IRB Protocol Modifications and Amendments

PURPOSE

This policy defines the process for seeking approval for modifications or amendments to approved research protocols.

SCOPE

BCOM agents involved in human subjects research, IRB Committee

RESPONSIBLE OFFICIAL(S)

Institutional Official, Director of Research, IRB Chairperson, IRB Committee

POLICY

A modification or amendment is a change in an approved research protocol. Researchers must submit any amendments to any approved protocol to the IRB for review and approval. The researcher may not modify a protocol without approval of the IRB except in emergent situations where modification of the protocol is necessary to eliminate immediate hazards to the research subjects. In such emergent situations, the IRB must be notified as soon as possible and appropriate amendments submitted for further review and approval. The IRB Chairperson may choose to suspend the research pending further review by the convened IRB.

Modifications or Amendments to Exempt Study Protocols

Federal regulations do not require continuing review for approved exempt research. However, any proposed and/or anticipated change(s) to an exempt protocol requires submission to the BCOM IRB for review and approval as an exempt study. Certain changes may disqualify the research from exempt status.

If information comes to the attention of the IRB suggesting that there are factors increasing the sensitivity and/or potential risk to human subjects in research that otherwise would appear to qualify for exemption under the criteria listed above, the IRB may, in its sole judgment, deem the protocol to be subject to expedited or full IRB review.

The IRB action on proposed amendments is communicated to the researcher in writing. Implementation of the amendments by the researcher can only begin after notification of approval is received.

Modifications or Amendments to Non-Exempt Studies

Minor amendments to previously approved protocols may be approved by expedited review or by full committee review. Minor amendments are defined as changes in the protocol that do not significantly alter the risk/benefit relationship or other study elements. The IRB, in reviewing the amendment(s), should determine if the changes have the potential to affect the research subjects' willingness to continue participation in the study. In such instances, the IRB may require the investigator to obtain re-consent of study participants . The IRB action on proposed amendments is communicated to the researcher in writing. Implementation of the amendments by the researcher can only begin after notification of approval is received.

Major amendments to previously approved protocols represent substantive changes that might increase the risk to human subjects enrolled in the study. Major amendments must be reviewed and acted on at a convened IRB using the Full Committee Review process. The IRB, in reviewing the amendment(s), should determine if the changes have the potential to affect the research subjects' willingness to continue their participation in the study. In such instances, the IRB may require the investigator to re-consent of study participants. The IRB action on proposed amendments is communicated to the researcher in writing. Implementation of the amendments by the researcher can only begin after notification of approval is received

APPROVAL PAGE

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APPROVED
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