

December 2009

THE RESEARCH INTEGRITY OFFICER (RIO) STUDY

Final Report

Prepared for

Sandra Titus, Ph.D.

Director, Intramural Research
U.S. Department of Health and Human Services
Office of Research Integrity
Suite 750 Tower Building
1101 Wootton Parkway
Rockville, MD 20852

Prepared by

Arthur J. Bonito, Ph.D.

Celia Eicheldinger, M.S.

Nancy Lenfestey, M.P.H.

Breda Munoz, Ph.D.

David Plotner, M.S.

Feng Yu, Ph.D.

RTI International
3040 Cornwallis Road
Research Triangle Park, NC 27709

RTI Project Number 0208490.014

RTI Project Number
0208490.014

THE RESEARCH INTEGRITY OFFICER (RIO) STUDY

Final Report

December 2009

Prepared for

Sandra Titus, Ph.D.

Director, Intramural Research
U.S. Department of Health and Human Services
Office of Research Integrity
Suite 750 Tower Building
1101 Wootton Parkway
Rockville, MD 20852

Prepared by

Arthur J. Bonito, Ph.D.

Celia Eicheldinger, M.S.

Nancy Lenfestey, M.P.H.

Breda Munoz, Ph.D.

David Plotner, M.S.

Feng Yu, Ph.D.

RTI International
3040 Cornwallis Road
Research Triangle Park, NC 27709

Contents

Section	Page
Executive Summary	ES-1
1. INTRODUCTION TO THE RIO STUDY	1-1
1.1 Background	1-1
1.2 Conceptual Perspective	1-3
2. STUDY PURPOSE	2-1
2.1 Study Goals.....	2-1
2.2 Project Overview	2-1
2.3 Project Objectives	2-3
3. STUDY METHODS	3-1
3.1 Identifying Institutional RIOs	3-1
3.1.1 Source of the Pilot Study Telephone Interview Participants	3-1
3.1.2 Source of the Phase I Telephone Interview Survey Participants	3-2
3.1.3 Source of the Phase II Web-Based Questionnaire Survey Participants	3-2
3.2 Conducting the Surveys	3-3
3.2.1 Conduct of the Pilot Study Survey	3-3
3.2.2 Conduct of the Phase I Telephone Interview Survey	3-3
3.2.3 Conduct of the Phase II Web-Based Questionnaire Survey.....	3-4
3.3 Weighting the Respondents to the Phase II Survey.....	3-5
3.4 Coding the Scenarios	3-6
3.5 Creating Analysis Variables.....	3-7
3.6 Conducting Analyses of the Interview and Survey Data	3-8
3.6.1 Measures of Scenario Coder Agreement	3-8
3.6.2 Statistically Testing Significance and Measuring Association.....	3-11
3.6.3 Statistically Modeling RIO Preparedness/Readiness.....	3-12
4. Phase I Interview Survey Analysis results	4-1
4.1 Descriptive Analysis of the Interview Data	4-1
4.1.1 Titles of Persons Performing the RIO Role.....	4-2

4.1.2	RIO Responses to the Scenarios in the Interview Survey	4-2
4.1.3	Candidate Predictors of Scenario Scores.....	4-11
4.2	Significant Associations with RIO Preparedness/Readiness.....	4-13
4.2.1	Variables from All Four Domains Associated with Preparedness/Readiness	4-13
4.2.2	Multiple Variable Analysis of RIO Preparedness/Readiness	4-15
5.	Phase Ii Web-Based Survey Analysis Results	5-1
5.1	Descriptive Results from the Web-Based Survey of RIOs	5-1
5.1.1	Personal Characteristics of RIOs	5-1
5.1.2	Training or Other Qualifications for Becoming a RIO	5-4
5.1.3	Research Misconduct-Related Experiences of RIOs.....	5-7
5.1.4	RIO’s Title, Responsibilities, and Organizational Characteristics	5-9
5.1.5	RIO Responses to the Scenarios.....	5-17
5.2	Significant Associations with RIO Preparedness/Readiness.....	5-24
5.2.1.	Personal Characteristics of RIOs and RIO Preparedness/Readiness	5-24
5.2.2	Training Completed for Becoming a RIO and Preparedness/Readiness	5-26
5.2.3	Research Misconduct-Related Experience and RIO Preparedness/Readiness	5-31
5.2.4	Organizational Characteristics and RIO Preparedness/Readiness	5-33
5.2.5	Multivariable Analysis of RIO Preparedness/Readiness	5-38
6.	CONCLUSIONS, LIMITATIONS, AND RECOMMENDATIONS FROM THE PHASE II SURVEY	6-1
6.1	Key Conclusions	6-1
6.2	Limitations of the Study	6-3
6.3	Study Recommendations.....	6-5
6.3.1	Recommendations for Institutions	6-5
6.3.2	Recommendations for the Office of Research Integrity	6-5
7.	References	7-1

Appendices

A	Appendix A Legislation Creating ORI	A-1
B	Appendix B Phase I Interview Schedule.....	B-1
C	Appendix C Phase II, Web-based, Self-Administered Questionnaire	C-1
D	Appendix D Weighting Procedures for Phase II Web-Based Survey	D-1
E	Appendix E Coding Instructions for Scenarios	E-1
F.	Appendix F Unweighted Frequencies for Report Section 5.....	F-1

Tables

Number		Page
3-1.	Phase I Interview Study Inter- and Intra-Coder Reliability Analysis Results.....	3-9
3.2.	Phase II Web-based Study Inter- and Intra-Coder Reliability Analysis Results	3-10
4-1.	Distribution of Titles When Performing Responsibilities of the RIO.....	4-2
4-2.	Distribution of RIO Survey Responses in Agreement with the Expert Consultants to Scenario 1 – Actions to Take When Sequestering Evidence	4-4
4-3.	Number of RIO Responses in Common with Expert Consultants for Scenario 1	4-4
4-4.	Distribution of RIO Survey Responses in Agreement with the Expert Consultants for Scenario 2 – Actions to Take When In Receipt of a Complainant Report Regarding Threat of Retaliation by the Respondent	4-6
4-5.	Number of RIO Responses in Common with Expert Consultants for Scenario 2	4-7
4-6.	Distribution of RIO Survey Responses in Agreement with the Expert Consultants for Scenario 3 – Actions to Take When Necessary to Coordinate Responsibilities with IRB.....	4-8
4-7.	Number of RIO Responses in Common with Expert Consultants for Scenario 3	4-8
4-8.	Total Number of RIO Responses in Common with Expert Consultants for All Three Scenarios Combined	4-9
4-9.	RIO Scenario Scores and Names and Distributions of Candidate Predictors of RIO Scenario Scores	4-10
4-10.	Summary of Statistically Significant Predictors of RIO Scenario Scores	4-14
4-11.	Summary of Near Statistically Significant Predictors of RIO Scenario Scores	4-15
4-12.	Summary of Multiple Variable Logistic Regression Model of RIO Scenario Scores	4-15
5-1.	Distributions of RIO’s Personal and Background Characteristics	5-2
5-2.	Types of Training and Other Qualifications Reported by RIOs as Preparing Them for Becoming Their Institution’s RIO.....	5-5
5-3.	Number of Training and Other Qualifications Reported by RIOs as Preparing Them for Becoming Their Institution’s RIO.....	5-6
5-4.	Number of Training and Other Qualifications of Great and Medium Relevance Reported by RIOs as Preparing Them for Becoming Their Institution’s RIO	5-6
5-5.	Distribution of Measures of RIO Activity-Related Experience.....	5-7
5-6.	Distribution of Titles Used When Performing Duties Assigned to the Person We Refer to as the RIO.....	5-10
5-7.	Distribution of Organizational Characteristics of RIOs’ Institution.....	5-12
5-8.	Distribution of Specific Institutional Responsibilities of RIOs	5-14
5-9.	Distribution of RIOs’ Additional Administrative Responsibilities	5-16

5-10	Distribution of RIO Survey Responses in Agreement with the Expert Consultants to Scenario 1 – Actions to Take When Sequestering Evidence	5-18
5-11.	Number of RIO Responses in Common with Expert Consultants for Scenario 1	5-19
5-12.	Distribution of RIO Survey Responses in Agreement with the Expert Consultants for Scenario 2 – Actions to Take When In Receipt of a Complainant Report Regarding Threat of Retaliation by the Respondent	5-20
5-13.	Number of RIO Responses in Common with Expert Consultants for Scenario 2	5-21
5-14.	Distribution of RIO Survey Responses in Agreement with the Expert Consultants for Scenario 3 – Actions to Take When Necessary to Coordinate Responsibilities with IRB.....	5-22
5-15.	Number of RIO Responses in Common with Expert Consultants for Scenario 3	5-23
5-16.	Total Number of RIO Responses in Common with Expert Consultants for All Three Scenarios Combined	5-23
5-17.	Personal Characteristic Variables Significantly Associated with the Total Scenario Score ($p \leq 0.05$)	5-25
5-18.	RIO Training Variables Significantly Associated with the Total Scenario Score ($p \leq 0.05$).....	5-27
5-19.	RIO Experience Variables Significantly Associated with the Total Scenario Score ($p \leq 0.05$).....	5-32
5-20.	Organizational Characteristics Significantly Associated with the Total Scenario Score ($p \leq 0.05$)	5-34
5-21.	Specific Institutional Responsibilities of RIO Significantly Associated with the Total Scenario Score ($p \leq 0.05$)	5-35
5-22.	RIO’s Additional Administrative Responsibilities Significantly Associated with the Total Scenario Score ($p \leq 0.05$)	5-37
5-23.	Results of Multivariable Logistic Regression Analysis of Personal Characteristics That Are Associated with RIOs Being High on the Total Scenario Score Dichotomy	5-39
5-24.	Results of Multivariable Logistic Regression Analysis of RIO Training Variables That Are Associated with RIOs Being High on the Total Scenario Score Dichotomy	5-40
5-25.	Results of Multivariable Logistic Regression Analysis of RIO’s Experiences that Are Associated with RIOs Being High on the Total Scenario Score Dichotomy	5-42
5-26.	Results of Multivariable Logistic Regression Analysis of Organizational Characteristics That Are Associated with RIOs Being High on the Total Scenario Score Dichotomy	5-43
5-27.	Results of Full Multivariable Logistic Regression Analysis of Characteristics (with Domains Noted) That Are Associated with RIOs Being High on the Total Scenario Score Dichotomy	5-45
5-28.	Final Results of Multivariable Logistic Regression Analysis of Characteristics (with Domains Noted) That Are Associated with RIOs Being High on the Total Scenario Score Dichotomy After Removing Non-Significant Predictors	5-48

EXECUTIVE SUMMARY

I. Introduction to the RIO Study

Background

Belief in the integrity of research is an essential part of the foundation for public support of research. Prior to 1986, the individual governmental funding agencies were responsible for monitoring the integrity of their own projects. Since 1992, the Office of Research Integrity (ORI) has been responsible for carrying out the legislatively imposed duty of overseeing organizations performing research funded by the U.S. Public Health Service (PHS). ORI assures that these organizations have procedures in place to receive, assess, and oversee the resolution of allegations of research misconduct. While there are few allegations made annually of research misconduct, it is nonetheless important to ORI that Research Integrity Officers (RIOs) be prepared and ready to handle such cases.

RTI International (RTI) conducted the RIO study to between September 2004 and December 2009 to provide ORI with in-depth and systematic information about RIOs —who they are, what they do, their experience and training, their position in the organizational structure, and how prepared or ready they are to perform their role. RIOs are at the core of a system intended to protect the research reputation of their organizations, as well as to identify and hold accountable perpetrators of research misconduct, such as falsification, fabrication, and plagiarism.

Conceptual Perspective

There are at least four possible domains of influence that can affect how a person performs as a RIO, and each is a focus of this research. These four domains are (1) the personal characteristics of the person serving in the RIO position, (2) the training the person has received or the qualifications acquired to perform in the position, (3) the experience that the person has had that is believed to have contributed to the RIO's development, and (4) a variety of institutional characteristics that encourage and support the performance of the RIO's responsibilities. In the present study, we examine how strongly variables in each of these domains are associated with influencing an individual's understanding of what a RIO should do, as demonstrated by their answers to questions about what the appropriate behavior would be in several challenging research misconduct scenarios faced by RIOs.

II. Study Purpose

Goals

The RIO study had two overall goals. The first goal was to assess the preparedness/readiness of RIOs in the United States who carry out the responsibilities

associated with adjudication/resolution of cases of alleged research misconduct. The second was to examine the association of a RIO's level of preparedness/readiness with (a) their positions and responsibilities in their institutions' organizational structure, (b) personal factors including their educational and professional background, (c) their actual experience performing in the role of RIO, and (d) the type and extent of training they received in preparation for performing this role.

Overview

The RIO study was performed in two phases, with survey data collection occurring in each. The two surveys were executed independently and with somewhat different objectives in mind, but were intended to be used in a complementary way to achieve the project goals. The Phase I survey was performed as a personal interview by telephone, whereas the Phase II survey was performed on the Internet (World Wide Web), and hence, was self-administered. Initial contact with research institutions to inform them of the RIO study and to identify the individuals serving as RIOs was made by e-mail for both phases. The follow-up with study participants in Phase I of the study was conducted by telephone, while follow up in Phase II of the study was conducted by e-mail.

The Phase I survey was conducted from March 2007 through June 2007 with a random stratified sample of 112 institutional RIOs. These semi-structured interviews were conducted by appointment over the telephone by a group of five trained, executive-level interviewers. Ninety-one interviews (81.3%) were completed for the Phase I survey, with each interview lasting slightly more than an hour on average. Because it was RTI's intention to use many of the same questions from the Phase I survey in the Phase II survey, the Phase I survey served as a large pilot test for the Phase II survey.

The Phase II survey was conducted between May 2008 and February 2009 using a self-administered questionnaire on a secure Internet web site. The survey questions consisted of items drawn or reformulated largely from the responses given in the Phase I interview. The final version of the Phase II, web-based survey had drop-down menus and fewer open-ended and other specify items that required coding than did the items in the Phase I interview survey. So as not to burden the RIO study participants with double participation in the study, the Phase II survey was directed at the 1,099 institutional RIOs who remained after we had randomly selected out the Phase I (112) sample and a small pilot study (20) sample. We successfully obtained some level of response to the Phase II survey from 651 (59.2%) of the 1,099 institutional RIOs.

Initial efforts to contact the RIOs with a letter to introduce the study were made by e-mail for both phases of the study. The letters were sent to the person listed in the ORI's electronic roster as the person responsible for submitting the institution's Annual Report on Possible Research Misconduct, as ORI had no actual listing of the RIOs. We believed that individuals responsible for submitting this report for their institution would either be the RIO

or be in a position to notify us of, or forward the e-mail to, the person serving as the RIO in the institution.

Objectives

To achieve the study goals, RTI sought to achieve the following intermediate project objectives:

- Develop appropriate data collection instruments to measure RIO preparedness/readiness, as well as items to obtain information on RIO characteristics, the RIOs' positions and responsibilities in their institutions, and their training and experience relevant to carrying out the role of RIO.
- Create an unduplicated list (sampling frame) from ORI electronic records of the persons responsible for submitting the legislatively required Annual Report on Possible Research Misconduct for U.S.-based institutions doing PHS-sponsored research.
- Prepare the materials needed to obtain the required clearances and reviews from the Office of Management and Budget (OMB) and the RTI institutional review board (IRB) for protection of the rights of research subjects.
- Conduct a personal interview survey by telephone with a small, heterogeneous sample of RIOs (Phase I).
- Conduct a web-based, self-administered questionnaire survey with as many of the institutional RIOs in U.S. institutions filing the Annual Report on Possible Research Misconduct with ORI (Phase II).
- Analyze the data collected, prepare a report, and address the issue of what variables contribute to or detract from the RIOs' preparedness/readiness to appropriately carry out their responsibilities.

III. Study Methods

Identifying Institutional RIOs

RTI was unable to obtain a complete and up-to-date electronic file of RIOs to use for identifying and contacting them to participate in this research project. Instead, we had to create a list from a copy of the electronic file that ORI maintains of the persons who submitted their institution's Annual Report on Possible Research Misconduct for 2005. This file contained the names, IPF number, and institution type (institution of higher education, research institute, or independent hospital) for each of the 1,758 institution entries, as well as the name, address, telephone number, and e-mail address of the person submitting each institution's 2005 report. RTI purged the ORI file of institutions not located in the United States or Puerto Rico. In an effort to reduce file multiplicities (duplications), we purged the file of all but one listing with the same institution name, contact person, or contact telephone number.

As a final step, we obtained the 2006 ORI file for the misconduct reports. We used that file to purge the records of any institutions no longer actively submitting reports, to update the names and e-mail addresses of the contact persons at the institutions that survived the cleaning, purging, and collapsing process of the 2005 file, as well as to add the names and contact information for institutions that submitted their first report in 2006. After this purging and updating process, RTI's final file of RIO contact information contained 1,231 entries. Stratified random samples of 112 and 20 were selected for the Phase I interview study and the pilot study, leaving the remaining 1099 as the group of RIOs to be solicited for the Phase II web-based survey.

Data Collection

Two senior researchers conducted the pilot study, initially contacting the sample members by U.S. mail with an advance letter and then by telephone to set up the interviews. A total of 13 pilot study interviews were conducted by telephone.

RTI introduced more automation into the recruitment and scheduling of the 112 RIOs for the Phase I telephone interviews. An advance letter was e-mailed to the person listed as responsible for submitting the last annual report to ORI; the letter explained the purpose of the study and asking whether the recipient was the RIO or the person who performed the functions of the RIO. If the recipient was the RIO or performed as the RIO, he/she was directed to click on a link and was taken to a secure site at RTI to select an interview day and time.

If the recipient was not the RIO, the e-mail asked that the person send a return e-mail to RTI indicating the name and e-mail address of the institution's RIO. The return e-mail triggered a slightly revised advance letter e-mail sent to the newly named RIO. If 2 weeks passed without a response to these e-mails, a project assistant initiated telephone contacts with the last person to whom an e-mail was sent. Of the 112 institutions in the Phase I survey, a total of 91 interviews were completed in the Phase I study. For eight institutions included in Phase I, RTI was unable to contact anyone who could assist us in identifying the RIO. In addition, there were 13 institutions in which the RIO refused to participate, was out of town, or could not find a convenient time for the interview. We conducted interviews with persons at 91 institutions—a response rate of 81.3%. As it turned out, six of the interviewed individuals indicated that they were not truly RIOs, but were appointed to be the institution's spokesperson.

The Phase II survey was performed using a self-administered, web-based questionnaire residing on a secure web site at RTI. The persons at the 1,099 institutions included in the Phase II survey who submitted the latest annual report to ORI were e-mailed an advance letter explaining the purpose of the study and asking for the name and e-mail address of the institution's RIO if the recipient was not the person who performed the responsibilities of the RIO. Approximately a week after the advance letter was e-mailed, RTI

sent another e-mail asking for the participation of the recipient in the survey. This letter also had a provision to identify someone else as the RIO and to return that information to RTI. If the recipient confirmed that he/she was the RIO, the recipient was asked to click on a link that took him/her to the questionnaire on a secure web site. Approximately 1 week to 10 days later, a thank you reminder e-mail was sent. One week to 10 days after the thank you e-mail, another reminder was sent. This process was repeated up to 12 times in an effort to obtain the highest response rate possible. Using this approach, RTI obtained 651 respondents to the questionnaire, a response rate of 59.2%.

Weighting the Respondents to the Phase II Survey

The RIO data analyzed in the Phase II web-based survey has been weighted to restore the proportionality of the sub-population of respondents to the full population of RIOs on the cleaned ORI list minus the 112 and 20 RIOs selected for the Phase I and pilot studies. Thus, the total weighted count in most tabulations is 1,099—the number of RIOs in the population being studied—and not the 651 who were actual study respondents. We did this because there is a risk that the distribution of RIO characteristics based on respondents alone will not be an accurate estimate of what the distribution of the same characteristic would have been if everyone in the population had responded.

We employed a post-stratification weight adjustment using the institution-type variable—institution of higher education, research institute, or independent hospital—to create a non-response adjustment weight for respondents. We used this because this variable was a key characteristic known for the entire population of RIOs and for which we knew there were different response rates. The study runs the risk of severely biased estimates without such weight adjustments. Simply reporting the distributions of the characteristics of respondents and thereby implying that they accurately estimate the distribution of characteristics of the population may result in misrepresentation.

It should be noted that an additional post-stratification adjustment was made to the Phase II weights to adjust for the unexpectedly large non-response to the three scenario questions (see below) in the Phase II survey. To more accurately estimate the results in the Phase II analysis of RIO preparedness/readiness, we post-stratified according to the five statistically significant variables from our analysis of variables related to not responding to the scenario questions. The multiple-variable analyses of RIO preparedness/readiness in the Phase II survey have been performed using the scenario question non-response adjusted weight discussed above.

Coding the Scenarios

We used a series of scenarios as the basis for assessing the preparedness/readiness of individuals to perform the RIO role. For the Phase I, telephone interview survey, we started with five scenarios, later deciding to only use three. The scenarios were developed

with the assistance of the ORI consultant, a former RIO who was currently assisting ORI in the development of training materials and activities for RIOs. The scenarios were intended to allow RIOs to illustrate their knowledge of doing the following as effectively as possible:

- (1) sequestering evidence,
- (2) protecting the “whistleblower” against retaliation, and
- (3) coordinating RIO responsibilities with those of the IRB.

The Phase I interviews with the RIOs were recorded, and a word processor transcribed the RIOs’ responses to the scenarios. The Phase II responses of RIOs to the scenarios on the web-based survey were printed out.

To assess the RIOs’ responses, RTI asked the ORI consultant and a second expert consultant (also a former RIO) to independently respond to each scenario as fully as possible with a statement beginning “I would do (fill) in that situation. Then I would do (fill), and then (fill),” etc. The consultants were asked to continue until they could think of no further things that they thought they should do in response to each scenario. Then, we created a list of actions that both of the consultants included in their responses to each scenario. The list of the consultants’ common responses became the basis for coding the transcripts of the three scenarios, which we used to assess the preparedness/readiness of RIOs to act appropriately and knowledgably in the RIO role. Coders were trained and assigned transcripts and printouts to code, awarding a point to a RIO for every response that coincided with one provided by the two consultant experts. The points were summed for each scenario and then across all three to create a total scenario score. The total scenario score was then dichotomized into high and low score RIO groups. We conducted an analysis of the coders work to assess their intra- and inter-coder reliability by having them independently code duplicates of their own work and replicates of each of the other coder’s work. Our analysis of the inter- and intra-coder agreement showed it to be good to very good – approximately 90% inter-coder agreement and 95% intra-coder agreement.

Creating Analysis Variables

There are fewer analysis variables utilized in the Phase I survey analysis than in the Phase II survey analysis, primarily because of the far smaller sample size in the Phase I survey. Another factor is the relatively low level of variation among sample members in the Phase I survey. Nonetheless, there are multiple variables in both analyses to cover the predictor domains of interest: personal characteristics, training, experience, and organizational characteristics. Many of the same variables have been included in both survey analyses.

The variables examined for association with the scenario score in both survey analyses were typically dichotomies (in Phase I, particularly) and ordinal categorical variables (mostly in Phase II). The variables were created either from pre-coded item

responses directly by collapsing ranges of continuous variables (like counts of things) and combining conceptually similar responses, or by manually coding responses to open-ended items into existing or new categories (in Phase I, especially) or “Other Specify” items (particularly in the Phase II survey).

Statistical Analysis

Analysis of the data from both phases of the project has been conducted to identify the relative contributions of variables from the four domains to the prediction of higher scenario scores. Overall descriptions have been prepared of the Phase I sample and the population represented in the Phase II survey. They include the scenario scores as well as variables from the four predictor variable domains. Typically, counts and percentages have been reported in the descriptive analyses. Statistical procedures to measure the association between the predictor variables and the scenario scores and to test for their significance have been performed for bi-variable tabulations. The last step of analysis in both phases has been to conduct multiple variable logistic regression in which the final model is parsed of non-significant predictor variables using backward elimination. The Phase II analyses are weighted to account for survey and scenario item non-response.

IV. Phase I Interview Study Results

Eight variables significantly associated with the scenario score and representing variables from all four domains were used as predictors in an initial multiple variable logistic regression. However, only three statistically significant variables remain in the final model parsed of non-significant variables. They represent one measure from the RIO personal characteristics domain and two from the institutional characteristics domain. None are variables representing the RIO training and experience domains.

The three variable model is statistically significant (Chi Square = 21.4348, Degrees of Freedom = 3, P-Value < 0.0001), with a rescaled R-Square equal to 0.3277. This indicates that the three variables together account for approximately one-third of the variation in the scenario scores. We did not expect that only one of the significant variables would contribute to higher RIO scenario scores. RIOs whose responsibilities included telling complainants just what exactly the institution would do to protect them from retaliation by the respondent had more than five (5.188) times the odds of scoring high on the scenario score as RIOs who did not have this particular responsibility. This is among the more difficult aspects of a RIO’s responsibilities, so it is not surprising that those RIOs who are aware of their charge to do it by their institutions are more likely to score high on the scenarios.

What is surprising is that the other two significant variables—whether a RIO self-identifies as being or having been a researcher and whether the RIO’s institution requires all researchers to participate in an RCR course—both detract from RIOs scoring high on the

scenario score. RIOs who self-identify as researchers and those whose institution requires researcher participation in an RCR course had 78% lower odds of scoring high on the scenario score as RIOs who did not identify as researchers or work in institutions that required RCR participation. We had expected that RIOs who were researchers would have a better understanding and appreciation of handling RIO responsibilities with investigations of the research process than those who did not consider themselves researchers. We had expected that institutions requiring RCR participation for researchers would have better-prepared RIOs as a result, since we anticipated that the RIOs would be involved in teaching in the program.

V. Phase II Web-Based Survey Results

Fifteen variables significantly associated with the scenario score and representing variables from all four domains were used as predictors in an initial multiple variable logistic regression. We used the backward elimination logistic regression analysis option in SAS to parse the model. Only 11 statistically significant variables remain in the final model parsed of non-significant variables. They represent three measures from the RIO personal characteristics domain and three from the institutional characteristics domain. Five are variables representing the RIO training domain, and only one came from the RIO experience domain. Four of the 11 statistically significant variables are associated with reduced odds of being in the high scenario score group, and there are seven variables associated with increased odds of being in the high scenario score group.

The four variables associated with reducing the odds of being in the high scenario score group in the final parsed model include the number of years they have been employed at the institution, whether they reported having had no training or qualifications for becoming RIO, whether they attended only one or two ORI-sponsored workshops as preparation for becoming RIO, and whether the RIO was also assigned responsibility for grants management.

With respect to the number of years employed by the institution, those employed at the institution more than 10 years but less than 20 years, and those employed at the institution 20 years or more, have 73% and 67% lower odds of being in the high scenario score group, respectively, than RIOs who have been employed by the institution for 2 years or less. Having attended one or two ORI-sponsored workshops is associated with RIOs having 73% lower odds of being in the high scenario score group than those who did not report attending only one or two ORI workshops. RIOs assigned responsibility for grants management activities have 55% lower odds of being in the high scenario score group than those who do not have such responsibility. Expectedly, RIOs who reported having had no formal training or qualifications for becoming a RIO have 63% lower odds of being in the high scenario score group.

The seven variables that are significantly associated with increasing the odds of being in the high scenario score group in the parsed model include (1) being very satisfied with the authority and independence as the RIO, (2) having been the RIO for more than 5 but not more than 10 years, (3) having attended ORI-sponsored boot camp for RIOS, (4) reporting having had training or experience in human subjects protection or IRB issues, (5) having responsibility for handling issues of financial conflict of interest, (6) having concerns that research misconduct did not come to the RIOS attention, and (7) the sum of training activities reported that were classified as being of most or medium relevance to becoming a RIO.

RIOs who report being very satisfied with the authority and independence they have as the RIO have increased odds of being in the high scenario score group by 120% over those RIOs who report being merely satisfied or dissatisfied. RIOs who have held the position for more than 5 years, but not more than 10 years, have 111% higher odds of being in the high scenario score group than those who have been the RIO for 2 years or less. In addition, having attended ORI-sponsored boot camp for RIOS increases the odds of being in the high scenario score group. RIOs who attended RIO boot camp have 604% higher odds of being in the high scenario score group.

The fourth variable associated with placing in the high scenario score group is RIOs who report being trained or experienced in human subjects protection or IRB issues. These RIOs have 131% higher odds of being in the high group than RIOs who do not report such training or qualifications. The next variable associated with being in the high scenario score group is having responsibility for handling issues of financial conflict of interest. Those RIOs who have responsibility for handling cases of alleged financial conflict of interest have 92% higher odds of scoring in the high group than those who do not. The seventh variable associated with being in the high scenario score group is the sum of training activities reported that we classified as being of most or medium relevance to becoming a RIO. RIOs with two and three to five training activities or other qualifications for becoming a RIO have 61% and 83% higher odds, respectively, of being in the high scenario score group than RIOs with none. With some of the non-significant variables removed, this variable was able to reach significance and also to indicate that the more activities reported, the greater the odds of being in the high score group in this reduced model.

