UNIVERSIDAD CENTRAL DEL CARIBE
INSTITUTIONAL REVIEW BOARD OFFICE
Hospital Universitario Dr. Ramón Ruíz Arnau
Bayamón, Puerto Rico

HUMAN SUBJECTS REVIEW COMMITTEE APPLICATION

APPLICATION TO INVOLVE HUMAN SUBJECTS IN RESEARCH

Note: Submit original signed documents and one electronically filed scanned copy of all application materials.

PROTECTING THE RIGHTS AND WELFARE OF HUMAN SUBJECTS IN RESEARCH AT UNIVERSIDAD CENTRAL DEL CARIBE (UCC)

The purpose of this application is to guarantee ethical principles based research protections of human subjects in research, ensure compliance with federal, state, and corporate regulations, and elicit from the Principal Investigator (PI), pertinent information which will facilitate a rapid and thorough review by the UCC Institutional Review Board (IRB).

SUMMARY GUIDELINES

UCC policy requires that all research involving human subjects* conducted by or under the direction of UCC personnel and students using any property or facility of UCC, regardless of location, must be submitted to the IRB for review and approval. Written notice of IRB approval must be issued before the Principal Investigator (PI) may initiate research. Only those documents (consent form, advertisement, questionnaires, etc.) that bear the IRB approval may be used in the conduct of research. Any change made to the protocol, consent form, or supporting documentation must be approved by the IRB before they can be implemented, as well. A review may be requested by submitting an addendum application to the IRB.

The IRB cannot approve a protocol for a period longer than one year and cannot, under any circumstances, grant retroactive approval. Continuing review is, therefore, required on a yearly basis. The IRB will issue a notification when an Application for Continuation is due. However, the Principal Investigator is responsible for ensuring that applications are submitted and approved before work is initiated and/or continued.

Human Subjects are defined by the federal regulations as "living individual(s) about whom an investigator conducting research obtains 1) data through intervention or interaction with the individual, or 2) identifiable private information*

1. PROJECT REVIEW

   The Faculty Advisor(s), Student Researcher(s), and any External Researcher(s) MUST complete the online training requirements in Human Subject Research, HIPAA for researchers and Responsible conduct of Research before submitting IRB application. Submit copies of each certificate for each advisor and researcher at the time of the IRB application submission.

2. Are there other participating Institutions requiring IRB review? Yes ☐ No ☐

   Where will the Research be conducted?

   _____

3. Project Title: _____

4. Participants (approximate number and all applicable categories):
   Number of participants: _____
   _____ Female _____ Male _____ Other

   ☐ Children (20 or younger)
   ☐ Patients in institutions
   ☐ Prisoners
   ☐ Adults (21 years of age or older)
   ☐ Medical students
   ☐ Faculty or external reviewers

☐ Pregnant women
☐ Other: Medical Students, 1st and 2nd yr

☐ Child Development Center

5. Will the research involve any of the following?

☐ Interviews
☐ Use of private information
☐ Use of private data/records
☐ Survey/questionnaire
☐ Behavior observation
☐ Deception
☐ Waiver of consent
☐ Controlled substance
☐ Study of diagnostic specimens
☐ Study of pathological specimens
☐ Venipuncture (<450cc)
☐ Radiation
☐ Personal identifying links to data
☐ Clinical Studies
☐ HIV/AIDS
☐ Hepatitis/TB/STD
☐ Culturally or socially Sensitive Issues
☐ Potential development of commercial products From human biological materials
☐ Use of bodily materials from a living individual or fetus
☐ Genetic research/analysis
☐ Genetic notification
☐ Data or tissues obtained specifically for this project
☐ Investigational drugs
☐ Investigational devices or materials
☐ Study of existing documents
☐ Minor change to previously approved research
☐ Human in vitro fertilization
☐ Micro-organisms or recombinant DNA
☐ PI or alternate as attending physician or caregiver
☐ Environmental alterations (habitat/lighting, etc.)
☐ Audio visual/tape recordings or photographs
☐ Moderate exercise by volunteers
☐ Individual observation or group behavior or characteristics
☐ Tools developed specifically for this study

6. REVIEW CATEGORY:

Note: Most research with children cannot be reviewed under exempt administrative review. The protocol would require either expedited or full board review. See HHS OHRP regulations.

