IRB APPLICATION FULL BOARD OR EXPEDITED REVIEW

SECTION A. GENERAL STUDY INFORMATION

1. **State the title of the proposed research.**

2. **Study Personnel** (Only CCC-UPR faculty and appropriate staff may be named as Principal Investigator. All students must list their faculty advisor as Principal Investigator (PI) below).

Principal Investigator/Faculty Advisor:	
Department:	
Departmental Address:	
Email:	
Phone:	
Student Investigator (if applicable):	
Graduation Year / level: (e.g., 2017 / undergraduate; 5th year /graduate	
Email:	
Phone:	
Study Contact Person:	
Email:	
Phone	

3. **List all co-investigators and key study personnel.** Provide the name of their department, departmental address, e-mail address, phone number and fax number *(if applicable)*.

Name, Department, Address, E-mail, Phone, Fax

4. **Briefly describe the role of each study personnel listed above (e.g., Research Coordinator, data collection, consent subjects, administer survey, etc.)**

Name	Role

5. **Is this a student project?** ☐ **Yes** ☐ **No**

If yes, please choose project type:

☐ **Junior Project** ☐ **Senior Thesis** ☐ **Master's Thesis** ☐ **Dissertation**

☐ **Other (describe):**

6. **Will research be conducted outside of the United States?** ☐ **Yes** ☐ **No**

If yes, complete International Supplement B and submit with the application for review.

7. **Please list the agencies that are funding or have been asked to fund this research. Attach a copy of the grant application submitted for funding.**

8. **State approximate dates for starting and ending this research project. (Note: The project must not start until it has been approved by the IRB.)**

Start: **Finish:**

SECTION B: RESEARCH PURPOSE

9. **Provide a summary of the purpose of your research project. Include a description of the background and rationale for the study, explain the research design, research methodology, hypotheses and goal(s). Specify the problems to be addressed, what is to be learned, and identify the specific objectives of the proposed research using non-technical language understood by a person unfamiliar with this area of research.**

10. **Describe in detail the procedures that will be used to achieve the objectives of the research project and specify what you will do with the results of your study (e.g., publish, share in presentation or conference, etc.)**

SECTION C: RESEARCH PROCEDURES:

11. **Categories of Research: The research involves the following (check all that apply):**

☐	**Education Research**	☐	**Internet-based research**
☐	**Questionnaires/Surveys**	☐	**Analysis of Existing Data**
☐	**Ethnographic/Field Research**	☐	**International Research (complete supplement B)**
☐	**Use of pre-existing Tissues**	☐	**Chart Review – retrospective**
☐	**EKG/EEG/fMRI/Chest X-ray**	☐	**Chart Review – prospective**
☐	**Clinical Observations**	☐	**Collection of Clinical Specimens**
☐	**Clinical Tests**	☐	**Tissue banking**
☐	**Drugs/Biologics (complete supplement F)**	☐	**Stored Data for Future Use (complete supplement E)**
☐	**Audio/Video recording**	☐	**Other:**

SECTION D: RESEARCH SETTING:

12. **Describe the settings in which research procedures will be carried out (e.g., hospital, clinic, school, home, lab, etc.)**

13. **Indicate all CCC-UPR campus sites, or off campus sites that are owned or operated by CCC-UPR, where the research procedures will be carried out.**

14. **Is this a multi-site, organization, or institution study?** ***Note: A multi-site study is any study where the CCC-UPR investigator is conducting research at a site(s) that is not owned, operated or under the control of CCC-UPR?***
    ☐ **Yes** ☐ **No**

    If yes, please specify the following:

    a. **Is the CCC-UPR Investigator the lead investigator for the multi-site study?** ☐ **Yes** ☐ **No**

    b. **Is CCC-UPR the lead site? If no, please specify.** ☐ **Yes** ☐ **No**

    c. **If either of the above is yes, describe the provisions for the management of information obtained from the different site that might be relevant to the protection of participants (e.g., data coordinating center).**

    d. **List all non-CCC-UPR sites where the procedures will be carried out. For each site, specify the contact information and indicate whether the site has IRB approval and/or has granted permission for the research to be conducted at that site.**

SECTION E: PARTICIPANT SELECTION AND POPULATION:

Equitable Subject Selection: Selection of subjects must be fair and equitable. That is, the selection process must avoid exploiting potential subjects (taking advantage of their circumstances) and minimize coercion.