The parsed or reduced model of 11 statistically significant independent variables from the domain-specific logistic regression analyses is estimated to account overall for approximately 50% of the variation in RIOs' scenario score, only about 2% less than the estimate we achieved with an earlier full model of fifteen variables. The parsed model eliminates four variables from the full model that do not reach statistical significance or contribute significantly to explaining the variation in the dependent variable. Reducing the model in this way provides a more parsimonious model containing the set of variables most strongly associated with the RIOs' scenario score.

VI. Conclusions, Limitations, and Recommendations

Conclusions

One key conclusion from this project surrounds the finding that not all RIOs are equally well-prepared and ready to handle the responsibilities entrusted to them by their institutions. Fully 97% of the RIOs in the Phase II survey gave fewer than half the number of potentially appropriate actions for three RIO scenarios given by the two expert consultants.

Another key conclusion stems from the finding that only a small proportion of the persons who carry out the responsibilities of RIOs actually carry the formal institutional title of RIO (or compliance officer)—only 18.2% in the Phase II survey. Not having research staff readily able to recognize the correct person or place in the institutional structure to report possible research misconduct may account for the small number of allegations reported.

Our primary analysis focus has not only been to characterize the RIOs and the institutional settings in which they function, but also to assess the impact of variation in variables representing four conceptual domains on whether RIOs are prepared and ready to perform in the RIO role. We have done this by investigating which survey variables contribute to the RIOs responses to three scenarios. Placement in the high scenario score group more closely reflects the responses of two expert consultants who are experienced former RIOs. Our remaining conclusions concern which variables are significantly related to having a high scenario score and in what way—positively (contributes to) or negative (detracts from).

The variables in the four domains we investigated include personal characteristics, training or qualifications to become the RIO, experience with performing RIO responsibilities, and organizational characteristics that incorporate the array of RIO and other administrative tasks assigned to the RIO, as well as characteristics of the organization. In the Phase II analysis results, at least one variable from each of the four domains emerges from our analysis as having an impact on RIO preparedness/readiness. However, not all of the statistically significant variables are associated with placing in the high scenario score group.

Three variables from the personal characteristics are associated with the scenario scores. One of the three—being employed by the institution for more than 2 years—is negatively associated with the scenario score. The other two personal characteristics are indicators of attitudes held by the RIOs—satisfaction with the authority and independence they enjoy as the RIO, and having concerns about research misconduct not being reported to the institution’s RIO—and both are positively associated with being in the high scenario score group.

Only one variable from the domain of variables representing a RIO's experience is in the final model: the number of years the RIO has been in the RIO position. It contributes to being in the high scenario score group.

Two variables from the organizational characteristics domain are included in the final model. One is positively associated with being in the high scenario score group—RIOs solely responsible for handling the institution's issues involving financial conflict of interest—and one is negatively associated —RIOs who are solely responsible for grants management in the institution.

Five of the variables from the training domain are significantly associated with the scenario score category. Two of them are negatively associated with scoring in the high scenario score group: RIOs who say they had no training or qualifications to be the RIO, and RIOs who report attending only one or two ORI-sponsored workshops as their preparation for becoming RIO. The remaining three training variables—RIOs who report that they attended the ORI-sponsored RIO boot camp, RIOs who report having had training or experience in human subjects or IRB issues, and RIOs who say they have participated in two or more training activities that we considered of most or medium relevance to the RIO position—are positively associated with being in the high scenario score group.

Limitations

The Phase I interview survey was exploratory and employed a random, stratified sample of RIOs. However, to assure inclusion of RIOs working in all research settings, the sample was not properly proportionate. Despite a very good response rate from the sample (81.3%), the results cannot be presumed to be more than suggestive for the full population of RIOs, applying fully only to the sample.

While we received a reasonably high rate of RIO participation in the Phase II, web-based survey (59.2%), the biggest limitations with the Phase II survey portion of this study are the survey non-response and the item non-response associated with the scenarios. In order to be able to make generalizations to the entire universe of RIOs included in the survey, we had to make survey and scenario item non-response adjustments to the survey weights. Doing this allows us to assume our results refer to the entire universe of RIOs surveyed.

Recommendations

Our analyses of the scenario scores are quite discouraging in their revelation of how limited the population of existing RIOs is in its preparedness/readiness to perform the role appropriately when compared to acknowledged, competent former RIOs. When compared to the two ex-RIO consultants, fewer than 3% of the RIOs surveyed gave even half the numbers of appropriate responses as to how they would act in difficult scenarios commonly faced by RIOs. Research institutions need to take seriously the responsibility to have well-

trained RIOs by providing more opportunities and incentives for them to pursue training. The institutions need to be reminded that it is their responsibility to provide capable persons to fulfill the responsibilities of the RIO, and this includes seeing that they do not have too many or competing responsibilities and that they get the needed training on a continuous basis. Calling the persons who implement the institution's research misconduct policy the RIO may help make them more visible to the institution's members and providing them with written job descriptions would assure that they knew what they were responsible for doing in the position.

At least one variable from each of the four conceptual domains is included in the statistical model we estimated from the Phase II, web-based survey data. The 11 variable model accounts for approximately 50% of the variation in the scenario score variable. The training domain includes the largest number of measures in the model, including some that are associated with achieving a high scenario score and some contributing to the achievement of a low scenario score.

Our analysis does not examine the relative importance of the four predictor domains (personal characteristics, RIO training, RIO experience, and organizational characteristics) to predicting the preparedness/readiness of RIOs to perform their responsibilities. Our focus has been the variables contribution to RIO preparedness/readiness. However, it is clear from the analysis of the responses to the web-based survey that appropriate training is critical. Training measures are identified most often in the analysis, and are identified as both advancing preparedness/readiness as well as inhibiting it. Thus, while some training or prior qualification for the RIO position may increase preparedness/readiness, some, as well as none, is associated with diminishing it.

One training opportunity above all stands out as being particularly good at fostering the appropriate RIO behavior: participation in the ORI-sponsored RIO boot camp. RIO boot camp is an extensive and intensive small group experience that involves RIOs in discussions of how to operate in the difficult situations in which they often find themselves. In its association with having high scenario scores, RIO boot camp stands in contrast to other types of training activities that represent shorter and more limited exposures.

Based on our analysis, to improve the preparedness/readiness of RIOs, we recommend that ORI encourages research institution to promote continuing education and training for their RIO, and especially participation in the ORI-sponsored RIO boot camp. Our analysis shows that merely making materials available that RIOs can obtain and review on their own from the ORI web site or providing short, low-commitment activities is not associated with high scenario scores. Rather, RIOs seem to benefit from the personal contact with other RIOs and the opportunities to discuss issues openly with more experienced persons that is part of the boot camp experience. Further, we recommend that ORI do what it can to provide more opportunities for RIOs to attend the boot camp sessions,

and that ORI make the boot camp sessions convenient for RIOs to attend that might include presenting the boot camps in shorter modules.

In addition we recommend that unique and effective aspects of the boot camp experience be developed into new training modes. One such mode could include a RIO network composed of RIOs with a mix of experience and training to provide needed support and discussion of issues of relevance to RIOs, written exercises to be worked by teams of RIOs, and other similar interactive modes of support and training.

1. INTRODUCTION TO THE RIO STUDY

RTI International (RTI) conducted the Research Integrity Officer (RIO) study to provide the Office of Research Integrity (ORI) in the U.S. Department of Health and Human Services (DHHS) with in-depth and systematic information about RIOs. RIOs are the persons at the core of a system intended to identify and hold accountable perpetrators of research misconduct, defined as falsification, fabrication, and plagiarism. Institutions are obligated to have such a person in place as a condition of receiving research funding from the U.S. Public Health Service (PHS). Institutions are required to acknowledge through an annual ORI assurance process that they have policies and procedures in place to respond to allegations of research misconduct. The assurance process includes the fact that the institution has designated a person, referred to as the RIO by ORI, to implement the procedures in accord with its policies governing allegations of research misconduct. As documented while conducting this project, staff referred to as RIOs by ORI have many different professional titles, hold various offices within their institutions, and serve in many different capacities. This report attempts to provide an accurate description and analysis of data collected during this research project designed to better describe these staff, to characterize their readiness to perform their responsibilities as RIOs, and to identify factors that are associated with a high level of RIO performance/readiness.

In this introductory section of this report, we provide some context for the study by discussing the background and development of the ORI and describing the challenges faced by individuals who serve as RIOs. The RIO role can look quite different depending on whether it is viewed from the perspective of the greater society, the research institution, or those persons who are performing their part in the research enterprise. The period of performance for the work described herein extended from early September 2004 until late December 2009.

1.1 Background

Credence in the advancement of science and integrity in scientific research provides an essential foundation for the public's support of research (IOM, 2002; Korenman et al., 1998). In the past, peer review has provided a basis for monitoring the quality of research and science; however, public scrutiny and congressional interest have led to an increasing demand for greater accountability and transparency in scientific research (Francis, 1999; IOM, 2002; Koppelman-White, 2006). Such accountability and transparency require integrity on the part of individual scientists (Korenman et al., 1998; Pascal, 2000) in the form of intellectual honesty and personal responsibility (IOM, 2002). Research integrity also requires a commitment by institutions to dedicate sufficient resources toward educating researchers and students on the responsible conduct of research (Pascal, 2000); promoting mentorship (Wright, Titus and Cornelison, 2008); and fostering an environment that

promotes explicit expectations, procedures, and consequences of conduct and upholds high ethical standards (IOM, 2002; Titus, Wells and Rhodes, 2008).

Prior to 1986, funding institutes within the PHS agencies were charged with the responsibility of receiving reports of research misconduct. In 1986, the National Institutes of Health (NIH) took a first step in creating a central locus of responsibility for research misconduct within the DHHS by assigning to its Institutional Liaison Office the tasks of receiving and responding to reports of research misconduct. Three years later, the PHS created two offices to handle research misconduct: the Office of Scientific Integrity (OSI) in the Office of the Director at the NIH, and the Office of Scientific Integrity Review (OSIR) in the DHHS Office of the Assistant Secretary for Health (OASH). These two offices merged in 1992 and formed the ORI (Federal Register, 1992; Pascal, 2000) (see Appendix A). In 1999, the role, mission, and structure of the ORI shifted from a focus on active investigation of alleged research misconduct, to one of oversight over institutional investigations into allegations of research misconduct. In addition, ORI was directed to make efforts to prevent research misconduct and to promote research integrity. (U.S. DHHS, 2009; IOM, 2002). In 2000, ORI launched the Research on Research Integrity (RRI) Program and began to conduct biennial research conferences on research integrity to further enhance the knowledge base and to develop a professional community focused on the responsible conduct of research; research integrity; and research misconduct. Also in 2000, ORI initiated the Rapid Response for Technical Assistance initiative, offering early and direct assistance to institutions assessing allegations of research misconduct. In 2002, ORI launched the Responsible Conduct of Research (RCR) Resource Development Program, designed to facilitate the development of materials for teaching RCR for use in the research community. ORI also began development of a training program for institutional RIOs in 2005, and subsequently developed an orientation video in 2006 and RIO boot camps in 2007 (U.S. DHHS, 2009).

RIOs play a key role in monitoring and maintaining institutional standards for research integrity. The RIOs often engage in a wide range of activities, including, but not limited to, defining research standards, educating researchers about the standards, and overseeing the investigation of allegations of research misconduct (Geller, 2002). A potentially controversial aspect of a RIO's responsibilities involves serving dual roles during dispute resolution between parties, because simultaneously serving as a representative of the institution and as a mediator may distort the objectivity and impartiality characterized as ideal for fair and effective mediation. Perceptions of such bias and conflicts of interest may, in the long-run, yield a damaging sense of distrust of institutional interventions (Francis, 1999; Geller, 2002). Hence, comprehensive training and explicit guidelines outlining the boundaries of the roles and responsibilities that reside within and outside of the scope of a RIO's responsibilities are critically important.

1.2 Conceptual Perspective

There is much interest in how RIOs are able to walk the tightrope between being seen as administrators who simultaneously represent the interests of the research institution and who hold the responsibility of promoting integrity in research. The former involves maintaining the institution's reputation for doing good research, whereas the latter could result in exposing an institution's failure to the scientific community and providers of institutional research funding. RIOs are required to perform both functions, and can be successful at doing so. The focus of the RIO study is to understand how these individuals acquire the necessary knowledge and skills to be successful in the RIO position.

There are at least four possible domains of influences that can affect how a person performs as a RIO, and variables in each domain are a focus of this research. These four domains are (1) the personal characteristics of the person serving in the RIO position, (2) the training the person has received or the qualifications acquired to perform in the position, (3) the experience that the person has had that is believed to have contributed to RIO development, and (4) a variety of institutional characteristics that encourage and support the performance of a RIO's responsibilities. In the present study, we examine how strongly variables in each of these domains are associated with differences in the RIOs' responses to questions about what their behavior would be in several challenging research misconduct scenarios often encountered by RIOs.

Included in the domain of **personal characteristics** would be elements of a RIO's behavior, such as being conscientious about performing the role, as well as how satisfied an individual is with how he/she is able to perform in the position, how secure the individual is in the position, his/her degree and major field of study, how involved the individual is with seeking research support, how often the individual has been a principal investigator on a grant, how long he/she has been employed by the institution, and whether the individual self-identifies as ever having been a researcher.

Among the variables included in the **training** domain are a host of activities and other potential bases for acquiring specific qualifications to perform as a RIO. These include participating in activities developed and provided under the sponsorship of ORI, such as workshops, conferences, and RIO boot camps; viewing a video on the responsibilities of RIOs; and reading ORI reports and other documents available on the ORI website. Variables also included an individual's experience as a researcher for at least 10 years; experience with research misconduct activities at another institution, either by assisting in organizing an inquiry or investigation or having served as a member on an inquiry or investigation; having assisted or been mentored by the previous RIO; having extensive contact with other RIOs at other institutions or with staff members at ORI; having assisted with the preparation of the institution's policy and procedures regarding how cases of alleged

research misconduct will be resolved; and having training or experience in human subjects issues, or as a research administrator.

The RIO **experience** domain includes measures of what the RIO has done and is doing in his/her current institution that could contribute to being a more effective RIO. Variables in this domain include how long the person has been the RIO; whether the RIO has ever handled any allegations, directed an inquiry, or held an investigation of alleged research misconduct; and how often the RIO confers with RIOs at other institutions or, off the record with ORI staff, about how to handle “hypothetical” situations that may arise in allegation cases.

Organizational characteristics constitute the last of the four domains of interest in this project. These characteristics are represented by structural features of the institution, as well as what the institution includes as RIO responsibilities, and the number and type of other administrative responsibilities besides that of RIO that are delegated to the person serving as the RIO.

Among the **structural features** are the RIO’s position in the institutional hierarchy, the type of institution, whether the institution has or requires participation in a responsible conduct of research course, whether the institution requires researchers to certify in writing that they are aware of the institution’s research misconduct policy, whether the person filling the RIO position actually carries the RIO title, whether the RIO has assistance in carrying out his/her RIO responsibilities, whether the person handling allegations of research misconduct is identified in the institution’s policy and procedures manual, whether the person filling the RIO position has a written job description, and whether the institution has reported an allegation in its annual report to ORI.

Among the **RIO responsibilities** of which sole or shared performance could be expected by the institution are: sequestering potential evidence, informing key officials of allegations or actions, informing researchers of the institution’s research misconduct policy, receiving allegations of research misconduct, handling allegations of more than just research misconduct, deciding whether there will be an inquiry or investigation, selecting members of the inquiry panel or investigation committee, informing complainants of their vulnerability from making an allegation, training the panel or committee, and the total number of these responsibilities.

The variables representing additional **non-RIO administrative duties** assigned to the person serving as the RIO include sole or shared responsibility for handling: financial conflicts of interest, protection of human subjects, animal protection, hazardous waste and radioactive materials, recombinant DNA, grants management, and the sum total of these non-RIO administrative responsibilities assigned to the RIO.

It is the purpose of this project to provide insight into which variables from which of these four domains are associated with an individual's understanding of how to respond as a capable and ready RIO when faced with scenarios not uncommon to situations encountered by RIOs as we have measured it. We expect that some of the variables will be associated in ways that actually detract from being capable and ready to perform the RIO role, while there are others that will contribute to the capability and readiness to handle what the scenarios represent.

2. STUDY PURPOSE

This section of the report discusses the questions that the RIO study was undertaken to address, the two phases of the study, and the objectives that we sought to achieve in the performance of the project via the conduct of the surveys included in each phase.

2.1 Study Goals

The RIO study had two overall goals. The first goal was to assess the preparedness/readiness of RIOs in the United States who conduct the responsibilities needed for successful resolution of alleged cases of research misconduct—falsification, fabrication, and plagiarism. The second goal was to examine the association of a RIO's level of preparedness/readiness with (a) their positions and responsibilities in their institutions' organizational structure; (b) personal factors, including their educational and professional background; (c) their actual experience performing in the role of RIO; and (d) the type and extent of training they received in preparation for performing this role.

2.2 Project Overview

The RIO study was designed to be performed in two phases and involved survey data collection to be performed in each phase. The two surveys were executed independently and with somewhat different objectives in mind, but were intended to be used in a complementary way to achieve the overall project goals. The Phase I survey (see Appendix B) was performed as a personal interview by telephone, whereas the Phase II survey (see Appendix C) was performed via the Internet, and hence, was self-administered. Initial contact with research institutions to inform them of the RIO study and to identify the individuals serving as RIOs was made by e-mail for both phases. The follow-up with study participants in Phase I of the study was conducted by telephone, while follow up in Phase II of the study was conducted by e-mail.

It should be noted that to prepare for the Phase I survey, we conducted a small pilot study with a random sample of RIOs, stratified by the three types of institutions that ORI wanted included in the surveys (i.e., institutions of higher education, research institutes, and independent hospitals). The pilot study was intended to test RTI's procedures for identifying and contacting the RIOs and to ensure that they properly understood and could respond to the survey questions, regardless of their institutional environment. It was particularly important to test whether the RIOs would understand, cooperate, and respond to the survey questions involving scenarios on which they were asked to comment. The pilot study was conducted over the telephone by the Project Director and a skilled executive-level interviewer. The pilot study involved interviewing nine RIOs initially, and interviewing another four RIOs after some changes were made to the survey questions.

The Phase I survey was conducted with a random stratified sample of 112 institutional RIOs. These semi-structured interviews were conducted by appointment over the telephone by a group of five trained, executive-level interviewers. Ninety-one interviews were completed for the Phase I survey, a response rate of 81.3%, with each interview lasting an average of slightly more than an hour. Because it was RTI's intention to use many of the same questions from the Phase I survey in the Phase II survey, the Phase I survey served in some ways as a large pilot test for the Phase II survey. The Phase I survey was conducted from March 2007 through June 2007.

The Phase II survey was conducted using a self-administered questionnaire on a secure Internet web site between May 2008 and February 2009. The survey questions consisted of items drawn or reformulated largely from the responses given in the Phase I interview. The final version of the Phase II, web-based survey had drop-down menus and fewer open-ended items and other specify response opportunities requiring coding than did the items in the Phase I interview survey. So as not to burden the RIO study participants with double participation in the study, the Phase II survey was directed at the 1,099 institutional RIOs who remained after we had randomly selected out the pilot study (20) and Phase I (112) samples. We successfully obtained some level of response to the Phase II survey from 651 of the 1,099 institutional RIOs, a response rate of 59.2%.

Initial efforts to contact the RIOs for both phases of the study were made by an e-mail letter introducing the RIO study. This letter was sent to the person listed in the ORI's electronic roster as the person responsible for submitting the institution's Annual Report on Possible Research Misconduct. We contacted this person because ORI had no actual listing of the individuals serving as RIOs. We believed that the individual responsible for submitting the institution's Annual Assurance report (required for an institution's PHS funds to be released) would be in a position to notify us of, or forward the e-mail to, the person serving as the RIO in the institution. Although some of these institutional contacts turned out also to be the institution's RIO, many were not; however, most were able to refer us to the RIO or the individual performing the activities of the RIO. The e-mail letters had a provision for making such a referral to us and for automatically sending a letter to the newly identified RIO to introduce the study to that person. As stated previously, in Phase I of the study, additional follow-up activities to identify or contact the RIOs were made by the assigned interviewers on the telephone. In Phase II, additional follow-up activities made use of up to 12 follow-up e-mails at 2-week intervals, telephone responses to queries in e-mail responses by sample members, use of different e-mail formats and protocols, and research into alternative, corrected, or new e-mail addresses from ORI records and institutions' websites.

2.3 Project Objectives

To achieve the study goals, RTI needed to achieve a number of intermediate project objectives. These objectives were planned to be performed in two phases and included the following:

- Develop appropriate data collection instruments to measure RIO preparedness/readiness, as well as items to obtain information on RIO characteristics, the RIOs' positions and responsibilities in their institutions, and their training and experience relevant to carrying out the role of RIO.
- Create an unduplicated list (sampling frame) from ORI electronic records of the persons responsible for submitting the legislatively required Annual Report on Possible Research Misconduct for U.S.-based institutions doing PHS-sponsored research.
- Prepare the materials needed to obtain the required clearances and reviews from the Office of Management and Budget (OMB) and the RTI institutional review board (IRB) for protection of the rights of research subjects.
- Conduct a personal interview survey by telephone with a heterogeneous sample of approximately 100 RIOs (Phase I).
- Conduct a web-based, self-administered questionnaire survey with the remaining institutional RIOs in U.S. institutions filing the Annual Report on Possible Research Misconduct with ORI (Phase II).
- Analyze the data collected, prepare a report, and address the issue of what variables contribute to or detract from the RIOs' preparedness/readiness to appropriately carry out their responsibilities.

The objectives of the Phase I, telephone survey included the following:

- Identify and conduct telephone interviews with up to 100 of the RIOs included in the Phase I sample.
- Engage RIOs in discussions about where they are positioned in their organizations, their responsibilities, and how they were prepared to be RIOs (e.g., training, mentoring by a former RIO); this information needed to be in enough detail to describe the diversity represented among RIOs.
- Refine the clarity and comprehension of the Phase I survey questions so that versions of similar items could be used in the Phase II, web-based survey.
- Modify some of the contact materials and procedures that RTI developed for Phase I so that these could be used to reach RIOs for the Phase II, web-based survey.
- Test the acceptability and effectiveness of using hypothetical research-misconduct scenarios to obtain an assessment of and individual's preparedness to serve as RIO.
- Use the diversity of answers to open-ended questions to develop drop-down menus of more standardized responses for similar questions to be asked in the Phase II, web-based survey.
- Suggest changes to the proposed Phase II web-based data collection instrument.

The objectives of the Phase II, web-based survey included the following:

- Obtain as many completed web-based surveys with RIOs as possible.
- Be able to accurately and completely describe the diversity represented among the RIOs in U.S. research institutions that file an Annual Report on Possible Research Misconduct with ORI.
- Statistically examine the factors hypothesized as associated with better preparedness/higher readiness to carry out the role responsibilities of the RIO.

These factors and their associated hypotheses included:

(a) An individual's professional position in the institutional structure.

We hypothesized that the higher an individual's position in the institutional hierarchy and the closer he/she is to the top person in the organization, the important it would be for the institution to assure that the person was fully prepared to serve as the RIO.

(b) An individual's responsibilities as RIO.

We hypothesized that the more focused an individual is on being the RIO, rather than focused on other distributed responsibilities, the better prepared he/she will be to serve in the role of RIO.

(c) An individual's educational and professional background.

We hypothesized that the better educated and more experienced scientists would be better prepared to be RIOs than those prepared academically in non-science fields.

(d) The amount of experience an individual has performing RIO activities.

We hypothesized that the greater an individual's experience in the RIO position, the better prepared he/she will be to fulfill the RIO responsibilities.

(e) The types and amount of training an individual has in preparation for assuming the RIO role.

We hypothesized that the more formal training and mentoring an individual received, the better prepared he/she would be to serve in the RIO role.

3. STUDY METHODS

This section discusses the study methods used for the RIO study, including how the RIOs were identified, contacted, and solicited to participate in the study. This section also presents the outcomes of our efforts for each of the major components (i.e., phases) of the project, reviews the statistical analyses and techniques that were employed, and describes how the data were combined and recoded to create variables in addition to those produced directly in response to pre-coded interview or questionnaire items.

3.1 Identifying Institutional RIOs

RTI was unable to obtain a complete and up-to-date electronic file of RIOs for use to identify and contact study participants for this research project; therefore, we had to create a list of these individuals using information culled from available sources. ORI provided us with a copy of an electronic file that it maintains of the persons who submitted their institution's Annual Report on Possible Research Misconduct for 2005. This file contained the names and IPF numbers for each of the 1,758 institution entries, as well as the name, address, telephone number, and e-mail address of the contact person submitting each institution's 2005 report. The file also included a code for institution type that indicated whether it was an institution of higher education, a research institute, or an independent hospital (per the three types of institutions ORI wanted included in the study).

RTI's first step was to purge the ORI file of institutions not located in the United States or Puerto Rico. Then, in an effort to reduce file multiplicities (duplications), we cleaned the file of all but one listing with the same institution name, contact person, or contact telephone number. These deletions involved cases in which we observed multiple hospitals in a chain or professional schools within a university with the same administrative person submitting the report to ORI and, we presumed, a common RIO as well. As a final step, we obtained the 2006 ORI file for the misconduct reports and used that file to purge the records of any institutions no longer actively submitting reports. We also used the 2006 file to update the names and e-mail addresses of the contact persons at the institutions that survived the cleaning, purging, and collapsing process of the 2005 file, as well as to add to the 2005 file the names and contact information for institutions that submitted their first report in 2006. After this purging and updating process, RTI's final file of RIO contact information contained 1,231 entries (this file is henceforth referred to as the cleaned ORI list).

3.1.1 Source of the Pilot Study Telephone Interview Participants

RTI randomly selected 20 institutions proportionately from across the three strata of the 1,119 remaining institutions on the cleaned ORI list after selection of the Phase I sample of 112. The persons identified as submitting the annual report to ORI were mailed an advance letter explaining the study and inviting the person serving as the institution's RIO

to be included in the pilot study. The letter recipient was asked to contact RTI by telephone to select a convenient time for an hour long interview. Those institutional representatives who did not call RTI within a week were called by one of the two senior staff members who conducted the pilot testing of the interview. After interviewing nine RIOs, the pilot test staff discussed and agreed upon changes to the interview to make the interview questions easier for the respondent to understand and for the interviewer to administer. An additional four interviews were conducted using the revised interview form, for a total of 13 pilot test interviews. None of the pilot test sample institutions was included in the Phase I or Phase II studies.

3.1.2 Source of the Phase I Telephone Interview Survey Participants

An objective of Phase I of the RIO study was to complete interviews with a sample of approximately 100 RIOs from institutions selected from the cleaned ORI list. As indicated earlier, all institutions receiving research funding from the PHS are required to submit these reports annually. The list of institutions that we received from ORI was partitioned into three sections that corresponded to the three different types of research settings—institutions of higher education, independent hospitals, and research institutes—that we used as sampling strata for selection of the sample for the Phase I survey to be conducted by telephone. To ensure representation in this sample of large research operations, we created another stratum defined by the institution's rank in the top 105 of the NIH's research awards for 2005.

To allow for institutions and RIOs who would refuse to participate in the survey, and for some that we might not be able to successfully contact, we selected 112 institutions for the Phase I interview survey out of the 1,231 included on the cleansed ORI list. Half of the Phase I sample was selected at random from within this "big money" stratum. The remaining half of the Phase I sample was selected at random at a rate proportionate to an institution's representation in the remaining three strata of the cleaned ORI list that RTI had prepared.

For eight institutions included in the ORI list, RTI was unable to contact anyone who could assist us in identifying the individual serving as the RIO at the institution. In addition, there were 13 institutions where the RIO either refused to participate in the survey, we not able to arrange for an interview with the RIO because the person was away during the study period, or there was no one presently in the RIO position. Overall, we conducted interviews with persons at 91 institutions (81.3%). As it turned out, six of these individuals indicated that they were not truly the RIO, but were appointed to be the institution's spokesperson.

3.1.3 Source of the Phase II Web-Based Questionnaire Survey Participants

The Phase II survey population consisted of the 1,099 RIOs associated with the institutions remaining on the cleaned ORI list after selection of the pilot study and Phase I

study samples. The procedures for contacting the individuals selected for the Phase II survey were much more automated than for the pilot and Phase I activities. We relied heavily on repeated e-mails and use of a secure RTI Internet site for the conduct of the Phase II survey.

