ASSURANCE OF COMPLIANCE WITH THE DEPARTMENT OF HEALTH AND HUMAN SERVICES REGULATIONS FOR THE PROTECTION OF HUMAN RESEARCH SUBJECTS

INSTITUTIONAL REVIEW BOARD

UNIVERSITY OF PUERTO RICO AT MAYAGÜEZ

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UNIVERSITY OF PUERTO RICO
MAYAGÜEZ, PUERTO RICO

The University of Puerto Rico at Mayagüez (UPRM), referred to as the "Institution", hereby assures that it will comply with the Department of Health and Human Services (HHS) Regulations for the Protection of Human Research Subjects [Title 45 Code of Federal Regulations, Part 46 as revised on January 15, 2009, and effective on July 14, 2009]. (Refer to: www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html). Therefore, this institution has established an Institutional Review Board (IRB) as an independent ethics committee, formally designated to approve, monitor and review biomedical and behavioral research involving humans, so as to comply faithfully with the regulations established by the HHS. **All research with human subjects conducted by any personnel affiliated with UPRM or requesting collaboration with, will comply with the standards established in these regulations, regardless of the source of funding or research setting.**

I. Statement of Applicability, Principles, and General Policies

A. Applicability

1. Except as noted in item 2 below, this assurance applies to all activities (laboratory, fieldwork, or classroom) which, as a whole or in part, involves research with human subjects if:
    a. the research is sponsored by this institution (UPRM), by any other institution affiliated with UPRM, or that carries out research at UPRM;
    b. the research has to do with institutional responsibilities and is conducted by or under the direction of any employee or agent of this institution who is connected with institutional responsibilities; or
    c. the research is conducted by or under the direction of any employee or agent of UPRM using any property or facilities of this institution; or
    d. the research involves the use of this institution's unpublished information to identify or contact human research subjects or prospective subjects.
2. Only provisions *III.A.1-3,9,* and *III.C.1.a, b, c* and *d* of this assurance apply to the activities listed above if the only involvement of human subjects will be in one or more of the categories exempted or waived under 45 CFR46.101 section (b), 1-6.

B. Ethical Principles

1. This institution is guided by ethical principles which apply to all research involving humans as subjects. In 1979, the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research published its report entitled "Ethical Principles and Guidelines for the Protection of Human Subjects of Research" (better known as The Belmont Report; April 18, 1979). The general principles identified by the National Commission in the Belmont Report are respect for persons, beneficence and justice. Although the Belmont Report included the prohibition to do harm within its

principle of beneficence, later bioethical reflection has distinguished between the principles of beneficence and non-maleficence (Cf. T. L. Beauchamp and James F. Childress, Principles of Biomedical Ethics, 5th, 2001). We adopt the later formulation, setting forth four general overarching principles for the guidance of all biomedical or behavioral research with human subjects at this Institution:

a. respect for persons

b. beneficence

c. justice

d. non-maleficence

2. In addition, the requirements set by 45 CFR 46 (as amended) will be met for all applicable HHS-funded research, and all other research without regard to the level and source of funding, with the exception of the requirement of reporting information to the HHS.

C. Institutional Policy

1. This institution acknowledges and accepts its responsibilities for protecting the rights and welfare of human research subjects covered by this assurance.

2. It is the policy of this institution to have an Institutional Review Board (IRB), established by this assurance, to review and approve all research covered by this assurance, except for those specifically exempted by 45 CFR 46. The involvement of human subjects in research will not be permitted until the IRB has reviewed and approved the research protocol[1], and has ensured that informed consent is obtained or waived in accordance with and to the extent required by 45 CFR 46.116 *(General requirements for informed consent).* Certification of IRB review and approval of all research protocols involving human subjects submitted to the HHS will be either included with the proposal or as soon as approved by the IRB. Furthermore, IRB review of all approved research activities will be conducted at appropriate intervals, at the discretion of the IRB, but not less than once per year.

3. It is the policy of this institution that, unless informed consent has been specifically waived by the IRB in accordance with Sections (c) and (d) of 45 CFR 46.116 *(General requirements for informed consent),* no principal investigator shall use humans as research subjects unless the principal investigator has obtained the legally effective informed consent of the subject or his/her legally authorized representative.

4. This institution acknowledges that it bears full responsibility for the execution and outcome of all research activities involving human subjects covered by this assurance.

    a. This institution will comply with the requirements set forth in 45 CFR 46.114 *(Cooperative research)* regarding cooperative research projects. When research covered by this assurance is conducted at or in cooperation with another entity, all provisions of this assurance remain in effect for that research. UPRM may accept, for the purpose of meeting the IRB review requirements, the review of an IRB established under another assurance of compliance. Such acceptance must be in writing and approved and signed by the corresponding official of the cooperating institutions. For those cases involving HHS-funded projects, a copy of the signed agreement will be forwarded to the Office for Protection from Research Risks (OPRR).

