Department of Veterans Affairs Veterans Health Administration Washington, DC 20420 VHA Directive 1058.04 Transmittal Sheet November 14, 2019

### DEBARMENTS AND SUSPENSIONS BASED ON IMPROPRIETY IN VA RESEARCH

- **1. REASON FOR ISSUE:** This Veterans Health Administration (VHA) directive establishes VHA policy for processing debarments and suspensions based on research impropriety in Department of Veterans Affairs (VA) research.
- 2. SUMMARY OF MAJOR CHANGES: None.
- **3. RELATED ISSUES:** VHA Directive 1058, The Office of Research Oversight, dated March 28, 2017; VHA Handbook 1058.01, Research Compliance Reporting Requirements, dated June 17, 2015; and VHA Handbook 1058.02, Research Misconduct, dated February 7, 2014.
- **4. RESPONSIBLE OFFICE:** The Office of Research Oversight (ORO) (10R) is responsible for the content of this directive. Questions may be referred to the Executive Director at 202-632-7620.
- **5. RESCISSIONS:** VHA Handbook 1058.04, Debarments and Suspensions Based on Research Impropriety in VA Research, dated April 15, 2013, is rescinded.
- **6. RECERTIFICATION:** This VHA directive is scheduled for recertification on or before the last working day of November 2024. This VHA directive will continue to serve as national VHA policy until it is recertified or rescinded.

# BY THE DIRECTION OF THE UNDER SECRETARY FOR HEALTH:

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

**NOTE:** All references herein to VA and VHA documents incorporate by reference subsequent VA and VHA documents on the same or similar subject matter.

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## DEBARMENTS AND SUSPENSIONS BASED ON IMPROPRIETY IN VA RESEARCH

#### 1. PURPOSE

This Veterans Health Administration (VHA) directive prescribes procedures for debarring and suspending persons who have been found to engage in research impropriety in Department of Veterans Affairs (VA) research, and the inclusion of those persons on the consolidated list of debarred, suspended, or ineligible persons. **AUTHORITY:** Title 38 United States Code (U.S.C.) 7307; Title 2 Code of Federal Regulations (CFR) parts 180 and 801; Executive Order 12549 (February 18, 1986).

#### 2. BACKGROUND

- a. Each Federal agency has adopted a set of policies and procedures known as the nonprocurement debarment and suspension common rule to implement Executive Order 12549. VA's implementing regulation is found at 2 CFR part 801.
- b. The Office of Management and Budget (OMB) Guidelines to Agencies in Governmentwide Debarment and Suspension (Nonprocurement), 2 CFR part 180, as supplemented by 2 CFR part 801, sets forth general procedures for initiating and processing nonprocurement debarment and suspension actions. These actions ensure the integrity of Federal research programs by excluding specified individuals from participating in these programs. This directive provides the necessary details for processing, when appropriate, nonprocurement debarment and suspension actions against persons based on their involvement in research impropriety in VA research.
- c. The Office of Research Oversight (ORO) serves as the primary VHA office that advises the Under Secretary for Health on all compliance matters related to human subject protections, laboratory animal welfare, research safety, research laboratory security, research information security, research misconduct, and other research improprieties. (See 38 U.S.C. 7307, and VHA Directive 1058, The Office of Research Oversight, dated March 28, 2017.) **NOTE:** Other research compliance matters not specified (e.g., financial misconduct) fall outside of ORO's jurisdiction.
- d. Debarments and suspensions are implemented to protect the public interest, rather than as disciplinary measures.
- e. Federal regulations provide that suspension and debarment actions are to be handled as informally as practicable, consistent with principles of fundamental fairness. Nothing in this directive is to be construed to limit or restrict the informality permitted by the regulations. (See 2 CFR 180.610; 180.740; 180.835.)
- f. When more than one Federal agency has an interest in a suspension or debarment covered by this directive, the agencies may consider designating one agency as the lead agency for making the decision. The procedures in this directive apply when either:

- (1) VA is the only Federal agency with an interest in a suspension or debarment; or
- (2) Additional Federal agencies have an interest in a suspension or debarment, and VA is designated as the lead agency.

