

# VHA Handbook 1058.02 “Research Misconduct”

*(Issued February 7, 2014)*

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## AGENDA

- I. Background Information
- II. Substantive Revisions
- III. Resources
- IV. Questions/Discussion

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## AGENDA

- I. Background Information**
- II. Substantive Revisions
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- IV. Questions/Discussion

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## BACKGROUND INFORMATION

### **Office of Research Oversight (ORO)**

- ORO serves as the primary VHA office for advising the Under Secretary for Health on, and exercising oversight of, matters pertaining to research misconduct (§7)
- ORO developed, and is responsible for, VHA Handbook 1058.02, "Research Misconduct"
  - All questions pertaining to the Handbook should be referred to ORO Central Office



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## BACKGROUND INFORMATION

### VHA Handbook 1058.02, “Research Misconduct”

- Establishes VA procedures for reporting, investigating, and resolving allegations of “research misconduct” involving VA employees and/or VA research
  - First version of the Handbook was issued in 2005 (as VHA Handbook 1058.2) in response to the issuance of the *Federal Policy on Research Misconduct*
  - Second version of the Handbook was issued in 2012 (as VHA Handbook 1058.02) without any substantive changes from the first version
  - Third (current) version issued February 7, 2014

## BACKGROUND INFORMATION

### VHA Handbook 1058.02, “Research Misconduct”

- With respect to the *Federal Policy*:
  - Adopts the **same definition** of research misconduct
  - Adopts the **same criteria** for making a finding of research misconduct
  - Establishes a **multi-phase framework** for responding to allegations of research misconduct
  - Establishes **safeguards** to protect the interests of those involved

## BACKGROUND INFORMATION

### VHA Handbook 1058.02, “Research Misconduct”

➤ **Scope**

- Only applies to “research misconduct” (§4b)
  - Defined as **fabrication, falsification, or plagiarism** in proposing, performing, or reviewing research, or in reporting research results (§3a)
  - Other research improprieties and noncompliance are *not* covered by the Handbook (§4c)

## BACKGROUND INFORMATION

**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 the 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. (Does **not** include authorship disputes.)

The **research record** is the record of data or results that embody the **facts resulting from scientific inquiry**, and includes, but is not limited to, research proposals, laboratory records, case report forms and data sheets, progress reports, abstracts, theses, oral presentations, internal reports, and journal articles.

Research misconduct does **not** include honest error or differences of opinion.

## BACKGROUND INFORMATION

### Example of ***Fabrication***:

- At a lab meeting, a graduate student presents data from an experiment that he claims to have conducted, but in reality was not conducted.



### Example of ***Falsification***:

- A post-doc conducts an experiment with 3 mice in an experimental group and 3 mice in a control group. The post-doc subsequently incorporates the results of the experiment in a figure, and intentionally labels the figure as representing the results from 9 mice per group (to increase the apparent robustness of the experiment).



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## BACKGROUND INFORMATION

### Example of ***Plagiarism***:

- While serving on a grant review panel, Dr. I.M. Rong reviews a proposal submitted by Dr. Wright. Dr. Rong subsequently incorporates into his own grant proposal the ideas that were in Dr. Wright's proposal. (Dr. Rong represents Dr. Wright's ideas as being his own and does not acknowledge Dr. Wright in his proposal.)



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## BACKGROUND INFORMATION

### VHA Handbook 1058.02, “Research Misconduct”

➤ **Scope**

- Applies to current or former VA employees, including without compensation (WOC) employees (§4a)
- Applies to VA contractors
- Does *NOT* apply to individuals who have never been VA employees or VA contractors (§4b(4))

## BACKGROUND INFORMATION

### VHA Handbook 1058.02, “Research Misconduct”

➤ **Multi-Phase Framework for Responding to Allegations**

1. Receipt of the allegation
2. Initial allegation assessment (threshold determination)
3. Inquiry\*
4. Investigation\*
5. Adjudication
6. ORO procedural review
7. Appeal

