DEPARTMENT OF HEALTH AND HUMAN SERVICES

45 CFR Part 46

RIN 0940–AA06

Office of Public Health and Science; Institutional Review Boards: Registration Requirements

AGENCY: Office of Public Health and Science, HHS.

ACTION: Final rule.

SUMMARY: The Office for Human Research Protections (OHRP), Office of Public Health and Science, Department of Health and Human Services (HHS), is adding a new subpart E to the HHS protection of human subjects regulations, which requires institutional review boards (IRB) 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. The registration information includes contact information, approximate numbers of all active protocols and active protocols involving research conducted or supported by HHS, and staffing for the IRB. The 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 this final rule, the IRB registration system is compatible with the IRB registration requirements of the Food and Drug Administration (FDA), which are simultaneously published as a final rule in this issue of the **Federal Register**, allowing the operation of a single HHS IRB registration system.

DATES: This rule is effective July 14, 2009. This protracted effective date is necessary to allow refinement of the electronic registration system so that it corresponds to this final rule and the FDA's final rule, and obtain Office of Management and Budget (OMB) review and approval for the information collection requirements of this rule.

Initial registration with all required information must be submitted within 60 days of the effective date of the rule, by September 14, 2009. For any IRB currently registered with OHRP, the institution or organization operating the IRB must submit all information required under this rule by the three-year expiration date previously assigned by OHRP or within 90 days of any changes regarding the contact person who provided the IRB registration information or the IRB chairperson.

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SUPPLEMENTARY INFORMATION:

I. Background

HHS, through OHRP, regulates research involving human subjects conducted or supported by HHS in regulations codified at 45 CFR part 46. The HHS protection of human subjects regulations address the appropriate role of IRBs in the human subject research enterprise. IRBs are boards, committees, or groups formally designated by an institution to conduct initial and continuing review 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.

OHRP has been operating a system of IRB registration since December 2000, which was initiated 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. 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 (i.e., a Federalwide Assurance [FWA]); (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) identify IRBs that are subject to HHS regulations for monitoring and oversight purposes.

The OHRP IRB registration system was designed to collect information required under the HHS human subjects protection regulations at 45 CFR 46.103. 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. The only type of assurance currently accepted by OHRP is an FWA. 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 IRB registration system 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.

On July 6, 2004, OHRP published in the **Federal Register** a Notice of Proposed Rulemaking (NPRM) seeking public comment on changes to the current IRB registration system administered by OHRP (69 FR 40584). OHRP proposed to amend the HHS human subjects protection regulations at 45 CFR part 46 by adding subpart F, entitled ''Registration of Institutional Review Boards.'' In the new subpart F, OHRP proposed 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, including the information that previously was provided on a voluntary basis, listed on the IRB registration form that is currently used by OHRP. 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 (69 FR 40556). OHRP and FDA proposed to use a single registration system, accessible on the OHRP Web site, in which all IRBs that review research conducted or supported by HHS or clinical investigations regulated by FDA can be registered.

The proposed subpart F specifically addressed who must register an IRB, what information an IRB must provide when registering, when an IRB must register, where an IRB can register, and how an IRB can revise its registration information.

In preparing the final rule, HHS has changed the designation of proposed subpart F to subpart E and changed the numbering of the provisions from §§ 46.601–605 to §§ 46.501–505.

II. Comments

Discussion of Individual Comments

During the public comment period that ended October 4, 2004, the Department received 13 public comments on the proposed rule from interested parties. In general, the comments were supportive of IRB registration, although some commenters disagreed with specific aspects of the proposed rule. The comments are summarized as follows:

1. What information must an IRB provide when registering? (Proposed § 46.602)

Proposed § 46.602 described the information to be submitted as part of the registration process. Specific comments were received on the following proposed data elements required for registration.

IRB Roster

OHRP proposed to collect an IRB roster that includes the names, earned degrees, gender, area of specialty and affiliation of each voting member (including the IRB chairperson) and alternate IRB members.

One commenter stated that the value or utility of collecting information about the IRB roster is not clear and that the collection may be quite burdensome. OHRP notes that the collection of IRB roster information by HHS for each IRB that is designated on an OHRP-approved FWA already is required by 45 CFR 46.103(b)(3), and thus has decided to delete this requirement from the final rule as unnecessarily duplicative. However, the IRB registration form will continue to include IRB roster information as part of the IRB registration process since this information is required by 45 CFR 46.103(b)(3).

