

Network of Patient Safety Databases (NPSD).

The Software Developer's meeting will focus on discussion of the implementation and use of Common Formats for Event Reporting—Hospital 1.1 and 1.2; the technical specifications, which provide direction to software developers that plan to implement the Common Formats electronically; and future development plans for the Common Formats. The technical specifications are a critical component that allow for the aggregation of patient safety event data.

The technical specifications consist of the following:

- data dictionary—defines data elements and their attributes (data element name, answer values, field length, guide for use, etc.) included in Common Formats;
- clinical document architecture (CDA) implementation guide—provides instructions for developing a file to transmit the Common Formats Patient Safety data from the PSO to the PSO PPC using the Common Formats;
- validation rules and errors document—specifies and defines the validation rules that will be applied to the Common Formats data elements submitted to the PSO PPC;
- Common Formats flow charts—diagrams the valid paths to complete generic and event specific formats (a complete event report);
- local specifications—provides specifications for processing, linking and reporting on events and details specifications for reports; and
- metadata registry—includes descriptive facts about information contained in the data dictionary to illustrate how such data corresponds with similar data elements used by other Federal agencies and standards development organizations [e.g., HL—7, International Standards Organization (ISO)].

Agenda, Registration and Other Information About the Meeting

The 2014 meeting will be an interactive forum designed to allow meeting participants not only to provide input, but also to respond to the input provided by others. The meeting agenda will include: an overview of Federal efforts related to the Common Formats; presentations and discussion of implementations of Common Formats Event Reporting—Hospital Version 1.1 and 1.2; discussion of next steps for upcoming Common Formats releases; and a review of data submission both by PSOs and by vendors on behalf of PSOs.

AHRQ requests that interested persons send an email to the PSO PPC

at support@psoppc.ORG for registration information. The meeting space will accommodate approximately 150 participants. A detailed agenda and logistical information will be provided to meeting registrants before the meeting. Prior to the meeting, AHRQ invites review of the technical specifications for Common Formats which can be accessed through AHRQ's PSO Web site at <http://www.pso.AHRQ.GOV/formats/commonfmt.htm>.

Dated: January 14, 2014.

Richard Kronick,

AHRQ Director.

[FR Doc. 2014-01242 Filed 1-22-14; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Meeting of the Presidential Commission for the Study of Bioethical Issues

AGENCY: Presidential Commission for the Study of Bioethical Issues, Office of the Assistant Secretary for Health, Office of the Secretary, Department of Health and Human Services.

ACTION: Notice of meeting.

SUMMARY: The Presidential Commission for the Study of Bioethical Issues (the Commission) will conduct its sixteenth meeting on February 10–11, 2014. At this meeting, the Commission will discuss the BRAIN Initiative and ongoing work in neuroscience.

DATES: The meeting will take place Monday, February 10, 2014, from 9 a.m. to approximately 5 p.m. and Tuesday, February 11, 2014, from 9 a.m. to approximately 5 p.m.

ADDRESSES: Washington Marriott, 1221 22nd St. NW., Washington, DC 20037. Telephone (202) 872-1500.

FOR FURTHER INFORMATION CONTACT:

Hillary Wicai Viers, Communications Director, Presidential Commission for the Study of Bioethical Issues, 1425 New York Avenue NW., Suite C-100, Washington, DC 20005. Telephone: 202-233-3960. Email: Hillary.Viers@bioethics.gov. Additional information may be obtained at www.bioethics.gov.

SUPPLEMENTARY INFORMATION: Pursuant to the Federal Advisory Committee Act of 1972, Public Law 92-463, 5 U.S.C. app. 2, notice is hereby given of the sixteenth meeting of the Commission. The meeting will be open to the public with attendance limited to space available. The meeting will also be webcast at www.bioethics.gov.

Under authority of Executive Order 13521, dated November 24, 2009, the

President established the Commission. The Commission is an expert panel of not more than 13 members who are drawn from the fields of bioethics, science, medicine, technology, engineering, law, philosophy, theology, or other areas of the humanities or social sciences. The Commission advises the President on bioethical issues arising from advances in biomedicine and related areas of science and technology. The Commission seeks to identify and promote policies and practices that ensure scientific research, health care delivery, and technological innovation are conducted in a socially and ethically responsible manner.

The main agenda item for the Commission's sixteenth meeting is to discuss the BRAIN Initiative and ongoing work in neuroscience.

The draft meeting agenda and other information about the Commission, including information about access to the webcast, will be available at www.bioethics.gov.

The Commission welcomes input from anyone wishing to provide public comment on any issue before it. Respectful debate of opposing views and active participation by citizens in public exchange of ideas enhances overall public understanding of the issues at hand and conclusions reached by the Commission. The Commission is particularly interested in receiving comments and questions during the meeting that are responsive to specific sessions. Written comments will be accepted at the registration desk and comment forms will be provided to members of the public in order to write down questions and comments for the Commission as they arise. To accommodate as many individuals as possible, the time for each question or comment may be limited. If the number of individuals wishing to pose a question or make a comment is greater than can reasonably be accommodated during the scheduled meeting, the Commission may make a random selection.

Written comments will also be accepted in advance of the meeting and are especially welcome. Please address written comments by email to info@bioethics.gov, or by mail to the following address: Public Commentary, Presidential Commission for the Study of Bioethical Issues, 1425 New York Avenue NW., Suite C-100, Washington, DC 20005. Comments will be made publicly available, including any personally identifiable or confidential business information that they contain. Trade secrets should not be submitted.

Anyone planning to attend the meeting who needs special assistance,

such as sign language interpretation or other reasonable accommodations, should notify Esther Yoo by telephone at (202) 233-3960, or email at Esther.Yoo@bioethics.gov in advance of the meeting. The Commission will make every effort to accommodate persons who need special assistance.