**NOTE:** Nothing in this directive precludes VA from settling a debarment or suspension action at any time, if it is in the best interest of the Federal Government. Voluntary exclusions, in which respondents agree to be excluded from specified transactions, have governmentwide effect (see 2 CFR 180.640).

#### 3. DEFINITIONS

- a. <u>Covered Transactions.</u> Covered transactions are all Federal transactions in which persons suspended or debarred may not be a participant or principal except under limited circumstances. These covered transactions are further defined at 2 CFR part 180, Subpart B and 2 CFR part 801.
- b. <u>Debarment.</u> 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 CFR part 180, as supplemented by 2 CFR part 801, and transactions covered under the Federal Acquisition Regulation (48 CFR part 1). A person so excluded is debarred. *NOTE:* For purposes of this directive, debarment does not refer to corrective or other actions proposed or implemented by VA that have VA-only effect (e.g., prohibition from conducting VA research, prohibition from receiving VA funding to conduct VA research).
- c. <u>Fact-Finding.</u> For purposes of this directive, fact-finding is a gathering of evidence through the presentation of witnesses and other material pertinent to the proposed action, which is accomplished through:
- (1) Informal meetings with the person subject to these debarment or suspension proceedings;
  - (2) Submissions of information, either orally or in writing, by the person; and
- (3) Any other method deemed appropriate by the Under Secretary for Health, or fact-finding designee.
- d. <u>Notice</u>. Notice is a written communication served in person, sent by certified mail or its equivalent, or sent electronically by Email or facsimile.
- e. **Person.** Person means any individual, corporation, partnership, association, unit of government, or legal entity, however organized.
- f. <u>Research.</u> Research is a systematic investigation including proposal and project development, testing, and evaluation designed to develop or contribute to generalizable knowledge. Research involves the testing of concepts by the scientific method of

formulating a hypothesis or research question, systematically collecting and recording relevant data, and interpreting the results in terms of the hypothesis or question.

- g. <u>Research Impropriety.</u> For purposes of this directive, research impropriety means research misconduct (as defined in paragraph 3.h.) or noncompliance with the laws, regulations, and policies regarding human subject protections, laboratory animal welfare, research safety, research laboratory security, and research information security. Research impropriety does not encompass improper procedures or conduct in areas outside of the mandate of ORO (for example, waste, fraud, abuse, or fiscal mismanagement).
- h. <u>Research Misconduct.</u> Research misconduct is fabrication, falsification, or plagiarism in proposing, performing, or reviewing research, or in reporting research results. *NOTE:* The terms fabrication, falsification, and plagiarism are further discussed in VHA Handbook 1058.02, Research Misconduct, dated February 7, 2014.
- i. **Respondent.** A respondent is a person against whom VA has initiated a debarment or suspension action.
- j. <u>Suspension</u>. 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 CFR part 180, as supplemented by 2 CFR part 801 and 48 CFR part 1 for a temporary period, pending completion of an investigation and any judicial or administrative proceedings that may ensue. A suspension may be followed by debarment proceedings, but the imposition of a suspension is not a prerequisite for initiating a debarment action. *NOTE:* For purposes of this directive, suspension does not refer to a temporary prohibition implemented by the VA that has VA-only effect (e.g., temporary halting of VA research, temporary prohibition from receiving VA funding to conduct VA research).
- k. <u>VA Research.</u> For the purposes of this directive, VA research is research conducted by VA investigators (serving on compensated, without compensation (WOC), or Intergovernmental Personnel Agreement (IPA) appointment) while on VA time. The research must be approved by the Research and Development (R&D) Committee before it is considered VA research and before it can be initiated.
- I. <u>Voluntary Exclusion</u>. A voluntary exclusion is a person's agreement to be excluded from covered transactions under the terms of a settlement between the person and one or more Federal agencies. A voluntary exclusion must have governmentwide effect.

#### 4. POLICY

It is VHA policy to impose Federal governmentwide suspension or debarment if warranted against persons who have been found to have engaged in research impropriety.

