Making the Right Moves in Handling Research Misconduct Allegations
March 24, 2000

Program Highlights

Introduction

Ada Sue Selwitz, Director of the Office of Research Integrity at the University of Kentucky, opened the broadcast by noting that there are four words that can strike fear into the hearts of administrators and researchers everywhere... "allegations of research misconduct." This four and one-half hour live satellite broadcast focused on making the right moves in handling misconduct allegations, providing practical advice and concentrating mostly on the processes involved.

The program included presentations and discussions of the following issues: (1) changes in Federal policies and regulations anticipated over the next 12 months; (2) receiving and assessing allegations; (3) gathering evidence; (4) conducting the inquiry; (5) investigation outcomes; and (6) living with the results.

This summary will provide program highlights and summarize key advice given by the conference faculty concerning good practices and lessons they had learned in handling misconduct allegations. More detailed information may be found in the attached copy of the speakers' slides, which are referenced throughout the summary below.

Changes in Federal Policies

The proposed new Federal definition of research misconduct is:

"Fabrication, falsification, or plagiarism in proposing, performing, or reviewing research or in reporting research results."

This new definition deletes the "serious deviation" clause, although the concept remains in that findings of research misconduct will still require "a significant departure from accepted practices." "Reviewing research" has been added and intentional or reckless acts are included for the first time. Findings must be proven by a preponderance of the evidence.

Research institutions have primary responsibility for preventing, detecting, investigating and adjudicating misconduct cases, whereas the Federal government will conduct oversight reviews but retain the right to conduct inquiries or investigations if necessary.

Education in the responsible conduct of research will be expanded to include all persons engaged in research or research training supported by grants, contracts, and cooperative agreements from agencies within in the Department of Health and Human Services (HHS). The new policy on this issue is expected to be published for public comment in October 2000.

Handling Allegations

Tina Gunsalus from the University of Illinois noted that allegations of research misconduct can sneak up on you, with disputes sometimes escalating into a "train wreck" situation if they are not handled properly. Much of the advice comes from institutions learning from their mistakes.

Indicators for using a formal process to assess allegations include: (1) if the allegation turns out to be true, it is a very serious problem; (2) if there is a history of low level problems (i.e., lots of "smoke"); (3) if volatile personalities are involved; and (4) if a large power imbalance exists between the parties involved.

There is a natural tendency to recoil from issues involving possible research misconduct. Most people want these issues to go away, but sometimes they don't. Imposing a process can protect the innocent as well as the institution.

Her advice to institutional officials was to maintain boundaries in their official role of receiving allegations, and to remain neutral in the dispute. It is also very important to remember that if the facts are true, the motive of the whistleblower is irrelevant.

Her general advice was:

1. Make decisons based on facts, not personalities;
2. Handle all situations as if they will become public;
3. Have a checklist to be sure you comply with all regulations;
4. Have good legal support;
5. Be prepared in advance; and
6. Remember this is about institutional integrity, not just compliance with Federal regulations.

In response to a question about overlapping jurisdictions, Ms. Gunsalus indicated that anything that is urgent or dangerous should be handled first, such as protecting human research subjects.

Preparing for Preliminary Inquiry

Robert Rich, formerly of Baylor University, opened this part of the program by addressing the question of "What do you do first?" when you've decided that you need to appoint an inquiry committee. He recommended that you appoint three senior scientists, an institutional official as an advisor or member of the committee, and he noted that good staff support is essential at this point.

Various parties need to be notified that an inquiry is being initiated. These parties include the inquiry committee members, as well as the respondent and the complainant in the case.

Depending on the particular situation, others may also need to be notified. Examples include chair of a department, senior institutional officials, chairs of compliance committees, university counsel, Federal agencies such as the Office of Protection from Research Risks (now known as the Office of Human Research Protections, OHRP) or the Food and Drug Administration (FDA).

There are lots of other people that don't need to know about the inquiry at this point. These include other faculty and staff, funding agencies, or anyone else. This is because it is essential to maintain confidentiality as best you can, and you need to emphasize to anyone you notify that they need to maintain confidentiality in this process.

The parties should be notified in writing.

Should the complainant (whistleblower) be identified to the respondent? Dr. Rich said the identity of the complainant is likely to be known, or will be known eventually, especially if the case proceeds to an investigation.

He also discussed when data and related materials needed to be secured. His suggestion was to do this at the time you notify the respondent, hopefully with the respondent's cooperation. In any case, securing data is best done privately, if possible, and outside of regular business hours.

What is secured? Well, the short answer is anything that may be relevant. This can include (1) lab notebooks; (2) all drafts of relevant manuscripts; (3) all drafts of grant applications; and (4) any other pertinent research materials. This step needs to be carefully planned, and you should prepare for some, but hopefully minimal, disruptions to the lab's work. This can be difficult, both practically and emotionally, but the data needs to be secured for the protection of the respondent as well as for the institution.