□ **Exempt Administrative Review** (based on the following categories):

□ a. Research conducted in established or commonly accepted educational setting, involving normal educational practices, such as (i) research on regular and special education instructional strategies, or (ii) research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.

□b. Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior, unless: (i) information obtained is recorded in such a manner that human subjects can be identified, directly or through identifiers linked to the subjects; and (ii) any disclosure of the human subjects' responses outside the research could reasonably place the subjects at risk or criminal or civil liability or be damaging to the subjects' financial standing, employability or reputation.

□c. Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior that is not exempt under paragraph (b) (2) of this section, if: (i) the human subjects are elected or appointed public officials or candidates for public office; or (ii) federal statute(s) require(s) without exception that the confidentiality of the personally identifiable information will be maintained throughout the research and thereafter.

□ d. Research involving the collection or study or existing data, documents, records, pathological specimens, or diagnostic specimens, if these sources are publicly available or if the information is recorded by the investigator in such a manner that subjects cannot be identified, directly or through identifiers linked to the subjects.

□ e. Research and demonstration projects which are conducted by or subject to the approval of department or agency heads, and which are designed to study, evaluate, or otherwise examine : (i) Public benefit or service programs; (ii) procedures for obtaining benefits or services under those programs; (iii) possible changes in or alternatives to those programs or procedures; or (iv) possible changes in methods or levels of payment for benefits or services under those programs.

□ f. Taste and food quality evaluation and consumer acceptance studies. (i) if wholesome foods without additives are consumed or (ii) if a food is consumed that contains a food ingredient at or below the level and for a use found to be safe, or agricultural chemical or environmental contaminant at or below the level found to be safe, by the Food and Drug Administration or approved by the Environmental Protection Agency or the Food Safety and Inspection Service of the U.S. Department of Agriculture.

□ **Expedited Review** (See HHS OHRP Expedited Review Criteria List):
Note: Submit original and one electronically filed copy of all application materials.

□ Collection of data from voice, digital, or image recordings made for research purposes
□ Moderate exercise, muscular strength testing, body composition and flexibility testing from healthy volunteers (excludes x-rays, or microwaves)
□ Non-manipulative, non-stressful research on individual or group behavior
□ Collection of biological specimens by noninvasive means (see full listing at link above)
□ Collection of blood samples by finger prick, heel stick, ear stick or venipuncture
□ Study of existing data, documented, records, or pathological or diagnostic specimens
□ Other: (see expedited link above and describe here)

□ **Full board Review**: Involves vulnerable populations including children, prisoners, pregnant women, neonates and fetuses. Note: include original application and one electronically filed copy.

7. ATTACHMENTS: All relevant project materials and documents, including:
☐ Surveys, questionnaires, interviews, and measurement instruments
☐ Informed Consent Form
☐ Assent script (for children when applicable)
☐ Included letters or approval/permission on letterhead from cooperating agencies schools, board of education, school districts, and other agencies.
☐ Debriefing statement or explanation sheet if applicable
☐ Participant recruitment materials (e.g., flyers, advertisements)
☐ Other: (describe other documents submitted here)

Send eight copies of this form (including one copy with original signatures) and eight copies of all relevant materials (consent forms, questionnaires, instruments, drug information summary, data collection forms, debriefing statement, advertisements, etc.) to the IRB Office. Do not leave blanks. Attach one copy of each research proposal, and/or one copy of the protocol and investigator's brochure for clinical trials. Student should attach one copy of thesis or dissertation proposals. For information and assistance, call Dr. Frances García, President, IRB (787)798-3001 ext. 2000 or IRB Official (787)798-3001 ext. 2006. Handwritten and /or incomplete forms will be returned. (Use 10 point type or larger throughout application). The contents of this application and attachments will be kept confidential within the limits of the law. Please refer to above control number for any correspondence concerning this study.

