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 revision of the currently approved collection for the OMB No. 0990-0278, Federalwide Assurance (FWA) Form. The form is currently approved through October 31, 2026. 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.

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.

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. 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"), codified for HHS at 45 CFR part 46, subpart A, 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)[1]. [45 CFR 46.103(a)].

The assurance must be executed by an individual authorized to act for the institution

[1] 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.

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 department or agency head prescribes [45 CFR 46.103(b)].

The Common Rule was revised in 2018. While the revised Common Rule (the "2018 Requirements") applies to regulated research initiated after January 21, 2019, certain research regulated by the Common Rule that was initiated before January 21, 2019, continues to follow the former version of the Common Rule (the "pre-2018 Requirements"). The requirements for an assurance to include a statement of ethical principles and to designate an IRB are included in the pre-2018 Requirements. However, 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 remove this information from the FWA form to adopt the changes at 45 CFR 46.103 of the 2018 Requirements and reduce burden on respondents. Updates to the software applications OHRP uses to manage the FWA application process will be deployed to enable such changes.

Additionally, as described in the preamble to the 2018 Requirements, OHRP intends to make a change to the assurance mechanism. Specifically, through this revision, OHRP seeks to eliminate the option on the current FWA form for 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 of an institution's nonexempt human subjects research regardless of the source of support (frequently referred to as "checking the box"). Currently, 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 historically has provided this option in the FWA, although this is not required by the Common Rule. In removing the "check the box" option from the FWA, institutions could, if they want, continue for purposes of their own internal policies to voluntarily extend Common Rule requirements to all research conducted by the institution, but this voluntary extension will no longer be part of the assurance process, and such research will not be subject to OHRP oversight.

Lastly, with this revision, OHRP is eliminating the requirement for institutions outside the U.S. to provide procedural standards (i.e., International Guidelines on Harmonization E-6 Guidelines for Good Clinical Practice, Canadian Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans, other standards for the protection of human subjects, etc.) they apply for human subjects research when assuring compliance with the Terms of the Federalwide Assurance. This change serves to simplify the FWA process for non-U.S. institutions.

2. Purpose and Use of the Information

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: This information is collected so that OHRP can confirm that the assurance satisfies the requirements of HHS regulations at 45 CFR 46.103(b). 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.

b) A list of component organizations 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) An applicability statement indicating that the assurance applies whenever an institution becomes engaged in human subjects research conducted or supported by any U.S. federal department or agency that has adopted the U.S. Federal Policy for the Protection of Human Subjects (also known as the Common Rule), unless the research is otherwise exempt from the requirements of the Common Rule, or the department or agency conducting or supporting the research determines that the research shall be conducted under a separate assurance.

Purpose: This information is provided on the FWA form to clarify when the assurance applies, and when it does not apply.

d) A statement that the institution assures that whenever it engages in research to which the assurance applies, it will comply with the Terms of the Federalwide Assurance.

Purpose: This information is provided on the FWA form, along with a hyperlink to the FWA Terms, for an institution to review before assuring that it will comply

with the Common Rule for research to which the FWA applies.

e) A statement that the institution assures that it will rely upon only IRBs registered with OHRP for review of research to which the FWA applies.

Purpose: This information is collected so that OHRP can confirm that the assurance satisfies the requirements of the HHS regulations at 45 CFR 46.103(a).

f) The name, degree(s) or suffix, institutional title, address, telephone 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.

g) The name, degree(s) or suffix, institutional title, institution name, address, telephone 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(b). 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 Federal Policy and find the FWA appropriate for the human subjects research which they conduct or support. This will enable these departments and agencies to confirm that a particular institution holds an applicable assurance approved for Federalwide use before that institution can use HHS award funds to support nonexempt human subjects research. 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.

Section 46.103(a) of the HHS regulations provides that each institution engaged in nonexempt human subjects research that is conducted or supported by a Federal department or agency provide written assurance satisfactory to the department or agency head. In keeping with satisfactory written assurance, OHRP puts in place requirements for an institution to update or renew its current FWA periodically: (i) every 5 years; and (ii) within 90 days after changes occur regarding the legal name of the institution, the Human Protections Administrator, or the Signatory Official. Timeframes for updates or renewals are provided to balance burden on institutions with OHRP's need for current information. Moreover, OHRP requires FWAs to be updated or renewed so that OHRP can periodically deactivate records of FWAs that are no longer needed and confirm that active assurances continue to satisfy the requirements of HHS regulations at 45 CFR 46.103(b). Also, FWA update or renewal information is 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 facilitates 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 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 (IAA). 45 CFR 46.103(e) provides that for nonexempt HHS conducted or supported human subjects research that takes place at an institution in which IRB oversight is conducted by an IRB that is not operated by the institution, the institution and the organization operating the IRB shall document the institution's reliance on the IRB for oversight of the research and the responsibilities that each entity will undertake to ensure compliance with the Common Rule. This documentation can occur, for example, through a written agreement between the relying institution and the reviewing IRB, by implementation of an institution-wide policy that identifies the reliance and the respective responsibilities of each party, or as set forth in a research protocol. OHRP's IAA

form provides sample text for institutions with an FWA to rely on an IRB of another institution. It can be used as a guide and a means, among other ways, for fulfilling the regulatory requirement at 45 CFR 46.103(e). Institutions are free to modify the sample form or develop their own agreement.