3.2 Conducting the Surveys

Previous discussion has alluded to the different types of survey data collection approaches employed in this project. The pilot study involved the most direct staff involvement of staff with respondents through a personal interview conducted by telephone. The Phase II survey had the least staff involvement. The Phase II survey was essentially a self-administered questionnaire administered over the Internet for which recruitment and follow-up of non-respondents was performed in an automated manner through the use of up to 12 e-mail letters. The Phase I telephone interview fell in between the other two surveys in terms of project staff involvement and personalization of the process.

3.2.1 Conduct of the Pilot Study Survey

Two senior researchers conducted the pilot study, initially contacting the sample members by mail with an advance letter, and then by telephone to set up the interviews. The researchers conducted the interviews over the telephone and found that the respondents were usually interested in the survey and quite willing to respond. A total of 13 pilot study interviews were conducted. In addition to the amount of time necessary to conduct the interview, the biggest limitation revealed by the pilot study interviews was the difficulty that respondents had responding to the five scenarios over the telephone; although the scenarios were key survey items, they were long to listen and respond to and often required that the interviewers repeat parts of the scenario to the respondents. The scenarios were intended to be used to measure how prepared or ready the RIOs were to handle difficult aspects of research misconduct cases; thus, it was important that they be clearly understood by study participants. However, some participants did not want to attempt to respond to the scenario questions, and others who did attempt a response admitted that they were not familiar enough with the RIO role to know what should be done in response to some of the scenario situations. It was apparent that there would be issues of non-response with the scenarios that even an interviewer prompting the participant might not be able to fully overcome. As a result of comments offered by the pilot test participants, RTI simplified the flow and wording of the interview scenarios section, and specified that the interviewers would need to be as patient and encouraging as possible to get reluctant RIOs to respond to the scenarios.

3.2.2 Conduct of the Phase I Telephone Interview Survey

RTI introduced more automation into the recruitment and scheduling of the 112 RIOs for the Phase I interviews. An advance letter was e-mailed to the person listed as

responsible for submitting the last annual report to ORI. The letter explained the purpose of the study and asked whether the recipient was the RIO or the person who performed the functions of the RIO. If the recipient was the RIO or performed as the RIO, he/she was directed to click on a link and was taken to a secure site at RTI to select an interview day and time. Once selected, an e-mail was sent to the RIO and the interviewer confirming the interview appointment. An automatic reminder was also sent out the day before the scheduled interview.

If the recipient was not the RIO, the advance letter e-mail asked that the person send a return e-mail to RTI indicating the name and e-mail address of the institution's RIO. The return e-mail automatically updated our list of RIO names and e-mail addresses and triggered a slightly revised advance letter e-mail sent to the newly named RIO. The process continued until a RIO responded by making an interview appointment. If 2 weeks passed without a response to these e-mails, a project assistant initiated telephone contacts with the last person to whom we e-mailed at the institution in an effort to set up the appointment for an interview with the RIO. A total of 91 interviews were completed in the Phase I study, a response rate of 81.3%.

3.2.3 Conduct of the Phase II Web-Based Questionnaire Survey

The Phase II survey was performed using a self-administered web-based questionnaire residing on a secure web site at RTI. The person who submitted the annual report to ORI at the 1,099 institutions included in the Phase II survey was sent an advance letter by e-mail explaining the purpose of the study. The letter asked the recipient to send the name and e-mail address of the institution's RIO to RTI by return e-mail if the recipient was not the RIO or the person who performed the responsibilities of the RIO. If a return e-mail was received, the list of persons and addresses being surveyed was updated, and a slightly revised advance letter was e-mailed to the newly named person. Approximately a week after the advance letter was e-mailed, RTI sent an e-mail seeking the participation of the recipient in the survey. This letter had the same provision as the advance letter: for the recipient to identify someone else as the RIO and to return that information to RTI. If the recipient confirmed that he/she was the RIO, the recipient was asked to click on a link that took him/her to the questionnaire on a secure web site. Approximately 1 week to 10 days later, a thank you reminder e-mail was sent. One week to 10 days after the thank you e-mail, another reminder was sent. This process was repeated up to 12 times in an effort to obtain the highest response rate possible. Each follow-up letter contained a slightly different text, and the pleading tone of the last chance letters for a response was also heightened. During the follow-up period, in an effort to assure that our e-mails were not being treated as spam and being discarded or blocked, we changed the format in which the reminders were sent, we removed attachments (logos), and we sent out the reminders in smaller batches. Where the institutional response rate was less than 50%, we looked up sample members' e-mail addresses in their institution's staff directory. Using this

combination approach, RTI obtained 651 completed questionnaires from RIOs, a response rate of 59.2%. Of the 651 responses, 427 (or 65.6%) were from the original persons who submitted the annual report to whom we addressed the advance letters soliciting RIO participation.

3.3 Weighting the Respondents to the Phase II Survey

The RIO data analyzed and reported in the Results section of the Phase II web-based survey has been weighted to restore the proportionality of the sub-population of respondents to the full population of RIOs. Thus, the total weighted count in most tabulations is 1,099—the number of RIOs in the population being studied—and not the 651 who were actual study respondents. We did this because there is a risk that the distribution of RIO characteristics based on respondents alone will not be an accurate estimate of what the distribution of the same characteristic would have been if everyone in the population of RIOs had responded.

We employed a post-stratification weight adjustment to assign the overall number and proportionality of the total population to the group of respondents. We used the institution-type variable—institution of higher education, research institute, or independent hospital—to create a non-response adjustment weight for respondents because this variable was a key characteristic known for the entire population of RIOs. When the non-response rate for a survey is relatively large, or if some strata in a survey do not respond at the same rate as the rest, it can be important to do something to restore the distributions of respondent characteristics to what they would have been had the response been at the same rate across the entire population; otherwise, a study runs the risk of severely biased estimates. Without such weight adjustment, simply reporting the distribution of the characteristics of respondents and implying that they estimate the distribution of characteristics of the population may result in the misrepresentation of the distribution of characteristics of the population. The method RTI used for creating the survey non-response weight adjustment is discussed in the first section of Appendix D.

It is important to note that due to the high rate of non-response to the scenario items in the Phase II survey, we also run the risk of biased estimates of the results of analyses to assess which variables influence the scenario scores we have used to measure RIO preparedness/readiness. For this reason, we performed further post-stratification adjustment to restore the overall proportionality of the total population to the group of scenario question respondents. We used five variables that we identified from a separate analysis conducted to identify variables related to whether a RIO responded to the scenario questions. These variables included the number of times the RIO has conferred with RIOs at other institutions, whether the RIO has responsibility for grant management issues, the number of years the RIO has been employed by the institution, whether the RIO has attended one or two ORI-sponsored workshops, and the number of medium or highly

relevant training activities identified as having been completed in preparation to be RIO. The method RTI used for creating the scenario questions non-response weight adjustment is discussed in the second section of Appendix D.

3.4 Coding the Scenarios

As indicated above, RTI used a series of scenarios as the basis for assessing the preparedness/readiness of individuals to perform the RIO role. For the Phase I, telephone interview survey, we included five scenarios, each providing an opportunity to demonstrate different skills and knowledge. It should be noted that for pragmatic reasons, we reduced the number of scenarios included in the Phase II web-based survey to three. To make the analysis of the data from the two phases consistent, we only analyzed the three scenarios included in Phase II in the Phase I analysis. The full set of five scenarios is contained in Section IV of the Phase I interview instrument and the three analyzed for this report include only numbers one, three, and four. The scenarios were developed with the assistance of the ORI consultant, himself a former RIO and currently assisting ORI in the development of training materials and activities for RIOs. The three scenarios analyzed in both phases were intended to allow RIOs to verbally illustrate their knowledge of doing the following as effectively as possible:

- (1) How to sequester evidence.
- (2) How to protect the “whistleblower” against retaliation.
- (3) How to coordinate RIO responsibilities with those of the IRB.

The entire Phase I interview with the RIOs was recorded, including the RIOs’ responses to the scenarios. A word processor transcribed the RIOs’ responses to the scenarios from the recordings. To the extent possible, extraneous comments by the interviewer and RIO were edited out of each scenario transcript. The typed transcript of the five scenarios was then reviewed and edited against the recorded scenario interview section for completeness and accuracy.

To develop a method for assessing the RIOs’ responses, RTI asked the ORI consultant and a second expert consultant (also a former RIO) to independently review each scenario and to respond to each scenario as fully as possible with a statement beginning “I would do this in that situation. Then I would do this, and then this,” etc. The consultants were asked to continue until they could think of no further things that they thought they should do in response to each scenario. Finally, we arrayed side by side the two consultants’ statements about what they would do without regard to order and created a single list of actions that both of the consultants included in their responses to each scenario. The full list of possible responses to each of the scenarios is presented in Appendix E, which provides the coding instructions for the scenarios. The list of common consultant responses became the basis for our coding of the transcribed responses of the RIOs to the

scenarios, which we used to assess the preparedness/readiness of RIOs to act appropriately and knowledgeably in the RIO role.

Two of the interviewers who conducted interviews with the RIOs in Phase I and were already familiar with the scenarios were trained by the Project Director to interpret the responses in the transcripts in light of the consultants' responses for each scenario. They were instructed to review the RIO's transcript for each scenario and to code whether each of the consultants' responses to the scenarios was present or absent in the responses of the RIOs. Coder training consisted of multiple iterations of practice walk-through coding exercises with the different transcripts; round-robin discussions of decisions about whether the transcripts contained one or more of the consultant responses for each scenario; and a thorough review and reconciliation of code assignments that were at odds with each other. The goal of the training session was to get as much agreement between the code assignments of the two coders with each other and the Project Director as possible.

As mentioned above, for a number of reasons, including the time it took respondents to answer and the difficulty RIOs seemed to have responding to some of the scenarios, we decided to cut from five to three the number of scenarios included in the Phase II web-based survey. Scenarios two and five from the Phase I survey were not included in the Phase II survey instrument. This adjustment was done in the hope that it would result in a high completion rate for the scenario questions in the absence of an interviewer to encourage responses. Unfortunately, it did not work that way, and only 56.7% (or 369) of the 651 Phase II survey respondents responded to all three of the scenario questions. For consistency in the analysis between the Phase I and Phase II surveys, we only performed analysis on the three scenarios in the Phase I survey that were also included in the Phase II survey. The multiple-variable analyses of RIO preparedness/readiness in the Phase II survey analysis have been performed using the scenario question non-response adjusted weight discussed above.

3.5 Creating Analysis Variables

In the Phase I interview study, analysis variables were typically created from combining pre-coded responses given to the interview questions. Some analysis variables involved coding open-ended items, while others with an "Other [Specify]" response option also needed to be coded. Some analysis variables were created by summing the number of responses given to an item allowing multiple responses or to a series of related items. Where appropriate, response values were assigned to some items that were skipped in the interview because of a previous response that made that item not applicable. The distributions of the Phase I interview analysis variables are presented later in Section 4 of this report

The self-administered questionnaire used for data collection in the Phase II web-based survey was simplified from the instrument used in the Phase I interview survey. There were not only fewer questions in the Phase II survey, but also fewer open-ended questions and items allowing “Other [Specify]” responses. Instead, important items that were open-ended in the interview survey were presented with drop-down menus of responses based on the responses obtained in Phase I. Analysis variables for the Phase II, web-based, self-administered questionnaire survey thus required less coding. Nonetheless, accommodations were made in the creation of response values for analysis variables that include items that were legitimately skipped because they did not apply. In addition, there were variables created based on summing the number of responses given to an item or series of items. To a great extent, the analysis variables created for the Phase II study were similar to those created in the Phase I study and covered the same four conceptual domains: personal characteristics, training, experience and institutional characteristics. Distribution of the Phase II survey analysis variables are presented later in Section 5 of this report.

3.6 Conducting Analyses of the Interview and Survey Data

RTI employed a very similar approach to analyzing the Phase I and Phase II surveys. Both phases employed the same conceptual approach and many of the same statistical tools and analytic conventions. In the following sections, we will discuss our analysis of the reliability of the scenario-response coding that was performed in both phases of the study and review the statistical techniques that were used to establish association and significance, and then to model the variables that contribute in a positive or negative way to the RIOs’ scenario scores through both phases of the project.

3.6.1 Measures of Scenario Coder Agreement

In both the Phase I interview survey and the Phase II web-based survey, we performed an analysis of the inter- and intra-coder reliability. Inter-rater reliability refers to how similarly two or more coders code the same information. Intra-coder reliability refers to how similarly the same coder codes the same information at two different times.

To assess inter-coder reliability in both study phases, each coder was randomly assigned several of another coder’s cases (each of which included all three scenarios) to independently code so we would have replicate pairs of three coded scenarios for the same sub-set of RIOs. We calculated several statistical measures of inter-coder agreement. These included: the number of disagreement between the coders, the percent agreement between the coders, two other commonly used statistical measures of coder agreement that correct for chance agreement — Cohen’s Kappa coefficient (K) and the intra-class correlation coefficient (R_{ICC}) (SAS, 2008), and one less commonly used measure, Gwet’s alternative chance-correlated coefficient (AC_1) (2001).

To assess intra-coder reliability, we had each coder independently duplicate the coding of a random sample of several cases that they had previously coded. We used the same measures of agreement for intra-coder reliability on the set of duplicates as was done with the replicates to assess inter-coder reliability.

For the Phase I interview survey we assessed the inter-coder reliability of the two coders who coded the transcripts of the recorded responses of the interviewed RIOs according to the scheme whose development was described earlier. (That scheme made use of the responses to the same three scenarios from the two former RIOs who served as consultants to the project.) In addition, we also conducted an assessment of intra-coder reliability in Phase I of the project.

Results of the analysis for Phase I are presented in Table 3-1. The number of disagreements in the inter-coder analysis is small, only 24 out of 234 item comparisons, resulting in an overall percent agreement observed in Phase I of 89.7%. The intra-coder reliability is even better, with only 10 disagreements out of the 260 item comparisons, for a percent agreement of 96.2%. The inter-coder agreement coefficients are closely in agreement with each other and high enough for inter-coder reliability to be considered good. The intra-coder coefficients are also in close agreement and high enough for the intra-coder reliability to be considered very good.

Table 3-1. Phase I Interview Study Inter- and Intra-Coder Reliability Analysis Results

Scenario Items/Case	Cases	Coders Compared	Total Items	Number of Disagreements	Percent Agreement	Kappa	r _{ICC}	AC ₁
26	9	Inter-Coder 1-2	234	24	89.7	0.73	0.73	0.68
26	10	Intra-Coder	260	10	96.2	0.87	0.87	0.85

We also performed an analysis of the inter- and intra-coder reliability of the coders in Phase II who coded from print outs of the keyed responses of the RIOs who responded to the same three scenarios presented in writing in the web-based survey. The test methods we employed differed slightly because there were four coders' efforts to be compared to each other instead of only two. To assess inter-coder reliability, each coder again independently coded a random sample of each other coder's cases. We compared each of coders as well as all four to each other. We assessed intra-coder reliability, again by having each coder recode a random sample of cases they had previously coded.

The results of the analysis of coder reliability in Phase II are presented in Table 3-2. The number of inter-coder item coding disagreements overall is only 121 out of 1,274 for a percent agreement of 90.5%. As can be seen from the table, the number of paired coder

disagreements ranged from 15 to 26, and the percent agreement between the individual pairs of coders ranged from 88.0% to 92.8%. The overall inter-coder reliability coefficients are not in as close agreement with each other as they are in the Phase I study, but the coefficients in Phase II are higher than in Phase I and high enough for overall inter-coder reliability to be considered good to very good.

The overall number of intra-coder disagreements in the Phase II study is 42 out of 936 item comparisons for an overall percent agreement of 95.3%. Overall Phase II study intra-coder coefficients are in closer agreement than for Phase II inter-coder reliability, and they are high enough for the intra-coder reliability to be considered very good. As can be seen from the table, the number of paired coder disagreements ranged from 5 to 14, and the percent intra-coder agreement between the individual pairs of coders ranged from 94.0% to 98.1%. The overall intra-coder reliability coefficients are in as close agreement with each other as they are in the Phase I study, and the coefficients in Phase II are about the same as in Phase I. They are high enough for overall intra-coder reliability in the Phase II study to be considered very good also.

Table 3.2. Phase II Web-based Study Inter- and Intra-Coder Reliability Analysis Results

Scenario	Items/ Case	Cases	Coders Compared	Total Items	Number of Disagreements	Percent Agreement	Kappa	r _{ICC}	AC ₁	
26			Inter-Coder							
			8	1-2	208	15	92.8	0.82	0.73	0.78
			9	1-3	234	26	88.9	0.68	0.58	0.62
			8	1-4	208	18	91.3	0.78	0.66	0.74
			8	2-3	208	25	88.0	0.69	0.58	0.62
			8	2-4	208	15	92.8	0.82	0.74	0.78
			8	3-4	208	22	89.4	0.71	0.59	0.66
			49	All	1,274	121	90.5	0.75	0.89	0.84
26			Intra-Coder							
			9	1	234	14	94.0	0.79	0.79	0.76
			8	2	208	10	95.2	0.88	0.88	0.85
			9	3	234	13	94.4	1.00	0.83	1.00
			10	4	260	5	98.1	0.94	0.94	0.93
			36	All	936	42	95.3	0.87	0.87	0.93
26			Coder-Consultant							
			8	1-C	208	27	87.2	0.64	0.55	0.57
			8	2-C	208	24	88.5	0.68	0.65	0.62
			8	3-C	208	23	88.9	0.67	0.59	0.61
			8	4-C	208	25	88.0	0.66	0.59	0.59
			32	All	832	99	88.1	0.66	0.57	0.81

In the Phase II study only, in addition to the study of inter-coder reliability comparing each coder to each of the other coders on the same scenarios, we also compared

each coder to a presumptive “gold standard”. The “gold standard” was represented by the primary expert consultant on the project who was asked to code the same three scenarios for the same randomly selected sample of composed of two randomly selected cases coded by each of the four coders.

The results of the “gold standard” analysis are presented in the lower portion of Table 3-2. It is immediately apparent on examining the number of disagreements and the percent agreements that the coders are much more consistent with each other than they are with the “gold standard”. An examination of the actual codes assigned by the gold standard and the coders to the RIOs’ responses reveals that the “gold standard” is stricter in coding RIO responses than the coders, i.e., the coders gave credit to RIOs for having more appropriate responses than did the “gold standard”. The substantive implication of this finding is that the coders found the RIOs who participated in the Phase II study to have greater preparedness/readiness to carry out their RIO responsibilities than would have been the case had the primary expert consultant (a former RIO) coded all of the RIO responses.

The table shows that there are 99 disagreements in how items should be coded out of the 832 items coded in common among the four coders and the “gold standard”, for a percent agreement of 88.1%, slightly lower than the 90.5% agreement measured among the four coders alone. However, it should also be noted that the percent agreement is quite similar across the four coder–“gold standard” pairings, ranging from 87.2% to 88.9%. This confirms that the difference is the result of how the “gold standard” coded. Despite this apparent disparity in their coding relative to the “gold standard”, the overall inter-coder reliability coefficients in this analysis indicate a level of overall inter-coder reliability in the Phase II study that is still considered to be good.

3.6.2 Statistically Testing Significance and Measuring Association

With the large number of potential predictor or explanatory variables collected in the both the interview and web-based surveys, the challenge in both phases has been to effectively and efficiently search through the variables to identify the ones that have the most potential to contribute (either positively or negatively) to a RIO’s scenario score. We had a mixture of grouped continuous, ordinal, and nominal variables as categorical predictors and the dichotomous measure of high or low scenario score as the outcome variable of interest.

The first pass through the data was to look for significant associations between the variables in each of the four predictor domains and the dichotomous scenario score. In both surveys, we used the SAS analysis software package (SAS, 2008) to cross tabulate each predictor by the outcome measure. The statistics used differed slightly because of the smaller Phase I sample size. For the Phase I survey analysis, we calculated Phi coefficients, to measure association between dichotomies, and the Chi Square statistic, a non-parametric test of statistical significance. We included as significant, associations within each domain

of variables with Chi Squares having a probability of 0.10 or less. For the Phase II survey, analysis we calculated Goodman and Kruskal's Gamma, an ordinal measure of association, and the Chi Square statistic, a non-parametric test of statistical significance. We included as significant, associations within each domain of variables with Chi Squares having a probability of 0.05 or less.

In preparation for estimating a statistical model based on the multiple significant variables from within each of the four predictor domains to predict the dichotomous scenario score, we calculated a correlation matrix among the significant variables within the four domains using Spearman's Rho, an ordinal measure of correlation. The reason for doing this was to avoid multi-collinearity in the multiple variable models that could render them unstable and not interpretable. Those pairs of variables that were very highly correlated with each other (at 0.60 or more) were identified and reviewed, and a decision was made to not include one of the variables from each highly correlated pair of variables in the multiple variable model. The presumption was that the highly correlated variables would likely account for the same variation in the outcome.

3.6.3 Statistically Modeling RIO Preparedness/Readiness

Multiple-variable statistical modeling was performed using the SAS Logistic Regression procedure. To further search through the variables found to be significantly associated with the scenario score, we estimated four separate multiple-variable models, one for each set of significant variables in the four predictor domains. In each case, the overall models were significant and contained a mixture of statistically significant and non-significant variables. The significant variables in the model, regardless of their predictive domain, were selected to be included in the next step in the analysis. The next step was a modeling effort in which all of the significant variables from the separate domain models were included in a multiple variable analysis of the scenario scores across the domains from which the predictors came. At this point, the analytic approach, which has to this point been the same in Phases I and II, diverged.

As we mentioned earlier, there was considerable item non-response to the three scenario items in the Phase II web-based survey. Whereas in the Phase I interview survey the interviewers could usually get respondents to give answers, even if the respondents were not sure of their correctness, with the web-based survey, respondents to the survey often skipped the scenario items when they did not have ready answers. We did not score them as zeros because some certainly had good responses but did not want to spend the time or make the effort to spell out what they would have done in the scenarios. Because we did not want to limit our analysis findings only to the group represented by the scenario item respondents, we decided to investigate whether any of the significant variables to be included in the multiple variable analysis of the scenario scores across the domains were significantly related to responding to the three scenario items.

We cross-tabulated each of the variables to be included in the model with whether or not the survey respondent responded to the scenario items and calculated Chi-Square tests of significance. Several of the variables slated to be used in the multiple variable analysis of the scenario scores across the four domains were significantly related to whether or not they responded to the scenario items. Based on this analysis, we decided to perform further post-stratification adjustments to the analysis weights, adjusting them for the distributions of the predictor variables that were associated with responding to the scenario items (see Appendix D). In this way, with the adjustment made to correct for survey and scenario item non-response bias, we were on safer ground for concluding that our findings could be applied to the entire sample of RIOs, and not be limited to survey and scenario item respondents alone.

The final step in the analysis of both Phases I and II consisted of using SAS to estimate a logistic regression model containing the significant predictors from the four separate domain-specific models. The only difference in the procedures is that the Phase II model, because of potential bias from survey and item non-response, was run on weighted data, whereas the Phase I model was not. As with the domain-specific models, there were significant and non-significant variables in the across-domain model. To parse the model of non-significant variables that contributed little or nothing to explaining differences in scenario scores from the model, we re-estimated the logistic regression model, employing the backward elimination option. For the logistic regression models, we reported the Max-rescaled R_2 as well as the Wald Chi Square, degrees of freedom, and p-values for the overall model in addition to the odds-ratios and confidence intervals for the levels of categorical variables in the model.

4. PHASE I INTERVIEW SURVEY ANALYSIS RESULTS

This section of the report refers exclusively to analysis of Phase I of the RIO study. In addition to reporting the results of our analysis in this section, we review the distributions of the variables included in each of the conceptual domains (i.e., personal characteristics, experience, training, and organizational characteristics) that we have hypothesized will be associated with participant's preparedness/readiness to perform as the RIO. We also review the distribution of the total scenario score measure on which we have based our assessment of preparedness/readiness to perform as the RIO.

4.1 Descriptive Analysis of the Interview Data

As indicated above, we adopted an eclectic conceptual approach in this exploratory research effort to determine the important factors that contribute to or detract from RIOs being well prepared and ready to carry out the responsibilities of their role, as represented by their total scenario scores. We specify four domains from which we expect there to be variables related to an RIO's scenario scores. These domains include (1) a RIO's personal characteristics (e.g., field of professional training, self-identification as a researcher), (2) characteristics of the institution in which the RIO works (e.g., where the RIO is positioned in the organizational hierarchy, responsibilities assigned to or shared by the RIO, whether the institution requires RCR training), (3) training that the RIO received in preparation for the RIO role (e.g., attending ORI-sponsored workshops, being mentored by a former RIO), and (4) the RIO's actual experience performing in the role of RIO (e.g., conducting investigations, sequestering evidence). We measure multiple variables in each domain that we identified for inclusion in the survey in order to tap into a variety of dimensions that we thought could affect an individual's performance as RIO, as represented by his/her scenario scores. Table 4-2 includes the dichotomy created from the total scenario scores. This table is also divided into the four domains, with the variables included in each domain, their dichotomous percent distribution, and the number of observations available for the analysis.

Some examples of specific relationships we expected to identify from our theoretical approach include the following:

- RIOs who are researchers, have a natural science background, and are very highly educated will be more capable in the RIO role than less educated, non-natural scientist, and non-researcher RIOs.
- RIOs who are high in the corporate structure of their institution and closer to the President/CEO are expected to be more capable because of the demands associated with closeness to the highest levels of the organization.
- RIOs who have more formal training from ORI or mentoring by a former RIO in preparation for assuming the RIO role will be more prepared than RIOs who have not had this experience.

- RIOs who have more experience doing the things that RIOs are expected to do, will be more prepared than RIOs who have not had this experience.
- RIOs who are more tied into a network of RIOs will be better prepared than RIOs who are not tied to such a network.
- RIOs who have more contact with ORI staff will be better prepared than RIOs who have less ORI contact.
- RIOs whose responsibilities are more specialized to only performing in the RIO role, who receive more help available as RIOs, who have more security in the RIO position, and who have a greater measure of budgetary independence are expected to be associated with being a better prepared RIO than those who do not.

4.1.1 Titles of Persons Performing the RIO Role

As can be seen from Table 4-1, the vast majority of individuals who perform the RIO responsibilities (e.g., managing the resolution of research misconduct allegations) do not formally carry the title of RIO in their institution. We found that only 30.6% of the RIO participants actually carry the title of RIO, or one very close to it, when conducting their RIO responsibilities. The second most-common title reported for when an individual is acting in the RIO role is Vice President (18.8%), most typically of research or academic affairs. Other titles reported for when individuals are performing RIO functions are President or Chief Executive Officer (CEO) (11.8%), Provost (8.2%), Chancellor (7.1%), or Dean (7.1%). It is worth noting that fewer than half (42.3%) of the RIOs who reported having the title of RIO carry the title of Vice President when they are **not** carrying out RIO responsibilities.

Table 4-1. Distribution of Titles When Performing Responsibilities of the RIO

Titles Reported by RIOs	Number	Percent
Research/Scientific Integrity Officer	26	30.6
Vice President (Includes Assistant, Associate, and Executive Vice Presidents)	16	18.8
President or CEO	10	11.8
Provost (Includes Deputy, Assistant, and Associate Provosts)	7	8.2
Chancellor (Includes Vice and Deputy Chancellors)	6	7.1
Dean (Includes Assistant and Associate Deans)	6	7.1
Others	14	16.4
Total	85	100.0

4.1.2 RIO Responses to the Scenarios in the Interview Survey

We asked the interview study participants to demonstrate their skills and knowledge by telling the interviewer what they would do with respect to the three scenarios or situations. Knowing what to do in these situations is critical to optimal performance in the position of RIO. The situations represented include (1) sequestering evidence, (2) protecting

“whistleblowers” against retaliation, and (3) coordinating RIO responsibilities with those of the IRB. The extent to which the RIOs indicated the same actions in their response to the scenarios as the consultants’ responses was intended to serve as our measure of the RIOs’ preparedness/readiness to fulfill their responsibilities. The greater the concurrence with the expert consultants, the better we felt that the RIOs would be when they needed to act by demonstrating their preparedness/readiness.

4.1.2.1 Responses to Scenario 1

This scenario describes a graduate student who calls the RIO to allege that her advisor was attempting to publish data from her dissertation without crediting her and that he is misrepresenting her data as well; however, the student does not “formally” make an allegation of misconduct at that time. Two days later, the student calls the RIO again to say that she is prepared to make the allegation and has a willing witness to the alleged misconduct, but that the advisor is at that time in the laboratory destroying evidence, i.e., shredding films and printouts.

The expert consultants identified a total of 10 common actions as among the most important and appropriate ones for a RIO to take in response to Scenario 1. Table 4-2 presents the proportion of RIO responses in agreement with each of the 10 actions suggested by the consultants. It should be noted that neither the consultants nor the RIOs were provided any of the potential responses as prompts or options in any of the scenarios.

