CLEVELAND VA MEDICAL RESEARCH AND EDUCATION FOUNDTAION CONFLICT OF INTEREST POLICY AND PROCEDURES

TITLE OF POLICY:

Financial Conflicts of Interest Policy for Public Health Service (PHS) Investigators

1.0 PURPOSE

Cleveland VA Medical Research and Education Foundation (CVAMREF) Financial Conflicts of Interest Policy for Public Health Service (PHS) Investigators outlines the disclosure reporting, review, and determination requirements as required 42 CFR 50, Subpart F, "Responsibility of Applicants for Promoting Objectivity in Research for which PHS Funding is Sought". The CVAMREF designated institutional official (DIO) appointed by the CVAMREF Board will bear primary responsibility for implementation of the Policy.

2.0 SCOPE

This Policy applies to any CVAMREF Investigator ("Investigator") applying for or receiving funding from the U.S. Public Health Service (PHS) (including the National Institutes of Health) and sponsors adopting the PHS regulations[1] ("PHS").

3.0 POLICY

Disclosure Requirements

All Investigators applying for or receiving funding from PHS must submit an internal, confidential disclosure of their and their family members' significant financial interests in the preceding twelve months in any related outside entity. In determining relatedness, Investigators should apply a standard of reasonableness, and when in doubt, disclose.

All Investigators must update disclosed information at least once annually and within 30 days of the discovery or acquisition of any new significant financial interest. A current disclosure must be on file prior to submitting an application for a sponsored project to the PHS and must be reviewed prior to initiating a new PHS award or funding modification.

Annual disclosures should include sufficiently detailed information for the DIO to appraise the risk of conflicts arising from the Investigator's or Investigator's family members' outside financial interests. Disclosures should include the identity of the entity in which the Investigator or family members hold a financial interest, the nature of the interest, any outside professional activity that was or will continue to be associated with the financial interest (e.g., service as a consultant, member of an advisory committee, or managerial or fiduciary role), and the size or value of the interest in a preceding 12-month period.

[1] Sponsors adopting the PHS regulations include the American Heart Association, American Cancer Society, Arthritis Foundation, Susan G. Komen Foundation, and the Alliance for Lupus Research.

Investigators who have no financial interests to disclose shall certify to that fact in writing. In addition, annual disclosures should include an affirmation that the Investigators is aware of this Policy.

Travel Disclosure Requirements

Any Investigator submitting a proposal to or receiving funding from the PHS must disclose to the DIO the occurrence of any reimbursed or sponsored travel (*i.e.,* that which is paid by an outside entity directly to or on behalf of the Investigator so that the exact monetary value may not be readily available) that falls within the following guidelines:

- Travel must be related to institutional responsibilities.
- Travel is not reimbursed through CVAMREF or VA Northeast Ohio Healthcare System.
- Travel is not being reimbursed or sponsored by a federal, state, or local government agency, or domestic or U.S.-based 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.
- Investigator has an aggregate of significant financial interests and travel reimbursements that exceed $5000 in the previous twelve months from a single entity. As an example,
  $4500 in non-travel significant financial interests and $1000 in travel reimbursements would exceed $5000 when aggregated from a single entity, and, therefore, would need to be disclosed.

Travel information must be disclosed within 30 days upon completion of the travel and must include the following information:

- The purpose of the trip
- The identity of the sponsor/organizer of the trip
- The destination of the trip
- The duration of the trip

Training Requirements

Each Investigator must complete training on this Policy prior to engaging in research funded by PHS and at least once every four years thereafter. Training will be needed to be completed immediately if CVAMREF revises this policy that affects the requirements for investigators, an investigator is new to CVAMREF, or if an investigator is not in compliance with the policy of management plan.

Sub-Recipient Investigators

If any portion of the funded research is performed by a sub-recipient, CVAMREF will take reasonable steps to ensure that sub- recipient investigators comply with the sponsor's applicable financial COI policy and regulations. CVAMREF will establish by written agreement with the sub-recipient Institution or Investigator the applicable governing FCOI policy.

- The sub-recipient will certify that its Institution's FCOI policy complies with the respective sponsor's regulations and, further, that the sub-recipient will report identified FCOIs for Investigators to CVAMREF within thirty (30) days so that the CVAMREF has sufficient time to report those FCOIs to the sponsor.

- Alternatively, if a sub-recipient lacks a sponsor compliant FCOI policy, the sub-recipient Investigator will be governed by this Policy.

4.0 DEFINITIONS

Designated Institutional Official: The CVAMREF "Designated Institutional Official" (DIO) appointed by the CVAMREF Board bears primary responsibility for implementation of this Policy; may be assisted by other CVAMREF staff, CVAMREF Board, or VA staff as needed

Family Member: Any member of the *Investigator's* immediate family, specifically, any dependent children or spouse

Financial Interest: Anything of monetary value received or held by an Investigator or family member, 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. Income from non-U.S. entities, including institutions of higher education, are included.

