Universidad Interamericana de Puerto Rico
Oficina del Presidente

RULES REGARDING THE PROTECTION OF HUMAN SUBJECTS IN RESEARCH

Normative Document A-1220-065

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 these rules which will stimulate research and, at the same time, protect human subjects that participate in research. These rules were developed in response to federal regulations regarding human subjects participating in research activities.

I. Legal Basis

This document is promulgated by virtue of the authority conferred upon the President by the Board of Trustees in the Bylaws of the University and is in accordance with established institutional policies and rules and the following federal regulations:

- Code of Federal Regulations (CFR) 45 CFR §46 (as amended July 19, 2018).
- 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).

II. Purpose

The purpose of this document is to assure that all research (externally funded or not) that involves human subjects is conducted in an ethical manner and that IAUPR complies with applicable government standards.

III. Scope

These rules apply to all University faculty, staff, and students using University facilities, the facilities of another institution, or any other off - campus sites. These rules also apply to external researchers from other institutions that have a Memorandum of

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Understanding (MOU) with IAUPR for this purpose, visitors, and users of campus or off campus University facilities.

These rules also apply 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. Definitions

The following terms and expressions have the meanings given below:

4.1 Biospecimen – Biological material stored in a biorepository for future research.

4.2 Human subject – A living individual about whom a researcher obtains:

4.2.1 data through intervention or interaction with the individual or
4.2.2 identifiable private information.

4.3 Identifiable biospecimen – Biological material for which the identity of the subject is, or may be, readily ascertained by the investigator or associated with the biospecimen.

4.4 Identifiable information - Information from which the identity of the subject is or may be readily ascertained or associated.

4.5 Informed consent - The voluntary agreement obtained from a subject (or the subject's legally authorized representative) to participate in research or a 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.

4.6 Interaction - Communication or interpersonal contact between researcher and subject.

4.7 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.

4.8 Institutional Academic Research Office (IARO) – Office responsible for the development, implementation, and operationalization of the IAUPR ethics programs to ensure institutional compliance.

4.9 Institutional Assurance – Document that certifies, to the Office of Human Research Protections of the US Department of Health and Human Services, that IAUPR complies with required regulations concerning the protection of human subjects that participate in research protocols developed by our researchers, graduate students, or external collaborators.

4.10 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.

4.11 Legal age subjects - In Puerto Rico, a legal age subject is a person over the age of 21 , as per Article 247 of the Puerto Rico Civil Code.

4.12 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.

4.13 On Line Research: Research methodology that includes the use of commercial virtual platforms or social media to collect human subjects data or information.

4.14 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.

4.15 Research and related activities - A systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge.

4.16 Scholarly and journalistic activities – These include oral history, journalism, biography, literary criticism, legal research, and historical scholarships, including the collection and use of information, that focus directly on a specific individual about whom the information is collected.

V. General Provisions

Researchers may request, from the IARO and the offices of the deans of academic affairs on any of the campuses, copies of the laws, regulations, policies, rules, procedures, and guides promulgated by the Office of Human Research Protections of the U. S. Department of Health and Human Services, the Federal Drug Administration, and other related agencies, as well as application forms and sample documents related to the protection of human sujbects that participate in research.

Before any research project involving human subjects can be started and conducted at IAUPR, it must be submitted for review to the IAUPR IRB. All proposals submitted to external 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."

Researchers interested in performing research studies at IAUPR must comply with IAUPR IRB submission requirements and include the endorsement of the department chair and dean of academic affairs or their designees.

VI. Institutional Responsibilities

The IAUPR is responsible for:

6.1 ensuring that the Institution provides the legal framework and resources needed by the IRB to be able to perform its compliance duties.

6.2 ensuring that all research involving human subjects, conducted under the auspices of the University or any campus-related organization, is reviewed and approved by the IRB prior to starting related research activity and inclusion of human subject participants, in accordance with 45 CFR 46 Department of Health and Human Services (DHHS) and, when applicable, 21 CFR 50 Federal Drug Administration (FDA).

6.3 ensuring that research conducted on any of the IAUPR premises by an external researcher complies with the applicable federal and institutional rules and regulations.

6.4 reviewing and reporting to corresponding federal agencies any unanticipated problems or adverse events involving risks to subjects

VII. Distribution of Responsibility

The responsibility for the protection of human subjects in research is shared among several parties, namely: the responsible project investigator, the department chair, the graduate student mentors, the dissertation committee, the office of the dean of academic affairs at the corresponding academic unit, the Institutional Review Board (IRB) and IRB-approved departmental review bodies at cooperating institutions who provide access to subjects.

7.1 Principal Investigator (PI) - The principal investigator is the individual responsible for conducting all research activities. Their primary responsibility is to ensure the protection of the rights and welfare of human subjects. This category also includes graduate students. Specifically, the PI is responsible for:

7.1.1 the research methods design.
7.1.2 adhering to ethical codes and applicable policies, rules, and procedures of the IAUPR, the sponsoring agency, and cooperating institutions, if any
7.1.3 supervising personnel carrying out the research, both in respect to appropriate research methods and the rights of human subjects, and ensuring that all project staff have current training certifications regarding the protection of the human subjects participating in the study
7.1.4 submitting, for IRB review, a complete application with all the required documentation and application forms, including a concise description of the research procedures
7.1.5 obtaining IRB approval for nonexempt research.
7.1.6 obtaining IRB approval for all revisions and amendments prior to inclusion of human subjects as participants,
7.1.7 requesting continuing review approval at least 30 days prior to the expiration date of original approval,
7.1.8 informing the IRB about any adverse event or unanticipated problem that could result in putting at risk possible participants,
7.1.9 maintaining records and files of all research procedures and data gathered,
7.1.10 providing authorization or collaboration letters from research sites,
7.1.11 ensuring the external or internal collaborating research site that the rights and wellbeing of participants will be safeguarded and that they do not have any conflict of interest with the research site.

