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Evaluating the Effectiveness of Institutional Efforts to Educate Staff on their Policies for Dealing with Research Misconduct and Research Integrity

Final Report

Prepared for

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EXECUTIVE SUMMARY

1. Introduction

1.1 *Study Purpose*

The U.S. Department of Health and Human Services' Office of Research Integrity (ORI) contracted with RTI International to conduct an evaluation of the effectiveness of efforts by U.S. medical schools to comply with the "dissemination" mandate of the U.S. Public Health Service's research misconduct regulations (42 CFR 93). The focus of this evaluation has been on the extent and nature of the compliance of U.S. medical schools with that part of the Federal regulations. ORI wanted this study to: assess the level of exposure that researchers in medical schools have had to their institution's policy and procedures for receiving and responding to allegations of research misconduct; measure the researchers' perception of their institution's commitment to dealing forthrightly with the issue of research misconduct; measure researchers' ability to identify and willingness to report research misconduct; and assess the extent to which researchers' exposure to the institution's policy and procedures, recognition of likely research misconduct, and their perceptions of their institution's commitment to dealing with research misconduct are associated with access to and depth and breadth of the research misconduct policy and procedures in their institution's research misconduct policy.

1.2 *Study Questions*

ORI has specified a number of specific research questions it wants addressed by this study. The research questions start off with a general query about how well informed members of the medical school research staffs are about their institution's research integrity policy and procedures. This question is followed by one dealing with how the members of the medical school research staff perceive their institution's commitment to properly handling research misconduct allegations. ORI wants to investigate whether there is an association between researcher's knowledge of their institution's policy and procedures and their perception of the institution's commitment to deal with allegations of misconduct.

Another of ORI's questions asks about researchers' ability to access the institution's research misconduct policy and procedures and about the breadth and depth of the informational domains covered in the policy.

The next questions that ORI wants addressed relate to the types of activities and processes most frequently used by institutions to effectively disseminate their research misconduct policies. Further, ORI is seeking to learn whether there are associations between the ways in which researchers are exposed to the institution's policy and procedures and achievement of high levels of research misconduct policy knowledge and more positive perceptions of their institution's commitment to proper adjudication of misconduct

allegations among the researchers. An additional question probes whether researchers are able to correctly identify likely research misconduct and be willing to respond to the suspicion of research misconduct by reporting it to the appropriate institutional official.

The final question asks about what individual characteristics (covariates such as age, gender, rank, field of study, research experience, experience with research misconduct proceedings, etc.) and other important factors are associated with researchers perceiving the effectiveness of their institution's efforts to properly implement and disseminate its research misconduct policy. Among the other factors to be considered in this multivariable analysis are knowledge of the institution's research misconduct policy and procedures, being able to correctly identify and respond appropriately to allegations of research misconduct, how researchers report they receive exposure from the institution in its research misconduct policy, and their readiness to report allegations of research misconduct.

2. Study Methodology

2.1 Data Collection

In this report, we have conducted an analysis of two separate but related data collection activities undertaken to address the goal of this project – to evaluate the effectiveness of U.S. medical school efforts to meet their responsibility to educate their researchers on identifying and reporting research misconduct. The first of the two data collection activities consisted of an abstraction of the research misconduct policies contents of 109 of the 115 U.S. medical schools with National Institutes of Health (NIH) research funding that we were able to locate on the internet. The goals of this activity were to assess how accessible the policies are, what key information they impart (their breadth), and the amount of detail they provide (their depth).

The second data collection activity was a web-based questionnaire survey of a stratified random sample of more than 10,750 medical school researchers (principal investigators) who are supported by research awards from the NIH. Five thousand one hundred researchers responded after receiving up to six e-mail requests for their participation. The survey questioned researchers about their demographic characteristics and educational background as well as their research experience. Researchers were also quizzed on their knowledge of their institution's research misconduct policy and their exposure to it. We also asked about how the institution informs researchers of its research misconduct policy. There were also questions about whether the researchers thought that the institution was effective in disseminating its research misconduct policy and in handling allegations. In addition, there were questions intended to assess how disposed researchers are to make allegations against colleagues. We also asked questions about the researchers experience with research misconduct proceedings and whether it has had an impact on their willingness to be involved in further research misconduct proceedings. In the final section of

the survey, we presented a series of brief scenarios intended to test how well researchers identify likely research misconduct and what they do if they recognize it.

2.2 Statistical Analysis

Our analysis consists of tabulations of survey responses and items abstracted from the research misconduct policies of U.S. medical school that were found on the Internet. Analyses of the survey data are weighted to account for non-response and disproportionate sampling of researchers. In addition, we conducted multivariable logistic regression analysis using SUDAAN statistical software to take account of the sampling design and weight adjustments. This analysis was performed to assess a model identifying variables associated with the perceptions of researchers about the effectiveness of their institution's research misconduct education and implementation efforts.

3. Study Findings

3.1 Differences in Medical School Research Misconduct Policies

In summary, the policies we reviewed vary in the range of topic areas they cover as well as the amount of detail included for each. While all of the policies include a definition of research misconduct and nearly all state that it includes falsification, fabrication and plagiarism, they vary in whether they define these terms (from 58.7% to 63.3%). Further, despite the fact that the majority of the policies include a statement that research misconduct applies to proposing and conducting research as well as reporting ones own research (97.3% each), there are differences in whether they also state that the policy applies to reviewing others' research; only 62.4% of them do. The amount of detail covered in the policies with regard to the type of research, e.g., PHS-funded, government-funded, private and publicly funded, and all research, to which the policy applies also differs (from 13.8% to 61.5%). Although a majority state who is bound to abide by the policy (89.0%), the policies differ in their specific statements that everyone is covered, or that faculty or non-faculty are covered by the policy (from 44.0% to 80.7%).

Even though about two-thirds of the policies state that individuals are obligated to report instances of alleged research misconduct very few of them provide information on what to include in the allegation (10.1%), and those differ in the details of what to include, i.e., name of respondent, name of witness, nature of the evidence, and when the misconduct was discovered (from 0.9% to 10.1%). As mentioned earlier, none of the policies state to include when the alleged research misconduct occurred or to specify the type of research misconduct, i.e., fabrication, falsification or plagiarism. There are also differences in the level of guidance provided in the policies with respect to how one should make the allegation –only in writing (25.7%) or orally (45.0%). Almost all include the name, position, title or contact information for the person who should receive the allegation though they vary considerably in whether they identify a particular person or position such

as the principal investigator (PI), the PI's department head, the RIO, the school dean, vice president, president, and so forth (from 0.9% to 41.3%).

While only about two-thirds of the policies discuss the criteria used to assess an allegation of research misconduct, they are dissimilar in the details of the allegation being credible, specific or meeting the definition of research misconduct (from 44.0% to 53.2%). Virtually all of the policies we reviewed mention avoiding a conflict of interest when assessing the allegation (98.2%) but the policies differ greatly in the category of persons to whom conflicts of interest specifically apply; from only 1.8% stating the conflict of interest avoidance applies to the institutional official, to 91.7% stating the members of the inquiry and investigation committees should avoid conflicts of interest. These policies are comprehensive on the amount of guidance they include for conducting the inquiry and investigation into allegations of research misconduct; almost all of the policies cover each of the items of information we coded for (from 89.9% to 98.2% of elements regarding to the inquiry process and between 90.8% and 98.2% of the specifics related to the investigation process).

The policies we reviewed provide more protections – rights and responsibilities – for respondents than they do for the whistleblowers. The policies also differ on the specifics of the rights and responsibilities for each. Although all of the policies specify the rights of the respondents, the respondent rights that are enumerated in the policies vary; they range from 3.7% stating the respondent has a right to appeal the decision to conduct an inquiry or investigation and 6.4% stating the respondent is presumed innocent, to the respondent having a right to receive a notification of findings and a copy of the inquiry and investigation reports (96.3% and 97.3% respectively). In contrast, 85% of the policies mention complainant rights and there is a wide range between the proportion that include the specific respondent rights for which we coded the policies ranging from the right to present or suggest witnesses (8.3%) and the right to counsel or an advisor and the right to present witnesses (16.5% respectively) to the right to receive notification of the findings (68.8%).

The same is true for the respondent and complainant responsibilities. Although about three-fourths of the policies specify what is required from the respondents, only about a third describe the responsibilities of the complainant. Again, the respondent responsibilities covered in the policies range from a very few of the discussing the need for the respondent to avoid talking with the press (1.8%), to about two-thirds of them stating the respondent has the responsibility to furnish data or records when requested and two-thirds stating the respondent has a general responsibility to cooperate with the investigation. Of the policies that mention complainant responsibilities, close to a third mention that the complainant should report instances of harassment; they are virtually silent on other important responsibilities, e.g., no contact with the respondent, obligation not to speak with the press or speak publically about the allegation. Although most of the policies say the institution will

protect the complainant (87.2%), they do not provide a lot of information on how that will happen.

The policies are not too different on their coverage of sanctions and the restoration of respondents' reputations. Almost all of them mention sanctions, and most state who decides the appropriate sanctions and who receives notification of the research misconduct finding. Additionally, almost all of the policies mention that the institution is responsible for restoring the respondents' reputation, though they vary in their description of who is responsible for doing so, and the steps to accomplish this task (a little less than two-thirds and a little less than half, respectively).

3.2 Results from the Survey of Researchers

Characteristics of the Medical School Researcher Population Surveyed

The survey was conducted among a predominantly middle-aged (nearly three-fourths are between 45 and 64 years of age), highly educated (greater than 99% have PhD/ScD, MD, or MD-PhD) group of NIH-funded researchers who are primarily male and trained in a basic/natural science. The researchers are quite experienced as a group (approximately 90% have 15 or more years of experience conducting biomedical research), hold relatively high academic rank in their medical schools, and have been employed at their institutions for reasonably long periods of time (more than two-thirds have been employed at their current institution for 10 or more years).

Research Misconduct Experience and Future Willingness to Participate in the Process

A very large majority of researchers (greater than 80%) report that they have never had an allegation of research misconduct made against them; never filed an allegation of research misconduct against a colleague; never given testimony as a witness in an inquiry or investigation into an allegation of research misconduct; and never been a member of an inquiry or investigation committee looking into an allegation of research misconduct. Of the subset of researchers that had prior experience as respondents (the accused), complainants (the accuser), or as witnesses, between 11.6% and 18.9% are less willing to be involved in future research misconduct reporting or proceedings as a result of their prior experience, whereas 15.3% of researchers serving as members of an inquiry or investigation committee say they are *more* willing to serve in the same way again. This reversal of willingness to be involved in such proceedings in the future suggests that the experience of researchers in the former roles is not as positive as the experience is for those involved on the committees adjudicating the allegations.

In addition, we asked the researchers to indicate what they thought was the importance of a variety of considerations that might influence a researcher's decision when contemplating whether or not to make an allegation. The considerations prioritized by researchers as being critical in their decision to make an allegation are: confidence that the

matter will be handled fairly and justly by the institution, recognition that if the misconduct is not halted that it could damage the research record, and having first-hand evidence of research misconduct. Maintaining the anonymity of the complainant was most often judged an unimportant consideration in the decision to report an allegation, but only by a small proportion of the researchers. The considerations deemed as having the greatest overall importance on dissuading researchers from reporting research misconduct are first, the expectation of damage to one's professional reputation and/or career, followed closely by the fear of retaliation by the respondent, and thirdly, the potential for ostracism by colleagues. Not knowing to whom research misconduct should be reported is viewed by nearly half of the researchers as an unimportant consideration in why research misconduct is not reported.

Exposure to and Knowledge of Institutional Research Misconduct Policy

The vast majority of the researchers (90%) report that they have read at least some part of their institution's research misconduct policy and procedures. However, only 44% have read their institution's policy and procedures fully. The majority of researchers (between 62.5% and 85.1%) also say that they are very or somewhat familiar with the Federal regulation's definition of activities that constitute research misconduct, to whom allegations of research misconduct should be officially reported, types of information that should be included in an allegation, the process for handling allegations of research misconduct, and their institution's procedures for protecting complainants from retaliation. However, only 34.4% to 15.6% of researchers claim to be very familiar with these issues. In addition, sizeable percentages (31.5% to 37.5%) say they are not very familiar or not familiar at all with the types of information that their institution's policy requests for an allegation, the process for handling allegations of research misconduct, and their institution's procedures for protecting complainants from retaliation.

We also asked the researchers to identify from a list of 10 behaviors that represent bad, unethical or illegal research practices the behaviors that are defined as research misconduct by the Federal regulations. Only 83.1% of researchers correctly identified all three – falsification, fabrication, and plagiarism. However, a majority of the researchers also identified one or more other of the listed behaviors as representing research misconduct as defined by the Federal regulations. While only 5.3% of the researchers correctly identified the three that are and the seven that are not considered research misconduct, it is troubling that more than half (56.8%) did not correctly identify the Federal definition status of more than five of the behaviors on the list.

Next, the survey asked researchers a series of six questions about specific aspects of their institution's research misconduct policy and procedures: does the policy discuss the process for determining whether research misconduct occurred; discuss institutional actions to protect complainants from retaliation; allow for making anonymous allegations of

research misconduct; allow allegations that are not made in writing; discuss institutional response to those who knowingly make false accusations; and discuss the protocol for assuring/protecting confidentiality of information obtained from inquiries/investigations. In five out of the six questions, 40% or more of the researchers respond that they don't know. We created a measure to summarize the number of issues across the six for which researchers responded "don't know" and found that more than one-third of researchers (36.8%) respond to the items with more "don't know" responses than yes or no responses combined.

Institutional Dissemination of Research Misconduct Policy and Procedures

According to half of the researchers, new research faculty and staff are typically exposed to institutional research misconduct policy and procedures in the first few days, within the first month of employment, or within the first year of employment. The other half of researchers report not knowing when new faculty are exposed to the institution's research misconduct policy or say that they are never exposed to it. The research misconduct policy and procedures are typically first presented to new research faculty and staff through a new employee group orientation (34.7%), via e-mails with a URL to visiting a website (28.5%), through distribution of a printed or electronic document (27.2%), a Responsible Conduct of Research (RCR) program (24.9%), or IRB continuing educational activities (24.4%). Regarding the format in which their institution's policy and procedures is first typically presented, a printed or electronic version of the faculty manual is the most common format (34.3%). Other responses given in order of frequency include: don't know, through an on-line course, and in a live group or workshop setting. Live one-on-one discussions are rarely used (0.6%). Most of the formats used do not typically permit immediate question and answer exchanges.

