

**ORGANIZING AN INSTITUTIONAL
INVESTIGATION ASSISTANCE
PROGRAM:
A FEASIBILITY STUDY FOR
THE OFFICE OF RESEARCH
INTEGRITY**

Final Report

Logicon/ROW Sciences
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EXECUTIVE SUMMARY

The Office of Research Integrity (ORI) is responsible for protecting the integrity of the Public Health Service (PHS) extramural and intramural research programs. ORI provides guidelines that define research integrity and research misconduct and include methods for preventing misconduct and reviewing allegations of misconduct. ORI also provides training to help institutions promote an environment for proper research conduct and telephone and onsite technical assistance to assist institutions in factfinding regarding potential misconduct.

ORI has received assurances from more than 4,000 organizations stating that they follow an established policy for handling allegations of research misconduct, consistent with PHS regulations. Although allegations of scientific misconduct are rare, institutions that receive a complaint may not have sufficient expertise or resources to properly handle inquiries or investigations. Organizations with a small research staff or narrow scopes of business may be further disadvantaged because they are unable to avoid conflicts of interest or do not have appropriate expertise. If an organization has conducted an inquiry of allegation related to PHS-funded research and determined that an investigation is required, it must report the allegation to ORI. In the past 5 years, 175 organizations have reported allegations to ORI.

The Department of Health and Human Services (DHHS) Review Group on Research Misconduct and Research Integrity recommended the formation of consortia of research organizations, scientific societies, and associations that can assist organizations in the conduct of factfinding when needed. These consortia have the potential to improve institutions' ability to respond to allegations, reduce the need for Federal factfinding, and improve the cost-effectiveness of factfinding. However, the recommendation raised questions that needed to be studied before further action was taken.

ORI executed a contract with Logicon/ROW Sciences to design and conduct a feasibility study to assess the need for and interest in consortia. Among the issues to be addressed were

- How different research institutions approach factfinding?
- The need for and level of interest in developing consortia to assist in responding to allegations of misconduct.
- The basis for establishing consortia (i.e., by location, organization size, research area).
- The capabilities and services that consortia should provide.

After input was solicited from ORI staff on the issue, a survey of organizations that have assurances on file with ORI was planned. Before the survey was developed, advice was solicited from experts through an Internet-based focus group. With the input from the focus group, a final survey was conceived and designed.

To ensure that opinions from various perspectives were obtained, the sampling plan needed to include organizations that had conducted factfinding of allegations as well as organizations of differing sizes and types. A sample of 1,000 organizations was planned so that enough responses from the various types of organizations could be obtained. All organizations that had reported an

allegation to ORI in the past 5 years were included. The remaining sample was selected randomly, stratified by institution type as defined by PHS.

The organization officials who had signed the assurance on file at ORI received personalized letters inviting them to participate in the study. Instructions for accessing the survey on the Web or receiving a copy by alternate means were included. Organizations that had not returned a completed survey after 4 weeks were called and asked to participate.

A total of 312 completed surveys were received for a response rate of 32 percent. Most responding organizations (40 percent) reported employing 1 to 10 researchers or faculty members, whereas approximately one-third (32 percent) had more than 100. Institutions of higher education accounted for 39 percent of study participants, and “other” organizations, which include small businesses, accounted for 29 percent. Almost 25 percent of responding organizations had received an allegation of research misconduct that led to an inquiry or investigation in the past 5 years. Large organizations were more likely than smaller organizations to report having received an allegation.

Most organizations indicated that they were likely to use their own institutions’ resources to respond to allegations of misconduct. Potential preferred sources of assistance would be ORI and outside advisors/consultants. Types of assistance that might be needed include general guidance on the process to respond to an allegation, legal guidance, and subject area expertise. Costs for these sources of assistance are likely to be a deciding factor on whether to use them.

Organizations demonstrated a reluctance to become a member of a consortium but would consider using services offered by a consortium. Answers to open-ended questions conveyed the perception that consortia could provide useful assistance but were not required. Study participants indicated that registries of consultants or institutions that have investigated allegations would be useful and require fewer resources to develop than consortia would.

The study findings do not demonstrate strong interest in or an outstanding need for the development of consortia. However, open-ended responses indicate that some organizations are misinformed about ORI’s mission and services. ORI should consider expanding its educational activities, providing more information to research organizations through its website, and overseeing the development of registries of advisors and institutions experienced with inquiries and investigations of allegations of research misconduct.

INTRODUCTION

The Office of Research Integrity (ORI) is responsible for protecting the integrity of Public Health Service (PHS) extramural and intramural research programs. ORI pursues this responsibility by maintaining oversight of the institutional handling of research misconduct allegations involving PHS-supported research. ORI also promotes research integrity and the responsible conduct of research (RCR) through educational and preventive activities, such as conducting conferences and workshops, developing publications, developing RCR resources, and presenting or exhibiting at scientific and professional meetings.