Approximate Number of Total Active Protocols

OHRP proposed to require submission of the approximate number of total active protocols undergoing initial and continuing review and the approximate number of active protocols supported by HHS. The proposal would have required identification of the range of the number of protocols reviewed in the preceding calendar year. A ''small'' number of protocols would be 1 to 25 protocols, ''medium'' 26 to 499 protocols, and ''large'' 500 or more protocols. OHRP explained that this information will enable it 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.

One commenter asserted that this collection poses an unnecessary reporting burden by going beyond the information needed to meet the registration requirements, and strongly recommended that OHRP limit its data collection to elements that support regulatory requirements. This commenter argued that the proposed data collection will not provide OHRP with information that assists in the constructive assessment of an institution's IRB activity, and, as a consequence, has limited value. The commenter noted that, for example, 24 cancer studies will most likely generate a significantly greater volume of work for an IRB than 500 social or statistical data analyses—many of the latter of which will be reviewed under expedited review procedures.

Two other commenters expressed concern about this information collection. One stated that, given the variety of protocols that are being performed at any large research university and the different oversight workloads that varying protocols require, such a crude measure might lead to erroneous interpretation of the registration data. This commenter asserted that, at a minimum, such data should be accompanied by a disclaimer to avoid misunderstanding, but that OHRP may want to reconsider the necessity and validity of such information. The second commenter said that it is unclear how useful or accurate such data would be in light of the following factors: The varying complexity of IRB review and protocol-driven research activity (e.g., social and behavioral, biomedical, phase 1, 2, or 3 studies, gene therapy); the level of IRB review (i.e., review at a convened meeting or expedited review process) required for different types of research protocols (e.g., chart reviews, interventions, survey research, continuation review, etc.); and the frequent and daily changes in the number of protocols reviewed by an IRB. The commenter recommended that this information collection be an optional question.

Another commenter questioned whether research volume per se is an accurate measure of the workload of an IRB. Acknowledging and appreciating that OHRP did not propose that institutions be required to supply specific numbers of active protocols undergoing initial and continuing review each year, this commenter had no objection to the proposal of numerical ranges that can be selected by registrants to describe their activity. However, the commenter urged that the information be interpreted carefully and cautiously in light of the importance of OHRP's proposed uses of the information collected.

Another commenter supported this information collection but encouraged OHRP to consider redefining the ranges as small 1–99, medium 100–499, large 500–1,999, and very large 2,000 or more. The commenter noted that there are a substantial number of organizations that oversee thousands of protocols and thus operate quite differently from those that oversee 500 protocols; further, there appears to be a small number of organizations with fewer than 25 protocols, and organizations with very few protocols often rely upon an IRB operated by another organization rather than form their own IRB.

After careful consideration of all comments, OHRP will retain this information requirement in the final rule for the reasons stated in the NPRM: This information will provide insight into an IRB's activity level and allow OHRP to more effectively assign its quality improvement, educational, and compliance oversight resources. However, given that the proposed protocol ranges were artificial, we have revised the rule to eliminate the ''small,'' ''medium'', and ''large'' ranges. Instead, the final rule requires submission of an approximate number of all active protocols and the approximate number of active protocols conducted or supported by HHS. For the purpose of the final rule, an ''active protocol'' is any protocol or study 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 twelve months. OHRP will utilize this data cautiously and does not intend to use this data to make presumptive or sweeping determinations regarding an institution's human subject protection program.

Approximate Number of Full-Time Equivalent Positions

OHRP proposed to require submission of the approximate number of full-time equivalent positions (FTEs) devoted to the IRB's administrative activities. 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 recordkeeping duties. In OHRP's experience, the number of FTEs compared to the volume of research is

one useful parameter 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).

