Training the Research Integrity Officers (RIO): The Federally Funded "RIO Boot Camps" Backward Design to Train for the Future

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Abstract

Research institutions receiving U. S. Public Health Service (PHS) funding must assure the Office of Research Integrity (ORI/OPHS/DHHS) that policies and procedures are in place conforming to 42 CFR 93 to investigate allegations of Misconduct in Research, defined as fabrication or falsification of research data, or plagiarism. An institutional official known as the Research Integrity Officer (RIO) generally administers these policies and procedures. The role of the RIO is complex, exacting, and unique. There is no closely analogous position

in the academy of higher education. Some university attorneys refer to the RIO's role as "quasi-judicial," but, in fact, the RIO functions variously as prosecutor, judge, mediator, counselor, teacher, and regulatory manager. Institutions rarely train their RIOs, and no professional society has provided training or support for RIOs. Serious errors by RIOs in handling allegations of research misconduct have landed in the press and in the courts and, in the worst cases, have cost their institutions millions of dollars, public embarrassment, and internal upheaval. The RIO Boot Camp project aims to train RIOs and to professionalize their roles. The RIO Boot Camps were developed in collaboration with the ORI Division of Investigative Oversight (DIO). This paper outlines the unique aspects of the curriculum and the pedagogical techniques used. Results of a survey of RIO Boot Camp participants provide a portrait of the roles and responsibilities of RIOs and the challenges they face. The paper concludes by discussing the planned final products of the RIO Boot Camp initiative and future efforts to support the RIOs.

Keywords: research integrity, training, research integrity officers

Introduction

A Scenario: Dr. Green, of Large University, oversees a number of research regulatory areas as Associate Vice President for Research. These roles include serving as the Research Integrity Officer (RIO). Dr. Green regularly reviews Institutional Review Board (IRB) minutes and on this day notices a report of a death of a research subject in a Phase II clinical trial of a new cancer drug Large University has patented. What elevates Dr. Green's concern is the statement in the IRB minutes that the consent form in the deceased subject's research file was not signed. The minutes state that the IRB will investigate the matter further. Vice President Green calls the IRB chair and asks to be kept informed. The next day the IRB chair calls Dr. Green to report that there is also a discrepancy between the information in the deceased patient's clinical file (age, time since original diagnosis, previous therapy) and the information listed on the research intake form for that patient, signed by one of the research nurses for the drug trial. There are also several instances where records completed by the same nurse for follow-up visits to monitor health after conclusion of therapy do not include the subjects' initials as required by the protocol.

While fictionalized, this scenario is based on an actual case and is representative of complex problems RIOs have to confront. In this case, urgent review is required under both the regulations protecting human research participants (45 CFR 46) and those covering possible misconduct in research (42 CFR 93). How should the institution organize this review so that handling the case in one venue does not compromise the handling of it in the other? Who does what? In what order?

Because RIOs are often at or near the apogee of the research regulatory structure of their institutions (having titles like that of Dr. Green), it often falls to them to conduct the regulatory triage in cases such as this one. Almost none of them has had any prior training in how to do it.

A Short History of the Position of RIO

Since 1989, every research institution that receives U. S. Public Health Service (PHS) funding has had to assure the Office of Research Integrity (ORI/OPHS/DHHS) that it has policies and procedures conforming to 42 CFR 93 for investigating allegations of Misconduct in Research, defined as fabrication or falsification of research data, or plagiarism (Price, 1994). These policies and procedures are generally administered by an institutional official who has become known as the Research Integrity Officer (RIO).

When the federal misconduct regulations were first promulgated, the position of RIO was not defined—or even mentioned—in either the PHS or the parallel National Science Foundation (NSF) regulations. That has not changed in the intervening 20 years. The RIO remains neither defined nor mentioned in the second generation regulations (42 CFR 93 and 45 CFR 689). Rather, the RIO's position and role have developed and evolved as a matter of necessity. ORI, concerned about the frequent mishandling of cases at research institutions, wanted a single liaison on whom it could rely. As it had already successfully advocated for the creation of similar positions for intramural research at NIH, ORI wanted RIOs at extramural institutions as well. At the research universities and institutes, misconduct allegations were typically handled at first by the vice president or chancellor for research, or a provost. As it became clear that misconduct cases were often highly complex and time-consuming, the administration of institutional misconduct procedures has become a specialized role assigned to one person, the RIO. Today, the RIO is usually a fairly senior official, typically an assistant or associate vice president or provost.

The RIO's Role and Responsibility

The role of the RIO is complex, exacting, and unique. There is no closely analogous position in the higher education academy. Some university attorneys refer to the RIO's role as "quasi-judicial," but, in fact, the RIO functions variously as prosecutor, judge, mediator, counselor, teacher, and regulatory manager. In the course of handling an allegation of misconduct in research, the RIO may be responsible for completing the following duties, among others: providing notice to respondents and providing all those involved in a case with notice of their rights and obligations under the procedures, conducting or participating in investigative interviews, sequestering data, conducting preliminary forensic analysis of questioned data and documents, selecting and training inquiry and investigative panels, drafting or reviewing inquiry or investigative panel reports, negotiating the regulatory matrix within research institutions, and serving as a liaison to federal oversight agencies. The RIO may also be responsible for triaging and managing particularly complex or difficult cases that involve more than one regulatory area (e.g., research misconduct, research involving human participants, and financial conflict of interest), assuring that the right steps are taken in the right order, protecting whistleblowers from retaliation, or addressing other exigent circumstances that require special handling and immediate notification of ORI or other oversight agencies (see 42 CFR 93.318).

