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 of the Office of Management and Budget (OMB) No. 0990-0279, Department of Health and Human Services (HHS) Institutional Review Board (IRB) Registration Form, with no changes, for a three-year period. That form was previously approved by OMB on February 4, 2019 and expired on February 28, 2022. It 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 for this three-year reinstatement of the OMB form No. 0990-0279 request.

OHRP's 2009 IRB Registration requirements are included in subpart E of 45 CFR part 46. Additionally, the requirement for a list of IRB members to be provided to OHRP is included in what is referred to in this document as the pre-2018 Protection of Human Subjects Regulations (the "pre-2018 Requirements"), or subpart A of 45 CFR part 46. The current request for reinstatement of the IRB Registration form OMB No. 0990-0279 does not include modifications.[1] While the 2018 Requirements do not include the requirement that appears in the pre-2018 rule that a list of the IRB members and their qualifications be included in an institution's assurance, OHRP is seeking to reinstate this information collection without changes, because the software applications OHRP uses to manage the IRB registration process must first be modified to enable such changes. OHRP is seeking this reinstatement to permit continuity while pursuing the appropriate software upgrades. Unless stated otherwise, subsequent references to subpart A of 45 CFR part 46 in this document refer to the pre-2018 Requirements.

The purpose of the IRB Registration Form is to provide a simplified procedure for: (1) institutions engaged in research conducted or supported by HHS to satisfy the HHS regulations for the protection of human subjects at 45 CFR 46.103(b), 45 CFR 46.107, and 45 CFR 46,

[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).

subpart E, Registration of Institutional Review Boards; and (2) IRBs, in the United States (US), to satisfy the FDA IRB regulations at 21 CFR 56.106. 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 Common Rule departments and agencies.

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."
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> Pursuant to the requirements of the PHS Act, HHS has promulgated regulations for the protection of human subjects at 45 CFR part 46. In accordance with HHS regulations at 45 CFR 46.103(b), assurances applicable to HHS-conducted or supported research shall include, among other things:
>
> (a) Designation of one or more IRBs established in accordance with the requirements of the HHS regulations [45 CFR

46.103(b)(2)].

(b) A list of IRB members identified by name, qualifications, and affiliations [45 CFR 46.103(b)(3)].

HHS regulations at 45 CFR 46.107 impose, among other things, the following requirements on IRBs:

> (a) Each IRB shall have at least five members with varying backgrounds [45 CFR 46.107(a)].
> (b) The IRB shall be sufficiently qualified through the experience and expertise of its members and the diversity of the members, including consideration of race, gender, and cultural backgrounds [45 CFR 46.107(a)].

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 the following information be provided 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)].

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 new collection of information requirement in "Institutional Review Boards; Registration and Use Requirements" codified at 21 CFR 56.106. The new 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.

Section 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.

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), 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 significant issues or problems arise that involve, or could involve, the institution, 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 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 quickly, if necessary, on important issues, and send educational material.

(f) For an OHRP-regulated IRB reviewing research subject to the pre-2018 Requirements, an IRB roster that includes each IRB member's name, earned degree(s), gender, designation as scientist or non-scientist, primary scientific or nonscientific specialty, and affiliation status of IRB member, including the chairperson and any alternate IRB members.

Purpose: This information is consistent with requirements of 45 CFR 46.103(b)(3) and 46.107(a) of the pre-2018 Requirements.

(g) 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.

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

Purpose: This information is consistent with the regulatory requirements at 45 CFR 46.103(b)(2). 45 CFR 46.103(b)(2) of the pre-2018 Requirements requires that assurances of compliance applicable to HHS- conducted or -supported research include designation of one or more IRBs for which, among other things, provisions are made for meeting space and for

sufficient staff to support each IRB's review and recordkeeping duties.

FDA:

The IRB registration form used for FDA-regulated IRBs is substantially similar to that used by OHRP, although fewer data or information elements exist due to statutory or regulatory differences in the respective agencies' IRB authorities.

