

**Comprehensive Cancer Center UPR  
Human Research Participant Protection Program  
CHARTER**

**AUTHORIZATION**

**In accordance with its FederalWide Assurance on file with the Department of Health and Human Services, Comprehensive Cancer Center of the University of Puerto Rico (CCC-UPR) has an Institutional Review Board for Human Participants (IRB). The IRB is a standing committee of the University Faculty.**

**COMMITMENT TO PROTECTING HUMAN PARTICIPANTS**

In order to protect the rights of all human participants involved in research at CCC-UPR, the University operates its human participant research programs under a Federal wide Assurance (FWA) with the Office of Human Research Protection (OHRP) within the Department of Health and Human Services. The FWA represents a fundamental commitment to the protection of human participants and applies to all CCC-UPR research involving human participants, regardless of the location of the research or its sources of funding, be they governmental agencies, nonprofit organizations, industry, or University funds. In addition, the FWA applies to all research that is conducted at CCC-UPR or using CCC-UPR resources regardless of who is conducting the research.

As part of its mission, CCC-UPR maintains a Human Research Protection Program that adheres to the principles outlined in the Belmont Report, the Declaration of Helsinki (as amended in 1989), and the Nuremberg Code as well as with the federal regulations, outlined in 45 CFR 46 and its Subparts A, B, C, and D, and the FDA regulations, outlined in 21 CFR 50 and 21 CFR 56.

In addition, the CCC-UPR complies with Puerto Rico State Public Health Law (Act Num. 81 of May 14, 1912- Organic Act; (Amended in 1976, law 13; 1977, law 126), (31 L.P.R.A. sec. 171)- Civil Code, Puerto Rico State regulations concerning the use of human participants in research, and Act 275 of 2012. Other laws that apply are: 1) Act 49 of April 2011 Public Policy Law of the Government of Puerto Rico for the Comprehensive Control of Cancer in Puerto Rico; 2) Law of the Central Registry of Cancer of Puerto Rico and repeal Act No. 28 of 1951; Cancer Program; 3) Law No. 113 of July 30, 2010. Letter of Rights of Patients and Cancer Survivors.

Act Num. 275 from September 27, 2012; 4) Health Insurance Code of Puerto Rico Law No. 194 of August 29, 2011, Title 26 Cap 112-Protection of the Health Information.

When research activities are being proposed to be conducted in other states and countries by CCC-UPR faculty, staff, and/or students, the research activities will be approved in compliance with the regulations for those specific research locations.

## **DEFINITIONS**

***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, and they would be included in this definition of Research.<sup>1</sup>

***Human participants*** mean a living individual about whom an investigator (whether professional or student) conducting research obtains:

- (1) Data through intervention or interaction with the individual, or
- (2) Identifiable private information.

***Intervention*** includes both physical procedures by which data are gathered and manipulations of the participant or the participant's environment that are performed for research purposes. Intervention includes communication or interpersonal contact between investigator and participant.

***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.

Private information includes: name; address; elements of dates related to an individual (e.g. birth date, marriage date, date of death, etc.); numbers (telephone, fax, social security, medical record, health beneficiary/health insurance, certificate or license numbers, vehicle numbers; account numbers (e.g. credit card), device identification numbers, serial numbers, and/or any unique identifying number, characteristics, or codes); email address; Web URLs; Internet Protocol addresses [IP]; biometric identifiers (e.g., voice, fingerprints); full-face photographs or comparable images; or biological samples or genetic material. Private information must be individually identifiable (i.e.,

the identity of the participant is or may readily be ascertained by the investigator or associated with the information) for obtaining the information to constitute research involving human participants.

*Investigator* - The individual(s) designated to have the appropriate level of authority and responsibility to direct the research project and/or activity.

## **ORGANIZATIONAL ROLES**

1. Without exception, all human participant research conducted by CCC-UPR investigators, students, and staff, and any others conducting research at CCC-UPR or utilizing CCC-UPR resources, must receive prior approval of CCC-UPR's Institutional Review Board for Human Participants (IRB). The IRB for Human Participants has the authority to review, approve, disapprove or require changes in research or related activities involving human participants. Research reviewed by the IRB may also be subject to other review and approval or disapproval by officials at CCC-UPR. However, those officials may not approve research that has not been approved by the IRB for Human Participants.
2. The IRB for Human Participants has the final determination as to what constitutes Research and the use of Human Participants. The IRB for Human Participants makes the final determination as to whether or not activities meet the definition of Research and if the activity needs to be reviewed and/or approved by the IRB for Human Participants. Investigators cannot exempt themselves and their activities from IRB review and approval. The approval by the IRB for Human Participants cannot occur after the data for a research activity has been collected.
3. The Executive Director serves as the Institutional Official for the Federal-Wide Assurance with OHRP. As such, the Executive Director, in consultation with the appropriate Directors, has oversight responsibility of the University's Human Research Protection Program.

