**Arnot Ogden Medical Center**

**(In affiliation with the**

**Lake Erie College of Osteopathic Medicine)**

**Research Proposal Guidelines**

Our goal is to facilitate your completion of a publishable research project that disseminates or advances medical knowledge. The more complete your initial proposal is, the quicker you will receive Institutional Review Board (IRB) exemption or approval.

Because projects vary greatly in goals and design, some elements of your proposal may need greater detail than others. **If an item below is not relevant, or if answering it requires information you have not yet obtained (such as the receipt of grant funding), state N/A or pending.**

Submit your completed proposal to Dr. Uma Yoganathan (uma.yoganathan@arnothealth.org) [and please copy Dr. Edwards ([frank.edwards@arnothealth.org](mailto:frank.edwards@arnothealth.org))].

*The following material describes the elements to include in your research proposal.*

***Create your proposal on a separate Word document***

***following the parts in the outline below.***

**Part 1 - Cover Material**

* + 1. Title of project
    2. Names of authors[[1]](#footnote-1) with institutional affiliations.
       1. If the project is a study involving human subjects (retrospective or prospective data), the cover sheet should attest that the investigators have completed the on-line Collaborative Institutional Training Initiative (CITI) module within the past 3 years, or that such training is in process.[[2]](#footnote-2)
       2. The name of the principle author should come first.
       3. List contact information for the principle author.
       4. **Every project must list at least one faculty member investigator.**
    3. **If you are applying for IRB exemption, indicate here the relevant paragraph number from the IRB Exemption Criteria document located on this website, and include a brief mention of why the project meets that exemption criteria. (Discuss with your research coordinator if in doubt).**

**Part 2 – Nature of the project**

1. Describe the question or issue your study is addressing (the research hypothesis, as applicable).
2. Describe the study’s design. Is it retrospective, prospective, observational, experimental, confirmatory, exploratory, a review, a meta-analysis, etc.?
3. If relevant, describe how participants will be sampled and how bias and variables will be controlled.
4. Detail the following items, as applicable:
   1. Interventions.
   2. Inclusion and exclusion criteria
   3. Primary outcome measure and any secondary outcome measures.
   4. Sample size.
   5. Duration of the project.
   6. Setting/location of the project.
   7. Statistical methods to be used.
   8. Description of data collection

**Part 3 – Literature Background**

Briefly discuss any scientific literature relevant to the project and include a list of references discussed. If your literature search is still ongoing, you may indicate that literature review is “pending.”

**Part 4- Risks/Benefits & Patient Privacy Protections**

Discuss potential risks to the subject, including the risk of breach of confidentiality or risk to private information. Detail safeguards or procedures to minimize risks. Likewise, mention any anticipated benefits to subjects and any potential benefits for society in the future. If the project involves new procedures, methodologies, medications, therapies or protocols, please mention potential cost savings or additional expenditures.

**Part 5 – Logistical Considerations**

Describe your data collection process. Address how you will maintain confidentiality of identifiable data, how long it will be stored, who will have access to identifiable information, etc. Attach a copy of any surveys, questionnaires, forms, recruitment materials, scripts, or any other document to be used as part of the study.

**Part 6 – Financial Considerations**

Describe whether your project will require separate funding or if its operation can be supported by existing finances. (i.e., “This project will require no outside funding). If funding will be required, please attach a separate sheet containing estimates of expenses (e.g., staffing support, equipment, medication, testing, analytics, etc.). Describe anticipated sources of funding. If the study will depend upon grant(s), indicate the amount and whether such funding has been applied for, or has already been secured.

**Part 7 – Consent process, if applicable**

Description of process by which informed consent will be obtained. Who will review consent forms with potential subjects? Who will answer potential subjects’ questions? Attach a copy of the proposed consent form for review.

**Part 8 –** **Waiver of informed consent requests, if applicable**

Any request by the investigator for waiver of the requirement of informed consent must include the following elements in the protocol:

1. Research involves no more than minimal risk to subjects.
2. Waiver will not adversely affect rights of subjects.
3. Research could not practicably be carried out without waiver or alteration.
4. Whenever appropriate, subjects will be provided with additional information after participation.
5. The research involves no procedures for which written consent is normally required outside of the research context.
6. The only record linking the subject and the research would be the consent document and the principal risk would be potential harm resulting from a breach of confidentiality.
7. Each subject will be asked whether the subject wants documentation linking the subject to the research and the subject’s wishes will govern.
8. For any request for the waiver or alteration of the HIPAA authorization requirement, complete a HIPAA Waiver Request form located at <https://lecom.edu/research/human-subjects-research-protection-protocol/>
   1. Discuss the following in the protocol:
      1. Plan to protect subjects’ protected health information from improper use or disclosure.
      2. Plan to destroy subjects’ protected health information as soon as the research allows.
      3. Is it practicable to obtain authorizations of subjects?
      4. Is it practicable to conduct the research without the subjects’ protected health information?

1. To be listed as an author, individuals must make substantial contributions to either the design of the project, the collection of data, or the writing of the study, and must approve the final draft. See: <http://www.icmje.org/recommendations/browse/roles-and-responsibilities/defining-the-role-of-authors-and-contributors.html> [↑](#footnote-ref-1)
2. <https://research.uci.edu/compliance/human-research-protections/docs/CITI-faqs-and-registration-instructions.html#1.4> [↑](#footnote-ref-2)