Supporting Statement for the Federalwide Assurance (FWA)

A. Background

The Office for Human Research Protections (OHRP) is requesting a three-year extension of the OMB No. 0990-0278, Federalwide Assurance (FWA) for the Protection of Human Subjects Form, currently approved through August 31, 2017, with no changes in the collected information. The purpose of the FWA 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 collection are research institutions engaged in HHS-conducted or –supported research involving human subjects.

B. 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 and welfare 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 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 16 other departments and agencies that have adopted the Federal Policy for the Protection of Human Subjects (the Federal Policy) 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)].

In accordance with HHS regulations at 45 CFR 46.103(b), assurances applicable to HHS-conducted or supported research shall at a minimum include:

(a) A statement of principles governing 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 regulations [45 CFR 46.103(b)(1)].

(b) Designation of one or more IRBs established in accordance with the requirements of the HHS regulations [45 CFR 46.103(b)(2)].

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

(d) Written procedures which the IRB will follow for conducting its reviews of research [45 CFR 46.103(b)(4)].

(e) Written procedures for ensuring prompt reporting to the IRB, appropriate institutional officials, and the Secretary of (i) any unanticipated problems involving risks to subjects or others or any serious or continuing noncompliance with 45 CFR part 46 or the requirements or determinations of the IRB; and (ii) any suspension or termination of IRB approval [45 CFR 46.103(b)(5)].

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 [45 CFR 46.103(c)].

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. The FWA provides a simplified assurance process that replaced the prior assurance mechanisms used by OHRP, all of which were more complicated and burdensome than the FWA. The information collected by OHRP through the FWA is the minimum necessary to satisfy the assurance requirements of the PHS Act and the requirements of HHS regulations at 45 CFR 46.103.

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 making an award to support research involving human subjects.

(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).

(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 (also known as the Common Rule, or the Federal Policy for the Protection of Human Subjects), 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 Federal Policy for the Protection of Human Subjects.

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 Federal Policy for the Protection of Human Subjects.

(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).

(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). 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 making an award to that institution to support research involving human subjects. 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 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 institution holding the FWA must execute an IRB Authorization Agreement with the organization operating the IRB. This agreement defines in writing the circumstances under which the IRB will be used by the institution submitting the FWA and both the signatory official of the institution submitting the FWA and the signatory official of the organization operating the IRB must sign the IRB Authorization form. The form is kept on file by both institutions and is to be made available to OHRP upon request. Institutions are free to modify the form or develop their own form to cover an IRB Authorization arrangement.

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 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 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 September 1, 2014 and February 10, 2017, OHRP approved 7,624 FWAs and 7,623 of these FWAs 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. 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

   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 requested during a 60-day period in the Federal Register issue that was published on March 6, 2017 (82 FR, No. 42, p 12615). No public comments were submitted during the comment period that closed on May 5, 2017.

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

require public requesters to submit a FOIA request in order to obtain 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 printed reports or disk files containing extracted information.

The public can retrieve 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 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

12 a. Annualized Hour Burden Estimate

Burden estimates with respect to the assurance requirements under HHS regulations at 45 CFR 46.103 were accounted for under the Paperwork Reduction Act Submission to OMB that was approved under Control Number 0990-0260. Specific burden estimates for the FWA form only are provided below.

The information being requested in the FWA form should be readily available to any institution engaged in human subjects research conducted or supported by HHS as part of its normal operating practices.

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	0.50	14,000

The estimate of the number of respondents is based upon the current (as of 2/10/2017) number of OHRP-approved FWAs (13,679) 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.

12 b. Annualized Cost Burden Estimate

OHRP staff 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.

Type of Respondent	Total Burden Hours	Hourly Wage Rate	Total Respondent Costs
Federalwide Assurance FWA	14000	$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 costs for reviewing assurances required under HHS regulations at 45 CFR 46.103 is $400,000

15. Program or Burden Changes

The annual burden will increase by 2950 from 11,050 hours to 14,000. We anticipate that respondents will increase by 5900 from 22100 to 28000 due to the need for more respondents to obtain a FWA.

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 is not seeking approval to not show the expiration date.

18. Certification Statement

Item (i) of the certification statement on page 2 of OMB 83-I is not applicable and, therefore, is not being certified.

C. Justification of Information Employing Statistical Methods

Not Applicable

LIST OF ATTACHMENTS [UPDATE THE FOLLOWING INFO]

Attachment 1 – Legal Authorities
- a. Section 491 of the Public Health Service Act
- b. Title 45 Code of Federal Regulations Part 46

Attachment 2 – FWA Terms of Assurance
- a. Proposed Terms

Attachment 3 – FWA Form
- a. Proposed Form

Attachment 4 – Instructions for completing the FWA form
- a. Proposed Instructions

Attachment 5 – Supplemental sample forms
- a. IRB Authorization Agreement
- b. Individual Investigator Agreement