Carl T Hayden Medical Research Foundation

(CTHMRF)

Investigator Conflict of Interest Policy

1. KEY DEFINITIONS

1. A ***clinical trial*** is a prospective or behavioral research study of human subjects that involves one or more Investigators who directly observe a person or people, and/or who collect data to answer a scientific or medical question about the safety or potential benefit of an intervention such as medication, device, teaching concept, training method or behavioral change.

2. ***Conflict of Commitment*** refers to situations in which an Investigator is dedicating time to OutsideActivities and Interests in excess of the time permitted by institutional policy, or to Outside Activities and Interests that may interfere with or detractfrom the Investigator's primary responsibility to CTHMRF. The issue regarding Conflicts of Commitmentis not necessarily financial or potential bias in judgment, but rather whether an Investigator's commitment of time and effort are inconsistent with his/her obligations and commitment to CTHMRF/ Phoenix Veterans Affairs Health Care Service (PVAHCS) and its interests.

3. ***Disclosure*** refers to the Investigator's disclosure of Significant Financial Interests and Outside Activities and Interests to CTHMRF/PVAHCS.

4. ***Federally funded research or PHS-funded research*** means any research funded by the Public Health Service (PHS) of the U.S. Department of Health and Human Services and any componentsof the PHS to which the authority involved may be delegated, including the National Institutes of Health (NIH). Others federal agencies include the National Science Foundation (NSF), Departmentof Defense (DOD), and Department of Energy (DOE).

5. ***Financial Conflict of Interest*** (FCOI) will be deemed to exist when CTHMRF's Conflict of Interest Committee reasonably determines that a Significant Financial Interest disclosed by an Investigatorcould directly and significantly affect the design, conduct or reporting of the Investigator's research, including but not limited to PHS-funded research, but with the exception of research funded throughPhase I support under the Small Business Innovation Research and Small Business Technology Transfer programs. Phase II SBIR and STTR programs are not exempt like Phase I and must comply with the regulation.

6. ***Foreign component*** refers to the performance of any significant scientific element or segment of a research project outside of the U.S., either by the recipient or by a researcher employed by a foreign entity, whether grant funds are expended.

7. ***Foreign entity*** refers to an organization located in a country other than the U.S. and its territories that is subject to the laws of that country, regardless of the citizenship of an Investigator at such organization.

8. Research is considered to involve ***human subjects*** when an Investigator conducting research obtains data through intervention or interaction with a living individual, or identifiable private information about a living individual.

9. ***Investigator*** refers to the Principal Investigator (PI) or Project Director (PD) and any other person regardless of title or position who is responsible for the design, conduct or reporting of research, and includes, by way of example, all PhDs, MDs, graduate students, non-faculty scientific staff at and above the level of research associate and any others deemed appropriate by CTHMRF's Conflict of Interest Committee. Collaborative and visiting researchers and subrecipient Investigators who are receiving federal funding awarded through CTHMRF/PVAHCS may also be deemed Investigators and be required to comply with this CTHMRF/PVAHCS Investigator Conflict of Interest Policy.

10. ***Institutional responsibilities*** mean an Investigator's professional activities on behalf of CTHMRF/PVAHCS including, but not limited to, research, research consultation, teaching, professional practice, institutional committee memberships and service on panels such as Institutional Review Boards orData and Safety Monitoring Boards.

11. ***Manage*** means taking action to address, reduce or eliminate a Financial Conflict of Interest or Conflict of Commitment so CTHMRF/PVAHCS can ensure, to the extent possible, that those responsible for thedesign, conduct and reporting of research will be free from bias.

12. ***Outside Activities and Interests*** means an Investigator's outside activities and relationships, even if not compensated and and/or not providing personal financial benefit. Outside Activities and Interests incorporate non-financial interests/relationships and include, for

example, the non- compensated provision of services for an outside entity (e.g., consulting, speaking, education, Advisory Board service, and Scientific Advisory Board service), and an Investigator's intellectual property rights and interests relating to any patents or copyrights (other than those owned by CTHMRF/PVAHCS) regardless of whether income has been received when the technology underlying the patent or copyright is related to the Investigator research at CTHMRF/PVAHCS .

13. ***Regulation or FCOI regulation*** refers to 42 CFR Part 50 Subpart F, Promoting Objectivity in Research (grants) and 45 CFR Part 94 (contracts). Refer to **Section 19, *Additional Resources***, for links to these federal regulations.

14. ***Report*** refers to CTHMRF's report of identified Financial Conflicts of Interest to the applicable fundingagency affected by the FCOI. In the case of NIH funding, a report about the identified FCOI will beentered into the eRA Commons FCOI Module. Other funding agencies may have separate reporting requirements, and these will be met as required.

15. ***Research*** means a systematic investigation, study or experiment designed to develop or contributeto generalizable knowledge relating broadly to public health or agriculture, and encompasses basic, translational and applied research. Research includes any activity for which research funding is available regardless of the source, including a research award, career development award, center grant award, fellowship award, infrastructure award, institutional training grant, program project award or research resources award.

