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Best Practices for Handling Research Misconduct: Guidance from the U.S. Regulations – Part I

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Best Practices for Handling Research Misconduct: Guidance from the U.S. Regulations

PART I – Procedures

- U.S. Process
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  - First Encounter with Respondent
  - "Bad Faith" Allegations
- Investigation Best Practices and Sequestration

Best Practices for Handling Research Misconduct: Guidance from the U.S. Regulations

PART II – Special Circumstances

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- Handling Admissions
- Time Limitations
- Plagiarism vs. Authorship Disputes
- Misconduct in Clinical Research

42 CFR PART 93

Federal Register

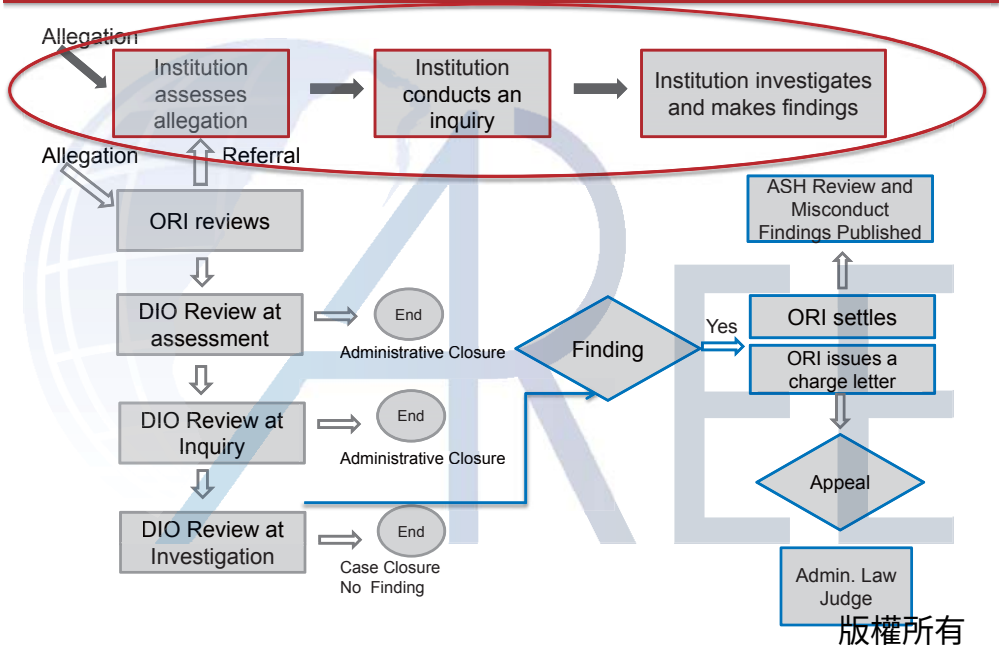
Tuesday,
May 17, 2005

The U.S. regulations for handling allegations of research misconduct in PHS funded research (NIH) are *specified* in 42 CFR Part 93

Part III

Department of Health and Human Services

42 CFR Parts 50 and 93
Public Health Service Policies on Research Misconduct; Final Rule



Institution Responsibilities

U.S. federal regulations:

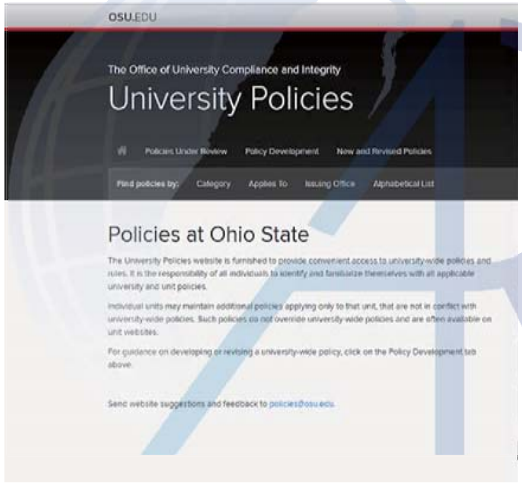
Institutions must have an *assurance* to obtain funds

Requirements:

1. Institutions must have written *policies and procedures* for managing allegations of research misconduct
   - Protects University officials managing the process
   - Protects all involved in process, Rs, Cs, witnesses and university

2. Institution's policy must include:
   - A thorough, competent, objective, and fair response to allegations of research misconduct

At Ohio State University:



Who Handles Research Misconduct Allegations at US Institutions?

Research Integrity Officer (RIO)

What is a RIO?

Although Not Defined by Regulation, the RIO's Role Has Evolved

- Administer the institution's procedures
- Assure compliance with those procedures
- Foster a research environment that discourages misconduct

The role for anyone handling allegations of research misconduct includes:

- Receive and assess allegations of misconduct
- Work with institutional legal counsel
- Prioritize complex allegations
- Provide notice and advice to respondent (accused), complainant (accuser), and other witnesses of rights under institution's policies and procedures

The role for anyone handling allegations of research misconduct includes:

- Sequester and safeguard evidence (discuss later)
- Protect whistleblowers/complainants from retaliation
- Keep senior administrators informed of the process
- Communicate with officials in other regulatory areas (e.g., protection of human subjects of research) in cases that involve more than one regulatory area

The role for anyone handling allegations of research misconduct includes:

- Staff and train committees reviewing data
- Draft/review reports; finalize a case; and implement actions (retractions, termination, etc.)
- Communicate federal oversight agencies
- Handle QRPs/DRPs (authorship, mentoring, data management, etc.)

