



CAMC Institute – Research and Grants Administration
CAMC/WVU-Charleston Division Institutional Scientific Review Board

Policy Title	Institutional Scientific Review Board
Version	1
Version Date	January 11, 2010
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SCOPE:

This policy details procedure for processing protocols submitted to the ISRB for review. The purpose of this policy is to:

1. Identify the types of protocols requiring ISRB review;
2. Create timelines to ensure timely review and response of submitted paperwork;
3. Define responsibilities of parties involved in the submission and review of submitted paperwork;
4. Detail forms of notification to study investigators and study staff of reviews of submitted paperwork; and
5. Define and detail the appeals process after ISRB review and response

1. Identify the type of protocol requiring ISRB review

ISRB review will be required and applied to any research study submitted to the Office of Research and Grants Administration that is investigator initiated and meets at least one of the following criteria:

- a. Randomizing patients to one or more treatment arms and/or;
- b. Collecting any tissue, blood, urine or other biological specimens for the use in research and/or;
- c. Reviewing, evaluating or assessing behaviors in a group or individual setting and/or;
- d. Recording individuals by voice, video or photograph.

In general, scientific review by the ISRB will not be required for (1) retrospective chart review studies when an investigator is collecting data and (2) research where individuals are conducting surveys, whether written, oral and/or computer based. The Research and Grants Administration staff will administratively review these two types of studies and will determine whether or not an ISRB review is necessary.

2. Create timelines to ensure timely review and response of submitted paperwork

All paperwork requiring ISRB review is due to the Office of Research and Grants Administration no later than the end of the first business day of each month for review at that month's ISRB meeting.

The Office of Research and Grants Administration will conduct an initial review of all submitted paperwork prior to providing to the members of the ISRB.

The Office of Research and Grants Administration will compile packets to be distributed to members of the ISRB within a time frame to allow members adequate time to conduct a thorough scientific review.

Monthly ISRB meetings will be scheduled for the second Monday of each month, granting there are not conflicts with holidays, etc.

The Office of Research and Grants Administration will create a letter detailing the comments, suggestions and requirements from the ISRB within an adequate time frame for study investigators and study staff to revise and return the study paperwork for further review. The letter will include a information on deadlines for resubmission of the revised paperwork for additional ISRB review.

Revisions and/or responses to the ISRB reviews must be submitted within three months of the initial review. If revised paperwork is not submitted during the three-month time it will be considered as a new submission to the Board.

3. Define responsibilities of parties involved in the submission and review of submitted paperwork

Principal Investigators maintain the ultimate responsibility for the submission of all paperwork for review within the time frames outlined in this policy.

At submission, the Office of Research and Grants Administration staff will conduct an initial review to ensure all paperwork is in order and the study is understandable. If concerns arise in the understanding of the study the paperwork will be forwarded to the ISRB Chair or his/her designee for review and comment.

After the Office staff and/or the ISRB Chair/designee has determined the study is adequate to move, forward packets will be prepared and distributed to all ISRB members scheduled to attend that month's meeting.

For each study, two ISRB members will be assigned as the Primary Reviewers.

The ISRB will review the submitted study during the convened ISRB meeting. After completion of review, the ISRB members present will determine the level of review required for the revised submission with choices being:

- a. Full ISRB committee

b. ISRB Chair only

Upon submission of the revised paperwork, the Office staff will conduct an initial review then forward the resubmitted paperwork to the Full ISRB or ISRB Chair or his/her designee as outlined in the initial ISRB review letter.

4. Detail forms of notification to study investigators and study staff of reviews of submitted paperwork

The Office of Research and Grants Administration staff will be responsible for all regular contact between the ISRB and study investigators and/or study staff.

If, after Office staff and/or ISRB Chair/designee review, it is determined the submitted paperwork is not adequate to be reviewed by the full ISRB, notification of this determination will be sent via email and/or phone call to the Principal Investigator and/or study coordinator. Further guidance will be provided to the Principal Investigator and/or study coordinator at this time.

The Office of Research and Grants Administration will create a letter detailing the comments, suggestions and requirements from the ISRB. This letter will be sent to the principal investigator and study staff listed on the application. The principal investigator and study staff will be asked to revise and return the study paperwork for further review, comment and/or approval.

After revised paperwork is received and reviewed, the Office staff will prepare review notification, as directed by the ISRB Chair or his/her designee to either be:

- a. Scientific Assurance
- b. Additional revisions required

5. Define and detail the appeals process after ISRB review and response

If, after receiving the ISRB response to submitted paperwork, the Principal Investigator disagrees with the Institutional Review Board's comments, the Investigator will need to notify the ISRB Chairperson in writing within 7 days to request an appeal. The letter needs to be submitted to the attention of the ISRB Coordinator. A separate subcommittee of three members will be appointed to serve as the Appeals Committee. One member each will be appointed by the ISRB and the Director of Research and Grants Administration on behalf of the President of CAMC Health Education and Research Institute and the Principal Investigator.

The subcommittee will review all submitted paperwork and ISRB meeting minutes prior to meeting with the Principal Investigator. Any decision made by the subcommittee advisory panel will become final with no further appeals process.