**POLICY**

This policy is designed to meet FDA requirements regarding Disclosure of Significant Financial Interests.

**RESPONSIBILITY**

Investigators

**DEFINITIONS**

**Investigator** means only a listed or identified investigator or sub-investigator who is directly involved in the treatment or evaluation of research subjects. The term also includes the spouse and each dependent child of the investigator.

**Significant financial interests** include, per 21CFR 54**:**

* **Compensation affected by the outcome of clinical studies** means compensation that could be higher for a favorable outcome than for an unfavorable outcome, such as compensation that is explicitly greater for a favorable result or compensation to the investigator in the form of an equity interest in the sponsor of a study or in the form of compensation tied to sales of the product, such as a royalty interest.
* **Significant equity interest** means any ownership interest, stock options, or other financial interest whose value cannot be readily determined through reference to public prices (generally, interests in a nonpublicly traded corporation), or any equity interest in a publicly traded corporation that exceeds $50,000
* **Proprietary interest** in the tested product means property or other financial interest in the product including, but not limited to, a patent, trademark, copyright or licensing agreement.
* **Significant payments** means payments made by the sponsor of a covered study to the investigator or the institution to support activities of the investigator that have a monetary value of more than $25,000, exclusive of the costs of conducting the clinical study or other clinical studies, (e.g., a grant to fund ongoing research, compensation in the form of equipment or retainers for ongoing consultation or honoraria)

**GUIDELINES**

* The FDA requires that financial disclosure information be collected for all investigators (21CFR 54).
* Any pharmaceutical company that submits a marketing application for any drug, biologic product, or device is required to submit certain information concerning the compensation to, and financial interests of, any clinical investigator participating in any clinical study submitted in the marketing application.
* The Pharmaceutical Management Branch, collects this information annually for all NCI-registered investigators.

**PROCEDURES**

Affiliate Responsibilities:

1. Each study team member reports annually all significant financial disclosures in the Registration and Credential Repository (RCR) (<https://ctepcore.nci.nih.gov/rcr/>).
2. A copy of the RCR Financial Disclosure form will be sent to UC-NCORP regulatory office.
3. Each study team member is responsible for reporting per their Institutional policies.

Consortium Responsibilities:

1. Reported significant financial disclosures are reviewed annually by the regulatory office
2. If a significant financial disclosure exists on a study that is opened by the UC-NCORP, this information will be added to the informed consent to disclose this interest to subjects.

**REFERENCE:**

21CFR 54

**ASSOCIATED FORMS:**

RCR Financial Disclosure form

**COMMITTEE APPROVAL:**

UC Policy and Procedure Committee