Traits

- Even-handedness
- Good listening skills
- Empathy
- Self-confidence *and* humility
- Courtesy *and* firmness
- Courage
- Sense of humor

Challenges

- Hostile/difficult witnesses, respondents and whistleblowers, and their attorneys
- Retaliation by persons in the institution against whistleblowers
- Bad faith/malicious allegations and allegations used as a political weapon
- University COI - powerful people at an institution working against the person handling the process
- Lack of University support – financial and logistical

Receiving Allegations
（接到檢舉/指控）

Receiving Allegations

In the US: **42 CFR Part §93.318** requires that institutions must notify ORI if certain conditions exist:

(a) Health or safety of the public is at risk, including an immediate need to protect human or animal subjects.

(b) HHS [other sponsor or institutional] resources or interests are threatened.

(c) Research activities should be suspended.

(d) There is reasonable indication of possible violations of civil or criminal law.

(g) The research community or public should be informed.

Receiving Allegations

In what order should critical issues in a misconduct case be addressed?

Hypothetical case: Research projects are larger, more multidisciplinary and more complex

A case that involves human subjects research, financial conflicts of interest, radiation safety and possible violation of criminal law (destruction of evidence).
What do you do? In what order? And, how do you keep review of a case under one policy from affecting the review under another policy?

Receiving Allegations

Critical to do the right thing in the right order:

A. Recommendation:
Person handling allegations, usually with University general counsel, should have authority to halt any misconduct proceeding, if needed, to complete other procedures required by law or policy
(ex. protection of human subjects, biosafety issues, etc.)

B. However, priority should be given to the review of an allegation of research misconduct over other internal University processes
(ex. protect data over authorship or mentorship issue)

Receiving Allegations

Critical to do the right thing in the right order:

Consider external issues:

1. Potential criminal investigation
2. Potential civil litigation (lawsuits)
3. Collaborators at another institution – what to do?

Receiving Allegations

Make a record of the handling of allegations to show you did the right thing

- Create activity logs
- Intake forms for initial conversations with complainants and respondents
- Prepare for interview recording/ transcribing

Have a team to help

- Institutional counsel; trained staff; subject matter experts; IT specialist; public affairs office; possibly security

Receiving Allegations

What do allegations look like?

- Very often vague and not specific
- Important to be fair to complainant; listen and be patient

How do allegations reach the RIO?

- In person with other staff to verify
- Telephone
- Anonymously

- Public Allegations

Receiving Allegations – SOP

Receiving Allegations

Date_____ Case#_____

1. Who is making the allegation:

- Made by Complainant?
- Referred by a person other than the Complainant?
- Presented anonymously?
- Presented in writing? Keep document
- Oral? Prepare document

Receiving Allegations

2. What is the Allegation?

- Obtain as much detail as possible, e.g., fabrication, falsification or plagiarism of what, by whom (name), doing what?

- Is the research in question published? If so, where?

Receiving Allegations

3. Who is the Respondent? (name, title, location)
   - Does the Respondent have collaborators in this research? If so, who are they?
   - Are there any collaborators at other Institutions? If so, who and where?
   - If public allegation, may not be able to name a Respondent until more information obtained.

Receiving Allegations

4. When and where did the alleged misconduct occur?
5. Is the alleged misconduct still going on?
6. What is the nature of the research in question?

   Does it involve special circumstances?
   - human or animal subjects?
   - hazardous materials or biologics?

Receiving Allegations

7. Does the complainant have evidence/data to support the allegation?
8. If so, where is that evidence?
9. Do others have evidence of the misconduct?
   - Who are they?
   - Where are they? (contact information)
   - What evidence does each have? Where is that evidence?
   - If public allegation, may not have any additional evidence until further examination

Receiving Allegations

10. What is the best way contact the complainant?

    Contact info: Address; E-mail; Phone; Cell phone

11. What is the complainant's relationship, if any, with the respondent?
12. Has the complainant been retaliated against or seem to be at risk for retaliation?
13. Does the complainant have "any other concerns to discuss"?

Not relevant to public allegations

Receiving Allegations

14. Note if there are any concerns about whether the allegation is made in "good faith"?
15. Provide complainant with University's misconduct policy, and explain procedures and what happens next.
16. Discuss the confidentiality of the process.
17. Allow the complainant to contact you, if necessary

Not relevant to public allegations

Receiving Allegations

Why This Level of Preparation?

When things go wrong, the problems often begin with the receipt of the allegation due to a lack of preparation for all unexpected challenges.

Receiving Allegations

Why This Level of Preparation?

"After you drive off the cliff, your options narrow."

- David Wright, former ORI Director

Assessing Allegations

（評估檢舉案）

Assessing an Allegation

In the US: **42 CFR §93.307**:

An inquiry is warranted if the allegation:

- Fits the definition of research misconduct (F/F/P)

and

- Is sufficiently credible and specific so that potential evidence of research misconduct may be identified

Low bar to move to inquiry

Assessing an Allegation

At Ohio State:
RIO with Dean Conduct the Preliminary Assessment

- Purpose of preliminary assessment is the same as defined in federal regulation
  - Fits definition of research misconduct?
  - Specific and credible?

Assessing an Allegation

At Ohio State:
RIO with Dean Conduct the Preliminary Assessment

- Is more information/evidence needed?
  - Others at University? Another University?
- Does anyone other than complainant need to be contacted? The respondent?
- Are there special circumstances that require prioritizing the issues?