Approximately half of the researchers (48.1%) indicate that research faculty and staff have an opportunity to attend a workshop, class, or other live presentation to obtain clarification or answers to questions about their institution's research misconduct policy and procedures. An almost equal percentage (42.2%) does not know whether research faculty and staff have such opportunities. The majority of researchers say the research misconduct policy and procedures are accessible on the institution's website or in a printed handbook that is readily available to faculty and staff in a library or other public location. However, rather sizable percentages of researchers do not know if the policy and procedures are available through these routes (26.3% and 41.2%, respectively).

The majority of researchers are not required to certify on a regular basis that they have reviewed the institution's research misconduct policy. Slightly less than one-third of the researchers say that they are required on an annual or biannual basis to certify that they have reviewed the institution's research misconduct policy and procedures. A similar percentage (31.0%) say they do not know, and more than one-quarter of researchers

indicate that they either provided a one-time acknowledgement or have no requirement to periodically certify that the policy has been reviewed. Notably, nearly half of the researchers (47.1%) say they have never been required to review the policy and procedures.

More than half of the researchers (56.8%) acknowledge having an RCR training program at their institution, however, a sizeable percentage of researchers (37.6%) say they do not know whether such a program exists at their institution. Nearly half of the researchers (47.0%) say they have participated in RCR training. A similar percentage of researchers (44.0%) say they have not, and 9.0% say they do not know if they have. Among those who participated in RCR training, nearly all (96.9%) say that the training discussed research misconduct.

More than nine in ten researchers (91.4%) say they have responsibility for overseeing the research of one or more doctoral degree students, post doctoral fellows, or otherwise mentoring new investigators in your institution. Among those with oversight and mentoring responsibilities, 17.8% note that they often discuss such issues with their students, post docs, or mentees, and more than half of these researchers (58.6%) acknowledge that they sometimes talk with those they mentor about issues related to research misconduct. On the other hand, nearly one-quarter of mentors say that they never (1.9%) or rarely (21.6%) discuss issues pertaining to research misconduct. Among the topics most often discussed are maintaining proper records (93.9%), activities considered research misconduct (73.2%), what it means to prepare an honest report of research results (69.3%), and the responsibility to report research misconduct (41.4%). Among the topics discussed least often, by from only 29.7% to 8.4% of researchers, with their mentees are repercussions of making an allegation on one's career, to whom to report allegations, impact of good faith but erroneous allegations, the process for resolving allegations, gathering evidence to support the allegation, the reaction of colleagues to making an allegation, how to report an allegation, and the time and energy involved in making an allegation.

Perceptions of the Institution's Efforts to Educate about Research Misconduct

Overall, researchers in US medical schools are very positive about their institution's efforts to educate faculty and staff on research misconduct. More than two-thirds of the researchers agree or strongly agree that their institution does all it can to assure that research faculty and staff are familiar with the institution's research misconduct policy and procedures, that it has made a concerted effort to educate its researchers about what constitutes research misconduct, and that their institutional climate makes researchers feel comfortable about reporting research misconduct to the appropriate official. However, more than half agree or strongly agree that there is a need for more opportunities to learn what faculty and staff should do when they have evidence of misconduct.

Approximately two-thirds feel that their institution has made a concerted effort to educate researchers about the person to whom they should report allegations of research misconduct, agree or strongly agree that “whistleblowers” need not fear being ostracized or marginalized by their peers, and agree or strongly agree that their institution’s efforts to protect “whistleblowers” are effective. However, a sizable percentage of researchers say that they do not know in answer to these questions. The large percentage of don’t know responses to our question about the effectiveness of the institution’s efforts to protect “whistleblowers” may be attributed to the fact that research misconduct proceedings are intended to occur in strict confidentiality and therefore, little should be known about how often such actions are needed and the nature of actions that have been taken to protect complainants.

Almost three-fourths of researchers agree or strongly agree that persons at their institutions entrusted to handle allegations of research misconduct are trained and able to arrive at a fair and impartial judgment. The fact that one-fifth do not know may be a result of a lack of knowledge regarding the identity of persons handling the institution’s misconduct proceedings.

Approximately one-third of researchers agree or strongly agree that their institution could do more to encourage reporting of suspected research misconduct. Similarly, nearly one-third of researchers agree or strongly agree that persons contemplating making an allegation of research misconduct at their institution should seriously consider the adverse impact it may have on their career opportunities. Slightly more than half of the researchers disagree or strongly disagree with a statement supporting the effectiveness of the institutions’ efforts to shelter whistleblowers from suffering adverse career impacts.

Researcher Propensity to Report Research Misconduct to an Institutional Official

We asked a series of questions intended to gauge the inclination of medical school researchers to make an allegation of research misconduct to the designated institutional officials. The vast majority of researchers (91.3%) agrees or strongly agrees that a researcher should be absolutely sure that a colleague committed research misconduct before making an allegation to an institutional official. A somewhat smaller majority say they would raise the suspicion of misconduct with the person they suspect before making an allegation to an institutional official. A majority of researchers agree with the statement that they would discuss their suspicions of research misconduct with other colleagues before deciding whether or not to report a colleague to an institutional official. Only a very small percentage of researchers (6.0%) agree or strongly agree with the statement that they would immediately report a colleague to an institutional official if they had the slightest suspicion that the person was involved in research misconduct. Half of the researchers disagree with the statement and 43.4% strongly disagree. Researchers seem to have a low propensity to make allegations, especially when it involves reporting to institutional officials.

Researcher's Ability to Identify and Willingness to Report Research Misconduct

Researchers seem to have a more expansive view of the Federal regulations' definition of research misconduct than is the reality. While reasonably large percentages correctly identify research misconduct according to the Federal regulation's definition (94.0% to 50.7%), large percentages (82.1% to 43.0%) also mistakenly identify as likely research misconduct what is admittedly bad research behavior that is not defined as research misconduct by the Federal regulations.

When asked about what they would do upon correctly identifying likely research misconduct, fairly consistently, the vast majority of researchers say they would talk with the person who is alleged to have committed the research misconduct or that person's supervisor rather than reporting it to the institutional official designated to handle allegations of research misconduct. Such actions could result in the unintended consequence of having the likely research misconduct covered-up rather than resolved according to institutional policy.

Multivariable Analysis of Researchers' Perception of the Effectiveness of Their Institutions' Research Misconduct Efforts

In the final phase of analysis, we performed a multivariable analysis employing logistic regression to model a dichotomous measure of how favorably researchers perceive their institution's efforts to implement and disseminate their research misconduct policy. The variables in the model improve the prediction of the researcher's perception of their institution's efforts to implement its policy, as well as to have its researchers know the policy, by more than 21%. The results indicate that researchers who: are in higher ranks, are very familiar with their institution's policy, are exposed to the institution's policy early in their employment, have been directed to review the policy, have had to certify to that annually, indicate that their institution makes the policy available on its web-site, makes a printed copy of the policy available in its handbook, gives researchers the opportunity to attend a policy presentation where they can ask questions about and get clarification of the policy are all associated with having higher odds of perceiving the institution's efforts favorably. On the other hand, not knowing selected aspects of the policy, having been a complainant at some time, and being in an environment where the research misconduct policy available on its web site is either long on policy breadth but short on depth or long on depth and short on breadth are associated with having lower odds of perceiving the institution's odds favorably.

4. Conclusions, Limitations, and Recommendations

4.1 Conclusions

From the survey that was conducted, we find that only 44% of the researchers have read their institution's research misconduct policy and procedures in its entirety and that

10% have not read it at all. In response to our request to indicate their level of knowledge of their institution's research misconduct policy and procedures on a continuum running from 0 (know nothing) to 10 (know all) 21% give responses below the midpoint of 5. In response to a query to indicate their level of familiarity (very, somewhat, not very, not at all) with five specific aspects of their institution's policy, 54% say they are not very familiar with any and 81% respond they are very familiar with two or fewer out of the five. In another effort to assess researchers' knowledge of key aspects of the policy, we asked them to identify from a list of ten activities, the ones that constitute research misconduct according to the Federal regulations. More than 20% did not correctly identify falsification, fabrication and plagiarism. When all ten items were scored as correctly identified according to Federal regulations as research misconduct or not research misconduct, 57% have correctly identified half or fewer. In a final effort to gauge researchers' familiarity with their institution's policy, we asked whether the policy addressed six basic issues to which they could reply no, yes, or don't know. We summed the number of don't know responses and found that 52% respond don't know to half or more of the items.

Based on the lack of knowledge of the policy demonstrated by large proportions of researchers, their own researchers' perceptions of how effective their institution's efforts have been, and the researchers' inability to correctly distinguish between likely research misconduct and other inappropriate research activity, we conclude that the efforts of the institutions have not been adequate to achieve an acceptable level of knowledge about the research misconduct policy.

4.2 Limitations

The survey response rate fell short of what we had expected, but only by a couple of percentage points (48% vs. 50%). There were 177 sampled researchers out of more than 10,000 for whom we did not have an e-mail address who never had a chance to respond and were not included in our analysis. We used weights to more fully represent the population of medical school researchers and to accommodate the different levels of non-response from each of the institutions. Because our sampling frame lacked information beyond the school name, post-stratification weighting according to demographic or other characteristics was not possible. Finally, for a few questions in the questionnaire, the item non-response rate approached 20%. Since all derived variables were only calculated for respondents with all needed data present, there are some respondents who did not get scored on some variables and who, therefore may not have been included in analyses using that item.

As we noted in the report, there were six institutions whose research misconduct policy we could not access on the internet. Thus they are not included among the medical schools whose policies we abstracted. There were in addition eight other medical schools whose research misconduct policy did not get abstracted because they did not receive at

least 10 NIH research grant awards during FYs 2005 and 2006 combined and hence had no researchers selected for inclusion in the web-based survey.

4.3 Recommendations

We have made recommendation for the attention of medical schools as well as for ORI.

Medical schools should update their research misconduct policy in areas as directed by a revised model policy from ORI. They need to incorporate more examples of what actions institution could take under specified circumstances. The policy should make complainants comfortable and secure feeling, but also want to be realistic for complainants.

Medical schools should require researchers to read and certify that they have read the policy upon being hired, and thereafter have them annually certify they have reviewed or taken a course or workshop that reviews and tests comprehension of the research misconduct material.

Make policy more available in printed form and on external internet.

Make more different ways of receiving policy available, including especially face to face small group sessions where scenarios could be discussed and questions could be asked about policy.

Need to take actions to counteract the perception that bad things happen to complainants.

ORI should update its model policy specifying areas to be enriched so there is more detail on what the institution will do and balance between the treatment of respondents and complainants. ORI should try to make the policies more uniform from place to place, but allow for differences in institutions size and structure.

ORI needs to require institutions to have new researchers read and certify they have read the policy.

ORI needs to require annually that researchers reread or take a course that will review and test key points of policy.

Investigate why the experiences of respondents, complainants and witnesses have so much negative impact on future willingness to participate than is true for members of the committee doing the inquiry/investigation. Also investigate why complainants have such negative perceptions of their institutions' efforts.

1. INTRODUCTION

1.1 Scope of the Project

The U.S. Department of Health and Human Services' Office of Research Integrity (ORI) contracted with RTI International to conduct an evaluation of the effectiveness of efforts by U.S. medical schools to comply with the "dissemination" mandate of the U.S. Public Health Service's research misconduct regulations (42 CFR 93). The focus of this evaluation has been on the extent and nature of the compliance of U.S. medical schools with that part of the Federal regulations which requires institutions to inform their research staff of the institution's policies and procedures for addressing allegations of research misconduct. (See Appendix A for relevant sub-part and sections)

In particular, ORI wanted this study to assess the level of exposure that medical school faculty conducting research have had to their institution's policy and procedures for receiving and responding to allegations of research misconduct. Further, ORI also wanted to measure the researchers' perception of their institution's commitment to dealing forthrightly with the issue of research misconduct. Additionally, ORI was interested in assessing the extent to which researchers' exposure to the institution's policy and procedures and their perceptions of their institution's commitment to dealing with research misconduct are associated with the actual application of the research misconduct policy and procedures that are described in their institution's research misconduct policy.

1.2 Specific Research Questions

ORI has specified a number of specific research questions it wants addressed by this study. The research questions start off with a general query about how well informed members of the medical school research staffs are about their institution's research integrity policy and procedures. This question is followed by one dealing with how the members of the medical school research staff perceive their institution's commitment to properly handling research misconduct allegations. ORI wants to investigate whether there is an association between researcher's knowledge of their institution's policy and procedures and their perception of the institution's commitment to deal with allegations of misconduct. We developed a questionnaire for researchers to complete to obtain data to be able to address this and other important questions.

Another of ORI's questions asks about researchers' ability to access the institution's research misconduct policy and procedures and about the breadth and depth of the informational domains covered in the policy. To assess these, we developed a procedure for searching the internet for the medical school's research misconduct policy, and a form into which we code how quickly we find it as well as the numbers of domains the policy covers and the depth in which it provides information on them. Using this information, ORI wants

to know whether there is a relationship between policy access and content and the research staff's knowledge of the institution's policy and its perception of the institution's commitment to proper adjudication of misconduct allegations.

The next questions that ORI wants addressed relate to the types of activities and processes most frequently used by institutions to effectively disseminate their research misconduct policies. Further, ORI is seeking to learn whether there are associations between the ways in which researchers are exposed to the institution's policy and procedures and achievement of high levels of research misconduct policy knowledge and more positive perceptions of their institution's commitment to proper adjudication of misconduct allegations among the researchers. An additional question probes whether researchers are able to correctly identify likely research misconduct and be willing to respond to the suspicion of research misconduct by reporting it to the appropriate institutional official.

