

February 1, 2008

RESPONSIBILITIES OF THE OFFICE OF RESEARCH OVERSIGHT

- 1. REASON FOR ISSUE.** This Veterans Health Administration (VHA) Directive defines the policy and responsibilities of the Office of Research Oversight (ORO) (10R) within VHA.
- 2. SUMMARY OF CONTENTS AND/OR MAJOR CHANGES.** This revises VHA Directive 1058 to add “research information security” and “governmentwide debarment and suspension based on research impropriety” to ORO’s areas of responsibility.
- 3. RELATED ISSUES.** VHA Handbooks 1058.1, 1058.2, 1058.03, and 1058.04
- 4. RESPONSIBLE OFFICIALS.** The Chief Officer, ORO (10R), is responsible for the contents of this Directive. Questions may be referred to (202) 565-4835.
- 5. RESCISSIONS.** VHA Directive 1058 dated October 28, 2004, is rescinded.
- 6. RECERTIFICATION.** This VHA Directive is scheduled for recertification on/before the last working day of February 2013.

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RESPONSIBILITIES OF THE OFFICE OF RESEARCH OVERSIGHT

1. PURPOSE: This Veterans Health Administration (VHA) Directive defines the policy and responsibilities of the Office of Research Oversight (ORO) (10R) within VHA.

2. BACKGROUND

a. Public Law (Pub. L.) 108-170, enacted December 2003, established ORO by statute (Title 38 United States Code (U.S.C.) 7307). ORO is the primary office in VHA for overseeing the responsible conduct of research and investigations of alleged research misconduct and other research improprieties. ORO promotes and enhances the responsible conduct of research in conformance with all applicable laws, regulations, and policies.

b. ORO develops working arrangements with VHA facilities (VHA medical centers, VHA health care systems, and VHA medical and regional office centers) and Veterans Integrated Service Networks (VISNs) to carry out its programs for human subject protections, laboratory animal welfare, research safety, research laboratory security, research information security, research misconduct, and other research improprieties. ORO also oversees procedures related to human research assurances, governmentwide nonprocurement debarment and suspension for research improprieties, and the reporting of adverse events and other unanticipated problems in research.

c. ORO serves as the chief VHA research compliance and assurance office for liaison with such offices as the Office for Human Research Protections (OHRP), the Office of Laboratory Animal Welfare (OLAW), the Food and Drug Administration (FDA), and the Office of Research Integrity (ORI) in the Department of Health and Human Services (DHHS); other Federal departments and agencies with like responsibilities, including signatories to the Federal Policy ("Common Rule") for the protection of human subjects; and various other external groups such as medical and dental school affiliates and professional organizations.

3. POLICY: It is VHA policy that ORO serves as the primary VHA office in advising the Under Secretary for Health on matters of compliance and assurance related to human subject protections, laboratory animal welfare, research safety, research laboratory security, research information security, research misconduct, and other research improprieties. ORO also oversees the procedures for governmentwide nonprocurement debarment and suspension for violations in these areas, and the reporting of adverse events and other unanticipated problems in research.

4. RESPONSIBILITIES: ORO is responsible for:

a. Reviewing allegations, indications, and findings related to impropriety in VHA research (i.e., noncompliance with the laws, regulations, and policies applicable to human subject protections, laboratory animal welfare, research safety, research laboratory security, and research information security), and conducting investigations as appropriate.

b. Overseeing inquiries and investigations of alleged research misconduct (i.e., fabrication, falsification, or plagiarism in research) in VHA, and conducting investigations, as appropriate.

c. Overseeing the procedures for governmentwide debarment and suspension set forth in VHA Handbook 1058.04.

d. Performing periodic prospective and for-cause reviews, and conducting investigations, as needed, at VHA facilities engaged in research, to assure compliance with the laws, regulations, and policies applicable to VHA research.

e. Overseeing the reporting of issues in VHA research related to human subject protections, laboratory animal welfare, research safety, research laboratory security, research information security, research misconduct, and other research improprieties.

f. Managing (in collaboration with DHHS) Federal Wide Assurances (FWAs) for VHA facilities conducting human subject research, and managing other assurances, as needed, for entities conducting human subject research supported by VA.

g. Advising VHA facilities regarding Memoranda of Understanding (MOUs) related to their research protection programs.

h. Collaborating with other Federal, VA, and VHA offices regarding the interpretation of policies and procedures related to human subject protections, laboratory animal welfare, research safety, research laboratory security, research information security, research misconduct, and other research improprieties.

i. Monitoring external accreditation activities conducted for VHA research programs.
NOTE: This is accomplished, in part, by reviewing reports from external accreditation organizations.

j. Developing specific areas of emphasis and expertise in research assurance and compliance activities.

k. Providing technical assistance and information to VHA research facilities and other audiences, as appropriate, to enhance and promote research compliance.

l. Submitting, by March 15 of each year, a report to the Committees on Veterans' Affairs of the Senate and House of Representatives describing the activities of ORO during the preceding calendar year. The report includes the following:

- (1) A summary of reviews of individual medical research programs completed by ORO,
- (2) Directives and other communications issued by ORO to the field,
- (3) Results of any investigations by ORO, and
- (4) Other pertinent information about ORO.

m. Reporting periodically to the Under Secretary for Health, the Secretary of Veterans Affairs, and the Committees on Veterans' Affairs of the Senate and House of Representatives any suspected lapse, from whatever cause or causes, in protecting the safety of human subjects and others, including employees, in VA medical research programs.

n. Carrying out other such duties as the Under Secretary for Health may require.

