L. Administrative Requirements

The EPA has examined the effects of the proposed State authorization decision discussed above and reached the conclusions set out below.

The Office of Management and Budget has exempted this action from the requirements of Executive Order 12866 (58 FR 51735, October 4, 1993), and therefore this action is not subject to review by OMB.

This action authorizes State requirements for the purpose of RCRA 3006 and imposes no additional requirements beyond those imposed by State law. Accordingly, the EPA certifies that this action will not have a significant economic impact on a substantial number of small entities under the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*).

Because this action authorizes pre-existing requirements under State law and does not impose any additional enforceable duty beyond that required by State law, it does not contain any unfunded mandate, or significantly or uniquely affect small governments, as described in the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4). For the same reason, this action also does not significantly or uniquely affect the communities of Tribal governments, as specified by Executive Order 13175 (65 FR 67249, November 9, 2000). This action will not have substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government, as specified in Executive Order 13132 (64 FR 43255, August 10, 1999), because it merely authorizes State requirements as part of the State RCRA hazardous waste program without altering the relationship or the distribution of power and responsibilities established by RCRA.

This action also is not subject to Executive Order 13045 (62 FR 19885, April 23, 1997), because it is not economically significant and it does not make decisions based on environmental health or safety risks. This rule is not subject to Executive Order 13211, ''Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use'' (66 FR 28355 (May 22, 2001)) because it is not a significant regulatory action under Executive Order 12866.

Under RCRA 3006(b), EPA grants a State's application for authorization as long as the State meets the criteria required by RCRA. It would thus be inconsistent with applicable law for EPA, when it reviews a State authorization application, to require the use of any particular voluntary consensus standard in place of another standard that otherwise satisfies the requirements of RCRA. Thus, the requirements of section 12(d) of the National Technology Transfer and Advancement Act of 1995 (15 U.S.C. 272 note) do not apply.

As required by section 3 of Executive Order 12988 (61 FR 4729, February 7, 1996), in issuing this rule, EPA has taken the necessary steps to eliminate drafting errors and ambiguity, minimize potential litigation, and provide a clear legal standard for affected conduct. EPA also has complied with Executive Order 12630 (53 FR 8859, March 15, 1988) by examining the takings implications of the rule in accordance with the Attorney General's Supplemental Guidelines for the Evaluation of Risk and Avoidance of Unanticipated Takings issued under the Executive Order.

This rule does not impose any information collection burden under the provisions of the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*).

List of Subjects in 40 CFR Part 271

Environmental protection, Administrative practice and procedure, Confidential business information, Hazardous materials transportation, Hazardous waste, Indians-lands, Intergovernmental relations, Penalties, Reporting and recordkeeping requirements.

Authority: RCRA sections 2002 and 3006, 42 U.S.C. 6912 and 6926.

Dated: June 23, 2004.

Robert W. Varney,

Regional Administrator, EPA New England.

[FR Doc. 04–15102 Filed 7–2–04; 8:45 am]

BILLING CODE 6560–50–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

45 CFR Part 46

RIN 0940–AA06

Institutional Review Boards: Registration Requirements

AGENCY: Office of Public Health and Science, HHS.

ACTION: Notice of proposed rulemaking.

SUMMARY: The Office for Human Research Protections (OHRP), Office of Public Health and Science, Department of Health and Human Services (HHS), is proposing to require registration of institutional review boards (IRBs) that review human subjects research conducted or supported by HHS and that are designated under an assurance of compliance approved for federalwide use by OHRP. The registration information would include contact information, approximate numbers of active protocols involving research conducted or supported by HHS, accreditation status, IRB membership, and staffing for the IRB. The proposed registration requirements will make it easier for OHRP to convey information to IRBs and will support the current IRB registration system operated by OHRP. Under the current OHRP IRB registration system, the submission of certain information is required by the existing HHS human subjects protection regulations, and certain other information may be submitted voluntarily. A request for the approval of this collection of information requirement will be submitted to the Office of Management and Budget (OMB) under the Paperwork Reduction Act. Under the proposed rule, all registration information will be required, making the IRB registration system uniform with the proposed IRB registration requirements of the Food and Drug Administration (FDA), and creating a single HHS IRB registration system. FDA simultaneously is publishing a proposed rule regarding FDA IRB registration requirements.