As can be seen from Table 4.2, the response given most frequently, by more than half of the RIOs (57.5%) who responded to Scenario 1, is that they would go immediately in person to the advisor’s lab to see what is going on. Almost half of the RIOs indicated that they would take the following actions: assert to the respondent the institution’s ownership of the data and then take possession of it (48.8%) or stop any on-going data destruction by the respondent (45.0%). Slightly less than a quarter of the RIOs (23.8%) indicated that they would inform institutional officials of the allegation and any actions that were taken, or inform the respondent of the allegation of research misconduct. Fewer than 1 of 10 RIOs said that they would seek to identify the data that are relevant to the misconduct allegation (7.5%) or ask if any data had been destroyed (6.3%). Only one RIO said he would explain the presumption of innocence to the respondent. No RIOs mentioned promising the respondent copies of the sequestered data so he could continue his work as little disturbed as possible or indicated that they would warn the respondent against retaliation.

Table 4-2. Distribution of RIO Survey Responses in Agreement with the Expert Consultants to Scenario 1 – Actions to Take When Sequestering Evidence

Action	Number	Percent
Go immediately in person to the lab to see what is going on.	46	57.5
Assert institution’s ownership of data and take possession of it.	39	48.8
Stop any on-going data destruction.	36	45.0
Inform institutional officials of allegation and actions taken.	19	23.8
Inform respondent of allegation of research misconduct.	19	23.8
Ascertain what data are relevant to the alleged research misconduct.	6	7.5
Ask if any data had been destroyed.	5	6.3
Explain to respondent about presumption of innocence (in best interest to cooperate fully and maintain confidentiality).	1	1.3
Promise respondent copies of all data sequestered.	0	0.0
Warn respondent against retaliation.	0	0.0

Table 4-3 presents the total number of RIO responses given that are in common with the consultants’ response list for Scenario 1. Fifteen percent of the RIOs had no responses that matched any of those given by the expert consultants. At the other end of the response continuum, only three RIOs (3.8%) gave more than four of the consultants’ responses. Nearly half of the RIOs (47.5%) mentioned one or two of the actions indicated by the expert consultants, and just 15.0% had four responses in common with the expert consultants.

Table 4-3. Number of RIO Responses in Common with Expert Consultants for Scenario 1

Number of RIO Responses in Common with Expert Consultant Responses	Number	Percent
None	12	15.0
One	14	17.5
Two	24	30.0
Three	15	18.8
Four	12	15.0
Five	2	2.5
Six	1	1.3

4.1.2.2 Responses to Scenario 2

The second scenario describes a situation in which the head of a laboratory (i.e., respondent) who drops in on an RIO runs into a laboratory technician (i.e., complainant) in

the hallway exiting from an appointment in the RIO's office. The complainant has previously told the RIO that she wants to remain anonymous because she fears what the respondent will do if he learns it is she who filed the research misconduct allegation. The complainant subsequently calls the RIO to report that the respondent saw her leaving the office and now strongly suspects that she is the complainant. The respondent has accused her of making the allegation, causing her to become ill and unable to work. She was especially disturbed because he followed her down the hall screaming at her as she tried to leave.

The expert consultants identified 11 response actions they would take that are important and appropriate for Scenario 2. Table 4-4 shows the distribution of responses provided by the RIOs to Scenario 2. There is not any activity mentioned by the expert consultants that as many as half or more of the RIOs indicated they would do. The expert consultant actions that are mentioned most often, but only by slightly more than 40 percent, are to remind the head of the laboratory about the institution's prohibition on retaliation against complainants and to work with the institution's administration to assure any measures put in place to protect the complainant are effective. Another action reported in common with the expert consults by approximately one-third of the RIOs is to immediately contact the head of the laboratory to ask whether the laboratory technician's account was accurate. Almost one-fourth of the RIOs said that they would contact the head of the laboratory and ask him not to draw any conclusions about the chance encounter with the laboratory technician in the hall outside the RIO's office, and consider moving the laboratory technician or the head of the laboratory to another work location. Nearly one of five RIOs indicated that precautions should have been taken to avoid such hallways encounters by having SOPs in place to clear way for witness, hold meetings in a different location, or use an alternate exit. One of ten or fewer RIOs mentioned: contacting the laboratory technician and telling her about what he told the head of the laboratory and instructing her to contact him if the encounter has any further repercussions; if witnesses verify the laboratory technician's story about the laboratory head's behavior, initiate institutional disciplinary action against the laboratory head; contact the laboratory technician and ask if there were witnesses to the laboratory head's behavior, and contact any witnesses to verify the laboratory technician's account and remind them of the institution's misconduct adjudication process, the need for confidentiality, and the policy on retaliation, while not revealing the nature of the allegation, No RIOs mentioned that they would have warned all of the parties against drop-in visits.

Table 4-4. Distribution of RIO Survey Responses in Agreement with the Expert Consultants for Scenario 2 – Actions to Take When In Receipt of a Complainant Report Regarding Threat of Retaliation by the Respondent

Action	Number	Percent
Remind the laboratory head about the institution’s prohibition on retaliation.	35	43.8
Work with the institutional administration to be sure that protections in place to protect the laboratory technician are working.	33	41.3
Immediately contact the head of the laboratory to ask whether the laboratory technician’s account was accurate.	28	35.0
Contact the head of the laboratory and ask him not to draw any conclusions about the chance encounter with the laboratory technician in the hall outside the RIO’s office.	19	23.8
Move the laboratory technician or the head of the laboratory to another location.	19	23.8
Have taken precautions to avoid such hallways encounters by having SOPs in place to clear way for witness, hold meetings in a different location, or use an alternate exit.	15	18.8
Contact the laboratory technician and tell her about what he told the head of the laboratory and instruct her to contact him if the encounter has any further repercussions.	8	10.0
If witnesses verify the laboratory technician’s story about the laboratory head’s behavior, initiate institutional disciplinary action against the laboratory head.	6	7.5
Contact the laboratory technician and ask if there were witnesses to the laboratory head’s behavior.	4	5.0
Contact any witnesses to verify the laboratory technician’s account and remind them of the institution’s misconduct adjudication process, the need for confidentiality, and the policy on retaliation, while not revealing the nature of the allegation.	2	2.5
Have warned all of the parties against “drop in” visits.	0	0.0

Table 4-5 presents the number of RIO responses given that correspond with any of the consultants’ responses for Scenario 2. As with Scenario 1, of the 11 potential actions identified by the consultants for Scenario 2, only one of the RIOs (1.3%) gave more than 8 actions in common with the expert consultants, with none reporting between 5 and 8. In addition, only 10 RIOs (12.5%) did not provide any responses in common with those of the consultants, and the same number reported 4 responses in common with the consultants. However, one-fifth of the RIOs mentioned one, and slightly more (22.5%) mentioned 3, and nearly one third (31.3%) gave 2 responses that correspond to actions reported by the expert consultants.

Table 4-5. Number of RIO Responses in Common with Expert Consultants for Scenario 2

Number of RIO Responses in Common with Expert Consultant Responses	Number	Percent
None	10	12.5
One	16	20.0
Two	25	31.3
Three	18	22.5
Four	10	12.5
Five	0	0.0
Six	0	0.0
Seven	0	0.0
Eight	0	0.0
Nine	1	1.3

4.1.2.3 Responses to Scenario 3

The final scenario describes the coordination and prioritization of responsibilities between the RIO and the institution's IRB regarding a number of protocol violations in a clinical trial. The violations involve allegations of backdating patient consent forms, ignoring protocol inclusion/exclusion criteria, and destruction of patient records associated with the clinical trial. The expert consultants identified five actions that they deemed appropriate to take under the circumstances described in Scenario 3 to prioritize the order in which they would handle the violations and to assign primary responsibility for acting on each of them. Table 4-6 presents the distribution of RIO responses corresponding to the five actions the expert consultants recommended be taken for Scenario 3.

Table 4-6 shows that nearly half of the RIOs (48.8%) would consider halting additional patient recruitment efforts, while nearly two of five (37.5%) would work with the IRB chair to decide who has jurisdiction over which of the presumed clinical trial infractions (back dating consents and destroying records). Just over one-fourth says they would work with the IRB chair and legal counsel to determine whether federal government oversight agencies should be informed of the alleged misconduct. Just over 15% (16.3%) indicate that they would take action to preserve the medical and other records of already enrolled patients, making copies as needed to assure their continued care. Surprisingly, only 15.0% state that they would work to determine the steps required to protect the health and safety of patients already enrolled in the trial.

Table 4-6. Distribution of RIO Survey Responses in Agreement with the Expert Consultants for Scenario 3 – Actions to Take When Necessary to Coordinate Responsibilities with IRB

Action	Number	Percent
Consider closing the trial to further patient recruitment.	39	48.8
Work with the IRB chair to decide who has jurisdiction over which of the presumed clinical trial infractions (back dating consents and destroying records).	30	37.5
Work with the IRB chair and discuss with institutional legal counsel whether any of the government watchdog agencies needed to be notified (FDA, OHRP, or ORI).	21	26.3
Take steps to preserve the medical and other records for patients already enrolled, making copies as needed to continue with care of those patients.	13	16.3
Determine what needs to be done to safeguard the health and safety of patients already enrolled in the trial.	12	15.0

Table 4-7 shows the number of RIO responses similar to the expert consultants’ five responses for Scenario 3. More than one in five RIOs do not specify taking any actions that correspond to the consultants’ responses. More than one third mention a single action mentioned by the expert consultants, and slightly more than one fourth mentions two of the same actions as the consultants. Just over 15% reports that they would perform three or four of the actions recommended by the expert consultants, and none of the RIOs respond with all five actions identified as appropriate by the consultants for the situation represented in Scenario 3.

Table 4-7. Number of RIO Responses in Common with Expert Consultants for Scenario 3

Number of RIO Responses in Common with Expert Consultant Responses	Number	Percent
None	18	22.2
One	28	34.6
Two	22	27.2
Three	9	11.1
Four	4	4.9
Five	0	0.0

4.1.2.4 Responses to All Three Scenarios Combined

Using these three scenarios, we gave the RIOs an opportunity to provide their most complete answers, suggesting what are the appropriate actions to take in these challenging, but not so unusual, situations for an RIO. Then, we compared their answers to the answers provided by the two expert consultants and gave credit to the RIOs when they responded with an answer that corresponded to one given by the expert consultants. Table 4-8 presents the total number of RIO and consultant responses given in common across the three scenarios.

Table 4-8. Total Number of RIO Responses in Common with Expert Consultants for All Three Scenarios Combined

Total Number of RIO Responses in Common with Expert Consultant Responses	Number	Percent
None	1	1.3
One	4	5.1
Two	2	2.5
Three	9	11.4
Four	12	15.2
Five	15	19.0
Six	8	10.1
Seven	8	10.1
Eight	7	8.9
Nine	3	3.8
Ten	8	10.1
Eleven	1	1.3
Twelve	0	0.0
Thirteen	0	0.0
Fourteen	0	0.0
Fifteen	1	1.3
Sixteen	0	0.0

The two expert consultants described a total of 26 common actions that they would both take in response to the situations represented by the three scenarios. As can be seen from Table 4-6, only one RIO (1.3%) who responded to all three scenarios did not recommend taking a single action that is in common with those mentioned by the expert consultants. Just slightly more than half of the RIOs (53.2%) identified between 1 and 5 of the same actions as the expert consultants, and approximately an equal number (45.6%) identified 6 to 15 actions in common with the expert consultants. At the highest end of the

continuum, only one of the RIOs (1.3%) provided as many as 15 actions in common with the expert consultants and only one other RIO gave more than 10 responses in common with the expert consultants. It should be noted that many of the RIOs gave answers that we did not credit because they were not mentioned as important or appropriate by the consultants.

It should be noted that for our further analysis, the distribution of total scenario scores has been dichotomized. It has been set as close to 50% as possible to maximize the variation in the variable available to be explained. As can be seen from Table 4-9, 45.6% of the RIOs is in the high scenario score group, with from 6 to 15 answers across the three scenarios in agreement with the two expert consultants.

Table 4-9. RIO Scenario Scores and Names and Distributions of Candidate Predictors of RIO Scenario Scores

Domain/Variable Name	Percent	Total N
<i>Total Score for the Three Scenarios</i>		
In High Scenario Score Group (6 to 15)	45.6	79
<i>RIO Characteristics</i>		
Self Identified as Researcher	59.5	79
Educational Degree Level:		
Has Ph.D.	51.9	79
Has M.D.	16.5	79
Has J.D.	13.9	79
Does Not Seek Research Support	16.5	79
In A Tenured Position	35.4	79
Extremely/Very Satisfied with Authority and Independence as RIO	69.2	78
Field of Study of Highest Degree:		
Natural Science	30.4	79
Social Science	25.3	79
Law	10.1	79
Medicine	17.7	79
Other	12.7	79
<i>Training/Preparation Received for RIO Role</i>		
Attended ORI Sponsored Training Sessions	48.1	79
Trained/Mentored By Incumbent RIO	16.5	79
Self-Taught from Materials Off of ORI Website	30.4	79
Talked with Other RIOs or ORI Staff	3.8	79
Did Nothing	27.9	79

Table 4-9. RIO Scenario Scores and Names and Distributions of Candidate Predictors of RIO Scenario Scores (continued)

Domain/Variable Name	Percent	Total N
Participated in Two or More Sources of Training	21.5	79
<i>Experience in RIO Role</i>		
Employed by Institution for More Than 2 Years	89.7	79
Been in RIO Role for More Than 2 Years	67.1	79
Has No Contact with RIOs at Other Institutions	59.7	77
Never Had to Sequester Evidence	49.4	79
Never Had Contact with ORI Staff	54.4	79
Never Had to Handle Research Misconduct Allegation	30.4	79
Never Had to Conduct a Research Misconduct (RM) Investigation	52.6	78
<i>Institutional Characteristics</i>		
RIO Has Other Administrative Duties	84.8	79
Institution Has A Policy Promoting RCR	82.3	79
Institution Requires Researchers to Participate in RCR	35.4	79
Institution Requires Annual researcher Certification of RM Policy Awareness	31.7	79
RIO Is Primary Person to Receive Allegations of Research Misconduct	78.5	79
RIO Has A Separate Operating RIO Budget	6.3	79
Institution Has No One Assisting RIO with Duties	25.3	79
Institution Has Reported RM Allegation to ORI in Past 5 Years	35.4	79
RIO Responsibilities at Institution Include:		
Informing Staff of What Constitutes Research Misconduct	79.8	79
Sequestering Evidence	80.8	78
Telling Key Officials about Allegations	87.2	78
Telling “Whistleblowers” of Risks They Face	84.6	78
Telling “Whistleblowers” What Protections Will Be Provided	72.2	79
Training Inquiry and Investigation Panels	88.5	78
No One Between RIO and CEO/Pres in Institutional Hierarchy	34.2	79

4.1.3 Candidate Predictors of Scenario Scores

From Table 4-9, it is clear from the **personal characteristics** of RIOs that more than two-thirds of RIOs are extremely or very satisfied with the authority and independence they have as RIOs. In addition, nearly 60% report that they consider themselves to be researchers now or did so at some time. Slightly more than one-third have the security of tenure as the RIO. More than half report having received a Ph.D. degree. About 30%

identify their major field of study to be natural science, and about a quarter report their field as being a social science. In light of this high level of research identification and training, it is not too surprising that only a small proportion of RIOs, about 16%, say they do not get involved in seeking research support.

The RIOs report having had little formal **training** or preparation for the RIO role in as can be seen from Table 4-9. Nearly 28% of RIOs report having done nothing to prepare themselves for the position. Only about 30% report using materials off of the ORI web-site to self-teach, and slightly fewer than half of them reported participation in any kind of ORI sponsored training, which would include workshops, conferences, and RIO boot camp. Very few (16%) report having been trained or mentored by their predecessor, and barely 4% say they were in extensive contact with RIOs at other institutions or with staff at ORI. Barely 22% of the interviewed RIOs reported participation in two or more training activities in preparation for being RIO.

In terms of RIO **experience** reported in Table 4-9, nearly 90% of the RIOs in the Phase I survey have been employed by their institution for more than 2 years, but only two-thirds report having been the RIO for more than 2 years. Almost 60% report they have never spoken to a RIO at another institution. With respect to how active they have been as RIOs, about 30% have never handled an allegation of research misconduct, nearly half have never had to sequester potential evidence, and slightly more than 50% have never conducted an investigation or been in contact with ORI staff. Overall, it appears as if RIOs have had relatively little experience and are not well integrated into the network of persons concerned with similar issues.

The final consideration in Table 4-9 is of the **institutional characteristics** of the setting in which the RIOs function and the responsibilities they assume as RIO or in other administrative capacities. Approximately 30% of the institutions require that researchers certify annually that they are aware of the institution's research misconduct policy. In more than 35% of the institutions, it is mandatory that their researchers participate in a Responsible Conduct in Research (RCR) course. However, more than 80% of the institutions have policies promoting RCR participation for their researchers. In more than 78% of the institutions, the person serving as RIO is the primary person receiving reports of research misconduct. Very few RIOs have separate RIO operating budgets (about 6%), but only a quarter of the RIOs do not have anyone to assist them with the work entailed by this position.

Nearly 85% of the RIOs report that they are responsible for other administrative duties besides those of RIO. Slightly more than one-third of RIOs report that there is no one between them and the institution's president or CEO in the institution's administrative hierarchy, and, from ORI administrative records, only about 35% of the RIOs' institutions

have reported any allegations of research misconduct made in their institutions during the previous 5 years (2003–2007).

Finally, while there is considerable variation in the distribution of organizational characteristics, there is considerable consistency in what responsibilities the institutions assign to their RIOs. The largest proportion make it the RIO's responsibility to train the inquiry panels and investigative committees (88%), and the smallest proportion has RIOs telling complainants ("whistleblowers") what protections the institution is prepared to offer them against retaliation (71%). The percentages for the remaining four responsibilities about which we inquired that the institutions regularly assigned to RIOs fell in between: informing the research staff of what constitutes research misconduct (80%), sequestering potential evidence (81%), telling complainants what risks they face (86%), and reporting allegations made to key institutional officials (85%).

4.2 Significant Associations with RIO Preparedness/Readiness

To identify the predictor variables that could most likely contribute to differences in scenario scores, we cross-tabulated dichotomies of each of those variables with whether the study participant scored in the top or bottom half of the distribution of scenario scores. The results of this analysis are contained in tables that follow. The objective of this analysis was to identify statistically significant variables to include as predictors in a multi-variable logistic regression analysis that would assist us in sifting through variables that are not unique in their impacts on RIO scenario scores. Such analysis allowed us to come up with a smaller set of predictors that were more independent in their association with the scenario score. Because of the small number of observations we have available in this exploratory study, we expected that only a few variables would show large enough differences to emerge as statistically significant. For this reason, we have set the criterion for significance relatively low at probability less than or equal to 0.10. We also decided to identify variables that do not reach significance, but come very close, at probability less than or equal to 0.15.

4.2.1 Variables from All Four Domains Associated with Preparedness/Readiness

Table 4-10 presents the eight variables that are significantly associated with a RIO's scenario score at the less than or equal to 0.10 probability level. In addition to the Chi Square value and its associated probability in the table, there is a Phi coefficient that measures the strength and direction of the relationship between each of the variables and a RIO's scenario score. Negative coefficients indicate that as the status of the RIO on the predictor variable changes from low to high, the RIO's status on the scenario score changes disproportionately from high to low. On the other hand, with positive coefficients, as the RIO's status on the variable changes from low to high, the RIO's status on the scenario score changes disproportionately from low to high as well. Thus, the three variables with the negative signs—self-identifying as a researcher, having a Ph.D., and serving as RIO in an

institution that requires researchers to participate in an RCR program—indicate that RIOs with those characteristics were more likely to have lower scenario scores (i.e., these variables detract from scoring in the top half of scenario scores when each of the predictors is considered alone). For the other five variables—being satisfied with one’s authority and independence, attending ORI-sponsored training for RIOs, being mentored or trained by prior RIO, having contact with RIOs at other institutions, being responsible for telling “whistleblowers” how the institution will protect them— the positive signs indicated that RIOs with those characteristics were more to have higher scenario scores, i.e., these variables contribute to RIOs scoring in the top half of scenario scores, again when each variable is considered by itself.

Table 4-10. Summary of Statistically Significant Predictors of RIO Scenario Scores

Variable Name	DF	Chi-Square	P-Value	Phi
RIO Self-Identified as Researcher	1	6.22	0.0127	- 0.28
RIO Has Ph.D. Degree	1	2.77	0.0958	- 0.19
RIO Is Satisfied with Authority and Independence	1	5.53	0.0187	+0.27
Institution Requires Researchers to Participate in RCR Program	1	7.40	0.0065	- 0.31
RIO Responsibilities Include Telling Whistleblowers What Will be Done to Protect Them	1	4.12	0.0425	+0.23
RIO Attended ORI Sponsored Training for RIOs	1	2.77	0.0958	+0.19
RIO Worked with/Was Mentored by Previous RIO	1	6.18	0.0130	+0.28
RIO Has Contact with RIOs at Other Institutions	1	4.41	0.0358	+0.24

Another four variables come close to reaching statistical significance, with a probability slightly greater than 0.10 but less than or equal to 0.15. These variables are presented in Table 4-11. While not statistically significant, the direction of the association suggests that all four of these variables—having administrative duties besides being RIO, being responsible for sequestering evidence, telling “whistleblowers” of the risks they face, and training members of the review and investigation panels—contribute to RIOs having scenario scores that are in the top half of the distribution.

Table 4-11. Summary of Near Statistically Significant Predictors of RIO Scenario Scores

Variable Name	DF	Chi-Square	P-Value	Phi
RIO Has Other Administrative Duties	1	2.41	0.1203	+0.17
RIO Responsibilities Include Sequestering Evidence	1	2.49	0.1147	+0.18
RIO Responsibilities Include Telling “Whistleblowers” of Risks They Face	1	2.26	0.1324	+0.17
RIO Responsibilities Include Training Review and Investigation Panels	1	2.11	0.1463	+0.16

4.2.2 Multiple Variable Analysis of RIO Preparedness/Readiness

In the initial logistic regression model to predict high RIO scenario scores that we estimated, we included as predictors the eight statistically significant variables from the tabulations with the scenario scores presented in Table 4-10. These variables included three variables from the RIO characteristics domain, two from the institutional characteristics domain, two from the training for RIO domain, and one from the RIO experience domain. We estimated the full eight-variable model, and then on a stepwise basis eliminated one variable at a time based on its level of non-significance. We re-estimated the model until there were no longer any non-significant variables left. The results of the final estimated model containing only three of the original eight variables are presented in Table 4-12.

Table 4-12. Summary of Multiple Variable Logistic Regression Model of RIO Scenario Scores

Variable Name	Chi-Square	DF	P-Value	Odds-Ratio	95% Confidence Interval	
RIO Self-Identified as Researcher	8.2868	1	0.0040	0.227	0.083	0.623
RIO’s Institution Requires Researchers to Participate in an RCR Program	7.0258	1	0.0080	0.222	0.073	0.675
RIO Responsibilities Include Telling Whistleblowers What Will Be Done to Protect Them	10.7320	1	0.0011	5.188	1.937	13.893

Chi Sq = 21.4348, df = 3, P-Value < 0.0001, Max-rescaled R^2 = 0.3277

The three significant variables that constitute the final model represent one measure from the RIO characteristics domain and two from the institutional characteristics domain, but there are no variables representing the RIO training and experience domains. The overall three variable model is statistically significant, with a Max-rescaled R^2 equal to nearly 0.33. This indicates that the three variables together account for approximately 33% of the variation in the scenario scores. It was unexpected that only one of the significant variables would be associated with higher RIO scenario scores. RIOs whose responsibilities included telling complainants just what exactly the institution would do to protect them from retaliation by the respondent had more than five (5.188) times the odds of scoring high on the scenario score as RIOs who did not have this particular responsibility. It is worth noting that 72% of the RIOs interviewed said that this was among their responsibilities. This is among the more difficult aspects of a RIO's responsibilities, so it is not surprising that those RIOs who are aware of their charge to do it by their institutions are more likely to score higher on the scenarios.

What was surprising, however, is that the other two significant variables—whether a RIO self-identifies as being or having been a researcher and whether the RIO's institution requires all researchers to participate in an RCR course—both detract from RIOs scoring high on the scenario score. RIOs who self-identify as researchers and those whose institution requires researcher participation in an RCR course had 78% lower odds of scoring high on the scenario score as RIOs who did not identify as researchers or work in institutions that required RCR participation. Fifty-nine percent of the RIOs said they either currently or formerly considered themselves to be researchers. We had expected that RIOs who were researchers would have a better understanding and appreciation of handling RIO responsibilities with investigations of the research process than those who did not consider themselves researchers. We clearly overestimated the importance of having a research background to being a successful RIO and underestimated the importance of having a more interpersonal, juridical, or administrative orientations in this regard. This might help explain why identifying as a researcher seems to detract from scoring high on the scenarios.

Something similar may be operating with regard to working in an institutional environment where RCR training is required for all researchers. It is notable that, while 82% of the study participants work in institutions where RCR participation is encouraged for researchers, only 35% indicate that researcher participation in RCR is required. We had expected that institutions requiring RCR participation to be sure that their researchers are well prepared to have been more likely to require that their RIOs also be well prepared. However, our analysis suggests that RIOs in institutions requiring RCR are not as well prepared as those in institutions where RCR is not required. It may be that the high performance expectations for researchers in such institutions by requiring RCR is assumed to lower the pressure on RIOs to be as well prepared as they should because the RCR course acts to reduce the likelihood of research misconduct occurring.

5. PHASE II WEB-BASED SURVEY ANALYSIS RESULTS

This section of the report presents results from RTI's analysis of the Phase II, web-based survey component of the RIO study. In this section, we also review the distributions of the variables included in each of the conceptual areas (i.e., personal characteristics, experience, training, and organizational characteristics) that we hypothesized would be associated with preparedness/readiness to perform as the RIO. In addition, we review the distribution of the total scenario score measure on which we based our assessment of preparedness/readiness to perform as the RIO.

5.1 Descriptive Results from the Web-Based Survey of RIOs

As indicated earlier, the RIO study was undertaken because very little is known about the personal and background characteristics, experience, and training of RIOs or the nature of the administrative and institutional structure within which they function. Even less is known about which, if any, of these factors are associated with (i.e., either contributing to or detracting from) an individual's preparedness/readiness to perform competently in the RIO role to implement the policies and procedures put in place by institutions for receiving and resolving allegations of research misconduct.

In the sections that follow, we present the analysis results from the Phase II, web-based survey conducted with RIOs from U.S. institutions that filed the required Annual Report on Possible Research Misconduct with ORI for 2005/2006. While we solicited the RIOs of all 1,099 of these institutions to participate in the Phase II survey, only 651 (59.2%) participated. So as to represent the entire Phase II sample of 1,099 RIOs, RTI weighted the results presented in the following sections to compensate for survey non-response. Note that an unweighted set of basic respondent tabulations is included in Appendix F. Nonetheless, the total number reported from measure to measure or section to section in this report will not always be consistent due to the failure of respondents to respond to all of the items included in the survey. This is particularly true of the scenario section of the survey, where we could only include those 369 Phase II participants (56.7%) who responded to all three of the scenarios in our analysis. To compensate for the item non-response for the scenario score variable, however, we further adjusted the weights for use in our modeling analysis.

5.1.1 Personal Characteristics of RIOs

From the Phase II survey, it is clear that RIOs do not constitute a homogeneous group. To get a better picture of their characteristics, we asked the RIOs a number of questions about their seniority at their institutions; involvement with research; educational level; disciplinary background; and assessment of satisfaction with the role they play as RIOs. The distributions of these personal and background characteristics are presented in Table 5-1.