Many research institutions have submitted assurances to ORI declaring that they have established and will follow procedures for responding to research misconduct allegations that comply with PHS regulations (42 CFR 50, Subpart A). They may not, however, have the capacity to conduct their own inquiries or investigations in a competent and cost-effective manner. Because an allegation of scientific misconduct is a low-probability event, most institutions do not develop the expertise needed to conduct proper inquiries or investigations. Also, many small to midsize organizations are unable to avoid conflicts of interest or acquire the required subject matter expertise.

To improve the ability of institutions to respond to allegations of scientific misconduct and to reduce the need for Federal factfinding, the Department of Health and Human Services Review Group on Research Misconduct and Research Integrity has recommended the formation of consortia that can conduct a factfinding when an individual institutional or organizational process is impractical. The Review Group indicated that consortia may be most useful

for small and midsize institutions, but also may be used by large institutions that have little or no experience with misconduct allegations. The Review Group stated that a consortium may be formed by institutions, professional organizations, or other profit or nonprofit groups formed specifically to conduct factfinding on behalf of institutions.

The recommendation to develop consortia raised several questions. These questions include the following:

- What existing resources do research institutions use (or plan to use when the need arises) to conduct factfinding?
- How much interest do research institutions have in joining a consortium formed for this purpose?
- What types of assistance would institutions seek when conducting factfinding?
- What is the basis (e.g., field of study, institutional type) for forming consortia?
- What additional sources of assistance would institutions like to see developed?
- How can ORI improve the services it offers to institutions?

If the level of interest in using and joining consortia is high enough to pursue development of consortia, several other questions would need to be answered:

- How many consortia should be established?
- What criteria should be adopted for membership in these consortia?

- How would the performance of consortia be evaluated?
- How would each consortium be managed? By whom?
- How much is the factfinding conducted by consortia expected to cost?
- How will consortia be funded? By the institutions that use the consortia? If not, by whom?

ORI engaged the services of Logicon/ROW Sciences to conceptualize and develop a study design and conduct the study. Specifically, the work was divided into four tasks: development of a study design, data collection, data analysis, and reporting of the study results.

To begin answering the first set of questions,

TASK ONE: STUDY DESIGN

STUDY POPULATION

To be eligible to receive research funding from PHS agencies, an organization must submit an assurance to ORI that the organization has established and will follow a policy for handling allegations of research misconduct that complies with PHS regulation, 42 CFR 50, Subpart A. ORI maintains a database of these institutions, including the address, name of the “responsible official” who signed the assurance, and institutional type. Designation of institutional type is based on the following PHS-defined categories:

- Higher education
- Research organization, institute, laboratory, foundation
- Independent hospital
- Educational organization, other than higher education
- Other health, human resources, or environmental organization
- Other (including small businesses)

There are approximately 4,000 institutions with assurances on file with ORI. If an institution has an allegation of misconduct, it is not required to report the allegation to ORI until the inquiry has been conducted and a decision to open an investigation has been made. In a 5-year period (1997–2001), about 175 organizations reported allegations to ORI that proceeded to an inquiry or investigation. Because receipt of a research misconduct allegation is a low-probability event, any study design should examine the needs and opinions of institutions that have had and that have not had allegations.

A survey of institutions was conceived as the most practical method for studying the need for consortia. Because the need for consortia was hypothesized to vary by institutional type and size, it was important to include all institutional types. To obtain 500 survey participants for sufficient statistical analysis, a sample size of 1,000 organizations was chosen. To obtain sufficient feedback from institutions that have actually investigated an allegation of misconduct, all 175 institutions that have reported allegations to ORI. The remaining institutions were selected randomly from strata by institutional type.

INSTRUMENT DEVELOPMENT

With the issues outlined above as a guide, a survey of institutions was planned. To gain further insight into potential questionnaire items, input was solicited from a representative group of experts identified by ORI.

To take advantage of newer technology and minimize the burden on the experts, their input was solicited through an Internet-based bulletin board. Each expert was contacted by telephone and/or e-mail to gain his or her cooperation. They were sent instructions for participation, which included an option to provide input by telephone; however, no one used this option. Potential questions were posted on a website, and experts could comment on the questions. All comments were stored in a database and reviewed by the study manager for appropriateness and clarity. After review, the comments were made available for all others to see and comment on. The website remained available 24 hours per day for 1 week. Participants were able to view others’ comments and make additional comments. This allowed a group process without requiring the experts

to convene at the same time to view and discuss the information.

The comments from the Internet “focus group” helped refine the questionnaire items and develop additional questions. The intent was to make most of the questions close-ended. The draft list of questions was then forwarded to ORI for review and comment.

