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SALUTARIS MD
POLICIES & PROCEDEURES

POLICY: RESEARCH FINANCIAL CONFILICT OF INTEREST POLICY
PREPARED: 12/1/2022
UPDATED:

I Purpose:

The purpose of this policy is to promote objectivity in research by establishing standards that provide a reasonable expectation that the design, conduct, or reporting of funded research, grants or cooperative agreements will be free from bias resulting from an Investigator's financial conflicts of interest (and/or of the Investigator's spouse and/or dependent children). This policy complies with the following federal regulations:

Title 42 Code of Federal Regulations (CFR), Part 50, Subpart F, Responsibility of Applicants for Promoting Objectivity in Research for Which PHS Funding is Sought

II Scope:

This policy applies to Investigators participating in, or planning to participate in the design, conduct, reporting or proposing research funded by Public Health Service (PHS) or National Institute of Health (NIH).

If a research project involves subcontractors, subgrantees, or sub-awardees (collectively subrecipients), the subrecipient institution must provide written assurance that a financial conflict of interest in research policy is in effect at that institution and compliant with all applicable federal regulations. Should Public Health Service (PHS) or National Institute of Health (NIH) funds be subcontracted by the Company to a subrecipient institution without a conflict of interest in research policy, a written agreement must state that this policy shall apply to the subrecipient.

III Definitions:

A. **Financial Interest** means anything of monetary value or potential monetary value held by the Investigator, the Investigator's spouse and/or dependent children, regardless of whether or not the value is readily ascertainable.

B. **Financial Conflict of Interest** means a Significant Financial Interest related to a research program or project that could directly and significantly affect the design, conduct or reporting of research. Examples include, but are not limited to, the following:

1. Investigator (and/or an Investigator's spouse and/or dependent children) entering into a paid consultancy with an outside entity that has an interest in the investigator's Investigator (and/or an investigator's spouse and/or dependent children) receiving royalties or non-royalty payments related to ongoing research;
2. Investigator (and/or an investigator's spouse and/or dependent children) having an equity interest (e.g., stocks, stock options, warrants) related to ongoing research.

This policy addresses individual financial conflicts of interest; however, the Company may also have conflicts of interest in research whenever the financial interests of the Company, or of an official acting within his or her authority on behalf of the Company , might affect—or reasonably appear to affect— the Company processes for the conduct, review, or oversight of research. If institutional conflicts of interest are identified via the process described below, they will normally be addressed in a manner that is consistent with this policy.

C. **Significant Financial Interest (SFI)** means a financial interest consisting of one or more of the following interests of the Investigator (and/or of the Investigator's spouse and/or dependent children) that reasonably appears to be related to the Investigator's institutional responsibilities:

i 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 the 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 interests includes any stock, stock option, or other ownership interest, as determined through reference to public prices or other reasonable measures of fair market value;

ii Regarding 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 (and/or the Investigator's spouse and/or dependent children) holds <u>any</u> equity interest (e.g., stock, stock option, or other ownership interest); or

iii Intellectual property rights and interests (e.g., patents, copyrights), upon receipt of income related to such rights and interests.

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. The Institution's FCOI policy will specify the details of this disclosure, which will include, at a minimum, the purpose of the trip, the identity of the sponsor/organizer, the destination, and the duration. In accordance with the Institution's FCOI policy, the institutional official(s) 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.

IV. Policy

Each year any investigator who conducts research on any Company project must disclose via the electronic system all significant financial interests (SFIs) that are relevant to an investigator's institutional research responsibilities or within 30 days after he/she becomes aware of new SFI or after a financial conflict of interest has been eliminated.

Investigators are required to complete the annual disclosure form even if they have no financial interest to report. Transactional disclosure by the PI is also required at the time a research proposal is submitted to the Company's Grants Director in order to ensure compliance with Federal disclosure and management requirements.

V. Procedure

A. Investigator Responsibilities

1. Disclose all significant financial interests,
2. Provide updates to disclosed information as needed,
3. If acting as the PI/PD, provide a list of individuals who meet the definition of "investigator" within the required disclosure timeline,
4. Complete all required training and education,
5. Complete the annual disclosure form even if they have no financial interests to report,
6. Ensure that an updated FCOI in Research Disclosure is on file at the time of Institutional Review Board (IRB) or the Institutional Animal Care and Use Board (IACUC) approval for any new research proposals.

B. Review of FCOIs

1. The Company FCOI administrator conducts an initial review of all disclosures. If necessary, the FCOI administrator obtains additional information from the investigator and other individuals to help determine whether the SFI disclosed is related to a proposed or existing sponsored project or program. The administrator then formally identifies cases that require further review by management.
2. The Company's Management and Scientific Advisory Board (SAB) will review the collected information to determine whether a financial conflict of interest exists by considering the following:

    a. Impact on integrity of research data;
    b. Risks to rights and safety of animal and/or human research subjects;
    c. Risks to the rights of students and trainees participating in research; and
    d. Appearance of conflicts of interest.

    e. If a financial conflict of interest is identified, the Company's Management and Scientific Advisory Board will determine whether the research can be undertaken.