## **CHARGE**

The IRB shall ensure the protection of human participants as subjects of research at CCC-UPR. The IRB shall:

- (a) Determine what activities constitute research and the use of human participants.
- (b) Review, approve, require modifications in (to secure approval), or disapprove all research activities covered by this policy prior to the commencement of the research.
- (c) Require that information given to participants as part of informed consent is in accordance with appropriate law, regulations, and international standards.<sup>2</sup> The IRB

for Human Participants may require that additional information be given to the participants when, in the IRB's judgment, the information would meaningfully add to the protection of the rights and welfare of participants.

(d) Require documentation of informed consent or waive documentation in accordance with federal and Puerto Rico laws and regulations. When research activities are being proposed to be conducted in other states and/or countries by CCC-UPR faculty, staff, and/or students, the research activities will be approved in compliance with the regulations for those specific research locations.<sup>3</sup>

(e) Notify investigators and the institution in writing of its decision to approve or disapprove the proposed research activity, or of modifications required to secure IRB approval of the research activity. If the IRB decides to disapprove a research activity, it shall include in its written notification a statement of the reasons for its decision and give the investigator an opportunity to respond in person or in writing.

(f) Conduct continuing review of research covered by this policy at intervals appropriate to the degree of risk, but not less than once per year, and have authority to observe or have a third party observe the consent process and the research.

(g) Suspend or terminate approval of research that is not being conducted in accordance with the IRB's requirements or that has been associated with unexpected serious harm to participants. Any suspension or termination of approval shall include a statement of the reasons for the IRB's action and shall be reported promptly to the investigator, appropriate institutional official, and the department or agency head.

## **MEMBERSHIP**

The IRB for Human Participants shall consist of ten to twelve members.

The CCC IRB meets the following criteria: The IRB has at least five members with varying backgrounds to promote complete and adequate review of research commonly conducted by the organization

1. The IRB is not comprised of either all male or all female members
2. The IRB is not comprised of members who represent only a single profession
3. At least one physician representing the scientist of CCC-UPR
4. At least one non-scientist
5. One non-affiliated person ("Community person") to the Institution or immediate family member of an affiliated person,
6. At least two members not otherwise affiliated with CCC-UPR; and (e) other members of the faculty to be able to review and approve research conducted by CCC-UPR. At least one member has primary concerns in nonscientific area
7. At least one member represents the perspective of research participants

Individuals who are responsible for business development are prohibited from serving as members or ex-officio members on the IRB and from carrying out day-to-day operations of the review process.

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<sup>3</sup> 45 CFR 46.117

## **1. Selection and Appointment**

### **IRB Members (Regular members and Alternate members)**

The IRB Chair and Medical Director are responsible for selecting members to serve on the IRB. The selection process is conducted in consultation with the Institutional Official, Department Chairs, and other IRB members.

All members shall be appointed by the IRB Chair upon recommendation of the President of the Faculty in consultation with the Director for Research. Members will serve terms of one to three-years and should provide representation primarily from the social, behavioral, and biological sciences. The Committee Chair shall be appointed from among the faculty members by the President upon recommendation of the Dean of the Faculty in consultation with the Director for Research. The Chair will serve for a term of one to three years after which time the Dean of the Faculty, in consultation with the Director for Research; will make a recommendation to the President concerning the appointment of a new Chair or the reappointment of the present chair. The IRB Chair may remove members from the committee if the member is not able to complete his/her responsibilities as an IRB member.

### **IRB Chair and Vice-Chair**

The Institutional Official and Medical Director are responsible for selecting the IRB Chair and Vice-Chair. The selection process is conducted in consultation with Department Chairs, and other IRB members. The Institutional Official will appoint the IRB Chair and Vice-Chair. The IRB Chair and Vice-Chair will receive an appointment letter after their appointment has been confirmed. There is no specified time limit for serving as an IRB Chair or Vice-Chair. The IRB Chair or Vice-Chair may resign at any time by submitting a letter of resignation to the Institutional Official. The Institutional Official may remove the IRB Chair or Vice-Chair from the committee if he/she is not able to complete his/her responsibilities as an IRB Chair or Vice-Chair.