The final question asks about what individual characteristics (covariates such as age, gender, rank, field of study, research experience, experience with research misconduct proceedings, etc.) and other important factors are associated with researchers perceiving the effectiveness of their institution's efforts to properly implement and disseminate its research misconduct policy. Among the other factors to be considered in this multivariable analysis are knowledge of the institution's research misconduct policy and procedures, being able to correctly identify and respond appropriately to allegations of research misconduct, how researchers report they receive exposure from the institution in its research misconduct policy, and their readiness to report allegations of research misconduct.

2. STUDY METHODS

In this report, we have conducted an analysis of two separate but related data collection activities undertaken to address the goal of this project – to evaluate the effectiveness of U.S. medical school efforts to meet their responsibility to educate their researchers on identifying and reporting research misconduct. The first of the two data collection activities consisted of an abstraction of the research misconduct policies contents of 109 of the 115 U.S. medical schools with National Institutes of Health (NIH) research funding that we were able to locate on the internet. The goals of this activity were to assess how accessible the policies are, what key information they impart (their breadth), and the amount of detail they provide (their depth). The data collection methodology for this activity is discussed in the next major section of this report.

The second data collection activity was a web-based questionnaire survey of a stratified random sample of more than 10,750 medical school researchers (principal investigators) who are supported by research awards from the NIH. Five thousand one hundred researchers responded after receiving up to six e-mail requests for their participation. The survey questioned researchers about their demographic characteristics and educational background as well as their research experience. Researchers were also quizzed on their knowledge of their institution's research misconduct policy and their exposure to it. We also asked about how the institution informs researchers of its research misconduct policy. There were also questions about whether the researchers thought that the institution was effective in disseminating its research misconduct policy and in handling allegations. In addition, there were questions intended to assess how disposed researchers are to make allegations against colleagues. We also asked questions about the researchers experience with research misconduct proceedings and whether it has had an impact on their willingness to be involved in further research misconduct proceedings. In the final section of the survey, we presented a series of brief scenarios intended to test how well researchers identify likely research misconduct and what they do if they recognize it. The conduct of this survey is discussed in this the remainder of this section.

2.1 Study Design

We employed a cross-sectional design in the conduct of the survey of medical school researchers performed in this study.

2.1.1 Definition of the Study Population

The population of interest for this survey was U.S. medical school researchers who were named as principal investigators on National Institutes of Health (NIH) research grant awards during the 2005 or 2006 fiscal years.

2.1.2 Stratification of the Sample

For this study, we selected a single stage stratified random sample of U.S. medical school-based researchers who were principal investigators on NIH research grant awards. We stratified by medical school and randomly selected a sample of principal investigators as a way to ensure that we selected actual researchers within each eligible medical school on the frame (list of NIH research grant awardees). Principal investigators were only included once on the frame, regardless of the size or number of awards received during 2005 or 2006.

At the time we selected the sample, there were 123 U.S. medical schools recognized by the American Association of Medical Colleges (AAMC) that had received any NIH research grant awards during fiscal years 2005 or 2006. Medical schools with fewer than 10 NIH-funded principal investigators, of which there were eight, were considered too small to be eligible and hence NIH-funded principal investigators in those institutions were not included in the sampling frame, leaving only 115 U.S. medical schools and their 16,336 NIH-funded principal investigators in the frame. Table 2-1 presents the distribution of the number of eligible medical schools sampled for researchers, and the rate at which the researchers associated with the institutions were sampled. The full list of eligible medical schools as well as the unduplicated number of principal investigators per medical school eligible for sample selection and the number who were actually e-mailed an advance letter informing them of the study and their selection into the sample is presented in Appendix B, Table 1. Note that only medical school researchers listed as NIH principal investigators on our sampling frame (see section 2.2.1 below for more details) were eligible for selection into our study sample and only those with an e-mail address could actually be e-mailed an advance letter.

Table 2-1. Distribution of the Rates at which Researchers were Selected from the Sampling Frame.

Rate of Sample Selection	Number of Medical Schools	Percent of Medical Schools
100.0%	57	49.6%
66.7% -95.5%	31	27.0%
32.6% - 64.5%	27	23.5%

2.1.3 Sampling Units

Our sampling units were the selected principal investigators from within each eligible medical school. The selected principal investigator sample members were solicited by e-mail and asked to complete a web-based survey questionnaire. The selected sample members were e-mailed an advance letter informing them of their selection into the survey. In a separate e-mail message, they were sent a URL to a secure web site with a logon and password that would allow them to gain access to complete their questionnaire. Multiple

reminders (up to six) were e-mailed to survey non-respondents every two weeks. Those who logged onto the web-site and completed more than one or two items were treated as respondents and sent reminders multiple reminders. We made a confidentiality commitment to the sample members not to release the identity of respondents, their item responses, or their institutional identities, and to only report data in our results aggregated or grouped so as not to allow individual or institutional identities to be recognized.

2.2 Sample Selection

We used a SAS procedure (proc survey select) to select the stratified random sample (SAS, 2008).

2.2.1 Sampling Frame Creation

The sampling frame was created from lists of U.S. medical school-based principal investigators receiving NIH research grant awards obtained from NIH for fiscal years 2005 and 2006. The listings included the name of each principal investigator as well as their medical school, mail address, e-mail address, academic department, project title, grant number, and award amount. The listing included separate entries for each grant awarded, thus for principal investigators with multiple grants there were multiple entries. To avoid multiplicities in the sample (sampling the same principal investigator more than once), we rolled up all of the multiple entries such that each principal investigator was listed only once on our frame. For rolled up entries, we retained the award amount for the largest grant amount and also summed the multiple award amounts for a total for each principal investigator, but these data were not used in sample selection.

For fiscal year 2005, there were 14,117 unique principal investigators and 123 unique medical schools on the research grant awardee list we obtained from NIH. For fiscal year 2006, there were 13,855 unique principal investigators and 122 unique medical schools on the NIH research grant awardee list. We combined the two lists to create the joint 2005 and 2006 sampling frame. The joint list included 16,374 unique principal investigators and 123 unique U.S. medical schools. However, as noted above, medical schools with too few researchers -- fewer than 10 principal investigators -- were not considered eligible, thus we removed eight medical schools and their NIH-funded principal investigators from the frame. This resulted in 115 medical schools and 16,336 principal investigators being included on the final sampling frame we employed for this study.

2.2.2 Sample Allocation

The number of principal investigators selected for each eligible school was based on the following:

- the number of principal investigators present in each medical school,

- the number of respondents needed to obtain 90% power assuming proportional estimates of 0.5 (most conservative) with 10% precision,
- and an assumed 50% response rate.

The resulting sampling allocation for each eligible medical school is contained in column two of Appendix B, Table 1, “number of selected PIs.” The medical schools are listed by number of principal investigators from fewest to most. The first 57 medical schools were sampled at a 100% sampling rate (number of principal investigators per school = number of selected principal investigators). The sampling rate for the remaining medical schools ranged from 95.5% to 32.6%. We selected a larger percentage from medical schools with fewer NIH-funded principal investigators. We assumed that we would achieve a 50% response rate, thus the number of selected principal investigators is double our expected number of respondents (see column three in Appendix B Table 1.).

2.2.3 Sampling Results

As described above, we assumed a 50% response rate across the board for our study. Overall, our assumption was very close to what we achieved. Because we were targeting a total of 5,377 respondents, we sampled 10,754 principal investigators (double the desired number of respondents). As it turned out, 177 of the principal investigators (1.1%) selected in the sample had no e-mail address in their NIH listing so we could not mail them an advance letter or invitation to participate in the survey. In total, we were able to send advance letters and invitations to participate in the survey to 10,577. Of the 10,577 sampled principal investigators, 5,100 researchers responded. The response rates varied somewhat across medical schools and ranged from as low as 5.6% to as high as 75.0%, yielding an overall response rate of 48.2%. The distribution of response rates presented in Table 2-2 shows that almost three-fourths (73.1%) of the medical schools had a researcher survey response rate of between 40.1% and 60.0%.

Table 2-2. Distribution of Medical School Research Survey Response Rates

Response Rate Range	Number of Medical Schools	Percent of Medical Schools
0.0%-20.0%	2	1.7%
20.1%-30.0%	2	1.7%
31.1%-40.0%	17	14.8%
40.1%-50.0%	41	35.7%
50.1%-60.0%	43	37.4%
60.1%-70.0%	7	6.1%
70.1%-80.0%	3	2.6%
Overall Rate 48.2%	115	100.0%

2.3 Weight Adjustments for the Survey Sample

Since a probability sampling design was used to select a random sample of principal investigators (PIs) from medical schools, each record in the survey data has an initial sampling weight associated to it. The sampling weights were adjusted twice, first to compensate for over-coverage issues in the sample (elements that do not belong to the population that were also included in the sample) and the population frame (non-population members included in the sampling frame), and later to account for non-respondents. Therefore, the entire weight calibration consists of the following steps: 1) Weight adjustment for over-coverage and 2) weight adjustment for non-responses. These weight adjustments were made at the school level.

First, ineligible persons who are not actually population members (i.e. medical school researchers for whom we received word from the medical school had retired, relocated/moved, changed employers, or were deceased) including PIs from the eight ineligible schools were eliminated from the sampling frame as well as the selected sample. Given that a stratified random sampling design was used to select the sample, the over-coverage adjusted sampling weights are calculated as N_h/n_h , where N_h is the adjusted stratum size in the frame and n_h is the adjusted sample size. Second, the non-response weight adjustment factors were calculated using $n_h/n'h$, where $n'h$ is the number of respondents in a given school. The final analysis weights were calculated as the product of the weighted adjustment factors obtained from these two steps.

The final population size is 16,159. The final adjusted total weights in the respondent data were summed to this control total. In addition, the final total weights by school in the respondent data were also adjusted to the total population at the school level.

Detailed counts are displayed in Tables 2-3 and 2-4.

Table 2-3. Total Population and Sample Counts

Group	Initial Count	Over-Coverage Count	Final Count
Sampling Frame	16,374	215 ^a	16,159
Selected Sample	10,754	177 ^b	10,577
Respondents	n/a	n/a	5,100

^a Includes 38 individuals from 8 ineligible schools, 91 ineligible PIs who were retired, relocated/moved, changed employers, or deceased, and 86 duplicates.

^b Includes 177 selected PIs for whom we did not have any mail address.

Table 2-4. Counts and Adjusted Weights of Medical School Principal Investigators

Medical School	Nh (Frame)	nh (Sample)	n'h Respondents)	Adjusted Weight
1	133	113	60	2.2167
2	24	24	7	3.4286
3	375	158	80	4.6875
4	29	29	7	4.1429
5	23	23	15	1.5333
6	108	108	55	1.9636
7	16	16	7	2.2857
8	312	149	57	5.4737
9	111	107	47	2.3617
10	153	122	56	2.7321
11	46	46	15	3.0667
12	152	120	64	2.3750
13	163	125	69	2.3623
14	126	112	50	2.5200
15	380	159	61	6.2295
16	247	144	56	4.4107
17	410	160	63	6.5079
18	156	119	40	3.9000
19	178	129	70	2.5429
20	67	67	35	1.9143
21	36	36	22	1.6364
22	38	38	20	1.9000
23	15	15	7	2.1429
24	74	74	43	1.7209
25	260	140	77	3.3766
26	14	14	10	1.4000
27	88	88	46	1.9130
28	244	143	62	3.9355
29	149	119	56	2.6607
30	101	101	47	2.1489
31	139	118	57	2.4386
32	219	137	68	3.2206
33	88	88	35	2.5143
34	84	84	33	2.5455
35	106	106	52	2.0385
36	21	21	10	2.1000
37	210	134	58	3.6207
38	21	21	10	2.1000

(continued)

Table 2-4. Counts and Adjusted Weights of Medical School Principal Investigators (continued)

Medical School	Nh (Frame)	nh (Sample)	n'h Respondents)	Adjusted Weight
39	196	134	78	2.5128
40	148	120	55	2.6909
41	70	70	37	1.8919
42	23	23	15	1.5333
43	229	138	75	3.0533
44	14	14	7	2.0000
45	244	141	56	4.3571
46	25	25	13	1.9231
47	224	137	62	3.6129
48	70	70	30	2.3333
49	251	141	64	3.9219
50	93	93	42	2.2143
51	61	61	24	2.5417
52	387	156	83	4.6627
53	104	104	59	1.7627
54	157	121	59	2.6610
55	150	120	53	2.8302
56	55	55	28	1.9643
57	93	93	35	2.6571
58	18	18	1	18.0000
59	195	129	69	2.8261
60	21	21	10	2.1000
61	281	147	60	4.6833
62	17	17	10	1.7000
63	116	108	41	2.8293
64	390	157	72	5.4167
65	362	156	55	6.5818
66	274	146	84	3.2619
67	123	112	50	2.4600
68	33	33	16	2.0625
69	104	104	42	2.4762
70	152	121	63	2.4127
71	10	10	6	1.6667
72	221	136	66	3.3485
73	203	135	76	2.6711
74	119	105	53	2.2453

(continued)

Table 2-4. Counts and Adjusted Weights of Medical School Principal Investigators (continued)

Medical School	Nh (Frame)	nh (Sample)	n'h Respondents)	Adjusted Weight
75	516	168	78	6.6154
76	21	21	8	2.6250
77	98	98	45	2.1778
78	54	54	28	1.9286
79	157	124	69	2.2754
80	26	26	15	1.7333
81	30	30	20	1.5000
82	46	46	29	1.5862
83	107	102	60	1.7833
84	59	59	34	1.7353
85	29	29	11	2.6364
86	51	51	24	2.1250
87	193	131	60	3.2167
88	12	12	9	1.3333
89	194	131	65	2.9846
90	148	120	62	2.3871
91	255	144	85	3.0000
92	476	165	71	6.7042
93	46	46	25	1.8400
94	226	139	81	2.7901
95	135	113	57	2.3684
96	11	11	8	1.3750
97	138	118	45	3.0667
98	53	53	32	1.6563
99	306	150	73	4.1918
100	52	52	31	1.6774
101	50	50	24	2.0833
102	17	17	9	1.8889
103	85	85	43	1.9767
104	56	56	20	2.8000
105	26	26	18	1.4444
106	314	151	87	3.6092
107	91	91	51	1.7843
108	162	123	70	2.3143
109	407	160	76	5.3553
110	367	156	82	4.4756
111	132	115	64	2.0625

(continued)

Table 2-4. Counts and Adjusted Weights of Medical School Principal Investigators (continued)

Medical School	Nh (Frame)	nh (Sample)	n'h Respondents)	Adjusted Weight
112	46	46	22	2.0909
113	377	157	69	5.4638
114	201	133	60	3.3500
115	40	40	4	10.0000
ALL	16,159	10,577	5,100	NA

2.4 Survey Data Collection Procedures

We created a web-based data collection system using ColdFusion MX7, running against an MS SQL Server 2003 database back end. The web-based data collection survey instrument was kept secure by use of an SSL certificate, ensuring encryption of all data transmitted across the internet. To access the survey data collection instrument required a username and password. Each user was issued a logical username, and a unique, randomly generated password. E-mail delivery of usernames and passwords in e-mail was performed after an advance e-mail and in follow-up e-mail reminders. Additionally, log-in credentials were provided, embedded in a hyperlink within the e-mail, so that survey sample members simply needed to click through to access their individual survey form.