[1] The phrase "research protocol" is generally regarded as any scientific plan of experimental observation, medical treatment, or human/animal testing designed to obtain data. The protocols submitted to the IRB for review may be independent research activities, without the need for external funding, or part of fund-seeking grant applications commonly known as research proposals. No attempt is made here to distinguish between the two, and the word "protocol" is used throughout the text to identify the research plan or activity intending to use human subjects.

b. This institution will make this assurance available to each individual conducting or reviewing research involving human subjects and to all concerned parties (i.e., principal investigators, department heads, clinical care staff, administrators, IRB members, participants).

5. This institution bears full responsibility for complying with all federal and local laws as they may relate to research covered by this assurance.
6. This institution has established and will maintain an IRB in accordance with 45 CFR 46. The IRB will have the authority and responsibility to review, require changes, approve, disapprove, suspend, or terminate research protocols involving human subjects.
7. This institution will provide sufficient and adequately trained administrative and clerical staff to support all IRB activities.
8. This institution will provide both office and meeting space for compliance with the responsibilities of the IRB Director, members, and clerical staff. This includes, but is not limited to (a) meeting space with computer projection facilities, (b) office space with secured and fireproof file cabinets, (c) workspace for a secretary, IRB Director, (d) space to meet with researchers, and (e) adequate computer equipment and office resources.
9. This institution will provide resources for the continuing development of IRB members and administrative and clerical staff such as:
    a. Training on policies, procedures, guidelines and regulations of principles and legal rights of human research participants through conferences and webinars (on-site or on-line).
    b. Acquisition of literature relevant to the responsibilities and functions of IRB members.
10. This institution encourages constructive communication among principal investigators, IRB Director and members, other institutional officials, and human subjects in order to protect the rights and welfare of the subjects.
11. This institution will maintain documentation of IRB activities as required by 45 CFR46.115 *(IRB records).*
12. This institution will supervise all IRB activities, at least once a year, to insure that its practices and procedures -designed for protecting the rights and welfare of human subjects- are being effectively applied and are in compliance with the requirements of 45 CFR 46 and this assurance.
13. This institution will comply with the policies set forth in Subpart B of 45 CFR 46 *("Additional Protections for Pregnant Women, Human Fetuses and Neonates Involved in Research")*, which provide additional protections for pregnant women, human fetuses and neonates involved in research, and human *in vitro* fertilization.
14. This institution will comply with the policies set forth in Subpart C of 45 CFR 46 *("Additional Protections Pertaining to Biomedical and Behavioral Research Involving Prisoners as Subject")*, which provide additional protections for biomedical and behavioral research involving prisoners as subjects.
15. This institution, in addition to complying with the requirements of Subpart D of 45 CFR 46 *("Additional Protections for Children Involved as Subjects in Research")*, will consider additional protections for children as subjects of research.
16. This institution will comply with all requirements, policies, and federal regulations set forth by HIPAA and FDA.

II. Definitions[2]

1. *Department or agency head* means the head of any federal department or agency and any other officer or employee of any department or agency to whom authority has been delegated.
2. *Institution* means any public or private entity or agency (including federal, state, and other agencies).
3. *Legally authorized representative* means an individual or judicial or other body authorized under applicable law to consent on behalf of a prospective subject to the subject's participation in the procedure(s) involved in the research.
4. *Research* means a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge. Activities which meet this definition constitute research for purposes of this policy, whether or not they are conducted or supported under a program which is considered research for other purposes. For example, some demonstration and service programs may include research activities.
5. *Research subject to regulation*, and similar terms are intended to encompass those research activities for which a federal department or agency has specific responsibility for regulating as a research activity, (for example, Investigational New Drug requirements administered by the Food and Drug Administration). It does not include research activities which are incidentally regulated by a federal department or agency solely as part of the department's or agency's broader responsibility to regulate certain types of activities whether research or non-research in nature (for example, Wage and Hour requirements administered by the Department of Labor).
6. *Human subject* means a living individual about whom an investigator (whether professional or student) conducting research obtains
    a. data through intervention or interaction with the individual, or
    b. identifiable private information.
7. *Intervention* includes both physical procedures by which data are gathered (for example, venipuncture) and manipulations of the subject or the subject's environment that are performed for research purposes. Interaction includes communication or interpersonal contact between investigator and subject. *Private information* includes information about behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place, and information which has been provided for specific purposes by an individual and which the individual can reasonably expect will not be made public (for example, a medical record). Private information must be individually identifiable (i.e., the identity of the subject is or may readily be ascertained by the investigator or associated with the information) in order for obtaining the information to constitute research involving human subjects.
8. *IRB* means an institutional review board established in accord with and for the purposes expressed in this policy.
9. *IRB approval* means the determination of the IRB that the research has been reviewed and may be conducted at an institution within the constraints set forth by the IRB and by other institutional and federal requirements.
10. *Minimal risk* means that 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.
11. *Certification* means the official notification by the institution to the supporting department or

[2] As presented in 45CFR46.102 (See http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html#46.102).

agency, in accordance with the requirements of this policy, that a research project or activity involving human subjects has been reviewed and approved by an IRB in accordance with an approved assurance.

