

	Office of Sponsor and Regulatory Oversight	Document #: <b>FI01-401-S01</b>
	<b>Instructions for the CCR OSRO Financial Disclosure Form</b>	Revision #: <b>1</b>
		Effective Date: <b>12NOV2019</b>

## Instructions:

- For each identified clinical study, each named Clinical Investigator on a clinical study must complete a F01-401-S01 CCR OSRO Financial Disclosure Form.
- Prior to completing this form, it is recommended that a completed copy of Form FDA 1572 Statement of Investigator be available.
- F01-401-S01 CCR OSRO Financial Disclosure Form is available as a fillable PDF. Alternatively, the Form may be printed and completed by hand using blue or black ink.
- All form fields must be completed.
- Attach supporting documentation where indicated.

## Reference:

Click on the title to link to the guidance. Referring to the guidance may assist in comprehension of the form. [Guidance for Clinical Investigators, Industry, and FDA Staff: Financial Disclosure by Clinical Investigators](#), dated February 2013.

## 1. Section 1: Investigator Identification

**Instructions** All fields in Section 1 must be completed with the information listed below in a-f. 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 Form FDA 1572.

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

## 2. Section 2: Financial Interest Statements

**Instructions** All investigators and sub-investigators listed on Form FDA 1572 must complete this section.

**Guidance** Identify 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 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 Form FDA 1572, is identified as an investigator in initial submissions or protocol amendments under an IND, or is identified as an investigator in a 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).

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- 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

**Instructions** The five financial interest statements in F01-401-S01 CCR OSRO Financial Disclosure Form must be answered by checking *Yes* or *No*, as appropriate.

**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 the 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. 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

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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.

- 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.*

- 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**

**Instructions** If any of the five financial interest statements are checked Yes, then a memo/statement must be included which specifies the nature and amount of the interest, arrangement, or payment, a description of the steps taken to minimize any potential bias, the applicable protocol number, name of investigator/sub-investigator and date the disclosure statement was signed. The memo/statement must accompany the F01-401-S01 CCR OSRO 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**

**Instructions** The fillable PDF Form allows for electronically signing the completed form. If the form is completed using this method, then the date field is not required. Conversely, a printed (hard copy) of F01-401-S01 CCR OSRO Financial Disclosure Form may be used. The investigator/sub-investigator listed in Section 1 must sign and date the form using blue or black ink.

#### **6. Submitting the completed form and attachments**

**Instructions** Completed forms and applicable attachments are submitted to:  
[OSROMonitoring@mail.nih.gov](mailto:OSROMonitoring@mail.nih.gov)

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The submitted F01-401-S01 CCR OSRO Financial Disclosure Form Form is reviewed by OSRO Monitoring for completeness. *Incomplete forms will be returned to the Investigator for correction.*

## **7. Maintaining current financial disclosure information**

- Instructions** 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 revised F01-401-S01 CCR OSRO Financial Disclosure Forms and attachments as these changes apply. Please retain copies of the submission for your files.
- 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.