U. S. Department of Health and Human Services (HHS)
Office for Human Research Protections
Federalwide Assurance (FWA) Form

Supporting Statement

Background

The Office of the Assistant Secretary for Health, Office for Human Research Protections (OHRP) is requesting a three-year extension of the OMB No. 0990-0278, Federalwide Assurance (FWA) Form, with no changes in the collected information. The form is currently approved through August 31, 2023. The purpose of the FWA form is to provide a simplified procedure for institutions engaged in research conducted or supported by the Department of Health and Human Services (HHS) to satisfy the assurance requirements of (1) Section 491(a) of the Public Health Service Act (the PHS Act) (42 U.S.C. 289); and (2) HHS regulations for the protection of human subjects at 45 CFR 46.103. The respondents for this information collection are institutions engaged in HHS-conducted or –supported research involving human subjects.

A. Justification

1. Need and Legal Basis

Section 491(a) of the PHS Act states that the Secretary shall by regulation require that each entity applying for HHS support to conduct research involving human subjects submit to HHS "assurances" satisfactory to the Secretary that it has established an institutional review board (IRB) to review the research 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[1]. These regulations require that each institution engaged in research which is covered by the regulations and which is conducted or supported by HHS provide written assurance satisfactory to the Secretary that it will comply with the requirements set forth in the regulations [45 CFR 46.103(a)]. In lieu of requiring submission of an assurance, each of the other departments and agencies that follow the Federal Policy for the Protection of Human Subjects (the Common Rule) shall accept the existence of a current assurance, appropriate for the research in question, on file with, and approved for Federalwide use by, the Office for Human Research Protections (OHRP) [45 CFR 46.103(a)].

The assurance must be executed by an individual authorized to act for the institution and to assume on behalf of the institution the obligations imposed by the HHS regulations, and must be filed in such form and manner as the Secretary prescribes

[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).

[45 CFR 46.103(c), pre-2018 Requirements; 45 CFR 46.103(b), 2018 Requirements].

OHRP is the HHS component charged with fulfilling the statutory mandates of these provisions of the PHS Act and enforcing HHS regulations at 45 CFR part 46. Currently the FWA is the only type of assurance OHRP accepts or approves.

OHRP anticipates that some respondents for this information collection are institutions that are engaged in nonexempt HHS-conducted or –supported human subjects research covered by two versions of the Common Rule: the pre-2018 Requirements and the 2018 Requirements. For example: some institutions are engaged in research that was initially approved by an IRB before January 21, 2019, (the general compliance date for the 2018 Requirements), and that research is covered by the pre-2018 Requirements. January 21, 2019, was the general compliance date for the 2018 Requirements. If those institutions are also engaged in some research that was initially approved by an IRB on or after January 21, 2019, then that research is covered by the 2018 Requirements.

The requirements for an assurance to include a statement of ethical principles and to designate an IRB are included in what is referred to in this document as the pre-2018 version of subpart A of 45 CFR part 46 (the "pre-2018 Requirements"). The current request for reinstatement of the FWA form OMB No. 0990-0278 does not include modifications. While the 2018 Requirements do not include the requirements that appear in the pre-2018 rule that assurances include a statement of the principles that govern how the institution fulfills human research protections responsibilities for research regardless of the source of support for the research, and designation of one or more IRBs that review research to which the assurance applies, OHRP is seeking to renew this information collection without changes, because the software applications OHRP uses to manage the FWA application process must first be modified to enable such changes. OHRP is seeking this renewal to permit continuity while pursuing the appropriate software upgrades.

The renewal also continues to allow U.S. institutions to voluntarily apply the Common Rule, or the Common Rule and subparts B, C, and D of the HHS regulations at 45 CFR part 46, to all an institution's nonexempt human subjects research regardless of the source of support (frequently referred to as "checking the box"). If an institution "checks the box" on the FWA form it submits to OHRP, OHRP may exercise compliance oversight authority over research in which that institution is engaged and that is covered by the institution's FWA, even if the research is not conducted or supported by HHS.

