Arnot Health

Steps for Submitting Research or QI Proposals

Contents:

1. DEFINITION OF ACRONYMS:

a. **SRB** (Arnot System Review Board & Privacy Committee)
   i. Led by Dr. James Freeman and Cathy Matthey, RN, Chief of Compliance, this committee reviews and approves all research and QI studies at Arnot with regard to patient confidentiality and privacy.

b. **IRB** (Institutional Review Board)
   i. The IRB is a federally mandated institutional body that must review and approve all human subject research. At Arnot, we use the LECOMT (Lake Erie College of Osteopathic Medicine) IRB, which is chaired by Dr. Irv Freeman at LECOME – Erie.

c. **RSG** (Arnot Research Steering Group)
   i. The Arnot RSG keeps track of all the projects, assigns research coordinators to projects, helps in project development, assists investigators in obtaining biostatistical assistance, and coordinates and ensures that all projects receive appropriate review and approval by the IRB and SRB. The RSG can issue IRB exemption letters. It is currently chaired by Dr. Frank Edwards.

d. **CITI Training** (Collaborative Institutional Training Initiative).
   i. CITI training is required for all individuals participating in human subject research (retrospective or prospective).
   ii. It is completed online, requires several hours, and needs to be renewed every 3 years. (See link to CITI training on the GME website)

2. RESEARCH PROJECTS:

a. All research projects conducted by Arnot Health residents, fellows, or faculty must first be reviewed by the Arnot GME Research Steering Group (RSG). The RSG will help you develop your ideas as needed and will facilitate the necessary steps for your project to receive approval by the Arnot System Review Board (SRB) and likewise receive either IRB exemption or IRB approval. (The Arnot RSG can issue IRB exemptions).

b. Begin the process by submitting to the lead Research Coordinator (RC) either a *Brief Research Proposal* form or, if your idea is already well-developed, a *Full Research Proposal* form. (PDFs of both are available for download on the GME webside).

c. The proposal should be submitted under the name of the project's principle investigator (PI).

d. All projects undertaken by residents or fellows must have at least one faculty member involved as an investigator. That individual should be listed on the proposal form when you submit. All investigators need to obtain a CITI training certificate.

e. If you intend to publish your study, please remember that for an individual to be listed as an author, that person must make substantial contributions to either the design of the project, the collection of data, or the writing of the article, and must approve the final draft.
(See: http://www.icmje.org/recommendations/browse/roles-and-responsibilities/defining-the-role-of-authors-and-contributors.html)

f. When you submit your proposal, the lead coordinator will assign a research coordinator to your project. The coordinator will then contact you to help begin the development and approval process.

g. The degree of involvement of a research coordinator in a given project will be up to the PI to determine. Their help can range from simply standing by to assist if needed, to becoming an actual co-author/investigator of the project (which is most often the case). Research coordinators may also submit their own proposals and serve as principle investigators.

h. Your research coordinator will discuss with you the potential for having the assistance of a LECOM-Elmira medical student on your project as well.

i. The general assistance provided by a research coordinator assigned to your project may include any of the following:

   i. Literature searches.
   ii. Facilitating the research design and development process.
   iii. Data gathering and storage.
   iv. Coordinating the process of obtaining statistical analyses of data.
   v. Assistance in the preparation of posters and articles.

3. QI PROJECTS

a. Definitions. QI projects often resemble clinical research, so what differentiates QI from research? The simplest answer is that *a QI project is focused on improving a process or treatment within a given department or institution.* The information generated is not designed to be disseminated to the medical community beyond the institution. As such, a QI project does not require IRB review or approval. but will require review by the Arnot

b. If, however, an investigator designs his or her QI project so that it will generate scientifically valid information that *will* be disseminated to the broader medical community, the project then becomes, by definition, a human subject research study and will require IRB input.

c. All QI projects conducted by Arnot Health residents and fellows, whether or not they are intended to be research, need to be processed by the Research Steering Group (RSG), which will coordinate review by the SRB and, if needed, by the IRB as well.

d. Initiating a QI project. To start your QI project, please fill out the downloadable QI Proposal form and submit it to the lead coordinator. An RC will make contact with you to assist.

e. When you submit a QI proposal, along with having a faculty mentor, you will need to have approval of your program director and the department chair.