ADIRONDACK HEALTH

TITLE:	Financial Disclosures	POLICY #: SOP-15
FOLDER NAME:	Institutional Review Board (IRB)	PAGE: 1 OF: 2
PREPARED BY:	Patricia Druzba, Ph.D. Chair, Institutional Review Board (IRB)	
EFFECTIVE DATE: 3/3/16	REVIEWED/REVISED:	
APPROVED BY: Patricia Druzba, PhD (Chair, IRB) Patricia Druzba PhD Chandler Ralph (CEO/President)		

1. In order to assure that no undue financial incentive exists between an Investigator and a sponsoring company, complete financial disclosures will be completed by each Investigator or Sub-Investigator and submitted to the IRB with the initial Application for Approval; again one year after completion of the study; and again at two years after completion of the study. Signatures on the form, indicate certification of the information contained on the form and it is a legal document. A sample of an acceptable form is located under the "Forms" tab on the website. Generally, the form provided to the Investigator by the sponsoring company is acceptable to the IRB.

2. Compensation based on study-outcomes is never allowed. For example, if the sponsor has separate reimbursement rates for positive outcomes compared with neutral or negative outcomes, the study will not be approved by this IRB.

3. Studies with compensation to an Investigator with a significant equity interest in the sponsoring company will not be approved, unless absolute procedures are in place and, during the entire study, in use, which will eliminate bias. For example, Dr. X is promised 51% of stock in the sponsoring company upon study completion. This must be reported to the IRB along with the plan for an unbiased, unrelated assessor for the data for the primary, secondary, and any other outcomes of that study.

4. Studies in which the Investigator has a proprietary interest, such as a patent, licensing agreement, or trademark, etc., in a tested product requires reporting to the IRB along with the same type of plan as in #3 above.

5. Payments to Investigators conducting a clinical trial, and the Institution with she/he is affiliated, may not have a monetary value in excess of $25,000, exclusive of clinical trial costs. For example, Dr. Y has agreed to be part of the Drug Z sponsor's speaker's bureau while he is conducting a trial on Drug Z. The amount Dr. Y will receive $5,000 per patient studied and $25,000 as part of the bureau. This is acceptable, if the rate per subject is commensurate with other investigators and the entire budget is submitted to the IRB. However, it must be monitored to be sure that Dr. Y, the Institution, the office or any of his/her relatives do not receive more than the budgeted amount.

6. The FDA will review all Financial Disclosures and will make the final determination of the reliability of the data provided on the Financial Disclosure Form. It can take any action it deems necessary to ensure the reliability of the study data.

REFERENCES:

CFR (Code of Federal Regulations): 21 CFR 54.1-5