FEDERAL COMMUNICATIONS COMMISSION

Information Collection Being Reviewed by the Federal Communications Commission

AGENCY: Federal Communications Commission.

ACTION: Notice and request for comments.

SUMMARY: As part of its continuing effort to reduce paperwork burdens, and as required by the Paperwork Reduction Act (PRA) of 1995 (44 U.S.C. 3501-3520), the Federal Communications Commission (FCC) invites the general public and other Federal agencies to take this opportunity to comment on the following information collection(s). Comments are requested concerning: whether the proposed collection of information is necessary for the proper performance of the functions of the Commission, including whether the information shall have practical utility; the accuracy of the Commission’s burden estimate; ways to enhance the quality, utility, and clarity of the information collected; ways to minimize the burden of the collection of information on the respondents, including the use of automated collection techniques or other forms of information technology; and ways to further reduce the information collection burden on small business concerns with fewer than 25 employees.

The FCC may not conduct or sponsor a collection of information unless it displays a currently valid control number. No person shall be subject to any penalty for failing to comply with a collection of information subject to the PRA that does not display a valid Office of Management and Budget (OMB) control number.

DATES: Written PRA comments should be submitted on or before August 13, 2012. If you anticipate that you will be submitting comments, but find it difficult to do so within the period of time allowed by this notice, you should advise the FCC contact listed below as soon as possible.

ADDRESSES: Direct all PRA comments to Cathy Williams, FCC, via email PRA@fcc.gov and to Cathy.Williams@fcc.gov.

FOR FURTHER INFORMATION CONTACT: For additional information about the information collection, contact Cathy Williams at (202) 418–2918.

OMB Control Number: 3060–0580.
Title: Section 76.1710, Operator Interests in Video Programming.
Form Number: N/A.
Type of Review: Extension of a currently approved collection.

Respondents: Business or other for-profit entities.

Number of Respondents and Responses: 1,500 respondents; 1,500 responses.

Estimated Time per Response: 15 hours.

Frequency of Response: Recordkeeping requirement.

Obligation to Respond: Required to obtain or retain benefits. Statutory authority for this information collection is contained in 47 Section 154(i) of the Communications Act of 1934, as amended.

Total Annual Burden: 22,500 hours.
Total Annual Costs: None.
Privacy Impact Assessment(s): No impact(s).

Nature and Extent of Confidentiality: There is no need for confidentiality and respondents are not being asked to submit confidential information to the Commission.

Needs and Uses: 47 CFR 76.1710 requires cable operators to maintain records in their public files for a period of three years regarding the nature and extent of their attributable interests in all video programming services. The records must be made available to members of the public, local franchising authorities and the Commission on reasonable notice and during regular business hours. The records will be reviewed by local franchising authorities and the Commission to monitor compliance with channel occupancy limits in respective local franchise areas.

Federal Communications Commission.

Marlene H. Dortch,
Secretary, Office of the Secretary, Office of Managing Director.
[FR Doc. 2012–14177 Filed 6–11–12; 8:45 am]
BILLING CODE 6712–01–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 Web site 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 August 13, 2012.

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, 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 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


Dated: June 7, 2012.

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

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.

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.

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.

BILLING CODE 4150–36–P