A Critical Problem for RIOs: Impetus for the RIO Boot Camps

RIOs are rarely trained by their institutions. There has typically been only one RIO per institution at any given time. The predecessor RIO has sometimes left the position in the aftermath of a case that has gone awry or as the result of cumulative frustration, so there may be no knowledgeable person at the institution left to train the new RIO. Until now, no professional association or government agency has provided any training. Initial survey data, collected through the RIO Boot Camps, suggest that RIOs stay on the job an average of five years. When the small group of RIOs with 10 or more years of service is factored out, the average is about three years. In either case, it is a short time to gain the experience requisite to learn this complex job, particularly because research misconduct occurs with relatively low frequency and, therefore, many RIOs have handled few cases. Further, and partially because of the way the position developed and evolved, institutional policies and procedures do not always provide the RIOs the authority necessary to fulfill their duties optimally.

Because careers are at stake and many allegations of research misconduct grow out of heated disputes among colleagues, misconduct cases are usually tendentious and often litigious. Serious errors by RIOs in handling such cases can and do end up in the press and in the courts, and in the worst cases lead to millions of dollars in costs, public embarrassment and internal upheaval for their institutions. When RIOs seriously mishandle cases, it can lead to the end of their careers. Mishandled cases also create a problem for ORI as well as for the institutions. ORI must rely on the adequacy of the cases made and findings relayed from the institutions for its oversight work and possible additional findings. The initial work done by the RIOs and their institutions makes it possible for PHS to make findings of research misconduct and to sustain those findings if the respondent appeals under 42 CFR 93.

This, in short, is the impetus for the ORI-sponsored in-service training program for RIOs—the RIO Boot Camp. RIOs are thrown into a critical, high-risk job for which they typically have had no training and for which there is no training model, or body of clearly applicable theory or methods. The first goal of the RIO Boot Camp program, then, is to create well-trained RIOs for research institutions. The second goal is to create, through the RIOs, better institutional policies and procedures for handling allegations, including the building of institutional teams supporting the RIO. Consequently, in 2006, ORI launched the RIO Boot Camp program to train RIOs and to professionalize their roles. Over the course of the seven RIO Boot Camps held to date, a third goal has emerged: providing a web resource to give RIOs centralized access to sample documents, policies and procedures, and technical material targeted to their needs (http://rioresource.org/).

Needs Assessment and Backwards Planning for the RIO Boot Camp

Scientist-Investigators from the Division of Investigative Oversight (DIO) at ORI and the first author (a consultant to ORI who served as a university RIO for 11 years) designed the RIO Boot Camp curriculum. Lack of a pre-existing training model or curriculum for training RIOs, and very little information about who the institutional RIOs were in terms of background and experience, posed a challenging problem. A decision was made to design the RIO Boot Camp curriculum backwards from the outcomes desired — a competent and professionalized corps of RIOs — and to determine what kind of program was needed to get there (Wiggins & McTighe, 2005).

An initial, informal needs assessment (conducted by talking with first generation RIO peers) revealed that almost none of the RIOs had any training for the job. They appeared to have inconsistent legal and logistical support at their institutions (in some cases very little). RIOs were also isolated. Discussion with approximately 30 RIOs at the first boot camps revealed that most had never talked with another RIO, much less seen other RIOs' work, and so they had no opportunity to learn from their peers' successes and errors. Nor did they usually seek advice from ORI in the handling of cases, sometimes viewing that office as a potentially hostile oversight agency. In short, many were flying blind into the storm with no navigational aids.

To provide the research community information about who RIOs were, and to arm new RIOs with information about "the RIO experience," a video was created, entitled, *The Role of the RIO* (September 2006). Nearly 1,700 copies of the video were distributed to research institutions in the U.S. and abroad. The video features approximately 30 minutes of interviews with, and conversation among, four experienced RIOs, augmented by several hours of indexed additional discussions with these RIOs on various aspects of the their responsibilities. *The Role of the RIO* is posted on ORI's website (http://ori.dhhs.gov/rio/riovideo/).

A Survey of RIOs, Legal Counsel and Staff Supporting RIOs

At the same time, information-gathering continued via surveys of and discussion with a broader group of approximately 60 RIOs at the early Boot Camps, with a wider focus on their length of experience as RIO, their administrative location within their institutional research regulatory structures, and the level of support they enjoyed. Information about their perceived needs was important to developing and promoting the curricular material. More recently, the following, more comprehensive survey was conducted of all those who had attended an RIO Boot Camp.