5. REFERENCES

a. Pub. L. 108-170, Section 401, Office of Research Oversight in Veterans Health Administration, codified at 38 U.S.C. 7307.

b. Title 38 U.S.C. 7303, Functions of Veterans Health Administration: Research Programs.

c. Title 2 CFR Subtitle A - Part 180, Office of Management and Budget (OMB) Guidelines to Agencies on Governmentwide Debarment and Suspension (Nonprocurement) (Common Rule); and Subtitle B - Part 801, Department of Veterans Affairs Implementation of OMB Guidance on Nonprocurement Debarment and Suspension (VA Nonprocurement Debarment Regulation).

d. Title 21 CFR Part 50, Protection of Human Subjects (FDA); Title 21 CFR Part 56, Institutional Review Boards; and Title 21 CFR Part 312, Investigational New Drug Application.

e. Title 38 CFR Part 16, Protection of Human Subjects (VA); Part 17.33, Patients' Rights; and Part 17.85, Treatment of Research-Related Injuries to Human Subjects.

f. Title 48 CFR Chapter 1, Federal Acquisition Regulation.

g. VHA Handbook 1058.1, Reporting Adverse Events in Research to the Office of Research Oversight.

h. VHA Handbook 1058.2, Research Misconduct.

i. VHA Handbook 1058.03, Assurance of Protection for Human Subjects in Research.

j. VHA Handbook 1058.04, Debarments and Suspensions Based on Research Impropriety in VA Research.

k. VHA Handbook 1200.1, The Research and Development (R&D) Committee Handbook.

l. VHA Handbook 1200.5, Requirements for the Protection of Human Research Subjects in Research.

m. VHA Handbook 1200.06, Control of Hazardous Agents in VA Research Laboratories.

n. VHA Handbook 1200.7, Use of Animals in Research.

- o. VHA Handbook 1200.8, Safety of Personnel Engaged in Research.

6. DEFINITIONS

a. **External Accreditation.** VHA contracts with external accrediting organizations to carry out reviews of VHA facilities conducting research involving human subjects or laboratory animals to ensure that these facilities are complying with appropriate laws, regulations, policies, and procedures.

b. **Adverse Event (AE) in Research.** An AE in research is any untoward occurrence (physical, psychological, social, or economic) in a human subject participating in research. An AE in research can be any unfavorable or unintended event, including abnormal laboratory findings, symptoms, or disease, or death associated with the research or the use of a medical investigational test article. An AE in research may occur even in the absence of any error or protocol deviation and does not necessarily have to be caused by any identifiable aspect of the research.

c. **Assurance of Compliance (Care and Use of Laboratory Animals).** Assurance of Compliance (Care and Use of Laboratory Animals) is a legally binding written document with the Department of Human Services Office of Laboratory Animal Welfare (DHHS OLAW) that commits an institution to comply with regulatory and policy responsibilities for animal welfare.

d. **Assurance of Compliance (Human Subjects) or Federal Wide Assurance (FWA).** An Assurance of Compliance (Human Subjects) or FWA is a legally binding written document that commits an institution to complying with the Federal Policy (Common Rule) and other applicable Federal and VA standards for the protection of human subjects.

e. **Debarment.** Debarment is an action to exclude a person from participating in the covered transactions listed in the governmentwide nonprocurement debarment and suspension common rule, as supplemented by the VA Nonprocurement Debarment Regulation, and the Federal Acquisition Regulation.

f. **Research.** For purposes of this Directive, research is medical research described in Title 38 U.S.C. 7303 (a)(2). This includes biomedical research, mental illness research, prosthetic and other rehabilitative research, and health care services research.

g. **Research Impropriety.** For purposes of this Directive, the term "research impropriety" refers to noncompliance with the laws, regulations, and policies regarding human subject protections, laboratory animal welfare, research safety, research laboratory security, research information security, and research misconduct. It does not encompass improper procedures or conduct in areas outside of the mandate of ORO (for example, waste, fraud, abuse, or fiscal mismanagement).

h. **Research Misconduct.** Research misconduct is fabrication, falsification, or plagiarism in proposing, performing, or reviewing research, or in reporting research results.

i. **Suspension.** Suspension is an action that immediately prohibits a person from participating in the covered transactions listed in the governmentwide nonprocurement debarment and suspension common rule, as supplemented by the VA Nonprocurement Debarment Regulation, and the Federal Acquisition Regulation for a temporary period, pending completion of an investigation and any judicial or administrative proceedings that may ensue.