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

INSTITUTIONAL REVIEW BOARD MEETINGS

Purpose:

The policies in this section provide the framework to ensure that IRB meetings are conducted and documented in a consistent manner in order to meet federal and institutional requirements.

Source:

45 CFR 46.109
21 CFR 56.109

Applicability:

IRB Staff, IRB Members

Background:

The Federal Regulations for Human Research Subject Protection assigns IRB the responsibility to review and the authority to approve, require modification in, table, or disapprove all research activities involving human subjects.

Policy:

The IRB will review proposed research at convened meetings on which a quorum is present, except when an expedited review procedure is applicable. The three IRB panels of the UPR MSC, will alternate in bi-weekly meetings throughout the academic year. Extra-ordinary meetings might be called by Chairperson and the IRB Office Director.

Procedure:

The UPR MSC has three constituted institutional review board panels. Currently IRB meetings are being held every two weeks throughout the academic year. Protocols may be submitted to the IRB at any time, however in order to be considered for IRB review, complete research project applications must be received two weeks prior to the IRB meetings. This ensures that the IRB Committee receives the assigned materials for review on time. In addition to timing, other considerations such as the topic of the research and the length of the agenda are taken to account for assigning a proposal to specific panel's meeting.

A yearly calendar of IRB meetings is posted in the IRB website and distributed to all IRB members by academic year. The Chairpersons of the IRB panels are expected to attend all meetings of the convened Board. The Director of the OPPHI, IRB Administrator or designee and the protocol managers will attend the scheduled meeting.

The agenda for the meeting and all protocol related documents are electronically available to the IRB members. The electronic IRB management system also allows IRB members to conduct electronic reviews. However, for the convenience of IRB members, paper copies of the meeting agenda, along with meeting materials, are also sent to IRB members in advance. Each member of the IRB will also receive a copy of the minutes of the previous meeting. The content of each IRB file is available for all IRB members to review before, during and after the meeting through IRBWISE or at the IRB office.

<u>Determination of Quorum</u>

In order for a research protocol to be approved, it shall receive the approval of the majority of the members present at the meeting.

- A quorum is defined as the majority (50% +1) of the voting members.
- A quorum consists of regular members and/or their alternate members and includes: at least one member whose primary concerns are in scientific areas, and one member whose primary concerns are in nonscientific areas.
- When FDA-regulated research is reviewed there shall be one member who is a physician, nurse or pharmacist.
- An alternate member may attend in the place of an absent regular

member in order to meet the quorum requirements outlined above.

- Consultants will not be used to establish a quorum and may not vote with the IRB.
- IRB members who leave the room due to a conflict of interest cannot be counted towards quorum.

Reviewer System

Each protocol on an IRB agenda will be assigned by the IRB Chair to a primary and a secondary reviewer. The primary reviewer will review and present the research proposal at the IRB meeting. Treatment protocols will have a physician, nurse or other qualified healthcare professional as the primary reviewer. The secondary reviewer will substitute for the primary reviewer if the latter is absent at the meeting, but will otherwise provide an additional level of review and discussion. After the primary and secondary reviewers have presented their comments, all Board members discuss the documents received for review and add their comments.

Designated alternates may be used. When alternates are used, the list of Committee members should identify the member(s) for whom each alternate may substitute. To ensure maintaining an appropriate quorum, the alternate's qualifications should be comparable to the member to be replaced. The Committee minutes will document when an alternate replaces a member. When an alternate substitute for a member, the alternate must have received and reviewed the same material that the member received or would have received.

Use of Consultants

As the need arises, the IRB may invite individuals with competence in special areas to assist in the review of complex issues that require experience beyond or in addition to what is available on the IRB. These individuals participate in the discussion of protocols but do not vote or count toward the quorum. When consultants are asked to review a protocol, they are asked to disclose to the IRB any conflict of interest related to the protocol. If they do, they will be excused from the review of the protocol and the IRB will identify another consultant.

Voting

Each action to be reviewed and voted upon at a convened IRB meeting requires a quorum, as defined above. To approve an action, a majority (50% +1) of the IRB voting members present must approve. Abstentions count toward the quorum but not toward the required majority. If a quorum should fail during a meeting either due to voting members leaving or because no non-scientist member is present, the IRB will not take any further actions or votes unless the quorum is restored. If the quorum cannot be restored, the meeting adjourns.

After a research project is discussed a motion is made and a vote taken under one of the following categories:

- **Approved**

  (1) Approval means that the study may be conducted as presented to the Board.

  (2) Approval is communicated to the investigator by IRBWISE system followed by an official letter signed by the IRB chair. The letter will specify items and version dates that have been approved.

  (3) A stamped, approved consent form will be available in the IRBWISE file or included with the letter, if applicable.

  (4) Requirements for the consenting process will be noted in the letter.

  (5) Reminders of the Principal Investigators' responsibilities will be defined as footer or an attachment in the approval letter.

- **Pending**

  (1) The Board requires minor changes or responses from the investigator for approving the study.