Tenured Versus Non-Tenured: Motivators and Barriers

Responses to research questions (3) Is there a difference in tenured and non-tenured faculty in perceived importance of grant writing motivators? and (4) Is there a difference in tenured and non-tenured faculty in perceived importance of barriers to grant writing? revealed one statistically significant difference ($p<.05$) between tenured and non-tenured faculty. Tenured COE faculty at the university found heavy teaching load to be a significantly more important barrier than non-tenured faculty. No statistically significant difference was found between tenured and non-tenured faculty in perceived importance of the motivators used in the survey. Appendix A reports the results of the univariate ANOVA for both motivators and barriers to grant writing.

Methodology

Research Instrument

An online questionnaire was designed to explore the role of the RIO and the roles of legal counsel and staff who support the RIO. The questionnaire consisted of three sections. The first section asked about RIO roles and responsibilities at their institutions.

The second section was concerned with information about the institutions' procedures, accessibility, and support for the role of the RIO. The final section collected information about difficult aspects of cases, including dealing with vulnerable whistleblowers and retaliation. To enhance face validity, the questionnaire was reviewed by several experienced RIOs and ORI officials, followed by pre-tests administered to participants at RIO Boot Camps. Feedback and comments were then integrated into the final online questionnaire.

Data Collection and Analysis

Profile of the Sample

The majority of respondents were RIOs (68.3%, *N*=56), followed by RIO Support Staff (17.1%, *N*=14) or Counsel (14.6%, *N*=12). Due to the nature of this paper, discussion of the results of the survey focuses primarily on responses by RIOs. A profile of RIOs who participated in the RIO Boot Camps is provided in Table 1.

The average length of service for RIOs was five years (*M*=5.19, *SD*=3.68); however, eight RIOs reported more than 10 years of service, making the mode of two years of service and the median of three years more representative of the population. Including experience as RIO at other institutions, the average length of overall service was also five years (*M*=5.20, *SD*=4.10), with a minimum of one year and a maximum of 15 years. Again, the mode of two years of service and the median of four years of service is more representative of the population.

The average number of research misconduct cases RIOs have handled or been involved in handling was eight (*M*=8.16, *SD*=10.36), with a minimum of zero and a maximum of 50. The most reported number of research misconduct cases was three and the median was four.

Fewer than half (42%) of RIOs indicated they were a member of the tenured faculty and the majority (83%) did not have a fixed-term appointment. Most (92%) had "at will" administrative appointments.

Most RIOs (90%) did not have an independent budget for their duties, and of those who did, the approximate size of their budget ranged from $10,000 to $100,000 per year, with most noting that budgets were determined as needed. Results also showed that RIOs work with little or no support staff, and in most cases, staff work part-time or on misconduct cases on an as-needed basis, "on loan" from their regular staff positions.

Table 1. Rank of Importance of Motivators and Barriers for Tenured and Non-Tenured Groups

RIO Characteristics (n=56)	Mean (Standard Deviation) or %
Years at current institution	5.19 (3.68) years (Range 1-16 years)
Total Years as RIO including other institutions	5.20 (4.10) (Range 1-15 years)
Hold a title other than RIO	98
Participate in Drafting/Revising Policy and Procedures	98
Average Number of Cases Involved/Handled	8.16 (10.36) cases (Range 0-50 cases)
Member of tenured faculty	42
Fixed term appointment	17
Administrative appointment "at will"	92
Independent budget for duties	10
Average number of findings of research misconduct (last 2 years)	1.54 (1.83) findings (Range 0-9 findings)
Average number of findings of research misconduct involving PHS or NSF funding (last 2 years)	1.13 (1.41)
Liaise with federal oversight agencies (ORI, NSF-OIG)	94

RIO Roles and Responsibilities

Almost all RIOs (98%) indicated they participated in drafting or revising their institution's policies and procedures for handling allegations of research misconduct.

Most RIOs (85%) are the individuals designated to receive allegations of misconduct at their institutions. Ninety-one percent inform key officials about receipt of a new allegation of research misconduct, and are responsible for triaging complex cases to decide who handles which part of the problem and in what order.

Almost all RIOs (91%) sequester data relevant to an allegation and protect potentially vulnerable whistleblowers (85%). Eighty-seven percent of RIOs conduct the assessment or "pre-inquiry;" 67 percent usually interview the complainant, and 56% usually interview the respondent. Key witnesses are sometimes interviewed by slightly over half of RIOs (59%).

In almost three-quarters of cases (73%), RIOs determine whether an inquiry is warranted. An ad hoc Inquiry Panel (74%) conducts the inquiry under the RIO institution's procedures in 74 percent of cases. Standing Inquiry Panels (17%) and in a few cases the RIO (9%) determine whether an Investigation is warranted. Half of the time, Inquiry Panel and Investigative Committee members are selected by the RIO (52%).

More than three-quarters (79%) of RIOs are responsible for informing the university about the research misconduct policy. In their administrative capacity, RIOs indicated they were responsible for the additional duties, mostly regulatory, shown in Table 2. Instruction and management of the Responsible Conduct of Research (RCR) (70%) and financial conflicts of interest (61%) were the top two areas of additional responsibility.

