

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) within VHA.

2. SUMMARY OF MAJOR CHANGES: None.

3. RELATED ISSUES: VHA Directive 1058.01, Research Compliance Reporting Requirements, dated October 22, 2020; VHA Directive 1058.02, Research Misconduct, dated July 10, 2020; VHA Directive 1058.03, Assurance of Protection for Human Subjects in Research, dated September 17, 2020; VHA Directive 1058.04, Debarments and Suspensions Based on Impropriety in VA Research, dated November 14, 2019.

4. RESPONSIBLE OFFICE: The Office of Research Oversight (10RO) is responsible for the contents of this directive. Questions may be referred to the Office of Research Oversight at 202-632-7620 or vha10roresearchoversightaction@va.gov.

5. RESCISSIONS: VHA Directive 1058, The Office of Research Oversight, dated March 28, 2017, is rescinded.

6. RECERTIFICATION: This VHA directive is scheduled for recertification on or before the last working day of December 2026. This VHA directive will continue to serve as national VHA policy until it is recertified or rescinded.

**BY DIRECTION OF THE OFFICE OF THE
UNDER SECRETARY FOR HEALTH:**

/s/ Douglas Bannerman, PhD
Executive Director, Office of Research
Oversight

NOTE: *All references herein to Department of Veterans Affairs (VA) and VHA documents incorporate by reference subsequent VA and VHA documents on the same or similar subject matter.*

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CONTENTS

OFFICE OF RESEARCH OVERSIGHT

1. PURPOSE..... 1

2. BACKGROUND..... 1

3. DEFINITIONS 1

4. POLICY 2

5. RESPONSIBILITIES 3

6. TRAINING..... 4

7. RECORDS MANAGEMENT..... 4

8. REFERENCES..... 5

OFFICE OF RESEARCH OVERSIGHT

1. PURPOSE

This Veterans Health Administration (VHA) directive defines the policy and responsibilities of the Office of Research Oversight (ORO) (10RO) within VHA.

AUTHORITY: 38 U.S.C. § 7307.

2. BACKGROUND

a. Established in 2003 (see 38 U.S.C. § 7307), ORO is the primary office in VHA for overseeing the responsible conduct of research and investigating alleged research improprieties. ORO promotes and enhances the responsible conduct of research in conformance with all applicable laws, regulations and policies.

b. ORO oversees Department of Veterans Affairs (VA) medical facility compliance with requirements pertaining to human subject protections, laboratory animal welfare, research safety, research laboratory security, and research information security. ORO conducts reviews and inspections of VA medical facility research programs; oversees the procedures for human subjects assurances, investigations of research misconduct allegations, and Governmentwide debarments and suspensions for research impropriety; reviews reports of unanticipated problems and serious or continuing noncompliance in research and assesses the adequacy of proposed responses to such events; and administers an education program for Research Compliance Officers (RCOs).

c. ORO serves as the chief VHA research compliance 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 (HHS); other Federal departments and agencies with like responsibilities, including signatories to the Federal Policy for the Protection of Human Subjects ("Common Rule"); and various other external groups. ORO also serves as the chief VHA program office for liaison with OHRP for purposes of administering human subjects assurances.

3. DEFINITIONS

a. **Assurance of Compliance (Human Subjects).** An assurance of compliance (human subjects) is a legally binding written document that commits an institution to complying with the Federal Policy for the Protection of Human Subjects ("Common Rule") and other applicable Federal and VA standards for the protection of human subjects. **NOTE:** *The term "Federalwide Assurance" or "FWA" refers to a specific type of assurance that is approved by HHS-OHRP for Federalwide use as specified in 38 C.F.R. § 16.103(a).*

b. **Debarment.** For purposes of this directive, debarment is an action taken by the Under Secretary for Health to exclude a person from participating on a Federal governmentwide basis in the covered transactions listed in 2 C.F.R. Part 180, as

supplemented by 2 C.F.R. Part 801, and transactions covered under the Federal Acquisition Regulation (48 C.F.R. Part 1). A person so excluded is debarred.

c. **Research.** Research is a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge. Activities that meet this definition constitute research for purposes of this directive, whether or not they are conducted or supported under a program that is considered research for other purposes. For example, some demonstration and service programs may include research activities. Pursuant to VHA Directive 1200.05(2), Requirement for the Protection of Human Subjects in Research, dated January 7, 2019, clinical investigations, including clinical investigations as defined under FDA regulations in 21 C.F.R. §§ 50.3, 312.3(b), and 812.3(h), are considered research. **NOTE:** *Regarding activities involving animals, research means any use of animals in research, testing, or training. For further information, see VHA Handbook 1200.07, Use of Animals in Research, dated November 23, 2011.*

d. **Research Impropriety.** For purposes of this directive, research impropriety is 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. Research impropriety does not encompass improper procedures or conduct in areas outside of the jurisdiction of ORO (for example, waste, fraud, abuse, or fiscal mismanagement).

e. **Research Misconduct.** Research misconduct is fabrication, falsification or plagiarism in proposing, performing or reviewing research, or in reporting research results. Research misconduct does not include honest error or differences of opinion. **NOTE:** *For more information, see Federal Policy on Research Misconduct, 65 Federal Register (FR) 76262 (December 6, 2000), and VHA Directive 1058.02, Research Misconduct, dated July 10, 2020.*

f. **Suspension.** For purposes of this directive, suspension is an action taken by the Under Secretary for Health that immediately prohibits a person from participating on a Federal Governmentwide basis in the covered transactions listed in 2 C.F.R. Part 180, as supplemented by 2 C.F.R. Part 801, and 48 C.F.R. Part 1 for a temporary period, pending completion of an investigation and any judicial or administrative proceedings that may ensue.