III. Implementation

A. Responsibilities of Principal Investigators

1. Qualifications

    a. Principal investigators and research collaborators shall submit evidence of a valid certification of approval of an IRB approved course in Human Subject Research for all non-exempt research projects and appropriate to the nature of the proposed research.

2. Determination of human subject involvement

    a. Principal investigators shall make an initial determination as to whether or not their research will involve human subjects as defined in 45 CFR 46.102 *(Definitions).*

    b. When the involvement of human research subjects defined in 45 CFR 46.102 *(Definitions)* is not clear, principal investigators should seek assistance from the IRB in making this determination.

3. Preparation of the research protocol

    a. Principal investigators shall prepare a protocol giving a complete description of the proposed research. In the protocol, principal investigators shall make provisions for the adequate protection of the rights and welfare of prospective human subjects and insure that pertinent laws and regulations are observed. This requirement applies even in cases where the research is exempt under 45 CFR46.101 *(To what does this policy apply?).*

    b. Principal investigators shall include a sample of a proposed informed consent form, other research tools, and all supporting documents as required by the Review Application, with the protocol.

    c. Principal investigators shall include documentation which addresses the involvement of other institutions in their research protocol.

    d. Principal investigators must disclose any financial reimbursements received by institutions involved in their research protocol.

4. Submission of documents to the IRB

    a. Submission of research protocol: Principal investigators shall submit all research protocols involving human subjects to the IRB on time allowing careful IRB review prior to the beginning of human subject participation in the proposed research protocol.

    b. Submission of a supplement of an original protocol: Principal investigators shall submit a supplement of an original protocol to the IRB when:

        1) it is proposed to involve human subjects, and the original activity had only indefinite plans for the involvement of human subjects;

        2) it is proposed to involve human subjects, and the original *activity* had no plans for the involvement of human subjects; or

        3) it is proposed to change the involvement of human subjects, and that involvement is significantly different from that which was initially approved by the IRB.

5. Obtaining informed consent or assent

    a. Principal investigators shall obtain informed consent in accordance with 45 CFR 46.116 *(General requirements for informed consent),* and with subpart D *(Additional protections for children involved as subjects in research),* and insure that no human subject will be involved in the research prior to obtaining such consent.

    b. Although Informed Consent must, as a rule, be documented in writing, it is important to remember that the requisite of Informed Consent is not to be reduced to its written documentation. Informed Consent is a process of communication between the investigator and the research subject or his/her legal representatives. Through this process the researcher provides the subject or his/her proxy the information necessary for the subject to make an autonomous choice to participate or not to participate in the experiment.

    c. Unless otherwise authorized by the IRB, principal investigators are responsible for insuring that the legally effective informed consent:

        1) is obtained from the subject and, in case of research involving subjects of diminished autonomy, the PI will obtain the subject's assent and the informed consent from the subject's legally authorized representative;

        2) is presented, both orally and in writing, in a language understandable to the subject or his/her representative;

        3) is obtained under circumstances that offer the subject or his/her representative sufficient opportunity to consider whether or not he or she should participate; and

        4) is free from exonerative or exculpatory language in which the subject or his/her representative is encouraged to waive or appear to waive any of his/her legal rights; and to release or to appear to release the principal investigator, sponsor, institution or its agents from, liability for negligence.

6. Providing basic elements of informed consent

    a. Unless otherwise authorized by the IRB, principal investigators shall provide, as a minimum, the following information to each subject:

        1) a statement that the study involves research, an explanation of the purpose of the research, the expected duration of the subjects' participation, a description of the procedures to be followed, and identification of any experimental procedures;

        2) a description of any reasonably foreseeable risks or discomforts to the subject;

        3) a description of any benefit to the subject or to others that may be reasonably expected from the research;

        4) a disclosure of appropriate alternative procedures or treatment, if any, that may be beneficial to the subject;

        5) a statement describing the extent to which the confidentiality of records identifying the subjects will be maintained;

        6) in research involving more than minimal risk, an explanation as to whether or not compensation and medical treatment will be available either through the grant or to the extent permitted by institutional regulations should injury occur;

        7) an explanation of whom to contact for answers to relevant questions about the research and the subject's rights, and of whom to contact in the event of a research-related injury to the subject;

8) a statement that participation is voluntary, that refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled, and that the subject may discontinue his/her participation at any time without penalty or loss of benefits to which he/she is otherwise entitled;

9) if appropriate, a statement indicating that any change in the conditions under which the subject was accepted as a participant may disqualify him/her as a research subject.

b. When required by the IRB, the principal investigator shall provide additional elements of informed consent, such as the following:

1) a statement that the particular treatment, intervention, or procedure may involve risks to the subject (or to the embryo or fetus, if the subject is or may become pregnant) which are currently unforeseeable;

2) anticipated circumstances under which the subject's participation may be terminated by the principal investigator without the subject's consent;

3) the consequences of a subject's decision to withdraw from the research and procedures for his/her orderly termination of participation;

4) a statement that significant new findings obtained during the course of the research, which may relate to the subject's willingness to continue participation, will be provided to the subject; and

5) the approximate number of subjects involved in the study.