2.4.1 Contacting Members of the Sample

The sample frame was loaded from data on an excel file containing all pertinent contact information, including e-mail address and institutional affiliation. Data were loaded into a user table in SQL Server, at which point a script was run to create a unique user name based in part on the users e-mail address. Another script was run to randomly generate a unique, strong password for each user

Users were solicited to participate in the survey by way of an e-mail advance or lead letter, followed about a week later by another e-mail letter which included the site URL, username, and password. The e-mail also contained a hyperlink with the username and password embedded in the link, so that users could simply click through to access the survey. Due to the large size of the sample (10,000+), all e-mail processes were conducted through a scheduled ColdFusion process. Sample order was randomized, and e-mails were sent out in small waves to avoid being flagged as spam, and to reduce load on RTI and institutional mail servers.

2.4.2 Data Collection Instrument

The web-based data collection instrument included dynamic sub-questions, such as free text fields to expand upon radio button selections of "other, specify." Additionally, skip

logic was used to suppress irrelevant questions based on specific responses. This was done to keep the respondents on track, and so as not to burden them with irrelevant questions based on their response. The bulk of the questions were phrased as closed ended with a fixed set of responses. If a response was left blank, an alert was brought to the respondent's attention, but the user was allowed to leave a response blank after reading the alert message. Users were allowed to leave the survey, and to pick up where they left off as long as it was necessary and until they had completed the survey. Completed surveys were no longer editable. Upon completion of the survey, the user had the option to generate a copy of their responses.

The web-based questionnaire we developed to survey the researchers is divided into seven sections. Each section has a different focus. The first section contains 11 items intended to provide a description of the respondents' education, training, employment, and research experience, as well as their demographic characteristics. The 9 items in the second section focus on the familiarity of the researchers with their institutions' policy and procedures regarding the report and resolution of allegations of research misconduct that are based on the Federal definition of research misconduct and their institutions' application of it as policy for all to follow.

In section 3 of the questionnaire, we ask 15 questions to learn about how and when the institutions disseminate their policy and procedures to their new institutional research staff, and we ask about any role that researchers' themselves play in educating new and future researchers regarding how to respond to suspicions of misconduct. In the fourth section, we have included 10 statements expressing different beliefs, feelings, and thoughts about how the researchers might perceive their institutions' commitment to identifying and resolving cases of research misconduct. Respondents were asked to indicate their level of agreement or disagreement with each of the statements.

The fifth section consists of four items expressing different levels of assuredness that a person might have to have to allege that a colleague had committed research misconduct. Respondents were asked to indicate their level of agreement or disagreement with the degree of assuredness expressed in each item before an allegation of research misconduct would be reported to the designated institutional official. In section 6 we ask four questions about the respondents' experience with research misconduct proceedings at the current or at a previous institution. If they have had experience with research misconduct in any capacity – as a respondent, complainant, witness or committee member – we also ask another question about whether the experience's impact has made them more open to being part of research misconduct proceedings or not. Also in this section we ask about how important the respondents believe 13 selected considerations are in a researchers' decision-making process of whether or not to make a formal allegation of research misconduct.

In the final section of the questionnaire, section 7, we presented nine brief scenarios. We asked the respondents to identify the ones that they thought represent likely cases of research misconduct according to the Federal regulations. For each scenario identified as a likely case of research misconduct, respondents were also asked who they would talk with about it, if anyone. A copy of the survey instrument is included in Appendix C and a set of unweighted frequencies appears in Appendix D.

2.4.3 Data Collection Process and Survey Period

The first wave of advance letter e-mails was sent out on July 28, 2009. Within a week of all of the initial advance letters informing the researchers of the survey being e-mailed, we began e-mailing the survey solicitation letters containing the needed URL, logon, and password for the sampled researchers to access the secure web-based survey. Approximately a week after the all of the solicitation letters were e-mailed, we sent out brief thank you/reminder notes to everyone who had been sent advance and solicitation letters. Thereafter, we e-mailed up to six additional reminder letters to non-respondents at approximately two to three week intervals. The reminders were each tailored to the diminishing time to respond and stressed the importance and urgency of participation. The last wave of survey reminders were e-mailed to non-respondents in the middle of December. The web site established for the data collection remained available to researchers wanting to complete the survey until January 13, 2010.

The data collection system contained administrative functions to tabulate non-response, partial, and completed questionnaire statuses for each sampled researcher in the system. Response status was used to determine to whom we would send follow-up reminders to solicit researcher participation. Additionally, all auto-generated and personal response e-mails that we received following our mail-outs were manually reviewed prior to sending the next follow-up e-mails. Based on a manually assigned status code from these e-mails, follow-ups were included or suspended accordingly. This was done to respect non-participation requests (refusals and other negative responses) from researchers, and to take into account feedback received from institutions about the current status of the researcher, i.e., no longer at the institution, retired, moved, deceased.

Final data were exported to SAS for analysis. Data were reviewed for consistency. Composite variables were derived and paired with a comprehensive code book mapping questions to responses and response codes. Data were analyzed so as not to be identifiable with individuals or medical schools and to protect confidentiality they have been further de-identified for delivery to ORI.

2.5 Statistical Analysis

The Cronbach's alpha statistic was used to assess the internal consistency of items intended to be used as scales, (e.g., the 10 items used to measure perceived effectiveness

of the institution's efforts to implement and disseminate its policy). An alpha of .8 is generally considered indicative of good internal consistency for a set of items to form a scale, values of 0.70 or greater are considered satisfactory, although an alpha of .6 may be acceptable for exploratory research (Nunnally, 1994; Carmines and Zeller, 1979).

Descriptive statistics in the form of means, frequencies, and cross-tabulations were used to summarize the policy abstraction and survey data that were collected. Unweighted (raw percentages of respondents to the survey) and weighted frequencies (survey percentages that have been adjusted for the survey design and to compensate for less than complete rates of participation (non-response) within medical schools) were produced. Unweighted frequencies are presented in Appendix D and describe the distribution of the different items included in the survey. Weighted frequencies, on the other hand, describe the distribution of the items in the population and are presented in the body of the text as their subject matter is described.

Correlation coefficients were calculated to evaluate the association between the potential predictors in order to correct for possible multicollinearity. Pairs of potential predictors with a correlation coefficient larger than or equal to 0.50 were considered highly correlated. In the case of highly correlated predictors, we retained only one of the correlated variables.

Logistic regression was used for examining the association of the binary outcome of interest (e.g., the researcher's perception of the effectiveness of their institutions' efforts to implement and disseminate their research misconduct policy) and a set of conceptually relevant control and independent variables. In the presence of complex survey data, SUDAAN® 10 Rlogist (SUDAAN, 2009) was used to take into account the sample design and the non-response adjustment. The adjusted Wald test statistic was used to evaluate the significance of the model parameters. Selection and inclusion of appropriate predictor variables was performed using a full vs reduced model approach. The pseudo R² was calculated to measure the proportion of variability in the outcome measure that is accounted for by the variables in the model. The likelihood ratio chi square test was used to test the hypothesis that at least one independent variable is a good predictor of the outcome. Odds ratios were calculated to evaluate the odds for changes in each level of the independent variables after holding the other predictors constant.

3. A DESCRIPTIVE ANALYSIS OF THE RESEARCH MISCONDUCT POLICIES OF U.S. MEDICAL SCHOOLS

In this section of the report we first provide a brief summary of the work already done by others to evaluate institutions' research misconduct policies and explain how our work adds to earlier research in this area. We also provide an overview of the methods we used and the results we obtained the research misconduct policy abstraction portion of this study. In the methods section we discuss the methods used to:

- locate and identify the medical schools' research misconduct policies on the internet,
- code the medical schools' research misconduct policies,
- describe the process and statistical procedures used to assess the reliability of the coding,
- develop the code form and train the abstractors, and
- develop measures for assessing the accessibility of the policies on the internet, as well as how we chose to measure the depth and breadth of the information contained in the policies.

In the results section, we present and discuss the distributions of information recoded on the code form from the medical school research misconduct policies we located on the internet.

3.1 Background and Introduction to the Research Misconduct Policy Review

Before addressing ORI's objective of evaluating whether ready access to and the content in medical schools' research misconduct policies are associated with researchers' perception of their institution's efforts to disseminate the policies to their researchers, we looked for other published studies that undertook to assess the qualities of institutions' research misconduct policies. We found few published works that related to identifying the many aspects of research misconduct policy content. One was commissioned by ORI and conducted by CHSP Consulting (2000) and a study conducted by Lind (2005). We also identified an unpublished paper by Lind (2008) that presented findings on the respondent and whistleblower protections provided for in the research misconduct policies of institutions with National Science Foundation funding.

The CHSP report analyzed a sample of 156 institutional research misconduct policies judged acceptable by ORI to identify the variation in methods institutions use to respond to allegations of research misconduct. CHSP used a code form that included 18 topic areas and had 89 separate questions, some of which included multiple response options. Each topic area consisted of a series of statements about the topic that generally required them to be coded as either present or absent. The topic areas included:

- the definition of scientific misconduct
- reporting of allegations
- pursuing the allegations
- maintaining confidentiality
- conflicts of interests
- appropriate expertise
- rights of respondents
- appointing the inquiry committee
- conduct of the inquiry
- content of inquiry report
- appointing the investigation committee
- conduct of the investigation
- content of investigation report
- sanctions
- appeals process
- restoration of reputation of respondent whistleblower, and
- interim administrative action

In their report to ORI, CHSP categorized the information it collected about these 18 topic areas into six domains:

- definition of research misconduct,
- reporting and pursuing allegations of research misconduct,
- ensuring a fair and appropriate investigation,
- rights of the respondent and complainant,
- inquiry and investigation in scientific misconduct policies,
- and other considerations.

CHSP found that slightly more than half the policies contain a definition of research misconduct that includes something beyond falsification, fabrication, and plagiarism but that only about a quarter of the policies obligate institutional members to report scientific misconduct. They also found that statements about conflict of interest in the policy apply most often only to persons on the inquiry (82%) and investigation (85%) committees.

Moreover they found universities mostly use ad hoc committees to conduct the inquiry and investigation into allegations of research misconduct; a little more than half (53%) the policies say an ad hoc committee will conduct the inquiry and similar statements

regarding the investigation committee appear in 80% of the policies. CHSP also found about a quarter of the policies mentioned the respondent's right to have an advisor during the inquiry phase and about 40% mentioned the respondent's right to an advisor during the investigation phase.

These policies most often designated the senior official as the person to impose sanctions if research misconduct occurred; three quarters of the policies stated what those sanctions might be and more than half stated the respondent has a right to appeal the finding.

Finally, all of the policies reviewed specify respondents' rights and more than half specify the respondents' responsibilities. Most of the policies CHSP reviewed include complainant rights and just over half state the complainant has the right to be protected from retaliation; 89% state that the institution will make efforts to protect the position and reputation of the complainant.

Lind (2005) developed her work from the CHSP report, using their coding form to develop her own version. She revised the CHSP code form to represent 20 topic areas that collapsed into five domains. The topic areas include:

- definition of research misconduct
- reporting allegations
- pursuing allegations
- mentoring
- maintaining confidentiality
- conflicts of interest
- appropriate expertise
- respondent rights
- restoring the respondent's reputation
- whistleblower rights and protections
- appointing the inquiry and investigation committees
- conducting the inquiry and investigation
- inquiry and investigation report content
- interim administrative actions
- decision makers and process

- sanctions
- appeals

The five domains included: background information; ensuring fairness; the inquiry and investigation process; respondent and complainant rights; and outcomes. The sample included the research misconduct policies of 41 universities with NIH and NSF-funded research projects. She coded these policies for a total of 500 pieces of information. Universities research misconduct policies were evaluated on their usefulness and accessibility. Lind determined usefulness by the amount of information contained in the policies, measured by a ratio score she developed. The number of mouse clicks required to reach the policy from the university website's homepage determined the accessibility of the policies to researchers in the institution.

Findings from this study indicated that the policies were not particularly accessible; she found that only about half required four or fewer clicks to access. She also found that the policies varied by topic area in their usefulness. Respondent and complainant rights and the inquiry and investigation process were the two content areas covered most completely in the policies with ratio scores of 0.79 and 0.71 respectively. Looking at the 20 topic areas, the ones with the most information covered in the policy, though not necessarily covered thoroughly, were respondent's rights (mean score of .95), investigation report (mean score of 0.98) and the inquiry report (mean score of .90). Ratio scores in Lind's study reflect the amount of information from each topic area or domain that is covered in the university's policy.

In an unpublished presentation given at the 2008 National Communication Association Annual Convention, Lind (2008) described additional work she did to evaluate the research misconduct policies from 86 universities with NIH funding. In this study, which was part of a larger study she conducted, Lind analyzed the policies to determine the extent to which they included overall protections for respondents and whistleblowers, e.g., respondent and whistleblower rights and responsibilities, format for reporting allegations, protections from retaliation, and so forth. The code form she used was based on the CHSP (2000) project and her own earlier (Lind, 2005) coding scheme. She evaluated the policies for the presence of a total of 66 pieces of information. In this study, Lind (2008) found that the policies she reviewed mentioned fewer protections for whistleblowers than for respondents - 54 of the 66 protections she coded were for respondents as compared to only 41 for complainants. Further she found that a greater number of the universities represented offered more protections for the respondent than for the complainant and seven of the universities did not cover complainant protections at all. In contrast only four did not cover respondent protections in their research misconduct policies.

