	University of Puerto Rico Medical Sciences Campus Human Research Subjects Protection Office	Effective: 9/1/2008
		Rev. 07/01/2014
ADMINISTRATIVE REVIEW		

Purpose:

To define the procedure for the administrative assessment of research project applications before IRB review.

Applicability:

IRB Staff

Sources:

OHRP Guidance on Written IRB Procedures

Policy:

The efficiency and effectiveness of the IRB is supported by administrative procedures that allow IRB members to have adequate time for thorough assessment of each proposed research project, and that the documentation they receive is complete and clear in order to facilitate the evaluation of the study design, procedures, and conditions.

Procedure:

Submissions

Upon receipt of an application submitted through the IRBWise, documents are sorted by category, submission deadline, and assignment to the appropriate IRB panel.

Administrative Assessment

The IRB staff conducts an administrative assessment of all study submissions received from investigators. The purpose of the administrative assessment is to verify the completeness of the application, including submission of all the required documentation and is not an official determination of the IRB.

There are several steps in the process of an application "pre-review" or administrative assessment. First an IRB Coordinator or "protocol manager", assesses the submission for completeness.

The submissions will be classified as one of the following:

- Application for New Research Project
- Application for Continuing Review
- Protocol Amendment
- Adverse Event Report
- Final Report / closure letter
- Miscellaneous

Then the documents are evaluated by the submission content. As part of this administrative assessment, a preliminary determination is made as to the type of review (Full Board, Expedited, or Exempt) required for the particular submission. Assignments to IRB panels are determined according to the scope of research with consideration given to date received and deadline for submission.

Incomplete Submissions

Incomplete applications are not presented for IRB review until the investigator provides all necessary materials as determined by the IRB staff. The protocol manager through IRBWISE notifies the submitting investigator of any outstanding documentation or additional information

requirement before the application is scheduled for review. The protocol manager returns to the investigator those incomplete applications that require substantial revision or additional information. The investigator must complete the request and re-submit the revised application.

Scheduling for Review

Complete applications that appear to meet qualifications for Exempt or Expedited review are presented to the IRB Chairperson or his/her designee. If a submission meets the Exempt or Expedited review requirements, the review is conducted as described in the SOP for Exempt and Expedite review. All other applications are added to the agenda for the next appropriate meeting for review by the convened IRB.