OHRP plans to remove the option to "check the box," but has chosen to retain the "check the box" option until at least a 5-year period has elapsed since the general compliance date of the 2018 Requirements. This means that the "check the box" option would be removed no earlier than January 21, 2024.

OHRP's choice to maintain the optional "check the box" aspect of the FWA form at least until January 21, 2024, is in response to concerns received from the regulated

community. These individuals expressed concerns unique to specific States, if the FWA form no longer includes the "check the box" option. In order to give institutions in these states additional time to accommodate this change, OHRP has chosen to retain the "check the box" option in the current request for reinstatement of the FWA form.

2. Information Users

The FWA collects the following information for the following purposes:

(a) The legal name, location and the current OHRP-approved assurance number (if the institution already has an FWA) of the institution filing the FWA.

Purpose: OHRP uses this information to identify the specific institution to which the FWA will apply. OHRP will make available the names and locations of institutions holding an approved FWA to all components of HHS that support research involving human subjects so that these components can confirm that a particular institution holds an approved assurance satisfactory to the Secretary before using HHS funds to support nonexempt human subjects research.

(b) A list of components over which the institution submitting the FWA has legal authority that operate under a different name; and any alternate names under which the institution operates.

Purpose: Sec 2 (a) above

(c) A checkbox indicating the statement of principles (Belmont Report, Declaration of Helsinki, or other) that govern the institution in the discharge of its responsibilities for protecting the rights and welfare of human subjects of research conducted at or sponsored by the institution, regardless of whether the research is subject to Federal regulation. When only the "Other" box is checked, the institution is asked to submit a copy of the statement of principles with the FWA form.

Purpose: This information is collected so that OHRP can confirm that the assurance satisfies the requirements of HHS regulations at 45 CFR 46.103(b)(1), pre-2018 Requirements.

(d) An optional checkbox which allows U.S. institutions to elect voluntarily to apply either 45 CFR part 46 and all its subparts, or just 45 CFR part 46, subpart A to all of its research regardless of the source of support for the research.

Purpose: OHRP uses this information to define precisely the applicability of the FWA.

(e) For the FWA of International (Non-U.S.) Institutions, a checkbox is to be completed indicating the procedural standards that the institution will apply to its U.S. federally supported research, in addition to the Common Rule.

Purpose: OHRP obtains this information in order to be informed of whether an international institution applies another procedural standard to the conduct of U.S. federally supported research, in addition to the Common Rule.

(f) A list of internal IRBs, by name and registration number, that an institution will rely upon to review the research to which the FWA applies; or, if the institution has no internal IRB the external IRB, by name and registration number that the institution will rely upon, or if only multiple external IRBs are relied upon, the name and registration number of the external IRB that reviews the largest percentage of research to which the FWA applies.

Purpose: This information is collected so that OHRP can confirm that the assurance satisfies the requirements of HHS regulations at 45 CFR 46.103(b)(2), pre-2018 Requirements.

(g) The name, degree(s) or suffix, institutional title, address, telephone number, facsimile number, and e-mail address of the Human Protections Administrator (i.e., the person who can serve as primary point of contact for the institution's system for protecting human subjects).

Purpose: This information is collected so that OHRP has a central point of contact at the institution for questions and issues related to the FWA and the institution's procedures for protecting human subjects. The information can be used by OHRP to disseminate important information and announcements related to human subject protections issues and provides a means for enhancing communication between OHRP and institutions engaged in research conducted or supported by HHS. The information also will facilitate OHRP's ability to conduct (i) its compliance oversight program that responds to allegations or indications of noncompliance with the HHS regulations at 45 CFR part 46 and the terms of the assurance; and (ii) its education program for providing clarification and guidance concerning ethical issues related to human subjects research.

