Supporting Statement for the Institutional Review Board (IRB)/Independent Ethics Committee (IEC) Registration Form

A. Background

The purpose of the IRB/IEC Registration 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); and (2) HHS regulations for the protection of human subjects at 45 CFR 46.103. The respondents for this collection are institutions or organizations operating IRBs/IECs, designated by an institution under an assurance of compliance approved for federalwide use by Office for Human Research Protections (OHRP) under 45 CFR 46.103(a), and that review human subjects research conducted or supported by HHS.

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 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 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 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)].

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 proposed IRB/IEC Registration Form provides a simplified electronic information collection process. Most of the information collected by OHRP through the IRB/IEC Registration Form is the minimum necessary to satisfy the requirements of HHS regulations at 45 CFR 46.103(b)(2) and (3). In addition, HHS has issued a notice of proposed rulemaking and is currently preparing a final rule requiring submission of most of the remaining information included in the IRB/IEC Registration Form.

2. Information Users

The IRB/IEC Registration Form collects the following information for the following purposes:

(a) The name and mailing address of the institution or organization operating the IRB.

Purpose: OHRP uses this information to identify the institution or organization operating the IRB/IEC, and to provide educational information to that institution.

(b) The name, earned degree, title, mailing address, phone and facsimile numbers, and e-mail address of the institution's or organization's senior or head official responsible for overseeing IRB/IEC activities.

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, title, telephone and facsimile numbers, and e-mail address of the person providing the registration information.

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, registration name and address.

Purpose: OHRP uses this information to identify the specific IRBs/IECs providing the registration information. OHRP will post a list of registered IRBs on its website, including the name and location of each IRB/IEC and the name and location of the organization operating the IRB/IEC. An institution submitting an assurance will include the IRB registration number for each IRB designated under its assurance, thereby eliminating the need for multiple submissions of the same information to OHRP.

(e) The IRB/IEC chairperson's name, earned degree, title, area of specialty, affiliation, gender, telephone and facsimile, and e-mail address.

Purpose: Collection of this information will help OHRP to contact the IRB/IEC chairperson quickly, if necessary, on important issues, send educational material and electronic mail, and confirm that the IRB membership meets the minimum regulatory requirements at 45 CFR 46.103(b)(3) and 46.107(a).

(f) An IRB roster that includes the name, gender, degree, scientific or nonscientific specialty, and affiliation of each voting and alternate IRB/IEC member.

Purpose: This information is collected so that OHRP can confirm that the requirements of 45 CFR 46.103(b)(3) and 46.107(a) are met.

(g) The approximate total number of active protocols undergoing initial and continuing IRB review, using the measures "small," "medium," and "large;" and, the approximate number of active protocols supported by HHS.

Purpose: OHRP will use this information: (i) to determine how active an IRB/IEC is, and; (ii) to assign its quality improvement, educational, and compliance oversight resources based on an IRB's activity level. OHRP will consider an active protocol to be any protocol or study for which an IRB/IEC

conducted a review (initial or continuing) during the preceding calendar year. OHRP will consider a "small" number of protocols to be 1 to 25 protocols, "medium" to be 26 to 499 protocols and "large" to be 500 protocols or more.

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

Purpose: This information is collected so that OHRP can assess whether the regulatory requirements at 45 CFR 46.103(b)(2) are being met. 45 CFR 46.103(b)(2) requires that assurances of compliance applicable to HHS-conducted or -supported research include designation of one or more IRBs/IECs for which, among other things, provisions are made for meeting space and for sufficient staff to support each IRB's review and recordkeeping duties. In OHRP's experience, the number of FTEs and the volume of research are useful parameters for assessing whether an IRB/IEC has sufficient staff.

(i) An indication of whether the institution or IRB organization is accredited, and if so, the date of the last accreditation and the name of the accrediting body or organization.

Purpose: OHRP uses this information to help evaluate the extent of IRB accreditation.

OHRP will make available information collected in the IRB/IEC Registration Form to the other Federal departments and agencies that have adopted the Federal Policy and who find that a Federalwide Assurance (FWA) is appropriate for the human subjects research which they conduct or support. The information will enable these departments and agencies to confirm that a particular institution holds an applicable assurance approved for Federalwide use and identify an institution's designated IRB(s) before making an award to that institution to support research involving human subjects.

3. Improved Information Technology

Organizations registering new IRBs/IECs or updating or renewing already registered IRBs may submit all information via the internet using an interactive page on the OHRP website. OHRP anticipates that the majority (more than 90%) of institutions needing to submit, update or renew an IRB/IEC registration will do so via the internet.

4. Duplication of Similar Information

The IRB/IEC Registration Form does not duplicate any other information collection by OHRP.

