This information below is provided in accordance with 21 CFR Part 54 in regard to the following clinical study.

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Sponsor/Funding Source Name:** |  | | **Investigational Product:** |  |
| **Protocol Number/Title:** | | | | |
| **Name of Investigator, Sub-Investigator Completing this Form:** | |  | | |
| **Institution Name:** | |  | **Address:** |  |

|  |  |
| --- | --- |
| Yes No | Indicate by marking Yes or No if any of the financial interests or arrangements of concern to the FDA (and described below) apply to you, your spouse, or dependent children: |
|  | Financial arrangement with the Sponsor/Funding Source, whereby the value of compensation to you, your spouse or dependent children could be influenced by the outcome of the study? This includes compensation that could be greater for a favorable clinical result, compensation in the form of an equity interest in the Sponsor/Funding Source or compensation tied to sales of the product tested in the above study such as a royalty interest.  If yes, the nature of the financial arrangement is as follows: |
|  | Proprietary interest in the Investigational Product such as patent rights or rights under a patent, trademark, copyright or licensing agreement?  If yes, the nature of the proprietary interest is as follows: |
|  | Do you, your spouse or dependent children, or any of you combined have a significant equity interest in the Sponsor/Funding Source such as an ownership interest, stock options or any other financial interest whose value cannot be readily determined through reference to public prices, or any equity interest in the Sponsor/Funding Source (if it is a publicly traded organization) exceeding $50,000, or any combination of these?  If yes, the amount and nature of the equity interest is as follows: |
|  | Have you, your spouse or dependent children, or any of you combined received payments from the Sponsor/Funding Source in excess of $25,000, exclusive of the costs of conducting the clinical studies, such as honoraria, a grant or grants to fund ongoing research, compensation in the form of equipment, or retainers for ongoing consultation?  If yes, the amount and nature of the payment is as follows: |

To the best of my knowledge, the information provided above is correct and complete. I understand that I am obligated to amend this statement and notify the Sponsor promptly if there is any change in this information during the conduct of the clinical studies listed above or during one year after the studies have been completed.

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Signature Date

**To be completed during the Site Close-Out:**

I confirm that I, my spouse or dependent children have no new financial interests or arrangements that would affect the above provided information.

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Signature Date