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 QI or research project that disseminates or advances our body of 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. Sowmya Srinivas (sowmya.srinivas@arnothealth.org) [and please copy Dr. Edwards (fedwards@arnothealth.org), Cathy Mathey (cmathey@arnothealth.org), and Robin Landolf (rlandolf@arnothealth.org)].

The following material describes the elements to include in your research proposal. Feel free to cut and paste this document and delete elements you do not need.

Essential elements of your proposal

Part 1 - Cover Material

i. Title of project
ii. Names of authors[1] with institutional affiliations.

[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

1. If the project is a study involving human subjects, the cover sheet should attest that the investigators have completed the on-line Collaborative Institutional Training Initiative (CITI) module within the past 3 years.[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.**

iii. If you are applying for IRB exemption, indicate here the paragraph number from the IRB Exemption Criteria list at the end of this document, with a brief discussion of why the project meets exemption criteria.

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:
    a. Interventions.
    b. Inclusion and exclusion criteria
    c. Primary outcome measure and any secondary outcome measures.
    d. Sample size.
    e. Duration of the project.
    f. Setting/location of the project.
    g. Statistical methods to be used.
    h. 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."

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[2] https://research.uci.edu/compliance/human-research-protections/docs/CITI-faqs-and-registration-instructions.html#1.4

Part 4- Risks/Benefits

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/
    - **a.** Discuss the following in the protocol:
        - **i.** Plan to protect subjects' protected health information from improper use or disclosure.
        - **ii.** Plan to destroy subjects' protected health information as soon as the research allows.
        - **iii.** Is it practicable to obtain authorizations of subjects?
        - **iv.** Is it practicable to conduct the research without the subjects' protected health information?

CRITERIA FOR EXEMPTION FROM THE REQUIREMENT FOR IRB REVIEW

Lake Erie Consortium for Osteopathic Medicine Training

 1. Research conducted in established or commonly accepted educational settings that involves normal educational practices that are not likely to adversely impact students' opportunity to learn required educational content or the assessment of educators who provide instruction. This includes most research on regular and special education instructional strategies and research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.

 2. Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior, unless:

(i) Information obtained is recorded in such manner that human subjects can be identified, directly or through identifiers linked to the subjects, and

(ii) Any disclosure of the human subjects' responses outside the research could reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, or reputation.

[The exemption for survey procedures, interview procedures, or observation of public behavior is not available for research involving children, except for observations of public behavior when the investigators do not participate in the activities being observed.]

 Research involving these methodologies but for which the data is recorded such that the identity of human subjects may be ascertained may qualify for "Exemption Following Limited IRB Review." Please see the last page of this application.

 3. Research involving benign behavioral interventions in conjunction with the collection of information from an adult subject through verbal or written responses (including data entry) or audiovisual recording if the subject prospectively agrees to the intervention and information collection and at least one of the following apply (*please indicate which you believe applies)*:

□ (i) Information obtained is recorded in such a manner that the identity of the human subjects cannot be readily ascertained, directly or through identifiers linked to the subjects

□ (ii) Any disclosure of the human subjects' responses outside the research would not reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, or reputation

[For the purposes of this provision, "benign behavioral interventions" are brief in duration, harmless, painless, not physically invasive, not likely to have a significant adverse lasting impact on the subjects, and the investigator has no reason to think the subjects will find the interventions offensive or embarrassing.]

NOTE: if the research involves deceiving the subjects regarding the nature or purpose of the research, this exemption is not applicable unless the subject authorizes the deception through a prospective agreement to participate in research in circumstances in which the subject is informed that he or she will be unaware of or misled regarding the nature or purposes of the research.

□ Research involving these methodologies but for which the data is recorded such that the identity of human subjects may be ascertained may qualify for "Exemption Following Limited IRB Review." Please see the last page of this application.

□ 4. Secondary research using identifiable private information or biospecimens if *(Choose one):*

□ (i) Those sources are publicly available,

□ (ii) If the information is recorded by the investigator in such a manner that the identity of subjects cannot be readily ascertained directly or through indirect identifiers linked to subjects, the investigator does not contact subjects, and the investigator will not re-identify subjects,

□ (iii) The research is regulated under HIPAA as "health care operation," "research," or "public health activities or purposes," or

□ (iv) the research is conducted by or on behalf of a Federal department or agency using government-generated or government-collected information obtained for nonresearch activities, if the research generates identifiable private information that is or will be maintained on information technology subject to federal regulations, if all the identifiable information will be maintained in systems of records subject to the Privacy Act of1974, and, if applicable, the information used was collected subject to the Paperwork Reduction Act of 1995.

☐ 5. Research and demonstration projects which are conducted or supported by or subject to the approval of federal department or agency heads, and which are designed to study, evaluate, or otherwise examine *(Choose one)*:

- ☐ (i) Public benefit or service programs;
- ☐ (ii) Procedures for obtaining benefits or services under those programs;
- ☐ (iii) Possible changes in or alternatives to those programs or procedures; or
- ☐ (iv) Possible changes in methods or levels of payment for benefits or services under those programs.

☐ 6. Taste and food quality evaluation and consumer acceptance studies, if *(choose one)*

- ☐ (i) Wholesome foods without additives are consumed or
- ☐ (ii) A food is consumed that contains a food ingredient at or below the level and for a use found to be safe, or agricultural or environmental contaminant at or below the level found to be safe, by the Food and Drug Administration or approved by the Environmental Protection Agency or the Food Safety and Inspection Service of the U.S. Department of Agriculture.

☐ 7. Storage or maintenance of identifiable private information or biospecimens for potential secondary research use if an IRB conducts a limited IRB review and makes the following determinations *(must meet all of the following)*:

- (i) Broad consent is obtained according to statute;
- (ii) Broad consent for storage is appropriately documented or waiver of documentation is appropriate; and
- (iii) If there is a change made for research purposes in the way the identifiable private information or identifiable biospecimens are stored or maintained, there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data.

☐ 8. Research involving the use of identifiable private information or identifiable biospecimens for secondary research use, if the following conditions are met (*must meet all of the following)*:

- (i) Broad consent for the storage, maintenance, and secondary research use of the identifiable private information or biospecimens was obtained in accordance with statute;
- (ii) Documentation of informed consent or waiver of documentation of consent was obtained in accordance with statute;
- (iii) An IRB conducts a limited IRB review (please see the last page of this application); and

(iv) The investigator does not include returning individual research results to subjects as part of the study plan.

EXEMPTION FOLLOWING LIMITED IRB REVIEW

For exemptions number 2, 3, and 8 above, exemption may be granted following a limited review as noted. To do so, the IRB must determine that there are adequate measures to protect the privacy of subjects and maintain the confidentiality of data.

In the description of your study, please detail what measures you will take to protect the privacy of subjects and maintain the confidentiality of data.