DATES: You may submit written or electronic comments on this proposed rule, RIN number 0940–AA06, by October 4, 2004.

ADDRESSES: You may submit comments by any of the following methods:

- Federal eRulemaking Portal: *http:www.regulations.gov.* Follow the instructions for submitting comments.
- E-mail: *irbregistrationohrp@osophs.dhhs.gov.*
- Fax: 301–402–2071.
- Mail to: Irene Stith-Coleman, Office for Human Research Protections, The Tower Building, 1101 Wootton Parkway, Suite 200, Rockville, MD 20852.
- Hand Delivery or Courier to: Irene Stith-Coleman, Office for Human Research Protections, The Tower Building, 1101 Wootton Parkway, Suite 200, Rockville, MD 20852

Comments received within the comment period will be available for public inspection as they are received, generally beginning approximately 3 weeks after publication of this notice, at the above address on Monday through Friday of each week from 8:30 a.m. to 4 p.m.

FOR FURTHER INFORMATION CONTACT: Irene Stith-Coleman, Office for Human Research Protections, The Tower Building, 1101 Wootton Parkway, Suite

200, Rockville, MD 20852, 301–402–7005 or by e-mail to: *(istithco@osophs.dhhs.gov).*

SUPPLEMENTARY INFORMATION:

I. Introduction

IRBs are boards, committees, or groups formally designated by an institution to review, approve, and have continuing oversight of research involving human subjects. An IRB's primary purpose during such reviews is to ensure the protection of the rights and welfare of human research subjects. The HHS regulations regarding the protection of human research subjects, which address the appropriate role of IRBs in helping to ensure this protection, are found at 45 CFR part 46.

In 1998, the HHS Office of Inspector General (OIG) issued several reports on IRBs. The OIG sought to identify the challenges facing IRBs and to make recommendations on improving Federal oversight of IRBs. One recommendation was that all IRBs should 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 before they result in ''serious transgressions.'' (Ref. 1, pp. 20 and 21).

After reviewing OIG's recommendation, OHRP concluded that IRB registration would serve several important goals. IRB registration would enable OHRP to: (1) Identify more precisely those IRBs reviewing research conducted or supported by HHS under an assurance of compliance approved for federalwide use by OHRP; (2) keep an accurate, up-to-date list of IRBs; (3) send educational information and other information to IRBs, increasing the efficiency of OHRP educational and outreach efforts; and (4) help OHRP identify IRBs that are subject to HHS regulations for monitoring and oversight purposes.

In December 2000, OHRP initiated a process for registering IRBs. This IRB registration system was designed to collect information required under the HHS human subjects protection regulations at 45 CFR 46.103(b)(3). That regulatory provision requires institutions that are engaged in human subjects research conducted or supported by HHS to file with OHRP an assurance of compliance with the HHS human subjects protection regulations. Under 45 CFR 46.103(a), other Federal Department or Agency heads shall accept an assurance on file with HHS that is approved for federalwide use by OHRP, and that is appropriate for the research in question. Among other things, assurances of compliance must include information on the institution's designated IRB, 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 IRB registration system also was 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. The current OHRP IRB registration form can be accessed at: *http://ohrp.osophs.dhhs.gov/humansubjects/assurance/regirb.rtf.*

OHRP now proposes to require that any IRB designated under an assurance of compliance approved for federalwide use by OHRP that reviews human subjects research conducted or supported by HHS submit most of the information listed on the IRB registration form that is currently used by OHRP. By requiring IRBs to provide such information, OHRP IRB registration requirements will become substantially consistent with requirements for IRB registration that are simultaneously being proposed by FDA elsewhere in this issue. OHRP and FDA plan to operate a single registration system for HHS in which all IRBs that review research conducted or supported by HHS or clinical investigations regulated by FDA can be registered. The HHS IRB registration system will be operated at a single Internet site on the OHRP Web site.