7. Documentation of informed consent

a. Principal investigators shall insure that informed consent is documented by using a written consent form approved by the IRB and signed by the subject or his/her legally authorized representative, unless this requirement is specifically waived by the IRB.

b. Principal investigators shall insure that each person signing the consent form is given a copy of that form.

c. Principal investigators may use a consent form stipulated by the IRB, if considered appropriate by the IRB. This IRB stipulated form may have one or two formats:

1) a "long form" consent document that embodies the elements of informed consent required by 45 CFR 46.116 *(General Requirements for informed consent)*. This form may be read to the subject or his/her legally authorized representative. However, the principal investigator shall give either the subject or his/her representative adequate opportunity to read the form before signing it; or

2) a "short form" consent document stating that the elements of informed consent required by 45 CFR 46.116 *(General Requirements for informed consent)* have been read to the subject or his/her legally authorized representative. When the "short form" is used, principal investigators shall insure that:

a) a witness is present at the oral presentation;

b) the document is signed by the subject or his/her representative;

c) the witness signs both the document and a copy of the written summary of the oral presentation, which received prior IRB approval;

d) the principal investigator obtaining consent signs both the document and a copy of the summary; and

e) a copy of both the signed document and summary is given to the subject or his/her representative.

d. Principal investigators shall place the consent documents signed by the human research subjects in a repository approved by the IRB and retain the signed consent or assent documents for the length of time stated in the protocol and approved by the IRB.

8. Submission of research reports to the IRB

   a. Principal investigators shall report the progress of the research involving human subjects as often as and in the manner prescribed by the IRB.

9. Submission of injury reports and reports of unanticipated problems involving risks

   a. Principal investigators shall report promptly to the IRB and, if applicable, to the appropriate federal agency department head any research-related injuries to the human subjects.

   b. Principal investigators shall report promptly to the IRB and, if applicable, to the appropriate federal agency department head any unanticipated problems, which involve risks to the human subjects or to other project participants.

10. Complying with IRB decisions

    a. Principal investigators shall comply with all IRB decisions, conditions, and requirements pertaining to their protocols.

    b. Principal investigators may appeal IRB decisions as specified in Section III.E.5.

11. Reporting changes or adverse events in the research

    a. Principal investigators shall report promptly to the IRB and to their department head any proposed changes in a research activity, which affect the subjects' protection from risks. Changes in research activities during the period for which IRB approval has already been given, shall not be initiated by the principal investigators without IRB review and approval, except where it is necessary to eliminate immediate hazards to the subjects.

    b. Principal investigators will inform the IRB, in a timely fashion and in writing, any intention to discontinue a proposed or approved research project or protocol.

    c. Principal investigators shall report immediately any adverse event encountered by human subjects participants while conducting the research protocol; including documentation of safety measures taken for the wellbeing of participants.

12. Attending IRB meetings

    Principal investigators and other interested parties are encouraged to attend IRB meetings whenever invited by the IRB. However, such invited guests should be ready to leave the meeting room if so requested by IRB chairperson.

13. Notifications to the IRB concerning investigational new drugs

    Principal investigators shall notify the Food and Drug Administration (FDA) and the IRB whenever it is anticipated that an investigational new drug or device exemption will be required as part of the research protocol involving human subjects.

B. IRB Structure

1. Institutional establishment of the IRB

   a. The IRB is established under this assurance at UPRM as an independent ethics committee, formally designated with the responsibility to review and monitor all research protocols

involving human subjects.

b. IRB members are appointed by the Dean of Academic Affairs. Colleges Deans make their recommendations of College representatives to the Dean of Academic Affairs (See Section III.B.3 below).

c. All appointments and reappointments will be for terms of three years. Regular members may not be reappointed for more than two consecutive terms and will commence on the first day of the semester.

d. The IRB Chairperson will be elected from amongst and by the members to a three-year term. Upon confirmation by the Dean of Academic Affairs, the Chairperson or another IRB member will serve as Director of the IRB office.

