By order of the Board of Governors of the Federal Reserve System, November 2, 2009.

Robert deV. Frierson,

Deputy Secretary of the Board.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Draft Guidance on Institutional Review Board Approval of Research With Conditions

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

ACTION: Notice.

SUMMARY: The Office for Human Research Protections (OHRP), Office of Public Health and Science, is announcing the availability of a draft guidance document entitled ''Guidance on IRB Approval of Research with Conditions,'' and is seeking comment on the draft guidance. The draft guidance document, when finalized, would provide OHRP's first formal guidance on this topic. The draft document, which is available on the OHRP Web site at *http://www.hhs.gov/ohrp/requests/,* is intended primarily for institutional review boards (IRBs), 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. OHRP will consider comments received before issuing the final guidance document.

DATES: Submit written comments by January 5, 2010.

ADDRESSES: Submit written requests for single copies of the draft guidance document entitled ''Guidance on IRB Approval of Research with Conditions'' to the Division of Policy and Assurances, Office for Human Research Protections,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 *See* the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the draft guidance document.

You may submit comments, identified by docket ID number HHS–OPHS–2009–0017, 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 Web page, click on the ''Submit a Comment'' action and follow the instructions.
- *Mail/Hand delivery/Courier [For paper, disk, or CD–ROM submissions]:* Michael A. Carome, M.D., Captain, U.S. Public Health Service, OHRP, 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: Michael A. Carome, M.D., Captain, U.S. Public Health Service, OHRP, 1101 Wootton Parkway, Suite 200, Rockville, MD 20852, 240–453–6900; e-mail *Michael.Carome@hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

A. Overview

OHRP is announcing the availability of a draft guidance document entitled ''Guidance on IRB Approval of Research with Conditions.'' The draft guidance document, when finalized, will represent OHRP's current thinking on this topic and will provide OHRP's first formal guidance on this topic. The draft 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 would apply 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, OHRP offers guidance on the following 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) 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?

(8) What must the IRB records include regarding the documentation of conditions of IRB approval of research?

B. Pertinent Recommendations by the Secretary's Advisory Committee on Human Research Protections (SACHRP) Related to Continuing Review and Expedited Review

In a March 14, 2007 letter, SACHRP transmitted to the Secretary of Health and Human Services recommendations regarding IRB continuing review and expedited review of research. Two of these recommendations are addressed by the draft guidance document. The following discussion describes OHRP's response to these SACHRP recommendations and identifies the

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[57] Minimum fee of $25 for an ODFI that originates forward items and the revenue associated with origination is less than $25. Minimum fee of $15 for an RDFI that does not originate forward transactions and the revenue associated with receipt is less than $15.

[58] Small files contain fewer than 2,500 items and large files contain 2,500 or more items. These origination fees do not apply to items that the Reserve Banks receive from the private-sector ACH operator.

[59] Receipt fees do not apply to items that the Reserve Banks send to the private-sector ACH operator.

[60] Depository institutions that meet Tier 2 volume requirements pay $0.0016 for all items. Eligible volume includes all forward receipt items originated through both the Reserve Banks and the private-sector operator that are delivered to the RDFI by the Reserve Banks.

[61] The account servicing fee applies to routing numbers that have received or originated FedACH transactions. Institutions that receive only U.S. government transactions or that elect to use the other operator exclusively are not assessed the account servicing fee.

[62] The FedACH settlement fee is applied to any routing number with activity during a month. This fee does not apply to routing numbers that use the Reserve Banks for U.S. government transactions only.

[63] The fee includes the transaction and addenda fees in addition to the conversion fee.

[64] The fee includes the transaction and addenda fees in addition to the voice response fee.

[65] The fee includes the notification of change processing fee.

[66] Limited services are offered in contingency situations.

[67] The fee includes the transaction fee in addition to the conversion fee.

[68] This per-item surcharge is in addition to the standard domestic origination and input file processing fees.

[69] This per-item surcharge is in addition to the standard domestic receipt fees.