7.2 Mentors and Dissertation Committees:

Mentors and dissertation committees will be responsible for:

7.2.1 guiding the student through the different stages of the research project to ensure that it meets required human subject research protection criteria,
7.2.2. supervising and warranting that the research is being conducted as approved by the IAUPR IRB,
7.2.3 ensuring that the graduate student human subject research protocol complies with internal campus requirements prior to submission of the research protocol for IRB review,
7.2.4 ensuring and certifying that the research methodology selected by the student has been developed in accordance with the particular characteristics of the population that will participate in the study and that it complies with the human subject research ethics standards as per applicable regulations,
7.2.5 maintaining their human subject research training credentials up-to-date.

7.3 Deans of Academic Affairs

The deans of academic affairs, or the persons they designate, will be responsible for:

7.3.1 ensuring that faculty, staff, and students are informed about the IAUPR IRB rules and procedures and of their responsibilities for protecting the rights and welfare of human subjects involved in research,

7.3.2 ensuring that the campus internal review process operates within IRB-approved guidelines,

7.3.3 ensuring that for any course offered by the department in which students are expected to serve as human subjects in research & related activities or as research assistants, notification to this effect is given in the course description or class syllabus,

7.3.4 reviewing and certifying in the required electronic platform that research protocols comply with submission requirements prior to the researcher or principal investigator submitting the protocol for IRB review,

7.3.5 promptly reporting to the IRB any unanticipated problems or adverse events their office becomes aware of that involve risks to subjects or others.

7.4 Institutional Academic Research Office

This office will be responsible for:

7.4.1 developing and implementing processes related to responsible conduct in research in the IAUPR system,

7.4.2 maintaining the institutional community, in collaboration with the IRB, informed about human subject research protection rules and regulations,

7.4.3 providing to researchers, in collaboration with the IRB, training in responsible conduct in research,

7.4.4 renewing and updating the Federal Wide Assurance with the US Department of Health and Human Services,

7.4.5 safeguarding and administering the electronic platforms used for protocol submission,

7.4.6 developing, and securing IRB reliance MOU's with third parties,

7.4.7 in collaboration with the IRB, evaluating and forwarding to proper institutional officers or federal agencies, any adverse events reports and corresponding corrective actions, resulting from an approved protocol,

7.4.8 closing or withdrawing protocols in the case of multiyear research projects that do not comply with the continuing review requirements for subsequent years.

7.5 Institutional Review Board

The IRB will be responsible for:

7.5.1 providing initial and continuing review of nonexempt research,
7.5.2 ascertaining acceptability of proposed research in terms of IAUPR rules and procedures,
7.5.3 preparing and maintaining adequate documentation of all IRB activities,
7.5.4 providing advice and information to investigators engaged in research involving human subjects,
7.5.5 developing rules, procedures, information, and instructions regarding human subject research in collaboration with the IOAR,
7.5.6 adjudicating differences and reviewing problems arising from research involving human subjects,
7.5.7 ensuring compliance with externally mandated policies, rules and regulations,
7.5.8 reporting to the Secretary of DHHS and appropriate institutional officials any serious or continuing noncompliance by investigators with the requirements and determinations of the IRB for externally funded research governed by DHHS regulations, as well as for non-externally funded research,
7.5.9. reviewing all revisions and modifications made to previously approved protocols.
7.5.10 reviewing continuing review request for multiyear protocols

7.6 External Institution or Individual Providing Access to Subjects

These institutions or individuals will be responsible for:

7.6.1 providing the external site collaboration or authorization letter duly signed by an authorized representative,
7.6.2 requiring evidence of IRB approval from the researcher prior to accessing the research sit,
7.6.3 providing warranty that services provided to participants by the external site or facility will not be affected or denied if the subject decides not to participate in the research study,
7.6.4 notifying the IARO about any violations, noncompliance, or adverse event that arises in studies performed by IAUPR researchers.

VIII. Violations

Violations to these rules will be submitted to the IRB at a convened meeting to decide whether additional information or further investigation is needed. The deans of

academic affairs, or the person they designate, as well as all other involved parties will be notified of all IRB decisions.

Upon determination that a violation of these rules has occurred, the IRB, as per applicable regulations, may require that the activity in question be halted until corrective action is taken. If the IRB determines that the violation involves possible scholarly or scientific misconduct, the chief executive officer of the academic unit will be notified, through the Vice Presidency of Academic & Student Affairs and appropriate action will be taken in accordance with established University assurances, policies, rules, and procedures.

IX. Severability

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.

X. Repeal and Amendments

This document revokes normative document A-IRB-013-2000R and any other normative document that conflicts with the provisions herein and may be amended or repealed by the President of IAUPR.

XI. Effective Date

This normative document will be effective immediately upon being signed by the President.

XII. Approval

Manuel J. Fernós
President

December 17, 2020
Date (M-D-Y)