



DEPARTMENT OF HEALTH AND HUMAN SERVICES

[Docket No. FDA-2015-D-3638]

Minutes of Institutional Review Board Meetings: Guidance for Institutions and Institutional Review Boards; Draft Guidance; Availability

AGENCY: The Office for Human Research Protections, Office of the Assistant Secretary for Health, Office of the Secretary, and the Food and Drug Administration, HHS

ACTION: Notice.

SUMMARY: The Office for Human Research Protections (OHRP), Office of the Assistant Secretary for Health, and the Food and Drug Administration (FDA) are announcing the availability of a draft guidance entitled “Minutes of Institutional Review Board (IRB) Meetings: Guidance for Institutions and IRBs.” The draft guidance is intended for institutions and IRBs that are responsible for the review and oversight of human subject research conducted or supported by the U.S. Department of Health and Human Services (HHS) or regulated by FDA. The purpose of the draft guidance is to assist institutions and IRBs in preparing and maintaining minutes of IRB meetings (also referred to in the guidance as minutes) that meet the regulatory requirements for minutes set forth in FDA and HHS regulations. The draft guidance also provides general recommendations on the type and amount of information to be included in the minutes.

DATES: You can comment on any guidance at any time (21 CFR 10.115(g)(5)). To ensure that we consider your comment on this draft guidance before we begin work on the final version of the guidance, submit either written or electronic comments by [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].

ADDRESSES: You may submit comments as follows:

Electronic Submissions

Submit electronic comments in the following way:

- Federal eRulemaking Portal: <http://www.regulations.gov>. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to <http://www.regulations.gov> will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on <http://www.regulations.gov>.
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see "Written/Paper Submissions" and "Instructions").

Written/Paper Submissions

Submit written/paper submissions as follows:

- Mail/Hand delivery/Courier (for written/paper submissions): Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

- For written/paper comments submitted to the Division of Dockets Management, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in “Instructions.”

Instructions: All submissions received must include the Docket No. FDA-2015-D-3638 for “Minutes of Institutional Review Board Meetings: Guidance for Institutions and Institutional Review Boards; Draft Guidance; Availability” publicly viewable at <http://www.regulations.gov> or at the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

- Confidential Submissions--To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states “THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION”. The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on <http://www.regulations.gov>. Submit both copies to the Division of Dockets Management. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as “confidential”. Any information marked as “confidential” will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA’s posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: <http://www.fda.gov/regulatoryinformation/dockets/default.htm>.

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to <http://www.regulations.gov> and insert the docket number, found in brackets in the heading of this document, into the “Search” box and follow the prompts and/or go to the Division of Dockets Management, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Janet Donnelly, Office of Good Clinical Practice, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 32, rm. 5167, Silver Spring, MD 20993-0002, 301-796-4187; or Irene Stith-Coleman, Office for Human Research Protections, 1101 Wootton Pkwy., Suite 200, Rockville, MD 20852, 240-453-6900.

SUPPLEMENTARY INFORMATION:

I. Background

OHRP and FDA are announcing the availability of a draft guidance document entitled “Minutes of Institutional Review Board Meetings: Guidance for Institutions and Institutional Review Boards; Draft Guidance; Availability.” Because IRBs have been cited in OHRP determination letters and FDA warning letters as having inadequate minutes, OHRP and FDA are providing recommendations on the type and amount of information to include in minutes in order to help IRBs meet the regulatory requirements for minutes.

To enhance human subject protection and reduce regulatory burden, OHRP and FDA have been actively working to harmonize the Agencies’ regulatory requirements and guidance for human subject research. This draft guidance document was developed as a part of these efforts. OHRP and FDA believe that it will be most helpful to the regulated community to issue a joint draft guidance document which will clearly demonstrate the Agencies’ harmonious approach to the topic of preparing and maintaining minutes of IRB meetings.

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the current thinking of OHRP and FDA on minutes of IRB meetings. It does not establish any rights for any person and is not binding on OHRP, FDA, or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations.

II. Paperwork Reduction Act of 1995

This draft guidance refers to previously approved collections of information. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501-3520). The collections of information referenced in this guidance that are related to IRB recordkeeping requirements under 21 CFR 56.115 have been approved under OMB control numbers 0910-0755 and 0910-0130. The collections of information referenced in this guidance that are related to IRB recordkeeping requirements under 45 CFR 46.115 have been approved under OMB control number 0990-0260.

III. Electronic Access

Persons with access to the Internet may obtain the document at either <http://www.fda.gov/ScienceResearch/SpecialTopics/RunningClinicalTrials/ProposedRegulationsandDraftGuidances/default.htm>, or <http://www.hhs.gov/ohrp/newsroom/index.html>, or <http://www.regulations.gov>.

Dated: October 23, 2015.

Karen B. DeSalvo,

Acting Assistant Secretary for Health.

U.S. Department of Health and Human Services

Dated: October 27, 2015.

Leslie Kux,

Assistant Commissioner for Policy,

U.S. Food and Drug Administration

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