16. ***Senior/key personnel*** means the Principal Investigator or Project Director and any other person identified as senior/key personnel by CTHMRF in the sponsored research application, progress reportor any other report submitted to the funding agency.

17. ***Significant Financial Interest*** means a financial interest of the Investigator and the Investigator'sspouse or domestic partner and dependent children, alone or in combination, that reasonably appears to be related to the Investigator's institutional responsibilities for CTHMRF. Types of financialinterests include remuneration, equity interests in a publicly and non-publicly traded entity, intellectual property rights and interests, and reimbursed or

sponsored travel. Refer to **Section 5, *What Should be Disclosed*?** for a more comprehensive description.

18. ***Small business innovation research*** (SBIR) is an award designed to support projects from smallbusinesses having commercial viability.

19. ***Small business technology transfer*** (SBTT) is a program under the SBIR program designed to foster technology innovation through cooperative efforts between small businesses and research institutions.

20. ***Sponsored/Reimbursed Travel*** is any travel expense related to an Investigator's institutional responsibilities that are either paid directly by a third party on behalf of Investigator so that the exact monetary value may not be readily available or for which the Investigator is reimbursed by a third party.

21. A ***subrecipient*** is defined as all non-CTHMRF/PVAHCS Investigators who are receiving funding awarded to CTHMRF/PVAHCS, including but not limited to collaborators, consortium members, consultants, contractors, subcontractors, and subawardees.

2. PURPOSE OF THE INVESTIGATOR CONFLICT OF INTEREST POLICY

Effective interactions between research institutions, government, the private sector, and industry are essential to bring about the rapid application of scientific discoveries to address the needs of the nation and to maintain the efficient translation of research findings. However, the resulting relationships, now encouraged in many forms, are increasingly complex, and may involve financial interests that give rise to a Financial Conflict ofInterest (FCOI) through its potential to directly and significantly impact the design, conduct or reporting of an Investigator's research in return for a financial benefit to the Investigator or his/her immediate family.

In addition, a Conflict of Commitment can arise if an Investigator's efforts for CTHMRF and the Phoenix Veterans Affairs Health Care System (PVAHCS) are diminished by commitments to outside endeavors. CTHMRF/PVAHCS investigators owe their primary professional allegiance to CTHMRF/PVAHCS, and their primary commitment of time and intellectual energies should be to CTHMRF/PVAHCS research and education programs. Consistent with the foregoing, many U.S. federal

agencies, including the National Institutes of Health(NIH) and National Science Foundation (NSF), require that their supported Investigators adequately disclose and report all of their outside professional activities, affiliations and appointments, whether or not compensated,and identify all resources made available in support of their research endeavors.

A Financial Conflict of Interest or a Conflict of Commitment may arise even though no improper conductor unethical behavior has occurred. CTHMRF/PVAHCS and its Investigators are responsible for identifying and then managing these Financial Conflict of Interests and Conflicts of Commitment to strengthen accountability and transparency,promote research objectivity, and maintain the integrity of research findings and prudent stewardship of public funds.

CTHMRF Investigator Conflict of Interest Policy was developed to comply with the specific 2011 federal requirements defined in the United States Department of Health and Human Services' Objectivity in Research Regulations 42 CFR Part 50 Subpart F (grants) and 45 CFR Part 94 (contracts). **Section 20, *Additional Resources,*** includes links to the federal regulations. The U.S. Public Health Service (PHS) oversees and monitors CTHMRF/PVAHCS /PVAHCS compliance with these regulations. PHS may inquire at any time before, during, or after a sponsored research award about an Investigator's Significant Financial Interest or Outside Activities and Interests, and CTHMRF review and response to such disclosure, regardless of whether the disclosure resulted in CTHMRF finding a FCOI.

All non-government employee (non-VA appointment) CTHMRF Investigators (hereafter referred to as investigators) are responsible for familiarizing themselves with the regulations so CTHMRF can effectively work with them to comply with these federal disclosure requirements. In turn, all Investigators will be notified about CTHMRF's conflict of interest requirements, as well as their disclosure responsibilities under this Investigator Conflict of Interest Policy.

CTHMRF's Conflict of Interest Committee administers this Policy and emphasize compliance with its requirements, including the review of Annual Disclosure Forms, the training and management of Investigators regarding Financial Conflict of Interest and Conflict of Commitment requirements, and the timely identification, reporting and management of FCOIs. In those instances where funding agency or sponsor has more stringent requirements and regulations relating to conflict of interest or conflict of commitment than those in the CTHMRF Investigator Conflict of Interest Policy, the requirements and regulations of that funding agency or sponsor will take precedence.

