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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Draft Guidance on Disclosing Reasonably Foreseeable Risks in Research Evaluating Standards of Care

AGENCY: Department of Health and Human Services (HHS), Office of the Secretary, Office of the Assistant Secretary for Health, Office for Human Research Protections; Extension of Comment Period.

ACTION: Notice.

SUMMARY: The Department of Health and Human Services (HHS), through the Office for Human Research Protections (OHRP) is extending the public comment period for a draft guidance document for the research community entitled "Draft Guidance on Disclosing Reasonably Foreseeable Risks in Research Evaluating Standards of Care." The availability of that draft document was published in the Federal Register on October 24, 2014, Volume79, Number 206, page 63629.

DATES: The comment period is extended by 30 days and thus will end on **[INSERT DATE 30 DAYS FROM THE INITIAL RESPONSE DATE OF DECEMBER 23, 2014]**.

ADDRESSES: Submit written requests for single copies of the draft guidance document entitled "Draft Guidance on Disclosing Reasonably Foreseeable Risks in Research Evaluating Standards of Care" to the Division of Policy and Assurances, Office for Human Research Protections, 1101

Wootton Parkway, Suite 200, Rockville, MD 20852. Send one self-addressed adhesive label to assist that office in processing your request, or fax your request to 301-402-2071. See the SUPPLEMENTARY INFORMATION section for information on electronic access to the draft guidance document.

You may submit comments identified by docket ID number HHS-OPHS-2014-0005 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, Ph.D., 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

SUPPLEMENTARY INFORMATION: The notice of availability of the draft guidance document was published in the Federal Register on October 24, 2014, Volume79, Number 206, page 63629, with a deadline for comments of December 23, 2014. OHRP is specifically addressing what risks to subjects are presented by research evaluating or comparing risks associated with standards of care, and which of these risks are reasonably foreseeable and should be disclosed to prospective research subjects as part of their informed consent. OHRP is soliciting written comments from all interested parties, including, but not limited to, IRB members, IRB staff, institutional officials, research institutions, investigators, research subject advocacy groups, ethicists, the regulated community, and the public at large. Since the notice of availability and draft guidance documents were published, the Department has received requests to extend the comment period to allow sufficient time for a full review of the draft guidance document. OHRP is committed to affording the public a meaningful opportunity to comment on the draft guidance document and welcomes comments.

Electronic Access

Persons with access to the Internet may obtain the draft guidance document on OHRP's Web site at *http://www.hhs.gov/ohrp/newsroom/rfc/index.html* or on the Federal Rulemaking Portal at *http://www.regulations.gov/*.

Dated: December 17, 2014.

Jerry Menikoff,

Director,

Office for Human Research Protections.

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