Our study builds on the work performed by CHSP Consulting and Lind. The code form we developed for our study includes a subset of 162 of the 500 variables Lind used, but, our

goal was slightly different from hers. Like Lind (2005), we coded the policies for their accessibility on the internet. However, rather than code them for usefulness, as Lind did, or look for those policies that included description of innovative methods for protecting respondents and complaints as CHSP Consulting did, our analytic focus is on the proportion of the medical school policies that include each of the main topics areas of interest. We also evaluate the depth and breadth of the policies, defined as the number of discrete pieces of information each topic area specifies and the number of topic areas covered, respectively.

3.2 Methodology

This section discusses the study methods used to locate and code research misconduct policies for the medical schools in the sub-study, including how we identified the institutions for inclusion in this part of the study. This section also reviews the statistical techniques we used to conduct the inter-and intra-coder reliabilities, describes how we determine the accessibility of the policies, how we approached coding the policies, and how we created variables to measure the depth and breadth of the institutions' research misconduct policies.

3.2.1 Sample of Research Misconduct Policies

We began with the 123 U.S. Medical Schools sampled for the web-based survey of medical school researchers who were principal investigators on NIH-sponsored research projects. As reported earlier, 8 of those institutions had fewer than 10 principal investigators receiving NIH research grant awards during 2005 and 2006, and those institutions were not included in the web survey. Neither did we include them in the sample of institutions whose research misconduct policies we sought to find and code. After searching the institution's website or using a Google web search, we were unable to locate or access the policies for four institutions. In another two instances, we were able to locate the policy but it was password protected and not accessible to persons outside of the institution. Thus, we were unable to code the research misconduct policies for a total of six medical schools. The final sample of cases for research misconduct policy reviews consisted of the 109 U.S. Medical Schools whose policies we could find on the internet and that had 10 or more unique principal investigators receiving NIH research awards between fiscal years 2005 and 2006.

3.2.2 Accessing Research Misconduct Policies

To locate the policies, we began the search by going to the American Association of Medical Colleges (AAMC) website to obtain a URL address to each institution's website. If we were unable to locate the policy in the medical school's website, we searched the university's home page, beginning with the research tab labeled "Research at", or "Research Corporation", or something similar that suggested the conduct of research. If that proved unsuccessful, we looked for a button or tab called Office of Sponsored Programs. Failing

that, we looked for a button or tab called Research Policies, Research Guidelines, Research Misconduct, or Misconduct Policy in that order. If the policy was not located using either of these methods, we entered a series of search terms in the search box appearing on the research tab of either the medical school website or the university's homepage. The search terms used included research misconduct, scientific misconduct, scientific integrity, and research integrity. Other terms we identified during our review of the institutions' websites were used if the aforementioned terms did not locate the policy. Examples of these include misconduct or fraud in research, faculty handbook, misconduct, research misconduct policy, and research policy. As a final alternative, we attempted to locate the policy using the Google search engine by entering the medical school name plus each of the search terms mentioned above. If this step failed, we closed the case and coded it as unable to locate the policy. There were four of these. If we located the policy but could not access it because the document or access to the relevant webpage was password protected, we finalized the case as unable to access the policy. There were two of these.

3.2.3 Measuring Accessibility of Research Misconduct Policies

To measure the accessibility of an institutions' research misconduct policy to someone looking for a copy of it on the institution's website, we counted the total number of mouse "clicks" and the total number of minutes required to get from the medical school's homepage to a copy of the document with the institution's research misconduct policy and procedures. Our measure of the total number of "clicks" was derived by taking the sum of the number of clicks needed to locate the research misconduct policy by searching on the medical school home page, and the number of clicks to get to the policy from the university's website if it was not found on the medical school home page, and the number of clicks needed to reach the research misconduct policy using a Google search if it was not found on either the medical school or university home page. The number of clicks was recorded separately for each of the sources used.

The total number of minutes spent to locate the policy was calculated in much the same way. It is the sum of the minutes spent searching for the policy using the medical school website as a starting point, plus the minutes spent searching for the policy on the university home page, and finally the minutes spent searching for the policy via Google. The number of minutes was recorded separately for each of the sources used.

We trained two junior research staff members in the process of locating the policies and in the standard procedures we established for counting the number of clicks and minutes. We recognized the possibility that our measures of the effort needed to locate the institutions' research misconduct policies might be inflated by a "learning curve" attributable to our lack of familiarity with the institutions' website. Because researchers in the institution would likely be more familiar with their website than our staff, we repeated both the clicks and minutes measurements a second time. Once we had located a research misconduct

policy and presumably became more familiar with the way the institutions' website was organized, we repeated the search to determine if we could be more "efficient" in our efforts to locate the policy. We thereby had a record of the number of clicks and minutes it took someone at least somewhat familiar with the website to locate the policy using what we expected would be a more direct route that would be more comparable to what it would take for a researcher at the institution at least somewhat familiar with the structure of the website.

3.2.4 Coding the Policy Contents

After locating the institutions' research misconduct policies, we used a code form that we developed to record the content present in the research misconduct policies. As mentioned above, the code form was based on a consolidation of the 20 topic areas covered in Lind's research and ten domains specified in ORI's Model Research Misconduct Policy. Our coding form for the policy content is structured around 17 topic areas that are combined to represent 11 domains. The 11 domains and the topic areas that comprise them include:

- definition of research misconduct
- reporting allegations of research misconduct
- pursuing allegations of research misconduct
- maintaining confidentiality
- conflicts of interests
- appropriate expertise
- appointing the inquiry committee, conducting the inquiry, and content of the inquiry report
- appointing the investigation committee, conducting the investigation, and content of the investigation report
- respondent rights and responsibilities
- complainant rights and responsibilities
- sanctions, the appeals process and restoration of respondents' rights

Our policy code form has 161 items for the abstractors to look for and code as being present or absent after they have found an institution's research misconduct policy. A copy of the code form is included in Appendix E. The 161 items represent subsets of items that specify (1) the 62 primary items about areas of the research misconduct policy that we thought were especially important to look for in the policies, and (2) the 99 follow-up items of details we chose to provide more specific information about aspects of some of the topic areas. The former we refer to as representing the breadth of the policy content, while the latter we refer to as providing the depth of the policy content.

The items we asked about in each of the 17 topic areas only required yes or no responses. However, in seven of the topic areas – definition of research misconduct, reporting allegations, pursuing allegations, conflicts of interest, rights and responsibilities of the respondent, appeals process, rights and responsibilities of the complainant – there were 19 items that had a total of 99 sub-items that asked about the presence or absence of more detailed information on the same topic. We created a policy's depth score from these 99 sub-items to indicate how much of the information represented by the sub-items was coded yes or present in the policy. The policy content depth indicator we created is the ratio of the total number of sub-items coded yes (or present) divided by 99, the total number of sub-items asked. The higher the depth score, the more information from the set of 99 sub-items from the seven topic areas that was included in the policy

We also created a policy's breadth of content score for each policy to indicate how many of the 62 different topics that we included in the 11 domains were addressed in the policy. Because the number of topic area items (not including follow-up items) present in the 11 different domains varied so much from domain to domain, and we wanted to consider the domains to be of equal importance, we computed the policy content breadth indicator as the mean of the proportion of primary items coded yes (present) in each domain. To do this we calculated the proportion of primary items coded yes in each domain, then summed the 11 domain proportions and divided by 11 to arrive at an overall mean breadth score for the policy. The higher the breadth score, the broader the scope of topics covered in the policy.

Two junior research staff members were trained by the task leader to independently code each research misconduct policy using the code form. To prepare the two junior research staffers for the policy coding task, they spent portions of five days discussing the meaning of the questions to be coded, then independently coding, and then discussing at length five actual research misconduct policies. The policy portion of the code form consists of a series of questions about the topics covered in the policy that can be answered by merely checking yes or no on the form. We used this dichotomous coding scheme: "1" if the item was present or discussed in the policy, and "0" if it was not. Each of the five policies used in training was coded, reviewed, and disagreements on coding were discussed as part of the group training to ensure abstractors understood the intent of each item as well as how to code them. The two project staffers who were trained to do the policy coding were each assigned approximately 60 policies to code.

3.2.5 Inter- and Intra-Rater Reliability

As a check on the standardization of the abstractors' interpretation and coding of the policies, we collected data to measure the inter-coder and intra-coder reliability of their work. Inter-rater reliability refers to how similarly two or more abstractors code the same information. Intra-coder reliability refers to how similarly the same coder codes the same

information at two different times. We designed a data collection activity to allow us to analyze the abstractors work to assess the consistency (reliability) of how they coded duplicates of their own work and replicates of the other coder’s work.

To assess inter-coder reliability, each coder was randomly assigned 10 of the other coder’s cases to independently code so we would have replicate coded pairs for the same sub-set of research misconduct policies. We calculated several statistical measures of inter-coder agreement. These included: the number of disagreement between the abstractors, the percent agreement between the abstractors, 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 (AC1) (2001).

To assess intra-coder reliability, we had each coder independently code a random sample of 10 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.

Results of the inter- and intra-coder reliability analysis are presented in Table 3-1. Overall the number of disagreements in the inter-coder analysis is fairly small, only 373 out of 3220 item comparisons, resulting in an overall percent agreement of 88.4%. The intra-coder reliability is even better, with only 278 disagreements out of the 3381 item comparisons, for a percent agreement of 91.8%. The inter-coder agreement coefficients are closely in agreement with each other (in the range of 0.77) and high enough for inter-coder reliability to be considered good. The intra-coder coefficients are also in close agreement (in the range of 0.84) and high enough for the intra-coder reliability to be considered very good.

Table 3-1. Research Misconduct Education Policy Inter- and Intra-Coder Reliability Analysis Results

Number of Items per Case	Number of Cases	Abstractors Compared	Total Items Compared	Number of Disagreements	Percent Agreement	Kappa	r_{ICC}	AC ₁
161	10 pairs	Inter-Coder 1-2	3220	373	88.4%	0.768	0.768	0.770
161	10/11 pairs	Intra-Coder 1-1, 2-2	3381	278	91.8%	0.834	0.849	0.835

3.3 Results of Research Misconduct Policy Coding

In this section we discuss the accessibility of the medical school research misconduct policies on the internet and we describe their depth and breadth. Next, we focus on a

description of the content of the institutions' research misconduct policies, presenting distributions of items coded as present in each domain.

3.3.1 Accessibility Results

We were able to locate more than four-fifths (88.1%) of the policies directly from the medical school website. The remaining policies were located from the university's home page. As shown in Table 3-2, the initial pass through required from 2 to 28 mouse clicks, with a mean of about 8 clicks before we located the institution's research misconduct policy. The time required to locate the policy starting from the same website ranged from under a minute to about 22 minutes, with an average of 4 minutes required to find it.

Locating the policies after we became familiar with the medical school and university websites was much easier and quicker. On average it took 4 clicks and one minute to locate the institutions' research misconduct policies on the second attempt, which represents a significant difference ($t = 9.3, p < .0001$ for the number of mouse clicks and $t = 8.4, p < .0001$ for the minutes to access the policy) between the two attempts. Hence, as we expected, persons familiar with the site would likely have an experience closer to our second attempt, but those not so familiar might have the more time consuming one we had at first.

Table 3-2. Mean Number of mean Clicks and Minutes Required to Locate Research Misconduct Policies on Institutional Websites

Variable Name	Number of Policies Accessed			Mean	Standard Deviation
	Minimum	Maximum			
Total clicks to locate	109	2	28	8.4	4.9
Total Minutes to locate	109	0.7	22	4.3	3.1
Clicks to locate using most direct route second time through	109	1	9	4.3	1.4
Minutes to locate using most direct route second time through	109	0.3	4	1.2	0.5

Using similar logic to that used by Lind (2005), if one assumes that a policy is difficult to locate if it requires more clicks than the average, then more than a three-fourths (78.0%) of the policies were hard to locate; it took more than the average of 1.2 minutes to locate most (83.5%) of them (Table 3-3 and Table 3-4). The easiest policy to find was located after only two clicks and in just under one minute. As mentioned above, we started our search by looking for a research tab on the medical school website and this proved to be the most fruitful path for the abstractors to follow; about two-thirds (67%) of the policies were located without employing a search engine or using search terms on the institutions'

websites. When search terms were used, research misconduct and scientific misconduct were the terms used most often (29.4% and 14.7%, respectively).