*Table 2. R*ank of Importance of Motivators and Barriers for Tenured and Non-Tenured Groups

Area of Responsibility (n=56)	%
Instruction and management – RCR	70
Financial conflicts of interest	61
Human subjects	48
Animal subjects	45
Recombinant DNA	36
Grants management	23
Radiation, chemical, biological hazards	23

Organizing Decisions for the RIO Boot Camps

Based on the information gathered, a peer-to-peer education model was designed to build core skills and knowledge among RIOs. To address the issue of RIO isolation, each RIO Boot Camp was limited to 25 or fewer participants so that the RIOs could get to know each other and to begin to build a professional community. RIOs from a list of the top 100 NIH grant recipient institutions were invited, as approximately 75% of the cases of alleged misconduct reported to ORI come from these institutions (Krueger, 2004). Scientist-Investigators from ORI participated, for the following reasons: to illustrate forensic techniques and best practices useful in misconduct cases; to let RIOs get to know them informally, building relationships they could subsequently call on should they need a consult on how to handle a case; and, more immediately, to give RIOs the chance to consult ORI informally while at the camp. It was emphasized that the DIO Scientist-Investigators were not conducting regulatory oversight, but attending the Boot Camp as colleagues. For that reason, the DIO did not attend some of the introductory sessions, by design, so that participants felt free to discuss candidly their reactions (including frustrations and complaints) with the oversight process and to make suggestions for its improvement. Because of the comparative inexperience of most of the participants, there was less peer-to-peer education in the first several RIO Boot Camps than expected. Nevertheless, participating RIOs, staff, and counsel made excellent suggestions about refining the initial curriculum. These suggestions were adopted.

Designing the Curriculum

Data gathered by the beginning of 2006 suggested that most of the RIOs attending the Boot Camps would be comparatively new to their jobs and have little relevant training or experience. Because most RIOs have much to learn about how and why misconduct in research occurs (a problem common to everyone concerned about misconduct in research) a basic approach was adopted: start at the beginning with a list of things an RIO would need to do to prepare to do this job. These things include reviewing institutional and federal misconduct policies and procedures, organizing the RIO office, establishing critical relationships within the institution and with the federal oversight agencies, and building the RIO team. The team is essential. Without it, a difficult job can be nearly impossible. The team the RIO can assemble depends both on budget for direct hires and diplomacy to tap colleagues from across the institution that the RIO can rely on for timely assistance. The RIO needs personal staff gifted in handling people and, ideally, staff with some training in forensics. Legal counsel, academic subject matters experts, IT experts, and a representative

of institutional police or security are also key team members. The request by many RCOs invited to the first Boot Camps to include their institutional counsel and support staff confirmed the importance of these individuals as team members; the Boot Camp design was expanded to include them.

The next step was to teach the critical tasks that an RIO must accomplish in handling cases and the critical skills that RIOs need to perform those tasks. Tasks and skills were presented in the order an RIO would need them, from the initial receipt of an allegation until the final resolution of a case. Because there are no defined theories or methods for training RIOs, established concepts and techniques from other types of professional training (e.g., criminal justice, medicine, aviation) were used wherever possible. A hybrid, eclectic version of the backward design model, fictionalized versions of actual cases, and anecdotes from cases were used, wherever possible, to illustrate problems an RIO confronts or critical decisions that must be made. Case-based education (i.e., story-telling) is a time-honored technique in professional education in part because, like good novels, it presents reality on a number of levels, developing emotional and intuitional as well as rational intelligence for handling highly complex issues. At its best, use of instructional cases can also provide the look and feel of the actual experience of handling a case. This is particularly important in areas where academic theory and methods are undeveloped or in dispute.

Receiving Allegations and Handling the "Front End" of Cases

The most critical part of an RIO's job is handling an allegation properly at the beginning. During the initial assessment of an allegation the RIO typically functions alone, with support, perhaps, by staff and counsel, but without the expert peer review committees that come into play later if an allegation warrants further review. Establishing the structure of a case properly is a complex task requiring the RIO to make several important decisions, and perhaps take action, in a context of uncertain information. If the RIO handles a case well at the beginning, it is likely to go smoothly. Conversely, if an RIO mishandles a case at the beginning, it may be irretrievably compromised. The institution may never be able to determine whether or not misconduct occurred. The institution may be liable for compliance actions by oversight agencies, and litigation initiated by respondents or disappointed complainants (whistleblowers) is a more probable outcome.

The problem in training RIOs to handle a case properly from the beginning is that allegations of misconduct may be presented in many ways: in person, by phone or e-mail, anonymously, and indirectly (e.g., by rumor). It is often difficult to distinguish allegations of misconduct that require the RIO's review under institutional policy from other problems or disputes that do not warrant review. Determining whether an allegation requires further review under the institution's procedures is called the Assessment, and constitutes the first of three stages (with the Inquiry and Investigation) that could lead to a finding of misconduct in research. The criteria for moving forward from Assessment to Inquiry are that an allegation is not trivial, and, specifically: a) the alleged conduct meets the regulatory definition of misconduct: fabrication, falsification or plagiarism; and b) the allegation(s) is sufficiently credible and specific so that potential evidence of research misconduct may be identified. Allegations that do not warrant further review under the misconduct procedures must likewise be handled with care, because some may require urgent referral to protect persons, research subjects, public safety, research data, funds, and equipment. In addition to any number of decisions the RIO may need to make about the applicability of institutional policies and local, state, and federal law, she or he has to determine whether:

1. There are any exigent circumstances listed in the PHS regulation at 42 CFR 93.318 (e.g., risk to public health and safety) or in other applicable regulations that require immediate notification of ORI or other oversight agencies.
2. The research data in question are at risk and need to be protected immediately.
3. Anyone related to the allegation is at possible risk of retaliation and needs to be protected.
4. There are other federal research regulations (e.g., those protecting research subjects) that apply and require immediate notice to and collaboration with the institutional officials overseeing those regulations.

