Puerto Rico Clinical and Translational Research Consortium

EXPIRED IRB

I. **Procedure Title:** Protocol with expired Institutional Review Board

II. **Overview/Procedure Description**

A. **Policy:** The Puerto Rico Clinical and Translational Research Consortium (PRCTRC) assures that all research protocols conducted in the PRCTRC are in compliance with the Institutional and Federal regulations.

B. **Purpose**: This policy establishes the process to follow after the Institutional Review Board (IRB) chair determines whether current participants may continue and what procedures are necessary to continue in an expired research protocol.

III. Area(s) of Responsibility

Regulatory Knowledge and Support Core (RKS), PRCTRC staff, Investigators/staff research.

IV. **Procedure Details**

1. The investigator will not be allowed to enrolled new participants.

2. The Research Subject Advocate (RSA) will request from the investigator a copy of the letter provided by the IRB chair which states if the continuation of research interventions or interactions in previously enrolled subjects should only continue (e.g., administration of study medication that the subject needs, blood samples to verify toxicity, etc.). A copy of this document will be kept in the investigator's study file.

3. The RSA is responsible for notifying the Supervisors of Clinical Research Resources and Facilities Core (CRF), Technologies and Resources for Core Laboratories (TRCL) and RKS Core Leader regarding what study procedures should continue for previously enrolled subjects in a study where the IRB approval has expired.

4. The RKS Core Leader will notify the Core Leaders of both CRF and TRCL when any protocol IRB approval expires. This notification will include the title of the protocol and the investigator's name.

5. The RSA will prepare a report to include: the number of participants involved, the research interventions or interactions, and the time period that took place regarding the procedures and the subjects. This report must not exceed the date for which the authorization was granted by the IRB. This document will be kept in the investigator's file.