**Instructions for IRB Protocol – revised 01-08-19**

The IRB protocol is the formal design or plan for the proposed experiment or research activity; specifically, it is the plan submitted to the IRB for review and subsequently, to an agency for research support. The protocol includes a description of the research design or methodology to be employed, the eligibility requirements for prospective subjects and controls, the treatment regimen(s), and the proposed methods of analysis that will be performed on the collected data. The following format should be used in developing the research protocol.

### Description of Study

**Purpose and Potential Benefits**

Summarize the background, rationale, nature, and significance of the proposed research.

**Location of Study**

Identify all sites at which research will be conducted.

**Dates of study**

Include month/day/year of start and end dates of study.

**Subjects**

Include estimated number and description of types of subjects (e.g., normal volunteers, pregnant women, students), age, sex, inclusion and exclusion criteria, and source of subjects.

**Methods and Procedures**

Provide details on subject recruitment, nature and type of evaluation, subject's time commitment, proposed follow-up, debriefings when indicated, and any other information necessary to evaluate the involvement of subjects in the research. Any media, including flyers, brochures, or other advertisements used to recruit human subject participation in a research study, must be submitted to the IRB for review and approval and must be included as part of the IRB submission package.

**Participant Payments or Costs**

Indicate whether the subjects will be offered an incentive to participate in the study and if so, in what form (e.g., cash, meals, taxi fare, etc.) and in what amount.

**Subject Confidentiality**

Indicate the extent to which confidentiality of records identifying subjects will be maintained. Be specific where will the records be maintained? Who will have access to the records? How records will be maintained, i.e., hardcopy or electronic? Etc.

**Potential Risks to Subjects**

Specify any risks (physical, social, psychological, legal), indicate precautions instituted to minimize risks, and describe procedures to be followed in the event of problems. Specify the results of pilot work or the work of others with similar procedures.

**Risk/Benefit Ratio**

Specify the level of risk in relation to anticipated benefits.

**Informed Consent**

A copy of all proposed informed consent forms must be attached to the research protocol. Refer to the Appendix D for all information pertaining to development of Informed Consent forms.

**Student PIs**

Student PIs must also submit a description of their roles and responsibilities in the project, the roles and responsibilities of their instructor(s), mentor(s), or advisor(s), and the procedures that are in place to ensure proper mentorship. If the student-lead project is funded or is part of a mentor/advisor’s larger program of research and scholarship, the student PI must also describe the contribution that the student-lead project makes to the larger program of research.