



## **CONFLICT OF INTEREST POLICY**

**Effective Date August 16<sup>th</sup>, 2022**

### **INTRODUCTION**

The purpose of this TRiNDS policy is to promote best practices for identifying, avoiding, and managing actual and/or perceived conflict of interest (COI) relating to TRiNDS work and research activities consistent with federal laws and regulations.

As a recipient of federal funds for federal research and contracting activities TRiNDS is responsible to comply with relevant regulations. The designated TRiNDS official is responsible for ensuring implementation of this policy. Should a perceived financial COI (FCOI) be suspected, the designated TRiNDS official may suspend all relevant activities until the FCOI is resolved or other action deemed appropriate by TRiNDS is implemented. Violation of any part of this policy may also constitute cause for disciplinary or other administrative action.

The policy applies to TRiNDS staff and TRiNDS Investigators and is intended to protect the interests of TRiNDS when contemplating entering a transaction or arrangement that may benefit the private interest of an employee, committee member, consultant, or other person which might result in a possible excess benefit transaction. This policy is intended to supplement, not replace any applicable state and federal laws governing COI.

### **DEFINITIONS**

**Conflict of Interest:** Any circumstance where the personal, professional, financial, or other private interests of a person or institution compromise or have the potential to compromise the exercise of professional judgment or obligations or may be perceived as doing so.

**Financial Interest:** Anything of monetary value received or held by an Investigator or an Investigator's spouse and/or dependent children, whether or not the value is readily ascertainable, including, but not limited to salary or other payments for services (e.g., consulting fees, honoraria, or paid authorships for other than scholarly works); any equity interests (e.g., stocks, stock options, or other ownership interests); and intellectual property rights and interests (e.g., patents, trademarks, service marks, and copyrights), upon receipt of royalties or other income related to such intellectual property rights and interests. Financial interest also includes any reimbursed or sponsored travel undertaken by the Investigator and related to his/her responsibilities at TRiNDS.

**Note:** This does not include the salary, royalties, or other remuneration from TRiNDS; 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), or equity interests or income from investment vehicles, such as mutual funds and retirement accounts, so long as the Investigator does not directly control the investment decisions made in these vehicles.

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**Institutional Official:** The individual within TRiNDS that is responsible for the solicitation and review of disclosures of significant financial interest (SFI). For the purposes of this policy the Institutional Official is designated as Lauren Morgenroth, CEO.

**Investigator:** Any individual who is responsible for the design, conduct, or reporting of public health service (PHS)-funded research. The definition may also include collaborators or consultants as appropriate.

**Significant Financial Interest (SFI):** A financial interest consisting of one or more of the following interests of the Investigator and those of the Investigator spouse and/or dependent children:

- a) with regard to any publicly traded entity, a SFI exists if the value of any remuneration received from the entity in the 12 months preceding the disclosure and the value of any equity interest in the entity as of the date of disclosure, exceeds \$5,000; or
- b) with regard to any non-publicly traded entity, a SFI exists if the value of any remuneration received from the entity in the 12 months preceding the disclosure, exceeds \$5,000; or
- c) if with a non-publicly traded entity, is an equity interest of any value during the 12 months preceding or as of the date of disclosure; or
- d) is income exceeding \$5,000 related to intellectual property rights and interests not reimbursed through TRiNDS; or
- e) is reimbursed or sponsored travel related to TRiNDS responsibilities.

## **POLICY STATEMENT**

Disclosure of SFI is essential to determine if a FCOI exists.

All TRiNDS Investigator(s) who are planning to or participating in research activity that is either partially or wholly supported by PHS funds must disclose their FCOI to the TRiNDS institutional official on an annual and on an ad hoc basis, as described below.

- Annual Reporting: The Investigator must disclose their SFI that are related to the Investigator's institutional responsibilities to the institution, through the TRiNDS institutional official, on an annual basis. All forms should be submitted to the institutional official or designee by July 1 of each calendar year.

- Ad Hoc Reporting: In addition to annual reporting, Investigators must disclose their SFI, through the TRiNDS institutional official, within 30 days of their initial appointment or employment. In addition, Investigators must disclose any newly acquired SFI within 30 days of discovering or acquiring the SFI.

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- Travel: Investigators must also disclose reimbursed or sponsored travel related to their institutional responsibilities, as defined above. Such disclosure 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 TRiNDS institutional official will determine whether the SFI constitutes a FCOI. If the SFI is determined to be an FCOI and if the FCOI could directly and significantly affect the design, conduct, or reporting of the PHS-funded research, they will act to discuss and approve the implementation of an FCOI management plan consistent with government regulation and promptly notify the PHS funding component (e.g., National Institutes of Health [NIH]) via an FCOI report.

All FCOI management plans contain (at minimum):

- Role and principal duties of the Investigator in the research project
- Conditions of the management plan
- How the management plan is designed to safeguard objectivity in the research project
- Confirmation of the Investigator's agreement to the management plan
- How the management plan will be monitored to ensure compliance

Non-disclosure of SFI or non-compliance with an FCOI management plan may subject the Investigator to discipline including, without limitation, suspension or termination of employment or contract.

## **TRAINING**

All TRiNDS Investigators must complete training on this policy and complete web-based training offered by PHS regulations at least every four (4) years. Investigators must save and print the FCOI Certificate as proof of completion.

## **REPORTING TO PHS**

The TRiNDS institutional official will report FCOI or non-compliance to PHS in accordance with PHS regulations.

## **CONFIDENTIALITY**

To the extent permitted by law, all disclosure forms, FCOI management plan(s) (as applicable), and related information will be confidential. However, TRiNDS may be required to make such information available to the PHS awarding component.

## **PUBLIC ACCESSIBILITY**

As required by PHS regulation, the TRiNDS FCOI policy is being made accessible on the TRiNDS website.

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If a PHS-funded investigator holds financial interests that are determined to be FCOI, as required by PHS regulation, these will also be posted on the website, as follows:

- Include the minimum elements required by the regulation;
- Update within thirty (30) days of a newly identified or acquired SFI;
- Update annually; and
- Remain available for three (3) years.

#### **REFERENCES**

21 CFR 54 Financial Disclosure by Clinical Investigators 1998

42 CFR 50, Subpart F Responsibility of Applicants for Promoting Objectivity in Research for Which PHS Funding Is Sought

45 CFR 94 Responsible Prospective Contractors

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