Two commenters objected to this proposed information requirement. One recommended that these data not be included in the registry, stating that there is no standard measure for IRB staffing and no formula for allocation of personnel to administer an IRB; the nature of the protocols reviewed—biomedical or social and behavioral sciences—has a direct impact on staffing decisions; and information on the number of full-time IRB staff positions is of limited value in assessing the institution's commitment to human subject protection. The commenter asserted that this collection poses an unnecessary reporting burden by going beyond the information needed to meet the registration requirements, and strongly recommended that OHRP limit its data collection to elements that support regulatory requirements. The commenter also stated that the request for information about the number of staff devoted to the IRB does not strengthen the value of the protocol data; and that as with the approximation of active protocols, the types of protocols reviewed and managed by the IRB staff—biomedical or social and behavioral sciences—have a direct effect on the allocation of resources. The second commenter urged that this information be interpreted carefully and cautiously in OHRP's determinations of whether or not an institution has made provisions for meeting space and sufficient staff to support the IRB's review and record keeping duties.

OHRP finds that collecting information on the number of FTEs allocated to IRB administrative activities poses little if any burden on institutions and would be helpful in OHRP's assessment of whether an IRB has sufficient staff, and therefore, OHRP has retained this requirement in the final rule. OHRP will utilize this data cautiously and intends neither to use this information as the only parameter for measuring regulatory compliance with 45 CFR 46.103(b)(2), nor to use this data to make presumptive or sweeping determinations regarding an institution's human subject protection program. OHRP has no intention of using this data to develop a formula for assessing the adequacy of IRB resources.

Accreditation Status

OHRP proposed to require submission of information regarding whether the institution or organization registering an IRB currently is accredited by a human subjects protection program accrediting organization, and if so, the date of its last accreditation and the name of the accrediting organization. OHRP stated that because accreditation is a developing concept, information on accreditation will help OHRP to evaluate the extent and value of IRB accreditation, and specifically solicited public comment related to the perceived value of collecting information on the accreditation status of IRBs.

Four commenters endorsed the collection of accreditation status information. Of these, two urged OHRP to use the accreditation of the institution, organization, or human research protection program as the unit of measure rather than IRB accreditation.

Four commenters objected to the proposed collection of accreditation status information. Two of these commenters indicated that the accreditation process is relatively new and noted that the names of accredited institutions and organizations are publicly accessible at sites that will present more up-to-date information than would be available in the HHS IRB registration database. One of the objecting commenters stated that the information may not be accurate, and another noted that accreditation has shown no proven benefit and no one set of accreditation standards has been developed or accepted.

In response to these comments, OHRP has decided to eliminate the requirement for reporting accreditation status from the final rule. Because similar information is publicly accessible, OHRP has determined that collection of this information through the IRB registration process is unnecessary.

Other Data Elements

One commenter noted that the data required for registration fails to include a parameter that would monitor whether IRB members have experience that would contribute to an adequate review of research studies involving children. The commenter requested that proposed § 46.602(e) be modified to require an indication of whether each IRB member has child health care and research expertise, and that proposed § 46.602(f) be expanded to include an estimate of the number of protocols an IRB reviewed that involved children. OHRP finds that the collection of such information is not necessary to further its goals of ensuring consistency with the requirements of 45 CFR 46.103(b)(3) that pertain to IRB composition.

One commenter suggested that the information collected from IRBs include a sense of the scope of vulnerable populations included in the research protocols, such as children, pregnant women, the elderly, and prisoners. OHRP finds that the collection of such information is not necessary to further the stated goals of the IRB registration system.

2. Where can an IRB register? (Proposed § 46.604)

Proposed § 46.604 directed IRBs to register at an 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.

One commenter expressed pleasure that IRB registration may be performed online, greatly easing the compliance burden associated with such a requirement. OHRP agrees that online registration simplifies the IRB registration process and expects that nearly all institutions or IRB organizations have the capability to register electronically. The final rule has been modified to now require that each IRB must be registered electronically 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.

3. How does an IRB revise its registration information? (Proposed § 46.605)

Proposed § 46.605 required that changes in the IRB contact, chairperson, or roster information be updated in the registry within 90 days. Whenever the electronic system is used to update or revise such information, the system instructs that all data on the IRB registration form be verified.

Proposed § 46.605 also considered 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.

One commenter expressed concern about the requirement for reporting the closure of an IRB within 30 days, noting that the closure process may take longer than 30 days and that imposition of this requirement would put an undue burden on IRBs and the supporting institutions. In response to this comment, OHRP has added clarifying language to the final rule (now § 46.505) to indicate that an institution's or organization's decision to disband a registered IRB designated under an FWA must be reported to OHRP within

30 days of permanent cessation of the IRB's review of HHS-conducted or supported research.

