ADIRONDACK HEALTH

TITLE:	Suspension or Termination of Research Activities and Lesser Administrative Activities	POLICY #: SOP-5
FOLDER NAME:	Institutional Review Board (IRB)	PAGE: 1 OF: 1
PREPARED BY:	Patricia Druzba, Ph.D. Chair, Institutional Review Board (IRB)	
EFFECTIVE DATE: 1/22/14		REVIEWED/REVISED: 12/6/14, 2/16
APPROVED BY: Patricia Druzba, PhD (Chair, IRB) Patricia Druzba PhD. Chandler Ralph (President & CEO)		

1. The IRB can suspend or terminate the research activities of any study under a number of circumstances. Some of them are listed below.
    a. Serious or continuous noncompliance by the PI or his/her staff with the protocol, the informed consent processes, or IRB, or GCP regulations.
    b. Serious unexpected harm to a subject or subject(s) which changed the balance between benefit and risk.
    c. The rights or welfare of subject(s) have been abridged.
2. Any suspension or termination of research activities must be reported promptly to the investigator, the appropriate institutional officials and the FDA.
3. An FDA inspector may review noncompliance complaints and issue a letter with her findings. It will include a suggested corrective action to return the investigator to compliance and a timeframe for completion of the action, known as CAPA.
    a. The Agency may take any or all of the following actions:
        i. withhold approval for new studies, direct that no new subjects be enrolled into the ongoing study;
        ii. place the PI and/or SI on the FDA disbarment list;
        iii. terminate ongoing subjects if that action would not endanger them;
        iv. if they find that the noncompliance creates a significant risk to the rights or welfare of the subject(s), they may notify State and other Federal regulatory agencies or any other agencies deemed appropriate of the deficiencies in the operation of the IRB;
        v. disqualify the IRB; and/or
        vi. publicly disclose the actions of the FDA.

REFERENCES:

CFR (Code of Federal Regulations): 21 CFR 312.70
NYCRR: N/A
HFAP: N/A