Standard Operating Procedure (SOP)

# Financial Disclosure (Sponsor-Investigator Managed)

## 1. Purpose

This SOP describes the process for collecting, reviewing, maintaining, and reporting financial disclosure information from Sponsor-Investigators, Clinical Investigators, and Sub-investigators in accordance with 21 CFR Part 54 for studies managed by sponsor-investigators. This ensures transparency, regulatory compliance, and protection of clinical trial data integrity.

## 2. Scope

This SOP applies to all sponsor-investigator studies conducted under IND/IDE where the Sponsor and Principal Investigator are the same individual. It covers:

* Initial and ongoing financial disclosures.
* Responsibilities for managing and reporting financial interests.
* Retention of financial disclosure documentation.

## 3. Responsibilities

**Sponsor-Investigator:**

* Ensures compliance with 21 CFR Part 54.
* Completes their own Financial Disclosure Form (FRM-QA-005A).
* Collects completed financial disclosure forms (FRM-QA-005A) from all investigators and sub-investigators.
* Reviews disclosures for accuracy and completeness.
* Assesses risks of bias if financial interests exist and documents mitigation steps.
* Submits FDA Form 3454 (no disclosable interests) or FDA Form 3455 (with disclosable interests) at the time of the marketing application submission.
* Ensures copies of the completed financial disclosure forms and copies of FDA Forms 3454/3455 are filed in the Trial Master File (TMF)/Regulatory Binder.
* Maintains records for the required retention period.

**Investigators and Sub-Investigators:**

* Complete and sign the Financial Disclosure Form truthfully.
* Disclose financial interests of themselves and immediate family members (spouse/domestic partner, dependent children, dependents living in the household).
* Promptly update disclosures if financial interests change during the trial or within one year following study completion.

**Quality/Compliance:**

* Audits records for completeness and compliance.
* Verifies retention and availability of disclosure documentation for FDA inspection.
* Ensures only current controlled forms are used.

## 4. Definitions

* **Immediate Family Member:** Spouse/domestic partner, dependent children, and other dependents living in the same household.
* **Equity Interest:** Ownership in the sponsor-investigator company, including stocks and stock options.
* **Significant Payments of Other Sorts (SPOOS):** Payments >$25,000 not related to study costs, such as equipment, honoraria, consulting, or retainers.
* **Proprietary Interest:** Rights such as patents, trademarks, copyrights, or licensing agreements related to the investigational product.
* **Compensation Tied to Outcomes:** Financial arrangements where compensation is affected by study results.

## 5. Procedure

**5.1 Collection of Disclosures**

* Before site initiation, distribute the Financial Disclosure Form (FRM-QA-005A) to all investigators and sub-investigators.
* Sponsor-Investigator completes their own form (FRM-QA-005A).
* Require completion and submission before study-related activities begin.
* File signed forms in the regulatory binder/Trial Master File (TMF).

**5.2 Review of Disclosures**

* Sponsor-Investigator reviews forms for completeness.
* If 'Yes' is selected, request additional supporting documentation (e.g., equity statements, contracts).
* Document risk assessment of potential bias.
* Implement mitigation measures if required (e.g., independent data review, additional monitoring).
* All positive financial disclosures and risk mitigations of potential biases shall be reviewed by the Investigational Review Board (IRB)/Independent Ethics Committee (IEC).

**5.3 Ongoing Updates**

* Require investigators to notify Sponsor-Investigator within 30 days of any changes in financial interests.
* If there are any changes from the original disclosure, collect updated forms and repeat risk assessment and IRB/IEC notification if positive changes at:  
   • Annual continuing review.  
   • Study close-out.
* Sponsor-Investigator ensures all updates are communicated to FDA using forms FDA Forms 3454/3455.
* Maintain all updated disclosures in the regulatory binder/TMF.

**5.4 Reporting to FDA**

* If no investigator has a disclosable interest, complete Form FDA 3454 at the time of marketing application. This form may be found on the FDA website.
* If any investigator has a disclosable interest, complete Form FDA 3455 for each investigator and submit it with the marketing application. This form may be found on the FDA website.
* Document rationale and risk/bias mitigation measures in submission.

**5.5 Retention of Records**

* Retain all financial disclosure documentation for:  
   • 2 years after approval of the marketing application, OR  
   • 2 years after study completion if no application is filed.
* Records must be available for FDA inspection under the BIMO Program (CP 7348.811).

## 6. References

* + 21 CFR Part 54: Financial Disclosure by Clinical Investigators
  + 21 CFR Parts 312 and 812 (IND/IDE regulations)
  + FDA Guidance: Financial Disclosure by Clinical Investigators (2013)
  + FDA BIMO Inspection Manual 7348.811
  + ICH E6(R3): Good Clinical Practice

## 7. Associated Documents

* FRM-QA-005A: Financial Disclosure Form

## 8. Revision History

|  |  |  |  |
| --- | --- | --- | --- |
| **Version Number** | **Description of Change** | **Effective Date** | **Retirement Date** |
| Version 1.0 | Original | dd-mmm-yyyy | dd-mmm-yyyy |
|  |  |  |  |

## 9. SOP Review/Approval\*

|  |  |
| --- | --- |
| **Sponsor-Investigator SOP Review/Approval Signature:**  ***Ink*** *or 21 CFR Part 11 Compliant Signature* |  |
| **Date:** | dd-mmm-yyyy |
| **Printed Name:** |  |
| **Independent/Quality Assurance SOP Review/Approval Signature:**  ***Ink*** *or 21 CFR Part 11 Compliant Signature* |  |
| **Date:** | dd-mmm-yyyy |
| **Printed Name:** |  |

**\****Implementation within 30 days of approval.*