OHRP notes that § 46.505 of the final rule has been modified from the proposed § 46.605 to delete the requirement that IRB roster changes must be submitted within 90 days, because 45 CFR 46.103(b)(3) already requires that changes in IRB roster information be reported to OHRP.

4. General Comments

Nine commenters specifically commented in support of the concept of IRB registration.

One commenter requested that FDA and OHRP maintain one common registration site that will automatically include currently registered IRBs and allow them to retain their currently assigned numbers. OHRP notes that such a common registration site has been created.

One commenter urged that the information required from registered IRBs be the same for both FDA and OHRP. OHRP finds that, because of the differing statutory and regulatory authorities of FDA and OHRP to collect IRB registration information, the information required from registered IRBs is not the same for both agencies. However, OHRP notes that § 46.502 of the final rule has been modified from the proposed § 46.602 to harmonize further OHRP's final rule with FDA's. These changes include the following:

- Section 46.502(a) (which was § 46.602(a) in the NPRM) was modified to remove the requirement to submit the earned degree and the title of the senior or head official of the institution or organization operating the IRB who is responsible for overseeing the activities performed by the IRB. This section also was modified to require submission of the street address (if different from the mailing address) for the institution or organization operating the IRB.
- Section 46.502(b) (which was § 46.602(b) in the NPRM) was modified to remove the requirement to submit the title of the contact person providing the registration information. This section also was modified to require submission of the mailing address of this contact person.
- Section 46.502(c) (which was § 46.602(c) in the NPRM) was modified to require submission of the IRB's phone number, facsimile number, mailing address, street address (if different from the mailing address), and electronic mail address.
- Section 46.502(d) (which was § 46.602(d) in the NPRM) was modified to remove the requirement to submit the gender, earned degree, title, mailing address, and facsimile number of the IRB chairperson.

As stated in the preamble to the proposed rule, the Internet registration site will request more information from IRBs reviewing research conducted or supported by HHS than from IRBs 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, the Internet site would clarify that IRBs regulated solely by FDA are not required to provide the additional information. Likewise, in those instances where the registration site would seek additional information from IRBs regulated by FDA but not regulated by HHS, the Internet site would clarify that IRBs regulated by HHS are not required to provide such information.

One commenter suggested that the rule make clear what of the information submitted is available through a Freedom of Information Act (FOIA) request. OHRP notes that although the IRB registration system information is subject to FOIA, disclosure determinations will be made in accordance with applicable exemptions.

One commenter questioned whether, if an IRB was originally registered with the U.S. Department of Education (ED) and reviews both ED and HHS research projects, the proposed registration update will meet the ED requirements. ED has informed OHRP that ED will rely upon the HHS IRB registration system and indicated that ED would ensure that the IRB will be registered with OHRP.

One commenter asserted that if HHS requires IRBs to register but does not require industry and investigators to use a registered IRB, then only the IRBs are at risk of being penalized for a failure to register. The commenter suggested that HHS should impose a financial penalty on the investigators and sponsors who do not use a registered IRB. OHRP declines to impose monetary penalties on investigators and sponsors who do not use a registered IRB for review of research. OHRP does not have the legal authority to impose fines for failure to maintain IRB registration information. Furthermore, OHRP notes that an IRB cannot be designated under an assurance of compliance approved for federalwide use by OHRP if it fails to register. OHRP believes that the registration requirement is both simple and straightforward, so it does not expect that institutions or organizations operating IRBs designated under FWAs will refuse or fail to register or revise their registration information.

One commenter asked whether IRBs will receive confirmation that the IRB is registered. Confirmation of registration will be provided to the registering entity under the IRB registration system.

One commenter expressed concern that the proposed rule change will hinder small- to medium-sized organizations which wish to conduct HHS-supported research because such smaller organizations may lack resources to support standing IRBs. OHRP finds that this regulatory change does not mandate that every research organization that receives HHS support must have its own IRB. OHRP anticipates that an institution without an IRB that wishes to conduct HHS-supported human subjects research may designate under its FWA an independent IRB or another institution's IRB for review of research, and that this IRB will be registered in accordance with the regulatory requirements.