3. WHO MUST COMPLY WITH THE INVESTIGATOR CONFLICT OF INTEREST POLICY?

CTHMRF implemented specific procedures for annual disclosure and review of all Significant Financial Interests and Outside Activities and Interests so that as an institution the highest standards of integrity and objectivity can be applied to the design, conduct and reporting of research carried out for CTHMRF/PVAHCS. This Policy applies to all CTHMRF Investigators who have not received a federal appointment (Veterans Affairs employment appointment or a "Without Compensation" (WOC) appointment), regardless of title or position who are responsible for the design, conduct or reporting of research and includes, by way of example, all PhDs, MDs, graduate students, non-facultystaff at and above the level of research associate and any others deemed appropriate by CTHMRFs Conflict of Interest Committee. Collaborative and visiting researchers and subrecipient Investigators who are receiving federally funded research through CTHMRF may also be required to comply with CTHMRF 's Investigator Conflict of Interest Policy.

4. MANDATED CONFLICT OF INTEREST TRAINING FOR ALL INVESTIGATORS

All Investigators who are subject to the Investigator Conflict of Interest Policy are mandated to completethe Investigator Conflict of Interest Training prior to engaging in research for or on behalf of CTHMRF/PVAHCS, andat least every four years thereafter or immediately if (1) an Investigator is new to CTHMRF/PVAHCS; (2) CTHMRF/PVAHCS's InvestigatorConflict of Interest Policy changes in a manner affecting Investigator requirements; or (3) CTHMRF/PVAHCS finds that an Investigator is non-compliant with CTHMRF/PVAHCS 's Investigator Conflict of Interest Policy or an applicable management plan.

Subrecipient Investigators who are subject to CTHMRF Investigator Conflict of Interest Policy and participate in PHS-funded research are also required to complete the Investigator Conflict of Interest Training, which will be provided to them as an electronic copy, and/or will be required to utilize the Veterans Affairs training portal for conflict of Interest training (TMS). Investigator training completion dates can be requested and are also monitored byCTHMRF's Signing Official.

5. WHAT SHOULD BE DISCLOSED?

Each of the following Significant Financial Interests and Outside Activities and Interests should be disclosed on the Annual Disclosure Form and described on an Appendix Form to the extent they reasonably appear to be related to the Investigator's Institutional Responsibilities. In the interest of full transparency, Investigators should err on the side of disclosure.

1. Regarding any **publicly traded entity,** domestic or foreign, the value of any remuneration received from the entity in the 12 months preceding the disclosure plus the value of any equity interest held in the entity as of the date of disclosure that, when aggregated, exceeds $5,000.

   - Remuneration includes salary and any payment for services not otherwise identified as salary, such as consulting fees, honoraria and paid authorship.

   - Equity interests include stocks, stock options, or other ownership interests, as determinedthrough reference to public prices or other reasonable measures of fair market value.

   Note: Disclosure is not required for income from investment vehicles, such as mutual funds,ETFs, and retirement accounts as long as the Investigator does not directly control the investment decisions made in these vehicles.

2. Regarding any **non-publicly traded entity,** domestic or foreign, (a) the value of any remuneration received from the entity in the 12 months preceding the disclosure that when aggregated exceeds $5,000, and (b) any equity interests in the entity (regardless of value) thatare held by the Investigator or his/her spouse or domestic partner or dependent children.

   - Equity interests include stocks, stock options, or other ownership interests.
   - If at the time of disclosure there is no reasonable basis for assessing the fair market value or percentage interest in the non-publicly traded entity, the Investigator must fully describe the nature of the equity interest, including the number of shares owned, voting rights, etc.

3. Financial interests received in connection with **patents, copyrights, know-how or other intellectual property rights** (e.g., royalties, license fees, equity or other consideration) that when aggregated over the prior 12 months exceeds $5,000, including consideration received pursuantto an agreement to share royalties related to such intellectual property rights.

   Note: Disclosure is not required for royalties, fees or other consideration paid to the Investigatorby CTHMRF for intellectual property owned by CTHMRF (i.e., not personally owned by the investigator).

4. Any **advisory relationship, consulting, outside teaching, or scientific/academic appointment** including adjunct, visiting or honorary, with any domestic entity (other than CTHMRF/PVAHCS), both paid and volunteer, as well as any unpaid appointment that provides the Investigator with access to, or in-kind support for, laboratory space, research materials, supplies, equipment, staffparticipation or living expenses.

   Note: Disclosure is not required for the following:

   - Salary or other remuneration received from CTHMRF if the Investigator is currently employed or appointed by CTHMRF/PVAHCS.
   - Income from seminars, lectures, or teaching engagements sponsored by a U.S. federal, state or local government agency, a U.S. institution of higher education, a U.S. academic teaching hospital, a U.S. medical center or a U.S. research institute that is affiliated with a
     U.S. institution of higher education as defined in 20 U.S.C. 1001(a).
   - Income from service on advisory committees or review panels for a U.S. federal, state or local government agency, a U.S. institution of higher education, a U.S. academic teaching hospital, a U.S. medical center or a U.S research institute that is affiliated with a U.S. institution of higher education as defined in 20 U.S.C. 1001(a).

