USF IRB PROTOCOL GUIDELINES

The PI and study title listed in the IRB application must match the PI and study title on the protocol. Please include version number and date on the first page of the protocol.

Guidelines for studies meeting the criteria for expedited or full Board review:
1. Rationale for the study, area of current scientific concern and why the research is needed;
2. Background information, description of existing research and information that is already known;
3. The research questions, objectives and purpose;
4. The study design including information that is needed to answer the research questions;
5. Sample size;
6. Study Population or inclusion and exclusion criteria;
7. The expected results of the research, such as reports, papers, and contributions to theory;
8. Name of the Principal Investigator and Faculty Advisor if applicable;
9. Any potential risks to the subjects;
10. Any experimental procedures or interventions that will be implemented;
11. Any potential benefits to subjects;
12. Human subjects considerations including
   - description of the informed consent process;
   - if applicable include a discussion of safeguards that are in place to protect potentially vulnerable subjects such as children, prisoners, the cognitively impaired, institutionalized or critically/terminally ill;
   - discussion of how the privacy and confidentiality of the subjects will be maintained.
13. If the study is greater than minimal risk, describe the data and safety monitoring plan, whether or not there is a data and safety monitoring board, how often data will be reviewed for safety, early stopping criteria, etc.
14. Research references;

Guidelines for studies meeting the criteria for exempt review by the IRB:
1. Rationale for the study, area of current scientific concern and why the research is needed;
2. Background information, description of existing research and information that is already known;
3. The research questions, objectives and purpose;
4. The study design including information that is needed to answer the research questions;
5. Sample size;
6. Study population or inclusion and exclusion criteria;
7. The expected results of the research, such as reports, papers, and contributions to theory;
8. Name of the Principal Investigator and Faculty Advisor if applicable
9. Any potential risks to the subjects;
10. Any potential benefits to subjects;
11. Human subjects considerations including
   - description of the informed consent process;
   - if applicable include a discussion of safeguards that are in place to protect potentially vulnerable subjects such as children, prisoners, the cognitively impaired, institutionalized or critically/terminally ill;
   - discussion of how the privacy and confidentiality of the subjects will be maintained.

If you have any questions, please call 974-5638.