Instructions:

- For each identified clinical study, each named Clinical Investigator on a clinical study (and listed on a Form FDA 1572 or F01-406-S02) 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 or F01-406-S02 Investigators Agreement for Investigational Device Exemption be available.
- F01-401-S01 CCR OSRO Financial Disclosure Form is available as a fillable PDF.
- All form fields must be completed.
- Attach supporting documentation where indicated.
- Send completed forms to SROSERDG@tech-res.com.

References:

Guidance for Clinical Investigators, Industry, and FDA Staff: Financial Disclosure by Clinical Investigators, dated February 2013. Note: Referring to the guidance may assist in comprehension of the form.

21 CFR Part 54: Financial Disclosure by Clinical Investigators

NIH Office of Technology Transfer (OTT) website: Information for NIH Inventors

1. Section 1: Investigator Identification

Instructions All fields in Section 1 must be completed with the information listed below in a-f. The term 'investigator' is all inclusive for those individuals named on Form FDA 1572 or F01-406-S02.

a. Name of Principal Investigator/Sub-Investigator: Match this name with the name listed in box 1 or box 6 of Form FDA 1572 or F01-406-S02.

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 or F01-406-S02.

e. CCR Protocol Number: As assigned by CCR and matches the protocol number listed in box 7 of Form FDA 1572 or F01-406-S02.

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 or F01-406-S02 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 or F01-406-S02, 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).

- **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.
- **Compensation affected by the outcome of clinical studies**: compensation that could be higher for a favorable outcome than for an unfavorable outcome, such as compensation that is explicitly greater for a favorable result or compensation to the investigator in the form of an equity interest in the sponsor of a covered study or in the form of compensation tied to sales of the product, such as a royalty interest.
- **Sponsor (of the covered clinical study)**: The party supporting a particular study at the time it is carried out (21 CFR Part 54.2(h)). "Support" includes those who provide material support – monetary support or the test product under study. This definition differs from the one in 21 CFR Parts 312 and 812, in which is the sponsor is the person who initiates or takes responsibility for a clinical investigation. In the context of the NCI Intramural program and this disclosure the Sponsor refers to any pharmaceticual collaborator supporting the clinical study under a CRADA.

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, Question C.1 and the NIH OTT website.

***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.

Note: Compensation does not include Center for Cancer Research (CCR) employment salary or payments to the NIH. Sponsor means either 1.) a pharmaceutical collaborator or 2.) the CCR for multicenter clinical trials or if there is no pharmaceutical collaborator.

***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 and the NIH OTT website.

Note: While proprietary interest filed or owned by the NIH should not be listed, if royalities are paid to the investigator, that fact should be disclosed. It is understood that the investigator cannot identify the amount of royalities to be paid.

***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.

Note: More than one sponsor may be identified for a covered clinical study. Each sponsor must be considered individually for financial disclosure purposes.

***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 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, Question C.1 and the NIH OTT website.

5. Signature and date

Instructions The completed F01-401-S01 CCR OSRO Financial Disclosure Form must be digitally signed by the investigator/sub-investigator listed in Section 1.

6. Submitting the completed form and attachments

Instructions Completed forms and applicable attachments are submitted to:

SROSERDG@tech-res.com

The submitted F01-401-S01 CCR OSRO Financial Disclosure Form is reviewed by OSRO 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 submissions 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.