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 provides a sample statement regarding 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 each such individual investigator submit a separate FWA document. 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 an FWA electronically submit all information for initial FWAs, or updates and renewals of existing FWAs, via the eFile web application on the OHRP website. This eliminates the need for submission of any paperwork, except for rare institutions that lack the ability to submit their FWAs electronically. All FWA applications have been submitted electronically for the current approved collection period and OHRP anticipates that all institutions will continue to submit FWA information electronically.

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. Furthermore, the simplified assurance procedure provided by the FWA reduces burdens on small entities by (i) eliminating the need for multiple assurance submissions (previously, OHRP in most cases required submission of a separate assurance, called a Single Project Assurance, for each HHS grant, contract, and cooperative agreement supporting human subjects research that was awarded to a small entity); and (ii) making it easier for small entities to identify and rely upon IRBs of other institutions. The FWA also facilitates collaboration between small businesses and large academic

institutions.

6. Less Frequent Collection

   The information collection schedule supports agency regulations pertaining to assurance requirements as set forth in 45 CFR 46.103.

7. Special Circumstances

   None.

8. *Federal Register* Notice/Outside Consultation

   Comments on this information collection were solicited in the *Federal Register* for a 60-day period. The 60-day period ended on January 21, 2025. OHRP received comments from two individuals.

   The first comments came from an individual who asked OHRP to confirm that the proposed changes to the FWA form were consistent with those provided in the notice of proposed rulemaking (NPRM) relating to the most recent revisions to the Common Rule, which was published in 2015. This individual also commented that removal of the option to "check the box" on the FWA form impacts the applicability of human subjects protections regulations in some states (e.g., Virginia). This individual asked OHRP for clarification on the burden estimates and questioned whether applying state laws or employing institutional policies for non-federally funded research should be considered in the burden estimates for this information collection.

   OHRP responded that adopting the 2018 Requirements changes for assurances at 45 CFR 46.103 into its online registration process has been planned since the publication of the NPRM in 2015. OHRP considered state laws and the potential impact on institutional policies, which is why implementation was delayed, to give the regulated community time to coordinate with their state legislatures. OHRP clarified that implementing these changes to the online FWA form is anticipated to result in a shorter FWA form and application process for respondents. As a result of the proposed changes to the form, burden hour estimates for the information collection decrease from 30 minutes to 20 minutes per application submission. OHRP reaffirmed that there may be state law considerations in certain states that may impact institutions that no longer "check the box,"and OHRP's actions do not directly affect those state laws. Finally, OHRP closed the response by detailing the proposed changes to the FWA form and providing resource materials that included the Supporting Statement, FWA form, terms, and instructions.

   The second comments came from an individual who expressed that any change to the form used for institutions to file their FWA with HHS should be widely publicized in

advance so that institutions can prepare any necessary changes to their policies and procedures, and prepare for implications related to state law and the discontinuance of the option to extend an FWA to be applicable to all nonexempt human subjects research regardless of funding. The individual also requested additional information and materials in response to the Federal Register Notice instructions.

OHRP responded with descriptions of the proposed FWA changes along with the proposed form, terms, and instructions to be used to adopt the 2018 Requirements changes for assurances at 45 CFR 46.103 into OHRP's online registration process. OHRP closed the response by pointing out that if the commenter decides to provide further comments, the commenter may follow the Federal Register Notice instructions to submit them. A link was provided to the FRN with details about where to find the instructions.

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, or assistance from OHRP, unauthorized users will not gain access to the FWA database. Requests for FWA information are fulfilled via electronic reports files 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 Federal Policy via a secure internet connection requiring a username and password. The public would need to contact OHRP to obtain this information. Of

note, the public and other agencies 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 2/27/2025) number of active OHRP-approved FWAs (12,533) and projecting that the number may increase to 13,000.

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, once a year.

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 0.33 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)	13,000	1.0	0.33	4,290
Total				4,290

OHRP estimates an average submitter's hourly wage rate of $53.87 per hour (for institutional officials, administrators, administrative staff). This is based on the 2025OPM hourly pay tables and is equivalent to a GS 12, step 5. The total annual costs for reading and understanding instructions and terms of assurance and entering the information via the internet are estimated to be 4,290 burden hours X $53.87/hour = $231,000.

12b. Estimated Burden Costs Table

Form name	Number of Respondents	Burden Hours	Hourly Wage	Total Respondent

				Cost
Federalwide Assurance (FWA)	13,000	4,290	$53.87	$231,000
Total				$231,000

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 costs for reviewing assurances required under HHS regulations at 45 CFR 46.103 is $400,000.

15. Program or Burden Changes

    The burden calculation has been adjusted accounting for the number of institutions that hold active FWAs, average responses per institutional annually, and the time required to complete an application. We estimate that there will be an average of 1 FWA application submission per institution annually (13,000 x 1 = 13,000) and that each application will require 20 minutes to complete, accounting for the estimated 4,290 response burden hours. This represents a decrease in annual burden hours of 9,710 hours compared to the previously approved burden. The change accounts for: 1) implementation of the 2018 Requirements burden reducing changes to the FWA, which provides a simplified, shorter application process for respondents; and 2) the fact that there are approximately 1,000 fewer institutions that hold an active FWA compared to the previously approved information collection period.

16. Publication and Tabulation Dates

    The list of institutions holding an approved FWA will be posted, and updated daily, on the OHRP website.

17. Expiration Date

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

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