2. IRB membership requirements

a. The IRB will consist of members from diverse backgrounds to promote and ensure the complete and adequate review of all research protocols covered by this assurance. IRB members will have the professional competence necessary to review all protocols submitted to them.

b. The IRB will be sufficiently qualified through the experience, expertise, and diversity of background of its members (including consideration of the racial and cultural backgrounds of members and sensitivity to issues such as community attitude) to promote respect for its advice and counsel in safeguarding the welfare of human subjects.

c. When research protocols involving a category of vulnerable subjects (i.e., prisoners, children, mentally disabled individuals) are reviewed, the IRB may invite in its reviewing body one or more individuals who have as a primary concern the welfare of these subjects. However, only the appointed IRB members will have the right to vote on all issues pertaining to such protocols.

d. The IRB will include both male and female members.

e. The IRB will include members representing a variety of professions.

f. The IRB will include at least one member whose primary expertise is in a non-science area.

g. The IRB will include at least one member who is not affiliated with the institution and who is not part of the immediate family of a person affiliated with the institution.

h. The IRB will include at least one member with research experience with human subjects in each one of the following areas: social sciences and health or biomedical sciences. It will also include an ethicist.

i. Faculty representatives may serve also as the ethicist or as the specialist in health or biomedical sciences or social sciences research.

3. IRB membership and qualifications

a. All IRB members shall have a valid certification of approval of a course in the ethical dimensions of research involving human subjects.

b. The IRB will consist of no less than nine and no more than eleven members, as follows:

- one faculty representative from the College of Agricultural Sciences (nominated by the Dean and Director/College of Agricultural Sciences);
- two faculty representative from the College of Arts and Sciences (nominated by the Dean/College of Arts and Sciences);
- one faculty representative from the College of Business Administration (nominated by the

Dean/College of Business Administration);

- one faculty representative from the College of Engineering (nominated by the Dean/ College of Engineering);
- one representative from the institutional administration (nominated by the Dean of Academic Affairs);
- one representative from the Office of Graduate Studies, (nominated by the Director of the Office of Graduate Studies);
- one external representative to the institutional community (nominated by the Dean of Academic Affairs);
- an ethicist (nominated by the Dean of Academic Affairs); and
- an expert in social sciences research methods (nominated by the Dean of Academic Affairs).
- a research expert in health or in the biomedical sciences (nominated by the Dean of Academic Affairs).

c. The Dean of Academic Affairs of UPRM recommends to the Chancellor.

d. If an IRB member does not complete his or her three-year term, the appointed substitute will complete the remainder of the term (instead of beginning a new three year term). Time served as a substitute will not be considered as a term.

e. The names and qualifications of the IRB members are appended to this document in accordance with Section (b)(3) of 45 CFR 46.103 *(Assuring compliance with this policy—research conducted or supported by any Federal Department of Agency)*.

4. IRB Director

a. Description:

1) Shall have, at least, a valid certification of approval of a course in the ethical dimensions of research involving human subjects from CITI and from NIH and will, ideally, be a Certified IRB Professional.

2) Shall be confirmed by the Dean of Academic Affairs based on the recommendation of the IRB members.

3) Will be appointed for a minimum three year term, which may be renewed for another term.

4) Shall have at six credits (50%) release time during the Fall and Winter semesters.

5) Will be an active member of PRIM&R (Public Responsibility in Medicine and Research) and is expected to attend its annual meeting.

b. The Director, who manages the IRB on a day-to-day basis, has at least the following responsibilities:

1) Analyze protocols and records to ensure completeness and compliance with appropriate federal, state, institutional policies and IRB guidelines;

2) Attend IRB meetings and assist in the preparation of minutes and post meeting communications with researchers;

3) Compose clear and concise detailed correspondence to investigators;

4) Provide guidance to the research community of IRB policies, procedures, IRB review

requirements as well as status of ongoing reviews;

5) Serve as a liaison with technical staff to enhance IRB management systems;

6) Maintain and update the IRB website, web content and facilitate its use by investigators and IRB members;

7) Ensure careful recordkeeping;

8) Develop drafts of IRB policies and procedures for consideration by the IRB;

9) Handle allegations, complaints, and noncompliance, and report to the proper authorities of adverse effects, unexpected events and noncompliance;

10) Facilitate off-site/cooperative research;

a) assess quality improvements/metrics for IRB and PIs;

b) manage staff and infrastructure.

C. IRB Responsibilities

1. Institutional determinations concerning exemptions, sponsorships, and certifications.

   a. The IRB shall receive from the principal investigators all research protocols which involve human subjects.

   b. The determination of exemption from IRB review, in accordance with 45 CFR 46.101 *(To what does this policy apply?)*, is made by the IRB Chair or the IRB Administrator.

   c. All research protocols (both exempted and those approved by the IRB) which are being submitted for HHS funding shall be forwarded to the HHS by the principal investigator. If the IRB requires modifications to a research protocol, the principal investigator must not forward the protocol to the HHS until the IRB has determined that such modifications are made. Each protocol submitted to the HHS must include one of the following:

      1) certification that the research was reviewed and approved by the IRB established under this assurance;

      2) certification that the research was reviewed and approved by an IRB established under another assurance (a copy of the signed agreement stipulated under I.C.4.a above must be included with the certification); or

      3) that the research was determined to be exempt from coverage under 45 CFR 46.101

      4) The IRB shall keep principal investigators informed of administrative decisions and procedures affecting their protocols, and shall return all disproved protocols to the principal investigators.