#### **5. RESPONSIBILITIES**

- a. <u>Under Secretary for Health.</u> As the debarring and suspending official for VHA per 2 CFR 801.930(a) and 801.1010(a), the Under Secretary for Health is responsible for:
  - (1) Ensuring overall VHA compliance with this directive.
- (2) Imposing suspensions or debarments against persons who have been found to have engaged in impropriety in VA research, and considering evidence presented by the respondent following notice of suspension or debarment.
- (3) Appointing a designee to conduct fact-finding and present the results to the Under Secretary for Health for consideration and action if required, as specified in paragraphs 6 and 7 below.
- b. <u>Deputy Under Secretary for Health for Operations and Management.</u> The Deputy Under Secretary for Health for Operations and Management is responsible for:
- (1) Communicating the contents of this directive to each of the Veterans Integrated Service Networks (VISNs).
- (2) Ensuring that each VISN Director has the sufficient resources to fulfill the terms of this directive in all VA medical facilities within that VISN.
- (3) Providing oversight of VISNs to assure compliance with this directive, relevant standards, and applicable regulations.
- c. **Executive Director, Office of Research Oversight.** The Executive Director, ORO is responsible for:
- (1) Reviewing recommendations from VA medical facilities for debarment and transmitting recommendations that adhere to 2 CFR 180.800 to the relevant VISN Director.
- (2) Forwarding VISN Director written opinions on debarment recommendations to the Under Secretary for Health.
- (3) Forwarding recommendations from VA medical facilities for suspension to the Under Secretary for Health.
- (4) Reviewing recommendations made directly to ORO from VA employees for suspension of a VA medical facility Director or VISN Director and forwarding procedurally sufficient recommendations per 2 CFR 180.700 to the Under Secretary for Health.
- (5) Ensuring that information listed at 2 CFR 180.520 for persons suspended or debarred under this directive is entered into the System for Award Management (SAM).

- (6) Reviewing recommendations made directly to ORO from VA employees for debarment of a VA medical facility Director and forwarding procedurally sufficient recommendations per 2 CFR 180.800 to the relevant VISN Director.
- (7) Reviewing recommendations made directly to ORO from VA employees for debarment of a VISN Director and forwarding procedurally sufficient recommendations to the Under Secretary for Health.
- (8) Issuing notices of suspension and proposed debarment to the respondent on behalf of the Under Secretary for Health as specified in paragraphs 6 and 7, respectively.
- (9) Serving as a consultant in any fact-finding proceeding covered by this directive, and providing notice of the Under Secretary for Health's decision following a fact-finding proceeding to the respondent.
- d. <u>Veterans Integrated Services Network Directors</u>. The VISN Director is responsible for reviewing debarment recommendations received by ORO and covered by this directive, and issuing a written opinion agreeing or disagreeing with the recommendation.
- e. **VA Medical Facility Directors.** The VA medical facility Director is responsible for:
- (1) Reviewing suspension recommendations made by VA medical facility employees and, if the recommendation meets the conditions set forth in 2 CFR 180.700, sending them to ORO for forwarding to the Under Secretary for Health, and sending a copy to the VA medical facility's VISN Director.
- (2) Reviewing debarment recommendations made by VA medical facility employees and forwarding them to ORO if they meet the requirements of 2 CFR 180.800.

#### 6. SUSPENSION

- a. <u>Suspension Recommendations.</u> Any VA employee may recommend a suspension, as defined by this directive, to the employee's VA medical facility Director. Such recommendations must adhere to the following requirements:
- (1) Suspension recommendations must be supported by documentary evidence that the conditions set forth in 2 CFR 180.700 exist. The cause for suspension must be based on research impropriety in VA research.
- (2) Except as provided in paragraph 6.a.(4), suspension recommendations must be made to the appropriate VA medical facility Director per the VA medical facility's procedures. The VA medical facility Director then forwards the recommendation, if it meets the requirements of subparagraph 6.a.(1), to ORO for forwarding to the Under Secretary for Health, with a copy to the VA medical facility's VISN Director. If the VA medical facility Director decides not to forward the recommendation to the Under

Secretary for Health, the reasons for that decision must be placed in writing and maintained in accordance with the relevant records control schedule. Such records are subject to ORO's review.

