

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Guidance on Institutional Review Board Approval of Research With Conditions

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: The Office for Human Research Protections (OHRP), Office of the Assistant Secretary for Health, is announcing the availability of a guidance document entitled "Guidance on IRB Approval of Research with Conditions." The guidance document provides OHRP's first formal guidance on this topic. The document, which is available on OHRP's Web site at <http://www.hhs.gov/ohrp/policy/conditionalapproval2010.html> or <http://www.hhs.gov/ohrp/policy/conditionalapproval2010.pdf>, is intended primarily for institutional review boards (IRB), investigators, Department of Health and Human Services (HHS) funding agencies, and others that may be responsible for the review, conduct, or oversight of human subject research conducted or supported by HHS. The guidance document announced in this notice finalizes the draft guidance that was made available for public comment through a notice in the **Federal Register** on November 6, 2009 (74 FR 57486). OHRP received comments on the draft guidance document from 12 individuals and organizations, and those comments were considered as the guidance was finalized.

DATES: Comments on OHRP guidance documents are welcome at any time.

ADDRESSES: Submit written requests for a single copy of the guidance document entitled, "Guidance on IRB Approval of Research with Conditions," 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 guidance document.

Submit written comments to Comments on Conditional IRB Approval Guidance, Office for Human Research Protections, 1101 Wootton Parkway, Suite 200, Rockville, MD 20852. Comments also may be sent via e-mail

to ohrp@hhs.gov or via facsimile at 240-402-2071.

FOR FURTHER INFORMATION CONTACT:

Irene Stith-Coleman, PhD, Office for Human Research Protections, 1101 Wootton Parkway, Suite 200, Rockville, MD 20852, 240-453-6900; e-mail Irene.Stith-Coleman@hhs.gov.

SUPPLEMENTARY INFORMATION:

I. Background

OHRP is announcing the availability of a guidance document entitled "Guidance on IRB Approval of Research with Conditions." The guidance document provides OHRP's first formal guidance on this topic. The document is intended primarily for IRBs, investigators, HHS funding agencies, and others that may be responsible for the review, conduct, or oversight of human subject research conducted or supported by HHS.

The guidance document applies to non-exempt human subjects research conducted or supported by HHS. It provides guidance on the authority of IRBs to approve research with conditions. In particular, the guidance addresses the following nine topics:

- (1) What actions can an IRB take when reviewing research?
- (2) What does *IRB approval with conditions* mean?
- (3) What circumstances preclude the IRB from approving research?
- (4) What circumstances permit the IRB to approve research with conditions?
- (5) How should the IRB handle changes to research that are proposed after the IRB has approved the research with conditions?
- (6) How do conditions on IRB approval at the time of initial review affect the initiation of research?
- (7) May an IRB approve some components of a proposed research study and defer taking action on other components at the time of initial review?
- (8) How do conditions on IRB approval at the time of continuing review, or at the time of review of proposed changes in previously approved research, affect ongoing research?
- (9) What must the IRB records include regarding the documentation of conditions of IRB approval of research?

The guidance document announced in this notice finalizes the draft guidance that was made available for public comment through a notice in the **Federal Register** on November 6, 2009 (74 FR 57486). OHRP received comments on the draft guidance document from 12 individuals and

organizations, and those comments were considered as the guidance was finalized. The majority of commenters expressed general support for the draft guidance document. The final guidance document is largely unchanged from what was proposed in the draft guidance, with only minor clarifying edits made in response to many of the comments.

II. Electronic Access

The guidance document is available on OHRP's Web site at <http://www.hhs.gov/ohrp/policy/conditionalapproval2010.html> or <http://www.hhs.gov/ohrp/policy/conditionalapproval2010.pdf>.

III. Comments

Interested persons may submit comments regarding this guidance document to OHRP at any time. Please see the **ADDRESSES** section for information on where to submit written comments.

Dated: November 24, 2010.

Jerry Menikoff,

Director, Office for Human Research Protections.

[FR Doc. 2010-30201 Filed 11-30-10; 8:45 am]

BILLING CODE 4150-36-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Guidance on Institutional Review Board Continuing Review of Research

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

ACTION: Notice.

SUMMARY: The Office for Human Research Protections (OHRP), Office of the Assistant Secretary for Health, is announcing the availability of a guidance document entitled "Guidance on IRB Continuing Review of Research." The guidance document supersedes OHRP's January 15, 2007 guidance entitled "Guidance on Continuing Review." The document, which is available on OHRP's Web site at <http://www.hhs.gov/ohrp/policy/continuingreview2010.html> or <http://www.hhs.gov/ohrp/policy/continuingreview2010.pdf>, is intended primarily for institutional review boards (IRB), investigators, Department of Health and Human Services (HHS) funding agencies, and others that may be responsible for the review, conduct, or oversight of human subject research

conducted or supported by HHS. The guidance document announced in this notice finalizes the draft guidance that was made available for public comment through a notice in the **Federal Register** on November 6, 2009 (74 FR 57487). OHRP received comments on the draft guidance document from 18 individuals and organizations, and those comments were considered as the guidance was finalized.

