Cautions and Recommendations
Preparing a Case for ORI

Ann A. Hohmann, PhD & Ranjini Ambalavanar, PhD
September 24, 2018
Cautions First

Mistakes that can make an ORI finding **almost impossible**
- Early in the process: allegation through sequestration
- Middle of the process: inquiry and investigation
- End: report and institutional documents

Issues that make the process **more difficult** for DIO investigators
- Overall
- Committee selection
- Interviews
- Analysis
- Reporting
Mistakes that can make an ORI finding almost impossible
Mistakes early in the process

- Department members do an investigation before reporting to the RIO or Complainant goes to talk with the Respondent to “work it out”

- A Respondent is fired before s/he can participate in the inquiry-investigation process

- An admission statement has words like “mistake,” “error,” “misunderstanding”

- The RIO uses the threat of sequestration as a tool to get Respondent to tell the truth.
Mistakes early in the process

- Sequestration is late, done by asking the Respondent for data, done by someone other than the RIO and the support IT staff with experience in forensic imaging, and/or it is not comprehensive

- The following is not recorded:
  - where each drive was (i.e., whose computer?) before removal (photo of each computer and associated drive would be very helpful)
  - make, model, serial number of the drive
  - software and hardware used to make forensic image
  - name and contact information of IT person making forensic image
  - date and time of sequestration

- Chain of custody documents are not created or kept current
Mistakes in the middle of the process

- Failure to follow the regulation regarding the stages required by an institution:
  - assessment
  - inquiry (no findings can be made; written report required)
  - investigation (where there must be clear findings of intentional and knowing misconduct for ORI if there is to be a federal finding; institutional definitions not relevant for report)

- Failure to notify Respondent of full scope of investigation – particularly if the scope expands as the investigation proceeds – or anyone is added as a Respondent
Mistakes in the middle of the process

- Failure to interview key members of a lab, who saw what happened and understand the character of the Respondent

- Allowing the Respondent and/or witnesses to sit in the room during interviews or to allow the Respondent to question the witnesses

- Allowing a member of the lab or someone with a COI to analyze data collected during sequestration

- Failure to verify the authenticity of witnesses, emails, or phone interview subjects
Mistakes late in the process

- No Deciding Official letter
- Conflicting statements between the Deciding Official and the Committee
Issues that make the process more difficult for DIO investigators
Issues that make the process more difficult for DIO investigators

Overall

- Failure to adequately address the scope of possible misconduct
  - grant applications, including progress reports
  - papers and presentations that were not included in the original allegations

- Ignoring ORI jurisdictional issues
  - PHS funding required (§93.102)
  - time limits (§93.105)

- Skipping any step of the process in the regulation without checking with ORI
Issues that make the process more difficult for DIO investigators

Overall

- Asking for extensions without providing clearly articulated reasons and a game plan for moving forward

- Failure to notify ORI when the institution wants to close the case based on the fact that the Respondent has admitted guilt, a settlement with the Respondent has been reached, or for any other reason except the closing of a case at the inquiry stage on the basis that an investigation is not warranted (§93.316)

- Respondent leaves the country or becomes unreachable
Issues that make the process more difficult for DIO investigators

Committee

- Inclusion of a person on the committee who is either junior or otherwise not qualified to judge whether there is FFP in the science of the Respondent, e.g., humanities faculty

Attorneys representing the Respondent will use this
Issues that make the process more difficult for DIO investigators

Interviews

- Allowing the Respondent or his/her attorney to interfere and/or intimidate committee members during an interview

- Mentioning documents, figures, or images in interviews without providing those looking at the transcripts or listening to interviews a reference to know what is being examined

- Failure to have transcripts checked by interviewee for accuracy and places where transcriptionist could not understand the words because of heavy accent, mumbling, soft voice, cross talk, jargon, etc. Lost words might prove to be critically important.
Issues that make the process more difficult for DIO investigators

Analysis

- Including issues outside of ORI’s jurisdiction, e.g. academic integrity
- Failure to separate human subjects violations from research misconduct
- Ignoring or failing to identify patterns of FFP and their significance
- Failure to determine who had access to which computers and whether accounts were secure or shared
Issues that make the process more difficult for DIO investigators

Analysis

- Assuming that problems with data are evidence of a knowing and intentional attempt to deceive
- Failure to look into contradictions between witnesses
- Assuming that whatever a particular witness says is true (or false)
- Failure to consider and comment on the Respondent’s responses to the report or findings
Issues that make the process more difficult for DIO investigators

Report/Reporting

- Names and qualifications of Inquiry and/or Investigation panel members are missing
- Report contains conflicting language that indicates both “knowing and intentional” and “mistake/error” or extenuating circumstances
- Failure to include final institutional administrative actions (§93.315)
Issues that make the process more difficult for DIO investigators

Report/Reporting

• No indication of what evidence the committee considered, e.g., if you sequestered and forensically imaged the hard drives, did anyone look at them? (§93.313(e))

• Failure to provide security information for every hard drive used by the committee to reach conclusions, i.e., who had access, was it password protected, and who had the password?

