Guidance for Institutional Review Boards (IRBs)

Frequently Asked Questions – IRB Registration

Additional copies of this guidance are available from:

Good Clinical Practice Program, HF-34
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http://www.fda.gov/ScienceResearch/SpecialTopics/RunningClinicalTrials/GuidancesInformationSheetsandNotices/default.htm

U.S. Department of Health and Human Services
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Office of the Commissioner
Office of Science and Health Coordination
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Contains Nonbinding Recommendations

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Guidance for IRBs Frequently Asked Questions IRB Registration

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This guidance is intended to assist institutional review boards (IRBs) in complying with the new requirement for IRB registration. (*See* 74 FR 2358 (Jan. 15, 2009))[1] This requirement is an amendment to Part 56, Institutional Review Boards, (21 CFR 56.106), that requires each IRB in the United States (U.S.) that reviews FDA-regulated studies to register. IRB registration information is entered into an Internet-based registration system maintained by the Department of Health and Human Services (HHS). This system is a modification of the one used by the Office for Human Research Protections (OHRP) for registration of IRBs that are designated by institutions under Federalwide Assurances (FWAs). OHRP has issued a similar rule requiring IRBs designed under FWAs to register or update their registration information at this modified site. (See 74 FR 2399 (Jan. 15, 2009))[2]

FDA's guidance documents, including this guidance, do not establish legally enforceable responsibilities. Instead, guidances describe the Agency's current thinking on a topic and should be viewed only as recommendations, unless specific regulatory or statutory requirements are cited. The use of the word *should* in Agency guidances means that something is suggested or recommended, but not required.

I. Rationale for the new requirement

1. Why is FDA requiring all IRBs that review FDA-regulated studies to register?

Because our information at the present time is derived from research and marketing applications, FDA (we) cannot be certain that we have current information about IRBs that review FDA-regulated studies. For example, some drug and device studies are exempt from the Investigational New Drug (IND, 21 CFR Part 312) and Investigational Device Exemptions (IDE, 21 CFR 812) submission requirements and are conducted without FDA involvement. In addition, many device studies (e.g., non-significant risk and many in vitro diagnostic (IVD) studies) are conducted with only IRB approval. We, therefore, do not have real-time information about these studies or the IRBs that review them.

[1] The Federal Register notice can be found at http://edocket.access.gpo.gov/2009/E9-682.htm
[2] This Federal Register notice can be found at http://edocket.access.gpo.gpv/2009/E9-588.htm

In addition, several reports from the HHS Office of Inspector General (OIG) regarding our oversight of the conduct of clinical studies[3] recommended IRB registration, stressing the importance of a comprehensive listing of all IRBs that review FDA-regulated research. The 2001 OIG report also expressed concern about our ability to assure an equivalent level of human subject protection in clinical studies of FDA-regulated products conducted outside of the U.S. as compared to those conducted in the U.S. While registration of non-U.S. IRBs (often referred to as Independent or Research Ethics Committees – IECs/RECs) is voluntary, information we receive from them will be helpful in addressing this concern.

2. Why does FDA believe this information is necessary?

The new rule will provide FDA, as well as other interested parties (e.g., the IRB community, sponsors, and clinical investigators), with a comprehensive listing of all U.S. IRBs that review FDA-regulated research. It will also provide information about non-U.S. IRBs/IECs/RECs that review FDA-regulated research and choose to voluntarily register. This more complete knowledge of IRBs that actively review FDA-regulated studies will:

- Facilitate our sharing of educational and other information with IRBs. We believe that the lack of an accurate, complete, and regularly updated listing of IRBs involved with the review of FDA-regulated studies limits our outreach and educational efforts;

- Assist us in scheduling and conducting IRB inspections under our bioresearch monitoring (BIMO) inspection program, by assuring up-to-date contact information; and

- Help us to prioritize IRB inspections.

3. Does registration imply that an IRB is in full compliance with 21 CFR Part 56 or is otherwise meeting a particular standard of competence or expertise?

No. IRB registration is not a form of accreditation or certification by FDA that the IRB is in full compliance with 21 CFR Part 56. While a U.S. IRB that reviews FDA-regulated studies must register to be in compliance with 21 CFR Part 56.106(a), IRB registration does not address issues regarding an IRB's competence or expertise nor does it require IRBs to meet a particular standard in order to conduct a review.

II. Registration requirements

4. Who must register?

Each IRB in the U.S. that either:

a. reviews clinical investigations regulated by FDA under sections 505(i) (21 U.S.C. 355(i)) or 520(g) (21 U.S.C. 360j(g)) of the Federal Food, Drug, and Cosmetic Act (the Act);

[3] "Institutional Review Boards – A Time for Reform" (1998) available at http://www.oig.hhs.gov/oei/reports/oei-01-97-00193.pdf; "The Globalization of Clinical Trials" (2001) available at http://oig.hhs.gov/oei/reports/oei-01-00-00190.pdf; and "The Food and Drug Administration's Oversight of Clinical Trials (2007) available at http://www.oig.hhs.gov/oei/reports/oei-01-06-00160.pdf.

or

b. reviews clinical investigations that are intended to support applications for research or marketing permits for FDA-regulated products. [See 21 CFR 56.106(a)]

5. May IRBs other than those required under 21 CFR 56.106(a), including those located outside of the U.S., register if they wish?

Yes, any IRB may choose to register voluntarily.

