MATRIX FINANCIAL DISCLOSURE/CERTIFICATION FORM – 21 CFR 54

Please complete all of the information below, including providing your signature where indicated. Once complete, scan the document and email it as instructed to the study sponsor. Retain the original form in your central files.

1. Name and Address of Study Sponsor:

2. Protocol Name:

3. Protocol Number:

4. Study Start Date (mm/dd/yyyy):

5. Principal Investigator (as listed on FDA Form 1572):

6. Your Name:
Institution Name and Address (including phone number):

7. Are you listed as the Principal Investigator on the FDA Form 1572? Yes ☐ No ☐

8. Indicate by marking YES or NO if any of the financial interests or arrangements of concern to US FDA (as described below) apply to you, your spouse, or dependent children. If you respond "yes" to any of the items, please provide the details of the interest or arrangement. Attachments to this document are permitted.

YES	NO	
☐	☐	Financial arrangements whereby the value of the compensation could be influenced by the outcome of the study. This could include, for example, compensation that is explicitly greater for a favorable outcome or compensation to the investigator in the form of an equity interest in the sponsor or in the form of compensation tied to sales of the product, such as a royalty interest. If yes, please describe:_____
☐	☐	Significant payments of other sorts, excluding the costs of conducting the study or other clinical studies. This could include, for example, payments made to the investigator or the institution to support activities that have a monetary value greater than $25,000 (i.e., a grant to fund ongoing research compensation in the form of equipment, or retainers for ongoing consultation of honoraria). If yes, please describe:_____
☐	☐	A proprietary or financial interest in the test product, i.e., patent, trademark, copyright, or licensing agreement. If yes, please describe:_____
☐	☐	A significant equity interest in the sponsor of the study. This would include, for example, any ownership interest, stock options, or other financial interest whose value cannot be easily determined through reference to public prices, or an equity interest in a publicly traded company exceeding $50,000. If yes, please describe:_____

In accordance with 21 CFR § 54.1 to 54.6, I declare that the information provided on this form is, to the best of my knowledge and belief, true, correct, and complete. Furthermore, **if my financial interests and arrangements, or those of my spouse and dependent children, change from the information provided above during the course of the study or within one year after the last participant has completed the study as specified in the protocol, I will complete a new Financial Disclosure/Certification Form to document this change and notify the study sponsor.**

9. Signature:	**10. Date:**

Dear MATRIX Colleague:

As a Principal Investigator (PI)/Investigator of Record (IoR) or sub-investigator who is directly involved in the treatment and/or evaluation of human subjects enrolled in clinical research that may be used to support a marketing application in the United States, you are required to complete, sign and date the following financial disclosure statement.

These statements are study specific. Every investigator listed on the *FDA Form 1572* is required by the U.S Federal Code of Regulations and MATRIX policies to complete and/or update the form at these specific times:

- Before being added to the *FDA Form 1572* and *Delegation of Authority/Duties Log (DoA/DoD)* (i.e., prior to beginning study-associated responsibilities); and
- Within 30 days of discovering or acquiring a relevant, new significant financial interest (SFI) during their time of study involvement and for one year following study end (i.e., last participant follow-up visit).

NOTE: *The study sponsor may request additional financial disclosure updates at their discretion.*

Your disclosure statement must include the relevant, significant financial relationships that you and/or your immediate family members may have with a study sponsor (i.e., an entity providing material support toward the conduct of the study) that could be affected by the outcome of the study:

1. Any compensation provided by a sponsor of the covered clinical study, in which the value of compensation could be affected by the study outcome.

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

3. Any equity interest in a sponsor of the covered clinical study. This would include, for example, any ownership interest, stock options or other financial interest whose value cannot be easily determined through reference to public prices, or an equity interest in a publicly traded company exceeding $50,000. 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.

4. Significant payments of other sorts that have a cumulative monetary value of $25,000 or more and are made by a 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 would include 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 covered clinical study or other clinical studies, or to provide other reimbursements such as retainers for ongoing consultation or honoraria.

In instances where a study may have more than one sponsor for financial disclosure purposes, US FDA interprets the regulation to mean that the dollar amounts triggering reporting apply separately to each sponsor.