PUERTO RICO OFFICE OF INSTITUTIONAL REVIEW BOARD
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MULTIPLE PROJECT ASSURANCE OF COMPLIANCE WITH DHHS REGULATIONS FOR PROTECTION OF HUMAN RESEARCH SUBJECTS

The Pontifical Catholic University of Puerto Rico, hereinafter referred to as "Institution", hereby gives assurance, as specified below, that it will comply with the Department of Health and Human Services (DHHS) regulations for the protection of human research subjects, (45 CFR Part 46, as amended as amended to include provisions of the Federal Policy for the Protection of Human Subjects (56 FR28003) as Subpart A, and as may be further amended during the approval period for this Assurance.

PART I – PRINCIPLES, POLICIES, AND APPLICABILITY

I. Ethical Principles

A. This Institution is guided by the ethical principles regarding all research involving humans, as set forth in the report of the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research entitled Ethical Principles and Guidelines for the Protection of Human Subjects of Research (the "Belmont Report"), regardless of whether the research is subject to Federal regulation or with whom conducted or source of support (i.e., sponsorship).

B. All Institutional and non-Institutional performance sites for this Institution, domestic or foreign, will be obligated by this Institution to conform to ethical principles which are at least equivalent to those of this Institution, as cited in the previous paragraph or as may be determined by the DHHS Secretary.

C. This Institution which is Roman Catholic must abide by the ethical norms published by the Holy See in Donum Vitae, February 22, 1987, Veritatis Splendor, August 6, 1993, and Evangelium Vitae, March 25, 1995. These documents are stricter than the Federal Policies for the Protection of Human Subjects in human embryo research. This Institution will respect human life from the moment of conception until the natural death of the subject treating the individual in all the stages of life as a human person whose dignity and rights must be respected.

II. Institutional Policy

A. All requirements of Title 45, CFR 46, of the Code of Federal regulations (45 CFR 46) will be met for all applicable DHHS-supported research regardless of sponsorship[1], except as otherwise noted in this Assurance. Federal funds for which this Assurance applies may not be expended for research involving human subjects unless the requirements of this Assurance have been satisfied.

B. Except for those categories specifically exempted or waived under Section 101(b)(1-6) or 101(i), all research covered by this Assurance will be reviewed and approved by an Institutional Review Board (IRB) which has been established under a Multiple Project Assurance (MPA). The involvement of human subjects in research covered by this assurance will not e permitted until an appropriate IRB has reviewed and approved the research protocol and informed consent has been obtained from the subject or the subject's legal representative (see Sections 111, 116, and 117).

C. This Institution assures that before human subjects are involved in nonexempt research covered by this Assurance, the RIB will give proper consideration to:

1. the risks to the subjects,
2. the anticipated benefits to the subjects and others,
3. the importance of the knowledge that may reasonably be expected to result, and the informed consent process to be employed.

D. Certification of RIB review and approval for al Federally-sponsored research involving human subjects will be submitted to the appropriate Federal department or agency. Compliance will occur within the time and in the manner prescribed for forwarding certifications of RIB review to DHHS or other Federal departments or agencies for which this Assurance applies. As required under Section 119, the RIB will review and recommend approval for involvement of human subjects in Federal research activities for which there was no prior intent for such involvement, but will not permit such involvement until certification of the IRB's review and approval is received by the appropriate Federal Department of agency.

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[1] Compliance with 45 CFR 46 regardless of sponsorship is elected by this Institution for internal consistency of operations. Election will require compliance with all requirements of 45 CFR 46 (Subparts A through D) and acceptance by other Federal departments and agencies without the need for preparing separate and additional Assurances.

E. Institutions that are not direct signatories to this Assurance are not authorized to cite this Assurance. This Institution will ensure that such other Institutions and investigators not bound by the provisions of this Assurance for DHHS-sponsored research will satisfactorily assure compliance with 45 CFR 46, as required (see Part 2, I, D and II, K), as a prior condition for involvement in human subject research which is under the auspices of this Institutions (see part I, III, A). Institutions that have entered into an

Inter-Institutional Amendment (IIA) to this Assurance must submit a Single Project Assurance (SPA) to the Office for Protection from Research Risks (OPRR) of DDHS for DHHS-sponsored research, on request, when that research is not conducted under the auspices of a signatory Institution to this Assurance.