5. All **reimbursed expenses, gifts, gratuities, favors, lodging, or entertainment offers** that whenaggregated over the prior 12 months is under $1,000. As a reminder, Investigators may not solicit or accept reimbursed expenses, gifts, gratuities, favors, lodging, or excessive entertainment for themselves, his/her spouse or domestic partner or dependent children, alone or in combination, or for any person or organization that does business or has the potential of doing business with CTHMRF/PVAHCS. Exempt from this prohibition are non-cash gifts of nominal value involving normal and ordinary social amenities or sales promotions.

6. **Sponsored/Reimbursed Travel** that meets the following criteria:

   - travel **within the United States** received from a U.S. entity that when aggregated exceeds $5,000.

Note: Disclosure is not required for Sponsored/Reimbursed Travel stemming from a U.S. federal,state, or local government agency, a U.S. institution of higher education as defined in 20 U.S.C. 1001(a), a U.S. academic teaching hospital, a U.S. medical center, or a U.S. research institute that is affiliated with a U.S. institution of higher education.

- travel **outside the United States** received from a U.S. or foreign entity* regardless of dollar amount.

*Foreign entities include, but are not limited to, those stemming from a foreign company or government, including local, provincial or equivalent governments, government agencies, institutions of higher education, academic teaching hospitals, medical centers, or research institutes that are affiliated with an institution of higher education.

Information needed for the disclosure of Sponsored/Reimbursed Travel:

- Identity of the sponsor/organizer.
- Month and year of the travel.
- Financial value by range of the travel.
- Value of any associated honorarium.
- Purpose of the travel.
- Destination of the travel.
- Time duration of the travel.

Most scientific journals have implemented policies requiring authors to declare competing financial interests in relation to work published in those journals. Such requirements, including how financial interests are defined under those policies, are distinct from federal requirements relating to federally funded research and should not be used as a guide to what information an Investigator needs to disclose under CTHMRF/PVAHCS 's InvestigatorConflict of Interest Policy

6. WHO MUST SUBMIT AN ANNUAL DISCLOSURE FORM?

At time of appointment/employment, all Investigators, including by way of example PhDs, MDs, graduatestudents, non-faculty scientific staff at and above the level of research associate and any others deemed appropriate, are required to enter an initial Annual Disclosure Form that describe all Significant Financial Interests and Outside Activities and Interests related to their Institutional Responsibilities and then submit a new Annual Disclosure Form each subsequent year thereafter. Refer to **Section 7, *Updating the Annual Disclosure Form*** for additional information. Submitted Annual Disclosure Forms

are retained in the Executive Directors office. Collaborative and visiting researchers and subrecipient Investigators who are subject to CTHMRF/PVAHCS 's Investigator Conflict of Interest Policy and participating in PHS-funded research are also required to submit an Annual Disclosure Form, which will be provided as an electronic copy or fillable .PDF.

7. UPDATING THE ANNUAL DISCLOSURE FORM

All Investigators who do not perform work under a government appointment are required to simultaneously submit a current, accurate Annual Disclosure Form that identify and describe both existing and new Significant Financial Interests andOutside Activities and Interests related to their Institutional Responsibilities to the Signing Official by the yearly November 15th deadline. Subrecipient Investigators will complete an Annual Disclosure Form based on their particular funding cycle. Updated disclosures should also include any FCOIs identified on a project that was transferred from another institution.

Investigators are required to promptly disclose Significant Financial Interests and Outside Activities andInterests to accurately reflect their external activities as follows:

1. Disclose Significant Financial Interests and Outside Activities and Interests no later than at the time ofapplication for PHS-funded research.
2. Within 30 days of acquiring and/or discovering a new Significant Financial Interest or Outside Activityor Interest, including through purchase, marriage, or inheritance.
3. Within 30 days of a material change to a previously disclosed Significant Financial Interest or OutsideActivity or Interest.
4. At least annually in accordance with the November 15th deadline, during the period of an award.

8. ANNUAL DISCLOSURE FORM REVIEWED BY THE CONFLICT OF INTEREST COMMITTEE

CTHMRF's SO will review the Annual Disclosure Form and any new or modified Significant Financial Interests or Outside Activities or Interests disclosed throughout the year, and as such, may request further information or clarification from the Investigator. CTHMRF's SO will review each of the Investigator's disclosures and determine whether a Significant Financial Interest or Outside Activity or Interest is related to PHS funded research.

