Protocol

- Please utilize this format for project submissions if you do not have a Sponsor’s Protocol.
- If a Sponsor’s Protocol is proposed, you must submit that protocol for IRB review and approval.
- If you have a sponsor’s protocol, but do not intend on doing certain parts of the research project described in the sponsor’s protocol, you must indicate which portions of the research project you will not be doing in Item 6 – Research Plan. Be very specific and include reference to page and section numbers when describing the differences between what you are doing and what is proposed in the sponsor’s protocol.
- The Protocol should be considered a research proposal and should not be a lengthy document. It should, however, contain all information relevant to the proposed research project.

1. Project Title:

   - The title MUST be exactly the same on all documents submitted to the IRB.
   - If this study is funded, the protocol title should match that of the grant. If multiple protocols are funded by the same grant, each protocol should contain the grant name with a sub-title to describe that particular protocol. For example, if the grant is titled “Grant Title”, then Protocol One would be titled “Grant Title: Protocol One”, Protocol Two would be titled “Grant Title: Protocol Two”, etc. In order to insure funding is adequately initiated by Grants & Contracts in the Division of Sponsored Research, please complete and submit DSR’s “Verification of IRB Title” form (located at http://rgp.ufl.edu/research/pdf/irb_2.pdf).

2. Investigator(s):

   - Provide the name of the Principal Investigator and all sub-Investigators.
   - Students must provide the names of the supervisory chair and committee members.

3. Abstract:

   - This should be a concise one or two paragraph summary of the study. You should summarize the problem, your hypothesis or study question, the reasons why you want to do the study, and what you will do.
4. Background:

- State the problem and provide justification for conducting the study
- Include a synopsis of relevant research literature and information on previous animal and/or human studies that have been conducted.
- Discuss why your research project is a logical step toward solving the problem and the importance of this next step.

5. Specific Aims:

- Identify the hypothesis or the objectives of the project.

6. Research Plan:

- Provide a thorough description of what you intend to do throughout the course of the study in a logical and sequential format, and how these activities will answer the study questions. Include in your description a sample flow chart or study visit schedule for an individual subject.
- Provide a clear and concise description of the treatment, intervention or observation to be carried out in the study. Clearly state the nature of the experimental control (that is, placebo, other treatment, historical) or the absence of a control and any randomization procedures.
- Describe completely all physical examinations, blood tests, x-rays, any special tests or procedures, surveys, questionnaires, and/or observations that will be used to obtain information about subjects. Describe who will be responsible for obtaining the information and in what type of setting the information will be obtained.
- Describe completely all drugs, devices or instruments that are being proposed.
- Describe the inclusion and exclusion criteria for this project.
  - You may wish to design inclusion and exclusion criteria with flexible parameters to avoid potential protocol deviations.
- Discuss procedures for recruiting and consenting potential study participants.
  - Describe the targeted study population (the target population should be representative of the population that may potentially benefit from the research) and the setting in which the research will take place
  - If you intend to use a vulnerable population, describe the scientific and ethical reasons for including them and what, if any, additional safeguards are needed to protect them.
  - Describe how potential subjects will be identified and recruited
  - Describe how subjects protected health information will be accessed and by whom.
  - Describe how consent will be obtained, by whom, and in what setting, and how and where consent will be documented.
• Discuss how research interventions differ from standard therapies, and alternatives to participation in the study, if they exist.
• Describe the statistical analysis you will use to analyze your data including sample size and associated power.
  o Briefly outline the data analyses that are proposed and who will do the analysis.
  o Describe your plan for conducting interim analysis. What stopping rules are in place?
• Is there a Data Safety Monitoring Board (DSMB) or an oversight committee for this research project?
  o Provide Information about the DSMB or committee including who is on the committee, how frequently will the committee meet, and when will you get information from the committee.
  o Describe your plans for monitoring study conduct and subject safety.
• Describe clearly the procedures you will use to protect the privacy of subjects and ensure confidentiality of all data and study records including hard copy and computer files.

7. Possible Discomforts and Risks:

• Identify all discomforts and risks (physical, psychological, social, and/or economic) study participants may encounter, listing more common risks first and less common risks separately.
• Identify potential financial risks study participants may incur.
  o Indicate any procedures, medications, tests, or therapies that study participants (or their insurer) will have to pay for. Are these considered standard therapy or are they specific to the research study?
• Describe procedures to protect against or minimize potential discomforts and risks.

8. Possible Benefits:

• Describe the potential benefits to subjects or to others that may be reasonably expected to result from the research.
  o If there is no potential for direct benefits, you must state this in the Informed Consent Form.
• Discuss why the risks to subjects are reasonable in relation to the anticipated benefits and in relation to the importance of the knowledge that may reasonably be gained. Will the research study benefit future populations?

9. Conflict of Interest:
• Describe any real or potential conflict of interest you or any other investigators may have with regard to this research project.

• When deciding whether a conflict may exist, consider the following:
  o Do you, the University of Florida, or any of the sub-investigators hold a patent or license for any material, object, or process used in this project?
  o Is a patent or license pending or under consideration or is there any intention to file a patent application at a later date?
  o Do you, the University of Florida, or any of the sub-investigators own stock in the company sponsoring the project?
  o Do you or any of the sub-investigators give presentations for or serve as a consultant to the sponsoring company on their behalf?

• Do you or any of the sub-investigators have any other possible conflict of interest?