1. PURPOSE

To ensure that financial disclosure concerning compensation to, and financial interests of, clinical Investigators conducting covered clinical studies is obtained and reported in accordance with the Food and Drug Administration (FDA) requirements as set forth in 21 CFR 54.

2. SCOPE

Applies to any clinical study that will be, or has been, submitted in a marketing application, that is relied upon to establish that the product is effective, and in which a single Investigator makes a significant contribution to the demonstration of safety.

3. RESPONSIBILITIES

The Principal Investigator (PI), Investigators, and Study Coordinators (SCs) have the responsibility to disclose any financial relationships with the study sponsor as required by the FDA and Creighton University policy.

4. BACKGROUND

In response to public concern regarding potential financial conflicts of interest of clinical Investigators who study products that undergo FDA review, the FDA published a final rule requiring anyone who submits a marketing application of any drug, biological part, or device to submit certain information concerning the compensation to, and financial interests of, any clinical Investigator conducting the kinds of research covered by the rule.

Effective February 2, 1999, applicants seeking marketing approval of any drug, biological product, or medical device are required to submit to the FDA a list of clinical Investigators who conducted covered clinical studies and to certify to the absence of certain financial interests of all clinical Investigators or to disclose those financial interests. Applicants must disclose the size and nature of the financial interest in question and any steps taken to minimize the potential for study bias that such an interest represents. The financial disclosures by all clinical Investigators are intended to ensure the identification and disclosure of financial interests and arrangements that could affect the reliability of data submitted to the FDA.

Before permitting an Investigator to begin participation in a clinical investigation, the sponsor shall obtain sufficient accurate financial information to allow the submission of complete and accurate verification or disclosure statements required under Part 54. Investigators are committed to promptly update this information if any relevant changes occur during the course of the investigation and for one year following completion of the

study. Sponsors and applicants need only report on the financial arrangements when the marketing application is submitted; however, they are required to keep updated financial information from the clinical Investigators in the company files during the course of the investigation and for one year following completion of a study.

5. PROCEDURE

5.1. Financial disclosure will be obtained for all clinical Investigators participating in clinical research studies.

5.1.1. Prior to Study Initiation

5.1.1.1. The sponsor of a clinical study will be responsible for collecting the financial information from the clinical Investigator(s). This activity may be delegated to designated sponsor representatives such as clinical research associates (CRAs), contract research organization (CRO) personnel, or independent contractors.

5.1.1.2. The clinical Investigator financial information should be collected from all clinical Investigators, per Creighton University Policy 3.1.10., "Externally-Sponsored Projects Financial Conflict of Interest." (The Clinical Investigator Certification/Disclosure Form may be used for financial information submission).

5.1.1.3. The clinical Investigator(s) will be instructed to report any updated information to the sponsor should significant changes occur throughout the course of the investigation and for a period of one year following the completion of the study.

5.1.1.4. The sponsor will document that financial disclosure has been obtained from the clinical Investigator(s). This documentation should be placed in both the sponsor and Investigator regulatory files.

5.1.2. During the Course of the Investigation

5.1.2.1. The sponsor of a clinical study will be responsible for collecting the financial information from the clinical Investigator(s) during the course of an investigation. This activity may be delegated to designated sponsor representatives such as CRAs, CRO personnel, or independent contractors.

5.1.2.2. The clinical Investigator financial information should be collected from all actively participating clinical Investigators at least annually for studies that are conducted over a period of time that is

greater than one year. The Clinical Investigator Certification/Disclosure Form may be used for financial information submission.

5.1.2.3. The sponsor will document each time that updated financial disclosure information is obtained from the clinical Investigator(s). This documentation should be placed in both the sponsor and Investigator regulatory files.

5.1.3. After Completion of the Study

5.1.3.1. The sponsor of a clinical study will be responsible for collecting the financial information from the clinical Investigator(s) through the period of one year after the completion of the study. This activity may be delegated to designated sponsor representatives such as CRAs, CRO personnel, or independent contractors. The Clinical Investigator Certification/Disclosure Form may be used for financial information submission.

5.1.3.2. If any clinical Investigator(s) does not respond to the request for updated financial disclosure information, documentation of the request for financial information submission should be sent to the clinical Investigator(s) and filed in both the sponsor's and Investigator regulatory files.

5.1.3.3. The sponsor will document that updated financial disclosure information was obtained from the clinical Investigator(s). This documentation should be placed in both the sponsor's and Investigator regulatory files.

6. TERMS & ABBREVIATIONS

CFR Code of Federal Regulations
CRA Clinical Research Associate
CRO Contract Research Organization
FDA Food and Drug Administration
PI Principal Investigator
SC Study Coordinator

7. REFERENCES

7.1. Title 21 CFR 54 - Financial Disclosure by Clinical Investigators
7.2. Title 21 CFR 312.53(c)(4) - Selecting Investigators and Monitors
7.3. Title 21 CFR 312.64(d) - Investigators Reports

7.4. Draft Guidance for Industry: Financial Disclosure by Clinical Investigators, 10/99.
7.5. Creighton University Conflict of Interest

8. ATTACHMENTS

None