

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 See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the draft guidance document.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, 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, 1101 Wootton Parkway, Suite 200, Rockville, MD 20852, 240-453-6900; email 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OHRP, Office of the Assistant Secretary for Health, is announcing the availability of a draft guidance document entitled “Draft Guidance on Considerations in Transferring a Previously-Approved Research Project to a New IRB or Research Institution.” The draft guidance document, when finalized, will represent OHRP’s current thinking on this topic and will provide OHRP’s first formal guidance on this topic.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 Web site 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,

Senior Advisor to the Director, Office for Human Research Protections.

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BILLING CODE 4150-36-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Decision To Evaluate a Petition To Designate a Class of Employees From the Clarksville Facility in Clarksville, TN, To Be Included in the Special Exposure Cohort

AGENCY: National Institute for Occupational Safety and Health (NIOSH), Centers for Disease Control and Prevention, Department of Health and Human Services.

ACTION: Notice.

SUMMARY: NIOSH gives notice as required by 42 CFR 83.12(e) of a decision to evaluate a petition to designate a class of employees from the Clarksville Facility in Clarksville, Tennessee, to be included in the Special Exposure Cohort under the Energy Employees Occupational Illness Compensation Program Act of 2000. The initial proposed definition for the class being evaluated, subject to revision as warranted by the evaluation, is as follows:

Facility: Clarksville Facility.

Location: Clarksville, Tennessee.

Job Titles and/or Job Duties: Workers potentially exposed to radioactive materials while working at the Clarksville facility.

Period of Employment: January 1, 1949 to December 31, 1967.

FOR FURTHER INFORMATION CONTACT:

Stuart L. Hinnefeld, Director, Division of Compensation Analysis and Support, National Institute for Occupational Safety and Health, 4676 Columbia Parkway, MS C-46, Cincinnati, OH 45226, Telephone 877-222-7570. Information requests can also be submitted by email to DCAS@CDC.GOV.

John Howard,

Director, National Institute for Occupational Safety and Health.

[FR Doc. 2012-14221 Filed 6-11-12; 8:45 am]

BILLING CODE 4163-19-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Decision To Evaluate a Petition To Designate a Class of Employees From the Medina Facility in San Antonio, TX, To Be Included in the Special Exposure Cohort

AGENCY: National Institute for Occupational Safety and Health (NIOSH), Centers for Disease Control and Prevention, Department of Health and Human Services.

ACTION: Notice.