Assessing an Allegation

At Ohio State:
RIO with Dean Conduct the Preliminary Assessment

- RIO and Dean (College of Respondent) write assessment report
  - Circumstances giving rise to allegation, describes review and final decision
- Allegations that fail to indicate possible RM are dismissed
- Allegations indicating possible RM move to inquiry

Assessing an Allegation

Potential Complications:

- The allegation is reported to someone else in the University
- Credible allegations are not assessed at all
- The allegation gets handled by someone with a real or perceived conflict of interest (complainant)
- Special circumstances are not handled properly

  Notice is not provided to administrators of other regulatory areas (e.g. IRB) that may be affected by the allegation

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Assessing an Allegation

Potential Complications:

- The complainant, if known, is not interviewed immediately, or at all
- Retaliation against complainants or witnesses not prevented
- Rumors of the allegation circulate; reputations are damaged
- “Bad Faith" Allegations

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“Bad Faith” Allegations

（惡意檢舉，誣告）

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“Bad Faith” Allegations

The federal regulations (42 CFR Part 93) do not define “bad faith”

"Bad Faith" Allegations

Good faith is defined, 42 CFR § 93.210

Good faith as applied to a complainant or witness, means having a belief in the truth of one's allegation or testimony that a reasonable person in the complainant's or witness's position could have based on the information known to the complainant or witness at the time.

"Bad Faith" Allegations

Good faith is defined, 42 CFR § 93.210

An allegation or cooperation with a research misconduct proceeding is not in good faith if made with knowing or reckless disregard for information that would negate the allegation or testimony.

"Bad Faith" Allegations

In introduction to regulation, 42 CFR Part 93:

Bad faith complainants are those who, under the definition of "good faith" . . . do not have a belief in the truth of their allegation that a reasonable person in the complainant's position could have based on the information known to the complainant at the time.

We have determined there is no need . . . to further address bad faith allegations, given that institutions may have internal standards of conduct . . .

"Bad Faith" Allegations

Based on the definition of "Good faith":

"Bad faith" complainants are those who do not have a belief in the truth of their allegation that a reasonable person in the complainant's position could have based on the information known to the complainant at the time, and acts with knowing or reckless disregard for information that would negate the allegation.

"Bad Faith" Allegations

Is it a bad faith allegation? How do you know?

- Most complainants believe in the merit of their allegations
- An allegation can lack sufficient credibility or specificity so that potential evidence of research misconduct cannot be identified but still may not be a bad faith allegation
- If institutions have procedures addressing bad faith allegations, the process should be fair in determining whether it is a bad faith allegation

"Bad Faith" Allegations

Recommendation for Institution Policy and Practice:

- Individuals handling process ("RIOs") should have the authority and responsibility to investigate instances of possible bad faith on the part of a complainants, witnesses, or committee members and to provide evidence of possible bad faith to the adjudicating authority.

"Bad Faith" Allegations

Recommendation for Institution Policy and Practice:

- A research misconduct policy should include:
  - requirement for complainants and witnesses (and committee members) to act in good faith as defined in the policy
  - conditions to investigate, adjudicate, and sanction bad faith allegations

"Bad Faith" Allegations

Ohio State Policy:

Frivolous Allegations are those allegations that are made in bad faith or with malice, are unsupported by credible evidence, and which are found to be without merit.

"Bad Faith" Allegations

Ohio State Policy:

Allegations of research misconduct are serious charges and should be supported by sufficient credible evidence.

"Bad Faith" Allegations

Ohio State Policy:

Filing frivolous allegations is an abuse of the procedures set forth in this Policy, and may result in disciplinary action under other University rules or procedures

Notification of Respondent

（通知被檢舉人/被通報人）

Respondent Notification

42 CFR §93.307 Responsibilities for maintenance and custody of research records and evidence.

(b) *Notice to Respondent and custody of research records.* At the time of or before beginning an inquiry, an institution must make a good faith effort to notify in writing the presumed Respondent, if any. If the inquiry subsequently identifies additional Respondents, the institution must notify them.

Respondent Notification

Good Practices for the initial meeting with Respondent (usually the RIO):

- Provide a written statement of the allegation(s)
- Provide a copy (*and* URL) of institution's research misconduct policy/website
- Explain Respondent's rights under the procedures, including right to counsel

Respondent Notification

Good Practices for the initial meeting with Respondent (usually the RIO):

- Explain need to maintain confidentiality
- Caution respondent to avoid retaliation, or any act that may appear retaliatory

Respondent Notification

Good Practices for the initial meeting with Respondent (usually the RIO):

The first encounter with the Respondent is critical:

- Set the tone for future encounters and winning the Respondent's cooperation
- Stabilize the situation, ensure protection from retaliation, explain Respondent's rights, and the process is also to protect Respondent
- Identify key issues that may be discussed during the inquiry/investigation

Respondent Notification

If the Respondent makes an admission of misconduct:

- Record the Respondent's statement or obtain a written and signed statement from the Respondent, detailing where, when and how the research misconduct occurred.

Respondent Notification

If the Respondent declares innocence, but can't offer compelling evidence or explanation to establish innocence:

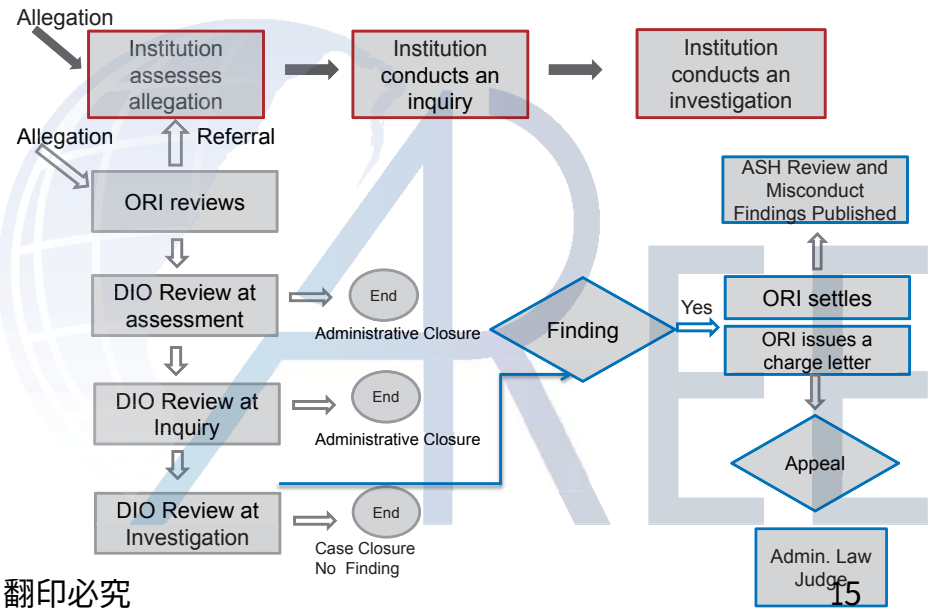
- Review the allegation in detail and ask Respondent to provide evidence/data related to each part of the allegation