4. POLICY

It is VHA policy that ORO serves as the primary VHA office in advising the Under Secretary for Health on matters of compliance related to human subject protections, laboratory animal welfare, research safety, research laboratory security, research information security, research misconduct and other research improprieties. Further, it is VHA policy that the Executive Director of ORO reports directly to the Under Secretary for Health without delegation as required by 38 U.S.C. § 7307(b)(1).

5. RESPONSIBILITIES

a. **Under Secretary for Health.** The Under Secretary for Health is responsible for ensuring overall VHA compliance with this directive.

b. **Executive Director, Office of Research Oversight.** The Executive Director, ORO, is responsible for:

(1) Ensuring ORO reviews VA research-related incidents reported to ORO, including reports of unanticipated problems and serious or continuing noncompliance with the laws, regulations, and policies applicable to human subject protections, laboratory animal welfare, research safety, research laboratory security and research information security, in accordance with the requirements of VHA Directive 1058.01, Research Compliance Reporting Requirements, dated October 22, 2020.

(2) Ensuring ORO provides oversight of VA medical facility remediation efforts to resolve such noncompliance reported to ORO in accordance with the requirements of VHA Directive 1058.01 and noncompliance identified by ORO directly or through other means (e.g., identified by a non-VA entity and reported by that entity directly to ORO).

(3) Ensuring ORO provides oversight of VA medical facility inquiries and investigations of alleged research misconduct (i.e., fabrication, falsification, or plagiarism in research) in VHA, as set forth in VHA Directive 1058.02.

(4) Ensuring ORO manages (in collaboration with HHS) Federalwide Assurances (FWAs) for VA medical facilities conducting human subjects research and manages other assurances of compliance, as needed, for entities conducting human subjects research supported by VA, as set forth in VHA Directive 1058.03, Assurance of Protection for Human Subjects in Research, dated September 17, 2020.

(5) Ensuring ORO provides oversight of the procedures for Governmentwide debarment and suspension based on impropriety in VA research, as set forth in VHA Directive 1058.04, Debarments and Suspensions Based on Research Impropriety in VA Research, dated November 14, 2019.

(6) Ensuring ORO performs periodic prospective reviews of VA medical facility research programs to ensure compliance with applicable laws, regulations, and policies pertaining to human subject protections, laboratory animal welfare, research safety, research laboratory security, and research information security.

(7) Ensuring ORO performs for-cause reviews into serious concerns raised about a VA medical facility's research oversight program when it is determined that such concerns are best investigated independently of the VA medical facility.

(8) Halting or limiting the activities of a VA research project that the ORO Executive Director reasonably believes place human subjects' lives or health at imminent risk pursuant to 38 U.S.C. § 7307(c)(3)(B).

(9) Ensuring ORO develops and conducts education programs for RCOs.

(10) Ensuring ORO provides technical assistance and information to VA medical facility research programs and other audiences, as appropriate, to enhance and promote research compliance.

(11) 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.

(12) 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:

(a) A summary of reviews of individual medical research programs completed by ORO.

(b) Directives and other communications issued by ORO to Veterans Integrated Services Networks (VISNs) and VA medical facilities.

(c) Results of any investigations by ORO.

(d) Other pertinent information about ORO.

(13) 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. **NOTE:** *Unless more frequent reporting is requested, ORO's submission of its annual report to the Committees on Veterans' Affairs of the Senate and House of Representatives in accordance with paragraph 5.b.(12) above constitutes fulfillment of the requirement to periodically report to the Committees.*

6. TRAINING

There are no formal training requirements associated with this directive.

7. RECORDS MANAGEMENT

All records regardless of format (e.g., paper, electronic, electronic systems) created by this directive must be managed as required by the National Archives and Records Administration (NARA) approved records schedules found in VHA Records Control Schedule (RCS) 10-1. The disposition schedule for research records is found in chapter 8 of RCS 10-1. Questions regarding any aspect of records management should be addressed to the appropriate Records Officer.

8. REFERENCES

- a. 38 U.S.C. § 7303.
- b. 38 U.S.C. § 7307.
- c. 2 C.F.R. Parts 180 and 801.
- d. 21 C.F.R. Parts 50, 56 and 312.
- e. 38 C.F.R. Part 16.
- f. 48 C.F.R. Part 1.
- g. VHA Directive 1058.01, Research Compliance Reporting Requirements, dated October 22, 2020.
- h. VHA Directive 1058.02, Research Misconduct, dated July 10, 2020.
- i. VHA Directive 1058.03, Assurance of Protection for Human Subjects in Research, dated September 17, 2020.
- j. VHA Directive 1058.04, Debarments and Suspensions Based on Research Impropriety in VA Research, dated November 14, 2019.
- k. VHA Directive 1200.05(2), Requirement for the Protection of Human Subjects in Research, dated January 7, 2019.
- l. VHA Handbook 1200.07, Use of Animals in Research, dated November 23, 2011.