F. This Institution will ensure that any of its affiliates materially engaged in the conduct of nonfederal sponsored research involving human subjects will possess mechanisms to protect human research subjects that are at least equivalent to those procedures provided for in the ethical principles to which this Institution is committed (see Part 1, I).

G. This Institution will comply with the requirements set forth in Section 114 of the regulations 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. This Institution may accept, for the purpose of meeting the IRB review requirements, the review of an IRB established under another Assurance of compliance with HHS. Such acceptance must be (a) in writing, (b)approved and signed by an official of this Institution's IRB, and (c) approved and signed by correlative officials of each of the other cooperating Institutions. The original of the signed understanding will serve as an addendum of this Assurance and will be forwarded to the OPRR of HHS by the IRB for approval.

H. This Institution shall provide each individual at the Institution conducting or reviewing human subject research (e.g., PIs, department heads, clinical care staff, research administrators, IRB members) with a copy of this Institutional assurance of compliance and copies of any future modifications which may be made to this assurance, with the exception of changes in IRB membership.

III. Applicability

A. Except for reasons in which the only involvement of humans is in one or more of the categories exempted or waived under Section 101(b)(1-6) or 101(I), this Assurance applies to all research involving human subjects, and all other activities which even in part involve such research, regardless of sponsorship[(1)], if one or more of the following apply:

1. the research is sponsored by this Institution, or
2. the research is conducted by or under the direction of any employee or agent of this Institution in connection with his or her Institutional responsibilities, or
3. the research is conducted by or under the direction of any employee or agent of this Institution using any property or facility of this Institution, or
4. the research involves the use of this Institution's nonpublic information to identify or contact human research subjects or prospective subjects.

B. All human subject research which is exempt under Section 101(b) (1-6) or 101 (i) will be conducted in accordance with: (1) the Elmont Report, (2) this Institution's administrative

procedures to ensure valid claims of exemption, and (3) orderly accounting for such activities.

C. Components of this Institution are bound by the provisions of this Assurance. Those components which can be expected to participate in human subject research sponsored by DHHS or other Federal departments or agencies for which this Assurance will apply are identified in Appendix A. Appendix A will be revised as changes occur and revisions forwarded to OPRR.

D. This Assurance must be accepted by other Federal departments or agencies that are bound by the Federal Policy for the Protection of Human Subjects when appropriate for the research in question and therefore applies to all human subject research so sponsored.[(1)] Research that is neither conducted nor supported by a Federal department or agency but is subject to regulation as defined in Section 102(e) must be reviewed and approved, in compliance with Sections 101, 102, and 107 through

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PART 2 – RESPONSIBILITIES

I. Institution

A. This Institution acknowledges that is bears full responsibility for the performance of all research involving human subjects, covered by this assurance, including complying with Federal, state, or local laws as they may relate to such research.

B. This Institution will require appropriate additional safeguards in research that involves: (1) fetuses, pregnant women, or human ova in vitro fertilization (see 45 CFR 46 Subpart B), (2) prisoners (see 45 CFR 46 Subpart C), (3) children (see 45 CFR 46 Subpart D), (4) the cognitively impaired, or (5) other potentially vulnerable groups.

C. This Institution, including all its named components (see Appendix A), acknowledges and accepts its responsibilities for protecting the rights and welfare of human subjects of research covered by this Assurance.

D. This Institution is responsible for acquiring appropriate Assurances or Amendments, when requested, and certifications of IRB review and approval for federally sponsored research from all its standing affiliates (see Appendix B) and Assurances or Agreements for all others, domestic or foreign, which may otherwise become affiliated on a limited basis in such research.

E. This Institution is responsible for ensuring that no affiliates cooperating in the conduct of federally sponsored research for which this Assurance applies do so without an appropriate assurance of compliance and satisfaction of RIB certification requirements.

F. In accordance with the compositional requirements of Section 107, this Institution has established the IRB listed in the attached roster (see Appendix C). Certain research

supported by the U.S. Department of Education will be reviewed in accordance with the requirements of Title 34 CFR Parts 350 and 356 which require that the IRB(s) include one person who is primarily concerned with the welfare of handicapped children or mentally disabled persons.

G. This Institution will provide both meeting space and sufficient staff to support the IRB's review and recordkeeping duties.

H. This Institution recognizes that involvement in research activities of any OPRR-recognized Cooperative Protocol Research Programs will involve additional reporting and recordkeeping requirements related to human subject protections.

