## 1. Purpose

To describe the requirements of making financial disclosures.

## 2. Scope

2.1. Center for Cancer Research (CCR) Investigators when they are working on studies conducted under a CCR-held Investigational New Drug application (IND) or Investigational Device Exemption (IDE), participating in a CCR-supported Non-Significant Risk (NSR) Device Study or supported by a CCR-held Master File under Office of Sponsor and Regulatory Oversight (OSRO) oversight are subject to financial disclosure requirements.

2.2. Spouses and dependent children of investigators are subject to financial disclosure requirements.

2.3. Limitation

2.3.1. Clinical study personnel are not bound to this procedure when working on non-IND, IDE or NSR studies and/or no interdepartmental collaboration with OSRO as Sponsor is required.

## 3. Responsibilities

3.1. OSRO serves as Sponsor with responsibility for the clinical investigation.

3.2. OSRO Clinical Monitoring manages the financial disclosure documentation process.

3.3. The OSRO Director assesses each clinical study for potential to support a marketing application.

3.4. Investigators will provide accurate and complete financial information.

## 4. References

4.1. 401 Conflict of Interest Policy

4.2. Guidance for Clinical Investigators, Industry, and FDA Staff: Financial Disclosure by Clinical Investigators, FDA, February 2013

4.3. 21 CFR Part 54: Financial Disclosure by Clinical Investigators

4.4. 203-S01 Essential Regulatory Documents

## 5. Definitions

Refer to the OSRO Lexicon.

## 6. Procedure

6.1. The Sponsor is required to obtain clinical investigator financial information before allowing the investigator to participate in a clinical study that would support a marketing application.

6.1.1. Each investigator listed in a form FDA 1572 or F01-406-S02 for a clinical study is required to submit a completed, signed F01-401-S01 CCR OSRO Financial Disclosure Form.

6.2. Clinical investigators shall

6.2.1. Certify the absence of certain financial interests and arrangements that could affect the reliability of data submitted to FDA, or

6.2.2. Disclose those financial interests and arrangements and identify steps taken to minimize the potential for bias.

6.2.3. Update F01-401-S01 CCR OSRO Financial Disclosure Form during the conduct of the trial and during one year after the studies have been completed if there is any change in the information.

6.3. Disclosable financial interests and arrangements are described below.

6.3.1. Note: the term sponsor as used below refers to the party supporting a study with monetary backing or providing the study agent at the time the study was carried out. For clarity, for the purpose of this section only (evaluating financial interests) CCR is not considered to be the sponsor.

6.3.2. Any compensation made to the investigator by any sponsor of the covered clinical study in which the value of compensation could be affected by the study outcome.

6.3.3. A proprietary interest in the tested product including, but not limited to, a patent, trademark, copyright or licensing agreement.

6.3.4. Any equity interest in any sponsor of the covered clinical study, i.e., any ownership interest, stock options, or other financial interest whose value cannot be readily determined through reference to public prices. The requirement applies to interests held during the time the clinical investigator is carrying out the study and for one year following completion of the study.

6.3.5. Any equity interest in any sponsor of the covered study if the sponsor is a publicly held company and the interest exceeds $50,000 in value. The requirement applies to interests held during the time the clinical investigator is carrying out the study and for one year following completion of the study.

6.3.6. Significant payments of other sorts (SPOOS) that have a cumulative monetary value of $25,000 or more and are made by any sponsor of a covered study to the investigator or the investigator's institution during the time the clinical investigator is carrying out the study and for one year following completion of the study.

This includes payments that support activities of the investigator (e.g., a grant to the investigator or to the institution to fund the investigator's ongoing research or compensation in the form of equipment), exclusive of the costs of conducting the clinical study or other clinical studies, or to provide other reimbursements such as retainers for ongoing consultation or honoraria.

6.3.7. F01-401-S01 CCR OSRO Financial Disclosure Form will be collected and assessed as part of the pre-study essential document collection process (Refer to 203-S01 Essential Regulatory Documents).

## 7. Associated Documents

7.1. F01-401-S01 CCR OSRO Financial Disclosure Form

7.2. FI01-401-S01 Instructions for the CCR OSRO Financial Disclosure Form

7.3. Form FDA 1572

7.4. F01-406-S02 Investigator Agreement for Investigational Device Exemption

## 8. Change Summary

| Revision Number | Effective Date | Description of Change |
|---|---|---|
| 1 | 12NOV2019 | New Document |
| 2 | 06APR2022 | Biennial Review<br>Updated document language as required<br>Step 2.1 – added NSR<br>Step 2.3.1 – added NSR<br>Section 4 – added hyperlinks<br>Step 6.4 – removed |
| 3 | 19JAN2024 | Section 5 – added hyperlink<br>Step 6.1.1 – removed and replaced. Each investigator on form FDA 1572 or F01-406-S02 is required to complete F01-401-S01.<br>Step 6.1.2 – removed<br>Section 7 – added hyperlinks<br>Step 7.3 – removed<br>Step 7.3 – added<br>Step 7.4 – added |