ADIRONDACK HEALTH

TITLE:	Ongoing Studies	POLICY #: SOP-4
FOLDER NAME:	Institutional Review Board (IRB)	PAGE: 1 OF: 2
PREPARED BY:	Patricia Druzba, Ph.D. Chair, Institutional Review Board (IRB)	
EFFECTIVE DATE: 12/5/14	REVIEWED/REVISED: 12/5/14, 2/16	
APPROVED BY: Patricia Druzba, PhD (Chair, IRB) Patricia Druzba PhD Chandler Ralph (President & CEO)		

1. The IRB may require a six-month report from the Investigator under special circumstances. For example, if the protocol is being conducted in the Emergency Room and the Informed Consent process has been waived for practical reasons. But there may be other reasons which will be delineated at the time of approval.
2. In general, each approved study must be reviewed at least yearly. This will be accomplished by:
    a. maintaining a list of Serious Adverse Events (SAEs) reported by the Principal Investigator or sponsor and reviewing it for unexpected events; this should be done on an on-going basis and submitted to the IRB within 48 hours of knowledge of it;
    b. reviewing the Annual Report submitted by the Investigator, which will include the number and types of minor adverse events which were not mentioned in the protocol, the Investigator's Brochure or the package insert (see the IRB Annual Report Form);
    c. reviewing copies of the informed consents obtained and verifying that the process was documented in the subject's medical record; and
    d. reviewing and approving any changes to the protocol, Investigator's Brochure or staff involved with running the study which have been requested since the initial approval.
3. If the benefits still outweigh the risks and the subjects have been properly consented and had their rights and welfare protected, the study may be re-approved. A clean copy of the Informed Consent Document and all other documents given to the subjects, will be re-stamped with the date of the re-approval and the new expiration date, which is defined as one day before the next yearly anniversary. If the consent changes with new information from the sponsor or any other entity, all active subjects will need to be re-consented following requirements in SOP-3.
4. The results of the continuing approval will be communicated to the Investigator as soon as practicable, along with the re-approved document(s) and a copy of the IRB membership list in effect at the time of the re-approval.
5. If the protocol is not re-approved, the reasons for disapproval shall be communicated to the Investigator as soon as practicable, but generally within one week after the meeting. The PI will then have a chance to respond and correct any deficiencies, answer any questions and re-apply for approval. This appeal can be done in writing or electronically as long as records are kept by each entity.

6. If all deficiencies are corrected and/or all questions answered, the Chair of the IRB may give the re-approval without going back to the entire Board, but the Chair must notify the entire Board at the next regularly scheduled meeting, of that action.
7. Expedited reviews can performed under certain circumstances:
    a. "Data-gathering" studies in which subjects are not being treated in any way and have no procedures of any kind performed on them. These studies will require the abbreviated informed consent to be reviewed at the same time.
    b. Studies with no more than minimal risk.
    c. Minor changes, usually administrative in nature, to a protocol or an Informed Consent Document which has already been approved by the full Board.
8. Expedited review cannot be used to approve any part of a study that had not been approved previously by the complete Board unless it meets at least one of the above circumstances.
9. The Principal Investigator will be notified of the action of the Board as soon as practicable, usually within one week.
10. The Chair of the IRB will inform the hospital administration of all decisions made by the IRB, if the CEO of the hospital is absent from a meeting in which such a decision is made. If the CEO is present, the administration will be deemed 'informed".

REFERENCES:

CFR (Code of Federal Regulations): 21 CFR 56-68
NYCRR: N/A
HFAP: N/A