



Inter American University of Puerto Rico
Office of the President

**INTER AMERICAN UNIVERSITY OF PUERTO RICO POLICY AND NORMS
REGARDING THE PROTECTION OF HUMAN SUBJECTS IN RESEARCH**

Normative Document A-IRB-013-2000R

Introduction

Guided by its Christian principles, Inter American University of Puerto Rico (IAUPR) promotes an intellectual, social, and moral environment that includes the protection of all persons involved in activities in which the Institution participates.

In harmony with this vision, IAUPR establishes this policy and norms which will stimulate research and at the same time protect human research subjects. This policy and norms reflect federal regulations developed in response to abuses to human subjects participating in research activities.

I. Legal Base

This document is promulgated by virtue of the authority conferred to the President by the Board of Trustees in the Bylaws of the University.

II. Purpose

The purpose of this document is to assure that all research and sponsored projects involving human subjects are conducted in an ethical manner and that IAUPR complies with government standards for research involving human subjects.

III. Applicability

This policy and norms apply to all University faculty, staff and students using University facilities, the facilities of another institution, or any other off campus site. The policy and norms also apply to visitors and users of the campus or off campus University facilities.


This document also applies to all research and related activities involving human subjects for which IAUPR is a responsible participant, regardless of whether the activity will receive funding or not, including questionnaires, interviews, and secondary data used in research activities.


IV. Sources

- 4.1 Code of Federal Regulations (CFR) 45 CFR § 46 (August 19, 1991, as amended).
- 4.2 The National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research. The Belmont Report: Ethical Principles and Guidelines for the Protection of Human Subjects of Research, April 18, 1979.

V. Definitions

In this document the following terms and expressions have the meaning given below:

- 
- 5.1 Human Subject - A living individual about whom a researcher obtains:
 - 5.1.1 data through intervention or interaction with the individual or;
 - 5.1.2 identifiable private information.
 - 5.2 Identifiable Information - Information from which the identity of the subject is or may be readily ascertained or associated.
 - 5.3 Informed Consent - The voluntary agreement obtained from a subject (or the subject's legally authorized representative) to participate in research or related activity, before participating in that activity. The consent must permit the individual (or legally authorized representative) to exercise free power of choice without undue inducement or any element of deceit, fraud, force, duress, or other form of coercion or constraint. Without this consent, the subject will not be able to participate in the research.
 - 5.4 Interaction - Communication or interpersonal contact between researcher and subject.
 - 5.5 Intervention - Includes both: (a) physical procedures and (b) manipulation of the subject by which data are gathered or the subject's environment is controlled for research purposes.
 - 5.6 Institutional Review Board (IRB) - Independent review group, established by the Institution, to review and oversee compliance of applicable rules and regulations in research projects that involve human subjects.

- 
- 5.7 Legal-Age Subjects - In Puerto Rico, a legal-age subject is a person over 21 years old as per Article 247 of the Puerto Rico Civil Code.
 - 5.8 Minimal Risk - The probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those normally encountered in daily life or during the performance of routine medical or psychological examinations or tests.
 - 5.9 Project Assurance - A contract with the federal government stipulating responsibilities of institutional officials, the IRB, and principal investigators for the conduct of research involving human subjects.
 - 5.10 Private Information - Information that an individual has provided for specific purposes and that the individual can reasonably expect will not be made public, or information about behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place.
 - 5.11 Research and Related Activities - A systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge.

Before any research project involving human subjects can be started and conducted at IAUPR, it must be submitted for review to the IAUPR Human Subjects IRB. All proposals submitted to funding sources must have approval from the IRB prior to submission or as specified by the funding source regulations. Only the IRB is authorized to designate review of a protocol as "pending."


VI. Information for Researchers

Laws, regulations, policies, norms and procedures, The Belmont Report, applications, sample forms, and pertinent information, such as periodicals, newsletters, and books, are maintained in the Office of the Dean of Academic Affairs of the Academic Units and at the IRB Office at the Vice Presidency for Academic & Student Affairs & Systemic Planning for the use of the researchers.

VII. Institutional Responsibilities

- 7.1 All research involving human subjects conducted under the auspices of the University, or any campus-related organization must be reviewed and approved by the IRB prior to commencement of the research activity.

Materials submitted for review should include the current "Application for Approval for Research Involving Human Subjects," a detailed protocol outlining all experimental procedures including anticipated risks and benefits to the subject, and consent forms (in accordance with 45 CFR 46 Department of Health and Human Services (DHHS) and, when applicable, 21 CFR 50 Federal Drug Administration (FDA). The application and supporting documents must be endorsed by the Department Chair and the Dean of Academic Affairs before submittal to the University IRB Administrator in the Vice Presidency for Academic and Student Affairs and Systemic Planning.

