



Policy Name: Full Board Initial Review Policy and Procedures			
Approved			Date: 11/01/08
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Replaces Policy: N/A			Dated: N/A

I. POLICY

A. No human research will be initiated without prospective IRB review and approval.

B. Required Elements

The protocol submitted to the IRB must include all required elements (adapted from the DHHS research grant application guide PHS 398). The protocol format is:

1. specific aims,
2. background and significance,
3. preliminary studies,
4. research design and methods,
5. protection of human subjects,
6. references/literature citations,
7. consultants,
8. facilities available,
9. investigator brochure if applicable, and
10. appendix to include surveys, questionnaires, study calendars, etc.

C. FDA Regulated Products

All studies involving FDA regulated products will be reviewed and approved in accordance with FDA regulations.

II. PROCEDURES

A. Submission by the Principal Investigator

1. The Investigator will electronically submit an application packet. Upon completion of the on-line submission, the Investigator will print, sign and hand deliver or fax a Statement of Assurance Form and, as appropriate a Conflict of Interest Form.

B. Processing by IRB Administration

1. Upon receipt of an application, the application is checked by the IRB staff for completeness. The Investigator will be notified by the IRB staff of additional items necessary to complete the submission.
2. Study personnel listed on the application are checked against the Compliance Office database to ensure required institutional training has been completed. If not all personnel have completed training, a letter is sent to the PI stating that IRB approval of the study will not be released until documentation that all study personnel have completed required education is received in the IRB office.
3. The application is assigned to the appropriate IRB and the IRB Administrator administratively reviews the application packet for regulatory compliance and adherence to established guidelines.

C. Assignment of Reviewer

1. In consultation with the Chair, the IRB Administrator will assign initial protocols and protocol amendments to primary reviewers.
 - a) Each Primary Review Group will include a minimum of three IRB members:
 - (1) one scientific member with the relevant expertise and knowledge needed to conduct an in depth review,
 - (2) one non-scientific member, and
 - (3) one member with the knowledge needed to conduct an in depth review.
 - b) No Board member who may have a conflict of interest is assigned to a study as primary reviewer.
2. If an IRB member notifies the Administrator that he/she does not feel competent to review a protocol/amendment assigned, the material will be reassigned.
3. The IRB Administrator will ensure the prisoner representative is a primary reviewer for any initial protocols involving prisoners and is a reviewer for any amendments and continuation applications for protocols involving prisoners; the prisoner representative will be a voting member of the convened meeting where these documents are discussed

D. Use of Non-IRB Members with Expertise

1. The IRB Administrator, chair, and/or any voting member may request additional expertise when reviewing a protocol.

2. The chair or designee will contact an individual with the expertise requested to determine:
 - a) credentials to provide the expertise, and
 - b) availability.
3. The required expertise will be sought among the MUSC faculty if available and without a conflict of interest.
4. The chair or designee will specify the concerns/questions requiring expert review.
5. The chair will notify the principal investigator that additional expertise has been secured to review the protocol and/or related documents.
6. The IRB Administrator will ensure the expert has all the materials required to review and address the concerns/questions.
7. Depending on the request and need for the additional expertise, the chair will ask the expert(s) to discuss concerns/questions with a Board member, document his/her review, and/or attend the relevant convened Board meeting.

E. Review Material for IRB Members

1. The complete application is made available to all IRB members by the IRB Administrator emailing a link address to all members. The application consists of the following items.
 - a) Request for Full Board Review Application,
 - b) Study protocol,
 - c) Investigator drug brochures,
 - d) The consent documents or waivers of consent documents,
 - e) HIPPA or HIPPA waiver document,
 - f) Advertisements,
 - g) Questionnaires and Surveys,
 - h) Budget,
 - i) Principal Investigator Statement of Assurance,
 - j) Conflict of Interest Disclosure, and
 - k) Drug and/or Device Sheets.
2. The primary reviewers are provided checklists for assessment to ensure consistency and completeness:
 - a) IRB Reviewer Checklist (Full Board Review)
 - b) Informed Consent Document Checklist
 - c) Special Subject Populations Checklist if applicable
 - (1) Children

- (2) Cognitively Impaired or Persons Unable to Consent
 - (3) Pregnant Women, Fetuses, Neonates
 - (4) Prisoners
3. All IRB reviewing members scheduled to attend a Board meeting are electronically sent a list of the protocols under initial review for the scheduled meeting at the same time primary reviewer groups receive their assignments electronically.
 4. The application submission is generally sent out 3 weeks prior to the next scheduled Board meeting.