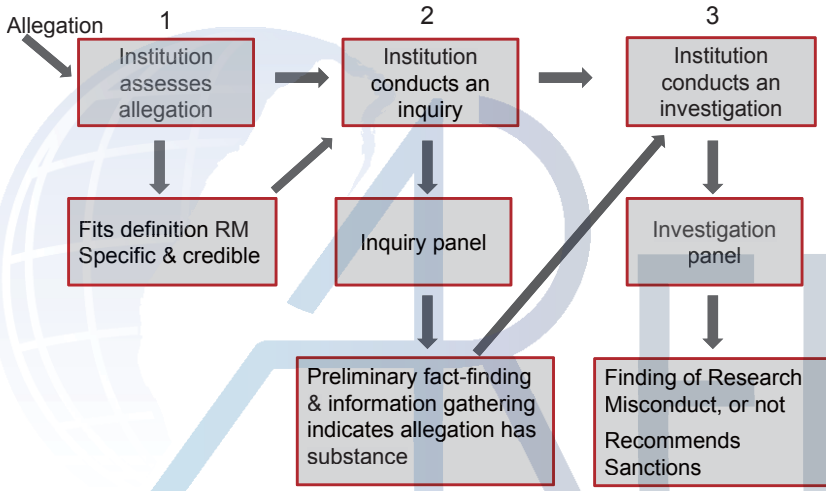
Respondent Notification

Use the critical first encounter with Respondent to identify and secure evidence critical to each part of the allegation

- Sequester broadly (all potentially pertinent data)
- **Sequester data immediately** (receipts signed by RIO and Respondent)

Investigation Procedures
（調查程序）





Best Practices - Investigation

Ensuring a fair investigation – 42 CFR §93.310(f)

Take reasonable steps to ensure an impartial and unbiased investigation to the maximum extent practicable, including participation of persons with appropriate scientific expertise who do not have unresolved personal professional, or financial conflicts of interest with those involved in the inquiry or investigation.

Best Practices - Investigation

How to ensure a fair investigation

- The panel should include the required disciplinary and technical expertise
- Panelists should be held in high regard
- Avoid, if possible, including vulnerable colleagues – e.g., assistant professors up for tenure

Best Practices - Investigation

How to ensure a fair investigation

- Ensure no conflicts of interest (COIs)
  - No collaborations or co-authorships
  - No financial interactions
  - No social/personal friendships
  - No prejudice against each other
  - Any reason that person cannot be fair and impartial to all?
  - Any reason *anyone else* would see a COI?

Best Practices - Investigation

How to ensure fair investigation

- Provide panel with general outline of the allegations
- Review Institution's Policy and Procedures, if available, with panel

Best Practices - Investigation

How to ensure a fair investigation

- In US, RIO and Counsel provide support (logistical, clerical, scientific) throughout process
- Review criteria for determining whether an investigation is warranted/misconduct occurred

Best Practices - Investigation

Proceed Systematically:

- Analyze all aspects of each allegation
- Consider evidence to support/or/refute each allegation
- Does more evidence need to be sequestered/obtained?

Best Practices - Investigation

Proceed Systematically:

- Who should be interviewed, in what order?
- Panel communications with Respondent, Complainant, Witnesses *always* through "RIO's" office

Best Practices - Investigation

Proceed Systematically:

- Review background reports
  e.g., Assessment/Inquiry Reports
- Review all existing evidence/data
- Is specific expertise required?
- Should other allegations or respondents should be added?
- Justify the conclusions with evidence

Interviews
（面談）

Best Practices - Investigation

Interviews – prepare in advance:

A list of general questions to initiate the interview

Develop the line of questioning for each allegation about which the interviewee may have knowledge

Best Practices - Investigation

Interviews – prepare in advance:

Develop specific, key questions

Identify the lead and follow-up person for each line of questions

Ensure all questions are answered; follow-up on inconsistent statements

Always pursue evasive, defensive, obfuscating answers

Best Practices - Investigation

Interviews – prepare in advance:

Stay focused; this should not be a collegial conversation

Allow respondent to talk – do not interrupt

In US, interviews are recorded or a court reporter transcribes the interview

Best Practices - Investigation

Interviews – prepare in advance:

Initiate all calls: do not let witness phone in; verify number and identity in advance.

Ask for identification for unknown, in person witnesses.

Conduct interviews sequentially, if possible, to prevent witness-to-witness communication

Data Sequestration
（資料封存）

Data Sequestration

42 CFR §93.305 Responsibilities form maintenance and custody of research records and evidence.

(a) Either before or when the institution notifies the Respondent of the allegation, inquiry or investigation, promptly take all reasonable and practical steps to obtain custody of all the research records and evidence needed to conduct the research misconduct proceeding, inventory the records and evidence, and sequester them in a secure manner . . .”

Data Sequestration

42 CFR §93.307 continued

(b) To the extent it has not already done so at the allegation stage, the institution must, on or before the date on which the Respondent is notified or the inquiry begins, whichever is earlier, promptly take all reasonable and practical steps to obtain custody of all the research records and evidence needed to conduct the research misconduct proceeding, inventory the records and evidence, and sequester them in a secure manner.