## **Responsibilities**

### **IRB Member Responsibilities**

IRB members are responsible for:

1. Attending monthly IRB meetings and participating in the review of research
2. Completing human subjects research training
3. Conducting and/or assisting with review of research by expedited procedures
4. Serving on IRB sub-committees as needed
5. Working with investigators to resolve issues related to IRB review
6. Maintaining current knowledge of applicable regulations, laws, and institutional policies
7. Participating in discussions of issues related to the review of human subjects research including policy development

IRB members should report any attempts of undue influence to the Institutional Official.

The responsibilities above apply to both regular members and alternate members.

### **Alternate IRB members**

Alternate members are appointed to serve as a substitute for a regular IRB member and/or to ensure that the IRB has the appropriate expertise to review research (e.g. prisoner representative, pharmacy representative, etc.). The IRB roster indicates which regular member for which the alternate can substitute. When an alternate member substitutes for a regular IRB member, the alternate receives and reviews the same materials as the regular IRB members. The IRB minutes will document when an alternate member substitutes for a regular member. If both a regular IRB member and his or her alternate(s) attend the same IRB meeting, the regular member is acting as the official voting member of the IRB for review of research protocols, unless the minutes clearly indicate otherwise. A designated alternate IRB member for a regular IRB member may substitute for the regular IRB member for an entire meeting or at any time during a meeting.

### **IRB Vice-Chair**

In addition to assuming the responsibilities of an IRB member, the IRB Vice-Chair is responsible for: supporting the IRB Chair, and assuming the duties of the IRB Chair when the IRB Chair is not available or has conflict.

### **IRB Chair**

In addition to assuming the responsibilities of an IRB member, the IRB Chair is responsible for:

1. Providing leadership and guidance to the IRB
2. Conducting convened IRB meeting
3. Reviewing minor deviations and/or other events that qualify for review by expedited procedures
4. Assisting with investigations/audits of investigators
5. Reviewing and signing correspondence related to IRB determinations
6. Ensuring that IRB members with a conflict of interest may be present for the discussion but not vote on the research where he/she has a conflict
7. Conducting review of IRB minutes
8. Selecting new IRB members
9. Assisting with the annual evaluation of the IRB

### **Consultants**

If the board does not have the appropriate expertise to review a research study, a consultant may be used to assist in the IRB review. Consultants may be used for exempt, expedited, and convened studies. The IRB Chair or designee will determine if a consultant is needed. In addition, any member of the IRB may request the use of a consultant during the review process. The IRB Chair or designee will contact the consultant to determine if he/she is able to act as a consultant to the IRB. The consultant will be asked to provide a written review. If determined to

be necessary, the consultant will be asked to attend the meeting. If the consultant attends the meeting, the consultant does not count towards quorum and cannot vote. The use of consultants will be documented in the meeting minutes.

## **ADMINISTRATIVE SUPPORT**

Persons requesting a decision on whether research or scholarly activity is subject to the Human Research Protection must contact IRB. The IRB staff will make the decision based on the following factors: (1) whether or not the activity is subject to CCC-UPR's FWA, (2) when the activity represents Research and involves Human Participants, and (3) whether or not CCC-UPR is "engaged" in the research activity. The staff will make the decision based on whether the activity is subject to CCC-UPR's FWA when the activity represents "research", involves humans as participants, and whether CCC-UPR is engaged in the research activity.

Determination requests made in writing (e-mail, or hard copy), must include sufficient documentation of the proposed research to allow a fully informed determination. The IRB will respond to these written requests with a written determination. The submitted materials and a copy of the determination letter will be kept on file.

The IRB and any subcommittees shall maintain minutes of all meetings and shall record their findings and recommendations as part of these minutes. These records shall be maintained in IRB office.

## **QUORUM**

A quorum will be at least 5 members of the IRB but one Non-scientist/non-affiliated (community member) must be present.

Members may not vote on own or immediate family/department projects. For reasons other than conflict of interest, abstentions do not alter the quorum, or change the number of votes required.

## **ANNUAL REPORT**

The IRB shall submit an annual report to the Executive Director on its activities for the year and shall make its report available to the Faculty. The Chair of the IRB shall also submit an annual report of IRB activities and deliberations to the Institutional Official and the Medical Director of Faculty.