C. Management of FCOIs

1. For cases that require action, a plan of action will be developed by members of the Company's Management and Scientific Advisory Board on a case-by-case basis. Such a plan will include some or all of the following as deemed appropriate:

    a. Public disclosure of significant financial interests (e.g., when presenting or publishing the research), if appropriate;
    b. Disclosure of significant financial interests directly to subjects involved in human research;
    c. Appointment of an independent monitor capable of taking measures to protect the design, conduct, and reporting of research;
    d. Modification of research plan;
    e. Change of personnel or personnel responsibilities or disqualification from participation in all or a portion of the research;
    f. Reduction or elimination of the financial interest (e.g., sale of an equity interest);
    g. Severance of relationships that create the actual or potential conflict of interest;
        a. If it proves impossible to reach an acceptable plan of action, funds will be returned to the sponsor.
        b. A draft of the plan of action will be provided to the Investigator for review and comment before it is finalized. The Investigator and their immediate supervisor must sign the approved plan to acknowledge their agreement to comply.
        c. If the Institution identifies an SFI that was not disclosed or reviewed in a timely manner it will initiate the review process and an interim plan of action will be implemented when necessary.

D. Monitoring

Investigator compliance with plans of action will be monitored by the Company's Management and Scientific Advisory Board. The frequency of monitoring will be dictated by sponsor/agency requirements and action plan provisions.

E. Research Involving Humans

1. Special consideration and scrutiny must be given to protect human subjects in research. Investigators with an identified financial conflict of interest or a significant financial interest that could directly and significantly affect the design, conduct, or reporting of the research shall not ordinarily participate in any research involving human subjects. This presumption against the participation in human subjects' research by financially interested individuals may be rebutted by compelling circumstances. Compelling justification may include factors such as unique

investigator expertise, unique institutional resources, unique access to particular patient populations, nature of the science, level of risk to human subjects and the degree to which the financial conflict of interest and the research are related.

2. The compelling justification and the degree of risk to human subjects must be presented and reviewed by the Scientific Advisory Board (SAB). If compelling circumstances justify a waiver of this policy, the research will be subject to the development and implementation of an action plan to ensure the safety of human subjects and the integrity of the research. The SAB must review the research with consideration given to the requirements of the action plan. The SAB may require additional safeguards to be implemented but may not determine less stringent financial conflict of interest management requirements.

F. Appeals

Investigators may appeal SAB decisions in writing within 15 days of receipt of the finalized action plan or other decision of the Board. The written appeal should include details regarding circumstances which support the request for a proposed revision to a SAC decision. An Appeals Board will be formed for purposes of investigating the appeal and making a final decision. A meeting of the Appeals Board will be convened to review the SFI information, the Management and Monitoring Plan, and previous meeting minutes, to make a decision. The Investigator may be invited to describe reasons for the appeal and to address further questions. The appeals process will take no more than 60 days from the date requested by the Investigator. The decision of the Appeals Board is final and binding.

G. Confidentiality

Financial and other information disclosed in compliance with this policy will be kept confidential and disclosed only on a need-to-know basis as required to perform appropriate review and evaluation required by the policy, except in the case of required public accessibility of identified financial conflicts of interest held by senior/key personnel.

H. Enforcement

Failure on the part of an Investigator to comply with this policy will result in disciplinary action and/or sanctions which may include formal reprimand, non-renewal/termination of appointment or affiliation, additional training requirements, additional supervision, closing existing research or denying future research by the Investigator, and/or any other enforcement action mandated by the applicable funding agency or the Company.

I. Reporting of Failures to Comply with the FCOI Policy

In the case where an Investigator or the Company is found by the SAB to have failed to be in compliance with the FCOI policy the SAB will complete, within 120 days a retrospective review of the incident. Incidents requiring a written review include:

1. Failure by the investigator to disclose a significant financial interest that is determined to by the Company to constitute a financial conflict of interest,
2. Failure by the Company to review or manage such a financial conflict of interest,
3. Failure by the investigator to comply with the financial conflict of interest management plan.
4. The retrospective review includes at a minimum the following key elements:
   a. Project Number,
   b. Project Title,
   c. PD/PI or contact PD/PI if multiple PD/PI model is used,
   d. Name of the investigator with the FCOI,
   e. Name of the entity which the Investigator has an FCOI,
   f. Reasons for the retrospective review,
   g. Detailed methodology used for the retrospective review (e.g., methodology of the review process, composition of the review panel documentation reviewed),
   h. Findings of the review, and
   i. Conclusions of the review.

J. Policy Revision

1. The Company may modify this policy to conform to organizational changes and circumstances including revisions to federal or state law or regulations. The SAC will have 30 business days to review and comment on any proposed revisions.
2. The Executive Board of the Company's Board of Directors is responsible for granting final approval for these policy revisions. It will review all proposed revisions, in collaboration with management, and will consider the Board's feedback during the review process. When necessary, procedures will be developed or modified to implement this policy.

VI. Additional Requirements

The following **additional** requirements also apply to all research funded by the PHS of the U.S.
Department of Health and Human Services and any PHS Awarding Component including the NIH.