Gathering Evidence

Dr. Rich's presentation was followed by an panel discussion. It was here that the moderator of this segment of the program, Chris Hansen, noted that the panel discussion would depart from the materials provided in the slides, so all panelists would be able to participate.
The panel discussion highlighted the following points:

1. Importance of planning process;
2. Preserve presumption of innocence and allow for minimal disruption to research;
3. Consider consulting ORI's rapid response team;
4. Securing of data may need to be an iterative process;
5. Securing data is very difficult, and should be done outside of business hours;
6. Try to minimize embarrassment for faculty and lab staff;
7. Importance of protecting confidentiality of research subjects;
8. Copy originals of materials and give copies back to the respondent;
9. Planning includes preparing teams that will secure data;
10. Time is of the essence and planning is essential—since you are trying to answer this question: What data do you need to prove or disprove the charges?

During the panel discussion, Dr. Price explained "chain of custody," to mean that no one had unsupervised access to the records so the integrity of the sequestered data is maintained. "Controlled access" means never letting others, especially the respondent or the complainant to have unsupervised access, if possible. An inventory is essential when data is sequestered. It was noted that sometimes the process of verifying sample can be destructive. Planning also includes receipts for all materials taken, and it is helpful if all materials have date stamps on them, and are documented to be true copies, if the originals can't be used.

The phone lines were opened for questions from the audience. The first question was "Who pays for all this work"? The panelists indicated that the institution does, and Ms. Gunsalus estimated that the process might cost about $8,000 to $20,000. There often needs to cost-sharing for unexpected time and expenses, particularly if more than one institution is involved.

Another question was "Should others do the inquiry or investigation?" It was noted that this process can be painful and horrible when it is done by non-professionals. But the panelists noted that this problem can be alleviated somewhat by having a standing committee handle inquiries, by providing adequate staff support. The panelists agreed that keeping institutional control of the process was important, and often institutions may choose an outside person or have the complainant and respondent suggest outside experts to help.

Conducting the Inquiry

David Wright, Michigan State University, reviewed the preliminary inquiry process. He noted that the PHS regulation states: "inquiry means information gathering and initial fact finding to determine whether an allegation or apparent instance of misconduct warrants an investigation."

The NSF regulation is similarly worded: " An 'inquiry' consists of preliminary information-gathering and preliminary fact-finding to determine whether an allegation or apparent instance of misconduct has substance."

Dr. Wright recommended that institutions triage allegations, attending to threats to research subjects or public health or other concerns first. He advised keeping key administrators informed and making sure that the data is secured. He recommended that the institutional official notify the respondent and complainant (whistleblower) in writing of the inquiry, and to brief each of them separately regarding their roles and rights in the process, and be given an opportunity to ask questions.

Dr. Wright emphasized that an inquiry is the "academic equivalent of a criminal investigation, not a civil law suit, so complainants are not parties but the respondent is." Both respondents and complainants should be told to keep this process is confidential. The respondent also should be reminded about not to retaliating, and be urged to cooperate.

The next step is to select an inquiry panel, if that is part of your institution's process. The inquiry panel should be briefed in person, where you review the purpose and nature of the inquiry process and confirm the absence of any conflicts of interest. Indemnification and legal support for the process needs to be discussed, as well as the logistical support to be provided. Expert witnesses or consultants, such as forensic specialists should be identified. Dr. Wright then reviewed the contents of a written charge to the inquiry panel.

Basically two critical questions need to be answered by the panel: (1) Does the alleged misconduct fit the regulatory definition of misconduct? (2) Is there credible evidence supporting the allegation? If the answer is yes to both, a formal investigation is warranted and you need to start preparing the report. Dr. Wright recommended that witnesses be interviewed sequentially and in private, rather than in a hearing format. He also suggested that interviews be recorded or transcribed by a court reporter, and a copy of the transcription be given to the witness to review for accuracy. He noted that different institutions have different rules on where legal counsel may be involved, but those conditions where they may be involved should be reviewed.

Dr. Wright indicated that an exhaustive investigation is not needed during the inquiry stage. He also noted on the other hand, however, that a "guilty plea" by the respondent should not be used to cover up wrongdoing.

Dr. Wright then reviewed the elements of the written inquiry report (see slides 97-101), and noted that panels should use the "preponderance of evidence" standard. He said that if an investigation is warranted, the report may be summary in nature, but that a more complete report is needed when the panel finds that no investigation is warranted. The draft report should be reviewed by counsel and by the respondent, and the panel needs to consider the respondent's comments in writing the final version of the inquiry report.

The inquiry panel's report is then forwarded to the deciding official at the institution, who either accepts the report and it's recommendation for an investigation or exoneration, or rejects the report and sends it back to the panel for more work. The respondent needs to be notified, the complainant needs to receive a summary copy of the panel's findings. If an investigation is warranted, institutional and agency officials will also need to be notified. Dr. Wright suggested working with an exonerated respondent to restore his or her reputation, if it had been damaged by negative publicity.

