Standard Operating Procedure

TVAREF SOP – 09 - Policy for Responding to Allegations of Research Misconduct

December 13, 2012

I. INTRODUCTION

A. General Information

In 1997, TVAREF was created in accordance with Title 38, United States Code (U.S.C.), sections 7361 through 7366, Congress allowed for the creation of Non-Profit Corporations (NPC) such as TVAREF for the purpose of providing flexible funding mechanisms for the conduct of research at VA Medical Centers.

TVAREF may facilitate the conduct of VA-approved research as described in sections 7303(a) and education and training in section 7303, 7471, 8154, and 1701(6)(B) of title 38, U.S.C. Each research project approved by the James A. Haley Veterans' Hospital (JAHVH) Research and Development Committee and each education activity approved by JAHVH Education Committee is considered to be a VA research project or a VA Education activity respectively, regardless of the source of funding, the entity administering the funds, or the research or education site.

While TVAREF is dedicated to the facilitation of VA approved research, it is incorporated in the state of Florida. Consequently, TVAREF is governed by both federal and state laws. TVAREF is a unique organization guided by a Board of Directors composed of the VA Director, Chief of Staff, etc. in the state of Florida. The fiduciary duty of the Board of Directors is to oversee and manage the affairs of TVAREF in accordance with VA regulations and state laws.

TVAREF was incorporated in the State of Florida for the purpose of providing the flexible funding mechanism for administering the budgets for Federal grants (DoD, NIH, PHS, etc.), pharmaceutical grants, and education and independent Association grants (American Heart Association, Muscular Dystrophy Association, American Diabetes Association, etc.).

B. General Policy

TVAREF supports the James A. Haley Veterans' Hospital in its research mission. The purpose is to promote biomedical and health services research by VA staff, both paid and without compensation (WOC) through comprehensive research resource management.

TVAREF is dedicated to uphold the highest standards related to scientific integrity. TVAREF, suppliers of grant accounts, clients of consultation services, and the public all have the right to expect and demand unbiased and factual information from professional researchers. Any intentional distortion of research data or intentional distortion of information or conclusions derived from research data constitutes misconduct in research and is prohibited by TVAREF policy.

An atmosphere of intellectual honesty enhances the research process and need not inhibit productivity and creativity. Establishing and maintaining such an atmosphere is a responsibility that must be accepted by all TVAREF personnel. Fortunately, research misconduct occurs very rarely. However, the potentially severe consequences to the academic reputation and creditability of TVAREF make it the responsibility of all to report promptly and confidentially indications of research misconduct.

C. Scope

This policy applies to federally-funded research and proposals submitted to Federal agencies for research funding (Public Health Service (PHS), Department of Defense (DoD), Department of Veterans Affairs (DVA), etc) as well as private industry sponsored grants. This policy and the associated procedures apply to all individuals at the TVAREF engaged in research that is guided by 42 C. F. R. Part 50, Subpart F (PHS); and Title 38, USC, 7307 and 65 Federal Register, 76260 (December 6, 2000).

This policy applies to any person paid by, under the control of, or affiliated with TVAREF, i.e., scientists, trainees, technicians, other staff members, students, fellows, guest researchers, or collaborators.

II. DEFINITIONS

Allegation means any written or oral statement or other indication of possible scientific misconduct made to an institutional official.

Conflict of interest means the real or apparent interference of one person's interests with the interests of another person, where potential bias may occur due to prior or existing personal or professional relationships.

Deciding Official means the institutional official who makes final determinations on allegations of scientific misconduct and any responsive institutional actions.

Employees for the purpose of this policy refers to both Department of Veterans affairs and Tampa VA Research and Education Foundation employees.

Facility means the James A. Haley Veterans' Hospital (JAHVH) a hospital within the of the Department of Veterans Affairs (DVA) that is responsible for the care of veterans and is responsible for the scientific misconduct and research integrity activities for research conducted at the facility.

Goodfaith allegation means an allegation made with the honest belief that scientific misconduct may have occurred. An allegation is not in good faith if it is made with reckless disregard for or willful ignorance of facts that would disprove the allegation.

Inquiry means gathering information and initial fact-finding to determine whether an allegation or apparent instance of scientific misconduct warrants an investigation.

Investigation means the formal process whereby a properly constituted Investigation Committee evaluates all the relevant facts, determines whether the evidence supports a finding of research misconduct, identifies the responsible individual(s), and assesses the seriousness of the misconduct.

ORI means the Office of Research Integrity, the office within the US Department of Health and Human Services (DHHS) that is responsible for the scientific misconduct and research integrity activities of the US Public Health Service.

