ADIRONDACK HEALTH

TITLE:	Study Initiation for Sponsored Studies – Drug and Device	POLICY #: SOP-2
FOLDER NAME:	Institutional Review Board (IRB)	PAGE: 1 OF: 3
PREPARED BY:	Patricia Druzba, Ph.D. Chair, Institutional Review Board (IRB)	
EFFECTIVE DATE: 12/3/14	REVIEWED/REVISED: 12/3/14, 2/16	
APPROVED BY: Patricia Druzba, PhD (Chair, IRB) Patricia Druzba PhD Chandler Ralph (President & CEO)		

1. The following documents are required to be submitted to the secretary of the IRB for review and approval before a study can be initiated at AMC. Submission must occur at least 14 days before the scheduled meeting. See the Meeting Calendar for the exact date.
    a. The sponsor's protocol.
    b. The draft informed consent. See Informed Consent Requirements in SOP #3.
    c. If juveniles are to be part of the study population, there must be an assent form submitted. See Assent Guidelines and sample Assent Form.
    d. If special populations (prisoners, subjects with dementia, emergency or comatose subjects) are to be part of the study population the subject's legal representative must give consent in the presence of a witness.
    e. If military personnel are to be part of the study, special circumstances may be discussed with the Chair of the IRB.
    f. Subject information sheets, if any.
    g. Subject scheduling cards, if any.
    h. Subject diary pages, if any.
    i. Any other information to be given to subjects, if any.
    j. FD1572, if any.
    k. The Investigator's Brochure or package insert, either of which must contain a table of common (expected) adverse events.
    l. Current CVs of the Principal Investigator (PI) and all Sub-Investigators (SI)
    m. IRB form of approvals from all affected departments. See Approvals Form.
    n. Biomedical engineering review of test devices and any other device supplied by the sponsor. Memo form is adequate.
    o. Copy of all the investigator's (PI and SI) financial disclosures.
    p. Any other documents requested by the IRB.
2. Although all members will receive a complete set of study documents, as secondary reviewers, each member will be responsible for certain sections of the review, based on their area of expertise. The IRB members will review the sections noted above (a), (b), (c), (d), (e), (f), (g), (h), (i) and (p) and report their questions, issues or comments to the Chair of the IRB at least two days before the scheduled meeting. The protocol will be reviewed to determine if it has a sound scientific basis, subjects will be selected on an equitable basis, if the privacy, rights and welfare of the subjects are as protected as

possible, and provision is made for adequate monitoring of the data to ensure the safety of the subjects.

3. The Chair of the IRB, as the primary reviewer, will review (a) – (p) and correlate all questions/issues from the members and the Chair will formulate the questions to be raised with the PI.
4. The PI and/or SI will be asked to attend the IRB meeting at which their protocol will be discussed. They may be asked any pertinent question by any IRB member at that time. The discussion will become part of the meeting minutes. They will not be allowed to vote or be present during the voting.
5. The PI will be apprised of the approval, conditional approval or disapproval of the study by written notice from the Chair or Vice Chair within one week of the vote.
6. If the study is not approved, the Chair or Vice Chair will communicate the disapproval of the study along with the reason(s) for the disapproval. Suggestions may be made by the Chair or Vice Chair to help the PI understand what is being requested by the IRB.
7. The PI may respond to the questions/issues and may re-submit the information to the Chair for approval. If all the issues are addressed appropriately, the protocol/informed consent/other document does not need to be voted on again but may simply be approved by the Chair or Vice Chair. If issues still remain, the Chair will contact the PI/SI and request specific changes before approval will be granted.
8. Conditional approval may be granted, for example, in the case that the protocol is approvable but the Informed Consent Document is not. However, the study may not start until full approval is granted.
9. Approval will be communicated to the PI in writing as soon as is practicable.
10. The recording secretary will "start the clock" on the beginning of the study, which is the date the study is completely approved. The approval will expire the day before the one year anniversary of the approval date or when the IRB determines the risks outweigh the benefits based on reports from the PI, the media, and/or the sponsor. The expiration date will not change even if the protocol, ICD or any other document is submitted for revision after initial approval and before the annual review.
11. The informed consent (and all other documents which will be given to subjects) will be stamped with the name of the IRB, the date it was approved and the date it expires.
12. PIs or SIs will not be allowed to use documents once past their expiration.
13. Any non-compliance with any of part of this SOP, or any other SOP, or Good Clinical Practices (GCPs) must be reported to the IRB immediately and may be grounds for the suspension or termination of the study.
14. In general, a progress report (continuing review) will be required from the PI several weeks before the yearly anniversary of the complete approval. There are times when earlier reporting may be required. The PI will be notified in writing of this earlier reporting, when complete approval is granted. The information from the PI will be given on the Continuing Review Form and will be accepted by the IRB as a complete report unless the IRB determines it would like information from an entity other than the PI. Continuing review approval will not be granted until the IRB receives that information and finds it acceptable and in complete congruence with the information received directly from the PI. The IRB may grant an extension for subject to remain on study while investigation takes place.

15. The IRB may also place restrictions on the study. For example, if the inclusion criterion for age is 18-75, the IRB may restrict admission to ages 21-70. The restrictions, if any, will be transmitted to the PI in writing.
16. No changes to the research protocol will be allowed after the IRB approval is granted, unless exigent circumstances exist. In which case, the IRB is to be informed of those circumstances as soon as possible, but in no case later than two working days. Under normal conditions, changes to the approved protocol can only take place after IRB review and approval of the requested changes.

REFERENCES:

CFR (Code of Federal Regulations): 21 CFR 312
NYCRR: N/A
HFAP: N/A