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Augusta University, Department of Emergency Medicine Faculty Handbook

Policy on Research Studies in the ED

REASON FOR POLICY

The Department of Emergency Medicine's goals include the provision of high quality emergency and urgent medical care to our patients within the setting of cutting-edge research, training, and education. This high level of care is provided to both adults and children within the Augusta University Health System and the Children's Hospital of Georgia emergency departments. Our research goals include collaborating with other departments in the Medical College of Georgia, other colleges, AU Discovery Institutes and other affiliated entities.

Our emergency department (ED) is a very busy facility with over 80,000 visits per year and is designated as a Level I Trauma Center. Multiple patients are seen simultaneously and their care involves a large number of physicians, fellows, residents, nurses, physician assistants, staff, and other personnel. Resources in the ED must focus first on maintaining the highest quality clinical care. In addition, the ED encourages high quality research in its facilities. The ED often has multiple ongoing studies and resources must be provided to ensure that patient care is not compromised.

The purpose of this policy is to improve the organization and quality of research conducted in the ED while maintaining patient flow and the highest quality of care. There is a need to effectively allocate and recuperate resources required to carry out research in the ED. To that end, **any** study that involves inclusion of participants who are patients in the ED will require: 1) approval from the ED Research Committee prior to starting, 2) involvement of at least one ED faculty member, and 3) budgetary inclusion of ED expenses.

ENTITIES AFFECTED BY THIS POLICY

Entities affected by this policy are any investigator using patients who are recruited, enrolled, or screened for a research project within the Emergency Department, or who uses the Emergency Department or Observation Unit for any study or clinical trial.

DEFINITIONS

ED - Emergency Department

PROCEDURES

1. There are two mechanisms by which a non-ED or a non-AU faculty member can obtain permission to conduct research projects within the Department of Emergency Medicine:*
 - a. Enlist ED faculty as co-investigators with direct funding (percentage effort) and publication rights.
 - b. Enlist an ED faculty member as a facilitator for the research project with budgetary inclusion for appropriate expenses.
2. Each non-ED faculty must contact the Vice Chairman of Academics and Research, Department of Emergency Medicine (Dr. Matt Lyon, mlyon@augusta.edu) or the Chairman, Department of Emergency Medicine (Dr. Richard Schwartz, rschwartz@augusta.edu) and provide a copy of the research protocol and/or grant proposal for approval within the Department.*
3. If approved, the department Research Committee, in concert with the Department Chair, will identify and contact potential ED faculty who are interested in participating in the project. The non-ED faculty will then schedule a short presentation for the Department Research Committee at the monthly meeting.
4. The non-ED faculty will coordinate with the ED faculty in the planning of the project using one of the two mechanisms noted in #1 above.
5. A non-ED faculty cannot carry out processes related to research in the ED without prior permission from the Research Committee, Department of Emergency Medicine.* A waiver of #1 may be possible if agreed to by the Research Committee and Department Chair.
6. If #1b is selected, then the cost structure is as follows:
 - a. \$50 per patient (all projects).
 - b. In addition, for industry sponsored projects:
 - i. \$250 per patient, per hour, in increments of 15 minutes.
 - ii. Additional time will be based on the amount of activities required for each participant and the additional time required for the participant to remain in the ED to complete study requirements.
 - c. A fee of \$35 per hour, per participant, will be added for additional tasks such as obtaining informed consent, maintaining regulatory records, administering questionnaires, providing follow-up information, etc.

After the study is initiated, the non-ED faculty will establish a regular schedule with ED faculty, fellows, residents, physician assistants, nurses, and staff to answer questions and provide updates on enrollment

and results. A report of study activity will be submitted by the research team to the Research Committee on a quarterly basis. Any presentations or publications based on the research will be forwarded to the Vice Chairman of Academics and Research, Department of Emergency Medicine (Dr. Matt Lyon, mlyon@augusta.edu) or the Chairman, Department of Emergency Medicine (Dr. Richard Schwartz, rschwartz@augusta.edu).

*Note: This permission does not include permission from the institutional review board (IRB) which must be obtained prior to the start of any study related activities.

RELATED DOCUMENTS, FORMS, AND TOOLS

Protocol Template

AUTHORIZING SIGNATURE

SIGNATURE OF PERSON THAT SIGNS POLICY

Date