ORO means the VHA office that advises the Under Secretary for Health on all compliance matters related to the protection of human research subjects, research misconduct, laboratory animal welfare, and research safety. ORO Central Office oversees VHA's research misconduct program in general and reviews all misconduct cases adjudicated by the VISN Directors.

PHS means the US Public Health Service, an operating component of the DHHS. PHS regulation means the Public Health Service regulation establishing standards for institutional inquiries and investigations into allegations of scientific misconduct, which is set forth at 42 C. F. R. Part 50, Subpart F, entitled "Responsibility of Applicants for Promoting Objectivity in Research for which PHS Funding is Sought."

PHS support means PHS grants, contracts, or cooperative agreements or applications therefore.

Research Integrity Officer means the Facility's institutional official responsible for assessing allegations of scientific misconduct and determining- when such allegations warrant inquiries and for overseeing inquiries and investigations.

Research Misconduct is defined as fabrication, falsification, or plagiarism in proposing, performing, or reviewing research, or in reporting research results.

Research record means any data, document, computer file, computer diskette, or any other written or non-written account or object that reasonably may be expected to provide evidence or information regarding the proposed, conducted, or reported research that constitutes the subject of an allegation of scientific misconduct. A research record includes, but is not limited to, grant or contract applications, whether funded or unfunded; grant or contract progress and other reports; laboratory notebooks; notes; correspondence; videos; photographs; X-ray film; slides; biological materials; computer files and printouts; manuscripts and publications;

equipment use logs; laboratory procurement records; animal facility records; human and animal subject protocols; consent forms; medical charts; and patient research files.

Respondent means the person against whom an allegation of scientific misconduct is directed or the person whose actions are the subject of the inquiry or investigation. There can be more than one respondent in any inquiry or investigation.

Retaliation means any action that adversely affects the employment or other institutional status of an individual that is taken by an institution or an employee because the individual has in good faith, made an allegation of scientific misconduct or of inadequate institutional response thereto or has cooperated in good faith with an investigation of such allegation.

Scientific misconduct or **misconduct in science** means fabrication, falsification, plagiarism, or other practices that seriously deviate from those that are commonly accepted within the scientific community for proposing, conducting, or reporting research. It does not include honest error or honest differences in interpretations or judgments of data.

Informant means a person who makes an allegation of scientific misconduct.

VISN (Veterans integrated Service Network) Director means the head of the designated regional service within the VA medical system. Each VA medical center belongs to a geographically-determined VISN and reports to the Director of that service.

III. RIGHTS AND RESPONSIBILITIES

A. Research Integrity Officer

The Director of the James A. Haley Veterans' Hospital has designated the ACOS/R&D as the permanent RIO at this facility. The RIO is responsible for overseeing all aspects of research misconduct Inquiries and Investigations except as otherwise provided herein.

1. The RIO is responsible for:

   (a) Receiving formal allegations of research misconduct, determining whether the alleged misconduct falls within the scope and meets the required threshold of these procedures (VA Handbook 0700), overseeing all Inquiries and Investigations, maintaining files of all documents and evidence, ensuring the confidentiality and security of those files, forwarding all information to the

appropriate offices or persons as required by these procedures, and otherwise acting as a liaison between the VA facility and ORO.

(b) Coordinating and monitoring the necessary steps for maintaining appropriate safeguards for Respondents and Informants.

(c) Receiving initial and continuing education and training in the handling of research misconduct allegations according to the information provided in Handbook 1058.02, and transmitting the information obtained in such training to members of Inquiry and Investigation Committees.

(d) Keeping the scientific and administrative staff of the facility informed of the policies and procedures in this Handbook and for overseeing the VA medical center's compliance with the provisions of Handbook VHA Handbook 1058.02.

(e) Demonstrating objectivity, both apparent and actual, in carrying out RIO duties.

B. Informants

1. Employees have a responsibility to report suspicions of misconduct in VA research if, after a careful assessment of the readily available facts, they honestly and reasonably believe there is credible evidence of misconduct.

2. Employees have a responsibility to cooperate in good faith with research misconduct reviews whether led by the Facility or an agency/entity with joint jurisdiction such as PHS, DoD, etc.

3. Facility authorities must make diligent efforts within the scope of their authority to protect from retaliation Informants who make good faith and reasonable allegations of research misconduct or who cooperate with an Inquiry or Investigation in good faith.

4. Employees, former employees, and applicants for employment who make allegations of research misconduct or cooperate with an Inquiry or Investigation consistent with the Whistleblower Protection Act of 1989, may seek redress for retaliation as provided under that Act (see Title 5 of the United States Code (U.S.C.) Section 1201 Notes, et seq.).

5. Informants' requests to protect their identities are to be honored as far as possible. In order to complete most Investigations, however, an Informant's identity and testimony may ultimately be required.

6. Informants may consult privately with the RIO before making a formal, written allegation. The RIO must:

(a) Indicate any deficiencies in the potential allegation, and

(b) Explain to the Informants the procedures for making an allegation and their responsibilities and safeguards under these procedures.

7. Informants who make good faith and reasonable allegations of research misconduct must be given an opportunity to provide testimony during the Inquiry and Investigation phases, to review portions of the Investigation Report pertinent to their own testimony, and to be informed of the general outcome of the Inquiry and Investigation as it relates to their allegations.

8. Employees whose research misconduct allegation or cooperation with an Inquiry or Investigation is not in good faith may be subject to disciplinary measures.

C. Respondent

1. Respondents must be given timely, written notification of the allegations made against them, a description of all such allegations, and reasonable access to the data and other evidence supporting the allegations.

2. Respondents will be given the opportunity to respond to allegations of research misconduct, the supporting evidence, proposed findings of research misconduct, and proposed corrective actions, if any. They must be promptly notified of final findings and actions.

3. Respondents must have the opportunity to be interviewed and present evidence during the Inquiry and Investigation and to provide comments on the Investigation report. Respondents are required to cooperate in good faith with any Inquiry or Investigation conducted pursuant to this Handbook. Inquiries and Investigations proceed regardless of Respondents' cooperation, and misconduct determinations are based on the available evidence.

4. Respondents may obtain the advice of legal counsel or a personal advisor who is not otherwise involved with the case. The counsel or advisor may be present at interviews with the Respondent, but may not speak for, or on behalf of, the Respondent during the Inquiry or Investigation.

5. Respondents are prohibited from retaliating against Informants who make good faith and reasonable allegations of research misconduct, even if such allegations are ultimately not substantiated. To the extent that allegations of research misconduct constitute disclosures under the Whistleblower Protection Act of 1989, individuals making such disclosures are covered by the protections of that Act, including protection from retaliation.

6. Respondents against whom a finding of research misconduct is made under these procedures must be afforded an opportunity to appeal that finding and proposed corrective action (See VHA Handbook 1058.02).

7. If another agency or entity has joint jurisdiction over a misconduct case, additional sanctions within the authority of that agency or entity may also apply.

8. Respondents who are not found guilty of committing research misconduct must be afforded reasonable assistance in restoring their reputations to the extent that Facility management deems appropriate, and within the scope of the Facilities authority.

D. Deciding Official

In keeping with VHA Handbook 1058.02, the VISN 8 Director will receive a research misconduct case from the Facility once its Investigation Report is completed. The VISN 8 Director will review the Investigation Report and all supporting documents before making a final adjudication of the matter.

IV. JOINT JURISDICTION

For every research misconduct allegation received, the VA medical center RIO must determine whether and what other non-VA agencies or entities have joint jurisdiction over the underlying research. Joint jurisdiction may be exerted by agencies or entities that co-sponsor or otherwise support the research, employ or provide academic privileges to the principal investigator(s) or support staff, or provide regulatory oversight. Examples include, but are not limited to: the VA medical center's academic affiliate, the Public Health Service (PHS) of the Department of Health and Human Services (HHS), the Food and Drug Administration (FDA), and other sponsors and regulators.

Joint Jurisdiction will be determined in accordance with VA Handbook 1058.02.

V. GENERAL PROCEDURES

A. Initial Report:

1. Any individual, including subjects or subjects' family, investigators, or research personnel, can initiate a complaint or inquiry about a research project conducted under the purview of this Facility. The Research Integrity Officer (RCO) serves as

the initial contact person for all concerns, complaints or allegations of misconduct or noncompliance (See Section III, A., 1, Responsibility of RIO).

2. The RIO notifies the Medical Center Director (MCD) of all allegations received.

B. Investigation:

1. Reports of Concerns or Complaints: The RIO will conduct an initial inquiry of fact finding as appropriate to the allegation of misconduct. The purpose of fact finding is to determine whether the allegation of misconduct contains all the threshold requirements for opening an Inquiry.

2. Reports of Allegations of Misconduct: If a research misconduct allegation meets the threshold requirements for misconduct, an Inquiry must be initiated for the sole purpose of determining whether sufficient evidence exists to open a formal Investigation (See VHA Handbook 1058.02, subpar. 13e and 15).