Sequestration SOP

- The federal regulation does not specify a process for sequestration
- An institution can allow sequestration without federal policy, if University policies allow sequestration
- **Without data, investigation will be inadequate**

Sequestration SOP

- University written policy can state that the university owns the research data generated by university employees using university facilities, with grants made to the university.
- Reference this research data policy in the research misconduct policy.
- Also include in the misconduct policy that the “RIO” has the authority and obligation to sequester evidence which, is necessary to evaluate and review an allegation of misconduct.

If you were to sequester, how would it be done:

Assemble a set of subject-matter advisors from key disciplines whom the RIO can call upon confidentially to review allegations and, when necessary, help plan and even participate in sequestration.

If you were to sequester, how would it be done:

Prepare sequestration team – typically, RIO, RIO assistants (preferably with some forensic training), institutional legal counsel, subject matter/disciplinary expert, IT experts, security.

Prepare for secure storage of sequestered data.

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If you were to sequester, how would it be done:

Sequester immediately (witnessed, signed receipts)

Begin record-keeping for all evidence, including data the Complainant or other witness may provide in the initial interview.

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If you were to sequester, how would it be done:

Plan to sequester broadly to pursue all leads; consider data that has not yet been identified, and where it might be - e.g., review recent grant proposals, manuscripts, publications. (The scope of the case may broaden)

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If you were to sequester, how would it be done:

Coordinate with IT for electronic evidence/data that may be pertinent (including e-mail) and where it is stored.

If you were to sequester, how would it be done:

For data in central facilities (e.g., university e-mail, shared data storage facilities), sequester immediately using appropriate technology.

If you were to sequester, how would it be done:

Carefully document all evidence

Some “RIOs” assign evidence #s to each piece of data after sequestration for tracking or create computer data base of all the evidence in a case

If you were to sequester, how would it be done:

Helpful to have signatures and dates on forms for releasing data and receiving it

Use a secure evidence room, or cabinet, to store data

If you were to sequester, how would it be done:

Supervise access to data

Consider how to handle Respondent resistance to sequestration

Some Institutions resist sequestering all sources of evidence for fear of invading Respondent's privacy.

Sequestration is the most critical aspect for resolving a case

Part I – End Questions?

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Best Practices for Handling Research Misconduct: Guidance from the U.S. Regulations – Part II

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PART II – Special Circumstances

- Handling Retaliation
- Corrections and Retractions
- Handling Admissions
- Time Limitations
- Plagiarism vs. Authorship Disputes
- Misconduct in Clinical Research

Tasks Assigned to RIO

- Know the University Policy & Develop SOPs
- Manage retaliation
- Manage corrections and retractions
- Monitor administrative actions or sanctions

Handling Retaliation
（處理「報復」）

Retaliation SOP

Retaliation defined in the regulation (42 CFR §93.226 as):

. . . an adverse action taken against a complainant, witness, or committee member by an institution or one of its members in response to —

(a) A good faith allegation of research misconduct; or

(b) Good faith cooperation with a research misconduct proceeding.

Retaliation SOP

Also under the General Responsibilities for compliance 42 CFR §93.300:

Institutions under this part must –

(d) protect the positions and reputations of good faith complainants, witnesses and committee members and protect them from retaliation by respondents and other institutional members

Retaliation SOP

Recommendations for Best Practices

1. The prohibition of retaliation should be included in the institution's research misconduct policy or other related policy, (& defined in policy) and also allow for the investigation of retaliation allegations, the adjudication of such cases, and the application of appropriate sanctions

Retaliation SOP

Recommendations for Best Practices

2. The person handling allegations ("RIO") should have the authority and responsibility to caution against retaliation for everyone connected to a misconduct case; and to investigate evidence or allegations of retaliation whenever they arise; and when allegations of retaliation appear to have substance the RIO should provide evidence to the appropriate adjudicating body.

Retaliation SOP

Recommendations for Best Practices

3. The "RIO" should provide notice of the institution's retaliation policy in initial conversations/interviews with complainants, witnesses, respondents, and any committees.

Retaliation SOP

Recommendations for Best Practices

4. The "RIO" should have the authority and responsibility to require interim actions by other administrators during the review of an allegation of misconduct to protect those who are at high risk for retaliation or may already have been retaliated against. This may require reassigning employees to work in other locations.

Retaliation SOP

Recommendations for Best Practices

5. The "RIO" should have the authority and responsibility to assess for potential conflicts of interest any institutional official or other employee assigned to play a role in protecting a complainant, witness or committee member from retaliation and have that individual recused a appropriate.

Retaliation SOP

Recommendations for Best Practices

6. At closure of the misconduct case, the RIO should take necessary actions to protect and, if necessary, restore the reputations of person who may have been retaliated against or persons charged with retaliation, but exonerated after review.

Corrections and Retractions
（更正和撤稿）

Corrections and Retractions

- Two goals for any misconduct proceeding:
  a) identifying individuals who may be responsible for research misconduct, and
  b) restoring the integrity of the research record.
- Attention focuses on Respondent(s) when cases go public
- Restoring the integrity of the research record is equally, or more, important

Corrections and Retractions

- Correction or retraction of publications and grant proposals which have been plagiarized or which contain fabricated or falsified data is a critical part of the process

Corrections and Retractions

- Important to identify all the affected data and text, sometimes looking beyond the initial allegations
- Research misconduct may be a “one-time occurrence,” but often one known instance of misconduct is part of an extensive pattern of fabrication, falsification or plagiarism by that respondent.

Corrections and Retractions

- At minimum, look to see if evidence exists for similar instances of falsification, fabrication, or plagiarism, and/or absence of supporting research data.
- If no evidence exists, there may be no way to verify prior research.