After revisions suggested by ORI were incorporated, the survey was pilot tested. Federal regulations allow pilot testing of surveys on fewer than 10 individuals or organizations. Through ORI’s database of institutions that have signed assurances, nine organizations were contacted and asked to participate in the pilot test. Four of the nine

institutions chosen had an allegation of misconduct. Appendix A contains a copy of the final questionnaire and accompanying cover letter.

OMB CLEARANCE

ORI then prepared a supporting statement and submitted it to the Office of Management and Budget (OMB). Clearance from OMB is required for all data collection efforts by Federal agencies that involve more than nine individuals or organizations. Clearance was received in August 2001.

TASK TWO: DATA COLLECTION

SURVEY SAMPLE

After clearance was received, ORI forwarded the most up-to-date list of institutions in the database, including the name of the institution, name and title of the responsible official, address, telephone number, and e-mail address. The institutions are grouped according to the six institutional categories used by the PHS. The database consisted of 4,252 institutions that have assurances on file with ORI. The files included 175 organizations that reported having had an allegation of research misconduct that led to the conduct of an inquiry or an investigation within the past 5 years. The remainder of the sample was chosen at random, but in proportion to the number of each institutional type in the population; this would ensure responses from all institutional types. Rounding to whole numbers resulted in a sample size of 1,001 (see Table 1).

SURVEY ADMINISTRATION

The responsible official at each institution received a personalized letter inviting the institution to participate in the study. Included with the letter were instructions for accessing the survey on the Internet using a unique "userid" (a number assigned between 1 and 1,001) and a password (generally the city from the mailing address), as well as a form to request a paper copy should the Internet not be a viable option. This reduced postage and printing costs. If letters were returned for incorrect or outdated addresses, the letters were resent to new addresses as identified by telephone or searches on the Internet. If no new address was found, e-mail was sent instead. In some cases, it became clear that the organization had been closed, and these were noted in the tracking database.

Table 1: Survey Population and Sample by PHS Institutional Categories

Institutional type	Population				Sample			
	No allegation		Allegation	Total	No allegation		Allegation	Total
	n	Percent	n	Percent	n	Percent		
Institution of higher education	754	18.5%	120	874	153	18.5%	120	273
Research Organization, Institute, Foundation, or Laboratory	298	7.3%	27	325	60	7.3%	27	87
Independent Hospital	216	5.3%	16	232	44	5.3%	16	60
Other educational organization	24	0.5%	0	24	5	0.5%	0	5
Other health, human resources, or environmental organization	389	9.5%	6	395	79	9.5%	6	85
Other (including small businesses)	2,396	58.8%	6	2,402	485	58.8%	6	491
Total	4,077		175	4,252	826		175	1,001

Organizations that had not responded after 4 weeks were called and reminded about the study. Those organizations who were contacted and agreed to participate were sent a copy of the survey and instructions for using the Internet version by e-mail, fax, or mail (according to the official's preference). The data collection period was closed 4 weeks after the phone calls began.

Study participants who chose to use the Internet version were able to log in as many times as they wanted and change and save their responses. Therefore, responses to the survey were downloaded only once—at the end of the data collection period.

TASK THREE: DATA ANALYSIS

ANALYSIS PLAN

As part of the study design, an analysis plan was developed. This plan was reviewed by ORI staff and revised as needed. Preliminary analyses were submitted to ORI staff for review prior to their inclusion in this report. Although the sample was stratified, no weights were used in analyses, since population estimates were not a purpose of this study.

Responses to the Internet version of the survey were recorded in a Microsoft Access database. This eliminated data entry error. Those responses received by other means (fax, mail, and e-mail) were entered into the database and reviewed for accuracy of entry. The quantitative data were then exported into SAS for analysis. Open-ended responses were coded and summarized.

RESPONSE RATE

A total of 312 responses were received by the cutoff date. Another 12 cover letters were returned because the institutions had closed or because the mailing address was incorrect and

no new address could be found. This reduced the sample size to 989, producing a response rate 312/989, or 32 percent. Table 2 shows the response rates by sampling strata.

Proportionally, more institutions of higher education and fewer small businesses responded than did the other types. Of the 175 institutions that had reported an allegation of misconduct to ORI, 68 (40 percent) responded.

A check of the ORI database was conducted by asking participants to classify the research institution for which they were responding. Table 3 shows a cross-tabulation between answers to self-reported institutional types (survey question 2) and the PHS institutional categories coded in the ORI database.

There is a reasonable level of agreement, but discrepancies exist, which indicate that either the definitions of these terms are not clear or mutually exclusive or that the ORI database may need more frequent confirmation of its information.

