

4.0 INSTITUTIONAL REVIEW BOARD: INVESTIGATOR COMMUNICATIONS

4.1 IRB Submissions

For paper submissions: Due to the delay in using campus mail, hand delivery is the best method of assuring prompt submission to the IRB Office (Ground Floor Hieber Building, use McKee Place Entrance), however it is not required. When submitting paperwork, please include an IRB Receipt Form (see Appendix A) which will be signed by an IRB staff member at the time of delivery. If campus mail is used, a copy of the Receipt Form will be faxed back to the principal investigator upon receipt of the research protocol by the IRB Office. If a copy is not returned after a reasonable amount of time, it is the investigator's responsibility to follow up by calling the IRB Office (412-383-1480).

For OSIRIS submissions: All new protocol submissions must be submitted through the University of Pittsburgh IRB's electronic submission system which can be accessed at www.osiris.pitt.edu.

4.2 IRB Telephone Communications - Information to be Readily Accessible

The following information should be readily available when telephoning (412-383-1480) the IRB Office to ascertain the status of a submitted protocol:

- The IRB number, if assigned
- The Principal Investigator's name
- Protocol title
- Date and type of submission

4.3 Communication within the OSIRIS system

Investigators and/or research coordinators can communicate with the IRB within the OSIRIS system by clicking on the "send comments to IRB staff" button under My Activities. Please note that this method should only be utilized to send a comment and not to respond to issues raised by the IRB during its review.

A complete history of the study is also available in the OSIRIS system under the History Tab. Investigators are encouraged to check the status of their submission and to contact the person listed as the "owner" of the study if the submission has remained in one state for a long period of time.

4.4 Written Communications of IRB Decisions

Decisions of the IRB will be communicated to principal investigators through a letter outlining the approval status and/or the concerns, questions and/or comments of the IRB. If the study has been sent into the IRB Office as a paper submission, communications will take place via e-mail. If the study is in OSIRIS, all communications will be included in the system. The system will automatically send an e-mail to the listed investigators and primary research coordinator when correspondence is available for viewing.

Decisions from a full board meeting will be verbally available the next day, however written communications are not released until the minutes of the meeting are reviewed and approved by the vice chair of the committee that performed the review and/or the IRB chair or vice chair. The latter requirement typically necessitates a period of five (5) working days from the IRB meeting date. **Initiation of the research study may not proceed until a written notification of final approval has been received from the IRB Office.**

The decisions of the IRB will fall into one of the following categories:

1. Full Approval

The principal investigator may initiate the study upon written notification of full approval of the research protocol and, if applicable, the informed consent document, from the IRB chairperson or vice chairperson.

2. Approval Subject to Modifications

This decision is conveyed when the protocol is recommended for approval by the IRB pending the investigator's response to IRB-directed changes.

For paper submissions: The principal investigator must provide a memorandum responding to the IRB's recommendations and a modified protocol and/or consent form with the respective changes highlighted. The principal investigator's response will be reviewed by the IRB chairperson or his/her designee. If the response is acceptable, the principal investigator will receive (i.e., typically within 5-7 working days following receipt of the response by the IRB office) written notification of IRB approval, and may then initiate the study.

For OSIRIS submissions: The principal investigator must provide a response to the IRB recommendations by modifying the OSIRIS application which includes the protocol and consent documents which is tracked by the OSIRIS system. The principal investigator's response will be reviewed by the IRB chairperson or his/her designee. If the response is acceptable, the principal investigator will receive (i.e., typically within 5-7 working days following receipt of the response by the IRB office) written notification of IRB approval, and may then initiate the study.

3. Reconsideration

This decision is conveyed when the IRB has a number of significant questions and concerns regarding the research protocol that could not be resolved at the IRB meeting. The principal investigator may not initiate the study until a response is received and the protocol reviewed at a subsequent full board meeting.

For paper submissions: The principal investigator must provide a memorandum responding to the IRB's concerns/comments, recommendations and/or questions. If the protocol and/or consent form is modified, the changes must be highlighted.

For OSIRIS submissions: The principal investigator must provide a response to the IRB recommendations by modifying the OSIRIS application which includes the protocol and consent documents which is tracked by the OSIRIS system.

Unless otherwise requested by the principal investigator (e.g., timeframe necessitates review prior to next scheduled meeting), the reconsideration response will be scheduled for review by the same full board committee that originally reviewed the research protocol. If the reconsideration response is submitted to a different IRB committee, the response will be reviewed by the primary reviewers of the original IRB in addition to the review by the second IRB committee. The Principal Investigator is encouraged to be present at the IRB committee meeting wherein his/her research protocol is being reconsidered for approval.

4. Disapproval

The IRB may disapprove a research protocol based on its identification of major scientific or ethical problems which, in the committee's opinion, cannot be readily resolved by the principal investigator. When a research protocol is disapproved by the IRB, the principal investigator is not authorized to initiate the study. A new protocol addressing the IRB's reason(s) for the initial disapproval must be resubmitted for full board review. The principal investigator must provide a memorandum responding to the IRB's concerns, comments, recommendations and/or questions. The new protocol must undergo all of the required ancillary reviews prior to submission to the IRB.