

FINANCIAL DISCLOSURE/CERTIFICATION FORM

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

1. Name and Address of Study IND Sponsor:

2. DAIDS ES Document ID and full protocol title:

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

5. Site ES Site ID:

6. Your Name:

Institution Name and Address (including phone number):

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

8. 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 **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: _____

YES **NO**

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 **NO**

A proprietary or financial interest in the test product such as a patent, trademark, copyright, or licensing agreement.

If yes, please describe: _____

YES **NO**

A significant equity interest in _____ which is 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 notify** _____.

9. Signature:

10. Date: