Supporting Statement for the Department of Health and Human Services (HHS) Institutional Review Board (IRB) Registration Form

A. Background

The Office for Human Research Protections (OHRP) and the Food and Drug Administration (FDA) are requesting a three-year extension of the OMB No. 0990-0279, Institutional Review Board (IRB) Registration Form, currently approved through June 30, 2012. This form was modified in 2009 to be consistent with IRB registration requirements that were adopted in July 2009 by the Office for Human Research Protections (OHRP) and the Food and Drug Administration (FDA), respectively. At that time OMB recommended that the information collection request required by OHRP's and FDA's IRB Registration rules be combined because the information would be submitted using the same form. A similar mechanism is being used for this request for a three-year extension of the OMB form No. 0990-0279.

The purpose of the IRB Registration Form is to provide a simplified procedure for institutions engaged in research conducted or supported by HHS to satisfy the assurance requirements of (1) Section 491(a) of the Public Health Service Act (the PHS Act); (2) HHS regulations for the protection of human subjects at 45 CFR 46.103; and, (3) FDA regulations for institutional review boards at 21 CFR 56.106. The respondents for this collection are institutions or organizations operating IRBs designated by an institution under an assurance of compliance approved for federalwide use by OHRP under 45 CFR 46.103(a) and IRBs that review human subjects research conducted or supported by HHS, or, in the case of FDA's requirements, each IRB in the United States that reviews clinical investigations regulated by FDA under sections 505(i) or 520(g) of the Federal Food, Drug and Cosmetic Act; and each IRB in the United States that reviews clinical investigations that are intended to support applications for research or marketing permits for FDA-regulated products.

B. Justification

OHRP:

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 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.

In December 2000, OHRP initiated a process for registering IRBs. The IRB registration system was developed in response to a 1998 HHS Office of Inspector General (OIG) recommendation that all IRBs register with the Federal government on a regular basis as part of an effort to develop a more streamlined, coordinated, and probing means of assessing IRB performance and to enhance the Federal government's ability to identify and respond to emerging problems. The OHRP IRB

registration system was designed to collect information required under the HHS human subjects protection regulations at 45 CFR 46.103.

Among other things, assurances of compliance must include information on the institution's designated IRB(s), and a list of IRB members identified by name, earned degrees, representative capacity, experience, and any employment or other relationship with the institution (45 CFR 46.103(b)(2),(3)).

The OHRP IRB registration system developed in December 2000 was also designed to collect additional information to be provided voluntarily by institutions or IRBs, regarding the accreditation status of the institution or IRB organization, total numbers of active research protocols reviewed by the IRB (including protocols supported by other Federal departments or agencies) and the nature of those protocols, and IRB staffing.

On July 6, 2004, OHRP published in the Federal Register (69 FR 40584) a Notice of Proposed Rulemaking (NPRM) seeking public comment on changes to the IRB registration system, that would require submission of the information being submitted on a voluntary basis. By requiring IRBs to provide such information, OHRP IRB registration requirements would become substantially consistent with requirements for IRB registration that were simultaneously proposed by FDA in the same issue of the Federal Register (69 FR 40556). OHRP and FDA proposed to use a single registration system, accessible on the OHRP website, in which all IRBs that review research conducted or supported by HHS or clinical investigations regulated by FDA could register.

The OHRP final IRB Registration Rule that was published in the Federal Register on January 12, 2009 (74 FR, No. 10, pp 2399-2405) and became effective on July 14, 2009 requires the following information must be provided to HHS when registering an IRB: the

- name, mailing address, and street address (if different from the mailing address) of the institution or organization operating the IRB(s); and the name, mailing address, phone number, facsimile number and email address of the senior officer or head official who is responsible for overseeing activities performed by the IRB;
- name, mailing address, phone and facsimile numbers and electronic email address of: (i) the senior officer or head official who is responsible for overseeing activities performed by that institution's or organization's IRB; and (ii) the contact person providing the registration information;
- name, if any assigned to the IRB by the institution or organization, and the IRB's mailing address, street address (if different from the mailing address), phone and facsimile numbers and electronic mail address;
- name, phone number and electronic mail address of the IRB chairperson;
- approximate number of all active protocols and approximate number of active protocols conducted or supported by HHS; and

- approximate number of full-time equivalent positions devoted to the IRB's administrative activities.

FDA:

The Food and Drug Administration (FDA) in 2009 requested OMB approval for two collections of information associated with IRB registration. The first collection of information was represented by the OMB form 0990-0279 developed jointly by OHRP and by FDA which was approved by OMB for use through June 30, 2012.