*\*May be conducted jointly with another institution.*

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## SUBSTANTIVE REVISIONS

### **VHA Handbook 1058.02, “Research Misconduct”**

- Considerations for the revision:
  - Maintain strict consistency with the *Federal Policy*
  - Increase ongoing oversight, clarify provisions, and revise problematic policies
  - Increase consistency with related VA policies
    - VHA Handbook 1058.04 (“Debarments and Suspensions Based on Research Impropriety in VA Research”)
    - VA Handbook 0700 (“Administrative Investigations”)
  - Increase harmonization with PHS policies (42 CFR 93)
  - Avoid creating barriers to conducting joint proceedings

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## SUBSTANTIVE REVISIONS

### VHA Handbook 1058.02, “Research Misconduct”

- ❑ Approach to the revision:
  - ❑ “Battle of ideas”
    - ❑ Two substantively different versions independently developed
      - ❑ Merits internally debated
      - ❑ Agreed upon concepts merged into a single document
      - ❑ Collegially debated and revised...
    - ❑ Reviewed by the Office of Research Integrity (ORI), HHS
      - ❑ Revised
  - ❑ Presented to InterAgency Working Group on RM
  - ❑ VAIQ Concurrence (ORD, Academic Affil., OGC, ORA, LMR ...)
    - ❑ Revised

## SUBSTANTIVE REVISIONS

**SCOPE**

## SUBSTANTIVE REVISIONS

Previous Version - Scope	Current Version - Scope
<ul style="list-style-type: none"> <li>• If a matter involves both research misconduct and non-research misconduct issues, a single administrative investigation may be convened to review all related issues.</li> </ul>	<ul style="list-style-type: none"> <li>• Allegations other than those of research misconduct must be referred to relevant authorities for action under <i>other</i> applicable policies and procedures. (§4c(2))</li> <li>• Conclusions related to improprieties or noncompliance other than research misconduct may <i>not</i> be made as part of a research misconduct proceeding. (§4c(3))</li> </ul>

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## SUBSTANTIVE REVISIONS

**Rationale:**

- ❑ ORO found that Investigation Committees that reviewed both research misconduct and non-research misconduct issues:
  - ❑ Did *not* make distinct recommendations with regard to the research misconduct issues
  - ❑ Issued reports that did *not* delineate the basis (preponderance of evidence; intent) by which the findings of research misconduct were made
  - ❑ Misapplied the definition of research misconduct
    - ❑ Committees made findings of research misconduct on issues that did *not* meet the Federal definition of research misconduct – stretched definition

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## SUBSTANTIVE REVISIONS

The current Handbook provides **flexibility for joint research misconduct proceedings led by a non-VA entity**, where the non-VA entity wishes to convene a single administrative entity to examine both research misconduct and non-research misconduct issues. (§4c(4))



## SUBSTANTIVE REVISIONS

**Research  
Integrity  
Officer**

## SUBSTANTIVE REVISIONS

### Research Integrity Officer (RIO)

Each VA facility with an active research program must have a designated RIO to receive **research misconduct** allegations and oversee facility-conducted **research misconduct** proceedings (e.g., Inquiries and Investigations). (§10)



## SUBSTANTIVE REVISIONS

### Previous Version - RIO

- The facility Director must designate an individual from within the research program to serve as the Research Integrity Officer (RIO). The individual must have sufficient institutional authority and experience to fulfill the duties.

### Current Version - RIO

- The facility Director must appoint, in writing, an individual who is employed by that facility to serve as RIO. The individual must have previous experience conducting research and/or providing research administrative oversight, and sufficient institutional authority to be able to fulfill responsibilities. (§10a)
  - *No* requirement that the individual hold a position within the research program
- Changes in RIO personnel must be reported to ORO within 30 days (§10b)

## SUBSTANTIVE REVISIONS

### Rationale:

- ❑ Expansion of who can serve as RIO
  - ❑ To provide greater flexibility in selecting an individual to serve as RIO
    - ❑ Under the previous Handbook, some individuals with ideal skill sets were categorically excluded because they were not in the research program.
- ❑ Written appointment letter
  - ❑ To ensure that there is clarity at local facilities about who serves as the RIO
- ❑ Reporting of RIO personnel changes to ORO
  - ❑ To ensure the accuracy of a VHA-centralized resource that can be used by Informants and others to locate the contact information of the appropriate RIO

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## SUBSTANTIVE REVISIONS

**Informants/  
Other  
Sources**

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## SUBSTANTIVE REVISIONS

### Previous Version – Informants

- Did not clearly address differences between Informants and non-Informant sources
  - Geared towards “traditional model” of an individual walking into a RIO’s office and submitting a written allegation



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### Current Version – Informants

- Individuals who submit a written, dated, and signed allegation of research misconduct shall be considered Informants (§14c(5))
  - Informants may:
    - ✦ provide testimony
    - ✦ review the Inquiry Memo
    - ✦ review the draft Investigation Report and submit comments
    - ✦ be informed of the outcome
- Individuals who submit oral/anonymous allegations are non-Informant sources (§14c(6))
  - *Not* afforded same opportunities as an Informant

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## SUBSTANTIVE REVISIONS

### Rationale:

- ❑ To address changing nature of how allegations are received
  - ❑ Blogosphere/Websites
    - ❑ e.g., Retraction Watch; Science-Fraud.org; Copy, Shake, and Paste; etc.
  - ❑ Individuals submitting allegations using a pseudonym



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## SUBSTANTIVE REVISIONS

# Initial Allegation Assessment

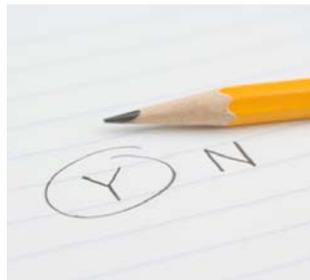
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## SUBSTANTIVE REVISIONS

### Initial Assessment of the Allegation

The ***purpose*** of the initial assessment is to determine whether an allegation meets certain threshold criteria for opening a research misconduct Inquiry. (§14e)



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<b>SUBSTANTIVE REVISIONS</b>	
Previous Version – Initial Allegation Assessment	Current Version – Initial Allegation Assessment
<ul style="list-style-type: none"> <li>• <b>RIO</b> determines whether the allegation meets the threshold requirements for opening an Inquiry                             <ul style="list-style-type: none"> <li>○ Allegation <u>on its face</u>:                                     <ul style="list-style-type: none"> <li>✦ involves VA research</li> <li>✦ is of research misconduct</li> <li>✦ represents a departure from accepted practices and <u>the misconduct as alleged was committed intentionally, knowingly, or recklessly</u></li> <li>✦ is not clearly frivolous</li> </ul> </li> </ul> </li> </ul>	<ul style="list-style-type: none"> <li>• <b>ORO</b> determines whether the allegation meets the threshold requirements for opening an Inquiry (§14e)                             <ul style="list-style-type: none"> <li>○ Allegation <u>on its face</u>:                                     <ul style="list-style-type: none"> <li>✦ falls within Handbook scope</li> <li>✦ is of research misconduct</li> <li>✦ does <i>not</i> constitute honest error, difference of opinion, or accepted practice</li> <li>✦ is <i>not</i> clearly frivolous</li> </ul> </li> </ul> </li> </ul>
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<b>SUBSTANTIVE REVISIONS</b>
<p><b>Rationale:</b></p> <ul style="list-style-type: none"> <li>❑ ORO found instances where:                             <ul style="list-style-type: none"> <li>❑ Inquiries were opened into allegations that on their face did <i>not</i> involve research misconduct</li> <li>❑ Inquiries were <i>not</i> opened into allegations that on their face did involve research misconduct</li> </ul> </li> <li>❑ To clarify language regarding the requirements for opening an Inquiry                             <ul style="list-style-type: none"> <li>❑ Many allegations on their face do not indicate whether the misconduct was conducted intentionally, knowingly, or recklessly                                     <ul style="list-style-type: none"> <li>❑ e.g., allegations referred by a journal editor or grant reviewer</li> </ul> </li> </ul> </li> </ul>
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**SUBSTANTIVE REVISIONS**

# Inquiry

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**SUBSTANTIVE REVISIONS**

**Inquiry**

The *sole purpose* of an Inquiry is to conduct a preliminary assessment of *readily available* evidence to determine whether an allegation has sufficient substance to warrant an Investigation. (§16b)

- ❑ STANDARD: Evidence that would raise a reasonable suspicion of research misconduct (§16c)



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## SUBSTANTIVE REVISIONS

Previous Version – Inquiry	Current Version – Inquiry
<ul style="list-style-type: none"> <li>• VA-led Inquiries must be completed within 30 days of being initiated</li> <li>• Written transcripts of interviews must be prepared</li> </ul>	<ul style="list-style-type: none"> <li>• VA-led Inquiries must be completed within 45 days of being initiated (§16d(2))</li> <li>• Interviews must be recorded; written transcripts optional (§16d(6)(c))</li> <li>• Inquiry may <i>not</i> determine that an allegation lacks sufficient substance based solely on a Respondent’s <u>unsubstantiated</u> claim of honest error (§16c(2))</li> </ul>

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## SUBSTANTIVE REVISIONS

**Rationale:**

- ❑ Change from 30 to 45 days for completion of Inquiry
  - ❑ Median number of days to complete VA-only Inquiries: **33**
- ❑ Written transcripts of Inquiry interviews *optional*
  - ❑ Contracting requirements at some facilities made procuring a transcription service difficult and needlessly delayed Inquiries
- ❑ Stipulation that an Inquiry may *not* determine an allegation lacks sufficient substance based solely on an ***unsubstantiated*** claim of honest error
  - ❑ VA had cases where Inquiry Committees determined that Investigations were *not* warranted solely on a Respondent’s unsubstantiated claim of honest error
  - ❑ Consistency with PHS policy (*see* section III.H in the preamble)




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## SUBSTANTIVE REVISIONS

# Investigation

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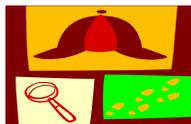
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## SUBSTANTIVE REVISIONS

### Investigation

The **purpose** of the Investigation is to make recommended findings about ***whether*** research misconduct occurred (§20b), and if so:

- the extent*** to which it occurred;
- who*** is responsible; and
- what ***corrective actions*** are appropriate



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## SUBSTANTIVE REVISIONS

Previous Version – <i>Ad hoc</i> Investigation Committee	Current Version – Alternate Provisions for Committees
<ul style="list-style-type: none"> <li>• In exceptional cases, an ORO <i>Ad Hoc</i> Committee may investigate allegations in lieu of a local VA facility committee.                             <ul style="list-style-type: none"> <li>○ e.g., cases in which the local VA facility is not prepared to or cannot handle allegations in accordance with VA policies</li> </ul> </li> </ul>	<ul style="list-style-type: none"> <li>• If the responsible VA facility is unable to handle the allegations, the VISN to which the facility belongs must appoint an <i>alternate VA facility</i> within the VISN to handle the allegations. (§8b)</li> <li>• If the responsible VA facility can handle the allegations, but cannot identify enough individuals to serve on an Investigation Committee, individuals from another facility within the VISN may be appointed. (§20c(4)(a)6)</li> </ul>

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## SUBSTANTIVE REVISIONS

**Rationale:**

- ❑ Removal of provision for an ORO *ad hoc* committee to conduct Investigations in exceptional cases
  - ❑ Who would provide oversight of the oversight office (ORO) *ad hoc* committee conducting the Investigation?
    - ❑ Potential conflict of interest in the same office providing oversight of its own actions
- ❑ Current Handbook facilitates the ability of Investigations to be conducted at the local/regional level



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<b>SUBSTANTIVE REVISIONS</b>	
Previous Version – Investigations	Current Version – Investigations
<ul style="list-style-type: none"> <li>• Respondent and Informant provided with 7 days to submit comments on draft report                             <ul style="list-style-type: none"> <li>○ No specification of when access to sequestered evidence is to be provided</li> </ul> </li>   <li>• Final Investigation Report issued within 90 days</li> </ul>	<ul style="list-style-type: none"> <li>• The RIO may <u>not</u> serve on the Investigation Committee (§20c(4)(a)<del>4</del>)</li> <li>• Draft report provided to ORO and OGC at least 60 days prior to end of Investigation (§20c(9)(d))</li> <li>• Respondent and Informant provided with at least 30 days to submit comments on draft report (§20c(9)(e))                             <ul style="list-style-type: none"> <li>○ Respondent given access to sequestered evidence supporting proposed findings at time draft report provided</li> </ul> </li> <li>• Final Investigation Report issued within 120 days (§20c(3)(a))</li> </ul>
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## SUBSTANTIVE REVISIONS

**Rationale:**

- RIO may not serve on the Investigation Committee
  - To preserve RIO independence and facilitate RIO's ability to serve as an intermediary between the Committee and the Respondent
  - RIO does provide administrative support to Committee*
  
- Draft report to ORO and OGC
  - To facilitate earlier identification of issues
  
- Respondent and Informant provided 30 days to review draft report and submit comments
  - Ensure ample time to review report and supporting evidence in complex cases
  - Harmonization with PHS policy (42 CFR §93.312(a))



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## SUBSTANTIVE REVISIONS

### Rationale:

- ❑ Designation of when to grant access to supporting sequestered evidence
  - ❑ When time of access was not designated, a Respondent demanded “real-time” access to all evidence, including transcripts from witness interviews
    - ❑ Respondent wanted to confront witnesses while an Investigation was ongoing 
  - ❑ Harmonization with PHS policy (42 CFR §93.312(a))
- ❑ Change from 90 to 120 days for completion of the Investigation
  - ❑ Investigations typically require more than 90 days
    - ❑ Median number of days for VA-only Investigations: **135**
  - ❑ Harmonization with PHS policy (42 CFR §93.311(a)) 

## SUBSTANTIVE REVISIONS

# Procedural Review

## SUBSTANTIVE REVISIONS

ORO reviews each case for *procedural conformance* with VA policies and procedures.

- Timeliness
- Objectivity
- Preservation of safeguards
- Thoroughness
- Competence
- Appropriate application of the definition of research misconduct



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## SUBSTANTIVE REVISIONS

Previous Version – ORO Procedural Review	Current Version – ORO Procedural Review
<ul style="list-style-type: none"> <li>• ORO case review conducted <b>after</b> the Adjudication phase</li> </ul> <pre> graph TD     A[INVESTIGATION] --&gt; B[ADJUDICATION]     B --&gt; C[ORO REVIEW]     C --&gt; D[RESPONDENT NOTIFIED]             </pre> 	<ul style="list-style-type: none"> <li>• ORO case review conducted <b>prior</b> to the Adjudication phase (§23c)</li> </ul> <pre> graph TD     A[INVESTIGATION] --&gt; B[ORO REVIEW]     B --&gt; C[ADJUDICATION]     C --&gt; D[ORO]     D --&gt; E[RESPONDENT NOTIFIED]             </pre> 
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## SUBSTANTIVE REVISIONS

### **Rationale:**

- ❑ To ensure that a case is procedurally sufficient *prior* to a VA determination being made (i.e., adjudication)
  - ❑ Under the previous Handbook, procedural concerns identified by ORO necessitated local VA facility actions/responses, which in turn, necessitated additional review by the Adjudicating official to determine whether the original adjudication should stand.

## SUBSTANTIVE REVISIONS

# Adjudication

## SUBSTANTIVE REVISIONS

### Adjudication

The **purpose** of the Adjudication phase is to make a VA determination about **whether** research misconduct has occurred (§24b), and if so:

- the extent** to which it occurred
- who** is responsible
- what **corrective actions** are appropriate
- The determination is made based on a review of the Investigation Report and supporting documents.



## SUBSTANTIVE REVISIONS

### Adjudication

Research misconduct cases are adjudicated by the Director of the VISN to which the local VA facility is assigned.

**Veterans Integrated Service Networks (VISNs)**



## SUBSTANTIVE REVISIONS

Previous Version – Adjudication	Current Version – Adjudication
<b>No substantive revisions made</b>	

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## SUBSTANTIVE REVISIONS

**Appeals**

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## SUBSTANTIVE REVISIONS

**Appeals**

- ❑ Appeal submissions (§25c)
  - ❑ Sent to the Under Secretary for Health (USH) through ORO
  - ❑ Must be filed in writing within **30 days** of receiving notice of research misconduct finding
  - ❑ Only named Respondent(s) may appeal
  - ❑ All research misconduct findings and proposed corrective actions may be appealed
- ❑ USH's decision on appeal submissions constitutes VA's *final* action (except for debarment) (§25c(3))



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## SUBSTANTIVE REVISIONS

Previous Version – Appeals	Current Version – Appeals
<b>No substantive revisions made</b>	

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**SUBSTANTIVE REVISIONS**

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**Publication  
of  
Findings**

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**SUBSTANTIVE REVISIONS**

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<b>Previous Version</b>	<b>Current Version</b>
<ul style="list-style-type: none"><li>• No provision for publicizing findings</li></ul>	<ul style="list-style-type: none"><li>• Provision to allow publication of findings of research misconduct (§§6i(5)(a) and 6k)<ul style="list-style-type: none"><li>○ Publishable information:<ul style="list-style-type: none"><li>✦ Respondent's name and position</li><li>✦ Findings</li><li>✦ Corrective actions</li></ul></li></ul></li></ul>



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## SUBSTANTIVE REVISIONS

### Considerations:



- ❑ Initially proposed to publish *all* VA research misconduct findings
  - ❑ Suggestion made to consider including *discretion* not to publicize
    - ❑ **SCENARIO:** In response to PI pressure, a first year graduate student falsifies control data and presents the falsified data at a lab meeting.
      - ❑ Should the student be “branded” by a public disclosure?
- ❑ ORO agreed that there should be a mechanism for discretion
  - ❑ Findings published as a corrective action
  - ❑ Findings published at ORO’s discretion (*if not implemented as a corrective action*)

## SUBSTANTIVE REVISIONS

Joint  
Jurisdiction

## SUBSTANTIVE REVISIONS

### Joint Jurisdiction

Inquiries and Investigations may be conducted jointly with other non-VA institutions when allegations involve research over which both VA and another non-VA institution have jurisdiction. (§15)

- ❑ May be led by VA or the non-VA institution
  - ❑ Applicable procedures of *lead* institution followed
- ❑ Must include representatives from both institutions
- ❑ Separate Adjudications



## SUBSTANTIVE REVISIONS

### Previous Version – Joint Jurisdiction

### Current Version – Joint Jurisdiction

- VA-only Inquiry may deem an allegation to have “sufficient substance” to warrant an Investigation based on another institution’s Inquiry determination
  - Non-VA institution must provide VA with its Inquiry Report;
  - VA Inquiry must determine the allegation falls within the scope of the Handbook; and
  - VA Inquiry must consider any additional evidence provided during the course of the VA Inquiry
    - ✦ Interviews still required

## SUBSTANTIVE REVISIONS

### **Rationale:**

- ❑ To enable VA “to catch up” with an institution with joint jurisdiction that has completed an Inquiry, so that the VA and non-VA institution may conduct a joint Investigation
  - ❑ Previous instances where VA has been notified of allegations after a non-VA entity has initiated, and in some cases completed, an Inquiry