Corrections and Retractions

- When it is determined that research is fabricated, falsified, or plagiarized, correction of the research record is required.
- Caution should be exercised in the timing, especially if the case becomes public, there is often pressure from coauthors and others to correct the literature rapidly.

Corrections and Retractions

- Rapid corrections or retractions can result in incomplete or inaccurate corrections (or statements assigning responsibility) before all of the facts are known.
- There may be consequences for innocent co-authors.
- The institution may work with the journal to determine the appropriate timing for a correction or retraction.

Corrections and Retractions

- When the decision to retract a paper is made, the retraction of journal articles is sometimes difficult
  - Journals may require a signature of the corresponding author, and sometimes all the co-authors, for the retraction
- One of these will likely be the respondent who may be reluctant to cooperate
- A conversation with an editor can often lead to a strategy for retraction.

Corrections and Retractions

- Someone at the institution (usually the RIO in the US) monitors retractions to assure they occur.
- The RIO may track the questioned articles for a year or 18 months.

Monitoring Other Administrative Actions

- After an institution makes a finding of misconduct against one or more respondents, it typically imposes sanctions (a.k.a. administrative actions)
- Actions may be, up to and including dismissal of the respondent(s).

Monitoring Other Administrative Actions

- When dismissal is not sought, institutions may place respondents on probation with specific conditions for specific periods
  1. The institution may require the respondent to agree to and cooperate in the retraction as a condition of continued employment

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Monitoring Other Administrative Actions

- When dismissal is not sought, institutions may place respondents on probation with specific conditions for specific periods
  2. The institution may require the respondent to identify all other places where the data/text in question has appeared so that it can be retracted as well

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Monitoring Other Administrative Actions

- When dismissal is not sought, institutions may place respondents on probation with specific conditions for specific periods
  3. The institution may exclude respondent from supervising junior researchers

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Monitoring Other Administrative Actions

- When dismissal is not sought, institutions may place respondents on probation with specific conditions for specific periods
  4. The institution may reprimand the respondent, exclude respondent from supervising junior researchers

Monitoring Other Administrative Actions

- When dismissal is not sought, institutions may place respondents on probation with specific conditions for specific periods

5. The institution may require that a respondent's research activities be supervised, similar to action taken by ORI

Monitoring Other Administrative Actions

- When dismissal is not sought, institutions may place respondents on probation with specific conditions for specific periods

6. The institution may de-tenure a faculty member or demote a respondent

Monitoring Other Administrative Actions

- When dismissal is not sought, institutions may place respondents on probation with specific conditions for specific periods

7. The institution may debar a respondent, similar to an action taken by ORI, preventing respondent from receiving PHS (NIH) funds for specific periods

Monitoring Other Administrative Actions

In the U.S., the RIO monitors that administrative actions are being enforced

- May create administrative teams appropriate for the specific case to monitor administrative actions, which includes representatives from:
  - Grants and Contracts Administration
  - Chair or Dean from Respondent's department
  - Dean of the graduate school.

Handling Admissions

（處理招認）

Handling Admissions

The Federal Regulations 42 CFR §93.316:

Completing the research misconduct process – ORI

a) ORI expects institutions to carry inquiries and investigations through to completion and to pursue diligently all significant issues.

Handling Admissions

The Federal Regulations 42 CFR §93.316:

Completing the research misconduct process – Institution

An institution must notify ORI in advance if the institution plans to close a case at the inquiry, investigation, or appeal stage on the basis that the respondent has admitted guilt, a settlement with the respondent has been reached, . . .

Handling Admissions

The Federal Regulations 42 CFR §93.316:

Completing the research misconduct process – ORI

b) After consulting with the institution on its basis for closing a case under paragraph (a) of this section, ORI may conduct an oversight review of the institution's handling of the case and take appropriate action including:

Handling Admissions

The Federal Regulations 42 CFR §93.316:

Completing the research misconduct process – ORI

(1) Approving or conditionally approving closure of the case;

(2) Directing the institution to complete its process;

(3) Referring the matter for further investigation by HHS; or,

(4) Taking a compliance action.

ORI needs to make its own findings for the government based on institution's research misconduct findings

Handling Admissions

What should Institutions consider?

Obtain written and signed statement of the F/F/P and admission *to research misconduct*

- I have decided not to contest the allegations of misconduct (not RM)
- I made a terrible error (not RM)
- Oral admission can be reversed (i.e., R claims coercion)

Handling Admissions

What should Institutions consider?

Obtain enough information to ensure that Respondent's admission is sufficient for a research misconduct finding for the institution and for the regulatory agency

- Know the specific F/F/P
- Consider full scope of F/F/P; potential obstruction by respondent to full scope

Handling Admissions

What should Institutions consider?

Institution may be involved in the signing an agreement for a voluntary settlement agreement between ORI, Respondent and/or Institution or can have a settlement agreement of its own

Handling Admissions

Settlements May Occur Without Admissions

- Institution makes a research misconduct finding
- Respondent *accepts the finding*
  Not an admission to research misconduct
- In the US – Institution reports settlement to ORI and ORI approves case closure
  - An Institution may consider written settlement without regulatory agency

Time Limitations

（追溯期）

Time Limitations

42 CFR §93.105 Time limitations.

(a) *Six-year limitation.* This part applies only to research misconduct occurring within six years of the date HHS or an institution receives an allegation of research misconduct.

Time Limitations

42 CFR §93.105 Time limitations.

(b) *Exceptions to the six-year limitation.*
Paragraph (a) of this section does not apply in the following instances:

(1) Subsequent use exception.

(2) Health or safety of the public exception.

