RESEARCH PROTOCOL CHECKLIST
Lake Erie College of Osteopathic Medicine

The following is a checklist of elements of a complete research protocol. Because each study is different, you may not need to provide the referenced information, or you may need to include additional information.

PROTOCOL COVER SHEET

TITLE

PRINCIPAL INVESTIGATOR
 Name
 Credentials/qualifications
 Institutional Affiliation
 Completion report showing CITI Training for Principal Investigator within past three years

ADDITIONAL INVESTIGATOR(S)
 Name(s)
 Role(s) in research
 Institutional Affiliation
 Credentials/qualifications
 Completion report(s) showing completion of CITI Training for appropriate role within past three years

RESEARCH QUESTION(S)/HYPOTHESIS

BRIEF REVIEW OF LITERATURE

METHODOLOGY
 Detailed description of methodology to be used including but not limited to the following:
- Description of recruitment and selection of subjects, including any inclusion and exclusion criteria
- Description of any instrumentation to be utilized
- Description of any planned interventions
- Description of data collection
- Description of data storage, including 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.

RISKS/BENEFITS

 Discussion of any risks to the subject.
 Discussion of any risk of breach of confidentiality or risk to private information of the subject.
 Discussion of any safeguards or procedures to minimize the risks.
 Discussion of any anticipated benefits to subjects.
 Discussion of any anticipated benefits for society in the future.

CONSENT PROCESS

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

WAIVER REQUESTS

 Any request by the investigator for waiver of the requirement of informed consent must include the following elements in the protocol:
    Research involves no more than minimal risk to subjects
    Waiver will not adversely affect rights of subjects
    Research could not practicably be carried out without waiver or alteration
    Whenever appropriate, subjects will be provided with additional information after participation.

 Any request by the investigator for waiver or alteration of any required elements of informed consent must include the following elements in the protocol:
    Research involves no more than minimal risk to subjects
    Waiver will not adversely affect rights of subjects
    Research could not practicably be carried out without waiver or alteration
    Whenever appropriate, subjects will be provided with additional information after participation.

 Any request by the investigator for waiver of the requirement of documentation of Informed Consent.
    Either A or B must be met:
        A. The research presents no more than minimal risk of harm to subjects and involves no procedures for which written consent is normally required outside of the research context.
        B. 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. Each subject

will be asked whether the subject wants documentation linking the subject to the research and the subject's wishes will govern.

 Any request by the investigator for the waiver or alteration of the HIPAA authorization requirement.

 Complete a HIPAA Waiver Request form is located at https://lecom.edu/research/irb/

Discuss the following in the protocol:

Plan to protect subjects' protected health information from improper use or disclosure.

Plan to destroy subjects' protected health information as soon as the research allows.

Is it practicable to obtain authorizations of subjects?

Is it practicable to conduct the research without the subjects' protected health information?