Institute for Medical Research, Inc.	Research Misconduct	No.	608
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		Revision Date	
		Final Approval	Approved by IMR Board of Directors: 4-26-11

Purpose

To establish IMR's policy regarding research misconduct by IMR personnel.

Scope

This policy is applicable to allegations of research misconduct by IMR personnel in respect to a research project that is supported by or through IMR. In other cases, for example an allegation regarding VA-funded research and DVAMC staff alone, the handling of allegations of research misconduct is governed by the policy and procedures in VHA Handbook 1058.02 ("Research Misconduct") and VHA Handbook 0700 ("Administrative Investigations)".

Policy

The Institute for Medical Research, Inc. (IMR) is committed to supporting the performance of scientific research with integrity and high ethical standards. IMR personnel are expected to exercise their integrity in carrying out their scientific activities and to provide reasonable supervision of those under their direction to ensure the integrity of the research being conducted. IMR has established the following policies and procedures to investigate and resolve alleged or apparent instances of misconduct in research.

Joint Jurisdiction

IMR shares jurisdiction over all IMR research activities with the Durham VA Medical Center (DVAMC). IMR will coordinate its response to allegations of research misconduct with DVAMC in order to maximize procedural uniformity and minimize duplication, while recognizing institutional autonomy.

IMR and DVAMC will make a good faith effort to conduct a joint inquiry and wherever possible a joint investigation in response to any allegation of research misconduct. DVAMC will take the lead in conducting the response to an allegation of research misconduct. IMR will, in such an event, designate at least one representative to participate in the inquiry and investigation.

Each inquiry and investigation will result in a single set of recommendations, though a minority opinion may be included. After review by its Board of Directors, IMR will accept the findings and recommendations of DVAMC-led joint inquiries, investigations, and adjudications.

Other Forms of Impropriety

This policy addresses allegations of research misconduct, defined as fabrication, falsification, and plagiarism of research proposals, data, or results. Authorship disputes other than plagiarism are not covered in this policy. It does not deal with ethical lapses or other types of professional misconduct, such as misallocation of funds, harassment or discrimination, violation of laws or

regulations established for the protection of human or animal subjects, or violations of other IMR or DVAMC policies, even if the alleged behavior involves or occurs in connection with research activity.

Confidentiality

To the extent allowed by law, the identity of respondents and whistleblowers shall be securely and confidentially maintained and no identifying information shall be disclosed, except to:

1. Those who need to know it in order to carry out a thorough, competent, objective and fair research misconduct proceeding;
2. PHS's ORI as it conducts its review of the research misconduct proceeding and any subsequent proceedings;
3. VA's ORO as it conducts its oversight of the proceedings.

To the extent allowed by law, any information obtained during the research misconduct proceeding that might identify the subjects of research shall be maintained securely and confidentially and shall not be disclosed, except to those who need access to it in order to carry out the research misconduct proceeding.

Definitions

A. Allegation means any written statement or other indication of possible scientific misconduct, whether directly or referred from the potential respondent's superior, IMR's Executive Director, or another source.

B. 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, professional, or financial relationships. Any such conflict which a reasonable person would consider to demonstrate potential bias will disqualify a person for selection to serve in research misconduct proceedings.

C. Good faith 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.

D. Inquiry means gathering information and initial fact-finding solely to determine whether an allegation or other readily available evidence of scientific misconduct warrants an investigation.

E. Investigation means the formal examination and evaluation of all relevant facts to determine if misconduct has occurred and, if so, to determine the responsible person(s) and the seriousness of the misconduct.

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

G. ORO means the Office of Research Oversight, the office within the U.S. Department of Veterans Affairs that is responsible for scientific misconduct policies and activities within the VA health care system.

H. PHS means the U.S. Public Health Service, an operating component of the DHHS.

I. 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 A, entitled "Responsibility of PHS Awardee and Applicant Institutions for Dealing With and Reporting Possible Misconduct in Science."

J. PHS support means PHS grants, contracts, or cooperative agreements or applications for the same.

K. Research Integrity Officer (RIO) means the DVAMC official responsible for receiving allegations of scientific misconduct, determining when such allegations warrant inquiries, and overseeing inquiries and investigations.

L. 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.

M. 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.

N. Research misconduct means fabrication, falsification, or plagiarism in proposing, performing, or reviewing research, or in reporting research results. “Fabrication” is making up data or results and recording or reporting them. “Falsification” is manipulating research materials, equipment, or processes, or changing or omitting data or results such that research is not accurately represented in the research record. “Plagiarism” is the appropriation of another person’s ideas, processes, results, or words without giving appropriate credit. Research misconduct does not include honest error or differences in opinion or interpretation of data.

ORI has a broader definition of research misconduct which includes other practices that seriously deviate from those commonly accepted within the scientific community (see 42 CFR Section 93.102(b), attached). If an institutional proceeding does not find sufficient evidence of research misconduct as defined here, ORI may choose to independently review the case based on its own standard of research misconduct.

O. 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.

P. IMR Personnel means any person who is employed by IMR, is an IMR Board member, or serves as an officer of IMR.

Q. Whistleblower means a person who makes an allegation of scientific misconduct.

Rights and Responsibilities

A. Research Integrity Officer (RIO)

The DVAMC Research Integrity Officer will have primary responsibility for implementing the procedures set forth in this document. The RIO will be well qualified to handle the procedural requirements involved and is sensitive to the varied demands made on those who conduct research, those who are accused of misconduct, and those who report apparent misconduct in good faith.

The RIO will appoint the inquiry and investigation committees and ensure that necessary and appropriate expertise is secured to carry out a thorough and authoritative evaluation of the relevant evidence in an inquiry or investigation. The RIO will attempt to ensure that confidentiality is maintained. The RIO will consult and cooperate with those IMR and DVAMC officers charged with responding to allegations of scientific misconduct in order to conduct a joint inquiry and investigation into such allegations.

The RIO will assist inquiry and investigation committees and all IMR and DVAMC personnel in complying with these procedures and with applicable standards imposed by government or external funding sources. The RIO is also responsible for maintaining files of all documents and evidence and for the confidentiality and the security of those files.

The RIO will report to ORI as required by regulation and keep ORI appraised of any developments during the course of the inquiry or investigation that may affect current or potential DHHS funding for the individual(s) under investigation or that PHS needs to know to ensure appropriate use of Federal funds and otherwise protect the public interest.

B. Whistleblower

The whistleblower will have an opportunity to testify before the inquiry and investigation committees, to review portions of the inquiry and investigation reports pertinent to his/her allegations or testimony, to be informed of the results of the inquiry and investigation, and to be protected from retaliation. Also, if the RIO has determined that the whistleblower may be able to provide pertinent information on any portions of the draft report; these portions will be given to the whistleblower for comment.

The whistleblower is responsible for making allegations in good faith, maintaining confidentiality, and cooperating with an inquiry or investigation.

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.

C. Respondent

The respondent will be informed of the allegations when an inquiry is opened and notified of the final determinations and resulting actions. All such notices will be in written form. The respondent will also have the opportunity to be interviewed by and present evidence to the inquiry and investigation committees, to review the draft inquiry and investigation reports, and to have the advice of legal counsel.

The respondent is responsible for maintaining confidentiality and cooperating with the conduct of an inquiry or investigation. If the respondent is not found guilty of scientific misconduct, he or she has the right to receive institutional assistance in restoring his or her reputation. If the respondent is found guilty of scientific misconduct, he or she has the right to appeal that finding and any proposed corrective measures.

D. DVAMC Director

The Director of DVAMC will receive the inquiry report and any written comments made by the respondent or whistleblower on the draft report, and determine based on those materials whether to proceed to conduct an investigation of the allegation.

The DVAMC Director is also *ex officio* a member of the IMR Board of Directors and will forward reports and/or documentation to the Board, as appropriate.

General Policies and Principles

Policies and Procedures are addressed in VHA Handbook 1058.2, Research & Misconduct and incorporated by reference.