- (3) ORO may make suspension recommendations directly to the Under Secretary for Health.
- (4) If a suspension is recommended against a VA medical facility Director or a VISN Director, the recommendation may be made directly to ORO. If ORO determines that the suspension recommendation is procedurally sufficient, ORO forwards the recommendation to the Under Secretary for Health.
- b. <u>Decision to Suspend.</u> A suspension is effective when the Under Secretary for Health signs a decision to suspend.
- (1) To impose a suspension, the Under Secretary for Health must determine that the conditions set forth in 2 CFR 180.700 exist.
- (2) In issuing a suspension, the Under Secretary for Health must consider the factors specified in 2 CFR 180.705. The decision whether to impose a suspension is within the full discretion of the Under Secretary for Health.
- c. <u>Notice of Suspension.</u> After the Under Secretary for Health signs a decision to suspend, ORO promptly issues a notice of the suspension to the respondent on behalf of the Under Secretary for Health.
- (1) The notice of suspension must be prepared according to the requirements of 2 CFR 180.715 and must specify the terms of the suspension. Copies of the Under Secretary for Health's decision, 2 CFR part 180 subpart G, and this directive are to be included with the notification.
- (2) The notice of suspension may be sent to the respondent, the respondent's identified counsel, or the respondent's agent for service of process, or to any of the respondent's partners, officers, directors, owners, or joint ventures.
- (3) There must be an effective receipt of the notice of suspension, which is defined as follows:
- (a) When delivered, if mailed to the last known street address, or 5 business days after the notice is sent if it is undeliverable;
- (b) When sent, if sent by facsimile, or 5 business days after the notice is sent if the facsimile is undeliverable; or
- (c) When delivered, if sent by Email, or 5 business days after the notice is sent if the Email is undeliverable.

- d. <u>Failure to Respond.</u> If no reply to the notice of suspension is received from the respondent or other individual specified in paragraph 6.c.(2) within 30 calendar days after effective receipt of the notice, the case is referred to the Under Secretary for Health for a decision to continue, modify, or terminate the suspension on the basis of information available.
- e. <u>Contesting a Suspension</u>. The respondent may contest a suspension by providing the Under Secretary for Health with information in opposition to the suspension within 30 calendar days after effective receipt of the notice of suspension.
  - (1) The respondent may contest the suspension orally or in writing.
- (2) If the respondent chooses to contest the suspension orally, within 30 calendar days of effective receipt of the notice of suspension, the respondent or the respondent's representative must contact the office of the Under Secretary for Health to arrange to personally present the information and argument. Any information provided orally that the respondent considers important must also be submitted in writing for the official record. (See 2 CFR 180.720; 815.)
- (3) In addition to any information and argument in opposition to the suspension, the respondent must submit the information specified in 2 CFR 180.730.
- (4) The respondent may authorize a representative to fulfill any of these requirements.
- f. <u>Additional Fact-Finding.</u> If the respondent contests a suspension orally or in writing according to the requirements of paragraph 6.e., additional fact-finding must be conducted as follows:
- (1) Only those submissions that raise a genuine dispute over facts material to the suspension are subject to additional fact-finding.
- (2) No additional fact-finding is to be conducted if any of the conditions listed in 2 CFR180.735(a) exist.
- (3) The Under Secretary for Health must appoint a designee to conduct the fact-finding and present the facts to the Under Secretary for Health for consideration and action. Because of ORO's role in the proceedings, it will not be designated as the fact-finder.
- (4) Fact-finding normally consists of informal meeting(s) between the Under Secretary for Health's designee and the respondent, the respondent's representative (at the option of the respondent), an ORO representative, and counsel from the Office of the General Counsel (OGC).
- (a) The respondent may submit documentary evidence, present witnesses, and confront any witness ORO presents.