Time Limitations

42 CFR §93.105 Time limitations.

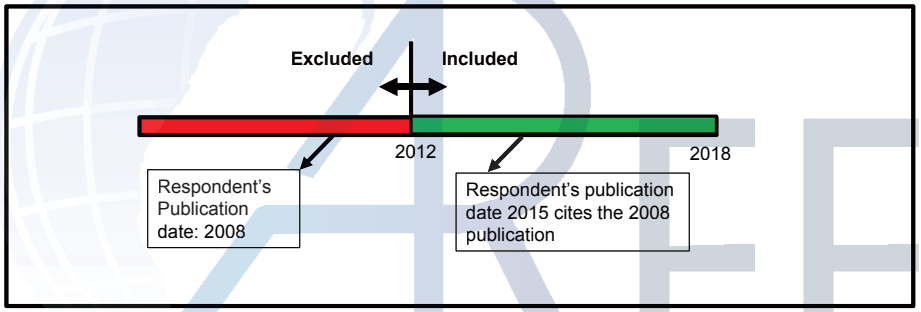
(2) *Health or safety of the public exception.* If ORI or the institution, following consultation with ORI, determines that the alleged misconduct, if it occurred, would possibly have a substantial adverse effect on the health or safety of the public.

Time Limitations

42 CFR §93.105 Time limitations.

(1) *Subsequent use exception.* The respondent continues or renews any incident of alleged research misconduct that occurred before the six-year limitation through the citation, republication or other use for the potential benefit of the respondent of the research record that is alleged to have been fabricated, falsified, or plagiarized.

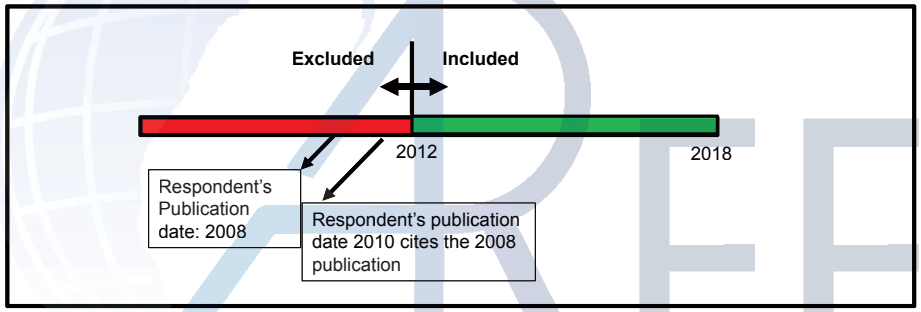
Subsequent use exception – 6 year time limit



Outcome: 2008 publication is **included** cited by Respondent in 2015 (within the six-year time limitation)

MEETS THE SUBSEQUENT USE EXCEPTION

Subsequent use exception – 6 year time limit



Outcome: 2008 publication is **excluded** cited by Respondent in 2010 (NOT within the six-year time limitation)

DOES NOT MEET THE SUBSEQUENT USE EXCEPTION

Plagiarism

Plagiarism vs. Authorship Dispute
(抄襲與作者爭議)

Plagiarism

42 C.F.R. § 93.103 Research misconduct.

Research misconduct means fabrication, falsification, or plagiarism in proposing, performing, or reviewing research, or in reporting research results.

(c) Plagiarism is the appropriation of another person's ideas, processes, results, or words without giving appropriate credit.

ORI website: https://ori.hhs.gov/ori-policy-plagiarism

ORI Policy on Plagiarism (*related to authorship*)

Many allegations of plagiarism involve disputes among former collaborators who participated jointly in the development or conduct of a research project, but who subsequently went their separate ways and made independent use of the jointly developed concepts, methods, descriptive language, or other product of the joint effort.

ORI website: https://ori.hhs.gov/ori-policy-plagiarism

ORI Policy on Plagiarism (*related to authorship*)

The ownership of the intellectual property in many such situations is seldom clear, and the collaborative history among the scientists often supports a presumption of implied consent to use the products of the collaboration by any of the former collaborators.

For this reason, ORI considers many such disputes to be authorship or credit disputes rather than plagiarism. Such disputes are referred to PHS agencies and extramural institutions for resolution.

At Ohio State University:

"University Policy and Procedures Concerning Research Misconduct"

Plagiarism. "Plagiarism" is the appropriation of the ideas, processes, results, or words of another person, without giving appropriate credit.

Ohio State policy does not described authorship dispute vs. plagiarism, but uses ORI's policy as guide.

Ohio State - Research Data University Policy

The university handles disputes regarding authorship as an academic issue.

Authorship Disputes

- Individual with complaint contacts (in writing) the PI and the chair or director of the academic unit(s) involved, for review of the matter
- The chair or director will:
  - investigate based on criteria for authorship or acknowledgment in the academic discipline/field, and
  - mediate a resolution to the dispute.
- Graduate students contact the graduate studies chair of their program.

Ohio State - Research Data University Policy

Data Policy describes how review is handled in the event of a conflict of interest of Chair, Director or Dean and to whom complaint is escalated.

Data Policy allows referral of credible plagiarism allegations to the Senior Vice President for Research and/or the RIO.

Plagiarism and the allegations are reviewed under the Research Misconduct policy.

Plagiarism

The Issue of Threshold

Plagiarism

ORI website: https://ori.hhs.gov/ori-policy-plagiarism

ORI Policy on Plagiarism

Substantial unattributed textual copying of another's work means the unattributed verbatim or nearly verbatim copying of sentences and paragraphs which materially mislead the ordinary reader regarding the contributions of the author.

Plagiarism

ORI website: https://ori.hhs.gov/ori-policy-plagiarism

ORI Policy on Plagiarism

ORI generally does not pursue the limited use of identical or nearly-identical phrases which describe a commonly-used methodology or previous research because ORI does not consider such use as substantially misleading to the reader or of great significance.

Plagiarism

ORI Policy on Plagiarism:

Plagiarism is:

"Substantial unattributed textual copying of another's work . . ."

