4164-01-P

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; 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 of availability.

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 guidance entitled "Minutes of Institutional Review Board Meetings; Guidance for Institutions and Institutional Review Boards." The guidance is intended for institutions and Institutional Review Boards (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 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 guidance also provides general recommendations on the type and amount of information to be included in the minutes. The guidance announced in this notice finalizes the draft guidance of the same title dated November 2015.

DATES: The announcement of the guidance is published in the *Federal Register* on [INSERT 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: https://www.regulations.gov. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to https://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 https://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): Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

- For written/paper comments submitted to the Dockets Management Staff, 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." Received comments will be placed in the docket and, except for those submitted as "Confidential Submissions," publicly viewable at https://www.regulations.gov or at the office of Dockets Management Staff 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 https://www.regulations.gov. Submit both copies to the Dockets Management Staff. 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: https://www.gpo.gov/fdsys/pkg/FR-2015-09-18/pdf/2015-23389.pdf.

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to https://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 Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

Submit written requests for single copies of the guidance to the Office of Good Clinical Practice (OGCP), Office of Special Medical Programs, Office of Medical Products and Tobacco, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 32, Rm. 5103, Silver Spring, MD 20993; or Division of Policy and Assurances, Office for Human Research Protections, 1101 Wootton Pkwy., suite 200, Rockville, MD 20852. Send one self-addressed adhesive label to assist the office in processing your requests. The guidance may also be obtained by mail by calling OGCP at 301-796-8340 or OHRP at 240-453-6900 or 866-447-4777. See the SUPPLEMENTARY INFORMATION section for electronic access to the guidance document.

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, 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 guidance document entitled "Minutes of Institutional Review Board Meetings; Guidance for Institutions and Institutional

Review Boards." OHRP and FDA are providing recommendations on the type and amount of information to include in 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 guidance document was developed as a part of these efforts. In addition, on December 13, 2016, the 21st Century Cures Act (Cures Act) (Pub. L. 114-255) was signed into law. Title III, section 3023 of the Cures Act requires the Secretary of HHS to harmonize differences between the HHS human subject regulations and FDA's human subject regulations. This guidance document is consistent with the goals of section 3023 of the Cures Act.

In the *Federal Register* of November 5, 2015 (80 FR 68545), OHRP and FDA announced the availability of the draft guidance of the same title dated November 2015. OHRP and FDA received several comments on the draft guidance, and those comments were considered as the guidance was finalized. Changes include modifying certain recommendations for inclusion of information in minutes when such information may be addressed in other IRB records. In addition, editorial changes were made to improve clarity. The guidance announced in this notice finalizes the draft guidance dated November 2015.

II. Significance of Guidance

The guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents 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. This guidance is not subject to Executive Order 12866.

III. Paperwork Reduction Act of 1995

This 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.

IV. Electronic Access

Persons with access to the Internet may obtain the document at https://www.fda.gov/ScienceResearch/SpecialTopics/RunningClinicalTrials/GuidancesInformationSheetsandNotices/ucm219433.htm, https://www.hhs.gov/ohrp/regulations-and-policy/guidance/alphabetical-list/index.html, or https://www.regulations.gov.

Dated: August 30, 2017.

_____

Don Wright,

Acting Assistant Secretary for Health.

Dated: Sep 15 2017.

_____

Anna K. Abram

Deputy Commissioner for Policy, Planning, Legislation, and Analysis.
[FR Doc. 2017-20405 Filed: 9/22/2017 8:45 am; Publication Date: 9/25/2017]