- (b) A transcribed record of the proceedings must be made available at cost to the respondent upon request, unless the respondent and ORO agree to waive the requirement for a transcript.
- (5) The respondent may opt to forgo the in-person meeting provided for under paragraph 6.f.(4) and instead submit documents to the Under Secretary for Health's designee for review. The respondent's decision to forgo an in-person meeting does not prohibit the designee from conducting in-person meetings with ORO, any witnesses that ORO may present, or OGC.
- (6) The Under Secretary for Health or the fact-finding designee may authorize other methods of fact-finding deemed appropriate in addition to, or in lieu of, the method specified in paragraph 6.f, provided that the fact-finding requirements of 2 CFR 180.745 are met.
- (7) Upon completion of the fact-finding, written findings of facts must be provided by the Under Secretary for Health's designee to the Under Secretary for Health for consideration and action, with a copy provided concurrently to ORO.
- g. <u>Under Secretary for Health's Decision</u>. The Under Secretary for Health decides whether to continue, modify, or terminate the suspension based on all information available including findings of facts submitted by the designee (paragraph 6.f.(7)), and arguments submitted by the respondent.
- (1) The Under Secretary for Health may reject any findings, in whole or in part, only after specifically determining them to be arbitrary, capricious, or clearly erroneous.
- (2) A written decision to continue, modify, or terminate the suspension must be made within 45 calendar days of receiving final submissions, information, and findings of fact. This period may be extended for good cause.
- (3) The period of suspension is determined according to the requirements set forth in 2 CFR 180.760.
- (4) ORO will provide written notice of the Under Secretary for Health's decision to the respondent.

#### 7. DEBARMENT

- a. <u>Debarment Recommendations.</u> Any VA employee may recommend a debarment covered by this directive. Such recommendations must adhere to the following requirements:
- (1) Debarment recommendations must be supported by documentary evidence of a cause listed in 2 CFR 180.800. For purposes of this directive, the cause for debarment must also be based on research impropriety in VA research.

- (2) Except as provided in paragraphs 7.a.(5) and 7.a.(6), debarment recommendations must be made to the appropriate VA medical facility Director per the VA medical facility's procedures. The VA medical facility Director then forwards all recommendations which meet the requirements of paragraph 7.a.(1) to ORO. If the VA medical facility Director decides not to forward the recommendation to ORO, the reasons for that decision must be placed in writing and maintained in accordance with the relevant records control schedule. Such records are subject to ORO's review.
- (3) If ORO determines that the debarment recommendation is procedurally sufficient, ORO forwards the recommendation to the relevant VISN Director.
- (4) The VISN Director reviews the debarment recommendation and issues a written opinion agreeing or disagreeing with the recommendation, including the specific reasons for the agreement or disagreement. The VISN Director then forwards the debarment recommendation and written opinion to the Under Secretary for Health, through ORO.
- (5) ORO and the VISN Director may make debarment recommendations directly to the Under Secretary for Health.
- (6) If a debarment is recommended against a VA medical facility Director, the recommendation may be made directly to ORO; after determining that the debarment recommendation is procedurally sufficient, ORO forwards the recommendation to the relevant VISN Director for review under paragraph 7.a.(4). If a debarment recommendation is made against a VISN Director, the recommendation may be made directly to ORO; after determining that the debarment recommendation is procedurally sufficient, ORO forwards the recommendation to the Under Secretary for Health.
- b. <u>Proposed Debarment.</u> After reviewing a debarment recommendation, the VISN Director's written opinion (where applicable), the causes for debarment in 2 CFR 180.800, and any other pertinent document, the Under Secretary for Health decides whether to propose debarment of the respondent. The decision whether to propose debarment is within the full discretion of the Under Secretary for Health.
- c. <u>Notice of Proposed Debarment.</u> If the Under Secretary for Health decides to propose a debarment, ORO issues a notice of proposed debarment to the respondent on behalf of the Under Secretary for Health.
- (1) The notice of proposed debarment is prepared according to the requirements of 2 CFR 180.805 and specifies the length and terms of the proposed debarment. Copies of 2 CFR part 180 subpart H, and this directive are to be included with the notification.
- (2) The notice of proposed debarment must be sent to the respondent, the respondent's identified counsel, or the respondent's agent for service of process, or any of the respondent's partners, officers, directors, owners, or joint ventures.
- (3) There must be an effective receipt of the notice of proposed debarment, which is defined as follows:

- (a) When delivered, if mailed to the last known street address, or 5 business days after the notice is sent if it is undeliverable;
- (b) When sent, if sent by facsimile, or 5 business days after the notice is sent if the facsimile is undeliverable; or
- (c) When delivered, if sent by Email, or 5 business days after the notice is sent if the Email is undeliverable.
- d. <u>Failure to Respond.</u> If no reply to the notice of proposed debarment is received from the respondent, or other individual specified in paragraph 7.c.(2) within 30 calendar days after effective receipt of the notice, the case is referred to the Under Secretary for Health for decision based on available information.
- e. <u>Contesting a Proposed Debarment.</u> The respondent may contest a proposed debarment by providing the Under Secretary for Health with information in opposition to the proposed debarment within 30 calendar days after effective receipt of the notice of proposed debarment.
  - (1) The respondent may contest the proposed debarment orally or in writing.
- (2) If the respondent chooses to contest the proposed debarment orally, within 30 calendar days of effective receipt of the notice of debarment, the respondent or the respondent's representative must contact the office of the Under Secretary for Health to arrange to personally present the information and argument. Any information provided orally that the respondent considers important must also be submitted in writing for the official record.
- (3) In addition to any information and argument in opposition to the proposed debarment, the respondent must submit the information specified in 2 CFR 180.825.
- (4) The respondent may authorize a representative to perform any of the functions contained in paragraph 7.e.
- f. <u>Additional Fact-Finding.</u> If the respondent contests a proposed debarment, additional fact-finding must be conducted as follows:
- (1) Only those submissions that raise a genuine dispute over the facts relevant to the proposed debarment are subject to additional fact-finding.
- (2) Additional fact-finding is not permitted if any of the conditions listed in 2 CFR 180.830(a) exist.
- (3) The Under Secretary for Health must appoint a designee to conduct the fact-finding and to present the facts to the Under Secretary for Health for consideration and action. Because of ORO's role in the proceedings, it will not be designated as the fact-finder.

- (4) The fact-finding normally consists of informal meeting(s) between the Under Secretary for Health's designee and the respondent, the respondent's representative (at the option of the respondent), an ORO representative, and counsel from OGC.
- (a) The respondent may submit documentary evidence, present witnesses, and confront any witness ORO presents.
- (b) A transcription of the proceedings must be made available at cost to the respondent upon request unless the respondent and ORO agree to waive the requirement for a transcript.
- (5) The respondent may forgo the in-person meeting provided for under paragraph 7.f.(4) and instead submit documents to the Under Secretary for Health's designee for review. The respondent's decision to forgo an in-person meeting does not prohibit the designee from conducting in-person meetings with ORO, any witnesses that ORO may present, or OGC.
- (6) The Under Secretary for Health or the fact-finding designee may authorize other methods of fact-finding deemed appropriate in addition to or in lieu of the method specified in paragraph 7.f., provided that the fact-finding requirements of 2 CFR 180.840 are met.
- (7) Upon completion of the fact-finding, written findings of facts must be provided by the designee to the Under Secretary for Health for consideration and action, with a copy provided concurrently to ORO.
- g. <u>Under Secretary for Health's Decision</u>. The Under Secretary for Health decides whether to affirm the debarment based on all information available, including findings of facts submitted by the designee (see paragraph 7.f.(7)), and arguments submitted by the respondent.
- (1) The Under Secretary for Health may reject any findings, in whole or in part, only after specifically determining them to be arbitrary, capricious, or clearly erroneous.
- (2) VA must establish the cause for debarment by a preponderance of the evidence, meaning that it is more likely than not that the cause for the debarment is established. If the proposed debarment is based upon a conviction or civil judgment, the standard of proof is met.
- (3) A written decision whether to debar must be made within 45 calendar days of receiving final submissions, information, and findings of fact. This period may be extended for good cause.
- (4) ORO provides written notice of the decision to the respondent, on behalf of the Under Secretary for Health, according to the requirements of 2 CFR 180.870(b).
- h. **Period of Debarment.** The period of debarment imposed is based upon the circumstances involved.