Dated: January 9, 2014.

Lisa M. Lee,

Executive Director, Presidential Commission for the Study of Bioethical Issues.

[FR Doc. 2014-01344 Filed 1-22-14; 8:45 am]

BILLING CODE 4154-06-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Agency for Healthcare Research and Quality

Scientific Information Request on Diagnostic Tests of Right Lower Quadrant Pain (Suspected Acute Appendicitis)

AGENCY: Agency for Healthcare Research and Quality (AHRQ), HHS.

ACTION: Request for Scientific Information Submissions.

SUMMARY: The Agency for Healthcare Research and Quality (AHRQ) is seeking scientific information submissions from the public on medical devices used for the diagnosis of right lower quadrant pain (suspected acute appendicitis), for example: Magnetic resonance imaging (MRI), computed tomography (CT), ultrasound (US), laparoscopic equipment, or assays. Scientific information is being solicited to inform our review of *Diagnosis of Right Lower Quadrant Pain (Suspected Acute Appendicitis)*, which is currently being conducted by the Evidence-based Practice Centers for the AHRQ Effective Health Care Program. Access to published and unpublished pertinent scientific information on medical devices used for the diagnosis of suspected acute appendicitis will improve the quality of this review. AHRQ is conducting this comparative effectiveness review pursuant to Section 1013 of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Public Law 108-173, and Section 902(a) of the Public Health Service Act, 42 U.S.C. 299a(a).

DATES: *Submission Deadline* on or before February 24, 2014.

ADDRESSES: Online submissions: <http://effectivehealthcare.AHRQ.gov/index.cfm/submit-scientific-information-packets>. Please select the study for which you are submitting

information from the list to upload your documents.

Email submissions: SIPS@epc-src.org.

Print submissions:

Mailing Address: Portland VA Research Foundation, Scientific Resource Center, ATTN: Scientific Information Packet Coordinator, PO Box 69539, Portland, OR 97239.

Shipping Address (FedEx, UPS, etc.): Portland VA Research Foundation, Scientific Resource Center, ATTN: Scientific Information Packet Coordinator, 3710 SW U.S. Veterans Hospital Road, Mail Code: R&D 71, Portland, OR 97239.

FOR FURTHER INFORMATION CONTACT:

Robin Paynter, Research Librarian, Telephone: 503-220-8262 ext. 58652 or Email: SIPS@epc-src.org.

SUPPLEMENTARY INFORMATION: The Agency for Healthcare Research and Quality has commissioned the Effective Health Care (EHC) Program Evidence-based Practice Centers to complete a review of the evidence for *Diagnosis of Right Lower Quadrant Pain (Suspected Acute Appendicitis)*.

The EHC Program is dedicated to identifying as many studies as possible that are relevant to the questions for each of its reviews. In order to do so, we are supplementing the usual manual and electronic database searches of the literature by requesting information from the public (e.g., details of studies conducted). We are looking for studies that report on the *Diagnosis of Right Lower Quadrant Pain (Suspected Acute Appendicitis)*, including those that describe adverse events. The entire research protocol, including the key questions, is also available online at: <http://effectivehealthcare.AHRQ.gov/search-for-guides-reviews-and-reports/?pageaction=displayproduct&productID=1827>.

This notice is to notify the public that the EHC program would find the following information on devices for the *Diagnosis of Right Lower Quadrant Pain (Suspected Acute Appendicitis)* helpful:

- A list of completed studies your company has sponsored for this indication. In the list, *indicate whether results are available on ClinicalTrials.gov along with the ClinicalTrials.gov trial number.*

- *For completed studies that do not have results on ClinicalTrials.gov*, a summary, including the following elements: study number, study period, design, methodology, indication and diagnosis, proper use instructions, inclusion and exclusion criteria, primary and secondary outcomes, baseline characteristics, number of patients screened/eligible/enrolled/lost

to follow-up/withdrawn/analyzed, effectiveness/efficacy, and safety results.

- *A list of ongoing studies your company has sponsored for this indication.* In the list, please provide the ClinicalTrials.gov trial number or, if the trial is not registered, the protocol for the study including a study number, the study period, design, methodology, indication and diagnosis, proper use instructions, inclusion and exclusion criteria, and primary and secondary outcomes.

- Description of whether the above studies constitute *ALL Phase II and above clinical trials* sponsored by your company for this indication and an index outlining the relevant information in each submitted file.

Your contribution is very beneficial to the Program. The contents of all submissions will be made available to the public upon request. Materials submitted must be publicly available or can be made public. Materials that are considered confidential; marketing materials; study types not included in the review; or information on indications not included in the review cannot be used by the Effective Health Care Program. This is a voluntary request for information, and all costs for complying with this request must be borne by the submitter.

The draft of this review will be posted on AHRQ's EHC program Web site and available for public comment for a period of 4 weeks. If you would like to be notified when the draft is posted, please sign up for the email list at: <http://effectivehealthcare.AHRQ.gov/index.cfm/join-the-email-list1>.

The systematic review will answer the following questions. This information is provided as background. AHRQ is not requesting that the public provide answers to these questions. The entire research protocol, is also available online at: <http://effectivehealthcare.AHRQ.gov/search-for-guides-reviews-and-reports/?pageaction=displayproduct&productID=1827>.

Key Questions (KQ)

KQ 1

What is the performance of alternative diagnostic tests, alone or in combination, for patients with right lower quadrant (RLQ) pain and suspected acute appendicitis?

I. What is the performance and comparative performance of alternative diagnostic tests in the following patient populations:

- A. Children
- B. Adults
- C. Non pregnant women of reproductive age