In brief, the IRB Registration Form pertaining to FDA-regulated IRBs covers the following information:

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

3. Improved Information Technology and Burden Reduction

OHRP:

Each IRB must be registered electronically through http://ohrp.cit.nih.gov/efile unless an institution or organization lacks the ability to register its IRB electronically. If an institution or organization lacks the ability to register an IRB electronically, it must send its IRB registration information in writing to OHRP.

FDA:

The collection of information relies primarily on the use of electronic collection techniques. FDA's final rule, however, does 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. Additionally, FDA has harmonized its registration requirements with OHRP to the maximum extent possible. (OHRP is the principal federal agency responsible for human subject protection issues as they relate to HHS-conducted or supported research involving human subjects. In contrast, FDA's human subject protection regulations apply to most research involving FDA-regulated products, regardless of federal funding.) If an IRB is subject to regulation by both FDA and OHRP, it needs to register only once. Therefore, no duplication of data exists.

5. Impact on Small Businesses or Other Small Entities

The information collection through the IRB Registration Form is simple and straightforward and represents the minimum amount of information necessary to satisfy the OHRP and FDA Registration Requirements. The information collection will not have a significant economic impact on a substantial number of small entities.

6. Consequences of Collecting the Information Less Frequently

OHRP:

The registration information for an IRB must be updated within 90 days after changes occur regarding the contact person who provided the IRB registration information or the IRB chairperson. Any renewal or update that is submitted to, and accepted by, OHRP begins a new 3-year effective period.

An institution's or organization's decision to disband a registered IRB which it is operating also must be reported to OHRP in writing within 30 days after permanent cessation of the IRB's review of HHS-conducted or -supported research.

Each IRB must renew its registration every 3 years.

Based upon OHRP's experience with prior IRB registration processes, less frequent collection would result in IRB registration information on file with OHRP which contains key information that is outdated and inaccurate. In addition, funding agencies that rely on the HHS IRB registration system will be able to rely on the IRB registration information for a current, accurate list of IRBs for an institution.

FDA:

Failure to register would impair FDA's ability to send information to an IRB and to identify an IRB for inspection. FDA uses inspections to determine an IRB's compliance with FDA requirements.

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:

Public comments were solicited for a 60-day period in the brows published on February 16, 2022 (87 FR32, p. 8853) on this proposed collection. No comments were submitted.

9. Explanation of any Payment/Gift to Respondents

OHRP and FDA:

No payments or gifts are provided to the respondents.

10. Assurance of Confidentiality Provided to Respondents

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. Justification for 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:

Burden estimates for the IRB Registration Form have not changed. The estimate of the number of respondents is based upon the current number of IRBs registered with HHS, approximately 5,808, and projecting that the number of respondents may increase to 6,000. Of the approximately 5,808 registered IRBs, 100% submitted their registration information electronically.

Of the 6,000 projected respondent IRBs, up to 350 are expected to submit new registration information one time and update registration information one time during the year and up to 5,650 are expected to update or renew IRB registration up to two times each year. The burden is estimated to average one hour for an initial IRB registration, and thirty minutes for updating or renewing the registration of a previously registered IRB. If on average 5,650 previous respondents submit information two times each year and on average 350 submit new registration information one time a year and update that IRB information one time a year, the total annual burden hours are projected to be 6,175 hours.

12A. Total Estimated Annualized Burden Table

Form name	Number of Respondents	Number of responses per respondent	Average burden per response (in hours)	Total Burden hours
IRB Registration 0990-0279 Update and Renew	5,650	2	30/60	5,650
IRB-Registration 0990-0279 Initial and Update	350	2	45/60	525
Total				6,175

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. Based on OHRP's experience in registering the IRBs currently registered, most of the respondents will be administrative staff persons (to include IRB Administrators) within organizations and institutions. The hourly wage is estimated to be $25 and the total burden cost is estimated to be $167,500.

12B. Total Estimated Annualized Burden Table

Form Name		Total Burden Hours	Hourly Wage Rate	Total Burden Dollars
IRB Registration 0990-0279		6,175	$25.00	$154,375
IRB-Registration 0990-0279 Initial and Update		525	$25.00	$13,125
Total				$167,500

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 annual burden estimate will not change, estimated to be 6,175 hours and $167,500.

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 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