[70] This minimum monthly charge will only be assessed if total settlement charges during a calendar month are less than $60.

[71] Special settlement arrangements use Fedwire funds transfers to effect settlement. Participants in arrangements and settlement agents are also charged the applicable Fedwire funds transfer fee for each transfer into and out of the settlement account.

[72] Premium options for FedLine Web W3 and FedLine Advantage A3 are limited to FedMail Fax.

[73] Network diversity supplemental charge of $1,200 a month may apply in addition to these fees.

section(s) of the draft guidance document that address each recommendation.

(1) *SACHRP Recommendation:* OHRP and the Food and Drug Administration should issue expanded guidance (a) clarifying that final approval of stipulations from convened meeting review (*i.e.,* ''contingent approval'') is not a form of expedited review; and (b) permitting IRBs to describe in their written policies and procedures ''stipulation mechanisms'' for verifying changes required for approval of proposed research under which (i) the IRB Chairperson, or designated member-reviewer, may exercise reasonable judgment in verifying that the stipulations of the convened IRB have been satisfied; and (ii) a qualified IRB administrator may verify that the investigator has implemented specific language (*e.g.,* in the protocol, informed consent document, or advertisements) dictated by the convened IRB (and requiring no subjective judgment on the part of the administrator).

OHRP's Response: OHRP agrees with this recommendation. Sections B and D of the draft guidance document in particular reflect OHRP's implementation of SACHRP's recommendation.

(2) *SACHRP Recommendation:* OHRP should modify its guidance on continuing review so that, when the study has been reviewed by the IRB (at a convened meeting or through an expedited process, as appropriate) and the IRB finds that there are no substantive concerns in terms of the risk-benefit relationship, informed consent, or other key protections, suspension of all research activity is not required when the expiration date passes, provided that IRB review is completed within 30 days past the expiration date.

OHRP's Response: OHRP agrees in general with the intent of this recommendation. OHRP has addressed this recommendation through its discussion of conditional approval by the IRB at the time of continuing review in section G of the draft guidance document.

II. Electronic Access

The draft guidance document is available on OHRP's Web site at *http://www.hhs.gov/ohrp/requests/.*

III. Request for Comments

OHRP requests comments on its draft guidance document. OHRP will consider all comments before issuing a final guidance document.

Dated: November 3, 2009.

Jerry Menikoff,

Director, Office for Human Research Protections.

[FR Doc. E9–26830 Filed 11–5–09; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Draft Guidance on Institutional Review Board Continuing Review of Research

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

ACTION: Notice.

SUMMARY: The Office for Human Research Protections (OHRP), Office of Public Health and Science, is announcing the availability of a draft guidance document entitled, ''Guidance on IRB Continuing Review of Research,'' and is seeking comment on the draft guidance. The draft guidance document, when finalized, will represent OHRP's current thinking on this topic and will supersede OHRP's January 15, 2007 guidance document entitled ''Guidance on Continuing Review,'' available at *http://www.hhs.gov/ohrp/humansubjects/guidance/contrev0107.htm.* The draft document, which is available on the OHRP Web site at *http://www.hhs.gov/ohrp/requests/,* is intended primarily for institutional review boards (IRBs), 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. OHRP will consider comments received before issuing the final guidance document.

DATES: Submit written comments by January 5, 2010.

ADDRESSES: Submit written requests for single copies of the draft 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 draft guidance document.

You may submit comments, identified by docket ID number HHS–OPHS–2009–0016, 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 Web page, click on the ''Submit a Comment'' action and follow the instructions.
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To enhance human subject protections and reduce regulatory burden, OHRP and the Food and Drug Administration have been actively working to harmonize the agencies' regulatory requirements and guidance for human subjects research. The draft guidance document was developed as a part of these efforts.

The guidance document would apply to non-exempt human subjects research conducted or supported by HHS. It provides guidance on the HHS regulations for the protection of human research subjects at 45 CFR part 46 related to IRB continuing review of research. In particular, the guidance addresses the following major topics:

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

(2) Process for Conducting Continuing Review;