Summary of Key Changes in the Final Rule

After considering the comments on the proposed rule, OHRP is adopting the rule largely as it was proposed. The following key changes have been made in the final rule:

1. The designation of proposed subpart F has changed to subpart E and the numbering of the provisions has changed from §§ 46.601–605 to 46.501–505.

2. The proposed requirement to collect 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 (which was § 46.602(e) in the NPRM) has been deleted from the final rule. However, the IRB registration form will continue to include IRB roster information as part of the IRB registration process since this information is required by 45 CFR 46.103(b)(3).

3. Section 46.502(a) of the final rule (which was § 46.602(a) in the NPRM) was modified to remove the requirement to submit the earned degree and title of the senior or head official of the organization or institution operating the IRB who is responsible for overseeing activities performed by the IRB. This section also was modified to require submission of the street address (if different from the mailing address) for the institution or organization operating the IRB.

4. Section 46.502(b) of the final rule (which was § 46.602(b) in the NPRM) was modified to remove the requirement to submit the title of the contact person providing the registration information. This section also was modified to require submission of the mailing address of this contact person.

5. Section 46.502(c) of the final rule (which was § 46.602(c) in the NPRM) was modified to require submission of the IRB's phone number, facsimile number, mailing address, street address (if different from the mailing address), and electronic mail address.

6. Section 46.502(d) of the final rule (which was § 46.602(d) in the NPRM) was modified to remove the requirement to submit the gender, earned degree, title, mailing address and facsimile number of the IRB chairperson.

7. Section 46.502(e) of the final rule (which was § 46.602(f) in the NPRM) was modified to require submission of the approximate number of all active protocols and active protocols conducted or supported by HHS, rather than the number ranges (small, medium, or large) for total active protocols and active protocols supported by HHS, as proposed in the NPRM.

8. The proposed requirement to submit information regarding whether the institution or IRB organization registering an IRB is accredited (which was in § 46.602(h) of the NPRM) has been deleted from the final rule.

9. Section 46.503 of the final rule (which was § 46.603 in the NPRM) was modified to clarify that IRB registration becomes effective when reviewed and accepted by OHRP, rather than when HHS posts registration information on its website.

10. Section 46.504 of the final rule (which was § 46.604 in the NPRM) was modified to require electronic submission of registration information unless an institution or organization lacks the ability to do so.

11. Section 46.505 of the final rule (which was § 46.605 in the NPRM) was modified to remove the requirement that information regarding IRB roster changes must be submitted within 90 days because 45 CFR 46.103(b)(3) already requires that changes in IRB roster information be reported to OHRP.

Other minor changes have been made in the final rule for purposes of clarity and accuracy.

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

An IRB cannot be designated under an FWA if it fails to register. If an FWA submitted to OHRP for approval designates an IRB that has not been registered, OHRP will not approve the FWA with the designation of that IRB.

If an IRB designated under an FWA fails to appropriately update its registration information in accordance with § 46.505 of the final rule, OHRP could restrict or revoke its approval of the FWA. For example, if an IRB fails to appropriately update its registration information in accordance with § 46.505 of the final rule, OHRP could take appropriate action under the institution's FWA and OHRP's compliance oversight policies and procedures. OHRP believes that the registration requirement in the final rule is both simple and straightforward, so it does not expect that institutions or organizations operating IRBs designated under FWAs will refuse or fail to register or update their registration information.

IV. Who Has Access to the IRB Registration Information Submitted to HHS?

OHRP has posted and will continue to post on its Web site the following information collected under the IRB registration process:

1. The name, location, 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. Provision of the IORG number allows OHRP to efficiently track and organize all IRB registration information submitted by the same institution or organization.

2. The name, location, registration expiration date, and OHRP-assigned registration number of each registered IRB. The first time an IRB is registered, OHRP assigns it a separate unique IRB registration number. This number is to be provided to OHRP whenever an institution or organization subsequently updates or renews an IRB registration. Provision of the IRB registration number allows OHRP to efficiently track and organize all IRB registration information submitted by an institution or organization for the same IRB. Furthermore, an institution submitting an FWA includes the IRB registration number for each IRB designated under its FWA, thereby eliminating the need for multiple submissions of the same registration information to OHRP.