- (1) Generally, debarment does not exceed 3 years; however, if circumstances warrant, the Under Secretary for Health may impose a longer period of debarment.
- (2) The Under Secretary for Health must take into consideration the recommended period of debarment, if any (paragraph 7.a.), and any mitigating and aggravating factors listed in 2 CFR 180.860.
- (3) At any time during the debarment period, the Under Secretary for Health may decide to remove the debarment, reduce the period of debarment, or amend the scope of the debarment, if indicated, after review of documentary evidence submitted by or on behalf of the respondent setting forth the appropriate grounds for granting of such relief. Such grounds may be, but are not limited to: newly discovered material evidence, reversal of a conviction, or the elimination of the cause for which debarment was imposed.
- i. <u>Reconsideration.</u> A debarred respondent may submit a written request to the Under Secretary for Health to reconsider the debarment decision or to reduce the period or scope of the debarment.
- (1) The respondent must support the written request for reconsideration with documentation.
- (2) The Under Secretary for Health may reduce or terminate the debarment based on factors set forth at 2 CFR 180.880.
- j. Extension of Debarment. The Under Secretary for Health may extend the debarment period based on factors set forth at 2 CFR 180.885. If an extension of the debarment period is proposed, the procedures outlined in 2 CFR part 180, as supplemented by 2 CFR part 801 and this directive, must be followed.

#### 8. SYSTEM FOR AWARD MANAGEMENT

- a. The System for Award Management (SAM) is a widely available source of the most current information about persons who are excluded or disqualified from covered transactions. SAM is maintained by the General Services Administration, and can be accessed at <a href="https://www.sam.gov/SAM/">https://www.sam.gov/SAM/</a>. When VA takes an action to exclude a person under the nonprocurement or procurement (48 CFR Chapter 1) debarment and suspension system, information about the excluded person is entered into SAM.
- b. ORO is responsible for entering the information listed at 2 CFR 180.520 into SAM and reporting health care practitioners to the National Practitioners Data Bank (NPDB) for debarments and suspensions taken under this directive.
- c. In addition to inclusion in SAM, ORO may publish the following, for the length of the debarment or suspension, in any ORO-authorized dissemination (including the ORO Web site: https://www.va.gov/oro/):

- (1) The name, affiliation, and debarment or suspension terms of any person debarred or suspended for research improprieties in VA research; and
  - (2) The cause of the debarment or suspension.

#### 9. TRAINING

There are no formal training requirements associated with this directive.

#### 10. RECORDS MANAGEMENT

All records regardless of format (paper, electronic, electronic systems) created in this directive shall be managed per the National Archives and Records Administration (NARA) approved records schedules found in VA Records Control Schedule 10-1. Questions regarding any aspect of records management should be addressed to the appropriate Records Manager or Records Liaison. The schedule for case records maintained throughout VHA for governmentwide suspensions and debarments based on research impropriety is found in RCS 10-1, code 8600.3.

#### 11. REFERENCES

- a. Pub. L. 108-170.
- b. 38 U.S.C. 7307.
- c. 2 CFR 180.
- d. 2 CFR 801.
- e. Executive Order 12549, 51 Fed. Reg. 6370 (February 18, 1986) "Debarment and Suspension" (3 CFR 1986 Comp., p. 189).
  - f. 48 CFR 1.
  - g. VHA Directive 1058, The Office of Research Oversight, dated March 28, 2017.
- h. VHA Directive 1200.01, Research and Development (R&D) Committee, dated January 24, 2019.
- i. VHA Handbook 1058.01, Research Compliance Reporting Requirements, dated June 17, 2015.
  - j. VHA Handbook 1058.02, Research Misconduct, dated February 7, 2014.