Additionally, FDA proposed to amend its regulations pertaining to IRBs. The final rule was published in the Federal Register (74 FR, No. 10, pp 2358-2369) on January 15, 2009 and became effective on July 14, 2009; it requires IRBs to register at a website accessible on the OHRP website and maintained by OHRP.

FDA took this action pursuant to a recommendation from the Office of the Inspector General, Department of Health and Human Services, to require all IRBs to register with the federal government to develop a more streamlined, coordinated, and probing means of assessing IRB performance and to enhance the government's ability to identify and respond to emerging problems. Information on registered IRBs makes it easier for FDA to send educational information to IRBs and to identify IRBs for inspection.

Insofar as its final rule is concerned, FDA requested approval from OMB of a new collection of information requirement in "Institutional Review Boards; Registration and Use Requirements" codified at 21 CFR 56.106. The new collection of information associated with the rule was projected to be 8,750 hours.

21 CFR 56.106(c) - Reporting

This provision requires an IRB to submit an initial registration to HHS. The initial registration may occur at any time, but each IRB must renew its registration every 3 years. Section 56.106(b) describes the contents of the registration information, such as:

- The name, mailing address, and street address (if different from the mailing address) of the institution operating the IRB and the name, mailing address, phone number, facsimile number, and electronic mail address of the senior officer of that institution who is responsible for overseeing activities performed by the IRB;
- The IRB's name, mailing address, street address (if different from the mailing address), phone number, facsimile number, and electronic mail address; each IRB chairperson's name, phone number, and electronic mail address; and the

name, mailing address, phone number, facsimile number, and electronic mail address of the contact person providing the registration information.

- The approximate number of active protocols involving FDA-regulated products reviewed. For purposes of this rule, an "active protocol" is any protocol for which an IRB conducted an initial review or a continuing review at a convened meeting or under an expedited review procedure during the preceding 12 months; and
- A description of the types of FDA-regulated products (such as biological products, color additives, food additives, human drugs, or medical devices) involved in the protocols that the IRB reviews.

21 CFR 56.106(e) - Reporting

This provision would require IRBs to revise their registration information:

- within 90 days if the IRB's contact or chairperson information changes;
- within 30 days if the IRB decides to disband or discontinue reviewing clinical investigations regulated by FDA; or
- for all other information changes, when the IRB renews its registration.

2. Information Users

OHRP:

The IRB Registration Form collects the following information from Institutions or Organizations operating IRBs that are regulated by OHRP, for the following purposes:

(a) The name, location, mailing address, street address (if different from the mailing address, and OHRP-assigned number (called an IORG number)) of each institution or organization that has registered an IRB. The IORG number is a unique number assigned by OHRP to an institution or organization the first time that it registers an IRB. This number is to be provided to OHRP whenever an institution or organization subsequently updates or renews the existing registration of any of its IRBs or registers a new IRB.

Purpose: OHRP uses this contact information to identify the institution or organization operating the IRB(s), and to provide educational information to that institution. Provision of the IORG number allows OHRP to efficiently track and organize all IRB registration information submitted by the same institution or organization.

(b) The name, earned degree(s), title or position, mailing address, phone number, facsimile numbers, and electronic mail address of the institution's or organization's senior officer or head official who is responsible for overseeing activities performed by the IRB.

(Note: submitting the following information for the institution's or organization's senior officer or head officer will be optional: earned degree(s), title or position)

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, earned degree(s), title or position, mailing address, phone number, facsimile number, and electronic mail address of the contact person providing the registration information.

(Note: submitting the following information for the contact person will be optional: earned degree(s), title or position)

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, IRB name, if any, assigned to the IRB by institution or organization operating the IRB, the IRB mailing address, street address (if different from the mailing address), phone number, facsimile number, and electronic mail address.

Purpose: OHRP uses this information to identify the specific IRBs for which registration information is provided. OHRP will post a list of registered IRBs on its website, including the name and location of each IRB and the name and location of the organization operating the IRB. 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 chairperson's name, earned degree(s), title or position, mailing address (if different from the mailing address of the institution or organization operating the IRB), phone number, facsimile number, and electronic email address.

(Note: submitting the following information for the IRB chairperson will be optional: earned degree(s), title or position, mailing address, and facsimile number)

Purpose: Collection of this information will help OHRP to contact the IRB chairperson quickly, if necessary, on important issues, and send educational material.

(f) An IRB roster that includes each IRB member's name, earned degree(s), sex, designation as scientist or non-scientist, primary scientific or nonscientific specialty, and affiliation status of IRB member, including the chairperson and any alternate IRB members.

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 number of all active research protocols and active protocols conducted or supported by HHS.

Purpose: OHRP will use this information to more effectively assign its quality improvement, educational and compliance oversight resources, and obtain insight into an IRB's activity level. OHRP will consider an active protocol to be any protocol for which an IRB conducted an initial or continuing review at a convened meeting or under an expedited review procedure during the preceding 12 months.

