

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Draft Guidance on Important Considerations for When Participation of Human Subjects in Research Is Discontinued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announcing the availability of a draft
guidance document entitled, "Guidance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seeking comment on the draft guidance.
The draft guidance document, when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single copies of the draft guidance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draft guidance document.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/](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 × 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.