Note: In making this assessment, the IRB will take into account the purpose of the research, the setting in which the research will be conducted as well as additional safeguards to protect vulnerable populations, such as children, prisoners, pregnant women, mentally disabled persons, or economically or educationally disadvantaged persons.

15. **Explain how the subject selection process in this research is fair and equitable, taking into account eligibility criteria, vulnerability and recruitment process:**

16. **The research involves the following (check all that apply):**

☐	**Healthy Participants**	☐	**Prisoners**
☐	**Students -- Specify School:**	☐	**Pregnant Women, Fetuses, or Neonates**
☐	**Children or Minors:** ***Complete Supplement C***	☐	**Cognitively Impaired:** ***Complete Supplement D***
☐	**Children who are Wards of the State**	☐	**Non-Spanish speakers**
☐	**Employees -- Specify Employer:**	☐	**Institutionalized Individuals (not prisoners)**

17. **Please provide a description of the participant population. Describe the characteristics of the participant population such as gender, age range, ethnic background and health status, as applicable to the research.**

18. Please provide a rationale for the use of special groups or subjects whose ability to give voluntary informed consent may be in question (e.g., cognitively impaired).

19. Provide the total number of research participants you anticipate are needed for this research (include number of participant records, specimens, etc., if applicable) for IRB approval.

20. In the chart below please indicate the number of subjects per category if known:

	MALE	FEMALE	TOTAL
ADULTS			
CHILDREN			
TOTAL	**0**	**0**	

21. Will any groups or categories of subjects be excluded from research? ☐ **Yes** ☐ **No**

If yes, please specify and provide the rationale for excluding these subjects:

SECTION F: PARTICIPANT RECRUITMENT PROCEDURES

22. Describe all inclusion / exclusion criteria that will be used to select research participants. Provide a detailed description of how research participants will be selected and by whom.

23. Describe your recruitment plan and attach all recruitment materials including advertisements, emails, flyer, letter of introduction, etc.

24. Check all recruitment materials that apply:

☐	**Letter of Introduction**
☐	**Recruitment Email**
☐	**Flyer**
☐	**Advertisements**
☐	**Other, please describe:**

25. **Will participants be recruited by searching records (e.g., school records, medical records, mailing list, databases, etc.)?** ☐ Yes ☐ No

    a. **If yes, will this include paper files?** ☐ Yes ☐ No

    b. **If yes, will this include electronic files?** ☐ Yes ☐ No

    State who will maintain these electronic files:

    c. **Will existing databases be utilized?** ☐ Yes ☐ No

    If yes, please specify types and locations of databases:

    d. **Other, please describe:**

26. **Will subjects be offered compensation for participating in the research?** ☐ Yes ☐ No

    If yes, describe the nature of the compensation. (Indicate the amount and schedule of payments as well as conditions for subject receiving compensation for participating in the research).

SECTION G: CONSENT PROCEDURES

Unless waived by the IRB, Informed Consent is necessary for all research involving human subjects and must be documented.

Note: For research involving children complete Supplement C or Supplement D for cognitively impaired subjects.

27. Do you plan to obtain signed documented consent from all study participants? ☐ **Yes** ☐ **No**

If yes, specify the following:

a. Specify where the informed consent process will take place:

b. Specify who will obtain consent and describe their experience in obtaining consent from subjects:

c. How will it be determined that the subjects or the subjects' authorized representatives understand the information presented?

d. If Spanish is not the subjects' native language, will translation be provided? ☐ **Yes** ☐ **No**

If no, or you plan to use oral consent, please complete Supplement A to request a waiver of consent or documentation. If you plan to use a consent form or oral script, please complete the template on the IRB website and attach a copy for IRB review.

28. Does the proposed research involve deception e.g., through provision of misinformation withholding information etc.? Explain why it is necessary to involve deception(s) in the research.

29. Provide a full account of the debriefing procedures to be followed, if deception will occur. If you plan to debrief, please attach a copy of the written debriefing or the debriefing interview protocol.