Consequently, the RIO Boot Camps was designed to focus intensively on the initiation of cases. Fictionalized versions of actual cases (like that involving Dr. Green at the beginning of this article) were prepared to see whether RIOs believed each scenario contained an allegation of misconduct that required institutional review, and what their decisions were with respect to the four questions above. Anecdotes about other cases, both from presenters and from Boot Camp participants, were also included, particularly about cases where things went wrong.

From other professions that confront complex, uncertain situations (e.g., aviation and emergency medicine) an emphasis was placed on disciplined, routinized behaviors (i.e., standard operating procedures [SOPs]), to be used when confronting critical tasks to assure that the necessary decisions are made and appropriate actions taken. An example would be initiating takeoff without lowering the flaps, which has had catastrophic consequences in aviation, and metaphorically speaking, can also be a fatal error for RIOs handling cases. The list of SOPs taken from the RIO Boot Camp Syllabus provided to RIOs is shown in Table 3.

*Table 3. R*ank of Importance of Motivators and Barriers for Tenured and Non-Tenured Groups

SOPs	
A.	New Allegation Intake Form
B.	Exigent Circumstances
C.	Triage Precedence and Procedures
D.	Retaliation
E.	Good and Bad Faith
F.	Sequestration
G.	Corrections and Retractions
H.	Monitoring Administrative Actions
I.	Retractions

The part of the curriculum to prepare RIOs to do the job and then to handle properly the front end of cases evolved to look like this:

RIO Boot Camp Syllabus
(Excerpts from Initial Handling of Allegations)

Receiving an Allegation

What does an Allegation look like?

Does it have to be in writing?

How does the allegation reach the RIO? Is it easy or hard for complainants to find the RIO?

How do you know if you have a credible allegation of research misconduct (exercise: evaluating sample allegations)

Documenting the processing of an allegation: best practices/activity logs/file keeping/notice of the allegation on need-to-know-basis

Communicating with other institutional officials about an allegation

Allegation Intake Form - SOP

Stabilizing the Case

Immediate review of possible exigencies

Exigent Circumstances - SOP

Triage, if necessary, to other regulatory committees/officials

Triage - SOP

Internal Notices

External contacts - e.g., with editors - at what stage?

Preventing/Handling Retaliation - SOP

Engaged Learning from Exemplars

Following the development of a typical case, the next sections of the curriculum include recruiting and training Inquiry and Investigative Committees. These committees are the expert peer review panels central to the second (Inquiry) and third (Investigation) stages of review of an allegation. While the first section of the curriculum is substantially knowledge-based (although it also teaches and tests skills such as the ability to conduct an Assessment), this second section, *Assisting Panels,* involves teaching and practicing critical, complex skills such as interviewing complainants as part of the Assessment, and interviewing respondents, potentially as part of providing notice and sequestering data. Teaching someone to teach others is an excellent pedagogical technique for learning to do the job independently.

The first section begins with the critical intake interview, where a complainant approaches an RIO in person to make an allegation of misconduct. As noted earlier, this is only one way in which allegations may come to RIOs, but it is a common way, and one that allows the RIO both to properly establish the structure of a potential case and to stabilize the situation to protect persons and evidence. The least experienced of the participating RIOs had never received an allegation of research misconduct. Many had relatively little practice in receiving an allegation, and fewer still had codified best practices for receiving one.

The New Allegation Intake SOP emphasizes disciplined, routinized behavior to handle uncertain and potentially volatile situations. Because there is only one "first interview" with a complainant, there may never be another opportunity to interact, as the complainant may subsequently decide not to cooperate. This may occur if the complainant opts to engage legal counsel, retract the claim or not be available for further discussion. It is therefore important to get it right the first time. Portions of the New Allegation SOP are provided in Table 4.