Table 2: Response Rates by Sampling Strata

PHS Institutional Categories	Sample		Response	
	n	Percent	n	Percent
Institution of higher education	270	27.3	117	37.5
Research organization, institute, foundation, or laboratory	87	8.8	28	9.0
Independent hospital	58	5.9	17	5.4
Other educational organization*	5	0.5	0	0.0
Other health, human resources, or environmental organization	85	8.6	28	9.0
Other (including small businesses)	484	48.9	122	39.1
Total	989	100.0	312	100.0

*Since no responses were received from this category, it will not appear in subsequent tables.

Table 3: Comparison of Self-Reported Institutional Type to Database Records

Type of institution	PHS Institutional Categories					
	Institution of higher education	Research organization, etc.	Independent hospital	Other health organization	Other, incl. small business	Total
Institution of higher education, not affiliated with academic medical center	70	0	1	1	0	72
Academic medical center or affiliated institution	42	1	6	2	1	52
Research organization, institute, foundation, or laboratory	1	23	0	11	30	65
Independent hospital	0	1	9	0	0	10
Educational organization other than higher education	0	0	0	1	2	3
Other health, human resources, or environmental organization	0	0	0	4	3	7
Federal or State Government	0	1	1	2	1	5
Other	1	1	0	7	83	92
Did not respond to question	3	1	0	0	2	6
Total	117	28	17	28	122	312

ANALYSES COMPLETED

Most analyses were basic frequencies and cross-tabulations of all survey items with PHS institutional categories and survey questions 1 to 4 (institution size and type, and the number of allegations in the past 5 years). Appendix B contains the frequencies of responses to each question, and Appendix C contains the cross-tabulations. Cross-tabulations by an affiliation with another institution for inquiries or investigations (question 3) are not shown

because only 12 percent of institutions that replied indicated that they had such an affiliation (85 percent did not have an affiliation, and 3 percent did not know). Appendix C contains percentages that are based on the total number of surveys received (312), and include a row and column for missing responses to items. However, for easier interpretation the results and recommendations sections report percentages based only on the number of responses received for the variables included in the tables. Appendix D provides a summary of comments received for the open-ended questions.

TASK FOUR: REPORT RESULTS

INSTITUTION CHARACTERISTICS

Most institutions (40 percent) reported having only 1 to 10 researchers employed at their institution (survey question 1). As one would expect, the majority of the institutions that reported employing more than 100 researchers (82 percent) were institutions of higher education, both affiliated and not affiliated with academic medical centers (see Table 4). Table 4 shows that those institutions reporting themselves as some “other” type are small businesses other than research organizations (the “other” category includes small organizations).

Almost all participants (85 percent) indicated that their institution did not have a formal affiliation to respond to allegations of research misconduct (survey question 3). Most of those that did have such an affiliation indicated that they were part of a multicampus university

system, such as many State colleges.

PHS defines research misconduct as “fabrication, falsification, plagiarism, or practices that seriously deviate from those that are commonly accepted within the scientific community for proposing, conducting, or reporting research. It does not include honest error or honest difference in interpretations or judgments of data.” However, institutions may use broader definitions of research misconduct. This may account for some differences between the survey answers and the ORI database.

Each organization was asked to indicate how many allegations of scientific misconduct it had received in the past 5 years resulting in inquiries or investigations (survey question 4). Most (77 percent) of the participants indicated

Table 4: Institution Size by Institutional Type

Type of institution	Number of researchers and faculty				
	1–10	11–100	Over 100	No response	Total
Institution of higher education	8	21	42	1	72
Academic medical center	3	7	41	0	51
Research organization	34	20	11	0	65
Independent hospital	3	5	2	0	10
Other educational organization	2	1	0	0	3
Other health organization	5	1	0	1	7
Federal or State Government	1	2	2	0	5
Other	69	20	3	0	92
No response	1	2	2	2	7
Total	126	79	103	4	312

that their organization had *not* had an allegation. Only 3 (out of 126) of the small organizations (between 1 and 10 faculty and researchers) had received any allegations, whereas 63 (out of 98) of the larger organizations (more than 100 faculty members and researchers) had received at least one allegation (see Table 5). Most (82 percent) of the organizations reporting three or more allegations were academic medical centers.

Table 5: Allegations by Institution Size

Number of faculty	Allegations			
	None	One or more	Missing	Total
1–10	98%	1%	1%	126
11–100	95%	5%	0	79
>100	34%	61%	5%	103
Missing	25%	50%	25%	4
Total	234	71	7	312

Note: Percentages sum to 100 percent across each row.

Throughout the open-ended comments, some study participants alluded to the nature of the allegations that they have experienced. They included

- 19 study participants who indicated that the allegation related to falsification of data and/or the methods used
- 12 institutions that had allegations of plagiarism or authorship disputes
- 3 institutions that had allegations related to proceeding on projects without appropriate institutional review board

approval or outside the scope of such approval

- 1 allegation that one or more staff people on the project were not appropriately qualified for their role (i.e., an interpreter may have introduced false answers because of an inability to accurately translate actual responses).

