ADIRONDACK HEALTH

TITLE:	Operations	POLICY #: SOP-1
FOLDER NAME:	Institutional Review Board (IRB)	PAGE: 1 OF: 2
PREPARED BY:	Patricia Druzba, Ph.D. Chair, Institutional Review Board (IRB)	
EFFECTIVE DATE: 1/22/14	REVIEWED/REVISED: 11/14, 1/16	
APPROVED BY: Patricia Druzba, PhD (Chair, IRB) Patricia Druzba PH.D. Chandler Ralph (President & CEO)		

How the Adirondack Medical Center Institutional Review Board (IRB) will operate:

1. The IRB will be known as the Adirondack Medical Center IRB, both here and in the Federal-wide Assurance Program. It will operate as an independent body and will hereafter be called the Board or the IRB. All communications to Investigators must be made in writing and on Board stationery; copies will be kept in the Board's files. In the future, all documents may be kept electronically but must be printable for inspection by regulatory agencies, as needed.
2. There will be a Chair, who will serve as the head of the Board and one or more Vice Chairs who serve as the head of the Board in the absence of the Chair, a Recording Secretary and as many members as the Board sees fit as long as the requirements of #3 below are met.
3. The IRB shall consist of at least five members with experience and expertise in safeguarding the rights and welfare of human subjects. To that end, the Board will have a diverse membership consisting of both genders from diverse professions and will include at least one member from a scientific background, one from a non-scientific background and one from the community who has no other affiliation with the institution other than the role as member of the Board. Each member shall have one vote and actions, approval or disapproval, may be taken after a simple majority vote which will be recorded in the minutes.
4. Individuals with specialized expertise may be invited for discussions at any time the Chair (or any member) requests; they will be known as guests or consultants in the minutes.
5. The Term of Service will be two years with the possibility of a second and third two-year term at the discretion of the Chair and the member.
6. A quorum will consist of three basic members which must include one member from a non-scientific background, one from a scientific background and one community member.
7. Currently, the Board meets every other month. However, meetings may be added or subtracted as needed.
8. No member may participate in the initial review of a protocol or continuing (6-month or annual) review of a project in which the member has a conflicting interest, except to provide information or expertise requested by the Board. That member may not be present during deliberations or voting and it must be so-noted in the minutes of that meeting.
9. Members of the IRB are covered by the hospital's insurance and perform their duties on a volunteer basis, so they will not be compensated.

10. Members will be required to attend at least the minimum number of meetings per year and may be asked to resign if they do not attend 80% of the meetings or if they fail to supply requested documents in a timely manner so as to delay proceedings of the Board.
11. The Chair of the Board will supply training to the other members on a monthly basis for the first year and thereafter, when the need arises. Members who start after the first year will have the training documents available in the Handbook and on the internal website, known as SharePoint when it becomes available.
12. Monthly meetings will take place on the third Thursday of every other month, unless otherwise required, in the Administration Board Room. Notices of meetings will be sent by the Recording Secretary sometime the week before the meeting and will have been published in the minutes of the previous meeting and on the SharePoint website when it becomes available,
13. The Board will operate according to written procedures (SOPs) for:
    a. conducting the initial and the continuing review and for reporting its findings and actions to the investigator and the institution;
    b. determining which projects require more frequent reporting to the IRB;
    c. which projects require verification from sources other than the investigator that no material changes have been made since initial IRB approval;
    d. for ensuring prompt reporting to the IRB of changes made to the research activities;
    e. for ensuring that research activities have not begun before Board approval, except in the case of removing an immediate hazard to a subject;
    f. for ensuring prompt reporting to the Board, appropriate institutional officials and the FDA of the following:
        i. unanticipated problems involving risks to human subjects or others,
        ii. serious or continuing non-compliance with any FDA regulation or the requirements of the Board, or
        iii. any suspension or termination of Board approval.
    g. The expedited review, by the Chair or the Chair's designee, of documents may be used in the following circumstances:
        i. the case of projects which involve no more than minimal risk to subjects, or
        ii. minor changes (usually administrative in nature) in a project that has been approved previously and the change will operate for less than one year until the next continuing review.

Expedited review may not disapprove research already approved. Disapproval can only take place with a non-expedited (full Board) review process. The FDA can terminate or suspend any IRB which abuses the expedited process.

REFERENCES:

CFR (Code of Federal Regulations): 21 CFR 56, 21 CFR 312.58, 21 CFR 312.53
NYCRR: N/A
HFAP: N/A