or agency, are required by the terms of the Federalwide Assurance (FWA) to rely upon only IRBs registered with OHRP for review of research to which the FWA applies. In this way, OHRP's FWA process, established pursuant to the requirements for assurances at 45 CFR 46.103, is linked to the regulatory requirements for IRB registration.

The respondents for this information collection are institutions or organizations operating IRBs that review human subjects research conducted or supported by HHS; or, in the case of FDA's requirements, each IRB in the United States that reviews clinical investigations regulated by FDA under sections 505(i) or 520(g) of the Federal Food, Drug and Cosmetic Act; and each IRB in the United States that reviews clinical investigations that are intended to support applications for research or marketing permits for FDA-regulated products. Many of the IRBs also review research conducted or supported by other Federal departments and agencies that have adopted the Federal Policy for the Protection of Human Subjects (the Common Rule).

A. Justification

1. Need and Legal Basis

OHRP:

OHRP is the HHS component charged with fulfilling the statutory mandates of the Public Health Service Act, as amended (PHS Act) and enforcing HHS regulations at 45 CFR part 46.

> Section 491 [289](a) of the PHS Act states:
> "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."

Pursuant to the requirements of the PHS Act, HHS has promulgated regulations for the protection of human subjects at 45 CFR part 46. These regulations require that each institution engaged in research covered by the policy shall provide written assurance satisfactory to the department or agency head that it will comply with the requirements of 45 CFR part 46, including the requirement that an institution certify to the department or agency head that the research has been reviewed and approved by an IRB (if such certification is required). [45 CFR 46.103(a) and (d)].

OHRP's 2009 IRB Registration requirements are included in subpart E of 45 CFR part 46. The requirement for a list of IRB members to be provided to OHRP is included in the pre-2018 Common Rule, or the "pre-2018 Requirements"[1] at 45 CFR 46.103(b)(3). However, the 2018 Requirements[2] at 45 CFR 46.103 do not include the requirement that appears in the pre-2018 Common Rule at 45 CFR 46.103(b)(3) that a list of the IRB members and their qualifications be included in an institution's assurance. Instead, the 2018 Requirements at 45 CFR 46.108(a)(2) require that the

[1] The pre-2018 Requirements was originally promulgated in 1991 (56 FR 28012, 28022) and amended on June 23, 2005 (70 FR 36325). The 2018 Protection of Human Subjects Regulations (or 2018 Requirements), codified at subpart A, 45 CFR part 46 (as amended), was 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).

[2] The revised Common Rule (also referred to as the "2018 Requirements"), codified at subpart A, 45 CFR part 46 (as amended), was 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). In this supporting statement, 45 CFR part 46 citations are to the 2018 Requirements unless specified otherwise.

IRB prepare and maintain a current list of IRB members internally. With this revision, OHRP is requesting that IRB roster member information no longer be collected on the IRB registration form to reflect 2018 Requirements and reduce burden on respondents. Updates to the software applications OHRP uses to manage the IRB registration process will be deployed to enable such changes.

HHS regulations at 45 CFR 46, subpart E, require, among other things, each IRB that reviews research involving human subjects conducted or supported by HHS to be registered with HHS.

The OHRP final IRB Registration Rule that was published in the Federal Register on January 15, 2009 (74 FR 2399) and became effective on July 14, 2009, 45 CFR 46, subpart E – Registration of Institutional Review Boards, requires organizations and institutions to submit the following information to HHS when registering an IRB:

- name, mailing address, and street address (if different from the mailing address) of the institution or organization operating the IRB(s); and the name, mailing address, phone number, facsimile number, and email address of the senior officer or head official of that institution or organization who is responsible for overseeing activities performed by the IRB [45 CFR 46.502(a)];
- name, mailing address, phone number, facsimile number, and electronic mail address of the contact person providing the registration information [45 CFR 46.502(b)];
- name, if any, assigned to the IRB by the institution or organization, and the IRB's mailing address, street address (if different from the mailing address), phone number, facsimile number, and electronic mail address [45 CFR 46.502(c)];
- name, phone number, and electronic mail address of the IRB chairperson [45 CFR 46.502(d)];
- approximate numbers of: (i) all active protocols; and (ii) active protocols conducted or supported by HHS. For the purpose of the regulation, an "active protocol" is any protocol for which the IRB conducted an initial review or continuing review at a convened meeting or under an expedited review procedure during the preceding twelve months [45 CFR 46.502(e)]; and,
- approximate number of full-time equivalent positions devoted to the IRB's administrative activities [45 CFR 46.502(f)].

Subpart E regulations at 45 CFR 45.505 provide requirements for when an IRB registration must be updated or renewed. OHRP collects information for IRB registration updates or renewals using the IRB Registration Form, (OMB) No. 0990-0279.