Almost 25 percent of organizations indicated that their institution received **one or more allegations** of research misconduct resulting in an inquiry or an investigation in the past 5 years.

CURRENT APPROACHES TO INVESTIGATING ALLEGATIONS

Institutions that have had allegations reported that they looked within their institution most often to conduct investigations (survey question 5). The second most commonly used source for assistance was ORI (see Table 6). Similarly, such institutions would be most likely to use internal resources or ORI for future investigations, although more institutions indicate that they would seek assistance from ORI in the future. Most organizations would use the same source for future investigations that they have used for past investigations (e.g., 85 percent of those whose institutions used internal resources for past investigations reported that they would use them in the future, and 95 percent of those reporting they had used ORI for past investigations reported that they would use ORI again). These trends are not related to the size or type of institution.

Table 6. Sources of Assistance in Conducting Investigations

Sources	Have used in investigations						Plan to use in future	
	Allegation 1		Allegation 2		Allegation 3			
Within institution or affiliate	60	95.2%	38	90.5%	27	81.8%	52	81.3%
Outside institution	13	20.6%	6	14.3%	3	9.1%	12	15.8%
ORI	21	33.3%	17	40.5%	11	33.3%	41	64.1%
Outside advisor/ consultant	10	15.9%	6	14.3%	5	15%	12	18.8%
Other	4	5.6%	3	6.3%	2	5.3%	8	11.3%

INTEREST IN CONSORTIA FOR ASSISTANCE AND EXPERTISE

The response rates for survey questions 9 to 11 were very low, with at least 160 participants (51 percent) not choosing any of the choices for these questions.¹ These questions inquired about the likelihood that the institution would rely on internal resources or a consortium in responding to allegations. The low response rate may indicate that responses to these questions should be considered carefully because it is likely that the concepts were not clear, the study participants had not given any thought to the issue, or participants had no reference point to respond to the questions.

“We would be interested in being involved in such an endeavor, but we would need to learn more about what it would entail.”

“Unlikely [to join] if the company had to commit significant time or money to consortium, as the company is primarily a development organization and has many layers of control to prevent research

misconduct. I would love to have access to the organization, however, if we ever face the issue.”

“We are a large and diverse institution with much expertise internally and would look for support/knowledge from our own constituency before going outside, although we are always eager to learn from the experience of others...”

“...It would be of greatest benefit if we had a ‘resource center’ to turn to when needed.”

Among those who completed these questions, most people (89 out of 146, or 61 percent) indicated that they were very likely or somewhat *likely* to rely entirely on resources available within their institution (survey question 9). Research organizations and other small institutions reported being less likely to seek assistance internally than were academic medical centers and other institutes of higher education (Table 7). This may be attributed to limited but very busy staff, a need for an

Those who answered these questions indicated that they were **likely** to rely entirely on within-institution assistance and were **unlikely** to become a member of a consortium designed to assist in responding to allegations.

¹A programming error in the Web-based version of the survey was found and corrected during the first week that the survey was in the field. This may account for as much as half of these missing values.

Table 7: Seeking Assistance from Within Institution by Institutional Type

Type of institution	Likelihood of seeking assistance from within institution							
	Very likely		Somewhat likely		Somewhat unlikely		Very unlikely	
	n	Percent	n	Percent	n	Percent	n	Percent
Institution of higher education	15	50.0	5	16.7	7	23.3	3	10.0
Academic medical center	15	65.2	3	13.0	4	17.4	1	4.4
Research organization	7	21.2	10	30.3	8	24.3	8	24.2
Independent hospital	4	57.1	1	14.3	1	14.3	1	14.3
Other educational organization	0	0.0	0	0.0	0	0	1	100.0
Other health organization	2	50.0	1	25.0	0	0.0	1	25.0
Federal or State Government	1	100.0	0	0.0	0	0.0	0	0
Other	15	34.9	7	16.3	5	11.6	16	37.2
Total	59	41.6	27	19.0	25	17.6	31	21.8

Note: Percentages sum to 100 across each row.

objective outside opinion in these situations, or an apparent perception by small businesses that they are less likely to encounter allegations. In the comments, participants indicated that providing a quick reference guide or checklist, legal guidance, and ORI-sponsored training would support the institutions in these endeavors.

Less than half of the study participants who responded to survey question 9 (42 percent) indicated that they were somewhat likely or very *likely* to become a member of a consortium designed to provide such assistance (question 10). Similarly, 47 percent (mostly the same participants) responded that it was somewhat or very likely that they might request services from a consortium (question 11). Academic medical centers and other institutions of higher education are more likely to be interested in becoming a member of a consortium (see Table 8) than are research organizations and other small

businesses. Similarly, organizations that have had at least one allegation are more likely to be interested in becoming a member of a consortium (see Table 9) than are organizations that have had no allegations.