Table 3-3. Total Number of Mouse Clicks Required to Locate Policies

Number of Mouse Clicks	Number	Percent	Cumulative Frequency	Cumulative Percent
2	1	0.9%	1	0.9%
3	7	6.4%	8	7.3%
4	16	14.7%	24	22.0%
5	15	13.8%	39	35.8%
6	10	9.2%	49	45.0%
7	7	6.4%	56	51.4%
8	11	10.1%	67	61.5%
9	7	6.4%	74	67.9%
10	2	1.8%	76	69.7%
11	7	6.4%	83	76.2%
12	5	4.6%	88	80.7%
13	5	4.6%	93	85.3%
14	6	5.5%	99	90.8%
15	3	2.8%	102	93.6%
16	3	2.8%	105	96.3%
19	1	0.9%	106	97.3%
24	1	0.9%	107	98.2%
26	1	0.9%	108	99.1%
28	1	0.9%	109	100.0%

Table 3-4. Total Number of Minutes Required to Locate Policies

<i>Number of Minutes to Locate</i>	<i>Number</i>	<i>Percent</i>	<i>Cumulative Frequency</i>	<i>Cumulative Percent</i>
0.7	1	0.9%	1	0.9%
1.0	16	14.7%	17	15.6%
1.2	1	0.9%	18	16.5%
1.3	2	1.8%	20	18.3%
1.4	1	0.9%	21	19.3%
1.5	1	0.9%	22	20.2%
1.6	1	0.9%	23	21.1%
1.7	4	3.7%	27	24.8%
2.0	22	20.2%	49	45.0%

(continued)

Table 3-4. Total Number of Minutes Required to Locate Policies (continued)

Number of Minutes to Locate	Number	Percent	Cumulative Frequency	Cumulative Percent
2.4	1	0.9%	50	45.9%
2.5	4	3.7%	54	49.5%
3.0	8	7.3%	62	56.9%
3.5	1	0.9%	63	57.8%
3.7	1	0.9%	64	58.7%
4.0	8	7.3%	72	66.1%
4.4	1	0.9%	73	67.0%
4.5	1	0.9%	74	67.9%
5.0	5	4.6%	79	72.5%
5.3	1	0.9%	80	73.4%
5.5	2	1.8%	82	75.2%
6.0	5	4.6%	87	79.8%
6.5	1	0.9%	88	80.7%
6.7	1	0.9%	89	81.7%
7.0	2	1.8%	91	83.5%
8.0	2	1.8%	93	85.3%
8.3	1	0.9%	94	86.2%
9.7	1	0.9%	95	87.2%
10.0	5	4.6%	100	91.7%
11.5	1	0.9%	101	92.7%
12.0	2	1.8%	103	94.5%
13.0	1	0.9%	104	95.4%
14.0	1	0.9%	105	96.3%
14.5	1	0.9%	106	97.2%
15.0	1	0.9%	107	98.2%
16.0	1	0.9%	108	99.1%
22.0	1	0.9%	109	100.0%

3.3.2 Results for Policy Depth and Breadth

We present the categorized set of policy depth and breadth scores in Table 3-5. We created as close to three equal-sized categories as possible for each. Recall that the policy depth refers to the proportion of the 99 sub-items in the seven selected topic areas that were answered yes or present in the policy. The seven topic areas are: 1) definition of research misconduct; 2) reporting allegations; 3) pursuing allegations; 4) conflicts of interest; 5) respondent rights and responsibilities; 6) the appeals process; and 7) complainant rights and responsibilities. Policy depth is intended to measure the amount of

detail in the policy. Policy breadth, on the other hand, is intended to measure the range of topic areas covered in the plan. It is the mean proportion of the 62 primary items answered yes or present across the 11 domains examined in the plans. As can be seen from the table, there is considerable variation across the policies with regard to both their depth and breath.

Table 3-5. Distribution of Policy Depth and Breadth Scores

Variable Name	Score Range	Number	Percent	Cumulative Frequency	Cumulative Percent
Policy Depth Score					
Low	0.16 - 0.33	34	31.2%	34	31.2%
Medium	0.34 - 0.43	35	32.1%	69	63.3%
High	0.44 - 0.60	40	36.7%	109	100.0%
Policy Breadth Score					
Low	0.36 - 0.67	37	33.9%	37	33.9%
Medium	0.68 - 0.81	35	32.1%	72	66.1%
High	0.82 - 0.90	37	33.9%	109	100.0%

3.3.3 Differences in Institutions' Research Misconduct Policies

In this section we examine the distributions for each of the items in the code form. We have presented the results of the questions from the 17 topic areas collapsed into their 11 domains, e.g., appointing the inquiry committee, conducting the inquiry, and the content of the inquiry report are topic areas presented together as one domain. Likewise, we combined the topic areas of appointing the investigation committee, conducting the investigation, and the content of the investigation report into a single domain as well. Because sanctions, the appeals process, and restoration of the respondents' rights deal with related issues, we also discussed findings for these topic areas in a single domain.

3.3.3.1 Definition of Research Misconduct Domain

Abstractors reviewed each policy to determine not only whether the policy included a definition of research misconduct, but also whether the policy defined research misconduct in terms of ORI's standard definition of research misconduct (i.e., falsification, fabrication, and plagiarism) or something else. Abstractors also reviewed the policies for the institutions' general approach to specifying to whom and what activities it covers in its definition of research misconduct. Table 3-6 presents the distributions of the items and sub-items for each of the topics areas related to how the policy defines research misconduct.

All institutions included plagiarism in their definition, and almost all included falsification and fabrication (98.2% and 99.1%, respectively) in the definition. However, only about two-thirds (63.3%) of the institutions' policies went the extra step in defining

Table 3-6. Definition of Research Misconduct

Characteristic	Present in Policy	Number	Percentage
Definition of Research Misconduct			
	Yes	109	100.0%
Includes Falsification			
	Yes	107	98.2%
	No	2	1.8%
Includes Fabrication			
	Yes	108	99.1%
	No	1	0.9%
Includes Plagiarism			
	Yes	109	100.0%
Components of Research Misconduct Defined			
	Yes	69	63.3%
	No	40	36.7%
Falsification Defined			
	Yes	68	62.4%
	No	41	37.6%
Fabrication Defined			
	Yes	64	58.7%
	No	45	41.3%
Plagiarism Defined			
	Yes	69	63.3%
	No	40	36.7%
Excludes Honest Error and Differences of Opinion			
	Yes	106	97.2%
	No	3	2.8%
Policy Discusses to What Research-related Activities it Applies			
	Yes	106	97.3%
	No	3	2.8%
Applies to Proposing Research			
	Yes	106	97.3%
	No	3	2.8%
Applies to Conducting Research			
	Yes	106	97.3%
	No	3	2.8%
Applies to Reporting (One's) Research			
	Yes	106	97.3%
	No	3	2.8%

(continued)

Table 3-6. Definition of Research Misconduct (continued)

Characteristic	Present in Policy	Number	Percentage
Applies to Reviewing (Others') Research			
	Yes	68	62.4%
	No	41	37.6%
Does the Policy Specify to What Categories of Funded-research It Applies			
	Yes	92	84.4%
	No	17	15.6%
Applies to PHS-funded research specifically			
	Yes	67	61.5%
	No	42	38.5%
Applies to all Government-funded research broadly			
	Yes	15	13.8%
	No	94	86.2%
Applies to all publicly and privately funded research			
	Yes	22	20.2%
	No	87	79.8%
Applies to all research regardless of funding source			
	Yes	60	55.1%
	No	49	45.0%
Policy states who in the institution is bound by it			
	Yes	97	89.0%
	No	12	11.0%
Contains a general statement that all parties are bound by the policy			
	Yes	48	44.0%
	No	61	56.0%
Faculty/senior research staff are covered by policy			
	Yes	88	80.7%
	No	21	19.3%
Non-faculty academic/research staff are covered by policy			
	Yes	84	77.1%
	No	25	22.9%
Students/trainees are covered by policy			
	Yes	82	75.2%
	No	27	24.8%
Includes Statute of limitations for reporting research misconduct			
	Yes	24	22.0%
	No	85	78.0%

what each of these terms mean, thereby leaving the definition to the interpretation of the individual reporting or investigating an allegation of research misconduct. Slightly fewer institutions (58.7%) define what fabrication means, than define what falsification and plagiarism mean (62.4 and 63.3% respectively), again leaving open to interpretation what the definition of terms actually is. Almost all (97.2%) policies we reviewed exclude honest error and differences of opinion from their definition of research misconduct.

To assess how broadly institutions' research misconduct policies are applied, we reviewed each to determine what activities are covered by the policy. Nearly all (97.3%) of the policies we reviewed discussed to what research-related activities their research misconduct policy applies, including proposing research, conducting research, and reporting ones' own research (97.3% respectively). While virtually all institutions discuss these research-related activities in their policies, more than a third (37.6%) do not include a discussion of ones' obligation when reviewing others' research.

We also reviewed the policies to determine whether they apply only to PHS-funded research or to institution's research generally. Most (84.4%) of the policies specifically stated which categories of funded research the policies cover. Nearly two thirds (61.5%) specifically state that the policy covers PHS-funded research activities, but only a few (13.8%) directly state that the policy applies to government funded research in general. A little more than half (55.1%) the policies we reviewed cover all research regardless of funding, and one-fifth (20.2%) specifically state that the policy covers both privately and publicly funded research.

The ORI's model policy for responding to allegations of research misconduct suggests that an institutions' research misconduct policy might include a general statement about the scientific community's ethics as it relates to research and the responsibility to report incidences of alleged research misconduct. To evaluate this topic, our review of the policies included an assessment of who or what category of researcher is covered by the institutions' research misconduct policy. Just under 90% of the polices state who is bound by the policy; most (80.7%) state that faculty and senior research staff including scientists, collaborators, and guest researchers, are obligated to abide by the policy. Slightly more than three fourths (77.1%) of the policies state that non-faculty, e.g., technicians, are bound by the policy, and about a three fourths (75.2%) state that student trainees, e.g., graduate students and post docs are bound by it. Less than a quarter (22%) of the policies mentioned a statute of limitations for reporting an allegation of research misconduct. By not including a statute of limitations, the policies of the remaining institutions likely leave open the possibility that individuals can report an allegation of research misconduct whenever it is discovered.

Table 3-7 shows the amount of detail the policies included with regards to defining research misconduct within the policies. Overall, almost all institutions (98.2%) include each of the three core elements of research misconduct in their definition and nearly all (92.3%)

define each of these terms. Of those that specify to what research activities the policy applies, about two-thirds (64.2%) of the policies state that it applies to all three research activities, e.g., proposing, conducting, reviewing and reporting research, and a little more than a third (35.1%) are detailed enough that they indicate that everyone, i.e., faculty and non-faculty researchers and students, is bound by the policy. Only a few policies (4.4%) are comprehensive with regards to the categories of funding to which the policy applies, i.e. the policy states it applies to all combinations of funding sources mentioned above. Finally, about one-third (35.1%) of the research misconduct policies we reviewed state that all four categories of individuals are bound by the policy.

Table 3-7. Depth of Information About Research Misconduct Covered in Policies

Characteristic	Frequency	Percent	Cumulative Frequency	Cumulative Percent
Number of research misconduct elements (FFP) included				
1	1	0.9%	1	0.9%
2	1	0.9%	2	1.8%
3	107	98.2%	109	100.0%
Number of research misconduct elements (FF) defined in policies				
1	1	1.4%	1	1.4%
2	4	5.8%	5	7.2%
3	64	92.8%	69	100.0%
Number of research-related activities included				
3	38	35.9%	38	35.9%
4	68	64.2%	106	100.0%
Number of categories of funding included in the policy				
1	37	40.2%	37	40.2%
2	46	50.0%	83	90.2%
3	5	5.4%	88	95.7%
4	4	4.4%	92	100.0%
Number of the types of individuals bound by the policy				
1	12	12.4%	12	12.4%
2	6	6.2%	18	18.6%
3	45	46.4%	63	65.0%
4	34	35.1%	97	100.0%

3.3.3.2 Reporting Allegations of Research Misconduct

The ORI's model policy suggests that institutions should include in their research misconduct policies a statement that conveys that institutional members are encouraged to report observed, suspected, or apparent research misconduct. Table 3-8 shows the

Table 3-8. Reporting of Allegations

Characteristic	Present in Policy	Number	Percentage
Obligation of Members to Report Research Misconduct			
	Yes	73	67.0%
	No	36	33.0%
Mention Elements to Include in the Allegation			
	Yes	11	10.1%
	No	98	89.9%
Include:			
Name of Respondent			
	Yes	5	4.6%
	No	104	95.4%
Name of Witness			
	Yes	1	0.9%
	No	108	99.1%
Nature of Evidence			
	Yes	11	10.1%
	No	98	89.9%
How Research Misconduct Was Discovered			
	No	109	100.0%
When the Research Misconduct Was Discovered			
	Yes	3	2.8%
	No	106	97.3%
Type of Research Misconduct Alleged (F, F, or P)			
	No	109	100.0%
Responsibility of Institutional Members to Cooperate			
	Yes	65	59.6%
	No	44	40.4%
Accept Anonymous Allegations			
	Yes	28	25.7%
	No	81	74.3%
Medium in which the Institution Will Accept an Allegation of Research Misconduct			
	Yes	79	72.5%
	No	30	27.5%

(continued)

Table 3-8. Reporting of Allegations (continued)

Characteristic	Present in Policy	Number	Percentage
Oral Allegations			
	Yes	49	45.0%
	No	60	55.1%
Only Written Allegations			
	Yes	28	25.7%
	No	81	74.3%
To Whom Allegations of Research Misconduct should be Reported			
	Yes	105	96.3%
	No	4	3.7%
Includes the Name, Position, Title, or Contact Information for the Person to Whom Allegations Should be Reported			
	Yes	103	94.5%
	No	6	5.5%
Specifically Identifies Appropriate Persons to Whom Allegations of Research Misconduct Should Be Reported			
Study's Principal Investigator (PI)			
	Yes	5	4.6%
	No	104	95.4%
The Study PI's Department Head			
	Yes	41	37.6%
	No	68	62.4%
The Institution's Research Integrity Officer (RIO)			
	Yes	45	41.3%
	No	64	58.7%
The Dean of the School			
	Yes	44	40.4%
	No	65	59.6%
Vice President/ Vice Chancellor/ Vice Provost			
	Yes	32	29.4%
	No	77	70.6%
Provost/ Chancellor/ President			
	Yes	8	7.3%
	No	101	92.7%

(continued)

Table 3-8. Reporting of Allegations (continued)

Characteristic	Present in Policy	Number	Percentage
Laboratory Director			
	Yes	1	0.9%
	No	108	99.1%
Chairperson of the Institution’s Research Integrity Committee			
	Yes	6	5.5%
	No	103	94.5%
Director, Sponsored Research Office			
	Yes	2	1.8%
	No	107	98.2%
Institutional Official (non-specific)			
	Yes	16	14.7%
	No	93	85.3%
States that Someone within the Institution May Be Notified of the Allegation			
	Yes	102	93.6%
	No	7	6.4%
States that Someone Outside the Institution May Be Notified of the Allegation			
	Yes	107	98.2%
	No	2	1.8%

proportion of the policies we reviewed that include such a statement, as well as the format of and content individuals are required to include with the allegation, and to whom the allegation should be reported.

