OBJECTIVE:

Describe the process for documenting financial disclosure as required by 21CFR 54.

REFERENCES:

21 CFR 54	Financial Disclosure
FDA form 3454	**Certification**: Financial Interests and Arrangements of Clinical Investigators
FDA form 3455	**Disclosure**: Financial Interests and Arrangements of Clinical Investigators
ICH E-6, § 8.2.4	Financial Aspects of the Trial
FDA	Guidance Document: Financial Disclosure by Clinical Investigators
OPHS-IRB Manual Section 8.5	Investigator's Role and Responsibilities: Investigator Conflict of Interest

SCOPE:

U.S. FDA regulations and good science require that the investigators conducting a clinical trial do not have a biased interest in the outcome. This document describes OCT's procedure for recognizing and reporting financial interests as required.

RESPONSIBILITY:

The sponsor holds ultimate responsibility for obtaining and submitting financial disclosure to FDA, per the requirements of 21 CFR 54. The site's responsibility for financial disclosure includes the responsibility for providing accurate and timely information, updating the sponsor when financial conditions change, updating the financial disclosure information for 1-year following the marketing application and, retaining relevant financial information for 2-years following the end of the trial.

Note that the regulations require financial disclosure for those studies that FDA will rely on to determine safety and efficacy and ultimately market approval. However, financial disclosure is required for most trials, which may be conducted long before it is clear whether the trial results will be used to support safety and efficacy. OCT will collect financial disclosure information for all trials regardless of the ultimate use of the trial data.

DEFINITIONS:

Compensation affected by the outcome of the trial: Compensation that could be higher for a favorable trial outcome compared to an unfavorable outcome.

Significant Equity Interest: Ownership interest, stock options or other financial interest whose value cannot be readily determined OR equity interest in a publicly traded corporation exceeding $50,000 held by the investigator, his/her spouse or dependent children.

Clinical Investigator: The principal investigator, co-investigator or sub investigator who is directly involved in the treatment or evaluation of research subjects.

Significant payments of other sorts (SPOO): Payments made from the sponsor to the investigator in excess of $25,000 exclusive of the cost of running the trial. SPOO payments might include honoraria, consulting fees, grants, etc.

PROCEDURE:

1.0 Determine if there are any financial arrangements or payments that would require disclosure under 21 CFR 54. Briefly these arrangements include:
- 1.1 Equity positions above $50,000 in the sponsor or other company situated to benefit from a favorable trial outcome.
- 1.2 Ownership interest whose value cannot be readily determined (e.g. non-publicly traded stocks)
- 1.3 Any significant payments of other sorts that either have been made or are promised to the clinical investigator

2.0 If there is no financial information that meets the criteria for reporting, report this to the sponsor, following the sponsor-mandated process, to enable the sponsor to file FDA form 3454 "Certification: Financial Interests and Arrangements of Clinical Investigators".

3.0 If there are financial considerations above the thresholds provided in 21 CFR 54, (1.1 through 1.3 above), detail these considerations and note where the documentation for these considerations resides. Note that FDA has access to view and copy the detailed documentation for these financial considerations.

4.0 Provide this information, as directed by the sponsor, at the beginning of the clinical trial.

5.0 Assure that, any time there is a material change in the financial arrangements covered by this procedure, the updated financial situation is promptly communicated to the sponsor.

6.0 The requirement for financial disclosure extends for 1-year after the completion of the trial. During that period, provide to the sponsor details of any changes that have

occurred. One year after completion of the trial, and if appropriate, advise the sponsor that no change has occurred.

7.0 The documentation of financial disclosure becomes part of the clinical record and must be retained (by the sponsor) for 2 years after the completion of the trial.

REVISION HISTORY

Rev	DCO	Description of Change	Approved by
1	08-012	Edited for clarity and style	Michael V.W. Bergamini