# IRB Voting and Actions

## PURPOSE
This policy defines the voting process and actions that the IRB may take on research protocols.

## SCOPE
All BCOM agents, students and trainees involved in human subjects research

## RESPONSIBLE OFFICIAL(S)
Institutional Official, Director of Research, IRB Staff, IRB Chairperson, IRB Committee Members

## POLICY
The IRB makes its independent determination whether to approve or disapprove the protocol based upon whether or not human subjects are adequately protected. Approved research is subject to continuing IRB review and must be reevaluated at least annually. IRB jurisdiction applies to all Research involving Human Subjects at BCOM and BIHP&R. Research that has been reviewed and approved by the IRB may be subject to review and disapproval by officials of BCOM or BIHP&R. However, those officials may not approve research if it has been disapproved by the IRB.
Actionable items by the IRB must be voted on and the vote recorded in the meeting minutes along with the motion as approved.

### IRB Actions
IRB deliberations of new research protocols and amendments result in various outcomes which are communicated in writing to the investigator by the IRB Chairperson after the IRB meeting.

- Full Approval
  A vote to approve an initial or continuing protocol indicates that all IRB concerns have been satisfactorily addressed and that the research may begin as soon as the investigator receives written documentation of IRB approval.

- Approval with Conditions
  A vote to approve with conditions indicates that the IRB has certain conditions that must be addressed before granting full approval. The investigator must address the conditions and the response must be reviewed by the IRB or a designated member of the IRB. A satisfactory response to the conditions will result in notification of "full approval" of the protocol. "Approval with Conditions" does not allow the investigator to begin research and/or data collection. The investigator must obtain "Full Approval" prior to beginning the research and/or data collection.

- Deferral
  A vote for "Deferral" occurs when the IRB is unable to approve initial or continuing research because it cannot make the determination required for approval. In such instances the IRB may defer the decision to a future date. If the IRB defers a decision on a research protocol, the research may not proceed until the IRB reviews the revised research project and approves it at a subsequent convened meeting.

- Disapproval
  A vote for "Disapproval" occurs if the IRB determines that the research cannot be conducted at BCOM, or by employees or agents of BCOM, or otherwise under the auspices of BCOM. When the project as proposed is disapproved the research may not go forward. Disapproval usually indicates that a proposal requires major changes that are not likely to be feasible without complete reassessment of the protocol by the investigator and/or sponsor.

- Suspension
  The IRB Chairperson or the convened IRB may suspend a study at any time if it is determined that further review or evaluation is required. The Institutional Official is notified immediately when a study is suspended. Suspension may be made on the basis of an adverse event, noncompliance or other danger to human subjects. Once a study has been suspended, the IRB must review the study at a convened meeting. The IRB may either remove the suspension or terminate the research project.

- Termination
  Although the chairperson may suspend a study, only the IRB is authorized to terminate a study. Decisions of the IRB to terminate a research study are made at a convened meeting of the IRB. The Institutional Official is informed of the IRB decision and is the responsible party for all required reports to federal agencies and funding organizations.

- Expired Protocols
  IRB Protocols that are not renewed by the date of expiration are automatically closed and the investigator is informed in writing. The IRB is informed of protocol expirations at a convened meeting. All research on the expired protocol must cease.

- Project Completion
  The investigator may elect to close a project prior to the protocol expiration date by completing an IRB closure form. Upon receipt of the completed IRB closure form, the IRB office is authorized to administratively close the research project. The researcher will not be permitted to have any further interaction with research subjects or their data in ways that would require ongoing IRB approval. The researcher may continue to analyze aggregate de-identified data sets following study closure, but may not enroll new subjects or further examine identified datasets.

## Administrative Action

- Administrative Termination of Approved Protocol
  Other BCOM Officials as well as certain state and federal agency officials may, in certain cases, decide that a research study that has been approved by the IRB may not be conducted. Reasons for such an action may relate to research that is viewed as inappropriate or research that is underfunded. In such instances, the BCOM Officials must notify the Investigator and IRB of the action in writing. The notification should indicate the reason for the institutional action. While BCOM Officials may terminate approved protocols, under no circumstances are BCOM, state or federal officials authorized to approve or reinstate research activities that have been disapproved, suspended or terminated by the IRB.

# APPROVAL PAGE

Approved by: _____

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