FDA:

The Food and Drug Administration (FDA) in 2009 requested OMB approval for two collections of information associated with IRB registration. The first collection of information was represented by the OMB form 0990-0279 developed jointly by OHRP and by FDA, which was approved by OMB for use through June 30, 2012 and again through June 30, 2015, October 31, 2018 and February 28, 2022.

Additionally, FDA proposed to amend its regulations pertaining to IRBs. The final rule was published in the Federal Register (74 FR 2358) on January 15, 2009 and became effective on July 14, 2009; it requires IRBs to register at a website accessible on the OHRP website and maintained by OHRP.

FDA took this action pursuant to a recommendation from the Office of the Inspector General, Department of Health and Human Services, to require all IRBs to register with the federal government to develop a more streamlined, coordinated, and probing means of assessing IRB performance and to enhance the government's ability to identify and respond to emerging problems. Information on registered IRBs makes it easier for FDA to send educational information to IRBs and to identify IRBs for inspection.

Insofar as its final rule is concerned, FDA requested approval from OMB of a collection of information requirement in "Institutional Review Boards; Registration and Use Requirements" codified at 21 CFR 56.106. The collection of information associated with the rule was projected to be 8,750 hours.

21 CFR 56.106(c) - Reporting

This provision requires an IRB to submit an initial registration to HHS. The initial registration may occur at any time, but each IRB must renew its registration every 3 years.

21 CFR 56.106(b) describes the contents of the registration information, such as:

- The name, mailing address, and street address (if different from the mailing address) of the institution operating the IRB and the name, mailing address, phone number, facsimile number, and electronic mail address of the senior officer of that institution who is responsible for overseeing activities performed by the IRB;
- The IRB's name, mailing address, street address (if different from the mailing address), phone number, facsimile number, and electronic mail address; each IRB chairperson's name, phone number, and electronic mail address; and the name, mailing address, phone number, facsimile number, and electronic mail address of the contact person providing the registration information.
- The approximate number of active protocols involving FDA-regulated products reviewed. For purposes of this rule, an "active protocol" is any

protocol for which an IRB conducted an initial review or a continuing review at a convened meeting or under an expedited review procedure during the preceding 12 months; and
- A description of the types of FDA-regulated products (such as biological products, color additives, food additives, human drugs, or medical devices) involved in the protocols that the IRB reviews.

21 CFR 56.106(e) - Reporting

This provision requires IRBs to revise their registration information:
- within 90 days if the IRB's contact or chairperson information changes;
- within 30 days if the IRB decides to review new types of FDA-regulated products, disband or discontinue reviewing clinical investigations regulated by FDA; or
- for all other information changes, when the IRB renews its registration.

The requested revisions to the IRB Registration Form and instructions also include updates to webpage links, OHRP contact information, and instructions for accurately completing current application fields on the IRB registration form. Brief instructions added in parenthetical descriptions include instructions for providing accurate IRB information, such as the approximate number of protocols the IRB reviews, and for providing accurate IORG and IRB panel names and addresses.

2. Purpose and Use of Information Collection

OHRP:

The IRB Registration Form collects the following information from institutions or organizations operating IRBs that are regulated by OHRP, for the following purposes:

(a) The name, location, mailing address, street address (if different from the mailing address, and OHRP-assigned number (called an IORG number) of each institution or organization that has registered an IRB. The IORG number is a unique number assigned by OHRP to an institution or organization the first time that it registers an IRB. This number is to be provided to OHRP whenever an institution or organization subsequently updates or renews the existing registration of any of its IRBs or registers a new IRB.

Purpose: OHRP uses this contact information to identify the institution or organization operating the IRB(s), to conduct compliance oversight activities, and to provide educational information to that institution. Provision of the IORG number allows OHRP to efficiently track and organize all IRB registration information submitted by the same institution or organization.

(b) The name, earned degree(s), title or position, mailing address, phone number, facsimile numbers, and electronic mail address of the institution's or organization's senior officer or head official who is responsible for overseeing activities performed by the IRB.

(Note: submitting the following information for the institution's or organization's senior officer or head officer is optional: middle initial, earned degree(s), title or position.)

Purpose: This information is collected so that OHRP can contact that person directly if human subjects protections issues or problems arise that involve, or could involve, the institution, to conduct compliance oversight activities, and to forward educational information to that person.

(c) The name, earned degree(s), title or position, mailing address, phone number, facsimile number, and electronic mail address of the contact person providing the registration information.

(Note: submitting the following information for the contact person is optional: middle initial, earned degree(s), title or position.)

Purpose: OHRP will use this information to communicate with that person directly on routine issues, forward information, and send electronic mail to that contact person.