The most common explanation given for the reported likelihood of joining a consortium was that no assistance outside the organization was needed. The second and third most common remarks indicated that the availability of outside assistance might be useful, but not required, and that participation would further burden busy people—especially those at small institutions. In explaining their reported likelihood of requesting services from a consortium, participants explained that they would use existing in-house resources first and use outside services only if recommended by those resources.

Table 8: Interest in Joining a Consortium by Institution Type

Type of institution	Likelihood of becoming a member of a consortium							
	Very likely		Somewhat likely		Somewhat unlikely		Very unlikely	
	n	Percent	n	Percent	n	Percent	n	Percent
Institution of higher education	4	13.3	15	50.0	5	16.7	6	20.0
Academic medical center	4	17.4	11	47.8	7	30.4	1	4.4
Research organization	4	12.1	7	12.2	9	27.3	13	39.4
Independent hospital	2	28.6	1	14.3	1	14.3	3	42.8
Other educational organization	0	0.0	0	0.0	0	0.0	1	100.0
Other health organization	0	0	3	75.0	1	25.0	0	0.0
Federal or State Government	0	0.0	0	0.0	1	100.0	0	0.0
Other	1	2.3	9	20.4	14	31.8	20	45.5
Total	15	10.5	46	32.2	38	26.6	44	30.8

Note: Percentages sum to 100 across each row.

Table 9: Interest in Joining a Consortium by Number of Allegations

Number of allegations	Likelihood of becoming a member of a consortium							
	Very likely		Somewhat likely		Somewhat unlikely		Very unlikely	
	n	Percent	n	Percent	n	Percent	n	Percent
None	12	10.7	31	27.7	28	25.0	41	36.6
One or more	4	11.8	15	44.1	11	32.4	5	14.7

Note: Percentages sum to 100 across each row.

TYPES OF ASSISTANCE NEEDED

Institutions most often reported asking for assistance with past investigations in the following two areas (question 6): overall guidance on the process and conducting inquiries (see Table 10). Other frequently reported assistance needs included legal issues and conducting preliminary assessments. Comments given in the “other” choice for these questions reinforced the need for legal advice, possibly from outside sources, and also indicated that the funding agency might be a source for assistance. Those institutions that have not had an allegation also indicated that they would need overall guidance on the process and legal issues (question 8). In general, compared with institutes of higher education, research organizations and other small businesses reported that they would need more types of assistance. The comments made in the “other” choice also included requests for a “how-to” guide for conducting inquiries and investigations.

The survey inquired about potential aspects of a consortium’s development that might influence membership and use. Incorporating several areas into a consortium’s scope of responsibility would make it more useful to institutions. Questionable research practices, conflicts of interest, and human subjects were the three most common items that, if included in the scope of a consortium’s responsibility, would most likely make the consortium more useful (question 12). However, the fourth most common item was “none.” These responses did not vary much by institution size or type.

BASIS FOR FORMING CONSORTIA

The most preferred basis for forming a consortium (question 13) was similar

institutional type, with scientific field being the second choice (see Table 11). As to who should organize consortia (question 14), the most preferred choices were individual institutions or associations (see Table 12). In addition, the following comments also show little perceived need for consortia:

“The more you expand the responsibilities, the less useful it is for academic misconduct.”

“We already have support mechanisms for many of these issues.”

ADDITIONAL SOURCES OF ASSISTANCE

The survey inquired about interest in using alternative sources, other than ORI, for assistance or expertise in investigating allegations (questions 15 to 19). The sources include the following (interest in using ORI will be discussed in the next section):

- Unaffiliated/outside institutions (question 15)
- Outside advisors/consultants (question 16)
- Institutional associations (e.g., the American Association of Medical Colleges) (question 17)
- Scientific societies (e.g., the American Association for the Advancement of Science) (question 18)
- Independent investigative firms (question 19).

Table 10. Areas for Assistance

Area	Assistance sought by institutions with allegation(s)		Assistance of institutions without allegations	
	n	Percent	n	Percent
Overall guidance	41	80.4%	141	58.5%
Conducting preliminary assessments	30	58.8%	53	22.0%
Maintaining confidentiality	14	27.5%	25	10.4%
Acquiring appropriate expertise	19	37.3%	79	32.9%
Handling conflicts of interest	5	9.8%	37	15.4%
Treatment of whistleblowers	18	35.3%	39	16.2%
Treatment of respondents	20	39.0%	33	13.7%
Management of committees	9	17.6%	23	9.5%
Conduct of inquiry	26	51.0%	74	30.7%
Conduct of investigation	16	31.4%	71	29.5%
Sequestration of evidence	18	33.3%	45	18.7%
Investigational techniques	10	19.6%	66	27.4%
Interviewing skills	3	5.8%	29	12.0%
Assessing evidence	14	27.5%	62	25.7%
Legal issues	31	60.8%	117	48.5%
Preparing reports	16	31.4%	73	30.3%
Other	4	7.8%	10	4.1%