(h) The approximate number of full-time equivalent (FTE) positions devoted to the IRB'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 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 has sufficient staff.

OHRP will make available information collected in the IRB 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.

FDA:

The IRB registration form used for FDA-regulated IRBs is substantially similar to that used by OHRP, although fewer data or information elements would exist due to statutory or regulatory differences in the respective agencies' IRB authorities.

In brief, the IRB Registration Form pertaining to FDA-regulated IRBs would cover the following information:

- The name, mailing address, and street address (if different from the mailing address) of the institution operating the IRB and the name, mailing address, phone number, facsimile number, and electronic mail address of the senior officer of that institution who is responsible for overseeing activities performed by the IRB;
- The IRB's name, mailing address, street address (if different from the mailing address), phone number, facsimile number, and electronic mail address; each IRB chairperson's name, phone number, and electronic mail address; and the name, mailing address, phone number, facsimile number, and electronic mail address of the contact person providing the registration information.
- The approximate number of active protocols involving FDA-regulated products reviewed. For purposes of this rule, an "active protocol" is any protocol for which an IRB conducted an initial review or a continuing review at a convened meeting or under an expedited review procedure during the preceding 12 months; and
- A description of the types of FDA-regulated products (such as biological products, color additives, food additives, human drugs, or medical devices) involved in the protocols that the IRB reviews.

FDA will use the registration information to identify IRBs for FDA inspection and to convey information to IRBs.

3. Improved Information Technology

OHRP:

Each IRB must be registered electronically through http://ohrp.cit.nih.gov/efile unless an institution or organization lacks the ability to register its IRB's electronically. If an institution or organization lacks the ability to register an IRB electronically, it must send its IRB registration information in writing to OHRP.

FDA:

The collection of information would rely primarily on the use of electronic collection techniques. FDA's final rule, however, does allow IRBs to register in writing if they lack the ability to register electronically.

4. Duplication of Similar Information

The IRB Registration Form does not duplicate any other information collection by OHRP or by FDA**.** Additionally, FDA has harmonized its registration requirements with OHRP to the maximum extent possible. (OHRP is the principal federal agency responsible for human subject protection issues as they relate to HHS-conducted or supported research involving human subjects. In contrast, FDA's human subject protection regulations apply to most research involving FDA-regulated products, regardless of federal funding.) If an IRB is subject to regulation by both FDA and OHRP, it would only register once. Therefore, no duplication of data exists.

5. Small Businesses

The information collection through the IRB Registration Form is simple and straightforward and represents the minimum amount of information necessary to satisfy the OHRP and FDA Registration Requirements. The information collection will not have a significant economic impact on a substantial number of small entities.

6. Less Frequent Collection

OHRP:

The registration information for an IRB must be updated within 90 days after changes occur regarding the contact person who provided the IRB registration information or the IRB chairperson. Any renewal or update that is submitted to, and accepted by, OHRP begins a new 3-year effective period.

An institution's or organization's decision to disband a registered IRB which it is operating also must be reported to OHRP in writing within 30 days after permanent cessation of the IRB's review of HHS-conducted or -supported research.

Each IRB must renew its registration every 3 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.

FDA:

Failure to register would impair FDA's ability to send information to an IRB and to identify an IRB for inspection. FDA uses inspections to determine an IRB's

compliance with FDA requirements.

7. Special Circumstances

None.

8. Federal Register Notice/Outside Consultation

OHRP and FDA:

On July 6, 2004, OHRP published in the Federal Register (69 FR, No. 128, pp 40584-40589) an NPRM seeking public comments to the IRB registration system developed in 2000. OHRP proposed to amend the HHS human subjects protection regulations at 45 CFR part 46 to require any IRB designated under an assurance of compliance approved for federalwide use by OHRP that reviews human subjects research conducted or supported by HHS to submit most of the information listed on the IRB registration form, including the information provided on a voluntary basis. By requiring IRBs to provide such information, OHRP IRB registration requirements would become substantially consistent with requirements for IRB registration that were simultaneously proposed by FDA in the same issue of the Federal Register (69 FR, No. 128, pp 40556-40562). OHRP and FDA proposed to use a single registration system, accessible on the OHRP website, in which all IRBs that review research conducted or supported by HHS or clinical investigations regulated by FDA could register.

OHRP received 13 comments during the 90-day comment period that ended October 4, 2004. After considering these public comments and consulting with FDA, OHRP adopted the rule largely as it was proposed; the final rule was published on January 15, 2009 and became effective on July 14, 2009. However, in response to public comments OHRP deleted from the final rule the proposed requirement regarding whether the institution or IRB organization registering an IRB was accredited by a human subjects protection program accrediting organization.