Table 5-1. Distributions of RIO’s Personal and Background Characteristics

Characteristic	Category/ Level	Weighted Number	Weighted Percent
Years Employed at the Institution			
	0 – 2 Years	118	11.3
	>2 – 10 Years	356	34.2
	>10 – 20 Years	204	19.6
	> 20 Years	364	35.0
Has Tenured Position			
	Yes	372	35.6
	No	355	34.0
	Not Available	317	30.4
Involvement Seeking Research Funding			
	Very Involved	503	46.5
	Somewhat, Slightly, or Not at All Involved	579	53.5
Identify as Researcher Primarily			
	Yes, Currently	193	18.6
	Yes, Formerly	312	30.1
	No, Never	532	51.3
Number of Times Research Grant PI			
	Never	614	59.6
	1 – 5 Times	147	15.3
	6 – 10 Times	131	12.7
	11+ Times	139	13.4
Advanced Degrees Held			
	Ph.D.	589	53.6
	M.D.	123	11.2
	J.D.	61	5.6
	Other Doctorate	43	4.0
	No Doctoral Degree	334	30.4

Table 5-1. Distributions of RIO’s Personal and Background Characteristics (continued)

Characteristic	Category/ Level	Weighted Number	Weighted Percent
Fields of Study/Disciplines Represented			
	Health – Medicine, Dentistry, Pharmacy, Public Health, Nursing, Epidemiology, Veterinary Medicine	174	17.0
	Law	53	5.2
	Social Science, Psychology, Social Work	152	14.8
	Science, Math, Statistics, Engineering	349	34.0
	Liberal Arts, Education, Fine Arts, Theology	146	14.2
	Business, Administration	152	14.8
Satisfied with Authority and Independence as RIO			
	Extremely Satisfied	269	27.9
	Very Satisfied	315	32.7
	Satisfied or Not Satisfied	378	39.3
Had Concerns that Research Misconduct Was Not Brought to RIO’s Attention			
	Yes	138	14.1
	No	840	85.9
Aware of Mishandled Allegations at Institution in the Past Five Years			
	Yes	29	3.0
	No	958	97.0

RIOs are very often long-time employees of an institution. More than a third of the RIOs have been employed at their current institution for more than 20 years, with some employed for as long as 50 years. Barely more than 10% are new employees (i.e., employed at the institution for 2 years or less). With regard to having job security, however, almost one-third (30.4%) reported being in organizations or positions for which there is no tenure available. Of the remaining two-thirds, approximately half have achieved tenure (35.6%).

Nearly half of the RIOs indicated that they are very actively involved in seeking out research funding. In fact, nearly one-fifth currently identify themselves as researchers,

while nearly one-third say that, at some time in the past, they considered themselves to be researchers. As a further indicator of how involved the RIOs have been in conducting research, we asked them how often they have been the principal investigator (PI) on a grant award. While an average of nearly three of five RIOs have never been PI on a research grant, more than one-quarter report having been a PI on five or more grants.

More than two-thirds of RIOs report having doctoral degrees of some kind, and more than half of them report having Ph.D.s. Slightly more than 10% of RIOs report having an M.D.; and 2.8% report having both of these degrees. Just 5.6% of RIOs report having a J.D. degree, but another 4.0% report having some other kind of doctoral degree.

In addition, while RIOs are extremely highly educated, there is considerable heterogeneity in the fields of study and disciplines represented in the ranks of RIOs. More than one-third report being from the natural or basic sciences, and an additional 17% report being trained in the health professions. Just under 15% each report their disciplines as business or administration; social science, psychology, or social work; and liberal arts, education, fine arts, or theology. The smallest group (only 5.2%) reports having training in law.

We asked the RIOs several questions to get a sense of how positively they feel about the RIO position at their institution. In particular, we asked how satisfied they were with the authority and independence they exercised. Almost one-third indicate that they are very satisfied and nearly 28% are extremely satisfied, while more than 35% respond that they are merely satisfied. Only 3.3% say they are not satisfied. To get a sense of whether the RIOs felt that things were working as they should be, more than 14% indicate that they have concerns that research misconduct has occurred at their institution and has not come to the attention of the RIO. On the other hand, only 3% say they are aware of allegations of research misconduct being mishandled at their institution in the previous 5 years.

5.1.2 Training or Other Qualifications for Becoming a RIO

The RIOs were asked to indicate from a drop-down menu which, if any, of the available types of training they had completed, or to indicate other qualifications they possessed as preparation for their assumption of the position of RIO. In addition to selecting things from the drop-down menu, the RIOs could specify other types of preparation they had that they considered appropriate training to be a RIO and which we subsequently coded and included in the data. The RIOs could select from the menu or write in up to five activities or experiences that they considered preparation apropos to assuming the RIO role.

Table 5-2 presents the numbers of RIOs who indicate they had each of the types of preparation to be RIO, or no formal training for the position at all. To make it easier to assess the kinds of activities performed in preparation, we have arranged the activities in the table in blocks according to what we presume to be their potential relevance or

Table 5–2. Types of Training and Other Qualifications Reported by RIOs as Preparing Them for Becoming Their Institution’s RIO

Type of Training Activities Reported as Basis for RIO Preparation	Weighted Number	Weighted Percent
No Formal Training	57	5.6
Activities Likely to Be of Great Direct Relevance		
Attended One or Two ORI Research Integrity Conferences	140	13.6
Attended One or Two ORI Research Integrity Workshops	59	5.7
Mentored by the Former RIO	53	5.1
Served as RIO or Compliance Officer at Another Institution	38	3.7
Attended ORI Boot Camp	30	2.9
Attended Three or More ORI Research Integrity Conferences	28	2.7
Learned by Working as an Assistant to the Former RIO	6	0.6
Attended Three or More ORI Research Integrity Workshops	5	0.6
Activities Likely to Be of Medium Direct Relevance		
Self-taught from Materials on the ORI Web Site	365	35.3
Wrote or Helped to Write the Institution’s RM Policy and Procedures	334	32.3
Had Experience Directing Misconduct Inquiries or Investigations	233	22.5
Had Experience as a Member of a RM Inquiry Investigation Committee	203	19.7
Participated in the Institution’s Responsible Conduct of Research Program	82	8.0
Viewed ORI DVD on the Responsibilities of the RIO	54	5.3
Had Extended Contact with RIOs at Other Institutions	22	2.1
Had Extended Contact with ORI Staff	15	1.4
Attended Workshops/Conferences on RM Sponsored by Related Associations (e.g., NCURA, SRA, NSPAA)	14	1.4
Learned through on the Job Training	13	1.3
Have Written Articles or Book Chapters on Research Misconduct	13	1.2
Worked Closely with the Institution’s General Counsel	2	0.2
Activities Likely to Be of Less or Unknown Direct Relevance		
Active Researcher for 10 or More Years	508	49.2
Had Training or Experience in Human Subjects or IRB Issues	483	46.8
Had Experience or Training as a Research Administrator	446	43.2
Had Training or Experience in Ethics	278	27.0
Had Legal Training or Experience	72	6.9

contribution to an individual’s specific preparation to perform in the RIO role. Slightly more than 1 of 20 RIOs (5.6%) indicates that they have no formal training or other qualifications to perform the responsibilities of a RIO. Further, it is clear from Table 5-2 that RIOs are

more likely to report activities that focus on more general integrity issues, and thus less likely to contribute specifically to what a RIO must be able to understand and do to be qualified and ready to fill the RIO position.

We created a count for each respondent to indicate the number of different activities RIOs report participating in as preparation or training for the RIO role by summing the number of activities they report as their training or qualifications, without regard to how directly relevant we believed the activity is to performing as a RIO. The distribution of this count is presented in Table 5-3 and suggests that while 1 in 20 (5.6%) of the RIOs have no training or qualifications, nearly three-quarters (72.4%) report three or more types of training or qualifications for being RIO.

Table 5-3. Number of Training and Other Qualifications Reported by RIOs as Preparing Them for Becoming Their Institution’s RIO

Number of Training Activities Performed or Qualifications Achieved in Preparation to Be RIO	Weighted Number	Weighted Percent
None	57	5.6
One	103	10.0
Two	124	12.0
Three	204	19.8
Four	187	18.1
Five	357	34.5
Total	1,033	100.0

However, there is quite a different picture presented when the qualifications we believe to be of less or unknown relevance to performing RIO responsibilities are removed from the count of activities, as shown in Table 5-4. When the count includes only those training activities or other qualifications that have medium or great likelihood to contribute to RIO readiness, nearly one of five (18.9%) have no training or qualifications and only one-fourth (24.5%) report having as many as three or more qualifications that we believe are at least of medium direct relevance to performing as a RIO.

Table 5-4. Number of Training and Other Qualifications of Great and Medium Relevance Reported by RIOs as Preparing Them for Becoming Their Institution’s RIO

Number of Training Activities or Qualifications of Great and Medium Relevance Reported in Preparation to Be RIO (Excludes Those Believed to Be of Less or Unknown Direct Relevance)	Weighted Number	Weighted Percent
None	195	18.9
One	281	27.2
Two	304	29.4
Three	191	18.5
Four	60	5.8
Five	2	0.2
Total	1,033	100.0

5.1.3 Research Misconduct-Related Experiences of RIOs

We expect that the amount of experience that RIOs have had performing activities commonly associated with resolving allegations of research misconduct would contribute to how well prepared they are at the time to carry out their designated RIO responsibilities. Table 5-5 presents the distributions of 10 measures about which we collected information that reflects different aspects of the RIOs' experience.

Table 5-5. Distribution of Measures of RIO Activity-Related Experience

Experience Measure	Weighted Number	Weighted Percent
Years Involved with Research Misconduct Issues		
0 – 2 Years	287	27.5
>2 – 5 Years	304	29.1
>5 – 10 Years	262	25.1
>10 – 37 Years	190	18.3
Years Serving as RIO at This Institution		
0 – 2 Years	361	34.7
>2 – 5 Years	317	30.4
>5 – 10 Years	217	20.9
>10 – 37 Years	146	14.1
Involved with Research Misconduct Issues at Another Institution		
Yes	214	20.5
No	831	79.5
Number of Research Misconduct Allegations Handled as RIO at This Institution		
None	645	63.0
One	138	13.5
Two or Three	142	13.9
Four to Forty	99	9.7
Number of Research Misconduct Inquiries Overseen as RIO at this Institution		
None	662	64.8
One	160	15.7
Two or Three	136	13.3
Four to Thirty	64	6.2
Number of Research Misconduct Investigations Managed as RIO at this Institution		
None	749	74.6
One	165	16.5
Two or Three	35	3.5
Four to Twenty	55	5.5

Table 5-5. Distribution of Measures of RIO Activity-Related Experience (continued)

Experience Measure	Weighted Number	Weighted Percent
Number of Research Misconduct Allegations Handled as RIO at This Institution Involving U.S.P.H. S. Funding		
None	774	85.8
One	96	10.6
Two to Fifteen	32	3.6
Number of Times Has Conferred with a RIO at Another Institution		
None	757	74.0
One	117	11.4
Two or Three	94	9.2
Four to Twenty-Five	55	5.4
Number of Different RIOs Has Conferred with at Other Institutions		
None	756	74.0
One or Two	217	21.3
Three to Fifteen	49	4.8
Number of Times Has Conferred Off the Record or About Hypothetical Research Misconduct Cases with a Federal Oversight Agency Like ORI		
None	767	75.0
One	124	12.1
Two or Three	93	9.1
Four to One Hundred	39	3.8

As can be seen in Table 5-5, only slightly more than one-fourth of RIOs (27.5%) report having been involved with issues related to research misconduct for 2 years or less. A slightly greater number report such involvement for between 2 and 5 years (29.1%), and considerably more (44.3%) state they have been involved from more than 5 years to as many as 37 years. It appears from the table that for some RIOs, involvement with issues of research misconduct antedates their becoming the RIO at their current institution. As compared to the amount of time they have been involved with research misconduct issues, RIOs have spent less time as RIO at their current institutions. More than one-third (34.7%) report having been RIO at their current institution for 2 years or less, and only 35% have been the RIO for more than 5 years. This suggests that although some of the participants may have become involved with the issues earlier in their careers at the institution, some may have been recruited from other institutions where they had experience working with issues related to research misconduct. Approximately one of five RIOs (20.5%) report being

involved with these kinds of issues at another institution before they joined their current organization.

Despite not being new to the institution and having had some experience with the issues associated with research misconduct, nearly two-thirds of the RIOs (63.0%) report never having to deal with an allegation of research misconduct in their current institution. Only about one of ten RIOs (9.7%) indicate that they had handled as many as four or more research misconduct allegations in their current institution, with slightly more than one-quarter (27.4%) having dealt with from one to three misconduct allegations. The number never having handled allegations involving PHS-funded research is even higher, nearly seven-eighths of the RIOs (85.8%).

As might be expected given the RIOs' low level of involvement with handling allegations, their involvement with oversight of inquiries into research misconduct and their management of investigations is even lower. Nearly two-thirds of the RIOs(64.8%) have never overseen an inquiry, and nearly three-quarters (74.6%) have never managed an investigation. In light of such a small workload handling allegations and their associated activities, it is not surprising that only about one-fourth of RIOs (26.1%) report interacting with RIOs at other institutions, or that fewer than 1 of 20 (4.8%) report conferring with more than 2 different RIOs. Much the same is true of having conferred with someone off the record or inquired about a hypothetical research misconduct case at a federal oversight agency, such as ORI. Seventy-five percent of RIOs report never having done so, and only a few (3.8%) indicate they have done so more than 3 times.

5.1.4 RIO's Title, Responsibilities, and Organizational Characteristics

We believe that the actual professional title of a person assigned to the RIO role may have some institutional importance because it can assist a potential complainant or "whistleblower" in identifying to whom they should report their allegations of research misconduct. In addition, placement in the organization's hierarchy may provide a clue to how much importance the institution associates with the RIO role. For this reason, we asked the RIOs to tell us what their title is when they are not performing RIO responsibilities, and we also asked them what their title is when they are performing in their role as RIO. The distribution of their titles when they are acting as the RIO is presented in Table 5-6. This table demonstrates that there is little consistency in what RIOs are actually called in their institutions, even when they are clearly specified to be performing their RIO responsibilities of receiving and resolving allegations of research misconduct.

Table 5-6. Distribution of Titles Used When Performing Duties Assigned to the Person We Refer to as the RIO

Title or Position	Weighted Number	Weighted Percent
Vice President (includes Assistant, Associate, Senior, and Executive)	241	22.6
Research/Scientific Integrity Officer (RIO)	143	13.4
Office, Center, or Program Director	131	12.3
Dean (includes Assistant and Associate)	94	8.8
Provost (includes Vice, Assistant, and Associate)	74	7.0
Compliance Officer	54	5.1
President or Chief Executive Officer	45	4.2
Professor (includes Assistant and Associate)	20	1.9
Chancellor (includes Assistant and Vice)	17	1.6
Department Chair or Head	17	1.6
General Counsel (includes Assistant and Associate)	5	0.5
Miscellaneous Administrative Titles (includes CFO, COO, CSO, CAO, CoS, Administrator, etc.)	226	21.2

As can be seen from Table 5-6, the institutional title of Vice President, including assistant, associate, senior, and executive Vice President, is the most frequently used title (22.6%) for institutional personnel when they are performing the responsibilities attributed to RIOs. Most often, these individuals are serving as VPs for Research or Academic Affairs. The Research Integrity Officer is only the second most often used title for personnel (13.4%) when performing RIO responsibilities, but not by much. The third most often reported title is Center, Program, or Office Director, often of Sponsored Programs, Ethics, or Research (12.3%). The title of Dean (including assistant and associate) is the fourth (8.8%) most frequently given title for the person carrying out the RIO responsibilities. The fifth most frequently cited (7.0%) title used while performing as a RIO is Provost (including vice, assistant, and associate). Compliance Officer (5.1%), a title that implies broader responsibilities than a RIO, which typically includes those of the RIO along with other responsibilities, is the sixth most frequently given title. These titles for the RIO are followed by President or Chief Executive Officer, Professor (of all levels), Chancellor (including vice and assistant), Department Chairperson, and General Counsel (including Assistant and Associate). A very large percent of the RIOs (21.6%) that carry some other less frequently reported administrative title, including Administrator, Chief Financial Officer, Chief Operating Officer, Chief of Staff, etc., have been grouped together in Table 5-6. It is worth noting that of the 143 RIOs who report carrying the title of RIO when performing the RIO responsibilities, only 24 (16.8%) report that they still use the RIO title when they are not

performing those responsibilities. Among the 119 RIOs who have other titles when they were not performing RIO responsibilities, the largest single group (26 or 21.8%) have the title of Vice President (including assistant, associate, senior, and executive).

In addition to their title, there are other organizational characteristics and administrative responsibilities that can distinguish RIOs and potentially affect their role performance. Table 5-7 contains the distributions of characteristics of the organization associated with the position of RIO at the institution.

It is clear from Table 5-7 that, according to the vast majority of RIOs (80.5%), their institutions specify in the institution's policy and procedures manual the person who is responsible for handling research misconduct allegations by title. Surprisingly, 8.1% do not know whether the title of the person responsible for dealing with research misconduct is mentioned in the manual. Almost exactly half of the RIOs (49.0%) reports that they have a written job description. Slightly fewer than half of the RIOs (48.3%) indicates that they have someone to assist them in carrying out their RIO duties. The persons mentioned typically provide clerical assistance, but also include administrative staff, such as the institution's legal counsel.

To assess how high in the institution's structure the individuals serving as RIOs are placed, we asked how many persons there are between them and the president or CEO of the institution. Nearly two of five RIOs (39.3%) report that there is no one between them and the president or CEO, suggesting that they report directly to the top level of management. In a very small number of cases, it was reported that the RIO is the president or CEO. Slightly more participants (42.4%) report having a single person between them and top management of the institution, while nearly one of five (18.3%) report being further away (by from two to six people) from reporting directly to the president or CEO.

Thirty-five percent of the RIOs indicates that they work in an institution that requires its researchers to participate in an RCR course to promote research integrity. Even more (47.0%) work at an institution that offers such a course, but does not require all researchers to take it. About one in five (18.0%) reports that their institutions do not offer such a course. We also asked the RIOs whether their institutions require researchers to sign a document indicating that they are aware of the institution's research misconduct policy. More than half (62.1%) say that they do not have such a requirement at their institution, while one-fourth (26.3%) do, and slightly more than 1 in 10 (11.6%) do not know whether their institutions have such a requirement.

Table 5-7. Distribution of Organizational Characteristics of RIOs' Institution

Organizational Characteristic	Category/Level	Weighted Number	Weighted Percent
Policy and Procedures Manual Identifies The Title of the Person Who Handles Research Misconduct Allegations			
	Yes	863	80.5
	No	122	11.4
	Don't Know	87	8.1
RIO Has a Written Job Description			
	Yes	522	49.0
	No	544	51.0
RIO Has Someone to Assist in Performing Duties			
	None	513	48.3
	One Person	287	27.0
	Two to Twelve Persons	262	24.7
Number of Persons between RIO and President/CEO			
	None	415	39.3
	One	448	42.4
	Two to Six	194	18.3
Does Institution Require or Offer Course on Responsible Conduct of Research (RCR)			
	Requires	340	35.0
	Offers	457	47.0
	Does Not Offer	175	18.0
Does the Institution Require Researchers to Sign They Are Aware of Research Misconduct Policy			
	Yes	230	26.3
	No	543	62.1
	Don't Know	101	11.6
Type of Institution			
	Higher Education	646	58.8
	Research Institute	243	22.1
	Independent Hospital	210	19.1
One of Top 100 NIH Funded Research Grantees			
	Yes	43	4.0
	No	1,055	96.0
Number of Research Misconduct Allegations Reported to ORI (2003 - 2007)			
	None	929	84.6
	One to Sixteen	170	15.4

Nearly 60% of the RIOs (58.8%) are employees of institutions of higher education. The rest are fairly evenly divided between research institutes (22.1%) and independent hospitals (19.1%). Four percent of the institutions represented in the survey number among the top 100 NIH-funded research grantees in 2005, and 15.4% report having at least one allegation of research misconduct reported to ORI in the previous 5 years.

We asked RIOs what specific activities they have been assigned responsibility to perform as the RIO by their institutions. In addition to variation in what tasks they have been given responsibility to perform, there is considerable variation across institutions with respect to whether the responsibility is theirs' alone or is shared with someone else. The distribution of responsibilities across 10 activities frequently performed by RIOs is presented in Table 5-8.

Table 5-8 shows that more than 70.8% of RIOs are responsible for sequestering evidence, but 93.3% have responsibility for reporting any allegations that have been made and any actions that have been taken to key institutional officials, such as the president or CEO. Of the eight remaining responsibilities, only two come close to being the sole responsibility of almost half of the RIOs—informing researchers of the institution's research misconduct policy (45.3%) and informing complainants of their vulnerability from making an allegation of research misconduct (42.9%). These two are responsibilities that Federal regulations indicate ought to be performed in every institution and presumably performed by the RIO. It is surprising that fewer than one-third of the RIOs (30.4%) indicate that they alone are the person designated to receive allegations of research misconduct, and nearly half (49.3%) said they share the responsibility of receiving allegations. It is also somewhat surprising that only 39.9% of RIOs indicate that they are solely responsible for assessing the allegation and deciding whether or not there should be an inquiry conducted, while 47.9% of RIOs say they share this responsibility. It is perfectly understandable that the activity for which RIOs report having the greatest shared (73.0%) and least sole responsibility (17.2%) is for handling allegations of misconduct that go beyond research misconduct.

Among the research misconduct activities that RIOs have the least responsibility for (alone or shared) is selecting the inquiry panel members (25.1%); selecting the investigation committee members (24.6%), likely because so many are drawn from standing institutional committees; and training the members of inquiry or investigation panels/committees (24.4%). Counting the number of sole and shared responsibilities across the 10 identified in the survey, there are very few for which RIOs have no responsibility, either alone or shared. Table 5-8 shows that nearly 9 of 10 RIOs (89.9%) have or share responsibility for six or more of these research misconduct activities, and nearly 4 of 10 (39.6%) have or share responsibility for all 10 of these activities.

Table 5-8. Distribution of Specific Institutional Responsibilities of RIOs

Specific RIO Responsibility	Category/Level	Weighted Number	Weighted Percent
Responsible for Sequestering Evidence			
	Yes	705	70.8
	No	291	29.2
Responsible for Informing Key Officials of Allegations/Actions			
	Yes	924	93.3
	No	66	6.7
Responsible for Informing Researchers about Institution’s Research Misconduct Policy			
	Yes	456	45.3
	Yes, Shared	365	36.2
	No	187	18.5
Primary Person Responsible for Receiving Allegations of Research Misconduct			
	Yes	308	30.4
	Yes, Shared	499	49.3
	No	207	20.4
Responsible for Handling Allegations of More than Research Misconduct			
	Yes	171	17.2
	Yes, Shared	724	73.0
	No	97	9.8
Responsible for Informing Complainants of Their Vulnerability from Making an Allegation			
	Yes	426	42.9
	Yes, Shared	389	39.2
	No	178	17.9
Responsible for Deciding Whether There Will Be an Inquiry			
	Yes	396	39.9
	Yes, Shared	476	47.9
	No	121	12.2
Responsible for Selecting Members of Inquiry Panel			
	Yes	295	29.9
	Yes, Shared	443	45.0
	No	247	25.1
Responsible for Selecting Members of Investigation Committee			
	Yes	278	28.5
	Yes, Shared	458	46.9
	No	240	24.6

Table 5-8. Distribution of Specific Institutional Responsibilities of RIOs (continued)

Specific RIO Responsibility	Category/Level	Weighted Number	Weighted Percent
Responsible for Training the Inquiry and Investigation Panel/Committee			
	Yes	386	39.6
	Yes, Shared	350	36.0
	No	237	24.4
Number of Sole or Shared RIO Responsibilities			
	None	12	1.2
	One	10	1.0
	Two	20	2.1
	Three	30	3.1
	Four	22	2.4
	Five	45	4.8
	Six	47	5.0
	Seven	77	8.1
	Eight	106	11.1
	Nine	207	21.7
	Ten	376	39.6

While increasing the number of RIO-related responsibilities can enhance the performance of RIOs, increasing the number of non-RIO related administrative responsibilities borne alone or shared in by RIOs can serve to distract their attention and dissipate their efforts away from their primary responsibilities as RIO. The survey asked RIOs questions about what kinds of additional non-RIO administrative responsibilities they handle; this information is presented in Table 5-9.

In only one of the six additional administrative areas does a majority of RIOs (51.5%) report having sole responsibility, and that area is for human subject's protection. Adding in the 28.6% of RIOs who share responsibility for human subject's protection makes this administrative area the largest involving RIOs (80.0%) outside of handling allegations of research misconduct. Grants management and financial conflicts of interest are the second and third most common areas in which RIOs have sole or shared administrative responsibility (72.4 and 72.9%, respectively). RIOs have the least sole or shared responsibility in the areas of animal protection (59.6%), hazardous waste and radioactivity (45.0%), and recombinant DNA (37.6%). Table 5-9 shows that the vast majority of RIOs have sole or shared responsibility (71.0%) for three or more of the additional areas of responsibility outside of handling research misconduct issues.

Table 5-9. Distribution of RIOs' Additional Administrative Responsibilities

Additional Administrative Responsibilities Assigned to or Shared by RIO	Category/Level	Weighted Number	Weighted Percent
Financial Conflict of Interest			
	Yes	447	43.5
	Yes, Shared	297	28.9
	No	283	27.6
Human Subjects Protection			
	Yes	524	51.5
	Yes, Shared	291	28.6
	No	204	20.0
Animal Protection			
	Yes	373	36.8
	Yes, Shared	231	22.8
	No	409	40.4
Hazardous Waste and Radioactive Materials			
	Yes	199	19.7
	Yes, Shared	255	25.3
	No	556	55.0
Recombinant DNA			
	Yes	220	22.0
	Yes, Shared	157	15.6
	No	627	62.4
Grants Management			
	Yes	441	43.3
	Yes, Shared	302	29.6
	No	277	27.1
Number of Additional Administrative Responsibilities Assigned to or Shared by RIO			
	None	58	5.8
	One	113	11.3
	Two	119	11.9
	Three	151	15.1
	Four	168	16.8
	Five	167	16.7
	Six	224	22.4

5.1.5 RIO Responses to the Scenarios

As we indicated in an earlier section, in the Phase II web-based survey we presented respondents with only three of the five scenarios that were included in the Phase I telephone interview. We reduced the number of scenarios used in our interview data analysis (and subsequently in the Phase II survey) because some of the interview respondents did not respond to the scenarios at all and because many who did respond commented that responding to them required too much time and thought. It was admittedly difficult for Phase I survey respondents because they had to respond to the scenarios by having them read to them, while the scenarios were in written form for the Phase II, web-based survey. Recall that the scenarios were developed with the assistance of the ORI consultant and the Project Officer. The list of actions represented in the tables that follow, however, are what the two expert consultants independently indicated were among the most important actions that they would both take if they were faced with the situations represented in the scenarios. A total of 369 of the Phase II 651 survey respondents (56.7%) responded to all three of the scenarios. The weighted responses to these items form the basis of the description and analysis of RIO preparedness/readiness.

We asked study participants to demonstrate their skills and knowledge by keying in what they would do with respect to the three scenarios or situations. Knowing what to do in these situations is critical to optimal performance in the position of RIO. The situations represented include sequestering evidence, protecting “whistleblowers” against retaliation, and coordinating RIO responsibilities with those of the IRB. (See Appendix E for the full versions of the scenarios presented to the RIOs.) The extent to which the RIOs indicate the same actions in their response to the scenarios as the consultants’ responses was intended to serve as our measure of the RIOs’ preparedness/readiness to fulfill their responsibilities. The greater the concurrence with the expert consultants, the better we felt that the RIOs would be when they needed to act by demonstrating their preparedness/ readiness.

5.1.5.1 RIO Responses to Scenario 1

Scenario 1 describes a graduate student who calls the RIO to allege that her advisor was attempting to publish data from her dissertation without crediting her and that he is misrepresenting her data as well; however, the student does not “formally” make an allegation of misconduct at that time. Two days later, the student calls the RIO again to say that she is prepared to make the allegation and has a willing witness to the alleged misconduct, but that the advisor is at that time in the laboratory destroying evidence, i.e., shredding films and printouts.

The expert consultants identified a total of 10 common actions as among the most important and appropriate ones for a RIO to take in response to Scenario 1. Table 5-10 presents the proportion of RIO responses in agreement with each of the 10 actions

suggested by the consultants. It should be noted that neither the consultants nor the RIOs were provided any of the potential responses as prompts or options in any of the scenarios.

Table 5-10. Distribution of RIO Survey Responses in Agreement with the Expert Consultants to Scenario 1 – Actions to Take When Sequestering Evidence

Action	Weighted Number	Weighted Percent
Inform institutional officials of allegation and actions taken.	323	46.2
Inform respondent of allegation of research misconduct.	293	41.9
Assert institution’s ownership of data and take possession of it.	287	41.0
Stop any on-going data destruction.	277	39.6
Go immediately in person to the lab to see what is going on.	218	31.2
Ascertain what data are relevant to the alleged research misconduct.	90	12.8
Warn respondent against retaliation.	23	3.3
Ask if any data had been destroyed.	14	2.1
Explain to respondent about presumption of innocence (in best interest to cooperate fully and maintain confidentiality).	10	1.5
Promise respondent copies of all data sequestered.	8	1.1

As can be seen from Table 5-10, the response given most frequently, but by fewer than half of the RIOs who responded to Scenario 1 (46.2%), is that they would inform institutional officials of the allegation and any actions that were taken. Approximately 40% of the RIOs indicated that they would take the following actions: inform the advisor (i.e., respondent) that an allegation of research misconduct has been made against him, assert to the respondent the institution’s ownership of the data and then take possession of it, or stop any on-going data destruction by the respondent. Less than a third of the RIOs (31.2%) indicated that they would go to the advisor’s laboratory immediately to assess what is going on. Slightly more than 1 of 10 (12.8%) said that they would seek to identify the data that are relevant to the misconduct allegation. Only 1 to 3% of the RIOs indicated that they would warn the respondent against retaliation, ask if any data had been destroyed, explain the presumption of innocence to the respondent, or promise the respondent copies of the sequestered data so he could continue his work as little disturbed as possible.