Table 4. RIO Boot Camp Standard Operating Procedures for Receiving an Allegation from a Complainant

SOP: Allegation Intake	
1.	What is the Allegation? (provide as much detail as possible at this stage, e.g. fabrication, falsification or plagiarism of)
2.	Who is the Respondent? (name, title, location)
3.	Does the Respondent have collaborators in this research? If so, who are they? List:
4.	What evidence does the Complainant have/know about to support the allegation? List:
5.	Are there any collaborators at other institutions? If so, list each collaborator with his/her institution.
6.	When and where did the alleged misconduct occur?
7.	Is the alleged misconduct still going on? (See Exigencies SOP)
8.	What is the nature of the research in which the misconduct allegedly occurred? (See Exigencies SOP and Triage SOP)
9.	Does the research involve human or animal subjects?
10.	Does the research involve hazardous materials or biologics? Select agents?
11.	Is the research extramurally funded? If so, by whom? Identify grant #s when possible.
12.	What evidence does the Complainant have/know about to support the allegation? Where is that evidence currently? List:
13.	Explain the procedures briefly, especially what will happen next (the assessment stage), when the Complainant will be notified of what has happened, and a Complainant's limited role in the procedures.
14.	Explain a Complainant's (witnesses') protections from retaliation under the procedures along with the obligation for all witnesses to act in good faith.
15.	Invite any questions the Complainant may have.
16.	Provide RIO's contact information and invite Complainant to contact RIO with any subsequent information, questions, or concerns.

As important as a comprehensive list of questions that need to be asked and information that needs to be obtained is, such a list does not provide RIOs with any instruction in how to engage the complainant to elicit as much information as possible and ensure future cooperation. Nor does the list provide guidance on how to assess a complainant's credibility, whether the complainant is vulnerable to retaliation or needs supportive psychological intervention to deal with stress. Techniques and literature from investigative interviewing can augment that training, but even these do not provide RIOs a direct sense of the actual experience of engaging a complainant for the first time.

RIO Smith's Interview of Complainant Heesun Chung

A 30-minute video was created to help address the issue of actual experience. The video featured "RIO Smith" interviewing a potentially vulnerable complainant, graduate student Heesun Chung. The video was a joint effort of the first author, experienced RIOs, and ORI staff.

Rather than professional actors, academics familiar with institutional policies and procedures for reviewing allegations of research misconduct were featured in the video. The amateurs were more likely to be recognized by RIO Boot Camp participants and future audiences as authentic academics behaving as they would in real situations. This choice was both cost effective and accurate in conveying the misconduct allegations.

The video was used to initiate an exercise in which Boot Camp participants were asked to interview colleagues who played Heesun Chung. These participants were briefed about Ms. Chung's background, her research, and the nature of her allegation. The interviewers are video-taped and receive a copy of the video to take home with them to review. This training video is important since, with very rare exceptions, RIOs have never seen another RIO work or had the chance to view themselves in their role as RIO. The Boot Camp participants also watched "RIO Smith" interviewing "Heesun Chung" and compared this to their own performances.

The Vogel Case

Developing the complainant interview video and piloting it, along with the associated training interviewing sessions at the initial RIO Boot Camp, led to a decision to further develop this same fictional case, which became "The Vogel Case" to show RIO Boot Camp participants the look and feel of subsequent stages of institutional review of an allegation. A number of the RIOs, their legal counsel and staff, had had little experience administering these subsequent stages of their institution's procedures. None had experienced the opportunity of watching other RIOs administer these procedures or to discuss best practices. To date, The Vogel Case videos include: 1) RIO Smith's intake interview with Heesun Chung; 2) a video on RIO Smith's carefully planned initial interview with the Respondent, Prof. Richard Vogel, in his lab, initial interviews with other lab members who might be witnesses or even respondents, and the sequestration of the data related to the allegation; 3) the briefing of the Inquiry Panel; 4) the Inquiry Panel's planning for the interview with a key witness and potential respondent, post- doctoral student Raju Shrestha; and 5) the Inquiry Panel's interview with Dr. Shrestha. There are three more video chapters of The Vogel Case in the planning stages, all having to do with the Investigation and final resolution of the case.

Development of The Vogel Case provided a number of additional pedagogical benefits, which were not foreseen at the beginning of the project. First, it allowed for the development, in the context of this specific case, of all the standard documents, letters, and forms that RIOs have to draft, participate in drafting, or review in the course of institutional review of an allegation of misconduct in research. These documents include the Assessment Report (prepared by the RIO), the Inquiry Report (prepared by the Inquiry Panel, but often drafted and always reviewed by the RIO), the Investigation Report (prepared by the Investigation Committee, but often drafted and always reviewed by the RIO), written notice to the Respondent of the allegation, itemized receipts for evidence sequestered and explanation of the sequestration process, briefing agendas for initial meetings of Inquiry Panels and Investigative committees, and other documents and forms. Preparing these documents for The Vogel Case brings to life questions of how to present, in official reports, the issues participants have discussed and are engaged in throughout the three-day RIO Boot Camp. In each instance, these documents represent an effort to establish best practices for

documents and forms. This has proved more effective than using template documents and discussing the contents in the abstract.

Second, because these model documents were completed for a case under discussion, participants could be asked to prepare their own reports (e.g., the critical RIO Assessment Report), and compare these to the "best practices" documents. The Assessment Report was a particular focus, because the RIO's proper framing of the allegation for further review, if warranted, by the peer review panels is critical to a successfully handled case. The correct framing of an allegation is not a trivial task; it is the basis of what will be reviewed in a subsequent inquiry or investigation phase. Using The Vogel Case, RIOs are shown how to identify the specific falsification, fabrication, or plagiarism being alleged, and to amend the allegations as new information is received, just as in a real case.