Institutional Responsibilities: Professional responsibilities associated with the Investigator's appointment or position, such as research, teaching, clinical activities, administration, and institutional, internal and external professional committee service

Investigator: Project Director or Principal Investigator and any other key person, regardless of title or position, who is responsible for the design, conduct, or reporting of research

Significant Financial Interest (SFI): SFI includes, but is not limited to, (1) financial compensation from consulting, employment, managerial, and fiduciary relationships above $5000; (2) equity and other financial interests above $5000; and (3) equity interests of any amount, or entitlement to the same, in a non-publicly traded, for-profit entity. In all cases, the SFI will be calculated per entity reported in the preceding twelve-month period and will be calculated on the aggregation of the sum total of the Investigator and family members.

Significant Financial Interest Exemptions:

- salary, royalties, or other remuneration from CVAMREF or the VA Northeast Ohio Healthcare System;

- income from the authorship of academic or scholarly works;
- income from seminars, lectures, or teaching engagements sponsored by or from advisory committees or review panels for U.S. federal, state or local governmental agencies; U.S. institutions of higher education; U.S. research institutes affiliated with institutions of higher education, academic teaching hospitals, and medical centers; 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

5.0 RESPONSIBLE PARTIES

5.1 CVAMREF Board of Directors: The CVAMREF Board of Directors is responsible for the overall policy, planning, and coordination of all CVAMREF activities. The Board of Directors approves the appointment of the DIO, provides support if a mutual agreement for FCOI management cannot be met between the DIO and Investigator, and appoints a committee to perform a retrospective review if required.

5.2 CVAMREF CEO: The CVAMREF CEO is responsible for developing and administering a business process that provides optimal internal controls for CVAMREF.

5.3 CVAMREF Designated Institutional Official (DIO): The CVAMREF DIO is appointed by the CVAMREF Board of Directors and will bear primary responsibility for implementation of this Policy. The DIO will review the internal financial interest disclosures submitted annually by the Investigators, perform the initial review of SFIs, implement management plans, and report to the sponsor as required. The DOI is also responsible for identifying Investigators and requesting updated disclosures as necessary.

5.4 Investigators: It is the responsibility of the investigator to fulfill training requirements as required, submit FCOIs to the DOI, notify the DOI if they are new to an institution, review and agree to follow his/her respective management plan as applicable, and self-monitor adherence to any respective management plans.

6.0 PROCEDURES

<u>Disclosure Review</u>

The DIO will ascertain whether the disclosed SFI represents a potential financial conflict of interest ("FCOI") based on the following criteria:

- Relatedness Standard – An Investigator's SFI is related to proposed research when the DIO reasonably determines that the SFI could be affected by the proposed research or is in an entity whose financial interest could be affected by the

proposed research.

- FCOI Standard - An FCOI exists if the DIO reasonably determines that the SFI related to the proposed research could directly and significantly affect the design, conduct or reporting of the proposed research.

The initial review is performed by the DIO who, in situations in which more information is needed, will consult with the Investigator. If the DIO and the Investigator agree that a potential FCOI exists, they will work jointly to implement preventative measures, or develop a management plan to manage, reduce or eliminate the conflict of interest.

If the DIO and Investigator cannot reach an agreement, the Investigator may appeal the decision to the CVAMREF Board of Directors, and the CVAMREF Board of Directors will present to the Investigator their final recommendation to resolve the potential conflict.

Management

For any identified FCOI, the DIO will take appropriate action to manage the conflict in order to reduce the potential for it to compromise the safety or validity of the research consistent with the requirements of 42 CFR 50.605(a). Research in which an Investigator is found to have a FCOI will not be permitted to proceed until a management plan is developed and implemented.

Investigators have an on-going obligation to adhere to an imposed management plan and failure to do so may be grounds for sanctions under this Policy. The DIO will monitor Investigator compliance with an imposed management plan on an ongoing basis until the completion of the sponsored research project. The CVAMREF Board of Directors may assist in providing a resolution.

Sponsor Reporting

The DOI will report financial conflicts of interest or non-compliance to PHS in accordance with PHS regulations. Prior to expenditure of funds, initial FCOI reports should be submitted to the NIH.