(h) The name, degree(s) or suffix, institutional title, address, telephone number, facsimile number, and e-mail address of the Signatory Official (i.e., the official legally authorized to represent the institution). The Signatory Official must assure that human subjects research to which the FWA applies is conducted in accordance with the terms of assurance and sign and date the FWA. The Signatory Official must electronically sign the FWA using the electronic submission system available through the OHRP Web site at http://ohrp.cit.nih.gov/efile/, unless the institution lacks the ability to submit its FWA electronically.

Purpose: This information is collected so that OHRP can confirm that the assurance satisfies the requirements of HHS regulations at 45 CFR 46.103(c), pre-2018 Requirements/45 CFR 46.103(b), 2018 Requirements. The information can be used by OHRP to disseminate important information and announcements related to human subject protections issues and to provide a means for enhancing communication between OHRP and institutions engaged in research conducted or supported by HHS. The information also will facilitate OHRP's ability to conduct (i) its compliance oversight program that responds to allegations or indications of noncompliance with the HHS regulations at 45 CFR part 46 and the terms of the assurance; and (ii) its education program for providing clarification and guidance concerning ethical issues related to human subjects research.

OHRP will make available information collected in the FWA to the other Federal departments and agencies that have adopted the Common Rule. This will enable these departments and agencies to confirm that a particular institution holds an applicable assurance approved for Federalwide use. The other Federal departments and agencies will also be able to use this information to contact appropriate institutional officials for questions and issues related to the human subjects research conducted or supported by these departments and agencies at the institution.

OHRP provides two supplemental sample forms that may be used by institutions submitting or holding FWAs, but which are not collected routinely by OHRP. The first form is an IRB Authorization Agreement. When an institution holding an OHRP-approved FWA relies upon an IRB operated by another organization or institution to review HHS-conducted research, the FWA-holding institution must document its reliance on the IRB for oversight of the research. The FWA-holding institution maintains this documentation, which is to be made available to OHRP upon request. The FWA-holding institution may, but need not, use OHRP's IRB Authorization Agreement to document its reliance.

The second supplemental form is an Individual Investigator Agreement. An institution with an approved FWA may use this form to extend the applicability of the FWA to individual investigators who are not otherwise employees or agents of an assured institution. The form defines in writing the circumstances under which the collaborating investigator is covered by the institution's FWA. The purpose of the form is to provide a simplified mechanism that allows an institution with an FWA to extend the applicability of its FWA to cover collaborating investigators, in lieu of OHRP requiring that such collaborating investigators' non-assured institution submit a separate FWA. The form is kept on file by the FWA institution and is to be made available to OHRP upon request. Institutions are free to modify the form or develop their own form to cover a collaborating individual investigator.

3. Improved Information Technology

Institutions submitting a FWA will electronically submit all information for initial FWAs, or updates and renewals of existing FWAs, including the signature of the

Signatory Official, via the internet using an interactive page on the OHRP website. OHRP has the technology that permits OHRP to accept electronic signatures of Signatory Officials for the FWA. This eliminates the need for submission of any paperwork, except for rare institutions that lack the ability to submit their FWAs electronically. Between January 1, 2021, and December 31, 2021, 3,403 FWAs were submitted to OHRP for approval and all were submitted electronically. OHRP anticipates that virtually all institutions will continue to submit FWA information electronically via the internet.

4. Duplication of Similar Information

   The FWA does not duplicate any other information collection by OHRP.

5. Small Businesses

   The information collected through the FWA represents the minimum amount of information necessary to satisfy the assurance requirements of the PHS Act and HHS regulations at 45 CFR 46.103. The information collection will not have a significant economic impact on a substantial number of small entities.

6. Less Frequent Collection

   Institutions are required to update the FWA within 90 days after changes occur regarding the legal name of the institution, the Human Protections Administrator or the Signatory Official. Each institution must renew its FWA every 5 years, even if no changes have occurred, in order to maintain an active FWA.

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 April 14, 2023 (88 FR 23092). No comments were submitted.

9. Payment/Gift to Respondent

   No payments or gifts are provided to the respondents.