Third, the documents permitted the instructors to work backwards from the content of the Inquiry Report (which must satisfy the requirements of the PHS regulation) to the planning of the Inquiry. This likewise proved a more productive exercise in the context of The Vogel Case than it would have as an abstract discussion. On several occasions, participants included in their exercises methods of handling issues in ways superior to their instructors, thus advancing by peer-to peer education the communal effort to refine best practices.

Fourth, the development of The Vogel Case allowed the Scientist-Investigators of DIO, the first author, and other consulting RIOs to combine their experience in handling allegations of misconduct in research, to design a case that includes: the kind of complex allegations and uncertainties that RIOs are likely to encounter; a large cast of investigators, research staff, and colleagues (on and off campus) involved in the case; and individuals with varying degrees of responsibility for or complicity in the misconduct. RIOs, counsel, and staff must stabilize the case to protect evidence, research subjects (whether animal or human), and possible vulnerable witnesses. They must also develop, in concert with the expert panels, strategies to establish the facts relevant to the allegation and to interpret those facts.

Finally, Boot Camp participants were able to develop and discuss the unfortunate instance of a junior co-investigator who is coerced by the respondent into complicity in misconduct. This is an especially troubling problem that RIOs, their counsel, and their institutions sometimes confront: what level of responsibility does one assign to and what level of sanctions, if any, should be imposed on vulnerable, junior investigators who are coerced into complicity in misconduct? The Boot Camp faculty spent many hours over a two-year period around the ORI conference table designing and refining The Vogel Case. As the case proceeded through various stages of development at the RIO Boot Camps, participants were engaged in discussions about how to develop it further, thus providing another mutual learning experience between participants and presenters.

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Forensics

Computing has revolutionized the conduct of science, most dramatically in the digital acquisition of data, its reduction and placement into a presentation, its submission for publication, and its subsequent distribution over the Internet. The time between observation and reporting can be a matter of hours, through a path totally unencumbered from past opportunities for detailed inspection by colleagues. Nowhere has this had more impact than in the manipulation of images and numerical data. Photo-editing software developed in recent years allows researchers to manipulate scientific images for inclusion in journal manuscripts and grant proposals. Spreadsheet technology allows researchers to record, analyze, and present numerical data with similar facility. While these software packages are generally a great boon to researchers, they also enable a range of ethical lapses from enhancing images to outright falsification (Rossner &Yamada, 2004). Simultaneously, software companies and DIO Scientist-Investigators have developed a range of tools and techniques (armamentarium) to detect the questionable manipulation of images and data. Similarly, the community now has access to better images via the Internet, thus increasing the likelihood for detection and for potential challenges to RIOs.

DIO personnel made presentations at the early RIO Boot Camps on tools and techniques for detecting questionable manipulations of images and digital data. As the RIO Boot Camp project continued to develop, this part of the curriculum was expanded and refined in two ways. First, "questioned data" from The Vogel Case were developed and shared with workshop participants through simple analytical techniques to demonstrate that the images had been manipulated. Second, the DIO team has been developing a set of forensic tutorials for use by RIOs. The goal is not to turn RIOs into forensic specialists, as most do not have the disciplinary background, and the detailed forensic analysis in cases is appropriately left to the expert Inquiry and Investigation Committees. However, it is

important for RIOs to achieve basic literacy in these tools and the techniques to make panels aware of them as needed, to be able to use them to assess questioned images and digital data during assessments, and to encourage their application by the expert faculty on the panels. In addition to these forensic tools DIO is also reviewing and demonstrating on-line plagiarism detection software (e.g., eTBLAST and Déjà Vu) (Mounir & Garner, 2008).

Finishing Up

The last portion of the RIO Boot Camp is devoted to special issues critical to the handling of cases and to review and discussion of steps that must be taken to conclude a case properly. Attorneys (including an HHS counsel) discuss with both RIOs and institutional counsel issues such as legally sufficient reports to ORI, standards of proof, legal challenges from respondents during institutional procedures, retaliatory and obstructionist tactics by respondents, and settling cases with legally sufficient admissions of misconduct by respondents. As the survey data of RIO Boot Camp participants show, many RIOs and institutional counsel have had to deal with difficult respondents. Consequently, these discussions are popular with participants. In addition, the RIO Boot Camps provide the opportunity for institutional counsel and HHS counsel to meet and talk informally, paving the way for consultation during difficult cases.

Reaching closure in research misconduct cases can be complicated. Most institutions have internal appeals processes for both the finding of misconduct and for any sanctions that may be imposed on respondents found responsible for misconduct. To remain in compliance with the PHS regulation, it is critical for institutions to have substantive appeals handled by panels with the requisite scientific expertise. Many institutions have had, and continue to have, difficulty in this regard. RIO Boot Camp participants focus, at the end of the workshop, on the final stages of a case: the sequencing of internal and external appeals; notice to ORI (in cases with PHS funding) and to other sponsors; determination of sanctions for guilty respondents; handling legal actions by respondents during the final stages of cases; and working with ORI as it considers additional findings in cases where the institution has found misconduct.