Table 11. Factors To Be Used as a Basis for Forming Consortia

Factor	Ranking of basis for forming a consortium							
	First		Second		Third		Fourth	
	n	Percent	n	Percent	n	Percent	n	Percent
Geographic proximity	61	17.7	46	18.2	58	25.2	86	34.1
Similar size	17	4.9	61	24.1	76	33.0	96	38.1
Similar institutional type	129	37.5	60	23.7	40	17.5	25	9.9
Scientific field	66	19.2	86	34.0	56	24.3	45	17.9
Total	344	100	253	100	230	100	252	100

Note: Percentages sum to 100 down each column.

Table 12. Organizations That Should Organize Consortia

Type of organization	Ranking of who should organized consortia							
	First		Second		Third		Fourth	
	n	Percent	n	Percent	n	Percent	n	Percent
Individual institutions	100	40.2	48	19.8	68	28.3	37	14.1
Individual associations	60	24.1	105	43.2	52	21.7	30	11.5
Scientific societies	64	25.7	66	27.1	81	33.8	37	14.1
Independent consultants	25	10.0	24	9.9	39	16.2	158	60.3
Total	249	100.0	243	100.0	240	100.0	262	100.0

Note: Percentages sum to 100 down each column.

The entity most frequently rated as being a likely source of assistance is outside advisors/consultants – generally known to key in-house individuals (see Table 13). These ratings are consistent across institutions of differing sizes and types, as well as across institutions with differing numbers of previous allegations.

Explanations given for responses to these survey items, including the following:

“Existing contacts and our judgement that they have thoughtful and competent leaders/administrators.”

“To help remove bias of staff members who might know a scientist accused of research misconduct. Also, experience of persons outside the institution would be beneficial to the investigational process.”

“Assurance of strict confidentiality; availability of anonymous abstracts of cases or types of issues, both at the inquiry and investigation level.”

These advisors would most often provide expertise in the scientific area of the research in question or legal advice. Low costs are imperative for many of these organizations, which explains their reluctance to turn to independent firms. Also of considerable concern in using these resources is the maintenance of confidentiality of the issue, the involved subjects, and the potential impact to the institution.

When asked if these resources would be used more if a registry of advisors or consultants was available, most study participants said “yes” (67 percent of responsible officials at unaffiliated institutions, 81 percent of consultants, and 58 percent of independent investigative firms). In addition, 77 percent of those who would find a registry of advisors/consultants useful also would like a certification program for them.

The last question asked about institutions’ preferences for further development of sources for assistance or expertise (question 21). The most preferred choice for most study participants was within the institution (it was ranked first by 111 study participants). ORI was the next most preferred choice (ranked first by 90 study participants). These

Table 13. Interest in Assistance From Alternative Sources, Other Than ORI

Source	Very Likely		Somewhat Likely		Somewhat Unlikely		Very Unlikely	
	n	Percent	n	Percent	n	Percent	n	Percent
Outside advisors/consultants	48	17.4	125	45.3	63	22.8	40	14.5
Scientific societies	36	12.9	99	35.5	87	31.2	57	20.4
Institutional associations	29	10.4	84	30.1	97	34.8	69	24.7
Unaffiliated/outside institutions	22	7.9	88	31.6	90	32.4	78	28.1
Independent investigative firms	10	3.6	53	19.2	95	34.4	118	42.8

Note: Percentages sum to 100 across each row.

preferences differed by size of institution (Table 14).

ORI SERVICES

The survey also asked organizations whether they would seek assistance from ORI. Almost all (83 percent) of the study participants indicated they were somewhat or very likely to request such assistance. In fact, of the 72 study participants who had previously contacted ORI for assistance, only 6 indicated that they were somewhat or very dissatisfied with the services received. Academic medical centers or affiliated institutions reported a much higher rate of contact with ORI (68 percent) than did other institutional types (29 percent). These institutions are more likely to

have had allegations. This may indicate that these institutions do not perceive a need to contact ORI until they have received allegations warranting investigations. However, when asked whether they might be hesitant to contact ORI, 203 participants indicated that they were not hesitant to contact ORI.

“ORI’s responses have always been top-notch.”

“...[We have] had difficulty getting consistent answers, and/or clear instructions/suggestions on how to proceed.”