OHRP currently posts all registered IRBs on its Web site, including the name and location of the organization operating the IRB(s), called the IRB organization, and the name and location of each IRB. Numbers are assigned to the IRB organization and each IRB is given a unique IRB registration number. An institution submitting an assurance includes the IRB registration number for each IRB designated under its assurance, thereby eliminating the need for multiple submissions of the same information to OHRP.

The Privacy Act does not apply to the information contained in the IRB registration database. OHRP will not be retrieving information about individuals from this Internet site by name or other individual identifier. Therefore, this Internet site will not be a ''system of records'' that would be subject to the requirements of the Privacy Act of 1974.

Upon the effective date of the rule, OHRP will continue to post the name and location of each registered IRB and its IRB registration number on the OHRP Web site. All other information collected in the IRB registration, including names of individual IRB members, would be subject to the Freedom of Information Act, and therefore, may be available to the public upon request. Beyond such access to the information, OHRP will maintain the confidentiality of the information submitted with the IRB registration to the extent allowed by law.

All of the IRB registration information that is submitted to the Internet site will be transferred to a separate server which will not be accessible via the Internet. In this manner, a high level of security can be maintained for the IRB Registration database.

OHRP will provide browse-only access to the database containing all information collected in the IRB Registration, via a password protected mechanism, to all Federal departments and agencies that have adopted the Federal Policy for the Protection of Human Subjects, known as the ''Common Rule,'' which HHS has codified as 45 CFR part 46, subpart A.

II. Description of the Proposed Rule

The proposed rule would amend the HHS human subjects protection regulations at 45 CFR part 46 by adding subpart F, entitled ''Registration of Institutional Review Boards.'' The proposed rule would require IRBs that review human subjects research conducted or supported by HHS and that are designated under an assurance of compliance approved for federalwide use by OHRP to register with HHS.

1. Who Must Register? (Proposed § 46.601)

Proposed § 46.601 requires registration of each IRB that is designated by an institution under an assurance of compliance with HHS human subjects protection regulations that has been approved for federalwide use by OHRP, under 45 CFR 46.103(a), and that reviews human subjects research conducted or supported by HHS.

Proposed § 46.601 also specifies that an individual authorized to act on behalf of the institution or IRB must submit the registration information. The individual may be an IRB member or any other person authorized by the institution, or IRB, to submit the registration information.

2. What Information Must an IRB Provide When Registering? (Proposed § 46.602)

Proposed § 46.602 describes the information to be submitted as part of the registration process. The proposal requires IRBs to provide the following information:

• The name and mailing address of the institution or organization operating the IRB; the name, earned degree, title, mailing address, phone number, fax number, and e-mail address of the senior or head official of that institution or organization who is responsible for overseeing the activities performed by the IRB; and the name, title, telephone number, fax number, and e-mail address of the person providing the registration information must be provided. The senior or head official should not be an IRB member or IRB staff. This information enables OHRP to identify the institution(s) or organization(s) with which the IRB is affiliated. Information about the senior or head official of the institution enables OHRP to 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. Information about the contact person enables OHRP to contact that person directly on routine issues, forward information, and send electronic mail to the contact person.

• The IRB number, registration name and address; the name, earned degree, title, area of specialty, affiliation, gender, telephone, fax, e-mail address, and mailing address of the IRB chairperson; and an IRB roster that includes the names, earned degrees, gender, area of specialty and affiliation of each voting (including the IRB chairperson) and alternate IRB members must be provided. Collection of this information is consistent with the requirements of 45 CFR 46.103(b)(3) and 46.107(a), and helps OHRP to contact the IRB chairperson quickly, if necessary, on important issues, to send educational information and electronic mail, and to confirm that IRB membership meets the minimum regulatory requirements.

• The approximate number of active protocols undergoing initial and continuing review; the approximate number of active protocols supported by HHS; and the approximate number of full time positions devoted to the IRB's administrative activities. In this proposal, ''active protocol'' would mean any protocol or study for which an IRB conducted an initial review or a continuing review during the preceding calendar year.

The proposal would not require an institution or IRB organization to report a specific number of protocols; instead, registration would indicate the range of the number of protocols reviewed in the preceding calendar year. The proposal would consider a ''small'' number of protocols to be 1 to 25 protocols, ''medium'' to be 26 to 499, and ''large'' to be 500 or more protocols. This information will enable OHRP to determine how active an IRB is and to assign its quality improvement, educational, and compliance oversight resources based on an IRB's activity level. For example, scheduling the site of an OHRP national workshop could involve assessment of the volume of research conducted by an institution in a potential locale. Furthermore, HHS regulations for the protection of human subjects at 45 CFR 46.103(b)(2) require that assurances of compliance applicable to HHS conducted or supported research include the designation of one or more IRBs for which, among other things, provisions are made for meeting space and sufficient staff to support the IRB's review and record keeping 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, as required by HHS regulations for the protection of human subjects at 45 CFR 46.103(b)(2).

• An indication as to whether the assured institution or IRB organization is currently accredited by a human subjects protection program accrediting organization, and if so, the date of its last accreditation and the name of that accrediting organization must be provided. OHRP recognizes that accreditation is a developing concept, so information on accreditation will help OHRP to evaluate the extent and value of IRB accreditation. OHRP specifically solicits public comment related to the perceived value of collecting information on the accreditation status of IRBs.

In addition, the IRB registration process includes information required by FDA under its proposed rule: the number of active protocols (small, medium, or large) involving FDA-regulated products reviewed (both initial reviews and continuing reviews); 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 active protocols that the IRB reviews.

Due to statutory and regulatory differences between OHRP and FDA, the Internet registration site may request more information from IRBs reviewing research conducted or supported by HHS than those reviewing clinical investigations regulated by FDA that are not conducted or supported by HHS. In those instances where the registration site would seek more information than FDA would require under its proposal, the internet site would clarify that IRBs regulated solely by FDA are not required to provide the additional information.

The proposed rule would not require submission of one element of information that currently is submitted voluntarily. It would not require IRBs to provide information on the approximate number of currently active protocols supported by other Federal departments or agencies. OHRP determined that collection of such information should not be required because the proposed rule would apply only to IRBs that are designated under an OHRP-approved assurance of compliance and that review research conducted or supported by HHS.

3. When Must an IRB Register? (Proposed § 46.603)

Proposed § 46.603 requires IRBs to register when designated under an assurance approved for federalwide use by OHRP. Specifically, the proposal would require an IRB to register when any institution files with OHRP an assurance of compliance with the HHS human subjects protection regulations under 45 CFR 46.103(a), that is to be approved for federalwide use by OHRP, and that designates the IRB to review human subjects research conducted or supported by HHS. IRB registration will become effective on the date that OHRP lists the IRB registration on its website.

To show how this would work, assume that an institution is engaged, for the first time, in human subjects research conducted or supported by HHS. The institution then would be subject to the HHS human subjects protection regulations, and would be required to file an assurance of compliance with those regulations under 45 CFR 46.103(a). Designation of an IRB is part of that assurance process. If the institution's assurance is submitted to, and approved for federalwide use by, OHRP, the IRB(s) designated under the assurance would have to register with HHS if not previously registered. Further, if the institution designates an additional IRB under its assurance, the additional IRB must first register and the assurance must be updated to include the new IRB. As discussed under item 5 below, OHRP will continue to recognize IRB registrations that were completed prior to the effective date of the rule, and will give such IRBs 90 days from the

effective date of the rule to submit to OHRP revisions to the existing registration information, if necessary, to meet additional requirements of the proposed rule.

Proposed § 46.603 also requires IRBs to renew their registrations every 3 years. Requiring IRBs to renew their registrations periodically helps to ensure that HHS information remains current.

4. Where Can an IRB Register? (Proposed § 46.604)

Proposed § 46.604 directs IRBs to register at a specific HHS Internet site or, if the institution or IRB organization lacks the ability to register electronically, to send registration information to OHRP's mailing address. Although Internet registration may be easier and faster than written registration, OHRP cannot determine how widespread Internet access is among IRBs. Thus, OHRP also allows for written registration in addition to Internet registration.

