ADIRONDACK HEALTH

TITLE:	Record Keeping	POLICY #: SOP-7
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: 12/8/14, 2/16	
APPROVED BY: Patricia Druzba, PhD (Chair, IRB) Patricia Druzba PhD Chandler Ralph (President & CEO)		

1. The following is a list of documents which must be kept in the IRB files, separated by investigator/project, which will be stored until 3 years after the research project has been completed or closed, unless a longer storage time is requested by the sponsor:

    a. Copies of all research protocols,
    b. Copies of all amendments to every protocol, if any,
    c. Member evaluations of each proposal,
    d. Each version of the Informed Consent Document (ICD) submitted for approval,
    e. Approved ICDs,
    f. Advertising (approved and not approved),
    g. Progress reports from the PI, annual or interim,
    h. Reports on injuries to subjects, adverse events and SAEs, if any,
    i. Records of continuing review of the protocol and AEs,
    j. Copies of all correspondence between the IRB and the PI,
    k. Statement(s) of significant new findings given to subjects,
    l. Any other documents that will be given to research subjects,
    m. Documents received directly from the sponsor, and
    n. Studies involving special populations or active duty military personnel may require other documentation for the IRB files.

2. The following is a list of documents which must be kept in the IRB General file:

    a. Minutes of all meetings
        (i) Attendance,
        (ii) Issues discussed,
        (iii) Summary of controversial issues and their resolution,
        (iv) Votes on actions-# voting, # for, # against, #abstaining,
        (v) Whether or not any investigator was present for the discussion and voting, which is prohibited,
        (vi) Basis for approval, requiring changes or disapproval,
        (vii) Actions taken,
        (viii) Training, and
        (ix) Q & A.

b. IRB membership lists, in the IRB general file
   (i) Names or initials of the members
   (ii) Gender
   (iii) Earned degree(s)
   (iv) Representative capacity
   (v) Indication of professional experience, including a current CV and other information, such as board certifications
   (vi) Employment by or other relationship to the Institution: full time employee, part time employee, member of the governing board, stockholder, paid consultant, or unpaid consultant

3. Written procedures, known as Standard Operating Procedure (SOPs), and
4. Any other documents pertaining to the operation of the IRB.
5. All IRB records are open to inspection and copying by the FDA upon reasonable notice.

REFERENCES:

CFR (Code of Federal Regulations): 21 CFR 56.115
NYCRR: N/A
HFAP: N/A