BILLING CODE: 4150-36-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Draft Guidance on Considerations in Transferring a Previously-Approved Research Project to a New IRB or Research Institution

AGENCY: Department of Health and Human Services (HHS), 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Human Research Protections (OHRP), Office of the Assistant Secretary for Health, is announcing the availability of a draft guidance document entitled "Draft Guidance on Considerations in Transferring a Previously-Approved Research Project to a New IRB or Research Institution," and is seeking comment on the draft guidance. The draft guidance document, when finalized, would provide OHRP's first formal guidance on this topic.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 website at http://www.hhs.gov/ohrp/newsroom/rfc/index.html, is intended primarily for institutional review boards (IRB), institutions, and investigators that are responsible for the review, conduct, or oversight of human subjects research conducted or supported by HHS. OHRP will consider comments received before issuing the final guidance document.

DATES: Submit written comments by [**INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER**].

ADDRESSES: Submit written requests for single copies of the draft guidance document entitled "Draft Guidance on Considerations in Transferring a Previously-Approved Research Project to a New IRB or Research Institution" to the Division of Policy and Assurances, Office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 See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the draft guidance document.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-OS-OPHS-2012-0005, 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]: Irene Stith-Coleman, PhD., 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, 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

A. Overview

OHRP, Office of the Assistant Secretary for Health, is announcing the availability of a draft guidance document entitled "Draft Guidance on Considerations in Transferring a Previously-Approved Research Project to a New IRB or Research Institution." 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, institutions, and investigators that may be responsible for the review, conduct, or oversight of human subjects research conducted or supported by HHS.

The guidance document would apply to non-exempt human subjects research conducted or supported by HHS. It presents common scenarios for transfer of a previously-approved research project to another institutional review board (IRB) or to a new engaged research institution, and outlines the administrative actions to be considered by IRBs, engaged institution(s), and investigators. In particular, the guidance addresses the following questions:

1. What is the regulatory background for research project transfer?
2. What actions may apply when the research project remains at the same institution, but responsibility for IRB review is transferred either from an *internal* to an *external* IRB, or from an *external* IRB to *another external* IRB ?
3. What actions may apply when the research project remains at the same institution, but responsibility for IRB review is transferred from one *internal* to another *internal* IRB?
4. What actions may apply when the research project is transferred to a *new engaged institution*?

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.

FDA has simultaneously published in this same issue of the Federal Register a draft guidance document entitled “Guidance for IRBs, Clinical Investigators, and Sponsors,

Considerations When Transferring Clinical Investigation Oversight to Another IRB" that is similar to OHRP's draft document.

FDA and OHRP recognize that the two documents may appear somewhat different as there are minor variations in formatting and some necessary variations due to differences in the regulated entities under FDA's and OHRP's jurisdiction. The agencies wish to stress, however, that our intent was to provide harmonized guidance to IRBs, sponsors, institutions, investigators, and other entities involved in the study oversight transfer process. FDA and OHRP will continue to work closely in the development of final guidance and appreciate comments from interested parties.

II. Electronic Access

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

Dated: June 7, 2012

Ivor Pritchard, Ph.D.
Senior Advisor to the Director
Office for Human Research Protections

[FR Doc. 2012-14287 Filed 06/11/2012 at 8:45 am; Publication Date: 06/12/2012]