If there are Significant Financial Interests or Outside Activities or Interests related to the Investigator's funded research, these relationships must be examined and dealt with according to CTHMRF and funding agency policies on conflict of interest. A personal financial interest with an entity would be reasonably considered

related to an Investigator's research in circumstances such as the following:

1. Entity sponsors research at CTHMRF/PVAHCS in which the Investigator is directly involved.
2. Entity has financial interests that could reasonably be considered to have a potential influence on the design, conduct or reporting of the Investigator's research.
3. Entity has a reasonable possibility of being financially affected by Investigator's research.
4. Entity makes monetary or in-kind gifts or loans to CTHMRF/PVAHCS that benefit the Investigator's research including a gift or loan of equipment.
5. Entity makes a product that is under study in research in which the Investigator is involved.
6. Entity licenses intellectual property from CTHMRF/PVAHCS in which the Investigator has a financial interest.
7. Entity has a Material Transfer Agreement to provide materials used in the Investigator's research or for materials provided by the Investigator to the entity.
8. Entity sponsors or makes a product that is under study in human subjects in which the Investigator is directly or indirectly involved.

CTHMRF's Conflict of Interest Committee, which is comprised of the CTHMRF Board of Directors (Comprised of community members and the Phoenix Veterans Affairs Health Center Service; Center Director, Chief of Staff, Associate Chief of Staff for Research, and Associate Chief of Staff for Education), reviews all Significant Financial Interests and Outside Activities and Interests to identify and address any issues.

A FCOI will be deemed to exist when CTHMRF, acting through its Conflict of Interest Committee and following the procedures described in this Investigator Conflict of Interest Policy, reasonably determines that a Significant Financial Interest could directly and significantly affect the design, conduct or reporting of the Investigator's research. CTHMRF's Conflict of Interest Committee reviews and analyzes the specific circumstancesof a Significant Financial Interest by taking into account such factors as the nature of the Investigator's relationship to an outside entity, the dollar value of that relationship, and the overlap between that relationship and the Investigator's research. CTHMRF's Conflict of Interest Committee may, if warranted, involve the Investigator in determining whether a Significant Financial Interest is related to the research in question.

A Conflict of Commitment will be deemed to exist when CTHMRF, acting through its Conflict of Interest Committee and following the procedures described in the Investigator Conflict of Interest Policy, reasonably determines that an Investigator's Outside Activities and Interests are inconsistent with his/her

obligations and commitments to CTHMRF and its interests. Conflicts of Commitment are handled in consultation with the Investigator and, if necessary, his/her supervisor, and generally result in reduction or elimination of one or moreOutside Activities and Interests.

9. MANAGING A FINANCIAL CONFLICT OF INTEREST

If a Significant Financial Interest is identified as a FCOI, CTHMRF's Conflict of Interest Committee will take action to manage the FCOI by robustly reducing or eliminating the conflict by designing a management plan or mechanism appropriate for the specific situation. During the design process, CTHMRF's Conflict of Interest Committee may query CTHMRF/PVAHCS 's Office of Sponsored Programs, the Internal Review Board, and the Veterans Affairs Ethics Committee of PVAHCS or any other CTHMRF Committees, departments or individuals as necessary to solicit additional information and alternate ideas. CTHMRF's Conflict of Interest Committee will, as necessary, accept, modify or reject the proposed management plan. After the management plan is approved byCTHMRF's Conflict of Interest Committee, the SO will forward a detailed letter to the Investigator describing the management plan and its implementation.

This written plan will require that the Investigator take certain steps according to guidelines approved byCTHMRF's Conflict of Interest Committee. Conditions or restrictions that might be imposed to manage a FCOI include the following:

- Disclosure of the FCOI to lab personnel and collaborators.
- Disclosure of the FCOI directly to human subject research participants.
- Disclosure of the FCOI in publications, journals, and posters, etc.
- Disclosure of the FCOI to audiences at conferences and seminars.
- Monitoring of research, proposals and data by independent peer reviewers.
- Modification of the research plan.
- Removal of an affected Investigator from participation in all or the portion of the research funded by the entity affected by a Significant Financial Interest.
- Divestiture of a Significant Financial Interest by the affected Investigator.
- Limiting the dollar value of fees received and/or stock ownership.
- Severance of the relationship creating the conflict.

The Investigator will be asked to review and sign the letter to acknowledge agreement with the management plan, or the Investigator may, at this point, appeal the findings of CTHMRF's Conflict of Interest Committee to CTHMRF's Director of the Board by forwarding a written request for reconsideration of these findings to CTHMRF'sDirector of the Board within thirty days. CTHMRF's Director of the Board will determine whether the FCOI exists and the appropriate plan for managing the FCOI. CTHMRF's Director of the Board, with majority concurrence of the board of directors has the final review and authority regarding the management of all FCOIs.

10. REPORTING A FINANCIAL CONFLICT OF INTEREST TO THE FUNDING AGENCY

CTHMRF will promptly notify the appropriate funding agency about any corrective action taken or to be taken in a situation of noncompliance.