I. PRINCIPAL INVESTIGATOR (Provide Correspondence will be directed to this person. You may designate a contact person other than yourself in section II., below.)
Name_____**Title**_____**Position** _____
Department _____**Division**_____
Mail box or address_____
Telephone_____**Fax**_____**E-mail** _____

II. CONTACT PERSON (Provide all the information requested. Unless also listed as a co-investigator in section V., below, this person does NOT have signatory authority with regard to this application.)
Name_____**Title**_____**Position** _____
Department_____**Division**_____
Mail box or address_____
Telephone_____**Fax**_____**E-mail** _____

III. TITLE OF PROJECT:_____

IV. SIGNATURES: The undersigned acknowledge that: 1. This application represents an accurate and complete description of the proposed research: 2. The research will be conducted in compliance with the recommendations of and only after approval has been received from the Human Subjects Review Committee (HSRC). The principal investigator is responsible for reporting any serious adverse events or problems to the HSRC, for requesting prior HSRC approval for modifications, and for requesting continuing review and approval.

A. **Investigator:** ____

TYPED NAME PLUS SIGNATURE DATE

B. **Faculty sponsor (for student):** ____

TYPED NAME PLUS SIGNATURE DATE

B. **The Chair, Dean, or Director signing below acknowledges that this proposed activity has received intra-mural review and approval of scientific merit and investigator qualification.**

____

TYPE NAME PLUS SIGNATURE DATE

______________________________ ____________ **Approve** ☐ **Disapprove** ☐

HUMAN SUBJECTS REVIEW COMMITTEE DATE

Subject to the following conditions: ____

____

Period of approval is one year, from ____________________ **through** ____________________

VALID ONLY AS LONG AS APPROVED PROCEDURES ARE FOLLOWED

V. CO-INVESTIGATOR (Provide all the information requested for each co-investigator. Add sheets if necessary.)

Name____________________**Title**____________________**Position** ____________________
Department____________________**Division**____________________
Mail box or address____
Telephone________________**Fax**____________________**E-mail** ____________________

Name____________________**Title**____________________**Position** ____________________
Department____________________**Division**____________________
Mail box or address____
Telephone________________**Fax**____________________**E-mail** ____________________

Name____________________**Title**____________________**Position** ____________________
Department____________________**Division**____________________
Mail box or address____
Telephone________________**Fax**____________________**E-mail** ____________________

Name____________________**Title**____________________**Position** ____________________
Department____________________**Division**____________________
Mail box or address____
Telephone________________**Fax**____________________**E-mail** ____________________

Name____________________**Title**____________________**Position** ____________________
Department____________________**Division**____________________
Mail box or address____
Telephone________________**Fax**____________________**E-mail** ____________________

VI. FUNDING: Project period from (_____) to (_____)

Are you seeking funding for this research? ☐ No ☐ Yes
If yes, submit one copy of the proposal summary or abstract with the application

Does the funding agency require IRB approval? ☐ No ☐ Yes ☐ N/A
If yes, provide all relevant forms, instructions, etc. with this application.

LIST EACH PROPOSED AND FUNDED GRANT OR CONTRACT RELEVANT TO THIS APPLICATION. IF NONE, CHECK HERE ☐. FOR CENTER OR PROGRAM PROJECT GRANTS LIST P.I. AND TITLE FOR EACH SEPARATE PROJECT OR CORE. ADD SHEETS IF NECESSARY.

A. Type of proposal: ☐ Research ☐ Contract ☐ Fellowship ☐ Training grant ☐ Subcontract ☐ Other

B. Name of principal investigator:

C. Name of funding agency:

D. **Agency's number (if assigned):**

E. **Title of proposal:**

F. **Inclusive dates: from_____through _____**

G. **Status: ☐ NEW ☐ Competing ☐ Non-competing renewal**

A. **Type of proposal: ☐ Research ☐ Contract ☐ Fellowship ☐ Training grant ☐ Subcontract ☐ Other**

B. **Name of principal investigator:**

C. **Name of funding agency:**

D. **Agency's number (if assigned):**

E. **Title of proposal:**

F. **Inclusive dates: from _____through _____**

G. **Status: ☐ NEW ☐ Competing ☐ Non-competing renewal**

A. Type of proposal: ☐ Research ☐ Contract ☐ Fellowship ☐ Training grant ☐ Subcontract ☐ Other

B. **Name of principal investigator:**

C. **Name of funding agency:**

D. **Agency's number (if assigned):**

E. **Title of proposal:**

F. **Inclusive dates: from _____through_____**

G. **Status: ☐ NEW ☐ Competing ☐ Non-competing renewal**

A. Type of proposal: ☐ Research ☐ Contract ☐ Fellowship ☐ Training grant ☐ Subcontract ☐ Other

B. **Name of principal investigator:**

C. **Name of funding agency:**

D. **Agency's number (if assigned):**

E. **Title of proposal:**

F. **Inclusive dates: from_____through_____**

G. **Status: ☐ NEW ☐ Competing ☐ Non-competing renewal**

VII. SUMMARY OF ACTIVITY. Answer in spaces provided (add numbered and referenced sheets when necessary). Do not refer to an accompanying grant or contract proposal.

A. BACKGROUND AND PURPOSE OF RESEARCH. Provide relevant background information and explain in lay language what research question(s)

B. RESEARCH PROCEDURES INVOLVED.

1. **Provide a complete description of : a the study design, and timing of all study procedures that will be performed. e.g., volume of blood, size of biopsy, drug administration, questionnaire, name of psychological test. Provide this information for each phase of the study (pilot, screening, intervention and follow-up). Use lay language. Attach study flow sheet, if available. Any changes in procedures at any time after study has IRB approval must be resubmitted to the Board prior to implementation.**

2. **Would subjects undergo these or similar procedures (medical, Psychological, educational, etc.), if they were not taking part in this research? ☐ No ☐ Yes. If "Yes," describe how the study procedures differ from what subjects would otherwise undergo.**

C. DECEPTION: If any deception or with holding of complete information is required for this activity, explain why this is necessary and attach a protocol explaining if, how, when, and by whom subjects will be debriefed.

D. SUBJECTS

1. **How many subjects will you need to complete this study? Number _____ Age range _____**
2. **Explain how you will achieve equitable subjects representation in the following categories. If not applicable, justify exclusions.**
   a. **Age (minors, elderly):**
   b. **Gender: Males and females:**
   c. **Ethnic and racial minority populations:**
3. **What characteristics (inclusion criteria) must subjects have to be in this study? (Answer for each subject group, if different.)**
4. **What characteristics (exclusion criteria), would exclude subjects who are otherwise eligible from this study? (Answer for each subject group, if different.)**
5. **Describe the subject recruitment strategies you will use for each group of subjects. (Attach advertisements, flyers, contact letters, telephone contact protocols, Health Sciences recruitment web site template, etc.)**
6. **Explain who will approach subjects to take part in the study and how this will be done to protect subjects' privacy. (Attach letters of cooperation from agencies, institutions or others involved in subject recruitment.)**
7. **Explain what steps you will take during the recruitment process to minimize potential coercion or the appearance of coercion.** *(Advocate for wards of the state, subjects with diminished capacity)*
8. **Will you give subjects gifts, payments, services without charge, or extra course credit? ☐ No ☐ Yes. If yes, explain:**
9. **Will any of the subjects or their third-party payers be charged for any study procedures? ☐ No ☐ Yes. If yes, explain:**

10. **Where will the study procedures be carried out? (Attach copies of IRB approvals or letters of cooperation from non-UCC research sites, if necessary.)**

11. **Do you anticipate recruiting vulnerable subjects? (***Pregnant women, prisoners, children, including wards of the state, subjects of diminished capacity or students?)*

E. RISKS AND BENEFITS

1. **Describe nature and degree of risk of possible injury, stress, discomfort, invasion of privacy, and other side effects from all study procedures, drugs and devices (standard and experimental), interviews and questionnaire. Include psycho-social risks as well as physiological risks. Include risks of withholding standard care or procedures if this is the case. Do not reference the consent form.**

2. **Explain what steps you will take to minimize risks of harm and to protect subjects' rights and welfare. (If you will include protected groups of subjects (***minors, including wards of the state, fetuses in utero, prisoners, , pregnant women, decisional impaired or economically or educationally disadvantaged subjects***) please identify the group(s) and answer this question for each group).**

