# Research Misconduct: Frequently Asked Questions (FAQs)

## I. EFFECTIVE DATE OF VHA DIRECTIVE 1058.02 ("RESEARCH MISCONDUCT")

### A. What is the issuance date of the version of VHA Directive 1058.02 ("Research Misconduct") that is currently in effect?

VHA Directive 1058.02, that is currently in effect was issued on July 10, 2020. This version replaced VHA Handbook 1058.02 that was issued on February 7, 2014.

### B. If an updated version of VHA Directive 1058.02 ("Research Misconduct") is issued while a research misconduct proceeding is already in progress, which version of the policy must be followed?

The requirements of the Research Misconduct policy version that was in effect at the time the initial (or only) Respondent was notified of research misconduct allegations against him/her must be followed for the subsequent duration of that entire case. For example, if Respondent A was formally notified of allegations against her on June 15, 2020, all subsequent procedural stages (e.g., inquiry, investigation, adjudication, and appeal) associated with the case would be subject to the requirements of the policy issued on February 7, 2014 (i.e., VHA Handbook 1058.02). If Respondent B in the same case was formally notified of allegations against him on July 15, 2020, the same version of the policy (VHA Handbook 1058.02; issued February 7, 2014) would apply to both Respondents in the case – even though a new version (VHA Directive 1058.02) was issued on July 10, 2020. If Respondent X in a different case was formally notified of allegations against him on July 12, 2020, VHA Directive 1058.02 issued on July 10, 2020, would be applicable to that case involving Respondent X.

## II. VHA DIRECTIVE 1058.02 POLICY AND PROCEDURAL CHANGES

### A. What changes have been incorporated into the version of VHA Directive 1058.02 ("Research Misconduct") that is currently in effect?

The current Directive retains the fundamental, procedural structure (e.g., inquiry, investigation, adjudication, and appeal) that conforms with the *Federal Policy on Research Misconduct* and that has been included in previous versions of VHA Handbook 1058.2/1058.02. However, the policy was amended to make certain procedures more efficient.

## III. VA FACILITY POLICIES AND PROCEDURES

### A. Are VA facilities required to develop facility-specific policies and procedures for responding to allegations of research misconduct?

No. VHA Directive 1058.02 provides detailed policies and procedures that obviate the need for facilities to develop local policies and procedures for responding to allegations of research misconduct. However, facility personnel may, at their discretion, develop supplemental procedures provided that the local procedures are compliant with those in the current Directive.

## IV. ORO NOTIFICATION OF RECEIPT OF AN ALLEGATION

### A. When should the Office of Research Oversight (ORO) be notified that an allegation of research misconduct has been received?

Within one (1) business day of receipt of a formal allegation of research misconduct, ORO must be notified of the allegation (*see* VHA Directive 1058.02 Appendix A §4.b.).

## V. RESEARCH INTEGRITY OFFICERS

### A. Does the RIO have to be the Associate Chief of Staff (ACOS) for Research and Development (R&D), the Deputy ACOS/R&D, the Administrative Officer (AO)/R&D, or the Research Compliance Officer (RCO)?

No. VHA Directive 1058.02 §5.f.(3) stipulates that the individual appointed as RIO must have previous experience conducting research or providing research administrative oversight, and sufficient institutional authority to be able to fulfill the required responsibilities of the position. The positions referenced in the FAQ are listed in the Directive only as examples of staff who might possibly be qualified to serve as RIOs.

### B. Does an individual serving in an administrative position within the Research Service have an unmanageable conflict of interest in serving as the RIO by virtue of his/her position?

Not necessarily. *See* VHA Directive 1058.02 §5.f.(3)(a). Several procedural requirements of the Directive adequately manage any apparent conflict of interest and ensure that procedural objectivity is properly maintained, including:

(i) The RIO must promptly notify ORO and the VA medical facility Director of all formal allegations of research misconduct that are received (*see* VHA Directive 1058.02 Appendix A §4.b).

(ii) If a RIO has a conflict of interest that cannot be appropriately managed with respect to the research, the respondent, the informant, or other key witnesses in a particular research misconduct case, the VA medical facility Director must appoint another individual to serve as an acting RIO for the case (*see* VHA Directive 1058.02 §5.f.(3)(c)).

(iii) If the RIO makes a determination that an allegation does not satisfy the requirements to initiate an inquiry, the VA medical facility Director and ORO both have the authority to nonetheless require that an inquiry be initiated (*see* VHA Directive 1058.02 Appendix A §4.d.(2)(b)).

(iv) If an inquiry report recommends that a case be closed without an investigation, the VA medical facility Director and ORO both have the authority to nonetheless require that an investigation be convened (*see* VHA Directive 1058.02 Appendix B §2.d.(1)(b), Appendix C §2.d.(1)(b), and Appendix D §2.c.(1)(b)).

(v) ORO conducts a procedural review of all research misconduct cases that involve an investigation and provides the outcome of its review to the VISN Director who subsequently adjudicates the case (*see* VHA Directive 1058.02 Appendix B §3.c.(2), Appendix C §3.c.(2), and Appendix D §3.c.(2)).

Given these procedural checks and balances, the VA medical facility Director may appoint an individual who serves in an administrative role within the Research Service to also serve as RIO.

