

DMID Financial Disclosure Form

C O N F I D E N T I A L

Form completion instructions:

The information provided below pertains to the named Clinical Investigator and clinical study. Please *print* or *type* the requested information, and include attachments where indicated. Maintain all original forms with the study site. Due to the confidential nature of this information, do not place this document in the regulatory file for the named clinical study. Completing all fields is required.

Investigator Identification

| | | |
|---|------------|---|
| Principal Investigator/Sub-Investigator Name: | Site Name: | Site Location (address, city, state, country) |
| Protocol Title (full): | | DMID Protocol #: |
| Investigational Product(s) / Device(s): | | |

If you answer YES to any of the Financial Interest statements below, please attach supporting documentation addressing the nature and amount of the interest, arrangement, or payment, and a description of the steps taken to minimize any potential bias.

Do you, your spouse or dependent child(ren)?

| | | | |
|-----------|---|--|---------------------------------------|
| 1. | Participate in any financial arrangement (entered into between any sponsor of the covered study and the clinical investigator involved in the conduct of the covered study), whereby the value of the compensation to you, for conducting the study, could be influenced by the outcome of the study? | Yes <input type="checkbox"/> | No <input type="checkbox"/> |
| 2. | Have a proprietary interest in the above named investigational product/device, including but not limited to patent rights or rights under a patent, trademark, copyright or licensing agreement? | Yes <input type="checkbox"/> | No <input type="checkbox"/> |
| 3. | Have any equity interest in any sponsor of the above-referenced covered study, such as an ownership interest, stock options or any other financial interest whose value cannot be readily determined through reference to public prices? 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. | Yes <input type="checkbox"/> | No <input type="checkbox"/> |
| 4. | Have any equity interest in any sponsor of the above-referenced covered study if the sponsor is a publicly held company, and the interest exceeds \$50,000 in value? 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. | Yes <input type="checkbox"/> | No <input type="checkbox"/> |
| 5. | Received <i>significant payments of other sorts</i> (SPOOS) by any sponsor of the above referenced covered study that have a cumulative monetary value of \$25,000 or more, inclusive of payments that support activities of the clinical 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), and exclusive of the costs of conducting the clinical study or other clinical studies, or to provide other reimbursements such as retainers for ongoing consultation or honoraria? | Yes <input type="checkbox"/> | No <input type="checkbox"/> |

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

| | |
|-----------------------------------|--------------------------------------|
| Signature of Investigator: | Signature Date (dd/mmm/yyyy): |
|-----------------------------------|--------------------------------------|

Send a copy of the Financial Disclosure and supporting documents to:

DMID CROMS Essential Regulatory Documents Group (ERDG)
 Technical Resources International, Inc.
 6500 Rock Spring Drive, Suite 650, Bethesda, MD 20817

Phone: 301-897-7437, Fax: 301-897-7482, Email: ERDG@dmdcros.com

Guidelines for Financial Disclosure Reporting

The following information is extracted from the (Feb 2013) [Guidance for Clinical Investigators, Industry, and FDA Staff Financial Disclosure by Clinical Investigators](#) (<http://www.fda.gov/downloads/RegulatoryInformation/Guidances/UCM341008.pdf>) to provide answers to specific questions related to required reporting:

1. Investigator Identification

Instruction All fields in this box should be completed with the information listed below a-g. The information may be printed on a hard copy of the form or typed on an electronic version of the form prior to printing. The term 'investigator' is all inclusive for those individuals named on the form FDA 1572.

- a. Form header: Provide Investigator information consistent with the investigator information box and the DMID protocol #.
- b. Name of Principal Investigator: Match this name with the name listed in box 1 or box 6 of the form FDA 1572.
- c. Site Name: Provide the full site name.
- d. Site Location: Provide the site address, city, state associated with the named individual.
- e. Full Protocol Title: Match this title with the protocol title listed in box 7 of the form FDA 1572.
- f. DMID Protocol Number: As assigned by DMID and matches the protocol number listed in box 7 of the form FDA 1572.
- g. Investigational Product(s) / Device(s): As identified in the protocol. Multiple products / devices can be listed on one form.

2. To whom this form applies

Instruction All investigators, co-investigators, and sub-investigators listed on the form FDA 1572 must complete this form.

Guidance Identify whose financial interests and arrangements which need to be reported (e.g., clinical investigators, their spouses and dependent children). **Refer to Guidance, [Section IV.D.](#), and Question D2.**

- **Clinical Investigator:** For purposes of financial disclosure, "clinical investigator" means only a listed or identified investigator or sub-Investigator who is directly involved in the treatment or evaluation of research subjects" (21 CFR § 54.2(d)), signs the Form FDA 1572, is identified as an investigator in initial submissions or protocol amendments under an IND, or is identified as an investigator in the marketing application. Individuals not included in the definition of 'clinical investigator' include hospital staff (nurses, residents, fellows, and office staff) who provide ancillary or intermittent care but who do not make direct and significant contribution to the data; individuals who only collect specimens or perform routine tests (such as blood pressure, EKG, x-ray)
- **Spouse and Dependent Child(ren):** The definition of clinical investigator in 21 CFR part 54 also includes the spouse and dependent children of the investigators and sub-Investigators who are required to report. The dollar amount that triggers reporting is the total of the financial interests of the investigator, spouse, and dependent children (21 CFR § 54.2(d)). If a spouse or dependent child is an employee of the sponsor, the clinical investigator should be identified as an employee of the sponsor and no further disclosure is required (21 CFR § 54.4.). **Refer to Guidance [Section III](#) and [Questions B.1](#) and [D.4](#).**
- **Dependent Child(ren):** A dependent child is the investigator's child (whether by blood or adoption), stepchild or foster child who is unmarried, and for whom the investigator provides more than one-half of the child's support. This would include a child who, at any time during the course of the study and for one year following completion of the study, is under the age of 19, under the age of 24 if a full-time student, or who is permanently and totally disabled. Such a child would generally have the same principal residence as the investigator.