5. How Does an IRB Revise Its Registration Information? (Proposed § 46.605)

Under proposed § 46.605, if contact or IRB membership registration information changes, the IRB must revise its registration information within 90 days of the change. All information involving changes other than changes in an IRB contact, an IRB chairperson or the IRB roster only need to be updated at the time of the 3 year renewal pursuant to proposed § 46.603. For example, if an IRB selects a new chairperson, the IRB, under proposed § 46.605, would revise its registration information within 90 days after the new chairperson's selection.

Proposed § 46.605 also considers an assured institution's or IRB organization's decision, to disband a registered IRB, or to stop reviewing research conducted or supported by HHS, to be a change that must be reported to HHS within 30 days. Requiring an IRB to report to HHS when it has disbanded or discontinued reviewing research conducted or supported by HHS will enable OHRP to stop sending educational information to the IRB and ensure that the HHS IRB registration system is accurate and up to date. More importantly, funding agencies that rely on the HHS IRB registration system will then be able to rely on the IRB registration website for a current, accurate list of designated IRBs for an institution.

OHRP will continue to recognize IRB registrations that were completed prior to the effective date of the rule, but will give IRBs that previously did not include complete information 90 days from the effective date of the rule to provide such information. That is, IRBs that chose not to provide registration information that previously was considered voluntary would be expected to complete the registration form and provide that information within 90 days of enactment of the rule.

Revised registration information may be submitted electronically to OHRP or, if an IRB lacks Internet access, in writing, to OHRP's mailing address.

6. What Happens if an IRB Does Not Register or Fails To Revise its Registration Information?

An IRB cannot be designated under an assurance of compliance approved for federalwide use by OHRP if it fails to register. For example, if an assurance submitted to OHRP for approval lists only one IRB that reviews research conducted or supported by HHS, and that IRB fails to register, OHRP would not approve that assurance. If an assurance approved for federalwide use by OHRP lists two or more IRBs that will review research conducted or supported by HHS, and one IRB fails to register, OHRP could issue a restricted approval of the assurance so that the unregistered IRB may not review HHS-conducted or supported research.

If an IRB designated under an assurance approved for federalwide use by OHRP fails to appropriately revise its registration information in accordance with § 46.605 of the proposed rule, OHRP could restrict or revoke its approval of the assurance. For example, if an IRB fails to appropriately revise its registration information in accordance with § 46.605 of the proposed rule, and the IRB is reviewing human subjects research conducted or supported by HHS, OHRP could take appropriate action under the institution's assurance and OHRP's compliance oversight policies and procedures. OHRP believes that the proposed registration requirement is both simple and straightforward, so it does not expect that many institutions or IRB organizations will refuse or fail to register or revise its registration information.

III. Implementation

OHRP intends to make any final rule based on this proposal effective within 60 days after the final rule is published in the **Federal Register**. Initial registration with all required information and required revisions to registration must be submitted within 60 days of the effective date of the rule. IRBs voluntarily may register before the required registration deadline.

IV. Legal Authority

Section 491 of the Public Health Service Act authorizes the Secretary, by regulation, to require each entity which applies for a grant, contract, or cooperative agreement under the Act for any project or program which involves the conduct of biomedical or behavioral research involving human subjects to submit assurances satisfactory to the Secretary that it has established an IRB to review research conducted at or supported by the entity in order to protect the rights of the human subjects (*see* 42 U.S.C. 289(a)). Section 491 of the Public Health Service Act also authorizes the Secretary to establish a program under which requests for clarification and guidance with respect to ethical issues raised in connection with biomedical or behavioral research involving human subjects are responded to promptly and appropriately (*see* 42 U.S.C. 289(b)). These authorities are delegated to OHRP (*see* 67 FR 10216–18, March 6, 2002).