5. Small Businesses

The information collection through the IRB/IEC Registration Form 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

Whenver there is a change in information on file with OHRP regarding an IRB/IEC registration, an update to the registration must be submitted to OHRP. Furthermore, institutions are required to submit a complete renewal to the IRB registration information at least every three years. This frequency of collection is required so that OHRP can ensure that the HHS IRB registration system is accurate and up-to-date. 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 website for a current, accurate list of designated IRBs for an institution.

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 IRB-registration form (OMB # 0990-0279). In general, the majority of comments supported the effectiveness and efficiency of the IRB registration system, including the form. On November 14, 2007, vol. 72, No.219; pp. 64081, 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 IRB/IEC Registration Form is, and always has been, considered releasable under the Freedom of Information Act (FOIA). The database used to track IRB registration data, referred to as the Human Assurance Tracking System (HATS), utilizes Microsoft SQL Server tables stored on a server 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 data. Without the appropriate username/password, unauthorized users will not gain access to the IRB registration database. IRB registration database tables will never be provided outside of OHRP. Requests for IRB registration information under the FOIA are fulfilled via printed reports or disk files containing extracted information. The public can retrieve limited data from the IRB registration 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, IRB renewal date, date of last IRB membership update, and institutions with OHRP-approved FWA that rely upon IRBs located at other OHRP-approved FWA institutions. Additional IRB registration 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. Of note, the public and other agencies do not have the ability to modify the IRB registration database tables.

11. Sensitive Questions

No sensitive information is being collected by the IRB registration system.

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 IRB Registration Form only are provided below.

The information being requested in the IRB registration system should be readily available to the institution or organization that registers the IRB.

Estimated Annualized Burden Table

Form name	Number of Respondents	Number of responses per respondent	Average burden per response (in hours)	Total Burden hours
IRB/IEC Registration	6,000	2	1	12,000

The estimate of the number of respondents is based upon the current number of IRBs registered with OHRP (5,700) and the assumption that this number may increase to up to 6,000 IRBs. Of the 6,000 IRBs, 2,000 would submit new registration information and update or renew registration information one time during the year and 4,000 of the 6,000 IRBs would update or renew IRB registration information up to two times each year.
The estimate of the number of responses per respondent is based upon the assumption

that an institution will need to submit an initial registration, or an update or renewal of a previously approved IRB registration, on average, every 12 months.

The estimate of the hours per response assumes that the majority of respondents will complete the IRB/IEC 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/IEC Registration Form; (ii) collect the information to complete the form; and (iii) enter the information requested on the IRB/IEC Registration Form. The estimate assumes that completion of a new or completely updated IRB/IEC registration (due at least every three years) will require 1 hour, and completion of a limited update or renewal of an IRB/IEC registration will require 0.5 hours. OHRP assumes the average wage rate is $40 per hour.

Of the projected 6,000 IRBs, OHRP estimates that 2,000 will complete one new registration and one update each year and the other 4,000 IRBs will complete 2 updates or renewals each year. The total annual burden costs for 6,000 IRBs are projected to be $280,000: 2,000 new IRBs x 1 hour x $40/hr = **$80,000**; 1 renewal/update of these 2,000 IRBs x 0.5 hr x $20/0.5 hr = **$40,000;** 4,000 will update/renewal IRBs x 0.5 hr x $20/0.5 hr = **$80,000**; 1 renewal/update of these 4,000 IRBs x 0.5 hr x $20/0. hr = **$80,000**. Thus, the total annual burden cost = **$280,000**: $80,000 + $40,000 +$80,000 + $80,000

Estimated Annualized Burden Table

Forms	**Total Burden Hours**	**Hourly Wage Rate**	**Total Burden Dollars**
IRB/IEC -0279	2,000	$40	$80,000
	2,000	$20	$40,000
IRB/IEC -0279	4,000	$20	$80,000
	4,000	$20	$80,000
			Total: $280,000

13. Capital Costs (Maintenance of Capital Costs)

There are no direct capital costs to respondents other than the time to review the instructions and to complete the IRB/IEC Registration 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 is $1,992,000.

15. Program or Burden Changes

The annual burden will increase from 3,500 hours to 12,000 hours and from $110,000 to $280,000 due to adjusting to correct errors in calculating burden. In additions, the number of IRBs increased from an estimated 5,000 to an estimated 6,000.

16. Publication and Tabulation Dates

The list of registered IRBs will be posted, and updated daily, on the OHRP website.

17. Expiration Date

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

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 – Instructions for completing the current IRB/IEC Registration Form
- a. Current Instructions
- b. Proposed Instructions

Attachment 3 - IRB/IEC Registration Form

- a. Current Form
- b. Proposed Form