How to Obtain Approval for Emergency Medicine / Emergency Department Research

The emergency department (ED) is the central point for patients to access emergency care and for UW faculty members, whether they be in the Department of Emergency Medicine (DEM) or other departments, to conduct research. The DEM recognizes the unique position of the ED in advancing science and is fully committed to supporting integrative, multi-disciplinary research.

To support the highest quality research in the ED, while also ensuring the safety of our patients, the safety of the clinical and research staff, and the efficiency of the clinical operations, we have created infrastructure to support the research and processes that must be followed before initiating the research.

All faculty and trainees in the DEM who wish to submit a research study for IRB review, as well as other researchers who wish to enroll ED patients or perform research activities within the ED at any UW hospital must have the study approved by the Emergency Medicine Research Committee (EMRC). For studies led by researchers outside the DEM, we strongly encourage engaging a DEM faculty member as an investigator. In most cases, the EMRC will require a DEM faculty member to be an investigator.

The mission of the EMRC is to assess the scientific merit of the research projects and the feasibility of implementing the study in the ED, and support researchers to improve proposed studies. The EMRC also ensures that the studies do not pose excessive subject burden, conflict with existing studies, interfere with patient care, impede departmental operations, or place patients, visitors, or staff at risk. The EMRC approval process is not meant to be a barrier to research. The committee meets twice a month, with more frequent meetings scheduled if needed.

EMRC Role in Improving and Safeguarding Research in the ED / DEM

The EMRC can provide review and feedback for potential researchers and research studies.

1. Request for Initial Approval of a Research Study
   Investigators wishing to receive initial approval for a study to be conducted in the ED must present their protocol to the EMRC. Committee members will review the materials, listen to the presentation and provide feedback and/or approval to the investigator. Investigators may be required to resubmit and/or present modified protocols based on feedback from the EMRC prior to approval. Investigators will be provided with a completed scientific review form from the EMRC listing specific comments and a summary of EMRC recommendations. If approved, the investigator will be provided with an initial approval letter, valid for one year.

   Required Materials:  EMRC Initial Approval Cover Sheet
                       Study protocol fully documenting the study processes
                       Forms, surveys etc. to be used in data collection
                       Any other study materials relevant to EMRC approval

2. Request for Re-Approval of an Ongoing Research Study
   If a research study that has been previously approved by the EMRC is continuing beyond the one-year approval and requires continuing review by the IRB, then the PI is responsible for submitting a request for re-approval to the EMRC. Without reapproval, the PI may not continue...
any portion of the study involving the ED and DEM support for IRB fees is not guaranteed. A presentation to the committee is generally not required for re-approval, but may be requested. If no significant changes have been made to the protocol, and no IRB violations/adverse events have occurred since the last review, a re-approval may be issued by the EMRC chair. Re-approval is for a period of one year.

Required Materials:  
- EMRC Re-Approval Cover Sheet
- Substantive changes to the protocol since last submission
- Description of any IRB violations / adverse events since last submission
- Any other study materials relevant to EMRC re-approval

3. Presentation to EMRC for Feedback on Proposed Research Ideas
If an investigator wishes to present a research concept to the EMRC for feedback (e.g. for a grant, research direction, etc.), they may do so. Although there is no formal requirement to submit materials, investigators are encouraged to provide whatever documents may be available to assist the committee members in providing meaningful feedback. Investigators will receive feedback from the committee regarding their presentation, but will generally not receive a formal scientific review document at this level of review.

How to Get Initial Approval of a Research Study
Prior to submitting a study for IRB review, all investigators must complete the steps below:
1. Contact the EMRC (608-263-6690 or emresearch@medicine.wisc.edu) to schedule a time to present the protocol to the EMRC. The presentation should be made by a faculty member who can engage in a discussion regarding the study.
2. Submit the IRB protocol and EMRC cover page to the EMRC in advance of the meeting. These document are due on the Friday prior to the planned presentation. This will be distributed to EMRC members.
3. Attend the meeting to briefly present the protocol and engage in a discussion regarding the study. This presentation should include:
   - The purpose
   - The timeline
   - The research methods including the study population, eligibility criteria, and recruitment objectives (N= ___)
   - ED resources needed
   - Impact on ED operations
   - Funding for research activities
   - Funding for IRB review
4. The EMRC will either approve the study or request changes. If approved, a letter will be provided to the study team. This letter must be submitted with the IRB application.

A well-structured protocol helps the EMRC efficiently review the study, the IRB efficiently review the study, and the research team ensure reliable and rigorous methods. The UW Health Sciences IRB has guidance for investigators within the “New Investigators Guide” (https://kb.wisc.edu/hsirbs/page.php?id=18842). Alternatively, the EMRC has a protocol template that can be used for this purpose. Please contact the office for this template.
How to Get Reapproval of a Research Study

Prior to submitting the continuing review to the IRB review, all investigators must complete the steps below:
1. Contact the EMRC (608-263-6690 or emresearch@medicine.wisc.edu) to request reapproval.
2. Submit the EMRC Reapproval Form with any needed supporting information.

How to Obtain Feedback on Proposed Research Ideas

Contact the EMRC (608-263-6690 or emresearch@medicine.wisc.edu) to schedule a time to present. Most presentation are limited to 30 minutes, but we will work with researchers to meet their needs.

For more information contact the Department of Emergency Medicine at emresearch@medicine.wisc.edu or email Dr. Manish N. Shah, the Vice Chair for Research & Academic Affairs at mnshah@medicine.wisc.edu.

Last Updated: July 14, 2016