Table 5-11 presents the total number of RIO responses given that are in common with the consultants’ response list for Scenario 1. Approximately 1 of 10 RIOs (10.4%) of the RIOs have no responses that matched any of those given by the expert consultants. At the other end of the response continuum, fewer than 1 of 10 of the RIOs (8.9%) have given

five or more of the consultant’s responses and none have more than 8 responses in common with the 10 responses on the expert consultants’ list. Just slightly more than half of the RIOs (52.3%) mention one or two of the actions indicated by the expert consultants and just over one-quarter (28.5%) have four or more responses in common with the expert consultants.

Table 5-11. Number of RIO Responses in Common with Expert Consultants for Scenario 1

Number of RIO Responses in Common with Expert Consultant Responses	Weighted Number	Weighted Percent
None	73	10.4
One	193	27.7
Two	172	24.6
Three	126	18.1
Four	73	10.4
Five	45	6.5
Six	12	1.8
Seven	3	0.4
Eight	2	0.2

5.1.5.2. *RIO Responses to Scenario 2*

Scenario 2 describes a situation in which the head of a laboratory (i.e., respondent) who drops in on an RIO runs into a laboratory technician (i.e., complainant) in the hallway exiting from an appointment in the RIO’s office. The complainant has previously told the RIO that she wants to remain anonymous because she fears what the respondent will do if he learns it is she who filed the research misconduct allegation. The complainant subsequently calls the RIO to report that the respondent saw her leaving the office and now strongly suspects that she is the complainant. The respondent has accused her of making the allegation, causing her to become ill and unable to work. She was especially disturbed because he followed her down the hall screaming at her as she tried to leave.

The expert consultants identified 11 response actions they would take that are important and appropriate for Scenario 2. Table 5-12 shows the distribution of responses provided by the RIOs to Scenario 2.

There is only one activity mentioned by the expert consultants that slightly more than half of the RIOs (50.4%) indicate they would do and that is to immediately contact the head of the laboratory to determine the accuracy of the laboratory technician’s account. The expert consultant action that is mentioned next most often, but by fewer than one-third of RIOs (31.9%), is to remind the head of the laboratory about the institution’s prohibition on retaliation against complainants. Two of the expert consultants’ recommended actions—moving the work site of the laboratory technician or the head of the laboratory, and working

with the institution’s administration to assure any measures put in place to protect the complainant are effective—were given by approximately one-fourth of the RIOs (from 27.0 and 22.8%). Another two actions were reported in common with the expert consults by approximately one-fifth of the RIOs (21.3 and 18.8%): if witnesses can verify the laboratory technician’s story, initiate institutional disciplinary action against the head of the laboratory; and inform the laboratory technician about the warning against retaliation given to the head of the laboratory, and instruct her to contact RIO if the seeming retaliation continues.

Table 5-12. Distribution of RIO Survey Responses in Agreement with the Expert Consultants for Scenario 2 – Actions to Take When In Receipt of a Complainant Report Regarding Threat of Retaliation by the Respondent

Action	Weighted Number	Weighted Percent
Immediately contact the head of the laboratory to ask whether the laboratory technician’s account was accurate.	344	50.4
Remind the laboratory head about the institution’s prohibition on retaliation.	222	31.9
Move the laboratory technician or the head of the laboratory to another location.	185	27.0
Work with the institutional administration to be sure that protections in place to protect the laboratory technician are working.	153	22.5
If witnesses verify the laboratory technician’s story about the laboratory head’s behavior, initiate institutional disciplinary action against the laboratory head.	145	21.3
Contact the laboratory technician and tell her about what he told the head of the laboratory and instruct her to contact him if the encounter has any further repercussions.	130	18.8
Contact the head of the laboratory and ask him not to draw any conclusions about the chance encounter with the laboratory technician in the hall outside the RIO’s office.	117	16.9
Have taken precautions to avoid such hallways encounters by having SOPs in place to clear way for witness, hold meetings in a different location, or use an alternate exit.	75	10.7
Contact any witnesses to verify the laboratory technician’s account and remind them of the institution’s misconduct adjudication process, the need for confidentiality, and the policy on retaliation, while not revealing the nature of the allegation.	65	9.5
Contact the laboratory technician and ask if there were witnesses to the laboratory head’s behavior.	54	8.0
Have warned all of the parties against “drop in” visits.	5	0.8

Table 5-13 presents the number of RIO responses given that correspond with any of the consultants' responses for Scenario 2. As with Scenario 1, of the 11 potential actions identified by the consultants for Scenario 2, none of the RIOs report more than 8 actions in common with the expert consultants, with only 1% reporting as many as either 7 or 8 matched responses. In addition, slightly more than 1 in 10 (12.4%) RIOs do not provide any responses in common with those of the consultants. However, approximately one-fourth of the RIOs mention one (23.7%) or two (28.2%) actions that correspond to actions reported by the expert consultants, but just one in five (19.8%) give as many as three actions in common with the consultants. Finally, fewer than one in five (15.9%) respond with five or more actions that agree with those given by the expert consultants.

Table 5-13. Number of RIO Responses in Common with Expert Consultants for Scenario 2

Number of RIO Responses in Common with Expert Consultant Responses	Weighted Number	Weighted Percent
None	87	12.4
One	167	23.7
Two	198	28.2
Three	139	19.8
Four	67	9.5
Five	28	4.0
Six	10	1.4
Seven	3	0.4
Eight	4	0.6

5.1.5.3 RIO Responses to Scenario 3

Scenario 3 describes the coordination and prioritization of responsibilities between the RIO and the institution's IRB regarding a number of protocol violations in a clinical trial. The violations involve allegations of backdating patient consent forms, ignoring protocol inclusion/exclusion criteria, and destruction of patient records associated with the clinical trial. The expert consultants identified five actions that they deemed appropriate to take under the circumstances described in Scenario 3 to prioritize the order in which they would handle the violations and to assign primary responsibility for acting on each of them. Table 5-13 presents the distribution of RIO responses corresponding to the five actions the expert consultants recommended be taken for Scenario 3.

Table 5-14 shows that nearly two-thirds of the RIOs (64.5%) say they would consider halting additional patient recruitment efforts, while nearly two of five (37.7%) say they would work with the IRB chair and legal counsel to determine whether federal government oversight agencies should be informed of the alleged misconduct. Less than one-third (29.3%) indicate that they would take action to preserve the medical and other records of already enrolled patients, making copies as needed to assure their continued

care. Surprisingly, only one in five RIOs (19.1%) say that they would work with the IRB chair to decide who has the jurisdiction and responsibility to deal with the trial irregularities, such as backdating and destroying records, and even fewer (11.9%) note that they would work to determine the steps required to protect the health and safety of patients already enrolled in the trial. These results may be partially related to the fact that approximately 80% have or share IRB as well as RIO responsibilities in their institutions.

Table 5-14. Distribution of RIO Survey Responses in Agreement with the Expert Consultants for Scenario 3 – Actions to Take When Necessary to Coordinate Responsibilities with IRB

Action	Weighted Number	Weighted Percent
Consider closing the trial to further patient recruitment.	416	64.5
Work with the IRB chair and discuss with institutional legal counsel whether any of the government watchdog agencies needed to be notified (FDA, OHRP, or ORI).	241	37.7
Take steps to preserve the medical and other records for patients already enrolled, making copies as needed to continue with care of those patients.	189	29.3
Work with the IRB chair to decide who has jurisdiction over which of the presumed clinical trial infractions (back dating consents and destroying records).	123	19.1
Determine what needs to be done to safeguard the health and safety of patients already enrolled in the trial.	77	11.9

Table 5-15 shows the number of RIO responses similar to the expert consultants’ five responses for Scenario 3. Just over 15% of RIOs (15.7%) do not specify taking any actions that correspond to the consultants’ responses. Nearly one third (32.6%) mention a single action mentioned by the expert consultants, and about the same proportion (31.0%) mention two of the same actions as the consultants. Just about one of five RIOs reports that they would perform three or four of the actions recommended by the expert consultants, and less than 1% (0.2%) respond with all five actions identified as appropriate by the consultants for the situation represented in Scenario 3.

Table 5-15. Number of RIO Responses in Common with Expert Consultants for Scenario 3

Number of RIO Responses in Common with Expert Consultant Responses	Weighted Number	Weighted Percent
None	101	15.7
One	210	32.6
Two	200	31.0
Three	99	15.3
Four	34	5.2
Five	2	0.2

5.1.5.4. *RIO Responses to All Three Scenarios Combined*

Using these three scenarios, we gave the RIOs an opportunity to provide their most complete answers, suggesting what are the appropriate actions to take in these challenging, but not so unusual, situations for a RIO. Then, we compared their answers to the answers provided by the two expert consultants and gave credit to the RIOs when they responded with an answer that corresponded to one given by the expert consultants. Table 5-16 presents the total number of RIO and consultant responses given in common across the three scenarios.

Table 5-16. Total Number of RIO Responses in Common with Expert Consultants for All Three Scenarios Combined

Total Number of RIO Responses in Common with Expert Consultant Responses	Weighted Number	Weighted Percent
None	3	0.5
One	25	4.1
Two	30	4.9
Three	77	12.4
Four	67	10.7
Five	89	14.2
Six	72	11.6
Seven	75	12.1
Eight	68	11.0
Nine	38	6.0
Ten	32	5.1
Eleven	22	3.5
Twelve	8	1.3
Thirteen	3	0.5
Fourteen	7	1.1
Fifteen	5	0.8
Sixteen	2	0.3

The two expert consultants described a total of 26 common actions that they would both take in response to the situations represented by the three scenarios. As can be seen

from Table 5-16, there are three RIOs (0.5%) who responded to all three scenarios who do not recommend taking a single action that is in common with those mentioned by the expert consultants. Fewer than half of the RIOs (46.3%) identified between 1 and 5 of the same actions as the expert consultants, and approximately an equal number (46.5%) identified 6 to 10 actions in common with the expert consultants. At the highest end of the continuum, only two of the RIOs (0.3%) provide as many as 16 actions in common with the expert consultants, the highest number given by RIOs. Allowing for 11 to 16 actions given in response to the three scenarios that are in common with the expert consultants only includes 7.5% of the RIOs. It should be noted that many of the RIOs gave answers that RTI did not credit because they were not mentioned as important or appropriate by the consultants.

5.2 Significant Associations with RIO Preparedness/Readiness

In this section, we endeavor to examine the relationships between the variables we hypothesized are associated with RIOs' level of preparedness/readiness. To do this, we have examined whether there is a statistically significant association between the independent variables that we have used to describe the RIOs (i.e., personal characteristics, training and preparation to be a RIO, research misconduct experience as a RIO, and organizational characteristics) and the measure we have created to assess our dependent variable, RIO preparedness/readiness (i.e., a dichotomy of the total scenario score representing low and high agreement with the expert consultants on what a RIO should do). If our experts' judgments can be presumed appropriate, then we can reasonably assert that the higher the agreement with the expert consultants, the more prepared or ready a RIO is to perform his/her role.

5.2.1. Personal Characteristics of RIOs and RIO Preparedness/Readiness

We cross-tabulated the 10 personal characteristics of RIOs that we identified at the beginning of this chapter in Table 5-1 by the dichotomized total scenario score and tested them for statistical significance using the Chi Square test. We then measured their level of association using the gamma statistic for ordinal variables. The column distributions of the five personal characteristics that were significantly related ($p \leq 0.05$) to the total scenario score are presented in Table 5-17, along with the p-value of the chi square and the gamma coefficient to provide an indication of the strength and direction of the association.

While the association is not uniform across the years of employment in the institution, RIOs employed by the institution for a shorter time period scored higher on the scenarios and, hence, as more prepared or ready to serve as RIO than those who have been there a longer time. This is clear from the fact that among RIOs who have been at the institution for 2 years or less, the proportion scoring in the high half of scenario scores is almost twice the column proportion scoring low, while among those employed at the

Table 5-17. Personal Characteristic Variables Significantly Associated with the Total Scenario Score (p<= 0.05)

Characteristic	Total Scenario Score (Column Percents)			Chi Sq	df	p- value	Gamma
	0-5	6-16	Total				
Years Employed at Institution							
0 – 2 Years	8.7%	16.3%	12.8%				
>2 – 10 Years	27.8%	33.2%	30.7%	19.1	3	0.000	-0.15
>10 – 20 Years	25.6%	14.1%	19.5%				
> 20 – 50 Years	38.0%	36.4%	37.1%				
N	289	331	620				
How Involved in Seeking Funds for Research							
Very Involved	50.8%	41.8%	46.0%	5.0	1	0.025	0.18
Somewhat/Slightly/Not at All	49.2%	58.2%	54.0%				
N	289	331	620				
Satisfaction with Authority and Independence as RIO							
Extremely Satisfied	27.9%	27.9%	27.9%				
Very Satisfied	26.4%	40.3%	33.8%	16.5	2	0.000	-0.15
Only Satisfied or Not Satisfied	45.7%	31.8%	38.3%				
N	285	331	616				
Concerned that Research Misconduct Did Not Come to Your Attention							
Yes	12.4%	18.8%	15.8%	4.7	1	0.029	-0.24
No	87.6%	81.3%	84.2%				
N	291	331	622				
RIO Is Tenured							
Yes	41.8%	33.3%	37.3%	4.7	1	0.030	0.18
No (includes not available)	58.2%	66.7%	62.7%				
N	291	331	622				

institution from 10 to 20 years, the split between high and low scenario score column proportions is almost the opposite.

Being very involved in the process of having to raise research funds is significantly associated with scoring low on the scenario scores. This is clearly demonstrated by the higher column proportion in the low category for the very involved respondents and the opposite for those RIOs who have a lesser degree of involvement with fund seeking for research.

The level of satisfaction expressed by RIOs with the authority and independence they experience performing in that role has a small association with their scenario score. RIOs who indicate that they are very satisfied with their authority and independence are about 50% more likely (40.3% vs. 26.4%) to respond in the high scenario score category than the low, and those who are only satisfied or not satisfied demonstrate the opposite tendency.

There is also an association between RIOs expressing concern that there is research misconduct being committed that is not coming to their attention and the magnitude of their scenario scores. Those with greater concern have moderately higher scores on the scenarios than those without this concern. This is apparent from the 50% greater probability (18.8% vs. 12.4%) they have to be in the high scenario score category than persons who say they have no concern about this.

The final personal characteristic that we find to be related to the scenario score is whether or not the RIO is tenured. Our analysis shows that RIOs who are not tenured (including those employed where there is no tenure track) are more likely to score in the upper half of scenario scores than RIOs with tenure.

The personal characteristics that did not achieve statistical significance when cross-tabulated against the total scenario score include: whether the RIO considers him or herself a researcher; how often the RIO has been a PI on a grant; whether the RIO has a Ph.D.; whether the RIO has an M.D.; the field of study represented by the RIO's highest degree; and whether the RIO is aware of any mishandled allegations at the institution in the previous 5 years.

5.2.2 Training Completed for Becoming a RIO and Preparedness/Readiness

We described earlier in Tables 5-2 through 5-4 the 31 variables representing the types and numbers of activities and qualifications reported by RIOs as their preparation to be an institution's RIO. In this section, we focus on the results of the cross-tabulation of each of the reported training activities by the total scenario score dichotomy to determine the activities that are statistically significant associated with being more prepared/ready to carry out the RIO responsibilities. The 11 training variables that are significantly related to the total scenario score are presented in Table 5-18. Unfortunately, only a small number of RIO participants gave responses that are among the activities that we expected to be more likely to contribute to better performance.

While only a small proportion of RIOs indicated that they did not have any training or qualification in preparation for becoming the RIO, not reporting receipt of any training is, as expected, significantly associated with having lower total scenario scores. Among those reporting no training, the percent scoring in the lower range of total scenario scores was more than four times as high (6.3% vs. 1.4%) as those scoring in the high range. This variation is as expected.

Table 5-18. RIO Training Variables Significantly Associated with the Total Scenario Score (p<= 0.05)

RIO Training Variable	Total Scenario Score (Column Percent)			Chi Sq	df	p- value	Gamma
	0-5	6-16	Total				
Reported No Formal Training or Qualifications to Be RIO							
Yes	6.3%	1.4%	3.7%	10.3	1	0.001	0.65
No	93.7%	98.6%	96.3%				
N	289	329	619				
Attended One or Two ORI Workshops							
Yes	9.5%	5.0%	7.1%	4.8	1	0.029	0.33
No	90.5%	95.0%	92.9%				
N	289	329	619				
Attended ORI Boot Camp							
Yes	0.6%	6.1%	3.5%	13.8	1	0.000	-0.83
No	99.4%	93.9%	96.5%				
N	289	329	619				
Attended One or Two ORI Conferences							
Yes	10.0%	19.2%	14.9%	10.4	1	0.001	-0.36
No	90.0%	80.8%	85.1%				
N	289	329	619				
Served As RIO or Compliance Officer at Another Institution							
Yes	1.6%	5.3%	3.5%	6.0	1	0.014	-0.55
No	98.4%	94.7%	96.5%				
N	289	329	619				
Has Been an Active Researcher for at Least Ten Years							
Yes	61.9%	52.7%	57.0%	5.3	1	0.022	0.19
No	38.1%	47.3%	43.0%				
N	289	329	619				
Has Had Experience Directing Research Misconduct Inquiries/Investigations							
Yes	19.1%	31.4%	25.6%	12.3	1	0.000	-0.32
No	80.90%	68.6%	74.4%				
N	289	329	619				
Has Had Experience Serving as a Member of an Inquiry/Investigation Committee							
Yes	14.1%	23.1%	18.9%	8.0	1	0.005	-0.29
No	85.9%	76.9%	81.1%				
N	289	329	619				

Table 5-18. RIO Training Variables Significantly Associated with the Total Scenario Score (p<= 0.05) (continued)

RIO Training Variable	Total Scenario Score (Column Percent)			Chi Sq	df	p-value	Gamma
	0-5	6-16	Total				
Has Had Experience/Training in Human Subject Protection/IRB Issues							
Yes	39.8%	53.3%	47.0%				
No	60.2%	46.7%	53.0%	11.2	1	0.001	-0.26
N	289	329	619				
Helped to Write the Institution's Research Misconduct Policy and Procedures							
Yes	29.9%	37.7%	34.1%				
No	70.1%	62.3%	65.9%	4.1	1	0.042	-0.17
N	289	329	619				
Total Number of Likely Most Relevant Training Choices Reported							
None	74.3%	62.0%	67.8%				
Only One	23.6%	30.2%	27.1%	15.3	2	0.000	0.29
Two or Three	2.2%	7.8%	5.2%				
N	289	329	619				
Total Number of Likely Medium Relevant Training Choices Reported							
None	26.9%	18.3%	22.3%				
Only One	38.3%	29.4%	33.6%				
Two	25.0%	36.9%	31.3%	19.4	3	0.000	0.25
Three or Four	9.8%	15.4%	12.8%				
N	289	329	619				
Total Number of Likely Most and Medium Relevant Training Choices Reported							
None	20.9%	12.3%	16.4%				
Only One	35.7%	21.9%	28.3%				
Two	23.2%	33.1%	28.5%	31.8	3	0.000	0.31
Three to Five	20.1%	32.7%	26.8%				
N	289	329	619				

However, attending only one or two ORI workshops is also significantly related to scenario scores, but unexpectedly, in the same direction as not having any training. Of those RIOs who report attending one or two ORI workshops as their preparation, almost twice the percent score in the low range of scores (9.5% vs. 5.0%) as compared to the high range. It should be noted that ORI has only rarely held workshops on its own. In recent

years ORI has on rare occasions held a workshop at a conference sponsored by another organization. The small percentage of RIOs that indicates they attended ORI sponsored workshops may be mistaken in their recollection of who sponsored what may have been a workshop on research integrity or misconduct.

Attendance at ORI boot camp for RIOs, while limited to only few RIOs thus far, is statistically associated with a remarkable relationship with the scenario score with virtually all of the RIOs attending boot camp scoring in the high score range. The percentage of boot camp attendees in the high scenario score is 10 times larger than in the low scenario score group (0.6% vs. 6.1%).

Whereas attending only one or two ORI workshops is significantly associated with placing at the low end of the range of total scenario scores, attending one or two conferences is significantly associated with scoring in the high end of total scenario scores. RIOs reporting that they have attended one or two ORI conferences are nearly twice as likely to score in the high group as in the low end of scenario scores (19.2% vs. 10.0%).

Having served as a RIO or Compliance Officer at another institution is also significantly associated with placing in the higher end of the total scenario score range. More than three times the percentage of those who came from an institution where they served in the RIO or Compliance Officer role scored in the high end of the total scenario score range as in the low end of that range (5.3% vs. 1.6%).

A large proportion of RIOs reported their experience as researchers for 10 years or more as a qualification for being the institution's RIO, and while statistically significant, the association indicates that being a researcher for 10 or more years is associated with scoring in the low end of the total scenario score rather than in the high end. RIOs who report having 10 or more years experience conducting research are 17% more likely to score in the low range of total scenario scores than in the high (61.9% vs. 52.7%). It is worth noting that we had included this activity in the category of activities being of least relevance to performing the duties of a RIO and expected no association. Instead, it appears to detract from getting a high scenario score.

RIOs who report having experience directing research misconduct inquiries or investigations are significantly more likely to have a total scenario score in the high end of scenario scores than in the low end by more than 60% (31.4% vs. 19.1%). Just about the same statistically significant relationship exists between RIOs who report experience being a member of an inquiry panel or investigation committee. Having experience as a panel or committee member is associated with more than a 60% higher likelihood of scoring in the high total scenario score group than in the low (23.1% vs. 14.1%).

While earlier in this chapter, we considered having training or experience in IRB or human subjects' protection issues to have little or unknown relevance to handling cases of

research misconduct, our analysis shows that the two are significantly related. RIOs who report IRB training have about 33% higher probability of having a total scenario score in the high end than in the low end of the distribution (53.3% vs. 39.8%). This relationship may be due to the similar level of attention to policy guidelines, procedures, and processes that participation in both activities involves, hence while our initial classification may have been correct on the basis of content, it may not have been on the basis of process and procedure.

Recall from earlier in this chapter that about a third of the RIOs reported having had a role in writing or helping to write their institution's research misconduct policy and procedures. There is a statistically significant association between having this experience and being in the high total scenario score group. RIOs who have participated in the writing of their institution's research misconduct policy are about 25% more likely to have a high total scenario score than a low one (37.7% vs. 29.9%).

The final few cross-tabulations involved counts of the number of activities or qualifications reported. We counted these according to the presumptive relevance category to which we classified them—most, medium, and least direct relevance—and combinations of these. Only the most and medium relevance activities are significantly related to the scenario score. In both cases, the greater the number of activities reported from those two categories, the greater the percentage of RIOs whose scenario score is in the high group (most 7.7% vs. 2.2%; medium 15.4% vs. 9.8%). The only combination count to reach statistical significance was the count of the most and medium relevance activities combined. The count of most and medium relevance activities indicates that the greater the number of activities from these two groups identified by RIOs, the higher the percentage associated with having a high total scenario score. In the highest category, the RIOs have more than a 60% greater chance of being in the high scenario score category than in the low (32.7% vs. 20.1%).

This cross-tabular analysis showed that many of the training activities and qualifications reported by RIOs are not statistically significantly associated with the total scenario score. These include activities and qualifications that we classified as being most, medium, and least relevant to knowing how to perform the RIO role. Among the activities we classified as being most relevant that are not related to the scenario score are being mentored by the former RIO, attending three or more ORI workshops or conferences, and working as an assistant to the former RIO. There are nine activities among those that are classified as being of medium relevance that are not significantly related to the total scenario score. These activities are learning from materials on the ORI web site, having a role in the institution's responsible conduct of research program, viewing the ORI DVD on the responsibilities of a RIO, having extended contact with RIOs at other institutions or with ORI staff, attending conferences on research misconduct sponsored by someone other than ORI, completing on-the-job training, writing books or articles on research misconduct, and working closely with an institution's General Council. Finally, three of the five activities that

were reported by respondents that we earlier classified as likely to have little or unknown relevance to being a RIO are not significant. These activities include having training or experience in ethics, law, and research administration.

5.2.3 Research Misconduct-Related Experience and RIO Preparedness/Readiness

The next analyses involve the research misconduct experience that the RIOs report having and examines whether the experience is associated with their total scenario score. The results are presented in Table 5-19 and include all but one of the 10 experience variables from Table 5-5 that we discussed earlier as being significantly related to the total scenario scores.

The length of time that a RIO has been involved with research misconduct activities and the length of time that he/she has served in the RIO position (admittedly similar measures) presents similar pictures of a RIO's association with the total scenario scores. Taking the two together, it appears that there is no real difference in the probability of being in the group with either low or high scenario scores, up to and including 2 years or 20 years and more. However, in the middle range of years (between 2 and less than 20 years) there does seem to be an association between having more years of experience performing in the RIO role and scoring higher on the scenario score. For both measures, those in the greater than 2 to 10 year category are more likely to be in the low end of the scenario score dichotomy, whereas those in the greater than 10 to less than 20 year category are more likely to be in the high end group. There is a 7 to 10 percentage point difference in scenario score group for these two periods of time on both measures.

RIOs having experience with research misconduct procedures at another institution are 50% more likely to be in the high scenario score group than in the low (25.8% vs. 17.2%). We found that the number of allegations handled is also related to a RIO's total scenario score. RIOs who have never handled an allegation are more likely to be in the lower scenario score group than in the high, and having dealt with one allegation does not seem to be associated with their scenario score. However, RIOs with the experience of having dealt with two or three allegations are 60% more likely to be in the high scenario score group (18.9% vs. 11.8%). A similar advantage with high scenario scores exists for RIOs who have handled four or more allegations (13.8% vs. 9.4%).

The number of research misconduct investigations handled by a RIO is also significantly related to a RIOs' total scenario score. It is related to the number of allegations handled because allegations are the initiating force for investigations. However, the relationship we find between the number of investigations managed by a RIO and a RIO's total scenario score is less clear and consistent than for the relationship between handling allegations and scenario scores, although it does indicate that having managed four or more

Table 5-19. RIO Experience Variables Significantly Associated with the Total Scenario Score (p<= 0.05)

RIO Experience Variable	Total Scenario Score (Column Percent)			Chi Sq	df	p-value	Gamma
	0-5	6-16	Total				
Years Involved with Research Misconduct Activities							
0 - 2 Years	26.3%	27.4%	26.7%	8.0	3	0.046	0.02
>2 - 10 Years	33.0%	25.8%	29.1%				
>10 - <20 Years	21.0%	29.6%	25.6%				
20 - 37 Years	20.0%	17.4%	18.6%				
N	289	331	620				
Years as Research Integrity Officer							
0 - 2 Years	32.9%	35.4%	34.2%	9.1	3	0.028	0.03
>2 - 10 Years	35.1%	25.0%	29.7%				
>10 - <20 Years	16.3%	23.0%	19.9%				
20 - 37 Years	15.7%	16.7%	16.2%				
N	289	331	620				
Experience with Research Misconduct Procedures at Another Institution							
Yes	17.2%	25.8%	21.8%	6.7	1	0.010	-0.25
No	82.8%	74.2%	78.2%				
N	291	331	622				
Number of Research Misconduct Allegations Handled as RIO							
None	64.4%	54.5%	59.1%	10.3	3	0.016	0.20
Only 1	14.4%	12.8%	13.6%				
2 to 3	11.8%	18.9%	15.6%				
4 to 40	9.4%	13.8%	11.7%				
N	291	329	620				
Number of Research Misconduct Investigations Handled as RIO							
None	72.8%	69.7%	71.1%	8.6	3	0.035	0.07
Only 1	16.0%	19.5%	17.9%				
2 to 3	5.5%	1.9%	3.6%				
4 to 20	5.8%	8.9%	7.4%				
N	285	324	609				
Number of Times Sequestered Evidence							
None	79.5%	67.7%	73.2%	20.9	2	0.000	0.23
Only 1	6.6%	18.8%	13.0%				
2 or more	14.0%	13.6%	13.8%				
N	291	329	620				
Number of Times Conferred with RIOs at Other Institutions							
None	74.2%	66.3%	70.0%	16.7	3	0.001	0.22
Only 1	15.1%	11.9%	13.4%				
2 to 3	8.0%	12.4%	10.3%				
4 to 25	2.7%	9.4%	6.3%				
N	291	329	620				
Number of Different RIOs With Whom Conferred							
None	74.2%	66.2%	70.0%	10.9	2	0.004	0.21
Only 1 or 2	23.1%	25.3%	24.3%				
3 or more	2.7%	8.5%	5.8%				
N	291	328	619				
Number of Times Conferred with Someone at Federal Oversight Agency Like ORI							
None	76.3%	69.2%	72.6%	10.6	3	0.014	0.16
Only 1	12.2%	13.9%	13.1%				
2 to 3	5.6%	12.6%	9.3%				
4 to 100	5.9%	4.2%	5.0%				
N	291	329	620				

research misconduct investigations is associated with about a 50% greater probability of being in the high scenario score group than in the low (8.9% vs. 5.8%).