2. Compliance with the investigational new drug or device certification requirement

   a. The IRB shall identify the test article (investigational new drug or device) in the certification to the HHS when the research protocol involves said test article, and state whether the 30-day interval between submission of applicant certification to the FDA and its response has elapsed or been waived, and/or whether use of the test article has been withheld or restricted by the FDA.

   b. If the 30-day interval has not expired and a waiver has not been issued, the principal investigator shall notify the HHS upon expiration of the interval.

3. Certification requirement in cases of supplements to HHS-funded protocols

The IRB shall submit a certification to the HHS, and when otherwise required by the HHS, a supplement to an original protocol, when:

a. it is proposed to involve human subjects, and the original activity had only indefinite plans for the involvement of human subjects;

b. it is proposed to involve human subjects, and the original activity had no plans for the involvement of human subjects; or

c. it is proposed to change the involvement of human subjects, and that involvement is significantly different from that which was initially approved by the IRB. In addition, the IRB shall insure that no human subjects are involved in research projects for which the filing of a supplement is required by the HHS, prior to review and approval of the submitted supplement by appropriate HHS officials.

4. Reporting requirements

a. The IRB shall report promptly information, as appropriate, to the Chancellor, OHRP, principal investigators, and department heads on a variety of issues. Information may flow from sources such as human subjects, principal investigators, or other institutional staff. Specifically, the IRB shall:

1) Report promptly to the OHRP any instances of research-related injuries to the subjects and unanticipated problems involving risks to subjects or other project participants;

2) Maintain documentation concerning the reasons for the suspension or termination of IRB approval of research protocols involving human subjects;

3) Report promptly any changes in IRB membership to the Chancellor and to all principal investigators with active IRB-approved protocols.

b. Any individual may report to the IRB any serious or continuing noncompliance with the requirements of this assurance or of any IRB determinations.

D. IRB Authorities

1. IRB review and approval of research protocols

a. The IRB shall have the responsibility to review and the authority to approve, require modification of, or disapprove research protocols or proposed changes in previously approved protocols involving human subjects.

b. The IRB shall approve research protocols provided that the following requirements are satisfied:

1) Risks to subjects are minimized:

a) by using procedures which are consistent with sound research design and which do not unnecessary place the subjects at risk; and

b) whenever appropriate, by using procedures already being performed on the subjects for diagnostic or treatment purposes.

2) Risks to subjects are justified according to the anticipated benefits and to the importance of the knowledge expected. In evaluating risks and benefits that may result from the research, the IRB shall not consider long-range effects of applying knowledge gained in the research (for example, the possible effects of the research on public policy) as among those research risk/benefits that fall within the purview of its responsibility.

3) Selection of subjects is equitable. In making this assessment, the IRB shall take into

account the purpose of the research, the setting in which the research will be conducted, and the special problems of research involving vulnerable populations such as children, prisoners, pregnant women, mentally disabled persons, or economically or educationally disadvantaged individuals.

4) Informed consent will be sought from each prospective subject or his/her legally authorized representative, in accordance with, and to the extent required by 45 CFR 46.116 *(General requirements for informed consent).*

5) Informed consent will be appropriately documented, in accordance with, and to the extent required by 45 CFR 46.117 *(Documentation of informed consent).*

6) Where appropriate, the protocol makes adequate provision for monitoring the data collected to insure the safety of subjects.

7) Where appropriate, there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data.

2. Documentation of informed consent

   a. In accordance with 45 CFR 46.117 *(Documentation of informed consent).* the IRB shall require documentation of informed consent by use of a written consent form, or may waive this requirement for some or all of the subjects if the IRB determines that:

      1) the only record linking the subject and the research would be the consent documents and the major risk will be potential harm resulting from a breach of confidentiality. Each subject will be asked whether or not he/she wants documentation linking the subject with the research, and the subject's wishes will prevail; or

      2) the research presents minimal risk of harm to the subjects, and involves no procedures for which a written consent form is normally required outside the research context.

   b. When the documentation requirement is waived, the IRB may require the principal investigator to provide the subjects with a written statement describing the research.

3. Waiver or alteration of informed consent

   The IRB may approve a consent procedure which does not include, or which alters, some or all of the elements of informed consent set forth in subsections (b), (c), and (d) of 45 CFR 46.116 *(General Requirements for informed consent)***,** or waive the requirement to obtain informed consent provided the IRB finds and documents that:

   a. the research involves minimal risk to the subjects;

   b. the waiver or alteration will not adversely affect the rights and welfare of the subjects;

   c. the research could not be carried out without the waiver or alteration; and

   d. whenever appropriate, the subjects will be provided with additional pertinent information during their participation.

4. Observation of the consent process and the research

   The IRB shall have the authority to observe or have a third party observe the informed consent process and all research activities in which humans participate as subjects.

