Albert Einstein College of Medicine
OF YESHIVA UNIVERSITY

Institutional
Review Board

Amendment Policy and Procedure

An amendment refers to any change to the protocol design, the informed consent document and/or procedure, or the advertisement/recruitment letter, from that originally approved by the IRB, regardless of how minor.

The Principal Investigator (PI) is responsible for obtaining written IRB approval for any proposed amendment to the protocol design, the informed consent document and/or procedure, or the advertisement/recruitment letter prior to its initiation, except in cases where changes are necessary to prevent apparent immediate harm to protocol subjects. In these emergent situations, the PI is responsible for promptly reporting these changes to the IRB.

For an amendment to the protocol design, the PI must submit to the IRB:

- A completed Amendment Form.
- A copy of the sponsor's correspondence and complete amendment, including the summary outline of the amendment (e.g., commercial or agency sponsored research), when applicable.
- A revised protocol. The revised protocol must have an updated version date/number.

For an amendment to the informed consent document and/or procedure, the PI must submit to the IRB:

- For amendments to protocols in PATS:
    - A completed Amendment Form.
    - A copy of the modified PATS ICD(s) with the added/removed text tracked.
- For amendments to protocols not in PATS:
    - A completed Amendment Form.
    - A copy of the currently approved/dated ICD.
    - A copy of the proposed ICD with the changes clearly highlighted. The revised ICD must have an updated version date/number.
    - A clean copy of the proposed ICD for approval/dating by the IRB.

For an amendment to the advertisement/recruitment letter, the PI must submit to the IRB:

- A completed Advertisement Form.

- A copy of the currently approved advertisement/recruitment letter.
- A copy of the proposed advertisement/recruitment letter with the changes clearly highlighted.
- A clean copy of the proposed advertisement/recruitment letter.

Protocol amendments that increase risk to participants, or those requiring substantive changes to the informed consent document, generally require Full Board Review. Examples are:

- Use of a new drug.
- Addition of an invasive procedure.
- Increase in medication dose or a decrease in dose that may increase the risk.
- Addition of vulnerable subjects as a study population.
- Changes in the inclusion/exclusion criteria that may involve populations at greater risk.
- Identification of new potentially significant risks.
- Collection of additional blood samples that exceed the limits permitted for expedited review.

Minor changes to the protocol can generally be reviewed by Expedited Review. These include:

- Administrative changes
- Minor consent form changes
- Minor changes to recruitment procedures, recruitment materials or submission of new recruitment materials to be used in accordance with approved recruitment methods
- Minor changes to study documents such as surveys, questionnaires or brochures
- New study documents to be distributed to or seen by subjects that are similar in substance to those previously approved
- Changes in payment to subjects or the amount subjects are paid or compensated that are not significant enough to affect the risk/benefit ratio of the study
- Decrease in the number and volume of sample collections as long as they do not negatively alter the risk/benefit ratio of the study
- Editorial changes that clarify but do not alter the existing meaning of a document
- Addition of or changes in study personnel
- Addition of a new study site (in many but not all cases)
- Translations of materials already reviewed and approved by an IRB

IRB deadline and meeting dates for full review are found on the IRB website. Expedited amendments are reviewed as they are received.

The Primary or Secondary Reviewer of the original protocol, or the IRB Chairman (or his/her designee), reviews the amendment to determine the level of review required. In compliance with federal guidelines, minor revisions and major revisions with minimal

risks to research participants may be reviewed and approved by expedited review procedures. An amendment cannot be disapproved by expedited review. However, the Chairman or IRB member may recommend that the amendment be reviewed by the full IRB.

Expedited Review:
For amendments receiving expedited review, the reviewer is provided with the amendment, the revised protocol with changes tracked, and applicable informed consent document(s) When all conditions have been met, the amendment is approved. The IRB provides written approval to the investigator together with the approved stamped revised informed consent, when applicable. Approved amendments are included on the IRB Agenda for the members' information.

Full Review:
Amendments requiring full board review are distributed to those members scheduled to attend the upcoming IRB meeting. In addition to the amendment, the Primary Reviewer of the protocol is provided, the revised protocol with changes tracked, the minutes from the IRB meeting at which the protocol was first reviewed, and the approved informed consent document(s). The investigator may be required to attend the IRB meeting. Subsequent to review and approval, the IRB provides written approval to the investigator together with the approved stamped informed consent, when applicable. For protocols conducted at the North Bronx Healthcare Network (JMC/NCB), the IRB Office forwards the approved amendment material to the appropriate administrative office for approval.

Dated: 3/22/02
Rev: 7/12/02
Rev: 8/26/02
Rev: 9/20/02
CCI/IRB Joint Policy - approved
Rev: 12/05 (Administrative)
Rev: 4/20/2012 (JEC approved)
Rev: 12/17/12 (Administrative)