### C. Is there a requirement for an appointment letter to be issued for the individual who serves as the RIO?

Yes. VHA Directive 1058.02 §5.f.(3) states that "[t]he VA medical facility Director is responsible for: … [a]ppointing, in writing, an individual who is employed by that VA medical facility to serve as the VA medical facility RIO."

### D. Are RIO personnel changes required to be reported to ORO?

Yes. VHA Directive 1058.02 §5.f.(3)(b) requires RIO personnel changes to be reported to the ORO Research Misconduct Officer within 30 days of the change being made.

### E. May a VA facility with a small research program rely on the RIO of another VA facility instead of appointing its own RIO?

A number of VA facilities with smaller research programs have established a Memorandum of Understanding (MOU) with a larger VA facility to use the latter's Institutional Review Board (IRB) and Research and Development Committee (R&DC) for oversight of the smaller VA facility's protocols. Regardless of these arrangements or the size of a VA facility's research program, VHA Directive 1058.02 §5.f.(3) requires the Director of *each* VA facility with an active research program to appoint an individual, *who is employed by that facility*, to serve as RIO.

There are important reasons for having an on-site RIO at each VA facility that is engaged in research. First, potential informants at each facility should have a point of contact who is readily accessible so that making an allegation of research misconduct is not overly burdensome. Second, if a research misconduct case does arise

at a facility, the case is often best handled by a RIO who has the appropriate authority and familiarity with the facility (by virtue of being employed there) to oversee the proceedings effectively. Also, because the RIO is responsible for overseeing the VA facility's general compliance with the research misconduct procedures, an off-site RIO may not be able to provide this oversight as readily or effectively as an on-site RIO.

### F. What are the education/training requirements for a RIO?

VHA Directive 1058.02 §5.g.(1) stipulates that RIOs must become familiar with the policies and procedures established in the Directive. RIOs may, at their discretion, consider availing themselves of additional applicable training including:

(i) VA TMS Web-based training, titled "Administrative Investigation Board (AIB) Member Training" (VA 4557027) available at https://www.tms.va.gov/SecureAuth35/ or https://logon.iam.va.gov/affwebservices/public/saml2sso?SPID=https://www.successfactors.com/VAHCM03;

(ii) In-person and Web-based training on research misconduct and the role of the RIO (*see* http://ori.hhs.gov/content/rio-boot-camp and http://ori.hhs.gov/video-role-rio);

(iii) Participation in the Association of Research Integrity Officers (ARIO) best practices discussions and the annual meeting (*see* https://www.ariohq.org/). Note: ARIO membership requires separate application and registration fee; and/or

(iv) Participation in teleconferences and other forums where ORO personnel present information related to VHA Directive 1058.02.

### G. What actions must be taken by the RIO to ensure that VA facility research personnel are aware of the policies and procedures established in VHA Directive 1058.02?

VHA Directive 1058.02 §5.g.(1) states that the RIO is responsible for "Being familiar with this directive and promoting awareness and understanding of this directive among VA medical facility employees who are engaged in research activities in their capacities as VA employees ." As written, there is no one specific prescriptive action that *must* be taken to satisfy this policy requirement; consequently, VA facility RIOs have leeway in determining what actions must be taken to satisfy this requirement at their local facilities. Actions that *may* be taken to satisfy this requirement include, but are not limited to: (1) sending VA facility research personnel an email notifying them of the issuance of the revised Directive, issued July 10, 2020; (2) providing VA facility research personnel with electronic or hard copies of the Directive; and/or (3) conducting training for VA facility research personnel on how the policies in the Directive are implemented at their facilities (e.g., instruction on how to report allegations of research misconduct).

## VI. AVAILABLE RESOURCES

### A. What resources are available to promote compliance with the requirements of VHA Directive 1058.02?

ORO provides remote training for Inquiry Committees and on-site training for Investigation Committees. In addition, ORO has developed notification templates and checklists that can be used by VA RIOs and facility personnel to facilitate compliance with the requirements of the Directive. ORO is also available for individual consultation with regard to particular issues that may arise during the course of a research misconduct proceeding. VA facility RIOs are encouraged to contact the ORO Research Misconduct Officer to learn more about the specific resources that are available.

## VII. RESEARCH MISCONDUCT INVESTIGATION COMMITTEES

### A. Does the ORO training for Investigation Committees satisfy the training requirement for Administrative Investigation Board members in VA Handbook 0700 (Chapter 1 §4.e.(2))?

Per correspondence with Office of General Counsel's Personnel Law Group (October 19, 2023) the ORO training is approved for the limited use in Research Misconduct Investigations only.

## VIII. PUBLICATION OF FINAL FINDINGS OF RESEARCH MISCONDUCT

### A. What type of information may VA publish regarding a final finding of research misconduct?

VHA Directive 1058.02 §8.l states that for *all* final findings of research misconduct VA may publish the respondent's name, the respondent's current or former VA position, a detailed summary of the findings of research misconduct, and the corrective actions imposed.

### B. In what venues may VA publish information regarding a final finding of research misconduct?

VA may publish information regarding final findings of research misconduct in any venue deemed appropriate, including, *but not limited to*: Government exclusionary lists (if relevant), the *Federal Register*, ORO's Web site, VA publications, and media outlets.