Sequestering potential evidence of research misconduct is also triggered by receipt of an allegation; hence, the expectation that the number of times a RIO has sequestered evidence is related to the scenario score in much the same way as it is related to having handled allegations. Having sequestered evidence at least once leads to over a 280% higher likelihood of the RIO being in the high scenario score group than in the low (18.8% vs. 6.6%). Having done it once seems to be a threshold over which more experience sequestering evidence does not appear to have any greater association with scenario scores.

Conferring with RIOs at other institutions is another experience that can boost a RIO's capability to handle aspects of misconduct cases and increase a RIO's effectiveness in filling the position. RTI's analysis suggests that the more times a RIO has contacted RIOs at other institutions, the greater the probability that the RIO will appear in the high scenario score category. There is a 50% greater likelihood of this occurring with two or three contacts with RIOs (12.4% vs. 8.0%) and more than a 300% greater likelihood with four or more contacts (9.4% vs. 2.7%). We also examined the significance of any association of contacting different RIOs with scenario score. Because there is so little interaction among RIOs in general, and what there is often occurs with the same person, we see little difference in scenario scores for a RIO having contact with one or two different RIOs. However, there is more than a 300% greater likelihood of a RIO being in the high scenario score group than the low related to having contact with three or more different RIOs (8.5% vs. 2.7%).

The final experience that we examined is the number of times a RIO conferred with someone at a Federal oversight agency, such as ORI, about a research misconduct issue (even if couched in hypothetical terms). Without any such contacts, RIOs are somewhat more likely to be in the low scenario score group (74.2% vs. 66.3%); however, with only one such contact, there is no association with the scenario score. RIOs having two to three contacts with a federal oversight agency have more than double the likelihood of being in the high scenario score group (12.6% vs. 5.6%).

5.2.4 Organizational Characteristics and RIO Preparedness/Readiness

The final set of cross-tabulations are between characteristics of the institutional settings within which the RIOs operate and their total scenario scores. These characteristics have been divided into three categories similar to those used earlier: organizational characteristics, specific institutional responsibilities of the RIO, and additional administrative responsibilities given to the RIO. The set of variables included in each category is represented in a separate table below.

Table 5-20 presents results of tabulations involving organizational characteristics. Five of the nine organizational characteristics that were described earlier are significantly associated with a RIO’s scenario score.

Not all organizations identify the title of the person handling allegations of research misconduct. However, RIOs in organizations where the title of the person who handles allegations of research misconduct is included in the institution’s policy and procedures manual are nearly 15% more likely (86.8% vs. 76.3%) to have a high scenario score than a low one.

Table 5-20. Organizational Characteristics Significantly Associated with the Total Scenario Score (p<= 0.05)

Organizational Characteristic	Total Scenario Score (Column Percent)			Chi Sq	df	p-value	Gamma
	0-5	6-16	Total				
Policy and Procedures Manual Identifies the Title of the Person Who Handles Allegations of Research Misconduct							
Yes	76.3%	86.8%	81.9%				
No	16.4%	7.5%	11.7%	13.	2	0.002	-0.31
Don’t Know	7.3%	5.7%	6.5%	0			
N	289	329	618				
Use RIO as Title for Person Handling Allegations of Research Misconduct							
Yes	17.0%	27.1%	22.4%				
No	83.0%	72.9%	77.6%	9.0	1	0.003	-0.29
N	286	325	611				
RIO Has Someone to Assist in Performing Duties							
None	51.5%	41.4%	46.1%				
One Person	26.6%	32.2%	29.6%	6.4	2	0.041	0.16
Two to Twelve Persons	21.9%	26.5%	24.3%				
N	291	331	622				
One of Top 100 NIH Funded Research Grantees							
Yes	2.7%	7.5%	5.2%				
No	97.3%	92.5%	94.8%	7.3	1	0.007	-0.50
N	291	331	622				
Research Misconduct Allegations Reported to ORI (2003-2007)							
None	87.5%	77.7%	82.3%				
One to Sixteen	12.5%	22.3%	17.7%	10.0	1	0.002	0.33
N	291	331	622				

We also indicated earlier that the persons we are referring to as RIOs go by many different titles, even when they are performing in the role of the RIO. RIOs in institutions where “RIO” (or Compliance Officer) is their official title when they are performing the role of the RIO are nearly 60% more likely to be in the high scenario score group (27.1% vs. 17.0%) than the low.

Belonging to an organization that provides assistance to the RIO performing his/her responsibilities is also associated with the RIO having a high scenario score rather than a

low one. RIOs who have one or more persons to assist them are more than 20% more likely to be in the high scenario score group than in the low (48.5% vs. 58.7%).

RIOs in institutions that are listed as among the top 100 NIH funded research grant recipients are also significantly more likely to be included in the high scenario score group than in the low (7.5% vs. 2.7%). And lastly, RIOs in institutions that reported to ORI between 2003 and 2007 that they had at least one research misconduct allegation registered are nearly 80% more likely to be in the high scenario score group than in the low (22.3% vs.12.5%).

Another dimension of the organization we investigated is the specific type of research misconduct related activities that the RIO is responsible for performing alone, as well as shared with someone else, and the sum of such responsibilities. Of the 10 specific institutional responsibilities related to research misconduct activities, 5 of them plus the sum of the RIOs' responsibilities are statistically significantly related to the RIOs' total scenario score. These are presented in Table 5-21.

Table 5-21. Specific Institutional Responsibilities of RIO Significantly Associated with the Total Scenario Score (p<= 0.05)

Specific Institutional Responsibilities of RIO	Total Scenario Score (Column Percent)			Chi Sq	df	p-value	Gamma
	0-5	6-16	Total				
Responsible for Sequestering Evidence							
Yes	69.8%	78.4%	74.4%	6.0	1	0.014	-0.22
No	30.2%	21.6%	25.6%				
N	291	331	622				
Responsible for Informing Key Officials of Allegations/Actions							
Yes	91.3%	96.6%	94.1%	8.0	1	0.005	-0.47
No	8.7%	3.4%	5.9%				
N	289	329	618				
Responsible for Handling Allegations of More than Research Misconduct							
Yes	18.1%	15.1%	16.5%	9.2	2	0.010	-0.06
Yes, Shared	69.1%	78.5%	74.1%				
No	12.7%	6.4%	9.4%				
N	289	329	618				
Responsible for Informing Complainants of Vulnerability from Making an Allegation							
Yes	38.5%	50.8%	45.0%	18.5	2	0.000	-0.27
Yes, Shared	38.3%	38.0%	38.2%				
No	23.2%	11.2%	16.8%				
N	291	329	620				
Responsible for Deciding Whether There Will Be an Inquiry							
Yes	39.1%	46.0%	42.8%	10.2	2	0.006	-0.18
Yes, Shared	45.1%	46.2%	45.7%				
No	15.8%	7.8%	11.5%				
N	289	331	620				

Table 5-21. Specific Institutional Responsibilities of RIO Significantly Associated with the Total Scenario Score (p<= 0.05) (continued)

Specific Institutional Responsibilities of RIO	Total Scenario Score (Column Percent)			Chi Sq	df	p-value	Gamma
	0-5	6-16	Total				
Number of Sole or Shared RIO Responsibilities							
Zero to Four	13.4%	6.8%	9.9%	9.6	4	0.048	0.13
Five or Six	10.4%	7.6%	8.9%				
Seven or Eight	16.4%	18.8%	17.7%				
Nine	22.5%	25.0%	23.8%				
Ten	37.3%	41.8%	39.7%				
N	288	326	614				

RIOs who indicate that they are responsible for sequestering potential evidence when an allegation of research misconduct is made are about 12% more likely to be in the high scenario score group than in the low (78.4% vs. 69.8%).

More than 94% of the RIOs respond that they are responsible for informing key officials of allegations of research misconduct that have been made and any subsequent actions that have been taken. Despite the overwhelming majority of RIOs being responsible for doing this, there is a nearly 6% greater probability of RIOs who perform this activity being in the high scenario score group than in the low that is statistically significant (96.6% vs. 91.3%).

The third responsibility significantly associated with RIOs being in the high scenario score group involves sharing responsibility with someone else for handling allegations of actions involving more than research misconduct. RIOs who report sharing responsibility for allegations of more than research misconduct with someone else are 13% more likely to be in the high scenario score group than in the low (78.5% vs. 69.1%).

The next statistically significant activity involves RIOs who are solely responsible for informing complainants of their vulnerability as a result of making an allegation of research misconduct. These RIOs are nearly 32% more likely to be in the high total scenario score group than in the low (50.8% vs. 38.5%).

RIOs who are solely responsible for deciding whether or not there will be an inquiry following an allegation of research misconduct are also significantly more likely to be in the high scenario score group. RIOs who decide whether there will be an inquiry are nearly 18% more likely to be in the high scenario score group (46.0% vs. 39.1%).

The final statistically significant measure involving the specific RIO responsibilities that is related to the total scenario score is the number of sole and shared responsibilities reported by RIOs. Those who have sole or shared responsibility of 7 or more of the 10

responsibilities we asked about have a 12% higher probability of being in the high scenario score group than in the low (85.6% vs.76.2%).

Five of the six additional administrative responsibilities not related to research misconduct that are sometimes assigned to or shared by RIOs are significantly associated with the total scenario score. Table 5-22 presents the results of the analysis of the association with preparedness/readiness of having additional administrative responsibilities not related to research misconduct assigned to the RIO.

Table 5-22. RIO's Additional Administrative Responsibilities Significantly Associated with the Total Scenario Score (p<= 0.05)

Additional Administrative Responsibilities	Total Scenario Score (Column Percent)			Chi Sq	df	P-value	Gamma
	0-5	6-16	Total				
Financial Conflict of Interest							
Yes	37.0%	48.5%	43.1%	10.6	2	0.005	-0.14
Yes, Shared	30.6%	21.0%	25.5%				
No	32.4%	30.5%	31.4%				
N	289	331	620				
Human Subjects Protection							
Yes	42.3%	54.4%	48.7%	9.0	2	0.011	-0.19
Yes, Shared	21.4%	16.8%	19.0%				
No	36.3%	28.8%	32.3%				
N	287	328	614				
Hazardous Waste and Radioactive Materials							
Yes	21.3%	18.6%	19.9%	6.6	2	0.036	-0.07
Yes, Shared	46.5%	56.7%	51.9%				
No	32.2%	24.8%	28.2%				
N	285	326	611				
Recombinant DNA							
Yes	17.9%	26.6%	22.6%	8.4	2	0.015	-0.10
Yes, Shared	66.0%	55.2%	60.2%				
No	16.1%	18.2%	17.2%				
N	282	324	607				
Grants Management							
Yes	45.5%	37.9%	41.4%	6.7	2	0.036	0.07
Yes, Shared	20.8%	29.4%	25.4%				
No	33.7%	32.7%	33.2%				
N	288	328	616				

Rather than being a source of competing attention and detracting from a RIO's scenario score, having or sharing specific additional administrative responsibilities is sometimes associated with having a high scenario score. RIOs who are given responsibility for dealing with issues of financial conflict of interest are 11.5% more likely to score high than low on the scenarios (48.5% vs. 37.0%). The results are similar with regard to having administrative responsibility for human subjects protection (IRB issues). RIOs who are responsible for human subjects protection are 12.1% more likely to score high than low on the scenarios (54.4% vs. 42.3%). Similarly, RIOs responsible for appropriate monitoring of

recombinant DNA are 8.7% more likely to be in the high scenario score group than the low (26.6% vs. 17.9%).

RIOs who share administrative responsibility (rather than being solely responsible) for oversight of hazardous wastes and radioactive materials for the institution are more likely to score high than low on the scenarios by 10.2% (56.7% vs. 46.5%). A very similar result is associated with RIOs who share responsibility for grants management issues. These individuals are 8.6% more likely to place in the high scenario score group than the low (29.4% vs. 20.8%).

We investigated the association with the total scenario score dichotomy of seven measures of additional administrative responsibility that could have been assigned to or shared by RIOs (six specific activity areas, and the total number of areas assigned or shared). Only two were not significantly related to the scenario score: the area of animal research subject protection, and the total number of all additional administrative areas for which the RIO is responsible or shares responsibility.

5.2.5 Multivariable Analysis of RIO Preparedness/Readiness

We have identified the variables that are statistically significantly associated with the total scenario score in each of the four conceptual domains when they were analyzed one at a time. The next step in the analysis process was to examine the association between all of the significant variables in a domain at the same time to establish the most important variables whose relationship to the scenario score is not represented by other variables in the same domain. To do this, we conducted a series of multiple variable logistic regression analyses for the set of individually statistically significant variables in each domain: personal characteristics, training, experience, and organizational characteristics. The results are presented for each domain in the following tables.

The next to the final step in the analysis of the Phase II web-based survey will be a single logistic regression analysis utilizing as predictors the statistically significant variables from the multiple variable analyses of each domain as predictors. The conclusion of the multiple variable analysis of the Phase II survey will consist of dropping out non-significant variables from the model one at a time to achieve a more parsimonious statistical model without sacrificing explanatory power.

5.2.5.1 Personal Characteristics and RIO Preparedness/Readiness

The logistic regression model using personal characteristics to assess the odds of the RIO being in the high scenario score group contained the five variables that, by themselves, are statistically significantly related to being in the high scenario score group. The results of the analysis are presented in Table 5-23. When analyzed together, only three of the five variables representing personal characteristics are statistically significant: years employed at the institution, satisfaction with authority and independence as RIO, and being concerned

that research misconduct has not been brought to the RIO's attention. Two of these variables contributed to being in the high score group, and one variable detracted.

Table 5-23. Results of Multivariable Logistic Regression Analysis of Personal Characteristics That Are Associated with RIOs Being High on the Total Scenario Score Dichotomy

Personal Characteristics	Odds Ratio	Lower 95% Confidence Limit	Upper 95% Confidence Limit	Wald Chi Square	P-Value of Wald
Years Employed at Institution				11.12	0.011
0 – 2 Years	1.00				
>2 – 10 Years	0.81	0.54	1.21		
>10 – 20 Years	0.45	0.28	0.72		
>20 – 50 Years	0.72	0.48	1.07		
How Involved in Seeking Funds for Research				1.85	0.174
Very Involved	0.80	0.59	1.10		
Somewhat/Slightly/Not at All	1.00				
Satisfied with Authority and Independence				26.94	0.000
Extremely Satisfied	1.85	1.24	2.75		
Very Satisfied	2.73	1.85	4.01		
Satisfied or Not Satisfied	1.00				
Concerns that Research Misconduct Did Not Come to Your Attention				9.56	0.002
Yes	2.08	1.31	3.32		
No	1.00				
RIO Is Tenured				0.76	0.384
Yes	0.85	0.59	1.22		
No (includes not available)	1.00				

Chi Sq = 43.3859, df = 8, P-Value < 0.0001, Max-rescaled R² = 0.1365

RIOs who have been employed by their institution for more than 10 to 20 years have 55% lower odds of being in the high scenario score group than RIOs employed by their institution for 2 years or less. RIOs employed for more than 2 to 10 years, or more than 20 to 50 years, do not differ from those employed by the institution for 2 years or less. Being extremely satisfied or very satisfied with one's authority and independence as RIO provides higher odds of being in the high scenario score group than RIOs who are either only satisfied or not satisfied by 85% and 173%, respectively. RIOs who are concerned that research misconduct has gone unreported to the RIO have 107% higher odds of being in the high scenario score group than those who do not express such a concern. The full model of personal characteristics is estimated to account for more than 13% of the variation in the RIOs' scenario scores.

5.2.5.2 Training and RIO Preparedness/Readiness

The second logistic regression model we estimated contained the 11 training measures that are individually associated with being in the high scenario score group. As can be seen from Table 5-24, when analyzed together, only seven of these training variables remain statistically significantly associated with scenario score. Among those that

are significant, four of the variables detract from the odds of being in the high scenario score group and only three enhance those odds.

Table 5-24. Results of Multivariable Logistic Regression Analysis of RIO Training Variables That Are Associated with RIOs Being High on the Total Scenario Score Dichotomy

Training Variables	Odds Ratio	Lower 95% Confidence Limit	Upper 95% Confidence Limit	Wald Chi Square	P-Value of Wald
Had No Formal Training to Be the RIO				6.90	0.009
Yes	0.26	0.09	0.71		
No	1.00				
Attended One or Two ORI-Sponsored Workshops				10.96	0.001
Yes	0.30	0.14	0.61		
No	1.00				
Attended ORI Boot Camp for RIOs				8.23	0.004
Yes	10.72	2.12	54.18		
No	1.00				
Attended One or Two ORI Conferences				3.83	0.050
Yes	1.71	1.00	2.91		
No	1.00				
Served As RIO or Compliance Officer at Another Institution				1.19	0.275
Yes	1.83	0.62	5.44		
No	1.00				
Been an Active Researcher for 10 Years or More				8.44	0.004
Yes	0.61	0.44	0.85		
No	1.00				
Had Experience Directing Research Misconduct Inquiries/ Investigations				2.49	0.115
Yes	1.45	0.91	2.31		
No	1.00				
Experience as Member of an Inquiry/Investigation Committee				2.76	0.097
Yes	1.54	0.93	2.57		
No	1.00				
Experience or Training in Human Subjects Protection/IRB Issues				11.96	0.001
Yes	1.80	1.29	2.51		
No	1.00				
Helped to Write the Institution’s Research Misconduct Policy and Procedures				0.05	0.829
Yes	0.95	0.61	1.49		
No	1.00				
Sum of Training Activities of High/Medium Relevance to Being RIO				8.90	0.031
None	1.00				
One	0.65	0.42	1.00		
Two	1.27	0.75	2.15		
Three to Five	1.18	0.58	2.39		

Chi Sq = 71.2671, df = 13, P-Value < 0.0001, Max-rescaled R² = 0.2451

RIOs who report not having had any training to fill the position have 74% lower odds of being in the high scenario score group than those who indicate having some kind of training for the position. This result is very similar for RIOs who report only attending one or

two ORI-sponsored workshops as their preparation or qualification for serving as RIO. Those who attended one or two ORI workshops have 70% lower odds of being in the high scenario score group than RIOs who did not. A third variable that reduces the odds of a RIO being in the high scenario score group is having been an active researcher for 10 years or more. The odds of being in the high scenario score group are 29% lower for RIOs who report having been an active researcher for 10 years or more. The last statistically significant variable that also detracts from being in the high scenario score group is a count of the number of training activities or other qualifications a RIO reported for the position. RIOs who reported only one training activity or qualification have 35% lower odds of being in the high scenario score group than those who report having none.

There is a dramatically large increase in the odds of being in the high scenario score group for RIOs who attended an ORI-sponsored RIO boot camp. Those who have participated in the boot camp have 972% higher odds of being in the high score group than those who have not. Attending one or two ORI-sponsored conferences also seems to contribute to higher scenario scores. RIOs who report attending one or two ORI conferences have 71% higher odds of being in the high scenario score group than those who have not. Having training in the protection of human subjects (IRB) increases the odds of a RIO being in the high scenario score group. RIOs who have had IRB training have 80% higher odds of being in the high scenario score group than those who have not had such training. The full model of training variables is estimated to account for about 25% of the variation in which group RIOs' place with respect to their scenario scores.

5.2.5.3 Experience and RIO Preparedness/Readiness

Our next effort to estimate a model using logistic regression included as predictors the five RIO experience variables that were individually statistically significant related to being in the high scenario score group. As can be seen from Table 5-25, only three of the experience measures remained statistically significant in the analysis of all five together. One measure detracted from being in the high scenario score group, and the other two contributed to being in the high scenario score group.

The two variables that were associated in a positive way with increased odds of scoring in the high scenario score group are having experience with research misconduct at a institution and the frequency with which the RIO conferred with RIOs at other institutions. Those RIOs with experience from a former institution have 53% higher odds of being in the high scenario score group. RIOs who report being in contact with RIOs at other institutions from 4 to 25 times have odds of being in the high scenario score group that are 214% higher than RIOs who have never been in contact with other RIOs. Those who report fewer

Table 5-25. Results of Multivariable Logistic Regression Analysis of RIO’s Experiences that Are Associated with RIOs Being High on the Total Scenario Score Dichotomy

Experience Variables	Odds Ratio	Lower 95% Confidence Limit	Upper 95% Confidence Limit	Wald Chi Square	P-Value of Wald
Years as Research Integrity Officer				10.07	0.018
0 - 2 Years	1.00				
>2 - 5 Years	0.62	0.44	0.87		
>5 - 10 Years	1.22	0.82	1.82		
>10 - 37 Years	0.84	0.53	1.32		
Experience with Research Misconduct at Previous Institution				4.52	0.034
Yes	1.53	1.03	2.25		
No	1.00				
Number of Research Misconduct Allegations Handled as RIO				4.50	0.213
None	1.00				
Only 1	1.00	0.61	1.65		
2 to 3	1.61	0.96	2.71		
4 to 40	1.58	0.85	2.93		
Number of Times Conferred with RIO at Other Institutions				9.66	0.022
None	1.00				
One	0.76	0.46	1.26		
Two or Three	1.33	0.72	2.47		
Four to Twenty-Five	3.14	1.31	7.51		
Number of Times Conferred with Someone at Federal Oversight Agency Like ORI				4.83	0.185
None	1.00				
Only 1	1.00	0.59	1.69		
2 to 3	1.61	0.83	3.15		
4 to 100	0.55	0.25	1.25		

Chi Sq = 36.5531, df = 13, P-Value = 0.0005, Max-rescaled R² = 0.1263

than 4 contacts with other RIOs do not differ significantly from RIOs who have had no contacts.

The length of time that a RIO has been in that position is statistically significantly related inversely to scoring in the high scenario group. RIOs who have held their positions for more than 2 years but up to 5 years have 38% lower odds of being in the high scenario score group than RIOs in their positions for 2 years or less. The full model of experience variables is estimated to account for about 13% of the variation in RIOs’ scenario scores.

5.2.5.4 Organizational Characteristics and RIO Preparedness/Readiness

We estimated a logistic regression model for the fourth domain of predictor variables: characteristics of the organization employing the RIO. Recall that these predictor variables represent three sub-domains that we earlier analyzed separately: organizational characteristics, RIO responsibilities, and additional administrative responsibilities assigned to RIOs. The statistically significant variables from this earlier analysis have been combined for this logistic regression modeling exercise. A total of 14 variables have been included in

this analysis to further refine the set of variables associated with where the RIOs place with regard to their scenario scores. The results of this analysis are presented in Table 5-26.

As can be seen from Table 5-26, our analysis of all of the organizational characteristics together finds that only 2 of the 14 organizational predictors remain statistically significantly associated with scenario score. One of the two is negatively associated with being in the high score group, and the other is positively associated.

Table 5-26. Results of Multivariable Logistic Regression Analysis of Organizational Characteristics That Are Associated with RIOs Being High on the Total Scenario Score Dichotomy

Organizational Characteristics	Odds Ratio	Lower 95% Confidence Limit	Upper 95% Confidence Limit	Wald Chi Square	P-Value of Wald
Use RIO as Title for Person Handling Allegations of Research Misconduct				0.00	0.964
Yes	1.01	0.64	1.60		
No	1.00				
One of Top 100 NIH Funded Research Grantees				2.13	0.145
Yes	1.99	0.79	5.02		
No	1.00				
Policy and Procedures Manual Identifies the Title of the Person Who Handles Allegations of Research Misconduct				0.29	0.864
Yes	1.15	0.69	1.92		
No	1.00				
Don't Know	1.05	0.48	2.32		
RIO Has Someone to Assist in Performing Duties				0.03	0.986
No One	1.00				
One Assistant	1.03	0.68	1.57		
Two – Twelve Assistants	1.04	0.66	1.63		
Responsible for Handling Financial Conflict of Interest				8.14	0.017
Yes	2.09	1.26	3.47		
Yes, Shared	1.59	0.95	2.67		
No	1.00				
Responsible for Human Subjects Protection				4.75	0.093
Yes	1.28	0.76	2.15		
Yes, Shared	0.77	0.45	1.33		
No	1.00				
Responsible for Recombinant DNA				0.66	0.719
Yes	1.18	0.72	1.94		
Yes, Shared	1.18	0.70	1.98		
No	1.00				
Responsible for Grants Management				14.03	0.001
Yes	0.40	0.25	0.65		
Yes, Shared	0.58	0.35	0.95		
No	1.00				
Responsible for Sequestering Evidence				0.02	0.881
Yes	1.04	0.66	1.63		
No	1.00				

Table 5-26. Results of Multivariable Logistic Regression Analysis of Organizational Characteristics That Are Associated with RIOs Being High on the Total Scenario Score Dichotomy (continued)

Organizational Characteristics	Odds Ratio	Lower 95% Confidence Limit	Upper 95% Confidence Limit	Wald Chi Square	P-Value of Wald
Responsible for Informing Key Officials of Allegations/Actions				0.31	0.575
Yes	0.82	0.40	1.66		
No	1.00				
Responsible for Handling Allegations of More than Research Misconduct and Establishing Priorities				3.42	0.181
Yes	0.51	0.23	1.17		
Yes, Shared	0.78	0.39	1.56		
No	1.00				
Responsible for Informing Complainants of Vulnerability from Making an Allegation and Providing Protection from Retaliation				5.40	0.672
Yes	1.86	1.00	3.46		
Yes, Shared	1.21	0.68	2.17		
No	1.00				
Responsible for Deciding Whether There Will Be an Inquiry				0.30	0.862
Yes	1.16	0.59	2.28		
Yes, Shared	1.06	0.56	2.02		
No	1.00				
Research Misconduct Allegations Reported to ORI (2003-2007)				0.26	0.613
None	1.00				
One to Sixteen	1.14	0.69	1.90		

Chi Sq = 49.0972, df = 23, P-Value = 0.0012, Max-rescaled R² = 0.1685

Negatively related to being in the high scenario score group is being part of an institution that has the RIO also responsible for grants management or sharing responsibility for it. RIOs who are responsible for grants management have 60% lower odds of being in the high scenario score group than RIOs who are not responsible for such activities. In addition, these RIOs have 42% lower odds of being in the high group even if they only share responsibility for grants management. Having the RIOs responsible for handling financial conflicts of interest is positively associated with having a high scenario score. RIOs who report they are responsible for handling cases of financial conflict of interest have 109% higher odds of being in the high scenario score group than RIOs who do not have this responsibility. Sharing the responsibility does not significantly increase the odds of scoring in the high group. The full model of organizational variables is estimated to account for about 17% of the variation in RIOs' scenario score.

5.2.5.5 Modeling RIO Preparedness/Readiness Across Personal Characteristics, Training, Experience, and Organizational Characteristics Domains

In this phase of the multiple variable logistic regression analysis, we have included all 15 of the statistically significant variables from the previous domain-specific, multiple variable logistic regression analyses in a cross-domain analysis. The results of the analysis

are presented in Table 5-27. Eleven of the 15 variables included in the model are statistically significant in their association with the scenario score group into which they placed, and four are not. Four of the 11 statistically significant variables are associated with lower odds of being in the high scenario score group, and six are associated with having higher odds of being in the high scenario score group. One variable—the number of RIO training activities that were reported that we felt were likely to be of most or medium relevance to becoming a RIO—while significant in the overall model, in the comparisons we made, despite being extremely close to reaching significance, did not meet the criterion for having a statistically significant association between any of its levels and the scenario score.

