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| <b>SOP TITLE: Financial Conflict of Interest</b>                               |
| <b>Version: 19 SEP 2023</b>  |
| <b>Previous Version(s): 13 APR 2021, 24 SEP 2020, 14 DEC 2017, 11 JUL 2016</b> |
| <b>Effective Date: 25 SEP 2023</b>   |

**BACKGROUND:**

When Sansum Diabetes Research Institute (“the Institute” or “SDRI”) clinical research studies are funded by Public Health Service (“PHS”) agencies or PHS Awarding Components, governance of financial conflict of interest (“FCOI”) applies. In addition, this Policy also applies to those non-PHS-sponsored funders reported by the Federal Demonstration Partnership as using the PHS regulations in their award terms also require adherence to applicable federal regulations concerning FCOI.

**OBJECTIVE:**

Implementation of this Policy promotes objectivity in research by establishing standards that provide a reasonable expectation that the design, conduct, and reporting of sponsored research covered by this Policy will be free from bias resulting from Investigator FCOI’s.

**DEFINITIONS:**

*Clinical Trial* means any research study that involves interaction with human subjects and the concurrent investigative use of drugs, biologics, devices or medical or other clinical procedures, such as surgery. For the purposes of this Policy, Clinical Trial refers to sponsored research complying with PHS Financial Conflict of Interest requirements.

*Conflict of Interest (COI)* exists whenever an individual or an institution is in a position to influence any Center business or transaction, research activity or other decisions in ways which could lead to any manner or form of personal gain for the individual or institution, regardless of source, or his/her family members or business interests. A potential conflict of interest also occurs when there is a divergence between an affiliate’s private interests and his/her professional obligations, such that an independent observer might reasonably question whether the individual’s professional actions or decisions may be affected by those private interests.

*Conflict Management Plan* is a plan developed by the Designated Official and Executive Director when a Financial Conflict of Interest (FCOI) has been identified, in order to appropriately manage a COI. Examples of conditions or restrictions that might be imposed to manage a financial conflict of interest include, but are not limited to:

- Public disclosure of financial conflicts of interest (e.g., when presenting or publishing the research);

- For research projects involving human subjects research, disclosure of financial conflicts of interest directly to participants;
- Appointment of an independent monitor capable of taking measures to protect the design, conduct, and reporting of the research against bias resulting from the financial conflict of interest;
- Modification of the research plan;
- Change of personnel or personnel responsibilities, or disqualification of personnel from participation in all or a portion of the research;
- Reduction or elimination of the financial interest (e.g., sale of an equity interest); or
- Severance of relationships that create financial conflicts.

***Designated Official*** means the individual within the Institution who is responsible for the solicitation and review of disclosures of significant financial interests including those of the Investigator's Family related to the Investigator's institutional responsibilities.

***Family*** means any member of the Investigator's immediate family, specifically, any dependent children, and spouse or domestic partner.

***Federal Demonstration Partnership (FDP)*** is an association of federal agencies, academic research institutions with administrative, faculty and technical representation, and research policy organizations that work to streamline the administration of federally sponsored research. The FDP voting membership is comprised of institutions, emerging research institutions, federal agencies and affiliate organizations and is funded by the following federal agencies: National Science Foundation, National Institutes of Health, Department of Defense, Department of Agriculture and the Environmental Protection Agency.

***Financial Conflict of Interest (FCOI)*** means a Significant Financial Interest (see definition, below) that the Designated Official reasonably determines could directly and significantly affect the design, conduct or reporting of PHS-funded research, or any sponsored research complying with PHS FCOI requirements.

***Financially Interested Companies (FICs)*** are any party that provides funding or support for the research project or whose financial interests would reasonably appear to have the potential to be directly or indirectly affected by the outcome or conduct of the research for whom conflict of interest is being examined. This may also include any other entities that may have a financial interest in this research, given the nature of the study that are not directly supporting the research (Other Notable FICs). The Designated Official maintains a list of these entities known to be associated with research conducted at SDRI.

