SPG & Version #	XXX/ V. X.0
Applies To	All Staff
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Approved By	*Signature*
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Conduct of Human Subject Research in Emergency Services Areas

Objective

To identify the minimum requirements of investigators and research teams planning on physically conducting human subject research in the Emergency Department (ED) of University Hospital (Adult Emergency Services (AES), Emergency Critical Care Center (EC3), Children's Emergency Services (CES) C S Mott Children's Hospital.

This specifically includes any/all research recruitment in the ED, regardless of the future location of the study (either inpatient or outpatient) and includes telemedicine based subject interaction, in addition to other forms of research.

These policy requirements allow the Department of Emergency Medicine to coordinate specific research project needs with other emergency services clinical, educational and research operations to maintain a safe and functioning environment for all concerned.

In the event of a vacant position preventing completion of the policy requirements below, the Chair, Department of Emergency Medicine, EM Associate Chair for Research, or Service Chief may identify an alternate.

Responsibilities

1. The investigator and research study team will be responsible for completing items 1-8.
2. The investigator and research study team will be responsible for informing the Assistant Director of Inpatient Research via email (bmunsey@med.umich.edu) of the submission of the *Request for AES Collaborator Form*

Policy / Procedure

Prior to starting any human subject research in the ED requiring a physical and/or telemedicine presence, the following items must be completed by the investigator and/or research team:

1. Notification on the intent to enroll in the ED via email to the following:
    - Notification of the Assistant Director of Inpatient Research (ADIR) on the intent to enroll in the ED.

The Assistant Director of Inpatient Research will work with the investigator and research team to ensure the items below are completed, assist in evaluation of the overall feasibility of the research in the ED, identify any existing competing and or co-enrolling trials, assist in communications with the ED and identification of potential Emergency Medicine collaborators.

- Notification of the Associate Chair for Research (ACR), Department of Emergency Medicine.

  The ACR will evaluate for potential competing trials, general suitability for the ED environment, assist in the identification of departmental co-investigators and other research operational issues.

- Notification of the leads for ED operations based on location, which currently is the Service Chief for the respective area (AES/CES).

  The Service chief will evaluate for general suitability for the ED environment, assess potential impact on clinical and educational missions, potentially assist in the identification of departmental co-investigators, and other clinical operational issues.

2. Identify ED faculty co-investigator on the project to serve as liaison between the project and ED areas where research is being conducted.
3. Identify resources required from the ED clinical and research areas and obtain approval from both the ACR and Service Chief for their use.
    - This may include, but is not limited to, identification of EM physician, nursing, technician, laboratory, radiology, staff, EMS, and triage resources required for the research.
4. Identify educational training required by the project for the ED area and obtain approval from both the ACR and Service Chief for their delivery.
    - This may include, but is not limited to, identification of EM physician, physician assistant, nursing, technician, laboratory, radiology, staff, EMS, and triage training required for the research.
5. Presentation of the research project to the appropriate emergency medicine faculty for informational purposes. This presentation of the project must occur prior to the initiation of the proposed research.
    - Additional notifications as determined by a specific project's needs.
6. Complete review and approval from the designated ED nursing research committee.
    - This is to ensure proper consideration of nursing workflow issues.
    - The investigator and research team are encouraged to contact the committee early to arrange a presentation date given the periodic nature of their meetings.

- An application for approval must be submitted to the Nursing Research and Translational Committee who will then engage AES nursing. https://umhealth.sharepoint.com/sites/Nursing-Governance/SitePages/RT.aspx

Definitions

1. AES – Adult Emergency Services (adult Emergency Department)
2. EC3 – Emergency Critical Care Center
3. CES – Children's Emergency Services (pediatric Emergency Department)
4. ACR – Associate Chair for Research
5. ADIR – Assistant Director for Inpatient Research

Attachments

A. Email notification template to the ACR, Service Chief(s), and ADIR
B. Request to Enroll Form

NOTIFICATION OF INTENT TO ENROLL PATIENTS IN THE EMERGENCY DEPARTMENT – COLLABORATOR REQUEST FORM

Email template:

This email template/example is to be sent by the Study Team *to the* EM faculty member for which the study team wishes to partner (if known), ACR, Service Chief, and ADIR. *If you have not yet identified an EM faculty member and would like assistance with this partnership, you'll be assisted during this process.*

TEMPLATE

To: ACR, Service Chief(s)ACCO, ADIR - If these individuals are unknown, email the Assistant Director of Inpatient Research directly at (bmunsey@med.umich.edu)

Subject: Emergency Department Collaborator Request

Dear Dr. Doe,

(PI) is conducting trial (XYZ) that plans to screen/approach/enroll patients from the Emergency Department (identify AES, EC3 and/or CES).

(Add any further trial information as necessary for clarify and informational purposes)

(Attached protocol/synopsis, and draft ICF - if available)

We would appreciate your review and interest in collaborating with Dr. PI on this new study.

Please do not hesitate to reach out with any questions. We look forward to receiving your feedback/assistance.