- 
- 7.2 For multiyear projects, IRB approval must be renewed annually. Renewal forms are sent to the principal investigator approximately 2 months prior to the end of the approval period. Projects are inactivated if response to renewal notification is not received by the end of the month in which the approval period lapses. If the project is to continue, the IRB Administrator must be notified in order to reactivate the project.
 - 7.3 Unanticipated problems involving risks to subjects or others must be reported promptly to the IRB for evaluation.
 - 7.4 Any revisions or amendments to the approved research activity must be submitted to, and approved by, the IRB prior to implementation of the revised/amended activity.

VIII. Distribution of Responsibility

The responsibility for the protection of subjects in research is distributed among several parties: the responsible project investigator, the departmental executive officer, the Institutional Review Board (IRB) and IRB-approved departmental review bodies, and those at cooperating institutions who provide access to subjects.

- 8.1 Responsible Project Investigator - The individual responsible for the conduct of the activity, i.e., the responsible project investigator, has primary responsibility for the protection of the rights and welfare of human subjects. Specifically, the investigator is responsible for:
 - 8.1.1 Carefully designing research methods,
 - 8.1.2 Adhering to ethical codes and applicable policies, norms and procedures of the IAUPR, the sponsoring agency, and cooperating institutions, if any,

- 8.1.3 Training and supervising personnel carrying out the research, both in respect to appropriate research methods and the rights of human subjects,
- 8.1.4 Obtaining prior (i.e. before any involvement of human subjects) approval for non-exempt human subjects research,
- 8.1.5 Obtaining prior approval for changes in a nonexempt research activity,
- 8.1.6 Reporting promptly to the IRB any unanticipated problems involving risks to subjects or others,
- 8.1.7 Retaining required records.

8.2 Campus Chief Academic Officer (i.e. Dean of Academic Affairs or Dean of Studies)

The Campus Chief of Academic Affairs is responsible for:

- 8.2.1 Ensuring that faculty, staff, and students are kept informed of the IAUPR policy, norms and procedures and of their responsibilities for protecting the rights and welfare of human subjects involved in research,
- 8.2.2 Ensuring that the campus review process, if any, operates within IRB-approved guidelines,
- 8.2.3 Ensuring that, for any course offered by the department in which students are expected to serve as human subjects in research & related activities, notification to this effect is given in the course description in the class schedules,
- 8.2.4 Reporting promptly to the IRB any unanticipated problems involving risks to subjects or others.

8.3 Institutional Review Board

The IRB is responsible for:

- 8.3.1 Providing initial and continuing review of nonexempt research,

8.3.2 Ascertaining acceptability of proposed research in terms of IAUPR policies, norms and procedures,

8.3.3 Prepare and maintain adequate documentation of all IRB activities,

8.3.4 Providing advice and information to investigators engaged in research involving human subjects.

The IAUPR IRB is additionally responsible for:

8.3.5 Developing policy, norms, procedures, information, and instructions regarding human subjects research,

8.3.6 Adjudicating differences and reviewing problems arising from research involving human subjects,

8.3.7 Ensuring compliance with externally mandated policies and regulations,

8.3.8 Reporting to the appropriate institutional officials and, for research governed by DHHS regulations, to the Secretary of DHHS, any serious or continuing noncompliance by investigators with the requirements and determinations of the IRB.

8.4 Individual or Institution Providing Access to Subjects

If access to research subjects is obtained through cooperating institutions, the authorized official of the cooperating institution must be informed of the research and should satisfy her or himself that the subjects' rights and welfare will be protected and that institutional commitments to the subjects will not be abridged. If professional practitioners or service agencies provide access to subjects, the individual providing access should ensure that his or her professional commitments to the clients are not abridged.

If the individual responsible for conduct of the activity is not an IAUPR employee or student, but the IAUPR is the cooperating institution providing access to research subjects, the individual providing access to the subjects is responsible for ensuring that IAUPR policies, norms and procedures, including review requirements, are met.

IX. Violations

- 9.1 Reports of violations of this policy and norms will be brought before the IRB at a convened meeting. The IRB will make a determination regarding the need for additional information or further investigation. The affected Chair and Dean will be notified of all correspondence between the committee and the involved parties. Upon determination that a violation of this policy and norms has occurred, the IRB may, for example, require that the activity in question be halted until such time that corrective action is taken. If the IRB determines that the violation involves possible scholarly or scientific misconduct, the Chancellor will be notified, through the Vice President of Academic Affairs and Systemic Planning, and appropriate action will be taken in accordance with established University assurances, policies, norms and procedures.

X. Severance Clause

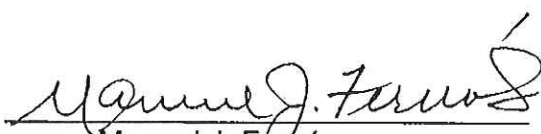
Each section or subsection of this document can be separated from the others. Therefore, if any part of this document is declared null by a competent authority, such decision will not affect those remaining.

XI. Repeal and Amendment

This document substitutes normative document A-IRB-013-2000 and may be amended or repealed by the President of IAUPR by his own initiative or as required by law.

XII. Effective Date

This document will become effective immediately after being signed by the President.


Manuel J. Fernós
President


Date (M-D-Y)