***Institution*** means any domestic or foreign, public or private, entity or organization (excluding a Federal agency) from which an Investigator (and spouse/domestic partner and dependent children) receives remuneration or in which any person has an ownership or equity interest. For the purposes of this Policy, *Institution* also refers to any entity or organization as describe above reported by the Federal Demonstration Partnership as using the PHS regulations in their award terms.

***Institutional responsibilities*** means the Investigator's professional responsibilities associated with his or her Institutional appointment or position, such as research, teaching, clinical activities and professional practice, administration, research consultation and institutional, internal and external professional committee service.

***Investigator*** means any individual who is responsible for the design, conduct, or reporting of PHS sponsored research, or proposals for such funding. This definition is not limited to those titled or budgeted as principal investigator or co-investigator on a particular proposal, and may include postdoctoral associates, senior scientists, research staff, or graduate students. The definition may also include collaborators or consultants as appropriate.

***New Significant Financial Interest (new SFI)*** means a different type or nature of SFI (e.g., royalty payment versus consulting fees) than what had previously been disclosed from the same source that meets or exceeds the threshold. In addition, a "new" SFI is also considered to be the same type or nature of SFI (e.g., royalty payment) from a different source (e.g., company A versus company B).

***Manage*** means taking action to address a financial conflict of interest, which can include reducing or eliminating the financial conflict of interest, to ensure, to the extent possible, that the design, conduct, and reporting of research will be free from bias.

***Public Health Service (PHS)*** means the Public Health Service of the U.S. Department of Health and Human Services, and any components of the PHS to which the authority of the PHS may be delegated. The components of the PHS include, but are not limited to, the Administration for Children and Families, Administration on Aging, Agency for Healthcare Research and Quality, Agency for Toxic Substances and Disease Registry, Centers for Disease Control and Prevention, Federal Occupational Health, Food and Drug Administration, Health Resources and Services Administration, Indian Health Service, National Institutes of Health, and Substance Abuse and Mental Health Services Administration.

***Research*** means a systematic investigation, study, or experiment designed to contribute to generalizable knowledge. The term encompasses basic and applied research (e.g., a published article, book or book chapter) and product development (e.g., a diagnostic test or drug).

***Senior/Key Personnel*** means the Project Director/Principal Investigator (PD/PI) and any other person identified as senior/key personnel by SDRI in the grant application, progress report, or any other report submitted to the NIH by SDRI under the regulation.

***Significant Financial Interest (SFI)*** means

- a) A financial interest consisting of one or more of the following interests of the Investigator (and those of the Investigator's spouse or domestic partner and dependent children) that reasonably appears to be related to the Investigator's institutional responsibilities:
  - With regard to any publicly traded entity, a significant financial interest exists if the value of any remuneration received from the entity in the twelve months preceding the disclosure and the

value of any equity interest in the entity as of the date of disclosure, when aggregated, exceeds \$5,000.

For purposes of this definition, remuneration includes salary and any payment for services not otherwise identified as salary (e.g., consulting fees, honoraria, paid authorship); equity interest includes any stock, stock option, or other ownership interest, as determined through reference to public prices or other reasonable measures of fair market value;