1. With regard to a **new NIH - sponsored research award**, CTHMRF will report the identified FCOI to the NIH through the electronic Research Administration (eRA) Commons FCOI Module. CTHMRF willsubmit the FCOI report before dispensing or spending any funds. If the FCOI is eliminated prior todispensing or spending any funds, then no FCOI report is required. In addition, CTHMRF is required to submit a FCOI report for FCOIs identified for subrecipient Investigators, if applicable. Refer to **Section 18, *Subrecipient Conflict of Interest Compliance***, for more information regarding subrecipients.
2. Regarding an **ongoing NIH - sponsored research award,** CTHMRF will report to the NIH throughthe eRA Commons FCOI Module information about the identified FCOI within 60 days of the FCOI'sidentification. For any Significant Financial Interest that is identified as a FCOI subsequent to CTHMRF's initial FCOI report during an ongoing NIH funded research project, CTHMRF shall within 60 days, review the Significant Financial Interest disclosure, determine whether it is related to the research, and, if so, implement on at least an interim basis, a management plan that shall specify the actions that have been and will be, taken to manage the FCOI.
3. Annual FCOI follow-up reports will be provided to the NIH for any FCOI previously reported by CTHMRF. The annual FCOI report will specify whether the FCOI is still being managed, describe any changes to the management plan or explain why the FCOI no longer exists. CTHMRF will provide annual FCOI reports for the duration of the project period, including extensions with or without funds, as prompted by the ERA Commons generated email that requests that the follow-up report be submitted.

4. CTHMRF will meet the reporting requirements pertaining to FCOIs for other federally funded agencies,including, DOD, DOE, NSF and USDA as instructed by the particular agency.
5. Regarding a **new, non-federally funded award**, CTHMRF may, if warranted, disclose through written notification, information about the identified FCOI to any corporation, educational institution, non-profit entity, private foundation, trust and individual donor before dispensing or spending any funds.
6. Regarding an **ongoing, non-federally funded award**, CTHMRF may, if warranted, disclose through written notification, information about the identified FCOI to any corporation, educationalinstitution, non-profit entity, private foundation, trust and individual donor during the award's duration.

11. WHAT INFORMATION IS SUBMITTED TO THE NIH ABOUT A FINANCIAL CONFLICT OF INTEREST?

Information submitted to the NIH about an identified FCOI includes the following:

- Project number/contract number.
- Name of the Principal Investigator or Project Director, or the contact PI/PD if a multiple PI/PD model is used.
- Name of the Investigator with the FCOI.
- Name of the entity with which the Investigator has the FCOI.
- Statement about how the FCOI was managed.
- The nature of the FCOI (e.g., equity interest, consulting fees, intellectual property rights and interests, travel reimbursement, and honoraria).
- The value of the financial interest; $0-$4,999, $5,000-$9,999, $10,000-$19,999; amounts between $20,000-$100,000 by increments of $20,000; amounts above $100,000 by increments of $50,000; or a statement that a value cannot be readily determined through reference to public prices or reasonable measures of fair market value.
- A description about how the FCOI relates to the research and the basis for CTHMRF's determination that a Significant Financial Interest conflicts with such research.

A description of the key elements of CTHMRF's management plan must also be submitted to the NIH including the following information:

- Role and principal duties of the conflicted 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 facilitate Investigator compliance.
- Other information as needed.

Other funding agencies outside the NIH may require that different information to be submitted, and CTHMRF will meet their requirements as instructed.

12. PUBLIC ACCESSIBILITY TO CTHMRF'S INVESTIGATOR CONFLICT OF INTEREST POLICY AND IDENTIFIED FINANCIAL CONFLICTS OF INTEREST

CTHMRF's Investigator Conflict of Interest Policy is publicly accessible by request via electronic or written request within 5 days. CTHMRF maintains public accessibility to Significant Financial Interests of senior/key personnel that were identified as FCOIs and reported to the NIH. As such, CTHMRF responds to all written requests for information within five business days and then releases the following information about such Significant Financial Interest.

- The name of the Investigator.
- The title and role of the Investigator with respect to the research project.
- Name of the entity with which the Significant Financial Interest is held.
- The nature of the Significant Financial Interest.
- Approximate value of the Significant Financial Interest as determined by dollar range $0-$4,999, $5,000-$9,999, $10,000-$19,999; amounts between $20,000-$100,000 by increments of $20,000; amounts above $100,000 by increments of $50,000; or a statement that a value cannot be readily determined through reference to public prices or reasonable measures of fair market value.

13. CONTINUED MONITORING OF A FINANCIAL CONFLICT OF INTEREST AND CTHMRF COMPLIANCE

CTHMRF continually monitors the FCOI and Investigator compliance with the FCOI management plan throughout the year and until the completion of the research project. As necessary, CTHMRF's Conflict of Interest Committee may require and develop a project specific monitoring process, which may include appointing a CTHMRF/PVAHCS designated official to assist with monitoring the FCOI Investigator compliance.

14. WHAT HAPPENS AFTER FCOI IS REPORTED TO THE NIH?

The NIH evaluates the FCOI information received through the eRA Commons FCOI Module to determineif CTHMRF's actions are sufficient to manage the identified FCOI. The NIH may request and review additional information before implementing, if needed, further corrective actions to ensure research objectivity. If the NIH decides that the FCOI will bias the objectivity of the funded research to such an extent that further corrective action is needed or that CTHMRF has not managed the FCOI in accordance with the regulation, it may impose special award conditions, suspend funding or enforce other actions until the matter is sufficiently resolved. Other funding agencies outside the NIH may have a different process, and CTHMRF will meet theirrequirements as instructed.

