
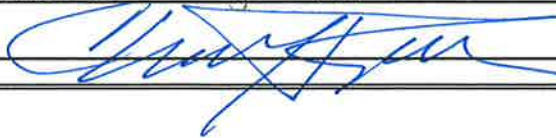


## ADIRONDACK HEALTH

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)		
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.

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- 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