- With regard to any non-publicly traded entity, a significant financial interest exists if the value of any remuneration received from the entity in the twelve months preceding the disclosure, when aggregated, exceeds \$5,000, or when the Investigator (or the Investigator's spouse, domestic partner, or dependent children) holds any equity interest (e.g., stock, stock option, or other ownership interest); or
  - Intellectual property rights and interests (e.g., patents, copyrights), upon receipt of income related to such rights and interests.
- b) Investigators also must disclose the occurrence of any reimbursed or sponsored travel (i.e., that which is paid on behalf of the Investigator and not reimbursed to the Investigator so that the exact monetary value may not be readily available), related to their institutional responsibilities; provided, however, that this disclosure requirement does not apply to travel that is reimbursed or sponsored by a Federal, state, or local government agency, an Institution of higher education as defined at 20 U.S.C. 1001(a), an academic teaching hospital, a medical center, or a research institute that is affiliated with an Institution of higher education.
- c) The details of this disclosure will include, at a minimum, the purpose of the trip, the identity of the sponsor/organizer, the destination, and the duration. The Designated Official will determine if further information is needed, including a determination or disclosure of monetary value, in order to determine whether the travel constitutes an FCOI with the PHS-funded research. The term Significant Financial Interest does not include the following types of financial interests: salary, royalties, or other remuneration paid by the Institution to the Investigator if the Investigator is currently employed or otherwise appointed by the Institution, including intellectual property rights assigned to the Institution and agreements to share in royalties related to such rights; any ownership interest in the Institution held by the Investigator, if the Institution is a commercial or for-profit organization; income from investment vehicles, such as mutual funds and retirement accounts, as long as the Investigator does not directly control the investment decisions made in these vehicles; income from seminars, lectures, or teaching engagements sponsored by a Federal, state, or local government agency, an Institution of higher education as defined at 20 U.S.C. 1001(a), an academic teaching hospital, a medical center, or a research institute that is affiliated with an Institution of higher education; or income from service on advisory committees or review panels for a Federal, state, or local government agency, an Institution of higher education as defined at 20 U.S.C. 1001(a), an academic teaching hospital, a medical center, or a research institute that is affiliated with an Institution of higher education.

## **RESPONSIBILITIES:**

This Policy is predicated on the expectation that Investigators should conduct their affairs so as to avoid or minimize conflicts of interest, and must respond appropriately when conflicts of interest arise. To that end, this Policy informs Investigators about situations that generate conflicts of interest related to research, provides mechanisms for Investigators and the Institution to manage those conflicts of interest that arise, and describes situations that are prohibited. Every Investigator has an obligation to become familiar with, and abide by, the provisions of this Policy. If a situation raising questions of conflict of interest arises, an Investigator should discuss the situation with the Designated Official.

The Designated Official at SDRI is the Executive Director. The Designated Official is responsible for ensuring implementation of this Policy and may suspend all relevant activities until the financial conflict of interest is resolved or other action deemed appropriate is implemented. Violation of any part of these policies may also constitute cause for disciplinary or other administrative action pursuant to this Policy.

This Policy only applies to Financial Conflict of Interest procedural review that is not already the responsibility of an industry sponsor or prime grant awardee, in which case the process and related forms are provided to SDRI and copies of those procedures and/or forms maintained within the study's regulatory binder. Forms completed under the purview of this Policy are maintained by the Designated Official.

## **PROCEDURES:**

### **1. DISCLOSURE OF SIGNIFICANT FINANCIAL INTERESTS**

All Investigators are required to disclose their Significant Financial Interests (SFI) related to sponsored research covered by this Policy to the Institution on an annual basis during the period of the award, as well as on an ad hoc basis, as described below. The Designated Official responsible for the solicitation, distribution, receipt, review and retention of SDRI's disclosure form, Attachment A, *Investigator's Financial Disclosure Statement*. This disclosure form contains the guidelines consistent with federal regulations that will enable the Designated Official to determine whether an Investigator's disclosed SFI is related to PHS-funded research and, if so related, determine whether the SFI is a FCOI. The Designated Official is also responsible for final review and reporting of FCOI or non-compliance to PHS or funding entity/organization complying with PHS requirements, in accordance with PHS regulations.

#### **a. Annual Disclosures**

All Investigators must disclose their SFI's that are related to the investigator's institutional responsibilities to SDRI, through the Designated Official, on an annual basis. All forms should be submitted to the Designated Official by April 13<sup>th</sup> of each calendar year, or as determined by Designated Official, to reflect financial equity or proprietary interests and/or financial arrangements for the prior calendar year.