By requiring IRB registration, the proposed rule would, if finalized, aid in the efficient implementation of the Public Health Service Act's provisions regarding assurances and providing guidance and education to IRBs involved in human subjects research conducted or supported by HHS. Moreover, by requiring IRBs to register, the proposed rule would enable OHRP to contact IRBs more quickly and efficiently on various issues, such as new regulatory requirements or policies or other matters related to the conduct of human subjects research. OHRP concludes that it has sufficient legal authority to issue the proposed rule.

V. Economic Impact Analysis

OHRP has examined the impact of the proposed rule under Executive Order 12866 and the Regulatory Flexibility Act (5 U.S.C. 601–612) (as amended by subtitle D of the Small Business Regulatory Fairness Act of 1996 (Pub. L. 104–121)), and the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4). Executive Order 12866 directs agencies to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity). Under the Regulatory Flexibility Act, if a rule has a significant impact on a substantial number of small entities, an agency must analyze regulatory options that

would minimize any significant impact of the rule on small entities.

Section 202(a) of the Unfunded Mandates Reform Act of 1995 requires that agencies prepare a written statement of anticipated costs and benefits before proposing any rule that may result in an expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of $100 million in any one year (adjusted annually for inflation).

The proposed rule is consistent with the principles set forth in Executive Order 12866 and these two statutes. As explained below, the proposed rule is not an economically significant regulatory action as defined in Executive Order 12866 and does not require a Regulatory Flexibility Act Analysis. The Unfunded Mandates Reform Act does not require HHS to prepare a statement of costs and benefits for the proposed rule because the proposed rule is not expected to result in any 1-year expenditure that would exceed $100 million adjusted for inflation. The current inflation-adjusted statutory threshold is approximately $110 million.

The proposed rule would require IRBs designated under an assurance of compliance approved for Federalwide use by OHRP to register with HHS. The information sought through the registration process would be minimal, consisting largely of names and addresses for a contact person, the institution operating the IRB (if an institution exists), the senior or head officer of the institution who is responsible for overseeing the activities performed by the IRB, the IRB chairperson, and limited information about the IRB members' gender, earned degree, scientific or nonscientific specialty, and affiliation. The registration would also indicate whether the IRB reviews a ''small,'' ''medium,'' or ''large'' number of research protocols. IRBs would also indicate whether they are accredited and, if so, identify the accrediting body or organization. OHRP estimates that initial IRB registration may require 1 hour to complete. If the average wage rate is $40 per hour, this means that each IRB would spend $40 for an initial registration ($40 per hour x 1 hour per initial registration).

OHRP estimates that renewal of registration would require less time, especially if the IRB is only verifying existing information. If renewal registration requires 30 minutes, then the cost of renewal registration to each IRB would be approximately $20 ($40 per hour x 0. 0.5 hour per renewal registration).

Revising an IRB's registration information would probably involve costs similar to renewal registration costs. If the revision requires 30 minutes, then the cost of revising an IRB's registration information would be approximately $20 per IRB.

Additionally, assuming that the maximum number of IRBs that would be subject to the proposed rule would be 5,000: 2,000 initial registrations; 1,000 renewals; and 2,000 revisions, the proposed rule, if finalized, would result in a 1-year expenditure of $140,000 (2,000 x $40 = $80,000; 1,000 x $20 = $20,000; and 2,000 x $20 = $40,000).

Given the minimal registration information that would be required and the low costs associated with registration, this proposed rule is not a significant regulatory action, and OHRP certifies that the proposed rule would not have a significant economic impact on a substantial number of small entities. The proposal is not a significant regulatory action under Executive Order 12866 and does not require a Regulatory Flexibility Act analysis.

Because the total expenditure under the rule will not result in a 1-year expenditure of $100 million or more, OHRP is not required to perform a cost-benefit analysis under the Unfunded Mandates Reform Act.

VI. Environmental Impact

OHRP has determined that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

This proposed rule contains information collection requirements that are subject to review by OMB under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). OHRP submitted the IRB Registration form to OMB for approval pursuant to the Paperwork Reduction Act prior to issuing this proposed rule.

Title: Institutional Review Boards: Registration Requirements.