  (2) The Board may vote to permit a specific reviewer (who has served as the primary reviewer for the study) or the Chairperson to review and accept the requested clarification/revisions.

  (3) Pending status is communicated by letter to the investigators.

Board recommendations are also available at the electronic file to facilitate the process.

(4) After the changes are submitted and reviewed, the Board appointed reviewer may recommend approval which will prompt staff to generate an approval letter.

- **Deferred**

(1) The Board has some major concerns which need to be addressed by the Investigator or the Board may require input from a consultant prior to making a decision.

(2) Deferral is communicated by letter to the Investigator.

(3) The research project must undergo another full board meeting after changes are made.

(4) Reasons for deferral must be stated during the research project discussion.

- **Disapproved**

(1) The Board denies approval for a specific project after review. A reviewer cannot disapprove a study. This action can only be taken by a convened Board.

(2) Disapproval is communicated by letter to the investigator.

(3) Reconsideration of disapproval may be requested by the investigator in writing and addressing the letter to the chairperson.

(4) Additional information may be made available to the Board before the reconsideration hearing. The investigator may appear before the Board if requested.

- **Acknowledged**

  (1) The Board acknowledges through a letter that a requested review has taken place.

  (2) The letter may request additional information or a response.

  (3) The Board's acknowledgement does not constitute approval.

  (4) Future action on the part of the investigator may be outlined in the Board's acknowledgement letter.

  (5) The Board acknowledges acceptance of the minutes of the previous meetings if there are no perceived discrepancies.

  (6) The Board acknowledges actions taken by the Expedited Reviewers.

- **Suspended:**

  Suspension is when research on an approved protocol is partially or completely stopped by the IRB pending future action. The IRB may find it is in the best interest of the enrolled subjects to allow continued participation in the research interventions or interactions, but enrollment of new subjects cannot occur during IRB suspension. The convened IRB will determine the appropriate actions and if a study is to be terminated. Examples include:

  (1) Occurrence of an unanticipated problem in research involving greater than minimal risk to subjects or others.

  (2) When IRB is investigating a research protocol for issues with serious or continuing non-compliance with federal regulations. Projects that have not recruited subjects and approval have remained suspended for more than six months are to be considered closed.

  (3) Expiration: When continuing review of a research protocol does not occur prior to the end of the approval period specified by the IRB, IRB approval expires automatically and a project's approval

is suspended.

(4) By request: Investigators and sponsors may at times need to temporarily suspend a protocol for a variety of other reasons not related to noncompliance or risk to subjects. In these cases, the IRB will suspend the study until the investigator requests in writing that the suspension be lifted. Such suspensions may need to be reported to the Institution as deemed necessary by the Chair or IRB.

- **Terminated:**

  The IRB permanently stops research procedures associated with an active approved protocol.

Convened Meeting using Speaker Phone

Only when not otherwise possible to have a quorum, when an IRB member is not physically able to be present during a convened meeting, but is available by telephone, the meeting can be convened using a speakerphone. The member who is not physically present will be connected to the rest of the members via speakerphone. In this manner, all members will be able to discuss the protocol even though one member is not physically present. Members participating by such speakerphone call may vote, provided they have had an opportunity to review all the materials the other members have reviewed.

IRB Meeting Minutes

The minutes of each IRB meeting will document the separate deliberations, actions, and votes for each protocol undergoing initial or continuing review by the convened IRB, and the vote on all IRB actions including the number of members voting for, against, and abstaining. The minutes must be sufficient in detail to demonstrate:

- **Attendance at the meeting**, including:
  - If an alternate is present and who they are representing.
  - The initial and continued presence of a majority of members

(quorum), including at least one non-scientist.
    - If a consultant is present.

- For each protocol discussed, the minutes should describe:

    - If a Committee Member is excused from the meeting due to a conflict of interest during the discussion and vote on the study. The name of the committee member is also recorded.
    - Actions taken by the IRB.
    - Discussion of any controversial issues and their resolutions, including the documentation of the consultant's findings.
    - The level of risk (e.g., minimal or greater than minimal).
    - Justification for any change in study design or risk level for amendments and continuing reviews.
    - The approval period, if less than one year.
    - The vote on these actions including the number of voting "for," "against," or "abstaining." (The IRB members at our institution frequently use consensus approach).
    - In order to document the continued existence of a quorum, votes should be recorded in the minutes using the following format: Total=xx, For: xx, Against: xx, and Abstained: xx (Board members who abstain are identified by name in the minutes).

When protocol revisions are requested or a proposal is disapproved, the basis for the revisions or disapproval is included.

Studies approved under exempt or expedited categories will be included in the corresponding minutes.

When approving research involving children, the meeting minutes must document the risk involved in the research and that the Committee made the findings in accordance with 45 CFR 46.404, 405, 406 and 407, and 21 CFR 50.51-54. The minutes must also document the assent process, including whether a waiver of assent has been approved, in accordance with 45 CFR 46.408 and 21 CFR 50.55 and 45 CFR 46.116 Subpart A.