**b. Ad hoc Disclosures**

In addition to annual disclosure, certain situations require ad hoc disclosure. All Investigators must disclose their Significant Financial Interests to SDRI, through the Designated Official, within thirty (30) days of their initial appointment or employment.

Prior to entering into PHS-funded research covered by this Policy where the Investigator has an SFI, the Investigator must affirm the currency of the annual disclosure or submit to the Designated Official an ad hoc updated disclosure of his or her SFI's with the Financially Interested Company ("FIC"). SDRI will not submit a research proposal unless the Investigator(s) have submitted such ad hoc disclosures.

In addition, all Investigators must submit to the Designated Official an ad hoc disclosure through the submission of Attachment A, *Investigator's Financial Disclosure Statement* of any SFI they acquire or discover during the course of the year within thirty (30) days of discovering or acquiring the New SFI. Examples of a New SFI include a purchase, marriage, or inheritance.

**c. Travel**

Investigators must also disclose reimbursed or sponsored travel related to their institutional responsibilities, as defined above in the definition of SFI. Such disclosures must include, at a minimum, the purpose of the trip, the identity of the sponsor/organizer, the destination, the duration, and, if known, the monetary value. The Designated Official will determine if additional information is needed (e.g., the monetary value if not already disclosed) to determine whether the travel constitutes an FCOI with the Investigator's research.

2. **REVIEW AND DECISION OF THE DESIGNATED OFFICIAL**

SDRI's Designated Official is responsible for the following disclosure review procedure with respect to reviewing and acting upon information disclosed in Attachment A, *Investigator's Financial Disclosure Statement*:

- a. **Distribution, Solicitation.** The Designated Official supports Investigators and/or Senior/Key Personnel to complete the *Investigator's Financial Disclosure Statement* on an annual or ad hoc basis as described above, by ensuring that this Policy and the *Investigator's Financial Disclosure Statement* form is readily electronically available. Staff may be prompted to complete the form by the Designated Official, as the status of such grants is known to the Designated Official through routine communication with SDRI's Executive Director and SDRI accounting staff.
- b. **Review, Receipt.** The Designated Official review all completed *Investigator's Financial Disclosure Statement* forms to identify where an SFI has been disclosed, and if that SFI related to awarded grants as described above (Section 2.a). Receipt is maintained through email correspondence.

If a disclosure form reveals an SFI, it will be reviewed promptly by the Designated Official in collaboration with SDRI's Executive Director for a determination of whether it constitutes an FCOI. A FCOI exists when the Designated Official determines that an SFI could directly and significantly affect the design, conduct, or reporting of PHS-sponsored research.

If an FCOI exists, the Designated Official will take action to manage the FCOI including the reduction or elimination of the conflict, as appropriate. The Designated Official will consult the Executive Director, or in the application of this Policy to particular situations. If the Designated Official and Executive Director determines that there is an FCOI that can be managed, he or she develops and implements a Conflict Management Plan *Management and Reporting of FCOI's*. The affected Investigator must formally agree to the proposed management strategies and sign the Conflict Management Plan before any related PHS-sponsored research proceeds.

- c. If the Delegated Official or Executive Director identifies an SFI that was not disclosed timely by an Investigator or not previously reviewed by SDRI, step b above will be completed within sixty (60) days of the discovery.
- d. The Designated Official and Executive Director will periodically review the ongoing activity, monitor the conduct of the activity (including use of students and postdoctoral appointees), to ensure open and timely dissemination of the research results, and to otherwise oversee compliance with the Conflict Management Plan.

### 3. REPORTING

The Designated Official will report financial conflicts of interest or non-compliance to PHS or funding entity/organization complying with PHS requirements in accordance with PHS regulations. If the funding for the Research is made available from a prime awardee, such reports shall be made to the prime awardee prior to the expenditure of any funds and within 60 days of any subsequently identified financial conflict of interest such that the prime awardee may fulfill their reporting obligations to the funding entity/organization.