Description: The proposed rule would require institutions and IRB organizations to register their designated IRBs with HHS.

Description of Respondents: Businesses and individuals.

The estimated annual burden associated with the current information collection is 3,500 hours. The estimated annual burden associated with the information collection requirements of this proposed rule is 3,500 hours. One element of information currently collected would not be collected after adoption of the proposed rule (*i.e.*, information on the approximate number of active protocols supported by other Federal departments or agencies).

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN (CURRENT)

45 CFR section	No. of respondents	Frequency of responses	Total annual responses	Hours per response	Total hours
§ 46.603 (initial registration)	2,000	1	2,000	1	2,000
§ 46.603 (re-registration)	0	0	0	0	0
§ 46.605 (revisions)	2,090	1	2,090	0.5	1045
Total					3,045

TABLE 2.—ESTIMATED ANNUAL REPORTING BURDEN (PROPOSED RULE)

45 CFR Section	No. of respondents	Frequency of responses	Total annual responses	Hours per response	Total hours
§ 46.603 (initial registration)	2,000	1	2,000	1	2,000
§ 46.603 (re-registration)	1,000	1	1,000	0.5	500
§ 46.605 (revisions)	2,000	1	2,000	0.5	1,000
Total					3,500

There are no capital costs or operating and maintenance costs associated with this collection of information.

OHRP's estimates are based on the following considerations. According to a 1998 OIG report, there are 3,000 to 5,000 IRBs in the United States, and most are associated with hospitals and academic centers (Ref. 1, p. 3). While not all IRBs review human subjects research conducted or supported by HHS or otherwise covered under an assurance approved by OHRP, the agency, for purposes of the Paperwork Reduction Act, will use 5,000 as the maximum number of IRBs subject to the proposed rule. Additionally, because the proposed rule would require basic information about an IRB (such as names and addresses) and because registration would, in most cases, be done electronically, OHRP assumes that registration currently takes, and will take (under the proposed rule), only 1 hour per IRB for new registrations, and one half hour per IRB for revisions or renewals.

Thus, the total burden hours would be 2,000 for new registrations per year (2,000 IRBs × 1 hour per IRB).

Renewal registration and revisions to existing registration information should require less time than initial registration. OHRP assumes that renewal registration and revisions currently takes, and will take (under the proposed rule), only 30 minutes per IRB for a total of 500 burden hours for renewals (1,000 IRBs × 0.5 hour = 500) and 1,000 for revisions (2,000 IRBs hour × .5 hour) = 1,000 hours.

A notice seeking public comments on the existing IRB registration requirements was published in the **Federal Register** on April 19, 2002 (67 FR 19438). OHRP is inviting additional comments on both the current information collection and the proposed information collection.

Request for Comment: In compliance with the requirements of section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 for an agency to provide opportunity for public comment on current information collections and also on proposed information collection projects, OHRP invites comments on: (1) Whether the collection of information is necessary for the proper performance of OHRP's functions, including whether the information will have practical utility; (2) the accuracy of OHRP's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology. In this same issue of the **Federal Register**, OHRP also is soliciting public comment on the information collection in the Federalwide Assurance (FWA).

Interested persons are requested to send comments regarding the current and proposed information collections by August 5, 2004 to the following:

Department of Health and Human Services, Naomi Cook, OS/ASBTF/OIRM/OIRM/OITP, IT Desk Officer/GPEA, 200 Independence Ave., SW., Washington, DC 20201

and

Office of Information and Regulatory Affairs, Office of Management and Budget, fax number (202) 395–6974, Attn: Fumie Yokota.

VIII. Federalism

OHRP has analyzed this proposed rule in accordance with the principles set forth in Executive Order 13132. OHRP has determined that the rule does not contain policies that have substantial direct effects on the States, on the relationship between the National Government and the States, or on the distribution of power and responsibilities among the various levels of government. Accordingly, the agency has concluded that the rule does not contain policies that have federalism implications as defined in the order and, consequently, a federalism summary impact statement is not required.

