



**INTER AMERICAN UNIVERSITY OF PUERTO RICO
INSTITUTIONAL REVIEW BOARD**

**APPLICATION TO INVOLVE
HUMAN SUBJECTS IN RESEARCH
(Form ORE-IRB-1)**

TITLE: _____

PRINCIPAL INVESTIGATOR'S NAME, TELEPHONE AND POSTAL ADDRESS:

DEPARTMENT _____ **PROGRAM CAMPUS** _____

**NAME, TITLE, TELEPHONE AND ADDRESS OF ALTERNATE CONTACT: (FACULTY RESEARCH
ADVISOR OR DEPARTMENT CHAIRPERSON)**

Date Submitted: _____

Project Time Period:

Start Date: _____ **Ending Date:** _____

Other Participating Institutions Including Subcontractors: Yes____ **No**____

Participating Institutions requiring other IRB review: Yes____ **No**____

Where Will the Research Be Conducted?: _____

PROTECTING THE RIGHTS AND WELFARE OF HUMAN SUBJECTS IN RESEARCH AT INTER AMERICAN UNIVERSITY OF PUERTO RICO

The purpose of this application is to promote careful thought regarding the involvement and ethical treatment of human subjects in research, ensure compliance with federal, state, and corporate regulations, and elicit from the Principal Investigator, pertinent information which will facilitate a rapid and thorough review by the IAUPR Institutional Review Board (IRB).

“Notes” are provided as guidelines to help answer specific questions. Please answer each question or indicate that it is not applicable to the research being conducted. Call the IRB Administrator if you have questions.

SUMMARY GUIDELINES

IAUPR policy requires that all research involving human subjects* conducted by or under the direction of IAUPR personnel and students using any property or facility of IAUPR, 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 stamp 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”

Checklist

Application for Review

(Any of the following may be submitted by fax or e-mail; signed copies can be sent later)

Required Documentation for a New Application

- _____ **Application to Involve Human Subjects in Research** (IRB-1)
- _____ **Statement of Work or Research Proposal** - Send any information that you feel may help the IRB review the project.
- _____ **This list** indicating materials submitted.
- _____ **Informed Consent** (signed by PI)
- _____ **Advertisement, flyers, solicitation or other relevant documents or information that will be provided to participants**
- _____ **Questionnaires/surveys if applicable**

Student's Faculty Research Advisor Assurance Statement

This is to certify that I have reviewed this research protocol and that I attest to the scientific merit of this study and the competency of the investigator(s) to conduct the project. *(If the Principal Investigator is completing this project to meet the requirements of a Inter American University of Puerto Rico program, the student's faculty research advisor should sign the Signature Assurance Sheet)

Faculty Name (Typed/printed)	Signature	Date
Department Affiliation		Campus

I. SUMMARY

A. Will the research involve any of the following?

<p>— 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</p>	<p>___ 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 care giver ___ Environmental alternations (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</p>
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B. Using non-technical lay language, please provide:

(1) A brief description of the scientific objectives of the research.

(2) A brief, but specific description of the procedure(s) involving the human subjects. (If it will be pilot testing or trials, please specify how it will be conducted?). (USE ADDITIONAL PAGES IF NECESSARY).

II. THE HUMAN SUBJECTS

A. How many human subjects will be involved approximately?

Number: _____ **Age Range:** _____ **Sex:** _____

B. Period of involvement of human subjects? Date: From _____ **to** _____

C. Will the research involve any of the following subject population?

<input type="checkbox"/> Children under 21 years old* <input type="checkbox"/> Elderly* <input type="checkbox"/> Pregnant women* <input type="checkbox"/> Fetuses* <input type="checkbox"/> Prisoners or parolees* <input type="checkbox"/> IAUPR staff or families* <input type="checkbox"/> Institutional residents* <input type="checkbox"/> Genetically susceptible/impaired <input type="checkbox"/> Any population excluded <input type="checkbox"/> Emergency patients* <input type="checkbox"/> Physically impaired* <input type="checkbox"/> Students <input type="checkbox"/> Other (persons working or studying with PI) * Vulnerable subjects	<input type="checkbox"/> Terminally ill* <input type="checkbox"/> Comatose <input type="checkbox"/> Cancer patients <input type="checkbox"/> Cognitively or psychologically impaired* <input type="checkbox"/> Non-English or Spanish speaking* <input type="checkbox"/> Mental patients* <input type="checkbox"/> Human in vitro fertilization <input type="checkbox"/> Unable to give informed consent <input type="checkbox"/> Military personnel and/or immediate family <input type="checkbox"/> Culturally/ethnically, or other diverse subjects
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* IUAPR students

D. Will any vulnerable subjects (*) be included? If so, please identify and justify their involvement.

E. Who are the human subjects? Provide details for population(s) checked. Describe by age, gender, special characteristics, traits, etc.

