

your organization must register with the Central Contractor Registry (CCR), which requires a Data Universal Number System (DUNS) number. A DUNS number is a unique number that identifies an organization and has been adopted by the Federal Government. The CCR is the central government repository for organizations working with the Federal government. The CCR collects, validates, stores and disseminates data in support of agency acquisitions. For grants, CCR stores an applicant's information, allowing Grants.gov to verify an organization's identity and identify key business contacts for the organization. An organization will be required to provide a DUNS number, an E-Business point-of-contact (POC) and a Marketing Partner ID Number (MPIN) when registering with CCR. Please note that CCR recently began validating the tax identification number with IRS/ Department of Treasury, which delays the activation of the registration by approximately 24–48 hours. Active CCR registrations and changes to registration information are passed to Grants.gov on a daily basis. A yearly validation of the CCR information is required to maintain an active registration.

- CCR Registration Assistance: 1–888–227–2423 (<http://www.ccr.gov>).

2. Register as an Authorized Organization Representative (AOR). An AOR is a person named by an organization to submit an application for funding consideration on behalf of the organization. In order to safeguard the security of your electronic information and to submit a Federal grant application via Grants.gov, an AOR must first obtain a Username and Password from Grants.gov. The organizational DUNS number will be needed to access the registration form, <http://grants.gov/Register1>. Completion of the registration form will provide a Grants.gov Username and Password. The AOR's must then register the Username and Password with Grants.gov, <http://grants.gov/Register2>.

3. Organization Authorizes Submitter (AOR). Grants.gov will send the organization's CCR E-Business point-of-contact (POC) an e-mail notifying them that someone from their organization has registered with Grants.gov and needs to be authorized as an AOR. The E-Business POC must log into Grants.gov, using their organization DUNS # and MPIN and authorize the AOR to submit an application via Grants.gov. The registration process is complete once the AOR has been authorized.

III. Time Allotted for Registration

Based on Grants.gov applicant feedback, it usually takes 3–5 days to complete registration with Grants.gov. Registrants should be aware that portions of the Grants.gov registration process leverage other governmentwide databases such as CCR. Some organizations have found it can take up to 2 weeks to complete the registration process when unexpected delays are encountered during the CCR registration process.

FOR FURTHER INFORMATION CONTACT: The Grants.gov Web site provides detailed registration checklists that guide users through the registration process. The checklists are available through the "Get Started" link on the Grants.gov Web site (<http://www.grants.gov>). Questions may also be referred to the Grants.gov Contact Center at 1–800–518–4726 or by e-mail at support@Grants.gov. A Webcast has been scheduled for the end of January 2006 specifically to cover the Grants.gov registration process. Interested organizations may sign-up for the Webcast at the Grants.gov Web site (<http://www.grants.gov>).

Dated: January 10, 2006.

Charles E. Johnson,

Assistant Secretary for Budget, Technology and Finance.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Agency for Healthcare Research and Quality

Agency Information Collection Activities: Proposed Collection; Comment Request

AGENCY: Agency for Healthcare Research and Quality, HHS.

ACTION: Notice.

SUMMARY: This notice announces the intention of the Agency for Healthcare Research and Quality (AHRQ) to request that the Office of Management and Budget (OMB) allow the proposed information collection project: "Security Checkpoints and Patients with Radiopharmaceuticals." In accordance with the Paperwork Reduction Act of 1995, 44 U.S.C. 3506(c)(2)(A), AHRQ invites the public to comment on this proposed information collection.

This proposed information collection was previously published in the **Federal Register** on November 2, 2005 and allowed 60 Days for public comment. No public comments were received. The

purpose of this notice is to allow an additional 30 Days for public comment.

DATES: Comments on this notice must be received by February 16, 2006.

ADDRESSES: Written comments should be submitted to: John Kraemer, at the Office of Information and Regulatory Affairs, OMB at the following e-mail address: John_Kraemer@omb.eop.gov and the fax number is (202) 395–6974.

Copies of the proposed collection plans, data collection instruments, and specific details on the estimated burden can be obtained from the AHRQ Reports Clearance Officer.

FOR FURTHER INFORMATION CONTACT: Cynthia D. McMichael, AHRQ, Reports Clearance Officer, (301) 427–1651.

SUPPLEMENTARY INFORMATION:

Proposed Project

"Security Checkpoints and Patients With Radiopharmaceuticals"

Patients receiving radioactive therapeutic or diagnostic compounds (called "radiopharmaceuticals") can emit radiation at the time when they are released from a hospital facility and present danger to their families and the public. In addition, these individuals might activate radiation detectors at airports, stadiums, and other public place, and will be stopped for questioning by law enforcement personnel. It is very important that hospitals provide patients with educational materials that explain the unique problems patients may face as a result of receiving this treatment, as well as provide guidance about how to respond to situations where law enforcement questions and other concerns may arise.