IX. Request for Comments

Interested persons may submit to OHRP (*see* **ADDRESSES**) written or electronic comments regarding this proposal by October 4, 2004.

X. Reference

The following reference is available from OHRP through the contact listed above or can be accessed at: *http://oig.hhs.gov/oei/ reports/oei- 01–97–00193.pdf.*

1. OIG, HHS, ''Institutional Review Boards: A Time for Reform,'' June 1998.

List of Subjects in 45 CFR Part 46

Health—Clinical research, Medical research, Human research subjects, Reporting and recordkeeping requirements

Dated: June 2, 2004.

Cristina V. Beato,

Acting Assistant Secretary for Health.

Approved: June 22, 2004.

Tommy G. Thompson,

Secretary of Health and Human Services.

For the reasons set forth in the preamble, it is proposed that 45 CFR part 46 be amended as follows:

PART 46—PROTECTION OF HUMAN SUBJECTS

1. The authority citation for 45 CFR part 46 continues to read as follows:

Authority: 5 U.S.C. 301; 42 U.S.C.289; 42 U.S.C.300v–1(b).

2. Subpart F is added to part 46 to read as follows:

Subpart F—Registration of Institutional Review Boards

Sec.

Subpart F—Registration of Institutional Review Boards

§ 46.601 Who must register?

Each IRB that is designated by an institution under an assurance of compliance approved for federalwide use by the Office for Human Research Protections (OHRP) under § 46.103(a) and that reviews research involving human subjects conducted or supported by the Department of Health and Human Services (HHS) must register with HHS. An individual authorized to act on behalf of the institution or IRB must submit the registration information.

§ 46.602 What information must an IRB provide?

Each IRB must provide the following information to HHS:

(a) The name and mailing address of the institution or organization operating the IRB; and the name, earned degree, title, mailing address, telephone number, facsimile number, and electronic mail address of the senior or head official of that institution or organization who is responsible for overseeing activities performed by the IRB;

(b) The name, title, telephone number, facsimile number, and electronic mail address of the contact person providing the registration information;

(c) The IRB number, registration name (for an initial registration, OHRP will assign the IRB number and registration name), and address;

(d) The name, gender, earned degree, title, mailing address, telephone number, facsimile number and electronic mail address of each IRB chairperson;

(e) An IRB roster that includes the name, gender, degree, scientific or nonscientific specialty, and affiliation of each voting and alternate IRB member, including the chairperson;

(f) Using the measures ''small,'' ''medium,'' and ''large,'' the approximate number of total active protocols undergoing initial and continuing review; and active protocols supported by HHS. For purposes of this subpart, an ''active protocol'' is any protocol or study for which an IRB conducted an initial review or a continuing review during the preceding calendar year. A ''small'' number of protocols is 1 to 25 protocols, ''medium'' is 26 to 499 protocols, and ''large'' is 500 protocols or more;

(g) The approximate number of full time positions devoted to the IRB's administrative activities;

(h) An indication 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.

§ 46.603 When must an IRB register?

Each IRB must register when designated under an assurance approved for federalwide use by OHRP under § 46.103(a). The registration will be effective for 3 years. Each IRB must renew its registration every three years. Any complete update or renewal that is submitted to, and approved by, OHRP, begins a new 3-year effective period. IRB registration becomes effective when HHS posts that information on its Web site.

§ 46.604 Where can an IRB register?

Each IRB may register electronically through [Web site address to be added in the final rule]. If an IRB lacks the ability to register electronically, it must send its registration information, in writing, to OHRP.

§ 46.605 How does an IRB revise its registration information?

If registration information regarding an IRB contact, an IRB chairperson or IRB roster changes, the IRB must revise that information within 90 days by submitting any changes in that information. An assured institution's or IRB organization's decision to disband a registered IRB or to discontinue reviewing research conducted or supported by HHS also must be reported within 30 days. All other information changes may be reported when the IRB renews its registration. The revised information may be sent to HHS either electronically or in writing in accordance with § 46.604.

[FR Doc. 04–14679 Filed 7–2–04; 8:45 am]

BILLING CODE 4150–36–P