# Form Revision History:

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

# Background and Regulatory Requirement

In accordance with 21 CFR Part 54 (Financial Disclosure by Clinical Investigators), all Sponsor-Investigators, investigators, and sub-investigators must disclose specific financial interests and arrangements that may present a potential conflict of interest. The FDA uses this information to assess the reliability of clinical data submitted in support of marketing applications.

Disclosures are required before participation in the study, during the study, and for one year following study completion. The Sponsor-Investigator is responsible for ensuring these disclosures are collected, updated, and retained.

# Instructions for Completion

1. Complete all sections of this form.

2. If you have no disclosable financial interests, check the applicable box and sign (wet signature or 21 CFR part 11 compliant signature)/date.

3. If you have disclosable interests, provide details in the spaces provided. Attach additional pages if necessary.

4. Submit the completed form to the Sponsor-Investigator before study initiation.

5. Update this form promptly if any relevant financial interest changes occur during the study or within one year after study completion.

6. Sign and date this form with a handwritten signature in ink. **Digital or electronic signatures are not accepted unless Part 11 11-compliant systems are in place.**

**NOTE –** The first page of Revision History, Background Information, and Instructions for Completion does not need to be included with the final documentation that is filed in the Investigative Site File or Regulatory Binder.

# Study Information

|  |  |
| --- | --- |
| **Study Title:**  |  |
| **Protocol Number:**  |  |
| **Sponsor-Investigator Name:**  |  |
| **Sponsor-Investigator Address:** |  |
|  |

# Individual Providing Financial Disclosure:

|  |  |
| --- | --- |
| **Name:**  |  |
| **Role in Study:**  | *Examples – Investigator, Sub-Investigator, Study Coordinator* |
| **Address:**  |  |
|  |
| **Telephone:** |  |
| **Email:** |  |

# Financial Disclosure (21 CFR Part 54)

| **Disclosure Category** **(21 CFR 54)** | **Requirement/Description** | **Investigator Response** | **Details / Comments** |
| --- | --- | --- | --- |
| No Financial Interests | Certify that neither **you** nor your *immediate family* has any financial interests with the Sponsor-Investigator. *Immediate family members include spouse/domestic partner and dependent children.* | ☐ Yes ☐ No |   |
| Equity Interest in Sponsor-Investigator | Ownership interests (stocks, stock options, or equity) > $50,000. | ☐ Yes ☐ No |   |
| Significant Payments of Other Sorts (SPOOS) | Payments > $25,000 (e.g., grants, equipment, retainers, honoraria, consulting fees). | ☐ Yes ☐ No |   |
| Proprietary Interest in Product | Any proprietary rights (patents, trademarks, copyrights, licensing agreements) in the investigational product. | ☐ Yes ☐ No |   |
| Compensation Tied to Study Outcome | Any compensation arrangement affected by study outcome. | ☐ Yes ☐ No |   |
| Other Relevant Financial Arrangements | Any additional financial interests that could reasonably affect data integrity. | ☐ Yes ☐ No |   |

# Certification

By signing below, I certify that:

* The information provided in this form is true, complete, and accurate to the best of my knowledge.
* I understand that I am required to update this disclosure promptly **if any relevant changes occur during the conduct of this study or within one year following its completion.**
* I acknowledge that my disclosure will be retained in the study’s regulatory binder and made available to the FDA upon request.
* I understand that only original handwritten signatures in **ink** are acceptable for this form unless a validated 21 CFR Part 11–compliant electronic signature is used.

|  |  |
| --- | --- |
| **Investigator Signature:** ***Ink*** *or 21 CFR Part 11 Compliant Signature*  |  |
| **Date:**  | dd-mmm-yyyy |
| **Printed Name:**  |  |