BILLING CODE: 4150-36-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Draft Guidance for Industry, Clinical Investigators, and Institutional Review Boards – Use of an Electronic Informed Consent in Clinical Investigations – Questions and Answers; Availability

AGENCY: Department of Health and Human Services, Office of the Secretary, Office of the Assistant Secretary for Health, Office for Human Research Protections.

ACTION: Notice.

SUMMARY: In this issue of the Federal Register, the Food and Drug Administration (FDA) is announcing the availability of draft guidance for industry, clinical investigators, and institutional review boards entitled "Use of Electronic Informed Consent in Clinical Investigations – Questions and Answers." The draft guidance provides recommendations for clinical investigators, sponsors, and institutional review boards (IRBs) on the use of electronic media and processes to obtain informed consent for FDA-regulated clinical investigations of medical products, including human drug and biological products, medical devices, and combinations thereof.

To enhance human subject protection and reduce regulatory burden, the Department of Health and Human Services Office for Human Research Protections (OHRP) and FDA have been actively working to harmonize the agencies' regulatory requirements and guidance for human subject research, and the FDA draft guidance document was developed as a part of these efforts. Although the document is issued by FDA and is drafted as guidance that would apply to FDA-regulated clinical investigations, OHRP is considering whether to adopt the positions and recommendations proposed in this guidance for research regulated under the HHS protection of human subjects regulations, 45 CFR part 46, and to issue a joint OHRP and FDA guidance document on this topic when the final guidance document is developed. OHRP asks for public comment about whether a joint guidance document would be useful for the regulated community. In particular, OHRP is interested in public comment regarding whether FDA's draft guidance would be appropriate for all research regulated under 45 CFR part 46, including research studies other than clinical investigations or clinical trials, such as social and behavioral research studies. If different guidance should apply to social and behavioral research, or other non-FDA-regulated studies, OHRP asks that the public comments address how the guidance should differ from the proposed guidance for FDA-regulated clinical investigations.

OHRP specifically welcomes feedback regarding when it might or might not be appropriate, for studies other than clinical trials, for OHRP to recommend that researchers verify that the person signing the informed consent form is the subject participating in the research.

OHRP and FDA will consider these comments in deciding whether to issue a joint OHRP/FDA guidance document on this topic when the final guidance document is developed.

DATES: [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].

ADDRESSES: You may submit comments identified by docket ID number HHS-OPHS-2015-0002 by one of the following methods:

Federal eRulemaking Portal: http://www.regulations.gov. Enter the above docket ID number in the Enter Keyword or ID field and click on "Search." On the next page, click the "Submit a Comment" action and follow the instructions.

Mail/Hand delivery/Courier [For paper, disk, or CD-ROM submissions] to: Irene Stith-Coleman, Ph.D., Office for Human Research Protections, 1101 Wootton Parkway, Suite 200, Rockville, MD 20852.

Comments received, including any personal information, will be posted without change to *http://www.regulations.gov*

FOR FURTHER INFORMATION CONTACT: Irene Stith-Coleman, Office for Human Research Protections, Department of Health and Human Services, 1101 Wootton

Parkway, Suite 200, Rockville, MD 20852; phone 240-453-6900; email Irene.Stith-Coleman@hhs.gov.

Dated: March 3, 2015.

Jerry Menikoff,

Director, Office for Human Research Protections.

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