The panel then entertained questions. "Is it possible for an inquiry panel to identify and add charges and look into additional wrongdoing that emerges as part of the process?" Yes. When asked about working with students, the panel responded that issues arise that are intimidating and students are even more vulnerable than senior researchers. A student member could be included on the inquiry panel to be sensitive to this issue, because it is important to make the process fair and the feel fair for the person involved. The accused also should be given every opportunity to say everything that they think is relevant for his or her defense.

It was also noted that it is important for the respondent to have access to academic counsel about the process—this could be in the form of an advisor or staff support. The panelists acknowledged that this can be a terrifying process, and support from a trusted advisor or advocate for students can be helpful.

Dr. Price briefly reviewed the timing of the process, noting that an inquiry or investigation can be an iterative process involving Federal officials. He also noted that most cases do not result in misconduct findings.

The viewing audience was given an opportunity to call in questions. When asked about the standard of proof, Dr. Wright noted that "preponderance of the evidence" is the current standard contained in Federal regulations, rather than a higher standard such as "clear and convincing" or "beyond a reasonable doubt."

When asked about restoring reputations, it was suggested that the respondent be asked if anyone needed to be notified. Having the respondent guide this process, including seeing the content of any written notification is important.

Bad faith allegations were discussed briefly, and it was noted that some institutions have policies to handle bad faith allegations. Dr. Wright said that the fear of this happening is usually greater than the reality, although it does happen sometimes.

In response to a question about media interest in a case, the panelists indicated that any queries should be referred to the institution's public affairs office. That office should respond that the process is underway, and that there they have no comment.

Investigation Outcomes

Ada Sue Selwitz opened the next portion of the program by noting that there are two stages in handling allegations, and that the presenters had focused only on the inquiry stage so far. Due to time constraints, the presenters will be focusing next on investigation outcomes rather than the process of conducting an investigation itself.

Dr. Robert Rich, Emory University, reviewed the three possible outcomes of an investigation. Obviously, the happiest outcome would be no misconduct. He noted, however, that a "not guilty" finding may not necessarily mean that there were not lesser problems. Or the investigation may determine that fabrication, falsification, or plagiarism had occurred, using the preponderance of the evidence standard. A third possibility is that the respondent was engaged in behavior that falls under the category of "other university misconduct."

In writing the investigation report, Dr. Rich recommended that the committee summarize the accusation(s) and their context, describe the inquiry and investigation processes, and provide a detailed chronology of alleged misconduct. The report should deal with all the evidence, include data analysis, and have objective findings as well as judging the credibility of witnesses or experts. He also recommended that the committee give some

consideration indicating their opinion of possible university sanctions. The written report should be as jargon-free as possible, and be clearly written so third party reviewers will be able to understand the case. The committee should write the report in anticipation of litigation, and to be conscious to avoid potentially libelous or gratuitous comments.

The penultimate draft report should be given to the respondent for written comment or rebuttal, and those comments need to be included in full as an attachment to the report. Dr. Rich suggested that the writing tasks be broken up in complex cases involving multiple allegations, but edited carefully so that the report reads as a consistent whole.

The respondent needs to be given the opportunity to appeal a misconduct finding in writing to a different, and uninvolved university official. For this, institutions may wish to consider appointing a separate appeals committee. The appeals committee should address process issues, and not serve as a retrial of the facts of the case. A senior official makes the decision on the case after adjudication and the appeals processes are concluded, and will be responsible for implementing appropriate administrative actions.

Dr. Rich noted that the university process then leads to a Federal oversight review by ORI, and that other agencies may also need to be notified. And since the institution's ultimate obligation is to insure the integrity of the scientific record, the findings need to be reported to scientific community at large by notifying co-authors, collaborators, and correcting or retracting articles in scientific journals, or notifying officials at other institutions.

Living with the Results

Caroline Elmendorf, Chief Counsel for ORI, said that ORI needs to have continuing communication with the institution in a misconduct case, because ORI may need witnesses to testify before the Departmental Appeals Board (DAB). She also noted that if debarment is proposed, the institution has the responsibility for ensuring that the respondent does not use Federally funded resources or supplies.

The panel then responded to questions called in by the audience. In response to a question about who is responsible for handling cases that involve serious deviations from accepted practices, the panelists indicated that institutions should have their own standards that are in addition to the Federal standards. While discussing the dividing line between an inquiry and an investigation, it was suggested that the inquiry serves a triage function, and that more protections and more rigorous investigation is needed after that. Ms. Elmendorf noted that there are three basic issues that an inquiry needs to address: (1) whether there is credible evidence of misconduct, (2) whether it involves Public Health Service funds, and (3) whether it involves fabrication, falsification, or plagiarism. If those three criteria are met, the institution should move to an investigation.

Ms. Selwitz closed the video teleconference by saying she hoped that the audience found these presentations useful in previewing changes expected in Federal policies, as well as walking them through the processes of conducting inquiries and investigations into allegations of research misconduct.