Supporting Statement for the Federalwide Assurance (FWA)

A. Background

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); 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.

Section 491(b) of the Act requires HHS to establish a program (i) for responding promptly and appropriately to requests for clarification and guidance with respect to ethical issues raised in connection with biomedical or behavioral research involving human subjects; and (ii) for responding promptly and appropriately to information regarding incidences of violations of the rights of subjects of research conducted or supported by HHS.

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 other 15 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 the PHS Act and enforcing HHS regulations at 45 CFR part 46. The FWA provides a simplified assurance process that replaces 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, HHS Institution Profile File code (if known), Federal Entity Identification number (if known), and the current OHRP-approved assurance number 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: See 2 (a).

(c) A checkbox indicating the statement of principles (Belmont Report, Declaration of Helsinki, or other statement of principles) 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 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. institution 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 for 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. This form has been updated on page 2 to include the current version years for the Council for International Organizations of Medical Sciences (CIOMS) International Ethical Guidelines for Biomedical Research Involving Human Subjects, the Medical Research Council of Canada Tri-Council Policy Statement on Ethical Conduct for Research Involving Humans, and the Indian Council of Medical Research Ethical Guidelines for Biomedical Research on Human Subjects. The Terms of Assurance for International Institutions have also been updated in the same way.

(f) A list of the IRBs, by name and registration number, that are to be designated under 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)(2).

(g) The name, title, address, telephone number, facsimile number, and e-mail address of the human protection 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, title, address, telephone number, facsimile number, and e-mail address of the signatory official (i.e., the institutional official legally authorized to represent the institution. The institutional official must sign the FWA and assure that human subjects research to which the FWA applies in conducted in accordance with the terms of assurance.

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 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.

OHRP also provides two supplemental sample forms that may be used by institutions submitting or holding FWAs, but not are not collected routinely by OHRP. The first form is an IRB Authorization Agreement. An institution submitting an FWA that designates the IRB of another institution can use this form. The signatory official of the institution submitting the FWA and the signatory official of the institution with the IRB being designated both sign the form. The form defines in writing the circumstances under which the designated IRB will be used by the institution

submitting the FWA. The purpose of this form is to ensure that whenever an institution designates the IRB of another institution, the institution with the IRB being designated is aware of, and approves, such a designation. 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 such an arrangement.

The second supplemental form is an Unaffiliated Investigator Agreement. An institution with an approved FWA may use this form to extend the applicability of the FWA to individual investigators not otherwise affiliated with the institution who are collaborating on HHS-supported research being conducted by the institution holding the FWA. The form defines in writing the circumstances under which the unaffiliated 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 unaffiliated 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 such an arrangement

OHRP also 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.

3. Improved Information Technology

Institutions submitting a new FWA may submit all information for initial FWAs, or updates and renewals of existing FWAs, except for the signature of the signatory official, via the internet using an interactive page on the OHRP website. The last page of the FWA with the signature of the signatory official still must be submitted on paper via mail or facsimile. As soon as technology permits, OHRP will accept electronic signatures for the FWA, thus eliminating the need for submission of any paperwork, except for institutions that lack internet access. OHRP anticipates that the majority of institutions needing to submit an FWA will do so via the internet. Currently more than 70% of institutions are submitting FWA information 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 whenever there are substantive changes at the institution with respect to key elements of information being collected on the FWA form. Furthermore, institutions are required to submit a complete renewal to the FWA at least every three years. This frequency of collection is required so that OHRP can ensure that the FWA still satisfies the requirements of HHS regulations at 45 CFR 46.103. Based upon OHRP's experience with prior assurance procedures, less frequent collection would result in FWAs on file with OHRP that contain key information that is outdated and inaccurate.

7. Special Circumstances

None.

8. *Federal Register* Notice/Outside Consultation

Public comments and outside consultation were solicited and addressed prior to obtaining OMB approval for the information collection on the current FWA forms (OMB # 0990-0278). In general, the majority of comments supported the effectiveness and efficiency of the assurance procedures provided by the FWA. On November 14, 2007, vol. 72, No.219; pp. 64081-64082, a notice announcing a 60-day period for public comments on the above cited information collection was published in the Federal Register. No comments were received from the public during that comment period.

9. Payment/Gift to Respondent

No payments or gifts are provided to the respondents.

10. Confidentiality

The information collected under the FWA is, and always has been, considered releasable under the Freedom of Information Act (FOIA). The database used to track FWA data, referred to as the Human Assurance Tracking System (HATS), is currently being redesigned to utilize Microsoft SQL Server tables stored on a server maintained by the Center for Information Technology, National Institutes of Health. The redesigned 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 under the FOIA 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 http://ohrp.cit.nih.gov/search/asearch.asp. 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 only 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. 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. Burden Estimate (Total Hours & Wages)

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 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
Federalwide Assurance	10,000	2.0	0.75	15,000

(FWA)				

The estimate of the number of respondents is based upon the current number of institutions that have OHRP-approved FWAs (9,395) and projecting that the number may increase to 10,000.

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 the majority of respondents will complete the FWA 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 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 0.75 hours.

The total annual costs of the FWA are estimated at 15,000 hours X $40/hour = $600,000.

Estimated Annualized Burden in Dollars Table

Form name	Total Burden Hours	Hourly Wage Rate	Total Burden Dollars
Federalwide Assurance (FWA)	15,000	$40	$600,000

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 and certifications of IRB approval required under HHS regulations at 45 CFR 46.103 is $1,992,000.

15. Program or Burden Changes

The annual burden will decrease from 22,500 hours to 15,000 hours and from $900,000 to $600,000.

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

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. Current Terms
- b. Proposed Terms

Attachment 3 – FWA Forms
- a. Current Form for Domestic (U.S.) institutions
- b. Current Form for International institutions
- c. Proposed Form for Domestic (U.S.) institutions
- d. Proposed Form for International institutions

Attachment 4 – Instructions for completing the FWA forms
- a. Instructions for Domestic (U.S.) institutions
- b. Instructions for International institutions

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