3. Initiation of Inquiry: The VA medical center Director must convene an Inquiry within 5 working days after a research misconduct allegation is received if the allegation meets the threshold requirements and it has been determined that the VA medical center will take lead responsibility for the Inquiry (See VHA Handbook 1058.02, subpar 13e and 12c(4).

(a). The following persons must be provided written notification of the misconduct allegation and the opening of an inquiry:

i. The named respondent(s);
ii. The Informant;
iii. The Director VISN 8;
iv. ORO Central Office;
v. The research misconduct oversight office for the agency or entity with joint jurisdiction (ORI).

(b) Inquiry review can be conducted by either the RIO or an Inquiry Committee appointed by the Facility Director.

i. If the RIO, or Inquiry Committee, finds that the available evidence is insufficient to justify opening an Investigation, and the VA medical center Director concurs, the VA case will be terminated.

ii. If the RIO, or Inquiry Committee, finds that the available evidence is sufficient to justify opening an Investigation, or if the VA medical center Director disagrees with a recommendation to terminate the case, an Investigation must be opened.

iii. The Inquiry Report (including final Inquiry Report) must normally be completed within 30 days from the initiation of the Inquiry. If an extension is required, the VA Facility Director shall submit a timely request to ORO Central Office which may grant such request at its discretion.

4. **Initiation of Investigation:** If the Inquiry results in a recommendation to open an Investigation, an Investigation must be initiated for the purpose of determining whether and to what extent research misconduct has occurred, who is responsible, and what corrective actions are appropriate

(a) Each Investigation must be conducted by an Investigation Committee composed of three to five individuals.

(b) The investigation committee must be constituted within 10 working days of the Inquiry's recommendation to pen an Investigation.

(c) The Investigation Committee may be either a standing committee which conducts all research misconduct Investigations for the VA medical center or an ad hoc committee reconstituted for each new misconduct allegation.

(d) The Investigation Review (including final Investigation Report) normally must be completed within 90 days from the initiation of the Investigation. If an extension is required, the VA medical center Director must notify ORO Central Office at least 5 working days prior to the end of the initial review period. ORO may grant an extension at its discretion.

(e) The Investigation Committee is to produce an Investigation Report that summarizes the research misconduct allegation, the evidence reviewed, and the Committee's recommendation about whether research misconduct occurred and, if so, the type and extent of misconduct, who is responsible, and appropriate corrective actions (see VA Handbook 0700).

5. Final Decision: The VISN Director reviews the Investigation Report and all supporting documents before making a final adjudication of the matter.

(a) After fully reviewing the case, the VISN Director makes a decision about whether research misconduct occurred, and if so, who is responsible, the type of misconduct involved (fabrication, falsification, and/or plagiarism), the extent or seriousness of the misconduct, and appropriate corrective actions.

(b) The review and final decision is to be completed within 30 days of the VISN Director's receipt of the Investigation Report.

(c) When the VISN Director has made a final decision on the merits of a research misconduct case, that decision is to be transmitted to ORO Central Office along with the Investigation Report.

6. Appeals : All final VA research misconduct findings and proposed corrective actions (including debarment, if applicable), except those based upon a conviction or civil judgment, may be appealed to the Under Secretary for Health (See VHA handbook 1058.02)

VI. REQUIREMENTS FOR REPORTING TO ORI

a. An institution's decision to initiate an investigation will be reported in writing to the Director, ORI, on or before the date the investigation begins. At a minimum, the notification should include the name of the person(s) against whom the allegations have been made, the general nature of the allegation as it relates to the PHS definition of scientific misconduct, and the PHS applications or grant number(s) involved.

b. ORI will be notified of the final outcome of the investigation and will be provided with a copy of the investigation report. Any significant variations from the provisions of the institutional policies and procedures will be explained in any reports submitted to ORI.

c. If an institution plans to terminate an inquiry or investigation for any reason without completing all relevant requirements of the PHS regulation, the Research Integrity Officer will submit a report of the planned termination to ORI, including a description of the reasons for the proposed termination.

VII. Record Retention

After a research misconduct case is closed (completion of a case and all ensuing related actions), the Research Integrity Officer must securely retain all research misconduct allegations and Inquiry and Investigation Reports with the underlying evidence, or copies, as appropriate, regardless of merit or outcome, until the expiration of their authorized retention period (VHA Handbook 1058.02, section 11).

References: VHA Handbook 1058.02, VA Handbook 0700, Research Service RSOP 7 dated December 2010, VHA Handbook 1200.17, 38 USC Subchapter IV.