I. This Institution is responsible for ensuring that it and all its affiliates comply fully with all applicable Federal policies and guidelines, including those concerning notification of seropositivity, counseling, and safeguarding confidentiality where research activities directly or indirectly involve the study of human immunodeficiency virus (HIV).

II. Office of Research Administration (ORA)

(Given the size of the Pontifical Catholic University and the limited number of research protocols that are submitted, the duties which correspond to this office will be completed by IRB.)

A. The IRB will receive from investigators, through their supervisors, all research protocols which involve human subjects, keep investigators informed of decisions and administrative processing, and return all disapproved protocols to them.

B. The IRB is responsible for reviewing the preliminary determinations of exemption by investigators and supervisors and for making the final determination based on Section 101 of the regulations. Notice of concurrence for all exempt research will be promptly conveyed in writing to the investigator.

C. The IRB will make the preliminary determination of eligibility for expedited review procedures (see Section 110). Expedited review of research activities will not be permitted where full board review is required.

D. The IRB will review all research (whether exempt or not) and decide whether the Institution will permit the research. Any other office of the Institution may not approve a research activity that has been disapproived by the IRB.

E. The IRB will forward certification of IRB approval of proposed research to the appropriate Federal department or agency only after al IRB-required modifications have been incorporated to the satisfaction of the IRB.

F. The IRB will designate procedures for the retention of signed consent documents for at least three years past completion of the research activity.

G. The IRB will maintain and arrange access for inspection of its records as provided for in Section 115.

H. The IRB is responsible for ensuring constructive communication among the research administrators, department heads, research investigators, clinical care staff, human subjects, and Institutional officials as a means of maintaining a high level of awareness regarding the safeguarding of the rights and welfare of the subjects.

I. The IRB will arrange for and document in its records that each individual who conducts or reviews human subject research has first been provided with a copy of this Assurance, as well as with ready access to copies of 45 CFR 46, regulations of other Federal departments or agencies as may apply, the Belmont Report, and all other pertinent Federal policies and guidelines related to the involvement of human subjects in research.

J. The IRB will report to the appropriate Institutional officials, the Office for Protection from Research Risks (OPRR), and any other sponsoring Federal department or agency head:

1. any injuries to human subjects or other unanticipated problems involving risks to subjects or others.
2. any serious or continuing noncompliance with the regulations or requirements of the IRB, and
3. any suspension or termination of IRB approval for research.

K. The IRB will ensure (a) solicitation, receipt, and management of all assurances of compliance (whatever the appropriate format), and certifications of IRB review (where appropriate) for all affiliates to this Institution (including those listed in Appendix B), and (b) subsequent submission of these documents to the proper authorities as a condition for involvement in human subject research activities sponsored by DHHS or any other Federal department or agency for which this Assurance applies.

L. The IRB will ensure that all affiliated performance sites that are not otherwise required to submit assurances of compliance with Federal regulations for the protection of research subjects at least document mechanisms to implement the equivalent of ethical principles to which this Institution is committed (see Part 1, i).

M. The IRB of this Institution will not accept for review any research protocol of any independent investigator who is not otherwise subject to the provisions of this Assurance.

N. The IRB will be responsible for procedural and recordkeeping audits not less than once every year for he purpose of detecting, correcting, and reporting (as required) administrative and/or material breaches in uniformly protecting the rights and welfare of human subjects as required at least by the regulations and as may otherwise be additionally required by this Institution.

O. The IRB will only review research protocols submitted by the faculty of this Institution

and will not consider cooperative research projects with other Institutions.

Institutional Review Board (IRB)

A. The IRB will review, and have the authority to approve, require modification in, or disapprove all research activities, including proposed changes in previously approved human subject research. For approved research, the IRB will determine which activities require continuing review more frequently than every twelve months or need verification that no changes have occurred if there was a previous IRB review and approval.

B. The IRB decisions and requirements for modifications will be promptly conveyed to investigators in writing. Written notification of decisions to disapprove will be accompanied by reasons for the decision with provision of an opportunity for reply by the investigator, in person or in writing.

C. Initial and continuing convened IRB reviews and approvals will occur in compliance with 45 CFR 46 and provisions of this Assurance for each project. Continuing reviews will be preceded by IRB receipt of appropriate progress reports from the investigator, including available study-wide findings.