### 4. INVESTIGATOR NON-COMPLIANCE

#### a. Disciplinary Action

In the event of an Investigator's failure to comply with this Policy, the Designated Official and SDRI's Executive Director may suspend all relevant activities or take other disciplinary action until the matter is resolved or other action deemed appropriate by the Designated Official and Executive Director is implemented.

A decision by the Designated Official and Executive Director to impose sanctions on an

Investigator because of failure to comply with this Policy, or failure to comply with the decision of the Designated Official and Executive Director, will be described in a written explanation of the decision to the investigator, and, where applicable, the IRB, and will notify the individual of the right to appeal the decision. SDRI will promptly notify the PHS Awarding Component or other entity/organization complying with PHS FCOI requirements of the action taken or to be taken. If the funding for the research is made available from a prime awardee, such notification shall be made promptly to the prime awardee for reporting to PHS or funding entity/organization covered under this Policy.

**b. Retrospective Review**

In addition, if the Designated Official determines that a FCOI was not identified or managed in a timely manner, including but not limited to an Investigator's failure to disclose a SFI that is determined to be a FCOI, or failure by an Investigator to materially comply with a management plan for a FCOI, the Designated Official will complete a retrospective review of the Investigator's activities and the sponsored research project covered under this Policy within 120 days of the date of determination, to ascertain whether the research conducted during the period of non-compliance was biased in the design, conduct or reporting of the research.

Documentation of the retrospective review shall include the project number, project title, PI, name of Investigator with the FCOI, name of the entity with which the Investigator has the FCOI, reason(s) for the retrospective review, detailed methodology used for the retrospective review, and findings and conclusions of the review.

The Designated Official will update any previously submitted report to the PHS, other entity/organization complying with PHS FCOI requirement, and/or the prime awardee relating to the research, specifying the actions that will be taken to manage the FCOI going forward. This retrospective review will be completed in the manner and within the time frame established in PHS regulations. If bias is found, SDRI will promptly notify the PHS Awarding Component or other entity/organization complying with PHS FCOI requirements and submit a mitigation report in accordance with the PHS regulations. The mitigation report will identify elements documented in the retrospective review, a description of the impact of the bias on the research project and the plan of action to eliminate or mitigate the effect of the bias.

Thereafter, SDRI will submit FCOI reports annually, in accordance with this regulation.

**c. Additional Actions**

Depending on the nature of the FCOI, SDRI may require additional mitigations. If a clinical research project has been designed, conducted or reported by an Investigator with a FCOI that was not managed or reported by SDRI, SDRI will require the Investigator involved to disclose the FCOI in each public presentation of the results of the research and to request an



addendum to previously published presentations.

## 5. TRAINING

- a. SDRI Investigators are informed at the time of appointment or initial employment of their disclosure responsibilities, pertinent federal regulations, and SDRI's FCOI policy, through the distribution and confirmation of receipt of this Policy through SDRI's HR training platform.

Distribution and confirmation of receipt of this FCOI Policy also occurs when SDRI amends it in a manner that affects the requirements of Investigators, or if the Designated Official determines that the Investigator has not complied with this Policy or with a Conflict Management Plan related to their activities.

- b. In addition, SDRI requires that each Investigator complete web-based FCOI training prior to engaging in research funded by PHS, and at least every four years thereafter. This training may also be required if the Designated Official and Executive Director determines that the Investigator has not complied with this Policy or with a Conflict Management Plan related to their activities. Web-based FCOI training is made available through the NIH at: (<http://grants.nih.gov/grants/policy/coi/tutorial2011/fcoi.htm>).

## 6. RECORD RETENTION

The Designated Official will retain all disclosure forms, Conflict Management Plans, and related documents for a period of three (3) years from the date the final expenditure report is submitted to the funding entity/organization covered by this Policy or to the prime awardee, unless any litigation, claim, financial management review, or audit is started before the expiration of the three (3) year period, the records shall be retained until all litigation, claims or audit findings involving the records have been resolved and final action taken. Where applicable, other dates of retention as specified in 45 CFR 75.361 may apply.

