



Policy Name: Convened Meetings of the IRB			
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I. POLICY

A. Introduction

The Institutional Review Boards of MUSC have the responsibilities, Ethical Principles, Authority and Independence as specified in HRPP Guide Section 2.1, functions as specified in HRPP Guide Section 2.2 is comprised of a membership as specified in HRPP Guide Section 2.3 and approves research activities as specified in HRPP Guide Section 2.4.

B. Convened Meetings

The IRBs shall meet regularly with meetings scheduled for the entire calendar year and posted on the IRB website. Members shall be informed of the meeting schedule prior to the end of the previous calendar year. When required, at least one member who is knowledgeable about or experienced in working with identified vulnerable populations or as the prisoner representative will be present. Members must contact the IRB office if they are unable to review for a meeting, and must find their replacement from the alternate list. In consultation with the Chair, the IRB Administrator will assign initial protocols and protocol amendments to primary reviewers, taking into consideration the knowledge of and experience required to review the research. The application, including agenda and materials related to the research is sent to the Primary Review Group between two and three weeks prior to the convened meeting. The meeting agenda is delivered to all IRB members (including those to participate via teleconference) the Friday prior to the meeting.

C. Primary Reviewers

Each Primary Review Group includes at least one scientific member and one non-scientific member as well as other reviewer(s). No reviewer will review a study if he/she has a conflict of interest. The IRB Chair, in consultation with the IRB Administrator, will assign studies to Primary Review Groups relative to expertise of the members. As determined by the IRB Administrator, appropriate parts of the OHRP and FDA regulations are referenced or attached to the application package for use by the reviewers. The Administrator will request Reviewer critiques by a

deadline. The primary and secondary reviewers shall perform an in-depth review of all materials provided to them.

D. Members Not Assigned As Reviewers

Members who are not assigned as the primary reviewers are also sent the Review Application, Human Subject document, and Informed Consent Document(s) and any advertisements for review at the same time that primary reviewer groups receive their assignments.

E. Quorum

A quorum of the membership of the IRB, including at least one physician-scientist and at least one member whose primary concerns are in nonscientific areas, must be met before a meeting can be convened. The presence of more than one-half the voting membership plus one shall constitute a *quorum*. Quorum shall be maintained for the discussion and vote on each research activity on the agenda. Members not present for, or recused from, the discussion shall not be counted towards the quorum. In the event an IRB member must participate by teleconference, the member will receive all pertinent material prior to the meeting and the minutes of the convened IRB meeting will reflect that the member participated by teleconference.

F. Guests

Guests are permitted to attend IRB meetings at the discretion of the IRB Chairperson and will be instructed that meeting discussions are confidential and cannot be disclosed to others.

G. Discussion and Vote

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. 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.

H. IRB Meeting Minutes

The Administrator prepares Minutes of the convened meeting, which are approved by the Chair. Minutes show attendance at meetings and actions taken by the Board including frequency of continuing review. Minutes document the vote on all IRB actions including the number voting for, against, recusing and those abstaining.

Specifically, the Minutes shall include:

1. Voting members (or alternates) present; (documented by sign-in sheet)
2. Voting members (or alternates) absent; and (documented by sign-in sheet)
3. Voting members (or alternates) participating via teleconference (videoconferencing not in use at MUSC);
4. Staff and guests, including consultants, present;
5. Action voted by the IRB;
6. Separate deliberation of each action;
7. Unless explicitly stated, research undergoing full board IRB review and approval is deemed to be greater than minimal risk and research undergoing expedited review or deemed exempt from IRB approval is deemed to be minimal risk.
8. The names of IRB members leaving a meeting during discussion of an action due to a conflict of interest and indication that the conflicting interest was the reason for the absence;
9. Number of votes for, against, and abstaining from voting;
10. Members attending but not present for the discussion and vote;
11. Replacement of a primary member by an alternate member;
12. Recusals of voting members;
13. For initial and continuing review, the IRB approval period, i.e., one year or less;
14. Findings and determinations of the IRB required by regulation including, when applicable, waiver or alteration of the consent process, research involving pregnant women, human fetuses and

neonates, research involving children, and research involving prisoners;

15. The approval period for initial and continuing reviews;
16. Justification for any deletion or substantive modification of information concerning risks or alternative procedures contained in the DHHS-approved sample consent document.
17. The rationale for significant risk/non-significant risk device determinations;
18. Deliberations on non-compliance and stipulated remedial action will include the rationale for determination of the non-compliance to be serious or continuing non-compliance;
19. Summary of the discussion of controversial issues and their resolution;
20. Modification required and/or additional information requested by the IRB;
21. Substantive modifications and/or clarifications relevant to regulatory criteria will be placed on the agenda of the next IRB convened meeting for review and approval or disapproval;
22. Chair or designee approval of research (VA and MUSC), approved in previous IRB meetings pending addressing minor modifications, and,
23. Basis for requiring changes or disapproving the research.

In addition, for VA research, the IRB minutes shall document the determination of the level of risk.

Minutes shall be available for review by the IRB at the next convened meeting and provided to the VAMC Research and Development Office within three weeks of the meeting date. Upon request, IRB minutes will be provided to Organizational Officials of other institutions who, by appropriate IRB Authorization Agreement, rely on the MUSC for IRB review. Minutes shall be retained by the Office of Research Integrity for at least five (5) years, and shall be available upon request to authorized representatives of DHHS and, when applicable, the NIH and FDA for inspection and copying onsite during normal business hours.