Table 14. Resource Development Preferences by Institution Size

Size	Within Institution as First Choice		ORI as First Choice		Total
	n	Percent	n	Percent	
1 to 100 employees	54	26.3	72	35.1	205
More than 100 employees	56	54.4	18	17.5	103

CONCLUSIONS AND RECOMMENDATIONS

The issues to be resolved by this study included the following:

- Current practices for investigating allegations of misconduct
- Level of interest in organizing consortia for investigating allegations of research misconduct
- Types of assistance needed to investigate allegations
- The basis for establishing consortia
- Preferred alternatives to developing consortia for assistance and expertise

CURRENT APPROACHES FOR INVESTIGATING ALLEGATIONS

Overall, participants indicated that they look within their own institution for assistance and expertise in conducting investigations into allegations of research misconduct. If they cannot find sufficient expertise within their institution, their next step would be to contact ORI or “experts” known to the institution’s officials in charge of overseeing research activities.

If institutions need additional assistance in investigating allegations, it usually relates to a need for specific scientific expertise in the subject matter of the research or to legal counsel. Those institutions who have not conducted investigations anticipate that they might need guidance on the approach to investigations as well as the subject matter or legal expertise.

INTEREST IN CONSORTIA

There is low to moderate interest in developing consortia as a mechanism for investigating allegations of research misconduct. This is demonstrated by the overall low response rate to the questionnaire and the even lower number of responses to question 10. Comments indicate that willingness to participate in consortia would depend on the layout of such an entity, that is required membership to use the services, costs, and services offered. Furthermore, development of consortia may require a relatively large investment of resources, compared to the need for investigative services.

The original hypothesis stated that consortia may be most useful for small and mid-sized institutions. However, these institutions expressed less willingness to join a consortium than did the larger academic institutions. The comments indicated that staff members at smaller organizations are too busy to belong to outside entities. The academic institutions indicated that they were more willing to offer expertise than need a consortium’s services.

A seemingly less costly alternative to consortia would be the development of a registry of responsible officials who have overseen investigations at their institutions and of advisors or consultants who can provide legal or scientific expertise. The registry would be most helpful if it provided current contact information, a schedule of fees for services, a summary of the person’s qualifications to serve in an advisory capacity, and references from those who have used this person’s services.

TYPES OF ASSISTANCE NEEDED

The types of expertise or assistance that institutions expect to need when they receive an allegation are overall guidance and subject matter expertise. In the comments received, the overall guidance was clarified as a need for guidelines on the process and advice from those who have conducted such investigations. Real-life examples also would be helpful. Participants requested this information in one of two ways: through the ORI website or through educational workshops.

BASIS FOR CONSORTIA

In some instances, study participants indicated that they currently belong to consortia – often State or regional university systems. This confirms study participants’ preferences that similar type of institution, rather than size, should be the basis for forming consortia. Scientific field appears to be the second strongest preference.

Should the development of consortia be pursued, research institutions expressed a slightly higher interest in using consortia services rather than becoming a member of one. Services that would be useful pertain to conducting investigations into issues such as conflicts of interest and human subjects protection. However, many study participants feel that there are simpler, less resource-intensive methods of investigating allegations.

ORI should consider the following actions:

- Marketing its mission and services
- Expanding its educational efforts
- Redesigning its website
- Developing registries of various types of assistance available.

ALTERNATIVE APPROACHES

The types of assistance that institutions believe they will require are overall guidance, legal advice, and scientific expertise to review the research in question. At present, information on most of these topics already exists on the ORI website (<http://ori.dhhs.gov>). However, the comments received imply that one or more of the following may be occurring:

- The study participants have not used the ORI website.
- The study participants find the navigability of the website confusing.
- The level of detail of the resources and publications on the website is insufficient.
- The study participants do not correctly understand ORI’s mission or services.
- The study participants have differing interpretations of “research misconduct,” “allegations,” the procedures to prevent misconduct and to invoke when an allegation does occur, and what constitutes appropriate conduct for federally funded research.

All of this implies a need for ORI to become a more visible resource to research organizations. ORI could benefit from marketing itself as a resource – rather than a regulatory agency – for institutions to use to ensure appropriate research conduct. As a part of this “marketing” effort, ORI should consider expanding its educational programs and publications on its website, through its networks, and workshops.

ORI could better serve researchers by continuing to provide guidance on handling misconduct when needed and by developing or facilitating the development of easily accessible registries of institutions experienced in conducting investigations and registries of advisors who are available to assist. This should prove to be less costly and more easily accessible than the development of consortia.

SATISFACTION WITH ORI

Those people who have contacted ORI are generally very satisfied with the service they have received. Institutions that report

multiple allegations appear to be more likely to report greater satisfaction (although the small numbers in this case should be interpreted with caution); this demonstrates that familiarity with ORI and its staff helps to improve satisfaction. This finding can be used as further evidence for the need for ORI to educate its audience about its mission and services. Some potentially helpful mechanisms include separate mailings explaining ORI's services, more attendance at research meetings, and better interaction with the project officers at the funding agencies.