## 7. CONFIDENTIALITY

To the extent permitted by law, all disclosure forms, Conflict Management Plans, and related information will be confidential. However, SDRI may be required to make such information available to the PHS Awarding Component and/or HHS, or to other awarding entity/organization, to a requestor of information concerning FCOI related to the sponsored funding or to the primary entity/organization who made the funding available to SDRI covered under this Policy, if requested or required. If SDRI is requested to provide disclosure forms, Conflict Management Plans, and related information to an outside entity, the Investigator will be informed of this disclosure.

## 8. SDRI POLICY CONCERNING SUBRECIPIENT REQUIREMENTS

Should SDRI or an SDRI Investigator enter into a written agreement with a subrecipient (e.g., subcontractors or consortium members), SDRI, as the awardee Institution, will take reasonable steps to ensure that any subrecipient Investigator complies with 42 CFR 50.604(c), by:

- a. Incorporating as part of a written agreement with the subrecipient, terms that establish whether the FCOI policy of the SDRI, or that of the subrecipient will apply to the subrecipient's Investigators. If the subrecipient's Investigators must comply with the subrecipient's FCOI policy, SDRI ensures that the subrecipient certifies as part of the agreement referenced above that its policy complies with 42 CFR Part 50 Subpart F. If the subrecipient cannot provide such certification, the agreement shall instead state that subrecipient Investigators are subject to the FCOI policy of SDRI for disclosing SFI's that are directly related to the subrecipient's work for SDRI. Additionally, if the subrecipient's Investigators must comply with the subrecipient's FCOI policy, the agreement referenced above shall specify time period(s) for the subrecipient to report all identified FCOI to SDRI. Such time period(s) shall be sufficient to enable SDRI to provide timely FCOI reports, as necessary, to the PHS. Alternatively, if the subrecipient's Investigators must comply with SDRI's FCOI policy, the agreement referenced above shall specify time period(s) for the subrecipient to submit all Investigator disclosures of SFI's to SDRI. Such time period(s) shall be sufficient to enable SDRI to comply timely with its review, management, and reporting obligations.
- b. Providing FCOI reports to the PHS Awarding Component regarding all FCOI's of all subrecipient Investigators consistent with this subpart, i.e., prior to the expenditure of funds and within 60 days of any subsequently identified FCOI.
- c. Identify the Designated Official(s) to solicit and review disclosures of significant financial interests from each Investigator who is planning to participate in, or is participating in, the PHS-funded research.

## 9. PUBLIC ACCESSIBILITY

SDRI posts this Policy, which is current and enforced, on its publicly accessible website at <https://www.sansum.org/>. Furthermore, prior to the expenditure of funds, SDRI will publish on a publicly accessible website or respond to any requestor within five (5) business days of the request, information concerning any SFI that meets the following criteria:

- a. The SFI was disclosed and is still held by the Senior and Key Personnel;
- b. A determination has been made that the SFI is related to the PHS-funded research; and
- c. A determination has been made that the SFI is an FCOI.

The information to be made available shall be consistent with the requirements of the PHS regulation.

## REFERENCES

42 CFR 50 Subpart F, Promoting Objectivity in Research

<http://www.ecfr.gov/cgi-bin/text-idx?rgn=div5&node=42:1.0.1.4.23>

Frequently Asked Questions (FAQs)- Responsibility of Applicants for Promoting Objectivity in Research applicable to grants and cooperative agreements (2011 Revised Regulations)

[http://grants.nih.gov/grants/policy/coi/coi\\_faqs.htm#3395](http://grants.nih.gov/grants/policy/coi/coi_faqs.htm#3395)

45 CFR 75.112 Uniform Administrative Requirements, Cost Principles, And Audit Requirements For HHS Awards; Conflict of Interest.