15. NON-COMPLIANCE AND ENFORCEMENT

CTHMRF will establish adequate enforcement mechanisms, provide for employee sanctions and take otheradministrative action, where appropriate, in the event an Investigator is non-compliant with the Investigator Conflict of Interest Policy or management plan. Violations of this Policy may be grounds for progressive disciplinary action including:

1. Placing a hold on the processing of new sponsored research applications from a non-compliantInvestigator.
2. Withholding disbursement or distribution of project-specific funding to the Investigator's laboratory.
3. Termination of employment.

An Investigator is non-compliant and in violation of the Policy if an Investigator fails to:

1. Submit an Annual Disclosure Form or provide an update to the Annual Disclosure Form by thedeadlines established for such submissions by CTHMRF's Conflict of Interest Committee.
2. Provide CTHMRF's Conflict of Interest Committee with written acknowledgement of a managementplan.
3. Provide CTHMRF's Conflict of Interest Committee with requested documentation regardingcompliance with a management plan.

If an Investigator fails to comply with CTHMRF's Investigator Conflict of Interest Policy or management plan, within120 days CTHMRF/PVAHCS will:

1. Complete a retrospective review of the key elements (see below) of the Investigator's activities andthe NIH funded research project to determine any bias in the design, conduct, or reporting of research.
2. Document the retrospective review.
3. Document CTHMRF's determination as to whether any NIH funded research, or portion thereof, conducted during the period of time of the Investigator's non-compliance with the Investigator Conflict of Interest Policy or management plan, was biased in the design, conduct, or reporting of such research.

If bias is found, CTHMRF will submit a mitigation report with the key elements (see below) addressing the impact of the bias on the research project, including the extent of the harm done, and any qualitative and quantitative data to support any actual or future harm, analysis of whether the project is salvageable and the actions CTHMRF has taken, or will take, to eliminate or mitigate the effect of the bias. Depending on the nature of the FCOI, CTHMRF may determine that additional interim measures are necessary with regard to the Investigator's participation in the research project between the date the FCOI is identified and the completion of CTHMRF/PVAHCS 's retrospective review. Thereafter, CTHMRF will submit FCOI reports as prescribed by the regulation.

Furthermore, if the NIH determines that one of its funded clinical research projects 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 an FCOI that was not managed or reported by CTHMRF,

CTHMRF shall 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.

The following key elements apply to both the retrospective review and mitigation report:

- Project number.
- Project title.
- The PI or contact PI/PD if a multiple PI model is used.
- Name of the Investigator with the FCOI.
- Name of the entity with which the Investigator has a FCOI.
- Reason(s) for the retrospective review.
- Detailed methodology used for the retrospective review including the methodology of the process, composition of the review panel, documents reviewed etc.
- Findings of the review.
- Conclusions of the review.

16. FCOI CERTIFICATION FORM SUBMISSION

The Principal Investigator or Project Director involved with a funding submission is required to enter a FCOI Form one week prior to submitting a sponsored research application requesting an amount greater than $5,000 from a corporation, educational institution, federally funded agency, non-profit entity, private foundation or trust in order to confirm the PI/PD's continued compliance with the Investigator Conflict of Interest policy.

The basic information needed to complete the FCOI form is as follows:

- Name of the Principal Investigator or Project Director.
- Name of the funding organization.
- The funding opportunity announcement.
- Submission deadline.
- Project title.
- Names of personnel who are responsible for the design, conduct or reporting on any of the proposed research, including non-CTHMRF/PVAHCS Investigators (domestic and foreign) such as collaborators, sub-recipients, or subcontractors proposed for funding.

The FCOI Form then confirms the following:

- That the Principal Investigator or Project Director has read the Investigator Conflict of Interest Policy and submitted an Annual Disclosure Form in the last 12 months.
- That the Principal Investigator or Project Director does not have any new or changed Significant Financial Interest information to disclose.
- Whether any Significant Financial Interest could directly and significantly affect the design, conduct or reporting of the research.
- The project's involvement in a clinical trial.
- The involvement of any foreign component.

CTHMRF's SO will contact any Principal Investigator or Project Director who fails to submit a FCOI Form. Upon receipt of an award notice of $5,000 or more, CTHMRF's SO will verify that a FCOI Form was entered into the FCOI portal, and if not, the Principal Investigator or Project Director must complete the FCOI Form in order for the award to be processed.