Although all other information collected by the IRB registration is subject to FOIA, disclosure determinations will be made in accordance with applicable exemptions.

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 OHRP will be transferred to a separate server which will not be publicly accessible. 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 database, 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.

V. Implementation

This rule is effective July 14, 2009. This protracted effective date is necessary to (a) allow refinement of the electronic registration system so that it corresponds to this final rule and to FDA's final rule, and (b) obtain OMB review and approval for the information collection requirements of this rule.

Initial registration with all required information must be submitted within 60 days of the effective date of the rule, by September 14, 2009. For any IRB currently registered with OHRP, the institution or organization operating the IRB must submit all information required under this rule by the three-year expiration date previously assigned by OHRP or within 90 days of any changes regarding the contact person who provided the IRB registration information or the IRB chairperson.

VI. 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 (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 (42 U.S.C. 289(b)). These authorities are delegated to OHRP (67 FR 10216–18, March 6, 2002).

By requiring IRB registration, the rule will 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, collection of the information required under the rule will 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 this rule.

VII. Economic Impact Analysis

OHRP has examined the impact of the 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). OHRP believes that this final rule is not a significant regulatory action as defined by the Executive Order.

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. Because the required registration information is minimal and the costs associated with registration is low, OHRP certifies that the final rule will not have a significant economic impact on a substantial number of small entities.

Section 202(a) of the Unfunded Mandates Reform Act of 1995 requires that an agency 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 current threshold after adjustment for inflation is $127 million, using the most current (2006) Implicit Price Deflator for the Gross Domestic Product. OHRP does not expect this final rule to result in any one-year expenditure that would meet or exceed this amount.

The rule requires IRBs designated under an assurance of compliance approved for Federalwide use by OHRP to register with HHS. The information sought through the registration process is minimal, consisting largely of the following: The name, mailing address, and street address (if different from the mailing address) for the institution or organization operating the IRB; the names, addresses, phone numbers, facsimile numbers, and electronic mail addresses of (i) the senior officer or head official of the institution or organization operating the IRB who is responsible for overseeing the activities performed by the IRB, and (ii) the contact person providing the registration information; the name, phone number, and electronic mail address of the IRB chairperson; and, the approximate numbers of all active research protocols, active protocols conducted or supported by HHS, and full-time equivalent positions devoted to the IRB's administrative activities.

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 will spend $40 for an initial registration ($40 per hour × 1 hour per initial registration).

OHRP estimates that the renewal or update of an IRB registration will require less time, especially if the IRB is only verifying existing information. If renewing or updating an IRB registration requires 30 minutes, then the cost of renewing or updating would be approximately $20 ($40 per hour × 0.5 hour per registration renewal or update).

Additionally, assuming that the maximum number of IRBs that will be subject to registration annually would be 6,000, OHRP estimates that 2,000 IRBs will complete one new registration and one update each year and the other 4,000 IRBs will complete two updates or renewals each year. The total annual burden costs for 6,000 IRBs are projected to be $280,000 (2,000 new IRB registrations × 1 hour × $40/hr = $80,000; 1 renewal/update of these 2,000 IRBs × 0.5 hr × $20/0.5 hr = $40,000; 4,000 IRBs will complete 2 updates/renewals each year, 4,000 IRBs × 0.5 hr × $20/0.5 hr × 2 = 160,000).

Given the minimal registration information that would be required and the low costs associated with registration, this rule is not a significant regulatory action, and OHRP certifies that the rule will not have a significant economic impact on a substantial number of small entities. The rule 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 one-year expenditure of $100 million or more, OHRP is not required to perform a cost-benefit analysis under the Unfunded Mandates Reform Act.

VIII. 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.

IX. Paperwork Reduction Act

This 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). In compliance with the Paperwork Reduction Act of 1995 (44 U.S.C. 3507(d)), OHRP will obtain OMB review and approval for the information collection requirements of this rule.

X. Federalism

OHRP has analyzed this 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, we have 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.

List of Subjects in 45 CFR Part 46

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

Dated: December 31, 2008.

Donald Wright,

Principal Deputy Assistant Secretary for Health.

Approved: January 6, 2009.

Michael O. Leavitt,

Secretary of Health and Human Services.