Once approved at an IRB meeting, minutes may not be altered by anyone, including a higher authority.

I. Guidance Material for IRB Members Available On-Line and During IRB Meetings

Appendix A contains the verbiage of posters permanently displayed in the IRB conference room where all convened IRB meetings are held. The information is also on the IRB website

<http://research.musc.edu/ori/irb/home.htm>

Criteria for Approval of Research

To approve research under 45 CFR 46.111 (OHRP), 21 CFR 56.111 (FDA) and/or 38 CFR 16.111 (VA), the IRB must determine that all of the following criteria are satisfied:

Risks to Participants

- Risks to participants are minimized by using procedures which are consistent with sound research design and which do not unnecessarily expose participants to risk.
- Risks to participants are minimized whenever appropriate, by using procedures already being performed on the participants for diagnostic or treatment purposes.
- Risks to participants are reasonable in relation to anticipated benefits, if any, to participants, and the importance of the knowledge that may reasonably be expected to result.

Selection of Participants

- Selection of participants is equitable taking into account the purposes of the research, the setting in which the research will be conducted, the special problems of research involving vulnerable populations, the selection criteria, and the recruitment procedures.

Safety monitoring

- When appropriate, the research plan makes adequate provision for monitoring the data collected to ensure the safety of participants.

Privacy

- When appropriate, there are adequate provisions to protect the privacy of participants.

Confidentiality

- When appropriate, there are adequate provisions to maintain the confidentiality of data.

Vulnerable Populations

- When some or all of the participants are likely to be vulnerable to coercion or undue influence, such as children, prisoners, pregnant women, mentally disabled persons or economically or educationally disadvantaged persons, additional safeguards are included in the study to protect the rights and welfare of these participants. *(Note: Subpart B of the DHHS regulations specifies additional protections for pregnant women; Subpart C of the DHHS regulations, for prisoners; and Subpart D of the DHHS and FDA regulations, for children.)*

Informed Consent

- Informed consent will be sought from each prospective participant or the participant's legally authorized representative in keeping with the criteria for content and process.

The process for obtaining consent must incorporate all of the following:

- The investigator will obtain the legally effective informed consent of the participant or the participant's legally authorized representative.
- Consent will be sought only under circumstances that provide the prospective participant or the representative sufficient opportunity to consider whether or not to participate.
- Consent will be sought only under circumstances that minimize the possibility of coercion or undue influence.
- The information that is given to the participant or the representative shall be in language understandable to the participant or the representative.
- The informed consent does not include any exculpatory language through which the participant or the representative is made to waive or appear to waive any of the participant's legal rights.
- The informed consent does not release or appear to release the investigator, the sponsor, the institution, or its agents from liability for negligence.

Additional Considerations:

- ***For FDA-regulated Research:***
 - A statement that notes the possibility that the Food and Drug Administration may inspect the records.
- ***For research involving more than minimal risk:***
 - An explanation as to whether any compensation is available if injury occurs.
 - If compensation is available, what it consists of, or where further information may be obtained.
 - An explanation as to whether any medical treatments are available if injury occurs.
 - If medical treatments are available if injury occurs, what it consists of, or where further information may be obtained.

Information that must be provided as part of the interaction with the participant *and* in the documentation of the consent process, unless waived or altered:

- A statement that the study involves research.
- An explanation of the purposes of the research.
- The expected duration of the participant's participation.
- A description of the procedures to be followed.
- Identification of any procedures which are experimental.
- A description of any reasonably foreseeable risks or discomforts to the participant.
- A description of any benefits to the participant or to others which may reasonably be expected from the research.
- A disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the participant.
- A statement describing the extent, if any, to which confidentiality of records identifying the participant will be maintained
- An explanation of whom to contact for answers to pertinent questions about the research.
- An explanation of whom to contact for answers to pertinent questions about the research participant's rights.
- An explanation of whom to contact in the event of a research-related injury to the participant.
- Contact information for the research team for questions, concerns, or complaints.
- Contact information for someone independent of the research team for problems, concerns, questions, information or input.
- A statement that participation is voluntary.
- A statement that refusal to participate will involve no penalty or loss of benefits to which the participant is otherwise entitled.
- A statement that the participant may discontinue participation at any time without penalty or loss of benefits to which the participant is otherwise entitled.

Criteria for Approval of Research

Additional Considerations:

- ***For Initial Review:***
 - Should review be obtained more often than annually?
 - If this is a multi-site research study, is the management of information that might be relevant to the protection of participants adequate?

 - ***For Continuing Review:***
 - Should review be obtained more often than annually?
 - Should verification be obtained from sources other than the investigator that no material changes have taken place since prior IRB review?
 - Is the consent document accurate and complete?
 - If information has arisen that might affect the willingness of participants to continue to take part in the research, will it be provided to those participants?

 - ***For Review of Modifications to Previously Approved Research:***
 - If information has arisen that might affect the willingness of participants to continue to take part in the research, will it be provided to those participants?
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Belmont Report

The unifying ethical principles that form the basis for the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research:

- **respect** for persons: protecting the autonomy of all people and treating them with courtesy and respect and allowing for informed consent;
- **beneficence**: maximizing benefits for the research project while minimizing risks to the research subjects; and
- **justice**: ensuring reasonable, non-exploitative and well-considered procedures are administered fairly (the fair distribution of costs and benefits.)