6. How does an IRB submit an initial registration?

IRBs that are not already registered must submit an initial registration. IRBs can submit this registration electronically through http://ohrp.cit.nih.gov/efile. If your IRB lacks the ability to register electronically, it must send its registration information, in writing, to the Good Clinical Practice Program (HF-34), Office of Science and Health Coordination, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857.

As noted above, we are utilizing a modified version of the Internet-based system OHRP has employed for registration of IRBs designated under FWAs. Both OHRP and FDA will be using this same modified system.

The electronic registration system provides instructions to assist you in providing the appropriate information, depending on whether your IRB is subject to regulation by only OHRP, only FDA, or both OHRP and FDA.

7. What if my IRB is already registered in the OHRP system?

If your IRB is already registered in the OHRP system, the registration information must be updated to include all of the information required by FDA (see # 11 below). For IRBs that are currently reviewing FDA-regulated research, the additional information must be added to the database by September 14, 2009. For IRBs that are not currently reviewing FDA-regulated research, after the compliance date of September 14, 2009, they must update their registration information before they review any research involving FDA-regulated products. (See below for more information on the effective and compliance dates.)

8. What is the effective date of the final rule and, by what date, must IRBs complete an initial registration or submit additional information as required by the FDA rule?

This rule is effective July 14, 2009, but in order to allow IRBs adequate time, IRBs must submit initial registrations or make required revisions to their registrations by September 14, 2009. After September 14, 2009, if an IRB that is not reviewing FDA-regulated research intends to do so, this additional information must be submitted before the IRB reviews research involving FDA-regulated products.

9. Is assistance available if my IRB encounters technical problems when attempting to register electronically?

If your IRB encounters technical problems with the electronic registration system, it should contact an OHRP IRB Coordinator listed at http://www.hhs.gov/ohrp/daqi-staff.html.

10. Will my IRB receive confirmation that its registration was completed?

If your IRB registers electronically, it will receive a notification that registration was accepted by HHS, sent to the electronic e-mail address that it provided as part of the registration process.

If your IRB submits written information, as described in #6 above, an electronic notification will be sent once the information is successfully entered into the system and accepted by HHS.

11. What information does the final rule require from each IRB in the U.S. that reviews FDA-regulated studies?

The final rule requires the following information [see 21 CFR 56.106(b)]:

(1) 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;

(2) The IRB's name, mailing address, street address (if different from 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;

(3) 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

(4) 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.

III. Revisions to Information

12. Once my IRB is registered or its existing information is updated to comply with this rule, is registration permanent unless there is a change in required information?

No, an IRB is required to renew its registration and verify the required information every 3 years from the date of the last entry/change made to the registration information.

13. Once registered, when is an IRB required to revise its registration information?

The final rule specifies the following circumstances that require a revision to the registration information [see 21 CFR 56.106(e)]:

- If an IRB's contact or chairperson information changes, the IRB must revise its registration information within 90 days of the change.

- If an IRB decides to review new types of FDA-regulated products (e.g., to review device studies if it only reviewed drug studies previously) or to discontinue reviewing clinical investigations regulated by FDA, it must report this within 30 days of the change.

- If an IRB decides to disband, this must be reported within 30 days of permanent cessation of the IRB's review of research.

14. Do IRBs need to update the number of active protocols under review when changes occur?

No, we realize that the number of active protocols may change quite frequently and that continuously updating this information would be burdensome. Therefore, for changes in the number of active protocols, as well as any other additions or changes not specifically covered in 21 CFR 56.106(e) (see previous response), IRBs may wait to modify the information until it is necessary to change any of the information specified in #13 or time to renew its registration.

IV. Consequences of failure to register

15. What are the consequences of an IRB failing to register as required by the final rule?

An IRB that fails to register could be considered noncompliant with these regulations. As part of our inspectional activities, FDA may conduct an inspection of an IRB to verify compliance with regulatory requirements, including the requirement for an IRB to register under 21 CFR 56.106(a).

Sponsors and clinical investigators are required by FDA regulations governing the conduct of clinical studies (21 CFR Part 312 for drugs and biologics and 21 CFR Part 812 for devices) to use IRBs that comply with 21 CFR Part 56. Therefore, if a sponsor and/or clinical investigator submits a study for review to an unregistered IRB, that sponsor and/or clinical investigator could be considered noncompliant with FDA regulations.

In addition, we plan to use the information accrued through the IRB registration system to distribute educational materials to IRBs that review FDA-regulated studies (see #2 above). Therefore, sponsors and/or clinical investigators who use IRBs that are not registered run the risk that the IRB may not be familiar with our current policies.

V. Availability of information

16. Will the information in the registration system be available to the public?

As discussed in the preamble to both the proposed and final rules, the information that OHRP presently has publicly available on its website will remain available. That information includes the name and location of all organizations operating an IRB and the name and location of the associated IRB(s). (As noted above, this information is available at http://ohrp.cit.nih.gov/search/asearch.asp#ASUR).

Other available information is subject to public disclosure under the Freedom of Information Act (FOIA) as well as our public information regulations in 21 CFR Part 20 and therefore can be requested. Please note, however, that certain information may be withheld from public disclosure or may require an individual's consent for public disclosure [see, e.g., 21 CFR 20.63(e)].

In addition, we will not issue reports on IRB registration nor certificates to show that an IRB is registered. As noted previously, IRB registration does not address issues regarding an IRB's competence or expertise nor does it require IRBs to meet a particular standard in order to conduct a review.