5. IRB meetings

   a. All convened IRB meetings shall be conducted under and pursuant to *Robert 's Rules of Order*.

   b. All IRB members shall sign a non-disclosure agreement upon being confirmed as members and

before they attend their first meeting. The agreement is binding for the duration of their membership in the committee.

c. All persons attending an IRB meeting shall sign a non-disclosure agreement.

d. Convened IRB meetings shall occur:

1) at least three times per semester

2) at the call of the Director, when he/she deems the meeting necessary; and

3) upon the request of three or more members, within three weeks of such requests.

6. Frequency and continuing review

a. The IRB shall review at least annually all approved ongoing research protocols and determine which projects require increased frequency of observation.

b. The IRB shall conduct continuing review of its approved research activities at intervals appropriate to the degree of risk to the subjects, but not less than once per year.

7. Verification of change

The IRB shall determine which projects need verification from sources other than the principal investigators to insure that no significant changes have occurred since the previous IRB review. When necessary, the IRB will appoint, with the consent of the Dean of Academic Affairs, a person to conduct said review.

8. Suspension or termination of research approval

The IRB shall have the authority to suspend or terminate approval of a research activity that is not being conducted in accordance with IRB decisions, conditions, and requirements, or that has been associated with unexpected serious harm to the subjects.

9. Information, dissemination, and reporting requirements

a. The IRB shall have the authority and be responsible for promptly reporting information to OHRP on issues such as:

1) any serious or continuing noncompliance by principal investigators with IRB requirements; this information shall be reported promptly to the Chancellor who is responsible for reporting to the OHRP;

2) injuries to human subjects; information received by the IRB concerning injuries to subjects shall be reported promptly to the Chancellor who is responsible for reporting to the OHRP;

3) unanticipated problems; information received by the IRB concerning unanticipated problems involving risks to subjects or other project participants shall be reported promptly to the Chancellor who is responsible for reporting to the OHRP; or

4) suspension or termination of IRB approval; suspension or termination of approval of research protocols shall include a statement of the reasons for the IRB's action. The IRB shall report its decision promptly to the principal investigator, the Dean of Academic Affairs, Chancellor, and the OHRP.

b. In conjunction with this requirement, the IRB must be prepared to receive and act on information received from a variety of sources such as human subjects, principal investigators, or other institutional staff.

c. The IRB has the authority to suspend a principal investigator or a research collaborator from conducting research with human subjects for a reasonable amount of time in case of gross

ethical violations in human subject research or serious non-compliance with IRB requirements that result in harm to human subjects.

d. The IRB has the authority to revoke its approval of a research protocol that was not carried out as approved by the IRB, or was modified and carried out without previous IRB approval.

10. IRB records

a. The IRB shall prepare and maintain adequate documentation of its activities, including the following:

1) copies of all research protocols submitted, scientific evaluators, if any, that accompany such protocols, approved sample consent documents, progress reports submitted by principal investigators, reports of injuries to subjects, signed copies of consent documents, and all other documents the IRB may consider relevant;

2) minutes of IRB meetings including the names of attendees, actions taken, the vote on these actions (including the number of members voting for, against, and abstaining), the reasons for requiring changes in or disapproving research protocols, a written summary of the discussion of issues and their resolution, and dissenting reports and opinions. If a member in attendance has a conflict of interest regarding any research protocol, minutes shall show that this member did not participate in the review, except to provide information requested by the IRB, or was asked to leave the meeting;

3) records containing review activities;

4) copies of all relevant correspondence between the IRB and the principal investigators;

5) a list of IRB members as required by Section (b)(3) of 45 CFR 46. 103 (*Assuring compliance with this policy—research conducted or supported by any Federal Department of Agency*);

6) written procedures for the IRB as required by Section (b)(4) of 45 CFR 46. 103 (*Assuring compliance with this policy—research conducted or supported by any Federal Department of Agency*); and

7) statements of significant new findings provided to subjects, as required by Section (b)(5) of 45 CFR 46.116 (*General requirements for informed consent).*

a) The IRB shall maintain all records pertaining to a specific research activity for at least three years after the last IRB approval period for the activity has elapsed.

b) IRB records shall be accessible for inspection and copying by authorized HHS representatives at reasonable times and in a reasonable manner, or shall be copied and forwarded to the HHS when requested by authorized HHS representatives.

b. All IRB records are for the exclusive use of IRB members and staff.

c. UPRM officials must submit a written request to the IRB Director to have access to IRB records.

E. IRB Procedures

1. Review procedure

a. The IRB Director shall receive research protocols involving human subjects from the principal investigators and make them electronically available to all IRB members. Principal investigators are expected to provide in a timely manner all required documents, both electronically and in hard copy to the IRB Director, according to the procedures established by the IRB at UPRM.

b. The IRB Director shall determine whether or not the research protocol meets the criteria necessary for an expedited review process.

c. The IRB Director shall refer all research protocols to either expedited review or full committee review.