3. **Disclosures**

Instruction The five financial interest questions in the DMID Financial Disclosure form must all be checked *Yes* or *No*, as appropriate by the Investigator listed at the top of the form.

Guidance Identify the financial interests and arrangements that must be disclosed in detail. **Refer to Guidance, [Section III.B](#) and [Question C.1](#).**

Question 1:

Any compensation made to the investigator by any sponsor of the covered clinical study in which the value of compensation could be affected by study outcome. **Refer to Guidance [Section III.B.1](#).**

Question 2:

A proprietary interest in the tested product including, but not limited to, a patent, trademark, copyright or licensing agreement. **Refer to Guidance [Section III.B.2](#).**

Question 3:

Any equity interest in any sponsor of the covered clinical study, i.e., any ownership interest, stock options, or other financial interest whose value cannot be readily determined through reference to public prices. 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. **Refer to Guidance [Section III.B.3](#).**

Question 4:

Any equity interest in any sponsor of the covered study if the sponsor is a publicly held company and the interest exceeds \$50,000 in value. 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. FDA recognizes that the dollar value of an investigator's equity holding in a sponsoring company is likely to fluctuate during the course of a study. Clinical investigators should report an equity interest when the investigator becomes aware that the holding has exceeded the threshold and the investigator should use judgment in updating and reporting on fluctuations in equity interests exceeding \$50,000. FDA does not expect the investigator to report when an equity interest fluctuates below that threshold. The threshold amounts apply separately for each sponsor (**Refer to Guidance [Question E.1](#)**), but are cumulative for the investigator and his/her spouse and dependent children. (**Refer to [Section III.B](#)**). **Refer to Guidance [Section III.B.4](#) and [Questions C.2](#) and [C.3](#).**

Question 5:

Significant payments of other sorts (SPOOS) are payments that have a cumulative monetary value of \$25,000 or more and are made by any 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 clinical study or other clinical studies, or to provide other reimbursements such as retainers for ongoing consultation or honoraria. **Refer to Guidance [Section III.B.5](#) and [Questions C.4](#), [C.5](#) and [C.6](#).**

- **Refer to Guidance [Section IV](#), [Question C.4](#),**

“Significant payments of other sorts” would include, for example, payments, retainers and honoraria from a sponsor to a clinical investigator for activities such as participating on committees, providing consultation, or serving as a preceptor (21 CFR § 54.2(f)). Grants to fund ongoing research, including laboratory activities and equipment, and compensation in the form of actual equipment for the laboratory/clinic would also be considered significant payments of other sorts. This means that if an investigator were given equipment or money to purchase equipment for use in the laboratory/clinic but not in relation to the conduct of the clinical study, payment would be considered a significant payment of other sorts (21 CFR § 54.4(a)(3)(ii)). If, however, the investigator were provided with computer software or money to buy software needed for use in the clinical study that payment would not need to be reported.

- Refer to Guidance [Section IV](#), [Questions C.5](#), and [C.6](#) for additional information on SPOOS.

*Payments made to the institution that are not made on behalf of the investigator and are not specifically targeted towards the investigator generally would not need to be reported. Under certain circumstances, however, a grant made to an institution would be considered targeted towards the investigator (and therefore considered reportable); for example, if the grant is worded in such a way that only the investigator could fulfill it. The \$25,000 threshold amount for reporting SPOOS is based on the **cumulative** amount of SPOOS received by the clinical investigator (**including** payments made to the spouse and dependent children) **over the course of the study** and for one year following completion of the study.*

4. Supporting Documentation

- Instruction** If any of the five financial interest questions are checked **Yes**, a memo/statement should be included which specifies the nature and amount of the interest, a description of the steps taken to minimize any potential bias, applicable protocol number, name of Investigator, and date the disclosure statement was written, and the memo/statement must accompany the *DMID Financial Disclosure* form.
- Guidance** Identify the financial interests and arrangements that must be disclosed in detail. Refer to Guidance, [Section III.B](#) and [Question C.1](#).

5. Signature and date

- Instruction** A printed (hard copy) of the *DMID Financial Disclosure* form must be signed and hand dated by the Investigator listed at the top of the form. Please ensure the form header is completed to include the printed name of the Investigator, to ensure multiple pages can be associated with the signature page.

6. Submitting the completed form and attachments

- Instruction** The form must be completed in its entirety; each question must be answered, and the individual for whom the disclosure applies, must provide their signature and date. Forms will be reviewed by DMID CROMS ERDG for completeness. *Incomplete forms will be returned to the Investigator for correction.*

Completed forms and any attachments should be submitted to:

DMID-CROMS Essential Regulatory Documents Group (ERDG)
Technical Resources International, Inc.
6500 Rock Spring Drive, Suite 650
Bethesda, MD 20817
Fax: 301-897-7482
ERDG@dmidcroms.com

7. Maintaining current financial disclosure information

- Instruction** The financial disclosure information must be kept current during the course of the clinical study and for one year after the study is completed. Please submit and retain revised *DMID Financial Disclosure* forms and attachments as these changes apply.
- Guidance** Investigators are obligated to promptly update their financial disclosure information when relevant changes occur during the study and for one year following study completion. Refer to Guidance [Questions C.2](#) and [D.6](#).