3. **Is it possible that you will discover a subject's previously unknown condition (disease, suicidal intentions, genetic predisposition, etc.) as a result of study procedures? ☐ No ☐ Yes. If yes, explain how you will handle this situation.**

4. **Describe the anticipated benefits of this research for individual subjects in each subject group. If none, state "None".**

5. **Describe the anticipated benefits of this research for society, and explain how the benefits outweigh the risks.**

F. ADVERSE EVENTS OR EFFECTS

1. **Who will handle adverse events? ☐ Investigator ☐ Referral ☐ Other, explain:**

2. **Are you facilities and equipment adequate to handle possible adverse events? ☐ No ☐ Yes, explain:**

3. **Who will be financially responsible for treatment of physical injuries resulting from study procedures? WE DO NOT FORESEE ANY ADVERSE EVENTS.**

   ☐ Study sponsor ☐ Subject or subject's insurer ☐ Other, explain:

G. CONFIDENTIALITY OF RESEARCH DATA

1. **Will you retain any direct subject identifiers (names, Social Security numbers, patient, hospital laboratory or claim numbers, address, telephone numbers, locator information, etc.) ☐ No ☐ Yes. If yes, explain why this is necessary.**

2. **Will you retain a link between study code numbers and direct identifies? ☐ No ☐ Yes. If yes, explain why this is necessary and for how long you will keep this link.**

3. **Describe how you will protect data against disclosure to the public or to other researchers or non-researchers. Explain who (other than members of the research team) will have access to data (e.g. sponsors, advisers, government agencies, etc.)**

4. **Will you place a copy of the consent form or other study information in the subject's medical or other personal record? ☐ No ☐ Yes. If yes, explain why this is necessary.**

5. **Do you anticipate using any data (information, specimens, etc.) from this study for other studies in the future? ☐ No ☐ Yes. If yes, explain and include this information in the consent form.**

H. ADDITIONAL INFORMATION

1. **If the study will involve radiation exposure to subjects, e.g., X-rays, radioisotopes, what is status of review by Committee (RSC): ☐ Pending ☐ Approved (Attach one copy of approval.) ☐ NA**

2. **Will you need access to subjects' medical, academic, or other personal records for screening purposes or during this study? ☐ No ☐ Yes. If yes, specify types of records, what information you will take from the records and how you will use them.**

3. **Will you make audio-visual or tape recordings or photographs of subjects? ☐ No ☐ Yes. If yes, explain what type of recordings you will make, how long you will keep them, and if an, one other than the members of the research team will be able to see them.**

4. **Will your study involve use of equipment involving energy input to the subjects (EMG, EKG, MRI, ultrasound, etc.) ? ☐ No ☐ Yes. If yes, attach documentation that all equipment will be tested regularly by the Scientific Instrument Division or describe safety testing procedures you will use.**

5. **Does any member of the research team have a financial interest in the research or its products or in the study sponsor? ☐ No ☐ Yes. If yes, include documentation.**

L . CONSENT FORMS

☐ **Written (Attach copies of all consent and assent forms for each subject group.)**
☐ **Oral (Attach written scripts of oral consent and assent for each subject group.)**
☐ **Waiver (Attach written justification of waiver of consent per 45 CFR 46.116(d)**

Any changes in the Consent Form at any time after a study has IRB approval must be resubmitted to the Board prior to implementation.

Important:

The final rule will now generally expect consent forms to include a concise explanation at the beginning of the document, of the key information that would be most important to individuals contemplating participation in a particular study, including the purpose of the research, the risks and benefits and appropriate alternative treatments that might be beneficial to the prospective subject. (HHS.gov, Office for Human research Protections, Revised Common rule, January 19, 2017)
https://www.hhs.gov/ohrp/regulations-and-policy/regulations/finalized-revisions-common-rule/index.html

The Informed consent must begin with a concise and focused presentation of the key information that is most likely to assist a prospective subject or legally authorized representative in understanding the reasons why one might or might not want to participate in the research. This part of the informed consent must be organized and presented in a way that facilitates comprehension.