[http://www.ecfr.gov/cgi-bin/text-idx?node=pt45.1.75#se45.1.75\\_136](http://www.ecfr.gov/cgi-bin/text-idx?node=pt45.1.75#se45.1.75_136)

NIH Checklist for Policy Development

[http://grants.nih.gov/grants/policy/coi/checklist\\_policy\\_dev\\_20120412.pdf](http://grants.nih.gov/grants/policy/coi/checklist_policy_dev_20120412.pdf)

**ATTACHMENT A**

**INVESTIGATOR'S FINANCIAL DISCLOSURE STATEMENT**

**DISCLOSURE OF FINANCIAL INTERESTS AND ARRANGEMENTS**

**OF INVESTIGATOR OR OTHER RESEARCHER**

(This form must be completed by each Investigator,  
Co-Investigator, Sub-Investigator, or Senior/Key Personnel participating in the study)

As a condition of participating as a clinical investigator, co-investigator, and/or sub-investigator in the study conduct at Sansum Diabetes Research Institute ("SDRI") based on the protocol entitled, [Click here to enter text.](#), ("Clinical Trial") which is funded by [Click here to enter text.](#), please provide the appropriate information and responses to the following statements. This disclosure of financial interests applies to Investigators (which may include Sub- or Co-Investigators), Senior/Key Personnel, and their spouses and dependent children. It does not apply to any other office staff.

Financially Interested Companies (FICs) with respect to this study: [Click here to enter text.](#)  N/A

Other Notable FICs with respect to this study: [Click here to enter text.](#)  N/A

Personnel Name: [Click here to enter text.](#)

Date Form Completed: [Click here to enter a date.](#)

**Please mark the applicable checkboxes.**

I, including my spouse and dependent children, either separately or combined:

- Have financial arrangement(s) with a FIC, or Other Notable FIC, in which the value of the compensation for conducting the Trial could be influenced by the outcome of the Clinical Trial, such as bonus, royalty or other financial incentive (i.e., compensation that could be higher for a favorable outcome than for an unfavorable outcome).
- During the time of the Clinical Trial and for one year after its completion, have received or will receive from a FIC, or Other Notable FIC, payment(s) in the form of salary or any payment for services not otherwise identified as salary (e.g., 1. grants to fund other ongoing research, 2. honoraria, 3. paid authorship, 4. compensation in the form of equipment not for the Clinical Trial, 5. retainer for ongoing consultation, or 6. travel fees) that have a monetary value of more than \$5,000. Such payment(s) exclude the costs of conducting the Clinical Trial or other clinical studies.
- During the time of the Clinical Trial and for one year after its completion, will hold significant equity interest in a FIC, or Other Notable FIC. "Significant equity interest" means any (1) ownership interest, stock options or other ownership interest, as determined through reference to public prices or other reasonable measures of fair market value; or (2) equity interest in a publicly traded corporation that exceeds \$5,000.
- Has a proprietary interest(s) in the product tested in the Trial, including, but not limited to, a patent, trademark, copyright, or licensing agreement.
- Do not have any disclosable financial interests or arrangements.



For any of the first four statements above I have checked regarding disclosable financial arrangements, details of my financial arrangements and interests are attached as a *NOTE TO FILE*, along with a description of steps taken to minimize the potential bias of Clinical Trial results by any of the disclosed arrangements or interests.

I confirm that the information provided on this form is, to the best of my knowledge and belief, true, complete and correct. I also confirm to the extent I have provided any information about other individuals, I have appropriate permission to provide the financial information on their behalf to SDRI.

SDRI agrees to treat as confidential all financial arrangements and interests attached to this Form and to use such disclosure to meet the requirements placed on Sponsor under 21 CFR 54. Investigator acknowledges and agrees that Sponsor may use such disclosure for this purpose.

During the time of the Trial and for one year after its completion, I will notify SDRI's Executive Director in writing of any change to the information provided in this form. I agree to comply with any conditions or restrictions imposed by the SDRI to manage any real or perceived conflicts.

Printed Name: \_\_\_\_\_

Signature: \_\_\_\_\_

Title: \_\_\_\_\_

Date: \_\_\_\_\_