■ Accordingly, 45 CFR part 46 is 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 E is added to part 46 to read as follows:

Subpart E—Registration of Institutional Review Boards

Sec.
46.501 What IRBs must be registered?
46.502 What information must be provided when registering an IRB?
46.503 When must an IRB be registered?
46.504 How must an IRB be registered?
46.505 When must IRB registration information be renewed or updated?

§ 46.501 What IRBs must be registered?

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 be registered with HHS. An individual authorized to act on behalf of the institution or organization operating the IRB must submit the registration information.

§ 46.502 What information must be provided when registering an IRB?

The following information must be provided to HHS when registering an IRB:

(a) 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 electronic mail address of the senior officer or head official of that institution or organization who is responsible for overseeing activities performed by the IRB.

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

(c) The 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 number, facsimile number, and electronic mail address.

(d) The name, phone number, and electronic mail address of the IRB chairperson.

(e)(1) The approximate numbers of:

(i) All active protocols; and

(ii) Active protocols conducted or supported by HHS.

(2) For purpose of this regulation, an ''active protocol'' is any protocol for which the IRB conducted an initial review or a continuing review at a convened meeting or under an expedited review procedure during the preceding twelve months.

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

§ 46.503 When must an IRB be registered?

An IRB must be registered before it can be designated under an assurance approved for federalwide use by OHRP under § 46.103(a). IRB registration becomes effective when reviewed and accepted by OHRP. The registration will be effective for 3 years.

§ 46.504 How must an IRB be registered?

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.

§ 46.505 When must IRB registration information be renewed or updated?

(a) Each IRB must renew its registration every 3 years.

(b) 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. The updated registration information must be submitted in accordance with § 46.504.

(c) Any renewal or update that is submitted to, and accepted by, OHRP begins a new 3-year effective period.

(d) 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.

[FR Doc. E9–588 Filed 1–14–09; 8:45 am]

BILLING CODE 4150–36–P

FEDERAL COMMUNICATIONS COMMISSION

47 CFR Part 73

[MB Docket No. 05–312; FCC 08–256]

Digital Television Distributed Transmission System Technologies

AGENCY: Federal Communications Commission.

ACTION: Final rule; announcement of effective date.

SUMMARY: In this document, the Commission announces that the Office of Management and Budget (OMB) has approved, for a period of six months, the information collection(s) associated with section 73.626(f) of the rules, and that this rule will take effect as of the date of this notice. On December 5, 2008, the Commission published the summary document of the Report and Order, *In the Matter of the Digital Television Distributed Transmission System Technologies,* MB Docket No. 05–312, FCC 08–256, at 73 FR 74047. The Ordering Clause of the Report and Order stated that the Commission would publish a notice in the **Federal Register** announcing when OMB approval for this rule section which contains information collection requirements has been received and when the revised rule will take effect. This notice is consistent with the statement in the Report and Order.

DATES: Effective January 15, 2009.

FOR FURTHER INFORMATION CONTACT: For additional information, please contact Evan Baranoff, *Evan.Baranoff@fcc.gov,* of the Media Bureau, Policy Division, (202) 418–2120.

SUPPLEMENTARY INFORMATION: This document announces that, on December 29, 2008, OMB approved, for a period of six months, the information collection requirement(s) contained in Section 73.626(f) of the rules. The Commission publishes this notice to announce the effective date of this rule. If you have any comments on the burden estimates listed below, or how the Commission can improve the collections and reduce any burdens caused thereby, please contact Cathy Williams, Federal Communications Commission, Room 1–C823, 445 12th Street, SW., Washington, DC 20554. Please include OMB Control Numbers 3060–0027 and 3060–0029, in your correspondence. The Commission will also accept your comments via the Internet if you send them to *PRA@fcc.gov.*

To request materials in accessible formats for people with disabilities (Braille, large print, electronic files, audio format), send an e-mail to *fcc504@fcc.gov* or call the Consumer & Governmental Affairs Bureau at (202) 418–0530 (voice), (202) 418–0432 (TTY).

Synopsis

As required by the Paperwork Reduction Act of 1995 (44 U.S.C. 3507), the Commission is notifying the public that it received OMB approval on December 29, 2008, for the information collection requirement(s) contained in the Commission's rules at 47 CFR 73.626(f).

Under 5 CFR 1320, an agency may not conduct or sponsor a collection of