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 The guidance document announced in this notice finalizes the draft guidance that was made available for public comment through a notice in the **Federal Register** on November 6, 2009 (74 FR 57486). OHRP received comments on the draft guidance document from 12 individuals and organizations, and those comments were considered as the guidance was finalized.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

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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