

Key Dates

Release Date:

Response Due By:

Issued by

The Emergency Care Coordination Center (ECCC) of the U.S. Department of Health and Human Services and the trans-Federal Council on Emergency Medical Services (CEMC)

Purpose

This is a Request for Information (RFI) issued by the Emergency Care Coordination Center (ECCC) on behalf of the Council on Emergency Medical Care (CEMC) and the Federal Interagency Committee on Emergency Medical Services (FICEMS). Information is requested that will help identify and ascertain significant issues, key concepts, and approaches on the utilization of a centralized institutional-review board (IRB) or similar hybrid IRB model, such as models utilizing independent or non-local IRBs, to facilitate high priority, multi-center emergency care research. The information obtained by this RFI will assist in informing the development of a national conference to explore issues and concepts appropriate for further exploration.

Background

The Emergency Care Coordination Center (ECCC) was created in order to: (1) lead an enterprise to promote and fund research in emergency medicine and trauma health care, (2) promote regional partnerships and more effective emergency medical systems in order to enhance appropriate triage, distribution, and care of routine community patients, and (3) promote local, regional, and State emergency medical systems' preparedness for and response to public health events. The office addresses the full spectrum of issues that have impact on care in hospital emergency departments, encompassing the complete continuum of patient care from the pre-hospital environment to disposition from emergency or trauma care. The Office coordinates with existing executive departments and agencies that perform functions relating to emergency medical systems in order to ensure unified strategy, policy, and implementation.

Due to the time-sensitive nature in which emergency medical care must be provided, emergency care research faces unique circumstances not experienced by other medical specialties. Recognizing these limitations, improved mechanisms for coordination of IRBs should be explored.

The cancer community has successfully implemented a central process with therapeutic trials for cancer interventions that offer a contrast to current emergency care research collaborations. Coordination of large scale cancer research has been facilitated by the creation of Central IRBs that allow many academic and non-academic cancer centers to participate and offer their patients state-of-art therapies.

Information Requested

The ECCC seeks input regarding the issues of the need, scope, controversies, function, and mechanism of a national central IRB that addresses emergency care research. For the purposes of this RFI, please limit the scope of emergency care to care that is defined as beginning with an event, disease, or condition that causes an individual to seek care through EMS or in an ED setting and ending with departure from the ED (either by admission to another hospital department, through discharge from the ED, or via transfer to another hospital).

We welcome your comments, research findings, and/or practical experience on the following topics. Please provide concise responses to any or all of the following topics.

- 1. Existing Models.** Please provide information relating to existing models of Central, non-local, independent, or hybrid IRBs in emergency care research in terms of characteristics such as: overall structure and organization, boundaries and geography, governance or oversight mechanisms and authorities, membership, sustained financial support, communication / coordination of relationships amongst leadership, etc.
- 2. Analysis of Current Practices in Emergency Care Research involving rapid consent strategies and use of exception from informed consent.** Please provide information relating to current practice and priorities of existing systems or specific elements of research involving rapid consent strategies, community notification, and use of exception from informed consent in emergency care settings, development, and opportunities for improvement, especially with regard to the relationship of Central IRBs, hybrid models, and local IRBs. Please provide specific evidence where available and applicable.
- 3. Relationship between Central and Local IRBs.** Please provide information on the structural, functional, legal, ethical, and financial relationship between central and local IRBs, especially in emergency care research, but also in other fields of medicine that provide insights with a focus on working relationships and division of responsibilities between the two entities.
- 4. Opportunities and challenges of a national Central IRB for emergency care involving exception from informed consent.** Please share your opinions on the potential benefits, obstacles, drawbacks, and consequences (both intended and unintended) of a central IRB or hybrid IRB models for emergency care involving rapid consent and exception from informed consent.
- 5. Barriers to implementation of Central IRBs in emergency care research.** Please provide information relating to the real and or perceived barriers to implementation and utilization of Central IRBs for emergency care research.
- 6. Additional information.** Please provide any additional opinions, suggestions, or comments as to how the ECCC and the Emergency Care Enterprise can facilitate high-priority, emergency care research with special emphasis on exception from informed consent.

Please indicate which type of institution or organization you are primarily affiliated with (using the following categories):

Please indicate which type of institution(s) or organization(s) you are primarily affiliated with using the following categories:

- Academia
- Small Business
- Healthcare Facility
- Trauma or EMSS region
- Federal Government
- State Government
- Healthcare Professional
- IRB professional
- Researcher or research group member
- Patient Advocacy Group
- Other (briefly define)

Responses

This request for information is for planning purposes only and shall not be interpreted as a solicitation for applications or as an obligation on the part of the government. The government will not pay for the preparation of any information submitted or for the government's use of that information.

Responses may be submitted to eccc@hhs.gov by COB XXXX,xx 2010. Replies to individual questions are optional.

Inquiries

Specific questions about this RFI should be directed to the contacts listed below:

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References

1. <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?fr=50.24>
2. <http://www.fda.gov/ScienceResearch/SpecialTopics/RunningClinicalTrials/GuidancesInformationSheetsandNotices/ucm116351.htm>
3. <http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.htm>
4. <http://www.hhs.gov/ohrp/humansubjects/guidance/hsdc97-01.htm>
5. Committee on the Future of Emergency Care in the United States Health System. Hospital-Based Emergency Care – At the Breaking Point. Washington, DC: National Academies Press, 2007. Web. April 27, 2010

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