• Failure to send to ORI a copy of the evidence used by the committee to reach the conclusions found in the investigation report

• Sending additional documents or evidence to ORI – requested or not – without a cover letter and a case or accession number assigned by DIO
Organized Inquiry/Investigation Reports

ORI requires adequate reports to pursue its own findings or close a case without findings:

- **Avoid** placing the report and attachments in a single PDF file; it is hard to navigate.

- Electronic reports with separate Attachments/Exhibits on a thumb drive or CD preferred (avoid emailing reports).

- Place page numbers, dates, and author name(s) (if applicable – of the expert) in all documents, reports, expert opinion.

- Provide a timeline with your reports.

- Hyperlink the cited documents in the report (recommended).
Report Content – Some Suggestions

- Provide separate analysis of each allegation and submitted errata

- Identify the person(s) responsible (42 CFR §93.313), and each individual’s role leading to the knowing/intentional FFP

- Send us separate reports for each named Respondent

- Cite evidence from testimony or other sources, be specific with page, line number etc.

- Provide a summary of the facts/analysis and rationale for the conclusion for each issue

- Provide relevant data files in their original file format so that DIO can perform analyses
Report Content – Some Suggestions

- State the significance of the data manipulation

- Include committee’s responses to Respondent’s rebuttals; address credibility when necessary

- Provide clear statement of finding - whether or not misconduct occurred

- State why the Committee accepts or rejects an honest error argument, not taking the word from Respondents/witnesses

- Avoid ambiguity in findings

- Provide current or last known contact information of the Respondent
Additional Helpful Information in Reports

• Factors/knowledge supporting the Respondent’s awareness of risk
  ▪ Hostile laboratory environment
  ▪ Ignoring notification of possible data issues by a lab member or others
  ▪ Knowingly reporting/including F/F data in papers or grants
  ▪ Email evidence is very helpful

• Define “relevant research community” and “accepted practices” for the questioned subject
  ▪ Committee members CV
  ▪ Relevant sections from institutional policies
  ▪ Instruction to authors from journals
  ▪ Society guidelines

• How the issue at hand departs from accepted practices
Ambiguous Statements Such as…

• “Committee determined these may have been intentional “errors” to mislead Committee….”

• “…After reviewing this material the Committee unanimously agreed that there was some evidence of research misconduct without evidence of intent to deceive…”

• “Our analysis did support four allegations raised… The researcher copied an image, rotated it, and stretched it. The Committee finds this was research misconduct involving falsification of data, possibly due to recklessness, but also with some intent to deceive. The severity of the misconduct is moderate….”
Confusion

- “Allegations are credible….” - with no statement of findings in the report

- The evidence did not support a finding of research misconduct by NIH/ORI guidelines (unanimous decision) because the “research was not submitted for publication and will not be published.”

- The evidence did not support a finding of research misconduct by NIH/ORI because the project was “outside the scope of ORI oversight” (Leukemia grant, not NIH grant) – the data collection was supported by NIH grant
What is the Final Finding?

- Who did it?
- Fabricated/falsified/plagiarized?
- Why is it false?
- Why is it significant to science?
- What was the manipulation? (determine intent)
- What type of data?
- Affected area of science
- How many figures and reports are there? (determine scope)
- Where was it presented?
Issues/Findings - Specific and detailed

Respondent intentionally, knowingly, and recklessly engaged in research misconduct by ... **falsifying** histopathological data reported in fifty seven (57) images in two (2) published papers, one (1) submitted manuscript, two (2) poster presentations, and seven (7) of Respondent’s supervisor’s grant applications and **fabricating data for** the corresponding nineteen (19) summary bar graphs that were based on those false images.

Specifically, Respondent **trimmed**, resized and/or flipped ...and used portions of Figure 6 (right panel) of a draft R21 CA120017–01 grant application, representing an image of liver tumor two (2) days after injection of *Cp/plc*-bacteria, to represent unrelated results from different experiments in: Figure ... in grant ...
Case Summaries and NIH eRA Links to PHS Administrative Action Bulletin Board
Examine Submitted Errata

Questioned figure

Corrected new figure sent to the journal

Original Film provided for the questioned Figure

Enlarged to show the texture, streaks, colors and the arrangement of CMYK color spots parallel to the streaks on the band (40X, light microscope)
In Case of an Appeal…

Necessary institutional and federal procedures

HHS ORI bears the burden of establishing research misconduct

Points to Note:

- ORI's current process gives the right of appeal only to the Respondent
- Respondents will raise new defenses or elaborate on existing defenses
- ORI needs to pursue additional evidence to verify or rebut these new arguments
- Ongoing institutional cooperation is vital during appeal, as evidence continues to be developed during pre-trial phase
- Institution provides access to most evidence, e.g., scientific documents, equipment, the research site, financial records, phone records, etc.
- ORI often reaches out to institutional officials for willingness to testify, declarations, etc.
At the Institution…

Lack of Data

- Sloppy research records
- No guidance or standards for keeping data
- Not protected over time (conveniently lost)
- Accessible to multiple staff
- Not backed up and stored securely
- Researchers take data from the institution

Lack of Policies/guidelines

- Data storage/retention
- Acceptable image manipulation
- RCR training requirement
- Return of funds in cases of research fraud
- Culpability lies on grantee institution
Questions