A. Reporting

The Company will provide to the PHS Awarding Component a FCOI report as outlined in the regulations: Initial Report: Prior to expenditure of any funds under the NIH-funded research project, the Institution will provide a FCOI report regarding any SFI found to be a FCOI. The company will also provide a FCOI report within 60 calendar days from the date of a new SFI disclosure determined to be a FCOI, a new Investigator with an identified FCOI becomes engaged in the project or when the Institution identifies a FCOI not previously disclosed. This report will include the following information:

1. Grant/Contract Number
2. PD/PI
3. Name of Investigator with FCOI
4. Nature of the FCOI (e.g., equity, consulting fees, travel reimbursement or honoraria)
5. Value of the financial interest or a statement that the interest is one whose value cannot be readily determined through reference to public prices or other reasonable measures of fair market value
6. Description of how FCOI relates to PHS-funded research and the basis for the determination that the financial interest conflicts with such research
7. Key elements of the FCOI action plan

8. Annual updates to this report will be submitted to the PHS Awarding Component for the duration of the research project. The annual report will include:

    a. Status of the FCOI,
    b. Changes to the action plan,
    c. Justification that an FCOI no longer exists.

B. Subrecipients

1. For PHS-funded research that involves subcontractors, subgrantees or sub-awardees (collectively subrecipients) at other Institutions, the Company requires a written agreement that includes terms that establish whether the FCOI policy of the awardee Institution or that of the subrecipient Institution will apply to subrecipient Investigators. This agreement will specifically address time periods to meet disclosure and/or financial conflict of interest reporting requirements.
2. Subrecipient Institutions who rely on their Financial Conflict of Interest policy must report identified financial conflicts of interests to the Company in sufficient time to allow the Company to report the FCOI to the PHS Awarding component.
3. Subrecipients who do not have such a conflict-of-interest policy will be required to follow the Company FCOI in Research policy. A subrecipient's failure to promptly

comply with the Company policy will be considered grounds for immediate termination by the Company of any applicable subcontract or subaward. The written agreement terms required by the Company will contain a provision that subrecipients will report to the Company as the pass-through entity, any identified FCOI in sufficient time to allow the company to report and manage the FCOI and meet the reporting obligations described above.

C. Public Accessibility

This policy will be posted on the Company's public website. In addition, information concerning identified FCOIs held by senior/key personnel will be made available to requestors via **an email** response within five business days from when the Research Official receives the request. This information may be requested by **emailing** INPUT COMPANY EMAIL HERE. The written response will include:

1. Senior/key personnel name
2. Senior/key personnel's role in the research project
3. Name of the entity in which the FCOI is held
4. Nature of the FCOI
5. Approximate dollar value of the FCOI or a statement that the value cannot be readily determined

6. This information will remain available for three years from the date the information was most recently updated.

D. Training Requirements

PHS-funded Investigators must complete FCOI training prior to engaging in research related to any PHS-funded grant or contract and at least every four years thereafter. Training must also be completed *as soon as reasonably possible* under the following circumstances:

1. This policy changes in a manner that affects Investigator requirements,
2. An Investigator is new to a subrecipient and will be working on PHS- funded research,
3. An Investigator is found to be noncompliant with this policy or their approved action plan.

E. Investigator/Institutional Non-Compliance

If an SFI is not disclosed or reviewed in a timely manner, the Company will review the Investigator's financial interest, and determine if it is related to PHS-funded research; determine whether an FCOI exists, and if so:

1. Implement an action plan for ongoing research, at a minimum implement an interim action plan
2. Complete a retrospective review of Investigator's activities and the PHS- funded research project within 120 days of a non-compliance finding to determine if bias was present in the design, conduct, or reporting of such research; and
3. If bias/non-compliance is found, the Institution will promptly inform the PHS Awarding Component by submitting a mitigation report

4. If the retrospective review finds that the Investigator knew or should have known about the FCOI related to his/her institutional responsibilities, but failed to disclose in compliance with this policy, the costs associated with the retrospective review and mitigation report may be pulled from the subrecipient's Indirect Cost Allocation portion. If the Department of Health and Human Services determines that a PHS funded clinical research project whose purpose is to evaluate the safety or effectiveness of a drug, medical device, or treatment has been designed, conducted, or reported by an Investigator with a conflicting interest that was not managed or reported to the Company , the Investigator must disclose the FCOI in each public presentation of the results of the research and must request an addendum to previously published presentations.

F. Reporting Requirements

If the Company is unable to satisfactorily manage a conflict of interest involving NIH funding, it will appropriately notify NIH's Office of the General Counsel.

VII. Responsibilities and Authorities:

Investigators participating in, or planning to participate in the design, conduct, or reporting of research including Public Health Service (PHS) or National Institute of Health (NIH) funded research at the Company have the authority and responsibility for the activities in this policy.

VIII. Records

The Company will maintain all records related to the implementation of this policy for at least three years after:

A. the date of creation,
B. the date of termination or completion of a research award or contract,
C. the submission of the final expenditures report, or
D. the date of final resolution of any investigation, audit, or similar action involving the records.