Not Pursue if:

" . . . limited use of identical or nearly-identical phrases"

What does *substantial or limited* mean?

Without definitions, difficult to know what is plagiarism

Plagiarism

What is the threshold for an allegation of plagiarism to be pursued as a research misconduct matter

- Is plagiarism mostly decided subjectively by institutions? On a case-by-case basis?
- Can we quantitate what gives merit to a plagiarism allegation?
  - Software (iThenticate) results of 5%, 10% or greater; what should be reviewed

Plagiarism

What is the threshold for an allegation of plagiarism to be pursued as a research misconduct matter?

- Is copying background, with no intent to mislead, be pursued as a research misconduct matter?
  - If not, how is this managed? Other University Policy?
  - What if entire background section in paper or thesis copied?
- Should institutions/journals develop standards? Policies? Is it even possible?

More Questions than Answers!

Plagiarism

What about "self-plagiarism"?

Self-plagiarism is using one's own work in another context, without citation that it was used previously.

The real concern with plagiarism is about misrepresentation of the origin of the work (not an issue here).

Good practice – an author should ensure that a reader knows the material was used previously through appropriate citation.

Plagiarism

What about "self-plagiarism"?

Self-plagiarism may also involve copyright infringement.

Copyright infringement is a very broad term.

The law gives the author of the work (the copyright holder) certain rights that include the right to reproduce (copy), distribute or display the work.

Traditionally, the author of a publication transfers the copyright to the journal publisher.

Good practice – always cite previous research properly

Misconduct in Clinical Research

（臨床研究中的不當行為）

Clinical Research Misconduct

vs.

IRB Issues

Research Misconduct in Clinical Research

Falsifications:

- Substitutions of one subject's record or samples for another's
- Altering eligibility dates, test results etc
- Falsifying dates of data collection to conform with protocol
- Altering patient data to conform to ones hypothesis

Research Misconduct in Clinical Research

Fabrications:

- Not conducting interviews with subjects and creating records of the interview
- Making up patient visits and inserting that record into the medical chart
- Recording the results of follow-up visits that never occurred

Research Misconduct in Clinical Research

What is NOT research misconduct?

Certain issues are handled by other processes and *can* include:

- Failure to report an adverse event to the IRB or sponsor

Research Misconduct in Clinical Research

What is NOT research misconduct?

Certain issues are handled by other processes and *can* include:

- Protocol deviations, such as entering ineligible subjects, administering an off-protocol drug, etc.

THE OHIO STATE UNIVERSITY Office of Research

Research Misconduct in Clinical Research

What is NOT research misconduct?

Certain issues are handled by other processes and *can* include:

- Administering a trial drug to non-study participant

THE OHIO STATE UNIVERSITY Office of Research

Research Misconduct in Clinical Research

What is NOT research misconduct?

Certain issues are handled by other processes and *can* include:

- Forging a physician's signature

THE OHIO STATE UNIVERSITY Office of Research

Research Misconduct in Clinical Research

What is NOT research misconduct?

Certain issues are handled by other processes and *can* include:

- Breaches of patient confidentiality

Research Misconduct in Clinical Research

What is NOT research misconduct?

Certain issues are handled by other processes and *can* include:

- Failure to obtain informed consent

Research Misconduct in Clinical Research

Two issues may be difficult to assess as allegations of research misconduct?

- Falsification or fabrication of consent forms
- Entering ineligible subjects (or failing to enroll eligible subjects) without a record of falsification or fabrication of eligibility data

Research Misconduct in Clinical Research

Two issues may be difficult to assess as allegations of research misconduct?

- Falsification or fabrication of consent forms

§ 93.224 Research record.

Research record means the record of data or results that embody the facts resulting from scientific inquiry, including but not limited to, research proposals, laboratory records, both physical and electronic, progress reports, abstracts, theses, oral presentations, internal reports, journal articles, and any documents and materials provided to HHS or an institutional official by a respondent in the course of the research misconduct proceeding.

Research Misconduct in Clinical Research

Two issues may be difficult to assess as allegations of research misconduct?

- Entering ineligible subjects (or failing to enroll eligible subjects) without a record of falsification or fabrication of eligibility data

✓ No false record – no research misconduct

? Reporting research results using subjects that were not eligible. Is this research misconduct?

Research Misconduct in Clinical Research

Most Clinical Research

Misconduct is identified during

ROUTINE AUDITS

Research Misconduct in Clinical Research

During routine audits, be alert for "red flags" of possible falsification/fabrication of clinical records:

- Presence of 2 copies of a document that appear identical except that a test result, a date or other identifiers differ

Research Misconduct in Clinical Research

During routine audits, be alert for "red flags" of possible falsification/fabrication of clinical records:

- A document that is internally inconsistent (i.e. records of prescribed and administered drug dosages do not agree)

Research Misconduct in Clinical Research

During routine audits, be alert for "red flags" of possible falsification/fabrication of clinical records:

- A document in the research record that cannot that be found in the patient's medical record

Research Misconduct in Clinical Research

During routine audits, be alert for "red flags" of possible falsification/fabrication of clinical records:

- Copies of documents that appear to be altered

Research Misconduct in Clinical Research

During routine audits, be alert for "red flags" of possible falsification/fabrication of clinical records:

- Patient interviews are recorded in the research record, but no contact between interviewer and patient is documented anywhere

Research Misconduct in Clinical Research

During routine audits, be alert for "red flags" of possible falsification/fabrication of clinical records:

- Patient records show strict adherence to visit schedules

Research Misconduct in Clinical Research

- Unusually high recruitment rates
- Smaller than expected data variability
- Extreme differences as compared to other centers
- Lower than average adverse events

Research Misconduct in Clinical Research

When IRB protocol violations are seen - potential research misconduct is often seen

Be aware of those red flags!

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Part II – End Questions?

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