John Teeter,
Office of the Secretary, Paperwork Reduction Act Reports Clearance Officer.
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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Draft Guidance on Important Considerations for When Participation of Human Subjects in Research Is Discontinued

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

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Office for Human Research Protections (OHRP), Office of Public Health and Science, is announcing the availability of a draft guidance document entitled, ''Guidance on Important Considerations for When Participation of Human Subjects in Research is Discontinued,'' and is seeking comment on the draft guidance. The draft guidance document, when finalized, would provide OHRP's first formal guidance on this topic.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, and funding agencies that may be responsible for the review or oversight of human subject research conducted or supported by the Department of Health and Human Services (HHS). OHRP will consider comments received before issuing the final guidance document.

DATES: Submit written comments by January 30, 2009.

ADDRESSES: Submit written requests for single copies of the draft guidance document entitled, ''Guidance on Important Considerations for When Participation of Human Subjects in Research is Discontinued,'' to the Division of Policy and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 See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the draft guidance document.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 by any of the following methods:

- *E-mail: discontinueparticipation@hhs.gov.* Include ''Guidance on Discontinuation of Subject Participation'' in the subject line.
- *Fax:* 301–402–2071.
- *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 within the public comment period, including any personal information, will be made available to the public upon request.

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

The OHRP, Office of Public Health and Science, is announcing the availability of a draft guidance document entitled, ''Guidance on Important Considerations for When Participation of Human Subjects in Research is Discontinued.'' The draft guidance document, when finalized, would provide OHRP's first formal guidance on this topic. The draft document is intended primarily for IRBs, investigators, and funding agencies that may be responsible for the review or oversight of human subject research conducted or supported by HHS.

The proposed guidance document would apply to non-exempt human subjects research conducted or supported by HHS. It would provide guidance on important considerations for when participation of human subjects in research is discontinued, either because a subject voluntarily chooses to discontinue participation during the course of the research, or because an investigator terminates a subject's participation in the research without regard to the subject's consent. In particular, the proposed guidance addresses the following topics:

(1) What does the word *participation,* as used in HHS regulations at 45 CFR part 46, subpart A, mean?

(2) What does *discontinuation of a subject's participation* in research mean?

(3) The distinction between a *complete* versus a *partial* discontinuation of a subject's participation in research.

(4) Clarification that investigators may continue to analyze already collected individually identifiable private information about a subject even when the subject's participation has been completely discontinued.

(5) Considerations regarding the discontinuation of a subject's participation in emergency research for which the requirements for obtaining informed consent were waived by the IRB.

(6) Clarification that research can continue to involve human subjects even when the participation of all subjects has been completed or discontinued.

(7) Recommendations for documenting the discontinuation of subjects' participation in research.

OHRP notes that the Food and Drug Administration (FDA) is publishing elsewhere in this issue a notice announcing the availability of a final guidance document entitled ''Guidance for Sponsors, Clinical Investigators, and IRBs: Data Retention When Subjects Withdraw from FDA-Regulated Clinical Trials.'' OHRP believes the interpretations provided in the proposed draft guidance are harmonious with those provided in FDA's final guidance document. In particular, FDA's guidance document explains that under applicable FDA law and regulations, data collected on study subjects enrolled in an FDA-regulated clinical trial up to the time of subject withdrawal must remain in the trial database in order for the study to be scientifically valid. Likewise, OHRP's proposed draft guidance clarifies that when a subject informs an investigator of his/her decision to discontinue participation in research, or an investigator decides to terminate a subject's participation regardless of the subject's consent, the investigator may continue to analyze already collected individually identifiable private information about that subject. In addition, OHRP believes that its proposed draft guidance document is consistent with the HIPAA Privacy Rule (45 CFR part 160 and Subparts A and E of 56 CFR part 164), where applicable. The Privacy Rule gives an individual the right to revoke Authorization in writing, except to the extent a covered entity has taken action in reliance on the Authorization. In the context of research, this reliance exception permits the continued use and disclosure of protected health information already obtained pursuant to the Authorization prior to its revocation, to the extent necessary to protect the integrity of the research study.

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/requests/.*

III. Request for Comments

OHRP is making its draft guidance document available for public comment. OHRP's guidance document will be finalized and issued after the public comments have been considered.

Dated: November 21, 2008.

Melody H. Lin,

Deputy Director, Office for Human Research Protections.