D. The IRB will observe the quorum requirements of Section 108(b). This Institution's IRB has effective knowledge of subject populations, Institutional constraints, differing legal requirements, and other factors which can foreseeable contribute to a determination of risks and benefits to subjects and subjects' informed consent and can properly judge the adequacy of information to be presented to subjects in accordance with requirements of Sections 103(d), 107(a), 111, and 116.

E. The IRB will determine, in accordance with the criteria found at 45 CFR 46.111 and Federal policies and guidelines for involvement of human subjects in HIV research, that protection for human research subjects are adequate.

F. The IRB will ensure that legally effective informed consent will be obtained and documented in a manner that meets the requirements of Sections 116 and 117. The IRB will have the authority to observe or have a third party observe the consent process.

G. Where appropriate, the IRB will determine that adequate additional protections are ensured for fetuses, pregnant women, prisoners, and children, as required by Subparts B, C, and D of 45 CFR 46. The IRB will notify OPRR promptly when IRB(s) membership(s) is modified to satisfy requirements of 45 CFR 46.303 and when the IRB fulfills its duties under 45 CFR 46.305c.)

H. Scheduled meetings of the IRB for review of each research activity will occur not less than every 12 months and may be more frequent, if required by the IRB on the basis of degree of risk to subjects. The IRB may be called into an interim review session by the Chairperson at the request of any IRB member or Institutional official to consider any matter concerned with the rights and welfare o any subject.

I. The IRB will prepare and maintain adequate documentation of its activities in accordance with Section 46.115.

J. In accordance with Section 113, the IRB will have the authority to suspend or terminate previously approved research that is not being conducted in accordance with the IRB requirements or that has been associated with unexpected serious harm to subjects.

K. The IRB for this Institution will ensure effective input (consultants or voting or nonvoting members) for all initial and continuing reviews conducted on behalf or performance sites where there will be human research subjects. IRB minutes will document attendance of those other than regular voting members.

L. The IRB will act with reasonable dispatch, upon request, to provide full board review of protocols of OPRR-recognized Cooperative Protocol Research Programs (CPRP). The IRB will not employ expedited review procedures for CPRP protocols when they are to be entered into for the purpose of research. Although emergency medical care based on such protocols is permitted without prior IRB approval, patients receiving emergency care under these conditions will not be counted as research subjects and resultant data will not be used for research purposes.

M. Certifications of IRB review and approval will be forwarded to the appropriate Federal department or agency for research sponsored by such departments or agencies.

IV. Research Investigator

A. Research investigators acknowledge and accept their responsibility for protecting the rights and welfare of human research subjects and for complying with all applicable provisions of this Assurance.

B. Research investigators who intend to involve human research subjects will not make the final determination of exemption from applicable Federal regulations or provisions of this Assurance.

C. Research investigators are responsible for providing a copy of the IRB-approved and signed informed consent document to each subject at the time of consent, unless the IRB has specifically waived this requirement. All signed consent documents are to be retained in a manner approved by the IRB.

D. Research investigators will promptly report proposed changes in previously approved human subject research activities to the IRB. The proposed changes will not be initiated without IRB review and approval, except where necessary to eliminate apparent immediate hazards to the subjects.

E. Research investigators are responsible for reporting progress of approved research to

IRB, as often as and in the manner prescribed by the approving IRB on the basis of risks to subjects, but no less than once a year.

F. Research investigators will promptly report to the IRB any injuries or other unanticipated problems involving risks to subjects and others.

G. No research investigator who is obligated by the provisions of this Assurance, any associated inter-Institutional Amendment, or NonInstitutional Investigator Agreement will seek to obtain research credit for, or use data from patient interventions that constitute the provision of emergency medical care without prior IRB approval. A physician may provide emergency medical care to a patient without prior IRB review and approval, to the extend permitted by law (see Section 116[f]). However, such activities will not be counted as research nor the data used in support of research.

H. Research investigators will advise the IRB, and the appropriate officials of other Institutions of the intent to admit human subjects who are involved in research protocols for which this Assurance or any related Inter-Institutional Amendment or Non Institutional Investigator Agreement applies. When such admission is planned or a frequent occurrence, those Institutions must possess an applicable OPRR-approved Assurance prior to involvement of such persons as human subjects in those research protocols.

V. Affiliated Institutions and Investigators

A. There are no affiliates Institutions or investigators.

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