SECTION H: RISK TO SUBJECTS:

Risks to research subjects posed by participation in research should be justified by the anticipated benefits to the subjects or society. This section is to assess "benefits" and "risks" to subjects including how those risks may be minimized -- i.e., the possibility of physical, psychological, sociological, breach of confidentiality, or other harm as a consequence of participation in the proposed research project. Please use as much space as needed to answer each question.

30. Risk Classification: What is the overall risk classification of the research?

NOTE - According to HHS regulations, minimal risk means: "The probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests."

- ☐ **Minimal**
- ☐ **Greater than minimal**

31. What are the possible anticipated risks and discomforts to the participants? Describe all possible risks including psychological physical sociological or economic harm (e.g., risk of criminal or civil liability, damage to their financial standing, employability, insurability, reputation, or stigmatization, etc.

Check all that apply, and describe each:

☐ **Loss of confidentiality, describe:**

☐ **Loss of Social Status, describe:**

☐ **Emotional stress or discomfort, describe:**

☐ **Physical injury or discomfort, describe:**

☐ **Loss of Employment, describe:**

32. Please describe any additional risks to participants or others:

33. Describe how you will minimize these risks and their potential impact to the participants or others?

34 Are there any direct benefits to the research participants? Note: Direct benefit is a valued or desired outcome; an advantage (please do not include monetary inducement or compensation).

☐ **Yes** ☐ **No** **If yes, please describe.**

35. In a few sentences, please address the benefits of the research, both to science and/or society.

36. If the risk in this study is more than minimal, explain how the risks are reasonable in relation to the benefits:

SECTION I: CONFIDENTIALITY, DATA AND SAFETY MANAGEMENT:

37. Will you record any demographic data or direct participant identifiers? ☐ **Yes** ☐ **No**

If yes, indicate the types of data that will be recorded:

☐ **Names** ☐ **Ethnicity**

☐	Addresses	☐	Marital Status
☐	Phone numbers	☐	Income
☐	Age	☐	Social Security Number
☐	Gender	☐	Job Title / Name of employer
☐	Other:		

38. Explain why it is necessary to maintain such identifiers and describe the coding system you will use to protect against disclosure.

39. Will you retain a link between study code number and direct identifiers after the data collection is complete?
☐ **Yes** ☐ **No**

If yes, explain why it is necessary and describe the coding system you will use to protect against disclosure (if different from above).

40. Describe what procedures will be used to ensure secure storage of study materials including, consent forms, survey responses, etc. during the course of the project. Specify who will have access to these materials:

41. Describe specifically what will be done with all study materials at the conclusion of the study. Include paper records, audio and video recordings, field notes, transcripts, etc. in your response. If materials are to be retained, describe the secure storage of those materials. **Please note:** Documentation of the signed informed consent of the subjects, written protocol, and other records related to conducted research that are typically held by investigators **must be retained for at least three years after completion of the research**.

42. In the event that outside organizations are involved (in data gathering, processing, and storage), how will the rights of the subjects be guaranteed by that agency?

43. If your proposed research involves more than minimal risk, describe the data and safety management plan (DSMP). The DSMP should address:

a. A description of the plan to monitor research progress and subject reactions, including who will do the monitoring and ensure monitoring will be accomplished
b. Identification of a Data Safety Monitor or Data Safety Monitoring Board, where applicable
c. A plan for dealing with adverse events and unanticipated problems involving risk to subjects or others
d. A description of the plan to assure compliance with reporting of adverse events and/or unanticipated problems involving risks to participants or others
e. A description of the plan to assure data accuracy and protocol compliance

SECTION J: TRAINING AND CERTIFICATION:

44. All research investigators who propose to work with human subjects in their studies must have human subjects training.

NOTE: The IRB will not issue final approval unless all proper training is completed or certifications are received. Certifications in HS, HIPAA, GCP. No more than three years of issued.

SIGNATURES

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

FACULTY OR STAFF PROJECTS

Principal Investigator (print or type name)

Professional Title

Signature

Date

STUDENT PROJECTS

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:

- Oversee and monitor the conduct of this research by communicating regularly with the student investigator;
- Assist with the resolution of any problems or concerns encountered during the research; risks to subjects or others.

I understand that as faculty advisor I am responsible for the conduct of this research.

Principal Investigator (print or type name)

Professional Title

Signature

Date

Student Investigator (print or type name)

Signature

Date