J. DRUGS, SUBSTANCES, AND DEVICES

1. **List all non-investigational drugs or other substances used to conduct this research (analgesics, anesthetics, drugs used to treat side effects, etc.). Include products used for standard clinical care if they are used in this study for research purposes.**

Name	Source	Dose	How administered

2. **List *all* investigational new drugs or other investigational substances to be used in the study. Include marketed products used "off-label" (different formulation, dose, route of administration, or indication). Provide:**

- ***ten* copies of a concise summary of information about the drug prepared by the investigator (including animal and human toxicity data, studies done in animals and humans to date):**
- ***one* copy of the investigator's Brochure.**
- **one copy the study protocol.**

Name	Source	Dose	How administered	IND Number	Phase of testing

3. **List all investigational devices you will use. Provide the information requested below and attach one copy of the company protocol. If there is no Investigational Device Exemption (IDE), explain why. Include a statement as to way the device qualifies as non-significant risk. Provide a copy of the FDA letter(s which states the device classification (PMA, 510k, Class I, II or custom device) and categorization (Category A or B). "Category A or B" means that Medicare may *not* be billed for the device or for services related to its use. "Category B" means that Medicare may be billed for services related to its use *if* the U.S. Health Care Finance Administration (HCFA) grants authorization.**

    a. **Name of the device:**

    b. **Investigational Device Exemption (IDE) number or FDA status:**

Conflict of Interest Report: completion required

Researchers must list his/her activities with respect to the following categories. Please list the name of any company with which you or immediate family have any of the following associations: *Note that there is no requirement to reveal or disclose the actual financial value of any relationship or affiliation.*

AFFILIATION/FINANCIAL INTEREST:	Y/N	NAME OF ORGANIZATION
1. University Grant Monies		
2. Grants from sources other than industry		
3. Grants from industry – related sources		
4. Share holders		
5. Employee of industry related sources		
6. Fiduciary position of any organization, association or society		
7. Consultant fee, speaker's bureau or advisory committee member		
8. Other		
9. Nothing to report		
Please attach documentation that may be used by the committee to conduct a Conflict of Interest Evaluation		

III. TITLE OF PROJECT: _____

#CONTROL _____

_____ _____

NAME **SIGNATURE**

_____

DATE

Principal Investigator Statement of Assurance

The proposed investigation involves the use of human subjects. I am submitting the form with a description of my project (*Title:* _____) prepared in accordance with the Universidad Central del Caribe/IRB policies for the protection of human subjects participating in research. I certify that the information provided in this application, and in all attachments, is complete and correct. As Principal Investigator/ Faculty Advisor, I have ultimate responsibility for the conduct of this study, the ethical performance of the project, the protection of the rights and welfare of human subjects and the strict adherence to any stipulations imposed by the *UCC/IRB*. I am aware of the University's policies concerning research involving human subjects and agree to the following:

1. Should I wish to make changes in the approved protocol for this project, I will submit them for review PRIOR to initiating the changes.
2. If any problems involving human subjects occur, I will immediately notify the chair of the *UCC/IRB*.
3. I will cooperate with the *UCC/IRB* requests to report on the status of the study
4. I will conduct this study only during the period approved by the *UCC/IRB* Administrator.
5. I will prepare and submit a continuing review request and supply all supporting documents to the *UCC/IRB* before the approval period has expired if it is necessary to continue the research project beyond the time period approved the *UCC/IRB*.
6. I will prepare and submit a final report upon completion of this research project.
7. I will maintain records of this research according to SSIRB guidelines.
8. I will obtain legally effective informed consent from each participant or their legal representative, unless waived by the *UCC/IRB*, using only the currently *UCC/IRB* approved stamped consent form .
9. I will complete and stay current with all training requirements.

I further certify that the proposed research is not currently underway and will not begin until approval has been obtained. I will not begin work on this project until I receive written notification of final *UCC/IRB* approval.

_____

Signature of Principal Investigator Date

_____

Signature of Faculty Advisor (if any) Date

As an advisor of student research, in the event that your student investigator is unreachable or fails to comply with the *UCC/IRB*'s request to complete renewal/progress report documents, your signature confirms that you will act as the liaison between the *UCC/IRB* and the student investigator, including responding to the *UCC/IRB*'s request to complete the required progress report form.

Your signature further assures that you agree to oversee the conduct of this research and compliance with all of the policies stated above.