The goal of the study is to determine what procedures are followed by hospitals when releasing patients treated with radioactive compounds.

The study will involve interviewing 60 health care providers who are directly involved in the release of patients treated with radioactive compounds.

Specifically, the interview protocol will be centered on the following topics:

- (1) How health care providers determine when patients receiving radiopharmaceuticals can be released from care?
- (2) What type of information is provided to patients to ensure safety to their families and the public?
- (3) How this information is communicated to patients?
- (4) What information is (or can be) provided to patients who may activate radiation detectors at security checkpoints so that their processing is

facilitated should questions regarding their medical procedures arise?

Best practices identified through the analyses of interview data could lead to the development of standardized procedures to: (a) Reduce secondary exposure to radiation by members of the patient's family and by the public; and (b) ensure that patients who activate radiation detectors at security checkpoints understand why they emit radiation and carry the appropriate documentation to validate their statements. The study findings will be disseminated to the health care community through a scholarly publication journal article (title is to be determined).

Data Confidentiality Provisions

Data collected by the contractor and the contractor's draft analyses will be retained for one year after final acceptance of all contract deliverables, unless, longer retention is requested by the agency for audit purposes.

All agency documents pertaining to the contract will be archived after the contract is completed and retained in accordance with a Federal Records Act of 1950 retention schedule.

Methods of Collection

The data will be collected using a telephone survey. The contractor will contact each health provider through appropriate management offices explaining this survey and ask to be directed to the appropriate, knowledgeable staff in their facility. The interviews will be conducted by telephone. If requested, the contractor will provide a copy of the interview questions in advance so that the hospital staff has time to obtain pertinent information. The contractor will also request copies of educational materials provided to patients, any specific tools used to calculate radiation dose to members of the public as well as other pertinent material. The contractor will obtain and evaluate the

referenced educational materials qualitatively, describing the content and detail of such materials and reviewing them for clarity. In addition, the contractor will analyze the responses to the interview questions quantitatively and qualitatively as appropriate.

To recruit the appropriate interviewees, we will first contact the Chief of medicine's office and ask the staff to refer us to the Head of the Department of Radiology/Radiation Oncology/Nuclear Medicine. (Based on our experience surveying health care providers, for smaller hospitals it is sometimes more effective to start with the Hospital Administrator's office.) We will introduce ourselves, explain the goals of the study, and volunteer to provide a cover letter describing the study and any letters of endorsement. We will then contact the Department Heads and request that they refer us to the appropriate, knowledgeable staff in their departments.

Estimated Annual Respondent Burden

Type of survey	Number of respondents	Estimated time per respondent in minutes	Estimated total burden hours	Estimated annual cost to the respondents
Telephone interviews	60	45	45	\$4500
Total	60	45	45	4500

Request for Comments

In accordance with the above cited legislation, comments on AHRQ's information collection are requested with regard to any of the following: (a) Whether the proposed collection of information is necessary for the proper performance of functions of AHRQ, including whether the information will have practical utility; (b) the accuracy of AHRQ's estimate of burden (including hours and cost) of the proposed collection of information; (c) ways to enhance the quality, utility and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information upon the respondents, including the use of automated collection techniques or other forms of information technology.

Comments submitted in response to this notice will be summarized and included in the request for OMB approval of the proposed information collection. All comments will become a matter of public record.

Dated: January 6, 2006.

Carolyn M. Clancy,
Director.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2005D-0122]

Guidance for Industry on Exploratory Investigational New Drug Studies; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a guidance for industry entitled "Exploratory IND Studies." This guidance describes the preclinical and clinical issues as well as chemistry, manufacturing, and controls information that should be considered when planning exploratory studies, including studies of closely related drugs or biologics, under an investigational new drug (IND) application.

DATES: Submit written or electronic comments on agency guidances at any time.

ADDRESSES: Submit written requests for single copies of this guidance to the Division of Drug Information (HFD-240), Center for Drug Evaluation and Research, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857. Send one self-addressed adhesive label to assist that office in processing your requests. Submit written comments on the guidance to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to <http://www.fda.gov/dockets/ecomments>. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

FOR FURTHER INFORMATION CONTACT: David Jacobson-Kram, Center for Drug Evaluation and Research (HFD-24), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-443-5346.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a guidance for industry entitled "Exploratory IND Studies." In its March