Abstractors found that about two thirds (67.0%) of the policies in our sample include a statement that institutional members are required to report suspected research misconduct, but only a very few (10.1%) specify the pieces of information that the allegation should include. Of the elements we looked for, the one most often cited is the nature of the evidence, and that was only specified in a very few (10.1%) of the policies. Notably, less than five percent (4.5%) of the policies state that the respondent’s name must be included in the allegation and none of them mention that the allegation should describe how the alleged research misconduct was discovered.

Further, virtually none (0.9%) state that the allegation should provide names of witnesses or information about when the research misconduct was discovered (2.8%), which one would expect might make it problematic to investigate the allegation. None of the policies reference the need for the allegation to include a description of the type of research misconduct being reported, i.e., falsification, fabrication, or plagiarism. A little less than two

thirds (59.6%) of the policies state that the institutions' employees are obligated to cooperate with the inquiry and investigation of an allegation of research misconduct.

We also coded the policies for whether the institution allows allegations of research misconduct to be made anonymously. Most policies (74.3%) did not include a statement to that effect. Despite that, almost three fourths (72.5%) did state the format in which the institution would accept the allegation; almost half (45%) accept oral reports of misconduct, and about a quarter (25.7%) state that the allegation must be made in writing.

Almost all (96.3%) of the institutions' policies state which institutional official, e.g., name or position, should receive the allegation. Of the choices we listed, the one included most often in the policies is the name, position, title or contact information of the person to whom the allegation should be reported (94.5%); followed by the Research Integrity Officer (41.3%), the dean of the affected school (40.4%), the principal investigator's department head (27.6%), and a vice president, vice chancellor, or vice provost (29.4%) of research. Fewer of the policies listed the study's principal investigator (4.6%), the provost or chancellor (7.3%), the chairperson of the research integrity committee (5.5%) and a non-specific institutional official (14.7%). Almost none mentioned the laboratory director (0.9%), or the director of sponsored research (1.8%).

Regulations require that institutions report the decision to initiate an investigation into an allegation of research misconduct to ORI. Almost all (98.2%) of the policies specify that the institution will notify individuals or organizations outside of the institution of the allegation. Close to 95 percent also state that certain individuals within the institution will be notified of the allegation.

To explore the depth of the policies with regards to reporting allegations, we looked at the distributions for each of the variables with follow-up items to determine how many of the policies included multiple items of interest. The results are presented in Table 3-9. Of the 11 policies that mention the elements to include when making an allegation or research misconduct, none include all on our list of important elements, and only slightly more than a quarter (three of the 11) include half of the six elements we looked for in the policies, and as noted above, none of these include whether the allegation relates to falsification, fabrication or plagiarism. This all implies that the policies do not provide much guidance on what should be included when one makes the allegation, which may lead to the RIO or other institutional official spending more time assessing whether the allegation warrants an inquiry.

Almost all (97.5%) of those that indicate the format for reporting the allegations only mention the one method, i.e., orally or in writing, and none state that the allegation can be reported both ways. Two of the policies mention reporting in a format that we were unable to code into one of our existing categories.

Table 3-9. Depth of Information on Reporting Allegations

Characteristic	Frequency	Percent	Cumulative Frequency	Cumulative Percent
Number of Elements Policies State Should Be Included in the Allegation				
1	6	54.6%	6	54.6%
2	2	18.2%	8	72.7%
3	3	27.3%	11	100.0%
Number of Ways Policies State the Allegation Can Be Reported				
0	2	2.5%	2	2.5%
1	77	97.5%	79	100.0%
Number of Policies Mentioning the Name, Position, Title or Contact Information for Person to Receive the Allegation				
0	2	1.9%	2	1.9%
1	103	98.1%	105	100.0%
Number of Persons Listed in the Policy to Whom Allegations Can Be Reported				
0	4	3.7%	4	3.7%
1	46	42.2%	50	45.9%
2	31	28.4%	81	74.3%
3	21	19.3%	102	93.6%
4	6	5.5%	108	99.1%
5	1	0.9%	109	100.0%

Of those that indicate the institutional official that should receive the allegation of research misconduct, virtually all (98.1%) include the name, position, title or contact information for that person. Having this information included in the policies makes it easier for a potential whistleblower to know to whom they should report and should make it easier to report instances of potential research misconduct. We included in our code form ten categories of persons who might receive the allegation. None of the policies listed all ten categories; only one listed as many as five persons or institutional officials as the appropriate person to whom institutional members could report allegations of research misconduct. A majority (70.6%) listed up to two individuals who could receive the allegation. In fact, some of the listed persons might actually be bad choices because of the possibility that they might have an incentive to make the allegation go away rather than to resolve it according to the policy.

3.3.3.3 Pursuing Allegations of Research Misconduct

Abstractors also examined policies for the criteria used to assess an allegation of research misconduct and for information on whether the institution will pursue an allegation when the respondent leaves the institution, when the complainant declines to make a formal allegation, or when the respondent admits that the misconduct occurred. We also looked for

information on who decides the whether the allegation warrants an inquiry. Table 3-10 presents the number and percent of policies that describe each of these items.

Table 3-10. Pursuing Allegations of Research Misconduct

Characteristic	Present in Policy	Number	Percentage
Describes the Criteria Used to Assess the Allegation			
	Yes	70	64.2%
	No	39	35.8%
Says the Allegation Must Be Credible			
	Yes	48	44.0%
	No	61	56.0%
Say the Allegation Must be Specific			
	Yes	61	56.0%
	No	48	44.0%
Says the Allegation Must Meet the Definition of Research Misconduct			
	Yes	58	53.2%
	No	51	46.8%
States Whether the Allegation will be Pursued if the Respondent Has Left the Institution			
	Yes	58	53.2%
	No	51	46.8%
Says the Institution Will Pursue an Allegation Without a Formal Allegation			
	Yes	15	13.8%
	No	94	86.2%
States Whether the Institution Will Pursue an Allegation When Respondents Admit Misconduct			
	Yes	30	27.5%
	No	79	72.5%
States Who Decides Whether an Allegation Warrants an Inquiry			
	Yes	99	90.8%
	No	10	9.2%

Only about two-thirds (64.2%) of the policies provide guidance on the criteria used to assess allegations of research misconduct; the deciding officials in approximately one-third of the institutions in this study are left to use their own judgment when assessing allegations they receive. Although more than half (56.0%) of the institutions' policies fail to state that the allegation of research misconduct must be credible for the institution to pursue it, the same proportion (56.0%) of policies state that the allegation must be specific enough to allow evidence to be identified that can support the allegation. As mentioned earlier, almost all of the policies we reviewed define research misconduct as falsification,

fabrication, and plagiarism; however, only a little more than half (53.2%) of the policies state that the allegation must meet the definition of research misconduct.

We also examined the policies for a description of when the institution would pursue an allegation of misconduct. Of the three categories of situations we examined, the one mentioned most often was pursuing the allegation if the respondent has left the institution. More than half (53.2%) of the policies state the allegation will still be pursued even if the respondent is no longer employed at the institution. A little more than a quarter (27.5%) of the policies say the institution will pursue the allegation even if the respondent admits to the misconduct, but very few (13.8%) of the policies state the institution will pursue the allegation if the complainant declines to make a formal allegation. Nearly all (90.8%) of the policies indicate who at the institution will decide if the allegation warrants conducting an inquiry.

In general, these policies are not very specific in detailing the criteria used to assess the allegation. More than a third do not even mention the criteria used to assess allegations of research misconduct. As indicated in Table 3-11, of those that do mention the criteria, just over a half (55.7%) mention all three criteria we looked for: that the allegation must be credible, must be specific, and that it must meet the definition of research misconduct.

Table 3-11. Count of the Number of Categories Used to Assess Credibility of the Allegation

Number	Frequency	Percent	Cumulative Frequency	Cumulative Percent
0	1	1.4%	1	1.4%
1	11	15.7%	12	17.1%
2	19	27.1%	31	44.3%
3	39	55.7%	70	100.0%

3.3.3.4 *Maintaining Confidentiality*

To make individuals feel comfortable reporting allegations of research misconduct and to ensure that allegations are handled in a professional manner, institutions ought to provide information on how they will guarantee confidentiality of any reported allegation. Table 3-12 presents the distributions for specific items of confidentiality described in the institutions' research misconduct policies. Almost all (98.2%) of the policies reviewed specifically state that individuals need to maintain confidentiality about the allegation and just over two-thirds (69.7%) state the measures that are used to make sure that confidentiality is maintained. However when discussing the topic in their policies, fewer than half (43.1%) go as far as mentioning that everyone involved with the allegation, inquiry, and investigation should maintain confidentiality. Further, these policies are virtually silent

on the whether sanctions are imposed if confidentiality is violated – only 6% mention that those who fail to maintain confidentiality will face penalties for doing so. Surprisingly, none of them mention that whistleblower protections are lost if confidentiality is violated by the complainant. Although the issue of confidentiality is covered in the policies, many are vague on the details related to this topic.

Table 3-12. Maintaining Confidentiality

Characteristic	Present in Policy	Number	Percentage
Maintain Confidentiality about the Allegation			
	Yes	107	98.2%
	No	2	1.8%
Everyone Involved Should Maintain Confidentiality			
	Yes	47	43.1%
	No	62	56.9%
Measures Used to Ensure that Confidentiality is Maintained			
	Yes	76	69.7%
	No	33	30.3%
Sanctions for Violating Confidentiality			
	Yes	7	6.4%
	No	102	93.6%
Failure of Complaint to Maintain Confidentiality Results in Loss of Whistleblower Protection			
	No	109	100.0%

3.3.3.5 Conflicts of Interest

Another important element of ensuring that institutions handle allegations of research misconduct fairly is the avoidance of a conflict of interest. The code form included several items related to this domain. As shown in Table 3-13, more than half of the policies (56.9%) define what is meant by a conflict of interest and almost all (98.2%) state that conflicts of interest must be avoided. To evaluate the level of detail with regard to conflict of interest, we also coded whether the policies specifically state to whom avoidance of conflict of interest applies. About a quarter (26.2%) of the policies include a statement or imply that all parties involved in the allegation should avoid a conflict of interest, and about a quarter (23.9%) state that the person to whom the allegation is being reported should not be involved if he or she has a conflict of interest in the matter.

Despite the fact that only a third (33.9%) of the policies state that the person who decides whether an inquiry or investigation into the allegation is appropriate, and just over a quarter (27.5%) include language that the person appointing the inquiry and investigation

Table 3-13. Conflicts of Interest

Characteristic	Present in Policy	Number	Percentage
Define what Constitutes a Conflict of Interest			
	Yes	62	56.9%
	No	47	43.1%
Mention Avoidance of Conflicts of Interest			
	Yes	107	98.2%
	No	2	1.8%
Conflict of Interest Avoidance Specifically Applies to:			
All Parties			
	Yes	29	26.6%
	No	80	73.4%
Person to whom the Allegation is Reported			
	Yes	26	23.9%
	No	83	76.2%
Person who decides whether an Inquiry/ Investigation is Warranted			
	Yes	37	33.9%
	No	72	66.1%
Person appointing the Inquiry/ Investigation Committee			
	Yes	30	27.5%
	No	79	72.5%
Members of the Inquiry/ Investigation Committee			
	Yes	100	91.7%
	No	9	8.3%
Members of the Inquiry/ Investigation Committee			
	Yes	100	91.7%
	No	9	8.3%
Person Who Decides Whether Misconduct Occurred			
	Yes	62	56.9%
	No	47	43.1%
Person Who Imposes Sanctions			
	Yes	14	12.8%
	No	95	87.2%
Person Who Hears Appeals of Decisions/ Results/ Sanctions			
	Yes	5	4.6%
	No	104	95.4%

(continued)

Table 3-13. Conflicts of Interest (continued)

Characteristic	Present in Policy	Number	Percentage
Witnesses			
	Yes	3	2.8%
	No	106	97.3%
Institutional Officials			
	Yes	2	1.8%
	No	107	98.2%
States Who Determines Whether a Conflict of Interest Exists			
	Yes	80	73.4%
	No	29	26.6%
Mentions that There Will be Sanctions for Failing to Reveal a Conflict of Interest			
	Yes	3	2.8%
	No	106	97.3%

committees should not have a conflict of interest, a very large majority (91.7%) stipulate that members of the inquiry and investigation committees should not have a conflict of interest in the matters involved in the allegation. Notably, only slightly more than half (56.7%) indicate that the person who decides research misconduct has occurred must not have a conflict of interest in the case. These policies are also relatively vague on the issue as it relates to the person who imposes the sanctions, hears the appeals, those who offer witness to the alleged research misconduct, and the institutional officials involved in the resolution of the allegation. Relatively few policies (12.8%, 4.6%, 2.8%, and 1.8% respectively) include information about these topics.

Authority for determining there is a conflict of interest is discussed in nearly three-quarters (73.4%) of the policies, but very few (2.8%) indicate that there will be sanctions for failure to reveal any conflicts of interest.

We analyzed the data in the code forms to determine how comprehensive the policies are with respect to the individuals who are required to avoid having a conflict of interest with the research that is the subject of the allegation or to disclose that such a conflict exists. As presented in Table 3-14, of the 107 policies that mention avoiding a conflict of interest, only one includes all ten categories of persons discussed earlier. Approximately 88% cover between 1 and 5 of the categories, which is an indication that the policies are only somewhat detailed on the subject of who should avoid being involved in the disposition of the allegation if they have a conflict of interest in the research involved with the allegation.

Table 3-14. Count of the Categories of Persons to Whom Avoiding Conflict of Interest Applies

Number of Categories Mentioned in Policies	Frequency	Percent	Cumulative Frequency	Cumulative Percent
1	31	29.0%	31	29.0%
2	27	25.2%	58	54.2%
3	24	22.4%	82	76.6%
4	4	3.8%	86	80.4%
5	8	7.5%	94	87.9%
6	5	4.7%	99	92.5%
7	4	3.7%	103	96.3%
8	3	2.8%	106	99.1%
10	1	0.9%	107	100.0%

3.3.3.6 Appropriate Expertise

As can be seen from Table 3-15, although almost all (96.3%) of the policies mention the need to have access to the expertise appropriate to the respondent’s research area when conducting an inquiry or investigation of an allegation, roughly two-thirds (64.2%) do not specify acceptable procedures for accessing the necessary expertise to review the allegation. We did not code the policies for who determines whether the committee has the appropriate expertise; therefore for those policies that do not specify the process, we do not have information on whether the designated institutional official has that responsibility or whether the need for the expertise is determined through some other mechanism, just that there are procedures.