Table 5-27. Results of Full Multivariable Logistic Regression Analysis of Characteristics (with Domains Noted) That Are Associated with RIOs Being High on the Total Scenario Score Dichotomy

Independent Variables	Odds Ratio	Lower 95% Confidence Limit	Upper 95% Confidence Limit	Wald Chi Square	P-Value of Wald
Years Employed at Institution (Personal Characteristics)				21.70	0.000
0 – 2 Years	1.00				
>2 – 10 Years	0.48	0.31	0.75		
>10 – <20 Years	0.30	0.19	0.49		
20 – 50 Years	0.29	0.19	0.45		
Satisfied with Authority and Independence (Personal Characteristics)				25.57	0.000
Extremely Satisfied	1.45	1.03	2.06		
Very Satisfied	2.59	1.81	3.69		
Satisfied or Not Satisfied	1.00				
Concern that Research Misconduct Did Not Come to Your Attention (Personal Characteristics)				5.27	0.022
Yes	1.70	1.14	2.54		
No	1.00				
Years Served as RIO (Experience)				20.73	0.000
0 – 2 Years	1.00				
>2 – 5 Years	0.82	0.57	1.18		
>5 – 10 Years	2.11	1.37	3.26		
>10 – 37 Years	1.47	0.91	2.37		
Experience with Research Misconduct at Previous Institution (Experience)				3.59	0.058
Yes	0.37	0.17	0.81		
No	1.00				
Number of Times Conferred with RIOs at Other Institutions (Experience)				7.05	0.070
None	1.00				
One	0.69	0.44	1.08		
Two or Three	1.20	0.71	2.02		
Four to Twenty –Five	2.01	0.92	4.42		
Has Had No Formal Training to Be the RIO (Training)				7.46	0.006
Yes	0.32	0.14	0.72		
No	1.00				

Table 5-27. Results of Full Multivariable Logistic Regression Analysis of Characteristics That Are Associated with RIOs Being High on the Total Scenario Score Dichotomy (continued)

Independent Variables	Odds Ratio	Lower 95% Confidence Limit	Upper 95% Confidence Limit	Wald Chi Square	P-Value of Wald
Attended One or Two ORI-Sponsored Workshops (Training)				17.06	0.000
Yes	0.26	0.14	0.49		
No	1.00				
Attended ORI-Sponsored Boot Camp for RIOs (Training)				8.61	0.033
Yes	6.02	1.82	19.95		
No	1.00				
Attended One or Two ORI Conferences (Training)				0.34	0.560
Yes	1.15	0.72	1.85		
No	1.00				
Been an Active Researcher for 10 Years or More (Training)				1.09	0.297
Yes	0.85	0.63	1.15		
No	1.00				
Experience or Training in Human Subjects Protection/IRB Issues (Training)				31.21	0.000
Yes	2.26	1.70	3.00		
No	1.00				
Sum of Training Activities of Most/Medium Relevance to Being RIO (Training)				20.15	0.000
None	1.00				
One	0.67	0.44	1.01		
Two	1.51	0.99	2.30		
Three to Five	1.58	0.98	2.57		
Responsible for Financial Conflict of Interest (Organizational Characteristic)				10.99	0.004
Yes	1.80	1.25	2.59		
Shared	1.17	0.80	1.70		
No	1.00				
Responsible for Grants Management (Organizational Characteristic)				21.40	0.000
Yes	0.45	0.32	0.64		
Shared	0.80	0.54	1.17		
No	1.00				

Chi Sq = 185.8588, df = 26, P-Value < 0.0001, Max-rescaled R² = 0.5280

The variables associated with reducing the odds of being in the high scenario score group include the number of years employed at the institution, whether a RIO reported having no training or qualifications to be a RIO, whether a RIO attended only one or two ORI-sponsored workshops as preparation for becoming RIO, and whether a RIO was also assigned responsibility for grants management. With respect to the number of years employed by the institution, those employed at the institution more than 2 and up to 10 years, more than 10 years but less than 20, and 20 years or more have 52%, 70%, and 71% lower odds of being in the high scenario score group, respectively, than RIOs who have been employed at an institution for 2 years or less. Not reporting any kind of training or

qualification to become RIO is associated with 68% lower odds of being in the high scenario score group than those who reported some training or qualifications. Having attended one or two ORI-sponsored workshops is associated with 74% lower odds of being in the high scenario score group than for those who did not report attending only one or two ORI workshops. RIOs assigned responsibility for grants management activities have 55% lower odds of being in the high scenario score group than those who do not have such responsibility.

There are six variables that are significantly associated with increased odds of being in the high scenario score group. RIOs who report being very satisfied with authority and independence as the RIO have increased odds of being in the high scenario score group by 159% over those RIOs who report being merely satisfied or dissatisfied. RIOs who have held the position for more than 5 years, but not more than 10 years, have 111% higher odds of being in the high scenario score group than those who have been the RIO for 2 years or less. Having attended ORI-sponsored boot camp increases the odds of being in the high scenario score group; RIOs who attended RIO boot camp have 502% higher odds of being in the high scenario score group. The next variable to be associated with placing in the high scenario score group are RIOs who report being trained or experienced in human subjects protection or IRB issues. These individuals have 126% higher odds of being in the high group than RIOs who do not report such a qualification. The final variable associated with being in the high scenario score group is having responsibility for handling issues of financial conflict of interest. RIOs who have responsibility for handling cases of alleged financial conflict of interest have 80% higher odds of scoring in the high group than those who do not. Overall, the full model of statistically significant independent variables resulting from the domain-specific logistic regression analyses is estimated to account for about 53% of the variation in RIO's scenario scores.

5.2.5.6 Parsing the Final Model of RIO Preparedness/Readiness

Because four of the variables in the full model are not statistically significant, as a final step in the analysis, we made an effort to achieve model parsimony by carrying the analysis a step further and eliminating the variables that contribute little or nothing to the explanation of the variation in which scenario score group the RIOs place. We used the backward elimination logistic regression analysis option in SAS to parse the model. It starts with all 15 of the variables in the model and then, based on statistical criteria of failing to reach statistical significance, one at a time removes the variables that are not significant until only significant ones remain. The results from that analysis are presented in Table 5-28. As a result of removing some of the non-significant variables from the model, there are now 11 of the 15 initial variables in the model that are statistically significant. There are still the same four variables associated with reduced odds of being in the high scenario score group, but there are now seven variables rather than six associated with increased odds of

being in the high scenario score group. One variable that was not significant in the full model that we estimated is now significant with fewer variables in the model.

Table 5-28. Final Results of Multivariable Logistic Regression Analysis of Characteristics (with Domains Noted) That Are Associated with RIOs Being High on the Total Scenario Score Dichotomy After Removing Non-Significant Predictors

Independent Variables	Odds Ratio	Lower 95% Confidence Limit	Upper 95% Confidence Limit	Wald Chi Square	P-Value of Wald
Years Employed at Institution (Personal Characteristics)				36.43	0.000
0 – 2 Years	1.00				
>2 – 10 Years	0.48	0.31	0.75		
>10 – <20 Years	0.30	0.19	0.49		
20 – 50 Years	0.29	0.19	0.45		
Satisfied with Authority and Independence (Personal Characteristics)				27.64	0.000
Extremely Satisfied	1.45	1.03	2.06		
Very Satisfied	2.59	1.81	3.69		
Satisfied or Not Satisfied	1.00				
Concerns that Research Misconduct Did Not Come to Your Attention (Personal Characteristics)				6.83	0.009
Yes	1.70	1.14	2.54		
No	1.00				
Years Served as RIO (Experience)				21.91	0.000
0 – 2 Years	1.00				
>2 – 5 Years	0.82	0.57	1.18		
>5 – 10 Years	2.11	1.37	3.26		
>10 – 37 Years	1.47	0.91	2.37		
Has Had No Formal Training to Be the RIO (Training)				6.17	0.013
Yes	0.37	0.17	0.81		
No	1.00				
Attended One or Two ORI-Sponsored Workshops (Training)				17.42	0.000
Yes	0.27	0.14	0.50		
No	1.00				
Attended ORI-Sponsored Boot Camp for RIOs (Training)				9.84	0.002
Yes	7.04	2.08	23.84		
No	1.00				
Experience or Training in Human Subjects Protection/IRB Issues (Training)				33.98	0.000
Yes	2.31	1.74	3.06		
No	1.00				
Sum of Training Activities of Most/Medium Relevance to Being RIO (Training)				30.37	0.000
None	1.00				
One	0.65	0.43	0.97		
Two	1.61	1.08	2.41		
Three to Five	1.83	1.17	2.85		
Responsible for Financial Conflict of Interest (Organizational Characteristics)				14.83	0.000
Yes	1.92	1.35	2.72		
Shared	1.18	0.81	1.71		
No	1.00				

Table 5-28. Final Results of Multivariable Logistic Regression Analysis of Characteristics That Are Associated with RIOs Being High on the Total Scenario Score Dichotomy After Removing Non-Significant Predictors (continued)

Independent Variables	Odds Ratio	Lower 95% Confidence Limit	Upper 95% Confidence Limit	Wald Chi Square	P-Value of Wald
Responsible for Grants Management (Organizational Characteristics)				19.44	0.000
Yes	0.48	0.35	0.67		
Shared	0.82	0.56	1.18		
No	1.00				

Chi Sq = 180.4323, df = 20, P-Value < 0.0001, Max-rescaled R² = 0.5110

While only 11 statistically significant variables remain in the final model parsed of non-significant variables, there are variables from all four predictor domains represented. They are represented by three measures from the RIO personal characteristics domain and two from the organizational characteristics domain. Five are variables representing the RIO training domain, but only one comes from the RIO experience domain. Four of the 11 statistically significant variables are associated with reduced odds of being in the high scenario score group, and there are seven variables associated with increased odds of being in the high scenario score group.

5.2.5.7 Variables Associated with Lower RIO Preparedness/Readiness

The same four variables associated with reducing the odds of being in the high scenario score group for the full model (i.e., the number of years employed at the institution, whether had no training or qualifications for becoming RIO, whether attended only one or two ORI-sponsored workshops as preparation for becoming RIO, and whether the RIO was also assigned responsibility for grants management) are significantly associated with reducing the odds of being in the high scenario score group in the parsed model as well. With respect to the number of years employed by the institution, those employed at the institution more than 2 years but 10 years or less, 10 or more years but less than 20 years, and those employed at the institution 20 years or more, have 52 %, 70% and 71% lower odds of being in the high scenario score group, respectively, than RIOs who have been employed by the institution for 2 years or less. Having attended one or two ORI-sponsored workshops is associated with 73% lower odds of being in the high scenario score group than for those who did not report attending only one or two ORI workshops. RIOs assigned responsibility for grants management activities have 55% lower odds of being in the high scenario score group than those who do not have such responsibility. RIOs who reported having had no formal training or qualifications for becoming a RIO have 63% lower odds of being in the high scenario score group.

5.2.5.8 Variables Associated with Higher RIO Preparedness/Readiness

All seven variables that are significantly associated with increased odds of being in the high scenario score group in the reduced model are the same as in the full model (i.e., being very satisfied with the authority and independence experienced as the RIO, having been the RIO for more than 5 years but not more than 10 years, having attended ORI-sponsored boot camp for RIOs, reporting having had training or experience in human subjects protection or IRB issues, having responsibility for handling issues of financial conflict of interest, having concerns that research misconduct did not come to the RIOs attention, and the sum of training activities reported that were classified as being of most or medium relevance to becoming a RIO).

RIOs who report being extremely and very satisfied with the authority and independence they have as the RIO have increased odds of being in the high scenario score group by 45% and 159% , respectively over those RIOs who report being merely satisfied or dissatisfied. RIOs who have held the position for more than 5 years but not more than 10 years have 111% higher odds of being in the high scenario score group than those who have been the RIO for 2 years or less. In addition, having attended ORI-sponsored boot camp for RIOs increases the odds of being in the high scenario score group. RIOs who attended RIO boot camp have 604% higher odds of being in the high scenario score group.

The fourth variable associated with placing in the high scenario score group occurs for those RIOs who report being trained or experienced in human subjects protection or IRB issues. These RIOs have 131% higher odds of being in the high group than RIOs who do not report such training or qualifications. The next variable associated with being in the high scenario score group is having responsibility for handling issues of financial conflict of interest. Those RIOs who have responsibility for handling cases of alleged financial conflict of interest have 92% higher odds of scoring in the high group than those who do not. The sixth variable associated with being in the high scenario score group consisted of RIOs expressing concerns that research misconduct may not have come to their attention. RIOs with this belief have 70% higher odds of being in the high scenario score group than those without it. The seventh variable associated with being in the high scenario score group is the sum of training activities reported that we classified as being of most or medium relevance to becoming a RIO. With the non-significant variables removed, this variable was able to reach significance and indicate that the more training activities reported, the greater the odds of being in the high score group in this reduced model. RIOs with two and three to five training activities or other qualifications for becoming a RIO have 61% and 83% higher odds, respectively, of being in the high scenario score group than RIOs with none.

The parsed or reduced model of 11 statistically significant independent variables from the domain-specific logistic regression analyses is estimated to account overall for approximately 51% of the variation in which group RIOs' place with respect to their scenario

score, only about 1% less than the estimate we achieved with the earlier full model of 15 variables. The parsed model eliminates four variables from the full model that do not reach statistical significance or contribute significantly to the variation accounted for in the dependent variable. Reducing the model in this way provides a more parsimonious model containing the set of variables most strongly associated with the RIO's scenario score.

6. CONCLUSIONS, LIMITATIONS, AND RECOMMENDATIONS FROM THE PHASE II SURVEY

In this final section of the report, we discuss the results of the analysis of the Phase II survey and the conclusions the analysis leads to about what factors contribute to well-informed and capable RIOs who are able to fulfill the responsibilities associated with handling allegations and investigations of research misconduct. In addition, we review the major limitations of the work we have performed. Finally, we endeavor to make sound recommendations for increasing the capabilities and readiness of RIOs based on our analytic results.

6.1 Key Conclusions

One key conclusion from this project surrounds the finding that not all RIOs are equally well-prepared and ready to handle the responsibilities entrusted to them by the Federal research misconduct regulations and their own institutions. Very few RIOs responded to the survey scenarios with a number of action responses that come close to matching the number of action responses suggested as appropriate by the two expert consultants. Fully 97% of the RIOs in the Phase II survey gave fewer than half the number of potentially appropriate actions identified as appropriate by the expert consultants. Whether institutional leaders are aware of the need for their RIOs to be better prepared to receive and handle allegations of misconduct will likely remain unacknowledged, with no effort made to ameliorate the condition until an allegation is made, an investigation is pursued, and something is mishandled. The fact that almost half of RIOs (49%) indicate that they do not have a written job description suggests that there is room for institutions to be more specific about responsibilities RIOs will have and what capabilities they will need to function in the position. In light of this, it is troubling that approximately 20% of RIOs report that it is not one of their sole or shared responsibilities to inform researchers of the institution's research misconduct policy, receive allegations of research misconduct, or inform complainants of their vulnerability to retaliation by making an allegation of misconduct. In addition, nearly 30% of RIOs say they have no role in sequestering evidence. These responsibilities are very often considered among the most critical that the RIO performs, and not knowing they are expected could leave them undone or less well done than they should be.

A second key conclusion is the finding that RIOs do not necessarily improve their capabilities over time, especially after being in the position for more than 10 years. It may be that the job becomes more routine and they become less enthusiastic. Our results suggest that even long time RIOs may be in need of continuing education while new RIOs are in need of initial training for the position. This may reflect the fact that research misconduct allegations are relatively rare events in most places. Nearly two-thirds of RIOs

(63.0%) report never having had to deal with an allegation of research misconduct so the opportunities to grow with experience does not really exist for most RIOs without some form of educational effort.

Another key conclusion stems from the finding that only a small proportion of the persons who carry out the responsibilities of RIOs actually carry the formal institutional title of RIO (or compliance officer), only 18.2% in the Phase II survey. This may speak to the lack of commitment and openness of the institutions to making staff aware of the institutional procedures and channels through which allegations of research misconduct can be made. Not having staff who are readily able to recognize the correct person or place in the institutional structure to report possible research misconduct may account for the small number of allegations reported. Institutions have a variety of ways to highlight and promote the stature and importance of administrative positions in the institution. Placement and titling of important persons in the institution is one way. By not elevating the RIO's position and making the title associated with the role one that is easy for staff to identify as the person responsible for handling issues of research misconduct and integrity, it may downplay the importance of recognizing and exposing research misconduct and discourage making allegations.

Our primary analysis focus has been not only to characterize the RIOs and the institutional settings in which they function, but also to assess the impact of variation in four predictor domains on whether RIOs are well prepared and ready to perform in the RIO role, i.e. their responses to three scenarios place them in the high scenario score group. Placement in the high scenario score group more closely reflects the responses of the two expert consultants, who are experienced former RIOs.

The four predictor domains we investigated include personal characteristics, training or qualifications to become the RIO, experience with performing RIO responsibilities, and organizational characteristics that incorporate the array of RIO and other administrative tasks assigned to the RIO, as well as characteristics of the organization. In the Phase II analysis results, at least one variable from each of the four domains emerges from our analysis as having an impact on RIO preparedness/readiness. However, not all of the statistically significant variables are associated with placing RIOs in the high scenario score group.

Three variables from the personal characteristics are associated with the scenario scores. One of the three—being employed by the institution for more than 2 years—is negatively associated with the scenario score. For long-time employees of an institution, the odds of scoring in the high scenario score group are from 50% to 70% less than if they had been working there for 2 years or less. The other two personal characteristics are indicators of attitudes held by the RIOs, and both are positively associated with being in the high scenario score group. RIOs who are extremely or very satisfied with the authority and

independence they enjoy as the RIO have from 55% to 155% higher odds of being in the high scenario score group than RIOs who merely say they are satisfied or say they are not satisfied with their authority and independence as the RIO. The final personal characteristic associated with being in the high scenario score group is having concerns that some research misconduct is not being reported to the institution's RIO. These concerns are associated with 70% higher odds of being in the high scenario score group.

Only one variable from the predictor domain representing a RIO's experience is in the final model and associated with being in the high scenario score group: the number of years the RIO has been in the RIO position. RIOs who have held the position for from more than 5 years to 10 years have 110% higher odds of being in the high scenario score group than those who have held the position for only 2 years or less.

Two variables from the organizational characteristics domain are included in the final model. One is positively associated with being in the high scenario score group, and one is negatively associated. RIOs solely responsible for handling the institution's issues involving financial conflict of interest have about 90% higher odds of being in the high scenario score group than those not involved in it at all. On the other hand, those RIOs who are also solely responsible for grants management in the institution have 55% lower odds of being in the high scenario score group than RIOs with no such responsibility.

Five of the variables from the training domain are significantly associated with the scenario score category. Two of them—RIOs who say they had no training or qualifications to be the RIO, and those RIOs who report attending one or two ORI-sponsored workshops as their preparation for becoming RIO—are negatively associated with scoring in the high scenario score group. These individuals have about 60% and 70% lower odds of being in the high scenario score group than those who report having some training and have attended something other than one or two workshops. The remaining three training variables are positively associated with being in the high scenario score group. RIOs who report that they attended the ORI-sponsored RIO boot camp have more than 600% higher odds of being in the high scenario score group than those who did not attend one of the sessions, and those who report having had training or experience in human subjects or IRB issues have 130% higher odds of being in the high scenario score group. RIOs who say they have participated in two or more training activities that we considered of most or medium relevance to the RIO position have from 60% to 80% higher odds of being in the high scenario score group than RIOs who report having participated in fewer training activities.

6.2 Limitations of the Study

The Phase I interview survey was intended to be exploratory and for that reason employed a random stratified, but not properly proportionate, sampling representation of RIOs to assure inclusion of RIOs working in all research settings and funding levels. Despite

a very good response rate from the sample (81.3%), the results cannot be presumed to be more than suggestive in an exploratory sense for the full population of RIOs, applying fully only to the sample of respondents.

While we received a reasonably high rate of RIO participation in the Phase II, web-based survey, the biggest limitation with the Phase II survey portion of this study is the survey non-response and the item non-response associated with the scenarios. We achieved a survey response rate of 59.2% however, in spite of this, only 56.7% of the respondents gave answers to all three of the scenarios. We used the three scenarios to create the scenario scores that we analyzed in this project. In order to be able to make generalizations to the entire universe of RIOs included in the frame, we had to make survey and item non-response adjustments to the sampling weights. Doing this has allowed us to assume that our results can be fairly applied to the universe of RIOs surveyed, not just those who responded.

While there is certainly merit in a study that seeks only to describe the characteristics of RIOs and their institutional settings, we wanted to do more. We wanted to examine whether there are differences in the capabilities/readiness of RIOs to do their job, and if there were, we wanted to identify and understand what factors contributed to them. We struggled to develop a suitable methodology for studying what RIOs do when faced with selectively structured situations that they might face when acting as a RIO. We settled on a fairly direct approach of asking them what they would do when faced with certain common scenarios RIOs can expect to face. As with all survey research, relying on self-reported behavior in hypothetical situations to represent what a person will actually do can raise questions about measurement validity. In other words, can we depend on a person to actually do in a real life situation what they say they would do when asked about a similar hypothetical situation? It's not so much that we are concerned about deception or the instability of the methodology so much as we are about how the pressures of being faced with a "real" situation – actual people, time pressures, and institutional environment – potentially change the situation and also the actual response.

A final point to mention as a limitation is the fact that differences between our sampling and data collection approach to the Phase I and Phase II studies do not make it possible to compare the results of the two studies. Recall that the Phase I study was a pilot study in which we wanted to assure inclusion of relatively rare RIO representatives to test the items in the data collection instrument. In Phase I we overrepresented RIOs from institutions receiving large NIH grant awards. In addition the data collection mode differed dramatically (i.e., interviews vs. self administered web-based questionnaire), and clearly influenced the response rates (81% vs. 59%). Because of our commitment to not solicit Phase I study respondents to participate in the Phase II survey, those 112 RIOs from Phase I were not included in the Phase II survey of 1099 RIOs.

6.3 Study Recommendations

6.3.1 Recommendations for Institutions

Our analysis of the scenario scores is quite discouraging in its revelation of how limited the cadre of existing RIOs is in its preparedness/readiness to perform the role appropriately when compared to recognized, experienced, competent RIOs. When compared to the two ex-RIO consultants, fewer than 3% of the RIOs surveyed gave even half-way comparable numbers of action responses as to how they would act in difficult scenarios commonly faced by RIOs. These results are, of course, partially due to the limited number of opportunities that the majority of RIOs have had to encounter even one person making an allegation of research misconduct, not to mention more than one. Research institutions need to take the responsibility to have well-trained RIOs seriously by providing more opportunities and incentives for them to pursue training on a continuing basis. Our analysis particularly indicated that even RIOs who have been filling the position for more than 10 years may profit from continuing education in what constitutes and how to carry out the RIO's job.

In addition, with only about half of RIOs reporting that they have a written job description, greater attention by the institution to more precisely specifying what a RIO is expected to do would likely be helpful. It would in the least assure that someone presumably trained to be the RIO would be responsible for doing the things associated with the responsibilities associated with RIOs like sequestering evidence, informing researchers of the institution's misconduct policy, receiving allegations and informing complainants what they risk when they file allegations and what protections they can be offered. With fewer than 20% of RIOs actually identified by title as the Research Integrity Office, it may contribute to the fact that very few allegations of research misconduct are reported. If it were more widely known that reports of such suspected misbehavior was encouraged in the institution, there might be more made. Clearly identifying the person to whom such reports should be made as the RIO, along with full specification of what the reports should contain would be steps in the right direction.

A somewhat surprising finding of the study is how many RIOs have responsibilities associated with the business side of research having responsibility for grants management or financial conflicts of interest and their relationship to RIO preparedness. While those dealing with conflict of interest scored higher in preparedness, those solely involved in financial management scored lower. This suggests that institutions need to be aware of assigning RIOs responsibilities that may detract rather than support their position as RIO.

6.3.2 Recommendations for the Office of Research Integrity

At least one variable from each of the four domains is included in the statistical model estimated from the Phase II, web-based survey data. The 11 variable model accounts

for approximately 50% of the variation in the scenario score groups. The training domain includes the largest number of measures in the model, including some that are associated with achieving a high scenario score and some contributing to the achievement of a low scenario score.

While we cannot fully explain the relative importance of the four predictor variable domains—personal characteristics, RIO training, RIO experience, and organizational characteristics—to predicting the preparedness/readiness of RIOs to perform their responsibilities, we can, however, safely draw some recommendations from it. It is clear from the analysis of the responses to the web-based survey that appropriate training is critical. Training measures are identified most often in the analysis, and they are identified as both advancing preparedness/readiness as well as inhibiting it. Thus, while some training or prior qualification for the RIO position may increase preparedness/readiness, some, as well as none, is associated with inadequate preparedness.

One training opportunity above all stands out as being particularly good at fostering the appropriate RIO behavior: participation in the ORI-sponsored RIO boot camp. RIO boot camp is an extensive and intensive small group experience that involves RIOs in discussions of how to operate in the difficult situations in which they often find themselves. RIO boot camp stands in contrast to other ORI-supported training activities, such as attending one or two topic-specific workshops that are associated with low, rather than high, scenario scores. Workshops typically represent short and limited exposures to RIO activities with limited opportunities for interaction. Also, the recognition by the RIO that he/she has not received adequate training or achieved any prior qualification is associated with low scenario scores. Further, reporting multiple training opportunities that one has had or qualifications that one has achieved that we identified as being of most or medium relevance to the RIO position are associated with higher scenario scores. We can say from our analysis that the amount and type of training that RIOs receive is important to their preparedness.

Based on this analysis, to improve the preparedness/readiness of RIOs, we recommend that ORI encourage more RIOs to participate in the boot camp training experience. Our analysis shows that merely making materials available that RIOs can obtain and review on their own from the ORI web site is not associated with higher scenario scores. Rather, these individuals seem to benefit from the personal contact with other RIOs and the opportunities to discuss issues openly with more experienced persons. Further, we recommend that ORI do what it can to provide more opportunities for RIOs to attend intensive and extensive training sessions similar to that of the RIO boot camp sessions, and that ORI make the boot camp and similar sessions more convenient for RIOs to attend.

While there may be time and resource limits to how many RIO boot camps ORI can hold, there are components of the boot camp experience that might be independently developed for greater RIO participation and interaction as well as training. In particular,

boot camp attendees make contact with other RIOs and form networks which can help one another to deal with questions and issues that arise. To replicate this spontaneous interaction, ORI might consider forming small networks for RIOs who could then meet periodically via conference call, Skype or other electronic media to discuss issues of common interest. The networks could be formed to include experienced RIOs who might mentor less experienced ones as they discuss issues. Those issues could even include scenarios prepared and distributed by ORI similar to the scenarios employed in this study. The results of such network meetings working on common issues could then be shared with ORI, compiled, and distributed to other RIOs.

ORI could then prepare and distribute the results of the common issue discussion compilations in the form of scripts and checklists to be used by RIOs. The scripts could identify and specify the important things to include in preparation for contacts with respondents, witnesses, and complainants to discuss the importance of confidentiality, prohibition of retaliation against complainants, or the hazards associated with making an allegation, for example. The check lists could enumerate the steps involved in taking certain actions such as sequestering evidence, training the investigative panel, or assessing the credibility of evidence at the basis of allegations.

7. REFERENCES

- Byrt T. How good is that agreement? *Epidemiology* 1996;7:561
- Francis, S. 1999. Developing a Federal Policy on Research Misconduct. *Science and Engineering Ethics*, 5, 261-272.
- Geller, L.N. 2002. Exploring the Role of the Research Integrity Officer: Commentary on 'Seven Ways to Plagiarize: Handling Real Allegations of Research Misconduct. *Science and Engineering Ethics*, 8(4): 540-542.
- Gwet, K. 2001 Handbook of Inter-Rater Reliability: How to measure the level of agreement between two or multiple raters: Stataxis Publishing Company, PO box 120185 Gaithersburg, MD. 309.
- Institute of Medicine National Research Council. 2002. *Integrity in Scientific Research: Creating an Environment that Promotes Responsible Conduct*. Washington, DC: National Academies Press.
- Koppelman-White, E. 2006. Research Misconduct and the Scientific Process: Continuing Quality Improvement. *Accountability in Research*, 13, 225-246.
- Korenman, S.G., Berk, R., Wenger, N.S., Lew, V. Evaluation of the Research Norms of Scientists and Administrators Responsible for Academic Research Integrity. *JAMA*, 279(1): 41-47.
- Pascal, C.B. 2000. Scientific Misconduct and Research Integrity for the Bench Scientist. *Scientific Misconduct and Research Integrity*, 224, 220-230.
- SAS (SAS Institute Inc). 2008. SAS OnlineDoc® 9.1.3. Cary, NC: SAS Institute Inc.
- Shrout, P.E. and Fleiss, Joseph L. (1979). "Intraclass Correlations: Uses in Assessing Rater Reliability". *Psychological Bulletin* 86 (2): 420-428.
- Sim, Julius and Wright, Chris. 2005. The Kappa Statistic in Reliability Studies: Use, Interpretation, and Sample Size Requirements. *Physical Therapy*; 85(3): p257-268
- Titus, S.L., Wells, J.A., Rhoades, L.J. 2008. Repairing Research Integrity. *Nature*, 453, 980-982.
- U.S. DHHS (Department of Health and Human Services). 2009. *1999 ORI Annual Report. 2009*. Retrieved from the Office of Research and Integrity website: http://ori.dhhs.gov/documents/annual_reports/ori_annual_report_1999.pdf.
- Wright, D.E., Titus, S.L., Cornelison, J.B. 2008. Mentoring and Research Misconduct: An Analysis of Research Mentoring in Closed ORI Cases. *Science and Engineering Ethics*, 14(3): 323-336.