2. Expedited review

a. The eligibility of some research protocols for review through the expedited procedure is in no way intended to negate or modify the policies of this institution expressed in this assurance or the other requirements of 45 CFR 46. The expedited review procedure will only be used in accordance with the regulations established by the OHRP.

b. The IRB may use the expedited review to review minor changes in previously approved research protocols during the period for which approval is authorized.

c. The only other research for which the IRB may use an expedited review procedure is that which involves minimal risk to the subjects, and which falls within the categories or research approved for expedited review by the OHRP policies.

d. Expedited review shall be conducted by the IRB Director. The Director can consult with others whose areas of expertise are relevant to the research project under review.

e. The IRB member(s) conducting the expedited review may exercise all the authorities of the IRB, except that the reviewer(s) may not disapprove the research protocol. The reviewer(s) shall refer any protocol which the reviewer(s) would have disapproved to the full committee for review. The reviewer(s) may also refer other protocols to the full committee whenever he/she believes that full committee review is warranted.

f. When the expedited review procedure is used, the IRB Director shall inform all other IRB members of research protocols which have been approved using this procedure.

g. Any member may request that a protocol, which has been approved under the expedited procedure, be reviewed by the full IRB in accordance with non-expedited procedures. A vote of the members present at the convened meeting will be taken concerning the request and the majority shall prevail.

3. Full committee review

a. Research protocols scheduled for review shall be distributed to all IRB members at least five days prior to the meetings.

b. The IRB may request the advice and recommendation of external, experts or consultants who will provide their services voluntarily. When it is determined that such individuals will be required to advise the IRB in its review of a protocol, the document shall also be distributed to the experts or consultants prior to the meeting. The experts or consultants may be present at the convened IRB meeting when the protocols are reviewed, but may not vote on any IRB issues.

c. The IRB's initial and continuing review of research protocols shall be conducted at convened meetings and at timely intervals.

d. A majority of the IRB membership constitute a quorum and is required in order to convene a meeting for the review of research protocols.

e. An IRB member whose concerns are primary in non-scientific areas must be present at the convened meeting before the IRB can conduct its review of research protocols.

f. For a research protocol to be approved, it must receive the approval of a majority of those

members present at the convened meeting.

g. No IRB member may participate in the initial or continuing review of a protocol in which he/she has a conflict of interest, except to provide information requested by the IRB.

h. In cases where research protocols were initially approved under expedited procedures and subsequently reviewed by non-expedited procedures, the decisions reached at the convened full IRB meeting shall supersede any decisions made through the expedited review.

4. IRB notification to principal investigators

   a. The IRB shall notify principal investigators its decisions, conditions, and requirements related to their research protocols.

   b. The IRB shall also provide the principal investigator the reasons for its decision to disapprove a research protocol, giving him/her adequate opportunity to respond.

5. Appeal of IRB decisions and re-referral to the IRB

   Appeals of an IRB decision shall be directed to the Chancellor who will notify the IRB of such request. In each case, the Chancellor may name an appeals officer or committee to review the appeal and submit recommendations. If necessary, the appeal will be re-referred to the IRB as the final decisional authority. Institutional officials may not approve research protocols disapproved by the IRB (45 CFR 46.112 – *Review by institution*).

This assurance will be revised/updated by the IRB and submitted to the Administrative Board for certification every three years. However, amendments to specific line items or sections may be issued upon certification by the Administrative Board whenever appropriate.

IV. Institutional Endorsement

A. Authorized Institutional Officials (primary contacts):

Signature: _____ Date: _____

Name: Dr. John Fernández Van Cleve

Title: Chancellor of the University of Puerto Rico at Mayagüez

Signature: _____ Date: _____

Name: Dr. Betsy Morales

Title: Dean of Academic Affairs

Address: Office of Academic Affairs
Call Box 9000
Mayagüez, PR 00681-9000

Phone: (787) 265-3807, (787) 265-3808

e-mail: decano.aa@uprm.edu

B. IRB Chairperson

Signature:_____

Date: _____

Name: Dr. Rafael A. Boglio Martínez

Title: Assistant Professor

Address: Comité para la protección de los seres humanos en la investigación.
University of Puerto Rico
Call Box 9000
Mayagüez, PR 00681-9000

Phone: (787) 832-4040, ext. 6277

e-mail: cphsirum@uprm.edu

C. IRB Director

Signature:_____

Date: _____

Name: _Dr. Rafael A. Boglio Martínez

Title: __Assistant Professor____

Address: Comité para la protección de los seres humanos en la investigación.
University of Puerto Rico
Call Box 9000
Mayagüez, PR 00681-9000

Phone: (787) 832-4040, ext. 6277

e-mail: ___cpshirum@uprm.edu_____

IV. IRB Location

Postal Address: Call Box 9000
University of Puerto Rico
Mayagüez, PR 00681-9000

Physical Address: Celis 108
University of Puerto Rico
Mayagüez, PR

e-mail: cpshirum@uprm.edu