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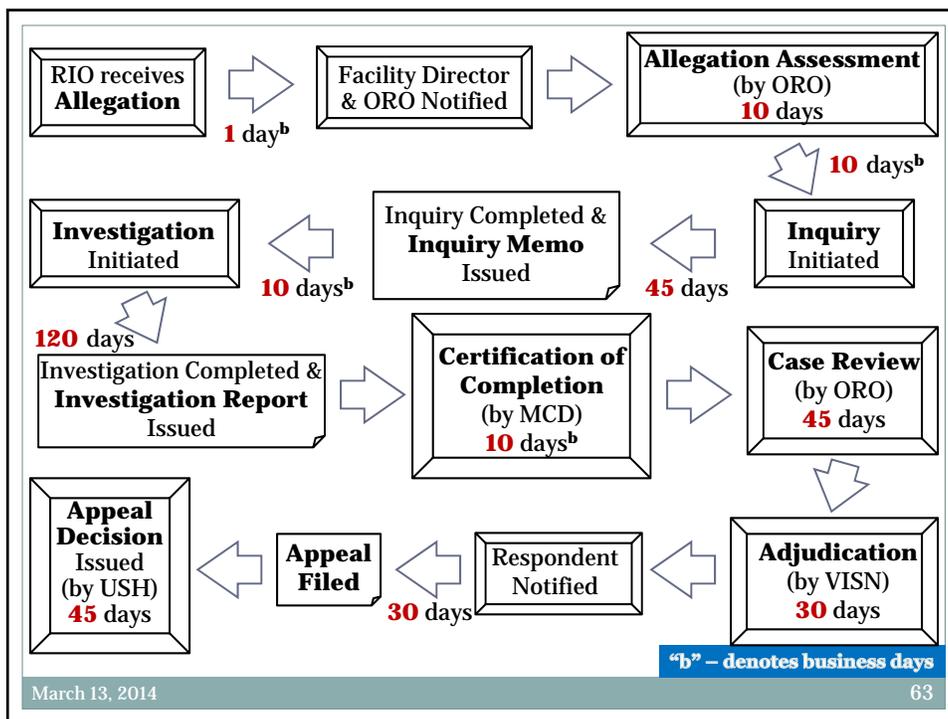
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## SUBSTANTIVE REVISIONS

# Procedural Summary

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## RESOURCES

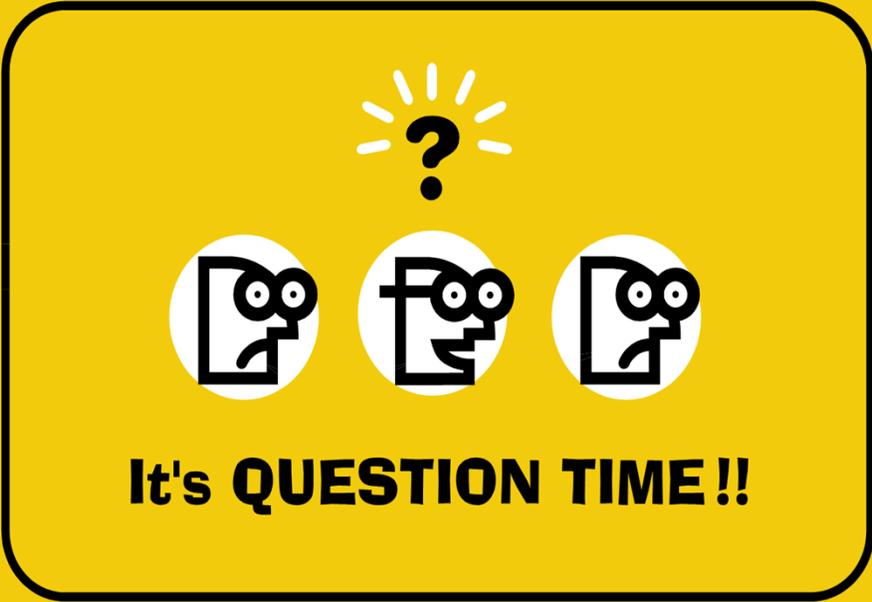
### ORO Research Misconduct Oversight Program Main Web page

- [http://www.va.gov/ORO/oro\\_research\\_misconduct.asp](http://www.va.gov/ORO/oro_research_misconduct.asp)
- VHA Handbook 1058.02
- RIO Contact List\***
- FAQs\***
- Checklists
  - RIO Appointment Checklist\***
  - RIO Processing of Allegations Checklist\***
  - Inquiry and Investigation Checklists
- Other



## RESOURCES

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**It's QUESTION TIME!!**

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