FCOI reports are to include the following:

- Project Number
- PD/PI or Contact PD/PI if a multiple PD/PI model is used
- The name of the investigator with the FCOI
- The name of the entity with which the investigator has a FCOI
- The nature of the Significant Financial Interest (SFI) a. i.e. equity, consulting fee, travel reimbursement, honorarium, etc.
- The value of the financial interest a. NOTE: Dollar ranges are permissible. See regulation for permissible ranges.
- Description of how the financial interest relates to the NIH-funded research and why the Institution determined that the financial interest conflicts with such research

- Description of the key elements of the Institution's Management Plan, including:
    - Role and principal duties of the conflicted Investigator in the research project
    - Conditions of the Management Plan Within 60 days of identification of an investigator who is newly participating in the project
    - How the Management Plan is designed to safeguard objectivity in the research project
    - Confirmation of the Investigator's agreement to the Management Plan e. How the Management Plan will be monitored to ensure Investigator compliance f. Other information as needed

In addition to initial FCOI reports, Institutions are required to submit FCOI reports under the following circumstances

- Within 60 days or new, or newly identified, FCOIs for existing investigators
- At least annually (at the same time as when the Institution is required to submit the annual progress report, multi-year report, if applicable, or at time of extension) to provide the status of the FCOI and any changes to the management plan, if applicable, until the completion of the project 4.
- Following a retrospective review to update a previously submitted report, if appropriate.

All initial, annual, and revised FCOI reports shall be submitted via eRA Commons FCOI Module.

Retrospective Review

If the DIO determines that the 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, a Board of Directors' appointed committee will complete a retrospective review of the Investigator's activities and the PHS-sponsored research project to determine 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 DIO will update any previously submitted report to the PHS or the prime PHS-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 timeframe established in PHS regulations. If bias is found, the DIO will promptly notify the PHS Awarding Component 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.

Record Retention

The DIO will retain all disclosure forms, conflict management plans, and related documents for a period of three years from the date the final expenditure report is submitted to the PHS or to the prime PHS awardee, unless any litigation, claim, financial management review, or audit is started before the expiration of the three-year period, the records shall be retained until all litigation, claims or audit findings involving the records have been resolved and final action taken.

Confidentiality

To the extent permitted by law, all disclosure forms, conflict management plans, and related information will be confidential. However, CVAMREF may be required to make such information available to the PHS Awarding Component and/or Department of Health and Human Services, to a requestor of information concerning financial conflict of interest related to PHS funding, or to the primary entity who made the funding available to CVAMREF, if requested or required. If CVAMREF is requested to provide disclosure forms, conflict management plans, and related information to an outside entity, the *Investigator* will be informed of this disclosure.

Public Accessibility

CVAMREF will respond to any requestor within five business days of the request information concerning any SFI that meets the following criteria, consistent with the requirements of the PHS regulation:

a) The SFI was disclosed and is still held by the Senior/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 a managed FCOI.

Noncompliance

In the event that the Institution determines noncompliance for SFIs not disclosed timely or previously reviewed or whenever a FCOI is not identified or managed in a timely manner:

- A retrospective review must be completed and documented within 120 days
- The retrospective review must be documented and at a minimum, include the following, consistent with the regulation:
    - Project Number
    - Project Title
    - PD/PI or contact PD/PI if a multiple PD/PI model is used
    - Name of the Investigator with the FCOI
    - Name of the entity with which the Investigator has a financial conflict of interest
    - Reason(s) for the retrospective review
    - Detailed methodology used for the retrospective review (i.e. methodology of the review process, composition of the review panel, documents reviewed)

- Findings of the review
- Conclusions of the review

- If appropriate, the Institution shall update the previously submitted FCOI report per the regulation.
- If bias is found with the design, conduct or reporting of NIH-funded research, the NIH must be promptly notified, and a Mitigation Report must be submitted to the NIH. The Designated Official shall inform the NIH in the form of a Mitigation Report.
- The Mitigation Report shall include the following elements in accordance with the regulation: At a minimum, the key elements documented in the retrospective review and a description of the impact of the bias on the research project and the Institution's plan of action or actions taken to eliminate or mitigate the effect of the bias (i.e. impact on the research project; extent of harm done, including any qualitative and quantitative data to support any actual or future harm; analysis of whether the research project is salvageable)

The Designated Official shall notify NIH promptly if an Investigator fails to comply with this FCOI policy or a FCOI management plan appears to have biased the design, conduct, or reporting of the NIH-funded research. Corrective action must also be taken for noncompliance with this policy or the Management Plan.

In any case in which the Department of Health and Human Services determines that a PHS-funded research project of clinical research whose purpose is to evaluate the safety of effectiveness of a drug, medical device, or treatment has been designed, conducted, or reported by an Investigator with a financial conflict of interest that was not managed or reported by the Institution as a required by the regulation, the Institution shall require the Investigator involved to:

- Disclose the FCOI in each public presentation of the results of the research
- Request an addendum to previously published presentations

Management plans and retrospective reviews shall be completed by the DOI.

7.1 RELATED DOCUMENTS

- *CVAMREF PHS Investigator Financial Disclosure Form*

8.0 REVISION HISTORY

Revision Letter	Author	Date	Description of Changes