[FR Doc. E8–28369 Filed 11–28–08; 8:45 am]

BILLING CODE 4150–36–P

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) approve the proposed information collection project: ''Colorado Regional Health Information Exchange (CORHIO)—Point of Care Exchange System Evaluation: Point of Care Questionnaires and Focus Groups.'' 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.

DATES: Comments on this notice must be received by January 30, 2009.

ADDRESSES: Written comments should be submitted to: Doris Lefkowitz, Reports Clearance Officer, AHRQ, by e-mail at *doris.lefkowitz@ahrq.hhs.gov.*

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: Doris Lefkowitz, AHRQ Reports Clearance Officer, (301) 427–1477, or by e-mail at *doris.lefkowitz@ahrq.hhs.gov.*

SUPPLEMENTARY INFORMATION:

Proposed Project

Colorado Regional Health Information Exchange (CORHIO)—Point of Care Exchange System Evaluation: Point of Care Questionnaires and Focus Groups

AHRQ proposes a case study of the point-of-care (POC) clinical exchange system at the Colorado Regional Health Information Exchange (CORHIO). The CORHIO is an AHRQ State and Regional Demonstration Project contract which supports the administrative and technical implementation of an information technology service to provide secure electronic transmission of clinical information between partner health care entities to improve the efficiency, quality, and safety of patient care.

The key element of CORHIO is the POC clinical exchange system, which doctors can use to access information about individual patients as they care for them. The POC clinical exchange system is an Internet-based portal which allows authorized users to log in and request clinical information for a specific patient. The POC clinical exchange system is composed of two functions: The patient search function and the data exchange function. The patient search function is supported by the CORHIO master patient index, which is an index of all the patients that have been seen within a given time period at CORHIO's partner health care organizations (HCOs). The patient search function allows users to enter identifying information for a patient, such as name, date of birth, or medical record number, and searches to determine if the patient has received medical care at one of the partner HCOs. The POC clinical exchange system will then display all potential matching identities available at the CORHIO partner HCOs. Users select the appropriate match, if it exists, and request available data for the selected patient. The data exchange function aggregates and displays the available data from multiple partner HCOs for the selected patient.

This proposed information collection will provide input from clinicians at four participating HCOs regarding the usability of the system and the value of the exchanged Clinical information to inform decision-making, patient disposition and potentially redundant test ordering. Additionally, this case study will provide important information to inform future design and phase implementation of the CORHIO system.

This case study is being conducted pursuant to AHRQ's statutory mandate to conduct and support research, evaluations and initiatives to advance the creation of effective linkages between various sources of health information, including the development of information networks (42 U.S.C. 299b-3(a)(3)).

Method of Collection

This case study includes 2 distinct data collections regarding the POC clinical exchange system:

1. POC Questionnaire—a survey of end-users at three emergency departments (ED) regarding their experiences with the POC clinical exchange system and its effect on patient care. This questionnaire will be used to collect data from the EDs for one week quarterly in 2009 and for the first quarter of 2010.

2. Focus Groups—focus groups with select high- and low-use users of the POC clinical exchange system from each of the three EDs and one Call Center. Focus groups will be conducted at 4 and 8 months after users begin using the POC system.

Estimated Annual Respondent Burden

Exhibit 1 shows the estimated burden hours for the respondents' time to participate in this project. The POC questionnaire will be administered to the three participating EDs only, while the focus groups will be held at both the EDs and the one participating call center. The POC questionnaire will be administered quarterly for an entire week at each ED. There are typically two doctors per shift, 21 shifts per week and an average of 25 patients seen by each doctor per shift. One attending physician per shift will respond, resulting in about 525 patient encounters per each ED over a one week period. Since the POC questionnaire will be completed for each patient seen, 525 questionnaires will be completed each quarter, resulting in about 2,100 completed questionnaires per year (4 quarters $\times$ 525 per quarter) per ED. The POC questionnaire is estimated to require about two minutes to complete.

However, the POC clinical exchange system will be used for only about 10 percent of the visits. This means that for 90 percent of the visits providers will check off ''Did not use'' and select a reason why they did not use the system, which will take 5 to 10 seconds. The maximum time of two minutes was used for all responses to calculate a conservative estimate of the burden.

The focus groups will be conducted twice a year at each of the four participating facilities and are expected to take one hour or less to complete. The maximum expected time of one hour was used to calculate a conservative estimate of the burden. The total burden hours for all data collections is estimated to be 242 hours.