ADIRONDACK HEALTH

TITLE:	Handling Allegations of Research Misconduct	POLICY #: SOP-8
FOLDER NAME:	Institutional Review Board (IRB)	PAGE: 1 OF: 1
PREPARED BY:	Patricia Druzba, Ph.D. Chair, Institutional Review Board (IRB)	
EFFECTIVE DATE: 12/9/14	REVIEWED/REVISED: 2/16	
APPROVED BY: Patricia Druzba, PhD (Chair, IRB) Patricia Druzba Ph.D Chandler Ralph (President & CEO)		

1. Research misconduct, otherwise known as fraud, is fabrication, falsification or plagiarism in performing clinical research or reporting of clinical research results. If an investigator and/or his/her staff are suspected of misconduct, the IRB Chair must be notified immediately. The Chair, or a designee, will investigate the allegations, generally by performing an audit of the investigator's study files and subject medical records. If the allegations are confirmed or further suspicion is aroused, the Chair will contact the CEO of the hospital with whatever data are available.
2. The CEO of Adirondack Health (AH) will contact the involved-staff member(s) and meet with them to discuss the allegations. If the CEO decides that the allegations have at least some validity, the research project(s) for that investigator will be put on hold. If, after further investigation, the allegations are found to be true, the investigator will be disbarred from conducting clinical trials at any and all AH institutions, and any other actions that the CEO may deem appropriate will be implemented.
3. The CEO will contact AH attorneys and together with the Chair of the IRB, will determine what action(s) need to be taken to protect any subjects already involved in the project.
4. The CEO will notify the sponsor of the study and the FDA when any action is taken to close down a study due to fraud.
5. The FDA has several options and they are not necessarily limited to this list:
    a. they may disqualify the investigator and staff from performing research;
    b. they may disqualify the data resulting from the investigator's efforts;
    c. they may disbar the investigator forever;
    d. they may suspend the site or the entire study; and/or
    e. they may prosecute the investigator and or staff.
6. Some of the reasons for disqualification include, but are not limited to:
    a. failure to obtain IRB approval of the protocol and/or the consent document;
    b. failure to obtain informed consent or to document it properly;
    c. deliberate submission of false data to the sponsor, the IRB or the Agency;
    d. poor record-keeping;
    e. refusal to allow audits or inspections;
    f. failure to follow the protocol; and/or
    g. failure to oversee all the aspects of the protocol.
7. Chair of the IRB will request a final deposition of the allegations from the FDA.

REFERENCES:

CFR (Code of Federal Regulations):

21 CFR 312.42, 21 CFR 312.44, 21 CFR 312.70, 21 CFR 56.120