F. Review Criteria - The primary reviewers are assigned to assess the following:

1. risks to the subjects have been minimized by using sound research design, and, whenever appropriate, using procedures already being performed on the subject for diagnostic or treatment purposes,
2. risks, including physical, psychological, social and economic risks, are reasonable relative to anticipated benefits,
3. selection of subjects is equitable,
4. the informed consent process and document are in compliance with MUSC policies and federal regulations,
5. provisions are adequate to protect the privacy of subjects and confidentiality of data,
6. if the research subjects include a vulnerable group, additional safeguards have been included to protect the rights and welfare of these subjects and that all special requirements for the populations have been adequately addressed, and
7. the recommended frequency of continuing review. Reviewers are encouraged to communicate with the Principal Investigator to more clearly understand the study and to clarify any issues.

G. Documentation of Primary Review

1. Using the designated review procedure, the primary reviewer (the Chair, Vice-Chair or the Chair's Designee) will have rights to enter reviewer comments to the on-line application.
2. The Administrator requests the reviewers' critiques by a stated deadline.
3. The primary reviewers finalize their reviews by categorizing their recommendation as approval, conditional approval, or disapproval and summarize the suggested modifications that may be required for the study to achieve an acceptable benefit/risk ratio.

4. The IRB staff enters the reviewers' comments into the electronic database and discusses these comments with the reviewers and IRB Chair as necessary for clarification.

H. Communication between IRB Administration and PI prior to meeting

1. The IRB staff sends all comments to the Principal Investigator and Study Coordinator electronically or by email. A date of when their response is due is given based on when the comments were received.
2. The Administrator checks the Principal Investigator's response and marks the changes to correspond with the comments and makes copies of the response for the Board's review.
3. The IRB Chair reviews the Principal Investigator's response and seeks additional information from reviewers and/or the Principal Investigator when necessary to clarify issues/concerns.
4. Additional Principal Investigator responses that come in after the agenda has been sent out will be reviewed by the Chair when possible to determine if additional information would be useful; all available investigator responses will be presented to the Board at the meeting.

I. Convened IRB

1. During the Board meeting, each initial study is presented by the Chair and/or Primary Reviewer(s), discussed and voted on individually. The Principal Investigator will be present if requested by any Board member or if the Chair/Administrator thinks the Investigator needs to be present to clarify issues/concerns.
2. The Board may approve, table, disapprove, or require modifications to secure approval. If the Board requests minor modifications which do not substantially impact the risk/benefit analysis, the Board may approve the study contingent on final review and approval by the Chair or the Chair's Designee. No required changes to the informed consent document will be deferred to the Chair's or Chair's Designee approval unless the Board has stipulated the wording of these changes. Changes that are substantive in nature must be brought back to the full Board at a convened meeting.

J. Communication between the Institutional Review Board and the Office of Research and Sponsored Programs

1. If the study is sponsored by a Corporate or Industry sponsor, the Approval form, Informed Consent and Budget are sent to the Office of Research and Sponsored Programs. ORSP will notify the

Administrator by email once the contract negotiations are complete and the study can be released. If there is a change in the budget from what was submitted to the IRB, ORSP will send a copy to the IRB.

K. Post-IRB Communication with the PI

1. The informed consent, HIPAA Authorization, and advertisements are date stamped with the approval date. The Principal Investigator is notified when the study is approved and can be released.
2. If the study is approved without substantive changes, the Administrator will prepare the approval for the Chair's signature.
3. If the study requires further modifications that are minor in nature, the Chair will review them; if acceptable, the Chair will sign the approval and the Administrator will prepare the study for release.
4. If required modifications are substantive in nature or if the Board tables or disapproves the study, the Chair or Chairs' Designee will notify the Principal Investigator in writing. Principal Investigator responses to substantive modifications due to table or disapproval are presented to the Full Board for review, discussion and vote at a convened meeting.
5. If a Principal Investigator has appealed the Board's decision in writing to the Chair, the Administrator will place the item on the next available agenda for full Board discussion and vote. The Principal Investigator will be notified of the date, time and place of the meeting.

L. Duration of Approval

1. For all approved research protocols, the IRB may determine that the research risk is of significant magnitude meriting review more frequently than on an annual basis. Examples of increased risk include sensitive issues (HIV and AIDS), vulnerable populations (school children) and safety (protocol deviations and AEs).
2. Unless renewed, a protocol is active for one year. The expiration date, the last day the protocol is approved, is calculated as 365 days after approval. The calculation of the approval period is based on the date of the convened meeting at which the IRB approves the protocol and not on the date when the reviewer approves any requested modifications.