DATES: Comments on OHRP guidance documents are welcome at any time.

ADDRESSES: Submit written requests for a single copy of the guidance document entitled, "Guidance on IRB Continuing Review of Research," 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 guidance document.

Submit written comments to Comments on Continuing Review Guidance, Office for Human Research Protections, 1101 Wootton Parkway, Suite 200, Rockville, MD 20852. Comments also may be sent via e-mail to ohrp@hhs.gov or via facsimile at 240-402-2071.

FOR FURTHER INFORMATION CONTACT: Irene Stith-Coleman, PhD, Office for Human Research Protections, 1101 Wootton Parkway, Suite 200, Rockville, MD 20852, 240-453-6900; e-mail Irene.Stith-Coleman@hhs.gov.

SUPPLEMENTARY INFORMATION:

I. Background

OHRP is announcing the availability of a guidance document entitled "Guidance on IRB Continuing Review of Research." The guidance document supersedes OHRP's January 15, 2007 guidance entitled "Guidance on Continuing Review." The document is intended primarily for IRBs, investigators, HHS funding agencies, and others that may be responsible for the review, conduct, or oversight of human subject research conducted or supported by HHS.

The guidance document applies to non-exempt human subjects research conducted or supported by HHS. It provides guidance on the authority of IRBs to approve research with conditions. In particular, the guidance addresses the following 11 topics:

(1) Key IRB Considerations When Evaluating Research Undergoing Continuing Review;

(2) Process for Conducting Continuing Review;

(3) Additional Considerations for Continuing Review of Multicenter Research Projects;

(4) When Expedited Review Procedures may be Used by an IRB for Continuing Review;

(5) Determining the Frequency of Continuing Review;

(6) Determining the Effective Date of Initial IRB Approval and the Dates for Continuing Review;

(7) Lapses in IRB Approval;

(8) Communicating the IRB's Continuing Review Determination to Investigators and the Institution;

(9) Suspension or Termination of IRB Approval of Research or Disapproval of Research at the Time of Continuing Review;

(10) Identifying the Point When Continuing Review is no Longer Necessary; and

(11) Continuing Review is Not Required for Exempt Human Subjects Research Projects.

The guidance document announced in this notice finalizes the draft guidance that was made available for public comment through a notice in the **Federal Register** on November 6, 2009 (74 FR 57487). OHRP received comments on the draft guidance document from 18 individuals and organizations, and those comments were considered as the guidance was finalized. The majority of commenters expressed general support for the draft guidance document. The final guidance document is largely unchanged from what was proposed in the draft guidance, with only minor clarifying edits made in response to many of the comments.

To enhance human subject protections and reduce regulatory burden, OHRP and the Food and Drug Administration (FDA) have been actively working to harmonize the agencies' regulatory requirements and guidance for human subjects research. The guidance document announced in this notice was developed as a part of these efforts. When FDA finalizes its related guidance entitled "Guidance for IRBs, Clinical Investigators, and Sponsors: IRB Continuing Review After Clinical Investigation Approval," which was made available in draft for public comment through a notice in the **Federal Register** on January 13, 2010 (75 FR 1790), OHRP will update the guidance document announced in this notice as needed to harmonize with FDA's final guidance document.

II. Electronic Access

The guidance document is available on OHRP's Web site at <http://www.hhs.gov/ohrp/policy/continuingreview2010.html> or <http://www.hhs.gov/ohrp/policy/continuingreview2010.pdf>.

III. Comments

Interested persons may submit comments regarding this guidance document to OHRP at any time. Please see the **ADDRESSES** section for information on where to submit written comments.

Dated: November 24, 2010.

Jerry Menikoff,

Director, Office for Human Research Protections.

[FR Doc. 2010-30198 Filed 11-30-10; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2010-N-0001]

Food Advisory Committee; Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA). The meeting will be open to the public.

Name of Committee: Food Advisory Committee.

General Function of the Committee: To provide advice and recommendations to the Agency on FDA's regulatory issues.

Date and Time: The meeting will be held on March 30 and 31, 2011, from 8:30 a.m. to 4:30 p.m.

Location: The Hilton Hotel, Silver Spring, 8727 Colesville Rd., Silver Spring, MD 20910, 301-589-5200.

Contact Person: Carolyn Jeletic, Center for Food Safety and Applied Nutrition (HFS-024), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, 301-436-1913 or FDA Advisory Committee Information Line, 1-800-741-8138 (301-443-0572 in the Washington, DC area), code 3014510564. Please call the Information Line for up-to-date information on this meeting. A notice in the **Federal Register** about last minute modifications that impact a previously announced advisory committee meeting cannot always be published quickly