(d) The IRB Registration number, IRB name, if any, assigned to the IRB by the institution or organization operating the IRB, the IRB mailing address (if different from the mailing address of the institution or organization operating the IRB(s)), street address (if different from the mailing address of the IRB), phone number, facsimile number, and electronic mail address.

Purpose: OHRP uses this information to identify the specific IRBs for which registration information is provided. 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.

(e) The IRB chairperson's name, earned degree(s), title or position, name of institution or organization (if different from the institution or organization operating the IRB), mailing address (if different from the mailing address of the institution or organization operating the IRB), phone number, facsimile number, and electronic email address.

(Note: submitting the following information for the IRB chairperson is optional: earned degree(s), title or position, name of institution or organization, mailing address, and facsimile number.)

Purpose: Collection of this information will help OHRP to contact the IRB chairperson, if necessary, on human subjects protections issues, conduct compliance oversight activities, and send educational material.

(f) The approximate number of all active research protocols and active protocols conducted or supported by HHS.

Purpose: OHRP uses this information to more effectively assign its educational and compliance oversight resources and to obtain insight into an IRB's activity level. OHRP considers an active protocol to be any protocol for which an IRB conducted an initial or continuing review at a convened meeting or under an expedited review procedure during the preceding 12 months.

(g) The approximate number of full-time equivalent (FTE) positions devoted to the IRB's administrative activities.

Purpose: This information is collected to provide OHRP with information related to the institution's fulfillment of 45 CFR 46.108(a)(1) of the 2018 Requirements, which requires that each IRB have access to sufficient staff to support the IRB's review and recordkeeping duties.

FDA:

In brief, the IRB Registration Form collects the following information from FDA-regulated IRBs:

- The name, mailing address, and street address (if different from the mailing address) of the institution operating the IRB and the name, mailing address, phone number, facsimile number, and electronic mail address of the senior officer of that institution who is responsible for overseeing activities performed by the IRB;

- The IRB's name, mailing address, street address (if different from the mailing address), phone number, facsimile number, and electronic mail address; each IRB chairperson's name, phone number, and electronic mail address; and the name, mailing address, phone number, facsimile number, and electronic mail address of the contact person providing the registration information.
- The approximate number of active protocols involving FDA-regulated products reviewed. For purposes of this rule, an "active protocol" is any protocol for which an IRB conducted an initial review or a continuing review at a convened meeting or under an expedited review procedure during the preceding 12 months; and
- A description of the types of FDA-regulated products (such as biological products, color additives, food additives, human drugs, or medical devices) involved in the protocols that the IRB reviews.

FDA IRB regulations at 21 CFR 56.106(c) provide that each IRB must renew its registration every 3 years. FDA regulations at 21 CFR 56.106(e) also provide requirements for how an IRB revises its registration information. This information is collected using the IRB Registration Form, (OMB) No. 0990-0279.

FDA uses the registration information to identify IRBs for FDA inspection and to convey information to IRBs.

3. Improved Information Technology and Burden Reduction

OHRP:

Institutions or organizations that register one or more IRBs submit all information for initial IRB registration, or IRB registration updates and renewals, via the eFile web application on the OHRP website. This eliminates the need for submission of paperwork, except for rare institutions that lack the ability to submit their IRB registration electronically. All IRB registration applications were submitted electronically for the current approved collection period and OHRP anticipates that all institutions will continue to submit information electronically.

FDA:

The collection of information relies primarily on the use of electronic collection techniques. FDA's IRB registration requirements at 21 CFR 56.106(d) allow IRBs to register in writing if they lack the ability to register electronically.

4. Efforts to Identify Duplication and Use of Similar Information

The IRB Registration Form does not duplicate any other information collection by OHRP or by FDA**.**

5. Impact on Small Businesses or Other Small Entities

   The information collection through the IRB Registration Form represents the minimum amount of information necessary to satisfy OHRP and FDA IRB registration requirements. The information collection will not have a significant economic impact on small entities.

6. Consequences of Collecting the Information Less Frequently

   OHRP:

   The information collection schedule supports agency regulations pertaining to IRB registration requirements as set forth in the HHS regulations at 45 CFR part 46, Subpart E.

   FDA:

   The information collection schedule supports agency regulations pertaining to IRB registration requirements as set forth in the FDA regulations at 21 CFR 56.106.

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

   There are no special circumstances for this information collection.

8. Comments in Response to the Federal Register Notice/Outside Consultation

   OHRP and FDA:

   Comments on this information collection were solicited in the *Federal Register* (90 FR 21784) for a 60-day period, which ended on 07/21/2025. There were no comments submitted.

9. Explanation of any Payment/Gift to Respondents

   OHRP and FDA:

   No payments or gifts are provided to the respondents.

