

SUS CLINICALS, INC.
FINANCIAL CONFLICT OF INTEREST IN RESEARCH (FCOIR) POLICY

I. Policy Information

Policy Title: Sus Clinicals, Inc. Policy on Financial Conflicts of Interest in Research

Policy Owner: Chief Financial Officer

Responsible Official: Chief Financial Officer

Approved by: Board of Directors

Date Approved: September 15, 2023

Effective Date: September 15, 2023

Targeted Review Date: September 15, 2025

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II. Overview

This policy is designed to ensure Sus Clinicals, Inc. (the “Company”) complies with conflict of interest policies established by external sponsors of research, in particular to research governed by, or where sponsors have adopted, the Public Health Services (PHS) regulations.

III. Scope

The Policy on Financial Conflicts of Interest in Research (FCOIR) applies to investigators and any other person responsible for the design, conduct or reporting of externally funded research, including senior/key personnel identified in a grant application or progress or final report of research (each an “investigator”). The FCOIR Policy applies as of submission of a funding proposal application and remains applicable through the life of the funding award or study.

IV. Statement of Policy

The Company seeks to promote objectivity in research by establishing standards that provide a reasonable expectation that the design, conduct, and reporting of research will be free from bias resulting from financial interests. The FCOIR Policy informs investigators about situations that generate financial conflicts of interest related to research and provides mechanisms for investigators and the Company to eliminate or manage financial conflicts of interest that arise.

V. Procedures

The Health and Human Services/PHS regulations on promoting objectivity in research apply to research projects supported by PHS agencies. Other non-federal entities may incorporate the PHS regulations in their award terms.

A. Definitions

Financial Conflict of Interest: A financial conflict of interest (FCOI) exists when the Company, through its designated officials, reasonably determines that an investigator’s significant financial interest (SFI) could directly and significantly affect the design, conduct, or reporting of the research.

Investigator: Investigator includes any person who is responsible for the design, conduct, or reporting of research, regardless of title or position.

Senior/Key Personnel: The Project Director or Principal Investigator and any other person (including consultants and advisors, if applicable) identified as senior/key personnel by the Company in the grant application, progress report, or any other report submitted to the PHS.

Significant Financial Interest: An SFI is defined at 42 C.F.R. § 50.603. SFI means a financial interest consisting of one or more of the following interests of the investigator (and spouse and dependent children) that reasonably appears related to the investigator's Company responsibilities with regard to:

- a publicly traded entity if the value of any remuneration received from the entity as of the date of disclosure and in the 12 months preceding the disclosure exceeds \$5,000, when aggregated. Remuneration includes salary, royalties, and other payments for services, such as consulting fees and honoraria paid authorship, equity interests, stock options or other ownership interests, as determined through public prices or reasonable measures of fair market value;
- a non-publicly traded entity, if the value of any remuneration received from the entity in the 12 months preceding the disclosure exceeds \$5,000 when aggregated, or when the investigator holds any equity interest;
- intellectual property rights and interests (e.g. patents, copyrights) upon receipt of income related to such rights and interest; and
- reimbursed or sponsored travel related to investigator's Company responsibilities if paid by a sponsor other than a federal, state, or local government agency, an institution of higher education as defined by 20 U.S.C. § 1001(a); an academic teaching hospital; a medical center; or a research institute affiliated with an institution of higher education.

The following financial interests are not considered to be an SFI:

- salary, royalties or other remunerations paid by the Company to the investigator if the investigator is currently employed or appointed by the Company, including intellectual property rights assigned to the Company and agreements to share royalties related to such rights;
- income from investment vehicles (mutual funds or retirement account that are not managed directly by the individual);
- income from seminars, lectures, or teaching engagements sponsored by a federal, state, or local government agency, an institution of higher education as defined by 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 by 20 U.S.C. § 1001(a)
 - (e.g., NIH review panel), an academic teaching hospital, a medical center, or a research institution that is affiliated with an institution of higher education.

B. Disclosure

Investigators must disclose any SFI that reasonably appears to be related to the investigator's Company responsibilities. Investigators must disclose SFIs annually and within 30 days of discovery or acquisition of a new or change in an SFI.

C. Review

Disclosed SFIs are reviewed by the Chief Executive Officer and Chief Financial Officer to assess if an SFI is reasonably related to a Company research project. The reviewers take into account the nature and extent of an investigator's role on a project, the nature and extent of an investigator's SFIs, and the nature of the research activity under review. If the SFI is reasonably related, the reviewers will assess if the SFI could directly and significantly affect the design, conduct, or reporting of the research.

Management of FCOIs may include, but is not limited to, disclosure, impartial review, reduction or elimination of the investigator's role in certain aspects of the study, and additional monitoring.

Reviews and determinations must occur prior to expenditure of funds for new projects, within 60 days of newly disclosed SFIs, and within 60 days of the addition of new investigators to projects.

D. Reporting

When the Company determines that an SFI is related to sponsored research, the Responsible Official or their delegate must submit reports as required by the sponsor. The Responsible Official must submit the FCOI Report:

- prior to the expenditure of funds;
- within 60 days of identification for an investigator who is newly participating in the project;
- within 60 days for new, or newly identified, FCOIs for existing investigators.

After the FCOI Report is initiated, the Responsible Official or their delegate must provide to the sponsor status updates and identify changes in management plans, at least annually, until the completion of the project.

E. Noncompliance

The following are examples of noncompliance with the FCOIR Policy:

- failure to submit a timely disclosure;
- submission of an incomplete, erroneous or misleading initial, updated or annual disclosure;
- failure to disclose information as required by the FCOIR Policy; and
- failure to comply with prescribed management plans.

When noncompliance is identified, the Responsible Official or their delegate will implement a management plan within 60 days.

In addition, the Responsible Official or their delegate must conduct a retrospective review of the investigator's research activities on the project to determine if there is bias in the design, conduct, or reporting of the research resulting from the financial conflict of interest. The retrospective review must be completed within 120 days of the determination of noncompliance. If bias is found in the course of the retrospective review, the Responsible Official must promptly notify the sponsor and submit a mitigation report that addresses the impact of the bias on the research and the Company's plan of action to eliminate or mitigate the effect of the bias.

F. Training

Each investigator on an award supported by the PHS must complete Company- approved conflicts of interest training prior to engaging in PHS-funded research and thereafter every four years unless immediate retraining is required for any of the following circumstances:

- the Company revises the FCOIR Policy and procedures in any manner that affects the requirements of the investigator;
- an investigator is new to the Company;
- the Company finds that an investigator is not in compliance with the FCOIR Policy or with an approved management plan.

G. Subrecipient Compliance

If the Company carries out the research through use of a subrecipient or subcontractor (“subrecipient”), the Company must require the subrecipient to comply with either the Company’s FCOIR Policy or the subrecipient’s financial conflicts of interest policy. If the latter, then the subrecipient must certify that its policy complies with the PHS regulations. The subrecipient agreement must specify deadlines for the subrecipient to submit all SFI disclosures or reports of conflicts to the Company so that the Company can meet its own reporting obligations.

H. Public Access to Information

Upon written request, the Company must make available to the public within five business days certain information about the SFIs held by senior/key personnel that constitute a FCOI related to the research. The minimal information to be provided is described at 42 C.F.R. § 50.605(a)(5)(ii). The Responsible Official or their delegate will coordinate requests and responses.