FDA published its proposed rule in the Federal Register on July 6, 2004 (69 FR 40556). As part of the rulemaking process, FDA invited comment on its estimated information collection burden. We did not receive any comments on those estimates.

FDA's estimates were developed in cooperation with OHRP. OHRP had experience with registering IRBs.

In addition, on March 24 2009, public comments were solicited on the estimated information collection burden in the combined IRB-Registration Form for a 30-day period (74 FR, No. 55, pp. 12362-12363). No public comments were submitted during the comment period that closed on April 23, 2009.

More recently public comments were requested during a 60-day period in the Federal Register issue that was published on April 18, 2012 (77 FR, No. 75, pp.23249-23250) No public comments were submitted during the comment period, which closed on June 18, 2012

9. Payment/Gift to Respondent

OHRP and FDA:

No payments or gifts are provided to the respondents.

10. Confidentiality

OHRP and FDA:

The information collected under the IRB Registration Form 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 request non-public IRB-Registration information.

The database used to track IRB registration data, referred to as the Human Assurance Tracking System (HATS) was redesigned in July 2009; it 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 or FDA. Requests for IRB Registration information are fulfilled via printed reports or disk file 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/search.aspx?styp=bsc. This link provides read only access to the name and location of IRB Organizations and their IRB(s) name, and date of last IRB membership update for those IRBs that must submit IRB membership information. Information provided to the public via the OHRP website does not include the names and contact information of the IRB Organization's Senior Officer/Head Official or Contact Person or IRB(s) Chairpersons. 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 that requires a username and password. Of note, the public and other agencies do not have the ability to modify the IRB registration database tables.

11. Sensitive Questions

OHRP and FDA:

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

12. Burden Estimate (Total Hours & Wages)

OHRP and FDA:

Burden estimates for the IRB Registration Form have not changed from the current burden estimate. The estimate of the number of respondents is based upon the current number of IRBs registered with HHS, approximately 6,100 IRBs, and projecting that the number of respondents may increase to 7,000. For the currently approved burden the number of respondents was also estimated to be 7,000, based on the number of IRBs registered with OHRP in March 2009 (approximately 6,000) and projecting that up to an additional 1,000 IRBs (largely FDA-regulated) would register as result of the new IRB registration requirements that became effective in July 2009.

Thirty eight percent of the estimated 6,100 IRBs currently registered with HHS are registered as OHRP- and FDA-regulated IRBs, 1.4 percent are registered as FDA only-regulated IRBs and the remaining 59 percent are registered as OHRP only-regulated IRBs. Ninety-eight percent of the estimated 6,100 registered IRBs submitted their registration information electronically.

Of the 7,000 respondent IRBs, up to 900 are expected to submit new registration information one time and update or renew registration information one time during the year and up to 6,100 are expected to update or renew IRB registration information up to two times each year. If on average 7,000 respondents submit information two times each year and each response takes on average one hour to complete, the total annual burden hours are projected to be 14,000.

Estimated Annualized Burden Table

Form name	Number of Respondents	Number of responses per respondent	Average burden per response (in hours)	Total Burden hours
IRB Registration 0990-0279	6,100	2	1	12,200
	900	2	1	1,800
Total				14,000

The estimate of the hours per response assumes that the majority of respondents will complete the IRB 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 Registration Form; (ii) collect the information to complete the form; and (iii) enter the information requested on the IRB Registration Form. Based on OHRP's experience in registering the IRBs currently registered, most of the respondents will be administrative staff persons within organizations and institutions. The hourly wage is estimated to be $25 and the total burden cost is estimated to be $350,000.

Estimated Annualized Burden Table

Form Name	Total Burden Hours	Hourly Wage Rate	Total Burden Dollars
IRB Registration 0990-0279	12,200	$25.00	$305,000
	1,800	$25.00	$45,000
Total			$350,000

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 Registration Form.

14. Cost to Federal Government

The estimated annual Federal costs for reviewing and accepting IRB Registrations is $400,000

15. Program or Burden Changes

The annual burden will not change. The total annual burden hours are projected to be 14,000 and the total burden cost is estimated to be $350,000.

16. Plans for Tabulation and Publication and Project Time Schedule

There are no plans to publish or tabulate the information.

17. Reason(s) Display of OMB Expiration Date is Inappropriate

Display of OMB expiration date is appropriate.

18. Exceptions to Certification for Paperwork Reduction Act Submissions

No 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

Attachment 2 – Instructions for completing the current IRB/IEC Registration Form
- a. Proposed Instructions

Attachment 3 - IRB Registration Form
- a. Proposed Form