

MTN-XXX FINANCIAL DISCLOSURE/CERTIFICATION FORM

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

1. Name and Address of Study Sponsor: **<INSERT NAME AND ADDRESS OF STUDY SPONSOR>**

2. Protocol Name: **<INSERT PROTOCOL NAME>**

3. Protocol Number: **<INSERT PROTOCOL NUMBER>**

4. Study Start Date (pre-filled by LOC): 5. Study End Date (may be left blank until study ends):

6. Principal Investigator (as listed on 1572):

7. Site Number:

8. Your Name:

Institution Name and Address (including phone number):

9. Are you listed as the investigator or a sub-investigator on the 1572 Form? Investigator Sub-investigator

10. Indicate by marking YES or NO if any of the financial interests or arrangements of concern to 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 <input type="checkbox"/> | NO <input type="checkbox"/> | 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: _____ |
| YES <input type="checkbox"/> | NO <input type="checkbox"/> | 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: _____ |
| YES <input type="checkbox"/> | NO <input type="checkbox"/> | A proprietary or financial interest in the test product such as a patent, trademark, copyright, or licensing agreement. If yes, please describe: _____ |
| YES <input type="checkbox"/> | NO <input type="checkbox"/> | 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 patient has completed the study as specified in the protocol, I will complete a new FD Form to document this change and notify the CRS Leader for my study site.**

11. Signature:

12. Date:

Guidance for Completing the Financial Disclosure/Certification Form

Dear MTN Colleague:

As a clinical Investigator, sub-investigator, Protocol Chair or Co-Chair, 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 (hand) date the following financial disclosure statement.

These statements are study-specific and every investigator listed on the *FDA Form 1572* or (for non-IND/IDE studies, as designated by LOC) the *DAIDS IoR Form* is required by the U.S Federal Code of Regulations, DAIDS and Network policies to complete and/or update the form at several, specific times:

- Before being added to the *FDA 1572 / DAIDS IoR Form* and *Delegation of Authority Log (DoA)* (i.e., prior to beginning their study-related responsibilities);
- Within 30 days of discovering or acquiring a new, relevant, significant financial interest (during their time of study involvement and for one year following);
- When being removed from the *FDA 1572 / DAIDS IoR Form* prior to study completion or stepping down as Protocol Chair or Co-Chair (i.e., having completed their study-related responsibilities);
- At the completion of all study-specific activities at the site (i.e., all Investigators and sub-investigators listed on the *FDA 1572 / DAIDS IoR Form* in effect at the time of the last follow-up must disclose). Protocol Chair and Co-Chairs must disclose at the completion of all study-specific activities at all sites.

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, FDA interprets the regulation to mean that the dollar amounts triggering reporting apply separately to each sponsor.