F. How, and by whom, will the human subjects will be identified and recruited?. Explain type of method(s) to be used in the identification contact and recruitment of subjects. Attach a copy of any planned advertisements/notices and letters to potential subjects. If the process is detailed in another document submitted to the Board. Please indicate document page number).

Note: Equitable inclusion of both men and women of all ages, and individuals from diverse racial/ethnic backgrounds is important to ensure that they receive an equal share of the benefits of research and that they do not bear a disproportionate share of its burdens. Participation should not be restricted without medical or scientific justification.

G. Explain how the relationship with the human subjects will be established?. (If the researcher, assistants or someone related to them has a personal or professional relationship to the subjects, explain in detail the procedures adopted to avoid coercion and/or maintaining confidentiality.) If a vulnerable population is included explain procedures adopted to avoid coercion.

Note: The identification and recruitment of subjects must be ethically and legally acceptable and free of coercion. Procedures used to recruit subjects should be designed to reach diverse populations. Vulnerable subjects, such as persons in nursing homes or institutions, should not be recruited merely for the sake of convenience.

III. RISKS AND BENEFITS

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

- minimal**
- greater than minimal**
- significant**
- or unknown?**

Note: According to DHHS/FDA 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”. “When the risks associated with a new procedure or product are unknown, they cannot be classified as minimal”.

B. Potential Risks and Discomforts: What are the potential risks/discomforts associated with each intervention or research procedure? If data are available, estimate, a) the probability that a given harm may occur, b) its severity, and c) its potential reversibility. Include what physical, emotional or social risks that will be faced by the participants.

Note: A risk/discomfort is a potential harm associated with the research that a reasonable person would consider important in deciding whether to participate in the research. Risks can be generally categorized as physical, psychological, sociological, economic, and legal.

Note: Societal benefits generally refer to the advancement of medical or scientific knowledge and/or possible future benefits.

- F. Therapeutic Alternatives: What therapeutic alternatives are reasonably available in the non-research and/or research context that may be of benefit to the potential subjects?**

Note: This section should include a reasonably detailed description of the therapeutic alternative that could be used to treat the patient should they elect not to participate in the protocol.

IV. FINANCIAL CONSIDERATIONS

- A. Cost: Will there be a compensation given for participation? Which cost will be reimbursed for travel and other expenses, if any? Will they receive services or other benefits instead of cash? What conditions must be fulfilled to receive full or partial payment?**

V. INFORMED CONSENT

Note: This section should clearly document that the investigator has an adequate plan in place to ensure existence of an acceptable level of comprehension before consent is documented. Willingness to sign the consent form is not an adequate demonstration of their understanding. Some investigators try to determine the level of prospective subjects comprehension by questioning them about the research. This approach is useful with children and adolescents, as well as with adults of uncertain capacity to consent.

- A. Does the informed consent procedure incorporate the following basic elements:**

_____ A simple and clear explanation of the purpose of the research and chronological description of the procedures the volunteer will be involved in, including an identification of those that are experimental.

- _____ A description of the attendant discomforts and risks.
- _____ A description of possible benefits.
- _____ An explanation of compensation to be expected.
- _____ A statement describing how privacy of data or personal information will be maintained.
- _____ A disclosure of appropriate alternative procedures that might be advantageous for the subject.
- _____ An offer to answer any inquiries concerning the procedures.
- _____ An instruction that the subject is free to withdraw his or her consent and to discontinue participation on the project or activity at any time.
- _____ Available sources of information and an explanation that the subject is free to ask questions at any time during the study.
- _____ Adequate documentation of informed consent.
- _____ Documentation of the method for informing subjects of the results of their participation in the research.
- _____ Statement of Informed Consent for use of video or recording.

B. Process of Consent: Please provide a brief but detailed description of the informed consent procedure to be employed to protect human subjects from undue influence or coercion.

Note: Only those individuals authorized to solicit consent may sign the consent form confirming that the prospective subject was provided the necessary information and that any questions were answered. Consider: a) the environment and location where informed consent will be solicited; b) the timing of the process (e.g., in relation to hospital admission, work situation, stressful events); c) involvement of someone other than the investigators to help explain the research; and d) opportunity (ample time) for the prospective subjects/representatives to discuss participation in the research with family, friends, or their advisors before signing the consent form

VI. INVOLVEMENT OF OTHER INSTITUTIONS

1. Describe any arrangements or agreements with other institutions which will directly affect the involvement of human subjects in this research. If applicable, provide letters of cooperation and or authorization.

2. Will human subjects review be required by any other institutions?

Yes____ Name of Institution:_____

No_____

3. Will research results be available to the institution in such a manner that participants can be easily identified? (Please elaborate).

VII. UNUSUAL ASPECTS OF THIS RESEARCH

Please note any unusual aspects of this research, which should be called to the attention of the Institutional Review Board for Human Subjects Research and may affect the rights of the Human Subjects.

VIII. DATA MANAGEMENT AND DISPOSAL

Please explain how data will be managed during the research process and how it will be stored or destroyed. If video or recordings were obtained, explain how it were obtained and the method of disposal.