10. Confidentiality

    OHRP and FDA:

The database used to maintain and store IRB registration information, known as the Human Assurance Tracking System (HATS), uses Microsoft SQL Server tables stored on a server that is hosted and maintained by the Center for Information Technology, National Institutes of Health. The HATS application screens and associated IRB registration tables/server utilize a username/password and appropriate session variables to access and modify the IRB registration information. Without the appropriate username/password, unauthorized users will not gain access to the IRB registration database. Requests for IRB Registration information, when provided, are presented via spreadsheet or printed reports or disk files containing extracted information.

The public can access some IRB registration information from the internet at http://ohrp.cit.nih.gov/search/search.aspx?styp=bsc (e.g., the name and location of IRB organizations and their IRB(s) name, date of last IRB membership update, IRB organizations and their IRB(s) status (active or deactivated) and expiration date). The public would need to contact OHRP to request non-public IRB registration information (e.g., the name or contact information of an IRB organization's senior officer, contact person or IRB chairperson).

11. Sensitive Questions

OHRP and FDA:

No sensitive information is being collected by the IRB registration system.

12. Estimates of Annualized Hour and Cost Burden

OHRP and FDA:

The estimate of the number of respondents is based upon the current number of IRBs registered with HHS, approximately 4,988 (as of July 13, 2026), and projecting that the number of respondents may increase to 5,350. Of the approximately 4,988 registered IRBs, 100% submitted their registration information electronically.

Of the 5,350 projected respondent IRBs, approximately 350 institutions or organizations are expected submit IRB registration information for the first time, and up to 5,000 institutions or organizations are expected to update or renew their existing IRB registration once each year. The burden is estimated to average 0.5 hours for an initial IRB registration, and for updating or renewing the registration of a previously registered IRB. If on average 5,000 previous respondents submit information once each year, and on average 350 submit new registration information one time a year, the total annual burden hours are projected to be 2,675 hours.

12A. Total Estimated Annualized Burden Table

Form	Respondents	Number of Respondents	Number of responses per respondent	Average burden per response (in hours)	Total Burden hours
IRB Registration Form 0990-0279	Institutions or Organizations that operate IRBs	5,350	1	0.5	2,675
Total		5,350	1	0.5	2,675

The estimate of the hours per response assumes that all respondents will complete the IRB Registration Form via internet on an interactive page on the OHRP website. 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.

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 reading and understanding instructions and entering the information on the IRB Registration Form via the internet are estimated to be 2,675 burden hours X $55.80/hour = $149,265, plus a 200% fully loaded rate of $298,530 that accounts for benefits, etc.

($149,265+$298,530= **$447,795**)

12B. Total Estimated Annualized Burden Table

Form	Total Burden Hours	Hourly Wage Rate	Total Burden Dollars
IRB Registration Form 0990-0279	2,675	$55.80	$149,265
Total	2,675	$55.80	$149,265

13. Estimates of Other Total Annual Cost Burden to Respondents or Recordkeepers/Capital Costs

There are no costs to respondents other than the time to review the instructions and to complete the IRB Registration form.

14. Annualized Cost to Federal Government

The estimated annual Federal costs for reviewing and accepting IRB Registrations is $353,000.

15. Explanation for Program Changes or Adjustments

The burden calculation has been adjusted accounting for the number of IRBs that register with HHS, the average responses per institution annually, and the time required to complete an application in light of burden-reducing elimination of the IRB roster. We estimate that there will be an average of 1 IRB registration update or renewal application submissions annually for IRBs currently registered with OHRP (5,000). We also estimate 350 institutions will register for the first time. The IRB registration form will take 30 minutes to complete for institutions registering for the first time (350) and for institutions updating or renewing their existing registration (5,000), accounting for the estimated 2,675 burden hours. This represents a decrease in annual burden hours of 3,500 hours compared to the previously approved burden. The change accounts for implementation of the 2018 Requirements at 45 CFR 46.103, thereby reducing the burden of registering or updating or renewing an IRB. The changes also result in a simplified, shorter application process and fewer registration updates for respondents.

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

OHRP requests a waiver of the requirement to post the OMB expiration date on the IRB Registration Form. Institutions sometimes see the OMB expiration date on their completed, accepted IRB registration form and incorrectly believe that it is the date on which their IRB registration expires. In addition to confusion, this can lead to failure to renew the IRB registration on time and potential noncompliance with the Common Rule. For this reason, we request approval to not list OMB's expiration date on the IRB Registration Form.

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 491 of the Public Health Service Act
b. Title 45 Code of Federal Regulations Part 46 and Title 21 Code of Federal Regulations Part 56

Attachment 2 – IRB Registration Form

Attachment 3 - Instructions for completing the IRB Registration Form