17. FOREIGN RESEARCH COMPONENTS

CTHMRF values its international collaborations, but the federal government remains concerned about foreign threats to the research infrastructure in the U.S. As such, CTHMRF Principal Investigators or Project Directors are asked to disclose on the Project Specific Certification Form any scientific element or segment of the project that is being conducted outside of the U.S., regardless of whether the foreign component will receive funding from the sponsored research application. In addition, the Principal Investigator or Project Director is asked to disclose if a foreign component provides the Principal Investigator or Project Director or any of their laboratory members with any resources or financial support, access to, or in-kind support for laboratory space, research materials, supplies, equipment or staff participation. CTHMRF's Board of Directors and/or federal funding agencies may request additional information regarding a foreign research component, and if needed, institute specific corrective actions to comply with the NIH Grants Policy statement. Refer to **Section 20, *Additional Resources***, for a link to the federal regulation.

Activities that meet the definition of a foreign component include, but are not limited to the following:

- The involvement of human subjects or animals from or in a foreign entity.
- Extensive foreign travel by recipient project staff for the purpose of data collection, surveying, sampling and similar activities.
- Any activity of the recipient that may have an impact on U.S. foreign policy through involvement in the affairs or environment of a foreign country.

- Collaborations with Investigators at a foreign site anticipated to result in co-authorship.
- Use of facilities or instrumentation at a foreign site.
- Receipt of financial support or resources from a foreign entity.

Note: Foreign travel for consultation is not considered a foreign component but requires disclosure as Sponsored/Reimbursed Travel. Refer to **Section 5, *What Should be Disclosed***, for more information about foreign travel disclosure.

18. SUBRECIPIENT CONFLICT OF INTEREST COMPLIANCE

A subrecipient relationship is established when federal funds flow down from or through CTHMRF to another individual or entity and the subrecipient will be conducting a substantive portion of a PHS-funded research projectand is accountable to CTHMRF for programmatic outcomes and compliance matters. Subrecipients, who include but are not limited to collaborators, consortium members, consultants, contractors, subcontractors and subawardees, are subject to CTHMRF's terms and conditions, and as such, CTHMRF will take reasonable steps to ensure that any subrecipient Investigator is in compliance with the federal FCOI regulation. CTHMRF will incorporate as part of a written agreement with the subrecipient, terms that establish whether CTHMRF's Investigator Conflict of Interest Policy or that of the subrecipient's institution will apply to the subrecipient Investigator.

If the subrecipient's conflict of interest policy applies to the subrecipient Investigator, the subrecipient institution will certify as part of the agreement with CTHMRF that it is in compliance with the federal FCOI regulation and that the institution's portion of the project is in compliance with the federal conflict of interest policy. If the subrecipient cannot provide the certification, the agreement shall state that the subrecipient Investigator is subject to CTHMRF's Investigator Conflict of Interest Policy for disclosing Significant Financial Interests that are directly related to the subrecipient's work for CTHMRF. CTHMRF will, if applicable, submit a FCOI report to the NIH through the eRA Commons FCOI Module for any FCOIs identified for a subrecipient Investigator. If the subrecipient's conflict of interest policy applies to the subrecipient Investigator, the agreement shall specify the time period for the subrecipient to report all identified FCOIs to CTHMRF. Such time period must be sufficient to enable CTHMRF to provide timely FCOI reports to the NIH as necessary, through the eRA Commons FCOI Module.

If the subrecipient Investigator is subject to CTHMRF's Investigator Conflict of Interest Policy, the agreement shall specify the time period for the subrecipient to submit all Investigator disclosures of Significant Financial Interests to CTHMRF. Such time period shall be sufficient to enable

CTHMRF to comply with its review, management, and reporting obligations under the regulation. CTHMRF will submit any NIH FCOI reports for a subrecipient Investigator through the eRA Commons FCOI Module. Other funding agencies outside the PHS may have a different process as it pertains to subrecipients, and CTHMRF will meet their requirements as instructed.

19. RECORD RETENTION

Records relating to conflict of interest matters covered under this Investigator Conflict of Interest Policy for PHS-funded research must be maintained for a minimum period of three years after any applicable research project's final financial report is submitted to the funding agency, or until three years after the final action has been taken on any audit, litigation or claim, whichever is longer. Records for conflict of interest matters relating to other funded research will be maintained in accordance with CTHMRF/PVAHCS 's Record Retention Policy.

20. ADDITIONAL RESOURCES AND PHS POLICY LINKS

Please contact CTHMRF's SO by email at Jeremy.Greene@va.gov to inquire about the Investigator Conflict of Interest Policy or about CTHMRF's compliance.

- See the United States Department of Health and Human Services' Objectivity in Research Regulations42 CFR Part 50 Subpart F (grants) (click this link) and 45 CFR Part 94.
- See the NIH's Office of Extramural Research Financial Conflict of Interest Web page: (click this link).
- See the NIH's training about FCOIs: (click this link).
- See the Reminders of NIH Policies on Other Support and on Policies Related to Financial Conflicts of Interests and Foreign Components to determine if additional disclosures should be made at JIT or in the next progress report: (click this link).
- See NIH Other Support Information Page: (click this link).
- See NSF Current and Pending Support FAQs: (click this link).