2015-1081

4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2015-D-0390]

Use of Electronic Informed Consent--Questions and Answers; Guidance for Institutional Review Boards, Investigators, and Sponsors; Availability

AGENCY: Food and Drug Administration and Office for Human Research Protections, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA) and the Office for Human Research Protections (OHRP), Department of Health and Human Services (HHS), are announcing the availability of a guidance entitled "Use of Electronic Informed Consent--Questions and Answers." The guidance is intended for institutional review boards (IRBs), investigators, and sponsors engaged in or responsible for oversight of human subject research under HHS and/or FDA regulations. The guidance provides recommendations on the use of electronic systems and processes that may employ multiple electronic media to obtain informed consent for both HHS-regulated human subject research and FDA-regulated clinical investigations of medical products, including human drug and biological products, medical devices, and combinations thereof. This guidance finalizes the draft guidance entitled "Use of Electronic Informed Consent in Clinical Investigations--Questions and Answers" issued in March 2015.

DATES: Submit either electronic or written comments on Agency guidances at any time.

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-0390 for "Use of Electronic Informed Consent--Questions and Answers; Guidance for Institutional Review Boards, Investigators, and Sponsors; Availability." Received comments will be placed in the docket and, except for those submitted as "Confidential Submissions," 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.

See section III of the SUPPLEMENTARY INFORMATION section for submitting written requests for single copies of this guidance and for electronic access to the guidance document.

FOR FURTHER INFORMATION CONTACT: Cheryl Grandinetti, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, rm. 3348, Silver Spring, MD 20993-0002, 301-796-2500; Nicole Wolanski, Office of Good Clinical Practice, Office of Special Medical Programs, Office of Medical Products and Tobacco, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 32, rm. 5108, Silver Spring, MD 20993, 301 796-6570; Stephen Ripley, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, rm. 7301, Silver Spring, MD 20993-0002, 240-402-7911; Irfan Khan, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, rm. 3459, Silver Spring, MD 20993, 1-800-638-2041 or 301-796-7100; or Irene Stith-Coleman, Office for Human Research Protections, 1101 Wootton Pkwy., suite 200, Rockville, MD 20852, 240-453-6900.

SUPPLEMENTARY INFORMATION:

I. Background

FDA and OHRP are announcing the availability of a guidance entitled "Use of Electronic Informed Consent--Questions and Answers." The guidance is intended for IRBs, investigators,

and sponsors responsible for oversight of human subject research under HHS and/or FDA regulations. The guidance provides recommendations on the use of electronic systems and processes that may employ multiple electronic media to obtain informed consent for both HHS-regulated human subject research and FDA-regulated clinical investigations of medical products, including human drug and biological products, medical devices, and combinations thereof. In particular, the guidance provides recommendations on procedures that may be followed when using an electronic informed consent (eIC) to help: (1) Ensure protection of the rights, safety, and welfare of human subjects; (2) facilitate the subject's comprehension of the information presented during the eIC process; (3) ensure that appropriate documentation of consent is obtained when electronic systems and processes that may employ multiple electronic media are used to obtain informed consent; and (4) ensure the quality and integrity of eIC data included in FDA applications and made available to FDA during inspections.

In the Federal Register of March 9, 2015 (80 FR 12496), FDA announced the availability of a draft guidance entitled "Use of Electronic Informed Consent in Clinical Investigations--Questions and Answers." FDA received a number of comments on the draft guidance. In response to these comments, this guidance provides further clarification on: (1) How to present information in the eIC to the subject; (2) how and where to conduct the eIC process; (3) how and when questions from subjects should be answered; (4) steps that may be taken to facilitate the subject's understanding; (5) how to convey additional information to the subject during the course of the research; (6) how to use electronic signatures to document eIC; (7) how to verify the identity of the subjects who will be electronically signing the informed consent; (8) how to use electronic informed consent for pediatric studies; (9) how to provide copies of the eIC to the subject; (10) steps that may be taken to ensure privacy, security, and confidentiality of the eIC

information; (11) how to obtain Health Insurance Portability and Accountability Act authorizations for research electronically; (12) what eIC materials the investigator should submit to the IRB; (13) what the IRB's responsibilities are in the eIC process; (14) the eIC documentation required for FDA submission with applications; (15) steps to ensure that eIC materials are archived appropriately for FDA-regulated clinical investigations; and (16) what eIC materials or documents FDA will require during an inspection.

In addition, in the Federal Register of March 9, 2015 (80 FR 12497), OHRP asked for public comment on whether OHRP should adopt the positions and recommendations proposed in the draft guidance for research regulated under the HHS protection of human subjects regulations, 45 CFR part 46, and whether OHRP and FDA should issue a joint guidance on this topic. In response to these comments, the final guidance was developed in collaboration with FDA and OHRP and is issued as a joint final guidance.

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 was developed as a part of these efforts. OHRP and FDA believe that it will be helpful to the regulated community to issue a joint guidance, which will clearly demonstrate the Agencies' collaborative approach to the topic of electronic informed consent.

This guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the current thinking of FDA and OHRP on the use of electronic informed consent. 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. The 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 in 21 CFR part 11 related to electronic records and electronic signatures have been approved under OMB control number 0910-0303; the collections of information in 21 CFR parts 50 and 56 related to protection of human subjects and to IRBs have been approved under OMB control number 0910-0755; the collections of information in 21 CFR 56.115 related to IRB recordkeeping requirements, which include requirements for records related to informed consent, have been approved under OMB control number 0910-0130; the collections of information in 21 CFR part 312 have been approved under OMB control number 0910-0014; and the collections of information in 21 CFR part 812 have been approved under OMB control number 0910-0078. The collections of information related to the protection of human subjects under 45 CFR part 46 and to IRB recordkeeping under 45 CFR 46.115 have been approved under OMB control number 0990-0260.

III. Addresses for Written Requests

Submit written requests for single copies of this guidance and for electronic access to the guidance document to one of the following Centers.

Center	Address	Telephone	Other Information
Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration	10001 New Hampshire Ave., Hillandale Building, 4th Floor, Silver Spring, MD 20993-0002		
Office of Good Clinical Practice, 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 20993-0002		

Office for Human Research Protections	1101 Wootton Pkwy., suite 200, Rockville, MD 20852		
Center for Biologics Evaluation and Research, Food and Drug Administration	10903 New Hampshire Ave., Bldg. 71, rm. 7301, Silver Spring, MD 20993-0002	240-7911-402	
Center for Devices and Radiological Health, Food and Drug Administration	10903 New Hampshire Ave., Bldg. 66, rm. 4621, Silver Spring, MD 20993	1-800-638-2041 or 301-796-7100	Send one self-addressed adhesive label to assist that office in processing your requests.

IV. Electronic Access

Persons with access to the Internet may obtain the guidance at http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm, http://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/Guidances/default.htm, http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default.htm, http://www.fda.gov/ScienceResearch/SpecialTopics/RunningClinicalTrials/GuidancesInformationSheetsandNotices/ucm219433.htm, http://www.fda.gov/ScienceResearch/SpecialTopics/RunningClinicalTrials/ProposedRegulationsandDraftGuidances/default.htm, http://www.hhs.gov/ohrp/newsroom/rfc/index.html, or http://www.regulations.gov.

Leslie Kux,

Assistant Commissioner for Policy,

Food and Drug Administration

Karen B. DeSalvo,

Acting Assistant Secretary for Health.

Department of Health and Human Services

[FR Doc. 2016-30146 Filed: 12/14/2016 8:45 am; Publication Date: 12/15/2016]