10. Confidentiality

    The information collected under the FWA in the past was considered releasable under the Freedom of Information Act (FOIA). However, currently OHRP no longer requires public requesters to submit a FOIA request in order to release non-public FWA information.

The database used to track FWA data, referred to as the Human Assurance Tracking System (HATS), uses Microsoft SQL Server tables stored on a server that are maintained by the Center for Information Technology, National Institutes of Health. The HATS application screens and associated FWA tables/server utilize a username/password and appropriate session variables to access and modify the FWA data. Without the appropriate username/password, unauthorized users will not gain access to the FWA database. FWA database tables will never be provided outside of OHRP. Requests for FWA information are fulfilled via electronic or printed reports or disks containing extracted information.

The public can retrieve some data from FWA database tables via the internet search screens found on the OHRP website at https://ohrp.cit.nih.gov/search/search.aspx?styp=bsc. This link provides read only access to the name, location, and FWA assurance number of institutions holding an active OHRP-approved FWA. Information provided to the public via the OHRP website does not include the names and contact information of the FWA Signatory Official or Human Protections Administrator identified in the FWA form. This information is accessible to appropriate representatives of the other Federal departments and agencies that have adopted the Common Rule via a secure internet connection requiring a username and password. Members of the public may contact OHRP to obtain this information. Of note, members of the public and other agencies' representatives do not have the ability to modify the FWA database tables.

11. Sensitive Questions

No sensitive information is being collected by the FWA.

12. Estimates of Annualized Burden Hours and Costs

The estimate of the number of respondents is based upon the current (as of 11/29/2022) number of active OHRP-approved FWAs (13,829) and projecting that the number may increase to 14,000.

The estimate of the number of responses per respondent is based upon the assumption that an institution will need to submit an initial FWA, or update or renew a previously approved FWA, on average every six months.

The estimate of the hours per response assumes that virtually all respondents will complete the FWA form via the 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 FWA; (ii) read and understand the FWA terms of assurance; and (iii) enter the information requested on the FWA form. The estimate assumes that completing a new FWA, or updating or renewing an existing FWA, on average, will be completed in 0.50 hours.

12a. Estimated Annualized Burden in Hours Table

Form name	Number of Respondents	Number of Responses per Respondent	Hours per Response	Response Burden Hours
Federalwide Assurance (FWA)	14,000	2.0	30/60	14,000
Total				14,000

OHRP estimates an average submitter's hourly wage rate of $40 per hour (for institutional officials, administrators, administrative staff). The total annual costs for reading and understanding instructions and terms of assurance and entering the information via the internet are estimated to be 14,000 burden hours X $40/hour = $560,000.

12b. Estimated Burden Costs Table

Form name	Number of Respondents	Burden Hours	Hourly Wage	Total Respondent Cost
Federalwide Assurance (FWA)	14,000	14,000	$40.00	$560,000
Total				$560,000

13. Capital Costs (Maintenance of Capital Costs)

There are no direct capital costs to respondents other than the time to review the Terms of Assurance and to complete the FWA form.

14. Cost to Federal Government

The estimated annual Federal Government cost is $220,935: $145,935 for reviewing and approving FWAs and $75,000 for operating, managing and hosting the database.

15. Program or Burden Changes

The annual burden will continue to be 14,000 hours. There is no program or adjustment change.

16. Publication and Tabulation Dates

Information on institutions that hold an approved FWA, is available on the OHRP website.

17. Expiration Date

OHRP is not seeking approval to not show the expiration date.

18. Exception to Certification for Paperwork Reduction Act Submissions

No certification 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 (pre-2018 Requirements)
c. Title 45 Code of Federal Regulations Part 46 (2018 Requirements)

Attachment 2 – FWA Terms of Assurance

Attachment 3 – FWA Form

Attachment 4 – Instructions for completing the FWA form

Attachment 5 – Supplemental sample forms

a. IRB Authorization Agreement
b. Individual Investigator Agreement