Emergency Medicine Research Committee (EMRC)

General Description and Operating Guidelines

General Description:

To evaluate scientific value of emergency medicine studies prior to submission to the RSRB, all EM-related projects must be approved by the Emergency Medicine Research Committee (EMRC). This includes projects that involve EM faculty, residents, fellows, or staff, as well as those that are planning to enroll ED patients. The mission of this committee is to assess the scientific merit of research projects and their feasibility and human subjects implications in the Emergency Department (ED), including ensuring that ED studies do not interfere with patient care responsibilities, impede patient flow, or overburden ED patients with multiple research requests in a single visit.

Membership:

The EMRC is made up of faculty, research staff, fellows, residents (only on rotation), graduate students, ED pharmacists and pharmacy residents, and others as appointed by the Chair. A current standing membership list is available from the EM Research Office. All meetings are open to all University members regardless of membership on the EMRC.

Meetings and Attendance:

EMRC meetings will be held at 11:15 am each Tuesday at the Saunders Research Building (specific location may vary within SRB). Protocols and documentation must be submitted by 4:00 PM on the Thursday preceding the scheduled meeting. An email confirming or cancelling each meeting will be sent out by close of business on the preceding Thursday. All presenting persons will be copied on this email, which will also announce the meeting location.

Members are expected to attend all confirmed EMRC meetings when available. If unable to attend a scheduled meeting, members are expected to notify the EM Research Office prior to the meeting. Members who are unable to attend the meeting are expected to review the protocol and submit comments to the EMRC Chair on the EMRC Scientific Review Form by 8am on the day of the EMRC meeting. Submission of substantial comments in this manner may, at the discretion of the EMRC Chair, count as being present. General expectations for attendance in a rolling 12 month period are determined by the Chair of the Department of Emergency Medicine for faculty and training program directors for trainees.

EMRC Process for Review, Approval and Re-Approval of Study Projects:

There are three pathways for review and feedback from the EMRC.

1) **Request for initial approval of a research project**
   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 an email from the EMRC chair listing specific comments and a summary of EMRC recommendations to the RSRB. A completed document including these comments will also be provided to the RSRB Board responsible for the proposal once final approval has been given by the EMRC. 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
   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 project**
   If a research project that has been previously approved by the EMRC and is continuing beyond the one year approval, the PI is responsible for submitting a request for re-approval to the EMRC. Without re-approval, the PI may not continue any portion of the study involving the Emergency Department. Documentation of EMRC approval is required as part of the Continuing Review application. A presentation to the committee is generally not required for re-approval, but may be requested by the EMRC or EMRC Chair. If no significant changes have been made to the protocol, and no RSRB 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. Unless deemed necessary by the EMRC Chair or requested by the RSRB or investigator, no formal scientific review document or feedback will be completed at this level of review.
   Required Materials: *EMRC Re-Approval Cover Sheet*
   Substantive changes to the protocol since last submission
   Description of any RSRB violations / adverse events since last submission
   Any other study materials relevant to EMRC re-approval

3) **Presentation to the EMRC for feedback on proposed research projects**
   If an investigator wishes to present a research concept to the EMRC for feedback (e.g. for a grant, manuscript, research direction, etc.), they may do so. This category of review is open to anyone wishing to do emergency medicine research. Although there is no formal requirement to submit materials, investigators are encouraged to provide whatever documents may be available to assist the committee members is 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. Additionally, no information will generally be shared with the RSRB from this level of review.

Responsibilities of EMRC to the URMC RSRB:

Consistent with URMC OSHP / RSRB policies and guidelines, the EMRC is responsible to:

1. Implement the department-specific policy and procedure for providing scientific review of human-subject research protocols, inclusive of the core standards established by the Institution, which includes Scientific Merit, Risk Identification and Management, and Investigator Qualifications and Resources.
2. Keep the RSRB informed of the department-specific approach to human subjects scientific review.
3. Share with the RSRB sufficient findings from related EMRC reviews, including assessment of investigator qualifications and sufficiency of resources, to support scientific review; and
4. Ensure that scientific review incorporating RSRB core standards, at a minimum, is conducted prior to release of the protocol for review by the RSRB.
5. Forward a summary of the scientific review to the RSRB

The EMRC will document all scientific reviews on the EMRC Scientific Review Form. The EMRC Chair will complete and sign the EMRC Scientific Review Form within three business days of the EMRC meeting. The completed form will be distributed to the appropriate RSRB Board liaison via the RSRB Online Submission System (ROSS).

If resubmission is required, the EMRC Scientific Review Form allows for tracking and approval of the proposal through resubmission.

Scheduling and Deadlines:

To schedule a presentation to the EMRC, contact the EM Research Office at emresearch@urmc.rochester.edu or by phone at 585-275-1198. Cover sheets and supporting materials must be received by 4:00 PM on the Thursday before the scheduled presentation date or the presentation will be cancelled and rescheduled. Re-approval requests are accepted continuously by email and will be acted upon within 5 (5) business days.