Both RIO Boot Camp participants and others recommend institutional post-mortems at the end of difficult cases so that the research community can learn from the case and, hopefully, improve the integrity of the research environment. Finally, participants rate their own institutions in terms of quality of their procedures, the integrity of the institutional research environment (including their RCR program), and support for the RIO.

The RIO in the Context of Institutional Compliance Programs

The RIO Boot Camps fill a pressing need for training a unique and critically important official in research institutions' compliance programs. While there are a number of other critically important research regulatory positions in universities, research hospitals and institutes (e.g., IRB chair, IACUC chair, Conflict of Interest Officer, Radiation Safety Officer), there are none that are closely analogous to the RIO, and such training programs as exist in these other areas are not pertinent to the role of the RIO. Usually working with peer review panels, these other regulatory officials oversee evaluation and approval of research that meets appropriate ethical and safety standards. Their work approximates the RIO's role

only when they are investigating potentially serious and deliberate non-compliance with the regulations they oversee. There are no known training programs or materials to investigate serious non-compliance in these areas. On the other hand, RIOs need to be familiar with these other regulatory areas because, more and more frequently, allegations of misconduct in research present issues that must be dealt with in multiple regulatory areas. This is one of the reasons that the cases presented for discussion and analysis at the RIO Boot Camps are complex. Interestingly, the survey results show that most of the RIOs have some responsibility for other regulatory areas (previously shown in Table 2).

It would also be helpful for training programs for chairs and committee members in other regulatory areas to include information on the requirements of the research misconduct regulations, so that these individuals know when they should communicate with the RIO. As noted earlier, RIOs are typically senior administrative officials with titles such as Associate Vice President (or Chancellor) for Research or Associate Provost. They are probably the best-situated people to oversee the triage of complex cases involving multiple research regulations. This happens best in integrated compliance programs.

Conclusion

Although curricular materials continue to be improved, the current RIO Boot Camp is now fully developed. There is more material than can be covered in the three-day camp. Among the important topics that remain to be covered is a detailed analysis of why misconduct cases at research institutions sometimes goes badly awry, how to prevent that, and what RIOs can do to recover when cases begin to spin out of control.

Among the reasons misconduct cases may be mishandled is the fact that alleged misconduct may be unreported and undiscovered. For example, 4 of 56 (8%) of participants in our survey said they knew of allegations of misconduct at their institution that had not been reported. Further, 7 of 56 (14%) reported that they knew of instances where individuals had been discouraged from filing an allegation. This can be the result of poor institutional policies and procedures or an "institutional culture of non-compliance," as a colleague once described his institution's attitude to the regulation. The problem may also be traced to the RIO. There are predictable problems, critical times, and critical decisions that RIOs face in the course of a case, especially a difficult case. If the right decisions are not made, or not made in a timely fashion, the case can be badly jeopardized. These difficult cases are more common than one might think. Characteristics of difficult cases are provided in Table 5. While only two RIOs (4%) reported the catastrophic instance of a misconduct case that cost their institution more than $1 million to resolve, most RIOs reported handling very difficult cases.

Table 5. RIO Boot Camp Standard Operating Procedures for Receiving an Allegation from a Complainant

Area of Difficulty (n=56)	%
Multiple allegations and counter-allegations	61
Internal grievances	52
Extensive obstructive or delaying tactics by respondents	45
Lawsuits	36
Allegations/charges against the RIO	20

To address these issues and others, an Advanced Topics RIO Boot Camp is planned that will feature "post-mortem" analyses of actual closed cases in ORI's files that presented unusual challenges for RIOs and their institutions. Current and former RIOs who handled particularly difficult cases will be invited to discuss those cases, and what they learned from the experience that might change practice. Protocols and best practices for RIOs to handle these critical moments and decisions will be developed. The Boot Camp will also include advanced, hands-on workshops on forensics and the final episodes of The Vogel Case.

Plans are underway to maintain the RIO Boot Camp curricular materials and other resources in a password-protected online manual for RIOs within two years. A professional association might also assist RIOs in sustaining their community and providing training of new members.

References

DHHS. (2005). *Code of Federal Regulations Title 45 - Public Welfare PART 46 Protection of Human Subjects.* Washington, DC: U.S. Department of Health & Human Services.

Dillman, D. A. (2000). *Mail and internet surveys:* The tailored design method. New York: Wiley.

Krueger, J. (2004). *Distribution of ORI extramural cases relative to NIH funding, 1992-2002.* Washington, DC: ORI.

Mounir, E., & Garner, H. (2008). A tale of two citations. *Nature, 451,* 397-399.

ORI. (2006). The Role of the RIO, from http://ori.dhhs.gov/rio/riovideo/

ORI. (2007). The RIO Resource, from http://rioresource.org/

Price, A. R. (1994). Definitions and boundaries of research misconduct: Perspectives from a federal government viewpoint. *The Journal of Higher Education, 65*(3), 286-297.

Rossner, M., & Yamada, K. (2004). What's in a picture? The temptation of image manipulation. *Journal of Cell Biology, 166*(1), 11-15.

Wiggins, G., & McTighe, J. (2005). *Understanding by design.* Alexandria, VA: Association for Supervision & Curriculum Development.