STUDY INFORMATION

1. State the title of your research:

2. **Study Investigators** (*All student and post doctorate applicants must list their faculty advisor as Principal Investigator below).* Please see PI eligibility criteria:

   Principal Investigator/Faculty Advisor:

   Department:

   Departmental Address:

   Email:

   Phone:

   Fax *(if applicable):*

   Student Investigator (*if applicable):*

   Student Year/level:

   Email:

   Phone:

   Study Contact Person:

   Email:

   Phone:

3. List all research personnel. Provide the name of their department, departmental address, e-mail address, phone number and fax number (if applicable). Briefly describe their role (i.e., Research Coordinator, consent subject, administer surveys, etc.)* All student and post doctorate applicants must list their faculty advisor as Principal Investigator and provide their departmental address, phone number and e-mail address above. *If more space is needed, continue on next page.*

4. Is this a student project? **Yes** ☐ **No** ☐ If yes, please check the appropriate box:

   ☐ Junior Project ☐ Senior Thesis ☐ Dissertation/Graduate

5. State the dates for starting and ending this research project. **(Note: The project may not start until a final determination has been issued.)**

RESEARCH PURPOSE

6. Summarize the purpose of the study and the hypotheses which are to be tested.

7. Describe subject recruitment procedures and/or data/biological specimen collection procedures, if applicable:
   a. Provide the number of subjects to be invited to participate or the number of biological specimen/data to be collected.

   b. Summarize the process of recruiting potential subjects. Specify inclusion and exclusion criteria when relevant and attach any recruitment announcements such as flyers, advertisements, etc. Specify how data/biological specimen will be obtained, if applicable

   c. Provide the specific name of the schools, country, clinic, or other agency from which subjects will be recruited and where the research will take place. This should include specimen repository, databank etc. where data/specimens will be collected, when applicable.

d. If your research plans include the collection or study of existing data, pathological or diagnostic specimens, please specify whether data will be restricted and if an agreement is in place prohibiting release of private identifiable information or you will be provided the key to coded information and provide such documentation, if applicable.

RESEARCH DESIGN

8. Describe the research design including each of the following:
   a. Describe all research procedures as they directly affect the subject(s).

   b. Include the estimated length of time for various procedures (e.g., interviews, completing questionnaires, etc.) and frequency of repetition; any manipulation including ones which may cause discomfort or inconvenience; and plans for follow-up, when applicable. This includes analysis of biological specimens/data.

   c. Include a copy of questionnaires, rating scales, list of variables to be collected or other instruments to be used, if applicable.

RISK TO SUBJECTS:

9. Describe any potential risks including physical, psychological, social, economic - monetary, reputational, legal or other potential risks.
   ****Minimal Risk** means that the risks of harm anticipated in the proposed research are not greater, considering probability and magnitude, than those ordinarily encountered in the daily life or during the performance of routine physical and psychological examinations or tests.

CONSENT PROCEDURES:

10. Describe consent procedures to be followed, including how, when, where, and by whom informed consent will be obtained, if applicable. Submit the consent form or consent script. Consent templates are available on CCC-UPR website **HERE**.

CONFIDENTIALITY:

11. Describe how data/study records will be kept confidential and specify safeguards to be implemented for protecting participant information and minimizing potential risks to subjects (i.e., password protected computer(s), file encryption, etc.).

12. All research investigators who propose to work with human subjects in their studies must have human subjects training.
Please note that the IRB will not issue a final determination unless all proper training is completed and certifications are received.

UNANTICIPATED PROBLEMS/ADVERSE EVENTS

13. Please refer to the reporting requirements.

Include the signature of the Investigator(s) and the date. Also include the advisor's signature, if applicable.

SIGNATURES

For faculty projects:

Principal Investigator's name: _____
Print

Principal investigator's signature: _____

Date: _____

For student projects:

Faculty Advisor Assurance:
I am the faculty advisor for the student submitting this protocol. By my signature, I certify that I have reviewed the protocol and believe that it is scientifically and ethically sound. Furthermore, I believe that the student has the necessary training, experience and knowledge to conduct the research in a manner consistent with the regulations governing human subject research and sound research principles. I agree to:

- Assist with the resolution of any problems or concerns encountered during the research;
- Assure that the CCC-UPR IRB is notified in the event of an adverse event or protocol deviation.
- Oversee and monitor the conduct of this research by communicating regularly with the student investigator; I understand that as faculty advisor I am responsible for the conduct of this research.

_____	_____
Faculty Advisor's print name	Student Investigator's print name
_____	_____
Faculty Advisor's Signature	Student Investigator's signature
Date: _____	Date: _____