Table 3-15. Appropriate Expertise

Characteristic	Present in Policy	Number	Percent
Access to Appropriate Expertise	Yes	105	96.3%
	No	4	3.7%
Procedures for Accessing Appropriate Expertise	Yes	39	35.8%
	No	70	64.2%

3.3.3.7 *Appointing the inquiry committee, conducting the inquiry, and content of the inquiry report*

To reach a conclusion about whether the alleged misconduct warrants an investigation, ORI requires that the institutions conduct an inquiry into the allegation. The policies reviewed are fairly detailed with regard to appointing the inquiry committee, conducting the inquiry and detailing the information to be included in the inquiry report. Table 3-16 shows that almost all sampled policies provide information on the mechanisms used to conduct the inquiry and specify the person or office responsible for identifying the individual who will conduct the inquiry, 93.6% and 92.7%, respectively. Ninety percent also include the criteria used to select members of the inquiry committee.

Table 3-16. Inquiry of the Research Misconduct

Characteristic	Present in Policy	Number	Percent
Mechanisms Used to Conduct the Inquiry			
	Yes	102	93.6%
	No	7	6.4%
Who is Responsible for Identifying the Person(s) Who Will Conduct the Inquiry			
	Yes	101	92.7%
	No	8	7.3%
Criteria Used to Select the Person(s) for the Inquiry			
	Yes	98	89.9%
	No	11	10.1%
Authority of the Person(s) Conducting the Inquiry			
	Yes	107	98.2%
	No	2	1.8%
Guidelines or Rules Governing the Inquiry			
	Yes	103	94.5%
	No	6	5.5%
Specifies Who Decides Whether an Investigation Should Be Conducted			
	Yes	104	95.4%
	No	5	4.6%
Specifies What Content the Inquiry Report Should Contain			
	Yes	101	92.7%
	No	8	7.3%

We found that nearly all (98.2%) of the policies detail the responsibilities of the person or persons conducting the inquiry and the authority these individuals have to carry out the inquiry into the allegation. Guidelines for conducting the inquiry are present in 94.5% of the policies and about the same percentage (95.1%) specifies who determines whether the allegation warrants an investigation.

After the inquiry is completed, the decision to move to a full investigation of the allegation and the process for reaching that decision should be documented in an inquiry report. Almost all (92.7%) of the research misconduct policies in our sample specify the topics to be included in the inquiry report.

3.3.3.8 *Appointing the investigation committee, conducting the investigation, and content of the investigation report*

Similar to the section of the policies discussing the inquiry process, nearly all of the policies provide detailed guidance on the process for investigating the alleged research misconduct (Table 3-17). The method for carrying out the investigation is described in 97.3% of the policies, and almost all (94.5%) identify who is responsible for appointing the investigation committee. Virtually all of the policies discuss: the criteria used to select the persons conducting the investigation (94.5%), the authority of the investigators (96.3%).

Table 3-17. Investigation into the Research Misconduct

Characteristic	Present in Policy	Number	Percent
Mechanisms Used to Conduct the Investigation			
	Yes	106	97.3%
	No	3	2.8%
Who Is Responsible for Identifying the Person(s) Conducting the Investigation			
	Yes	103	94.5%
	No	6	5.5%
Criteria Used to Select the Person(s) to Conduct the Investigation			
	Yes	104	95.4%
	No	5	4.6%
Authority of the Person(s) Conducting the Investigation			
	Yes	105	96.3%
	No	4	3.7%
Person(s) Conducting the Investigation is (are) Expected to Do			
	Yes	106	97.3%
	No	3	2.8%
Guidelines or Rules According to which the Investigation Will Be Conducted			
	Yes	107	98.2%
	No	2	1.8%
Decides Whether an Investigation Results in a Findings of Research Misconduct			
	Yes	106	97.3%
	No	3	2.8%
Specifies What Content the Investigation Report Should Contain			
	Yes	99	90.8%
	No	10	9.2%

As with conducting the inquiry, virtually all (97.3%) of the research misconduct policies include a description of what the investigation committee's duties and responsibilities are. Guidelines for conducting the investigation and the person responsible for deciding that research misconduct has occurred are included in virtually all of the policies (98.2% and 97.3%, respectively). More than 90% specify what the investigation report should contain.

3.3.3.9 Respondent Rights and Responsibilities

We coded the policies for the amount of information included relative to the issue of respondents' rights and separated the information into two general categories; respondents' rights and respondents' responsibilities. As shown in Table 3-18, our analysis found that all of the research misconduct policies in our sample discuss respondents' rights; however, they vary in the amount of detail or number of rights mentioned. Surprisingly very few (6.4%) state that the respondent has a presumption of innocence, but almost all (96.3%) state that the respondent will receive assistance restoring his or her reputation if the allegation is unfounded.

Table 3-18. Rights and Responsibilities of the Respondent

Characteristic	Present in Policy	Number	Percent
Specify Rights of Respondents			
	Yes	109	100.0%
Rights of the Respondent specifically mentioned:			
A Presumption of Innocence			
	Yes	7	6.4%
	No	102	93.6%
Institutional Assistance in Restoring One's Reputation			
	Yes	105	96.3%
	No	4	3.7%
Receive Written Notification of Allegation / Intent to Conduct an Inquiry/ Investigation			
	Yes	92	84.4%
	No	17	15.6%
Receive a copy of the Research Misconduct Policy			
	Yes	30	27.5%
	No	79	72.5%
Right to Counsel			
	Yes	82	75.2%
	No	27	24.8%
Right to Present own Position			
	Yes	95	87.2%
	No	14	12.8%

(continued)

Table 3-18. Rights and Responsibilities of Respondent (continued)

Characteristic	Present in Policy	Number	Percent
Right to Appeal the Decision to Conduct an Inquiry/ Investigation			
	Yes	4	3.7%
	No	105	96.3%
Receive Notification of Findings			
	Yes	105	96.3%
	No	4	3.7%
Receive Copy of Inquiry/ Investigation Report			
	Yes	106	97.3%
	No	3	2.8%
Right to Appeal Misconduct Finding			
	Yes	36	33.0%
	No	73	67.0%
Specifies What Is Required from Respondents			
	Yes	83	76.2%
	No	26	23.9%
Obligations of Respondents Mentioned:			
Refrain from Destroying Potential Evidence			
	Yes	38	34.9%
	No	71	65.1%
Submit to Interviews			
	Yes	66	60.6%
	No	43	39.5%
Furnish Data or Records as Requested			
	Yes	72	66.1%
	No	37	33.9%
General Obligation to Cooperate with Process			
	Yes	72	66.1%
	No	37	33.9%
Maintain Confidentiality			
	Yes	49	45.0%
	No	60	55.0%
Not to Speak to the Press about the Allegation			
	Yes	2	1.8%
	No	107	98.2%
Refrain from Retaliation			
	Yes	27	24.8%
	No	82	75.2%

Most policies (84.4%) specify that respondents will receive written notification of the allegation and the intent to conduct an inquiry or investigation; yet only about a quarter of them (27.5%) indicate the respondent will receive a copy of the institution's research misconduct policy. Even though very few of the institutions actively provide a copy of the research misconduct policy to the respondent, about three quarters of the policies state that respondents have a right to counsel or an advisor, and almost 90% state the respondent has the right to present his or her defense during the inquiry and investigation process.

Further, according to the policies reviewed, almost all institutions (96.3%) will notify the respondent of the findings, or notify them of significant new findings or changes in the inquiry and investigation process, and nearly all (97.3%) provide a copy or summary of the inquiry and investigation reports to the respondent. Most of the policies we reviewed are silent on the respondents' rights to appeal the findings, only about a third mention appealing a finding of research misconduct at all, and virtually none (3.7%) mention that respondents have a right to appeal the decision to conduct the inquiry and investigation in the first place.

Although all of the policies include a discussion of respondent's rights, only about three quarters (76.2%) of them include a discussion of respondent responsibilities. Only about a third of the policies (34.9%) specifically state that the accused, i.e., the respondent, should not destroy evidence that could be related to the allegation. This is an odd omission given that approximately two thirds of the policies state that the respondent is obligated to provide data or records requested as part of the allegation assessment. In addition, only about two thirds of the policies discuss the responsibility of the respondent to cooperate with the resolution process and to submit to and participate in interviews about the allegation (66.1% and 60.1%, respectively).

Although a majority of the policies indicate that respondents are required to participate in and cooperate with the inquiry and investigation, fewer discuss the need to maintain confidentiality. Maintaining confidentiality is one way to ensure protection of the respondent's reputation, yet surprisingly fewer than half (45.0%) of the policies directly mention that the respondent should maintain confidentiality with regards to the allegation. In addition, almost none (1.8%) admonish against speaking to the press about the alleged research misconduct. It is also surprising that only about a quarter of the policies (24.8%) mention that the respondent should not retaliate against the complainant.

As presented in Table 3-19 a little more than three quarters (78.9%) of the institutions' policies include between five and nine of the respondents rights we searched for, most of which are also specified in the ORI's model policy, very few were so detailed as to include all of the respondent rights we felt were important to include – about 10% of the policies include eight or more of the respondents rights and responsibilities - and none included all 10 of the respondent rights we included in our list.

Table 3-19. Number of Rights Specified in the Institutions' Policies

Characteristic	Frequency	Percent	Cumulative Frequency	Cumulative Percent
Number of Rights included				
1	2	1.8%	2	1.8%
3	6	5.5%	8	7.3%
4	6	5.5%	14	12.8%
5	9	8.3%	23	21.1%
6	41	37.6%	64	58.7%
7	34	31.2%	98	89.9%
8	10	9.2%	108	99.1%
9	1	0.9%	109	100.0%
Number of Responsibilities Included				
1	5	6.0%	5	6.0%
2	9	10.8%	14	16.9%
3	12	14.4%	26	31.3%
4	31	37.4%	57	68.7%
5	21	25.3%	78	94.0%
6	5	6.0%	83	100.0%

Further, of those policies that specified the respondents' responsibilities regarding the allegation, only a little more than two-thirds (68.7%) mention four or more of the responsibilities we looked for, and none mentioned all seven.

3.3.3.10 *Complainant Rights and Responsibilities*

As we did with the respondents' rights and responsibilities, we coded the policies for the amount of information they include on complainants' ("whistleblower") rights and responsibilities. As indicated in Table 3-20, we found that fewer polices specify the responsibilities of the complainant than include information on the respondent's responsibilities. Only about one- third (34.9%) describes the complainants' responsibilities. About a third (32.1%) state that the complaint should report incidences of harassment or retaliation; very few (1.8%) specify that the complainant should not be involved in the investigation unless asked, and surprisingly hardly any (0.9%) of the policies admonish against the complainant speaking to the press specifically. It is also surprising that none of the policies state that the complainant should avoid contact with the respondent or otherwise discuss the allegation publicly.

We also found that fewer of the research misconduct policies specify the rights of the complainant than specify the respondent's rights. Whereas all of the policies specified respondent rights, only a little more than four-fifths (85.3%) specify complainant's rights.

Table 3-20. Rights and Responsibilities of Complainants (“Whistleblowers”)

Characteristic	Present in Policy	Number	Percent
Policy Describes the Responsibilities of the Complainant			
	Yes	38	34.9%
	No	71	65.1%
Policy States Complainant Should:			
Have No Contact with the Respondent			
	No	109	100.0%
Have No Involvement in the Investigation, Except When Asked			
	Yes	2	1.8%
	No	107	98.2%
Not Discuss the Allegation Publicly			
	No	109	100.0%
Has Obligation Not to Speak to the Press about the Alleged Research Misconduct			
	Yes	1	0.9%
	No	108	99.1%
Report Any Incidents of Harassment or Retaliation			
	Yes	35	32.1%
	No	74	67.9%
Policy Specifies the Rights Accorded to a Complainant			
	Yes	93	85.3%
	No	16	14.7%
Does the Policy Specify the Right to:			
Advice or Guidance Prior to Formally Making Allegations			
	Yes	53	48.6%
	No	56	51.4%
Notification of Process/Policy			
	Yes	35	32.1%
	No	74	67.9%
Right to Counsel or Other Advisor			
	Yes	18	16.5%
	No	91	83.5%
Present or Suggest Witnesses			
	Yes	9	8.3%
	No	100	91.7%
Present Evidence			
	Yes	18	16.5%
	No	91	83.5%
Be Interviewed During Inquiry/ Investigation			
	Yes	42	38.5%
	No	67	61.5%

(continued)

**Table 3-20. Rights and Responsibilities of Complainants (“Whistleblowers”)
(continued)**

Characteristic	Present in Policy	Number	Percent
Receive Notification of Findings			
	Yes	75	68.8%
	No	34	31.2%
Receive Notification of Significant New Issues or Allegations or Changes in Process			
	Yes	25	22.9%
	No	84	77.1%
Receive Copy/ Summary of Inquiry/ Investigation Report			
	Yes	25	22.9%
	No	84	77.1%
Does the Institution Impose Obligations on Complainants			
	Yes	109	100.0%
What Obligations Does the Institution Impose on Complainants:			
Submit to Interviews by the Inquiry/ Investigation Committee			
	Yes	60	55.1%
	No	49	45.0%
Furnish Data or Records Requested by the Inquiry/ Investigation			
	Yes	60	55.1%
	No	49	45.0%
General Obligation to Cooperate with Inquiry/ Investigation			
	Yes	60	55.1%
	No	49	45.0%
Maintain Confidentiality			
	Yes	47	43.1%
	No	62	56.9%
Specific Obligation Not to Speak to the Press about the Alleged Research Misconduct			
	Yes	1	0.9%
	No	108	99.1%
Allegations be Made in Good Faith			
	Yes	100	91.7%
	No	9	8.3%
Mention Protection of the Complainant from Retaliation			
	Yes	95	87.2%
	No	14	12.8%
What Policy Specifies with Regard to Protecting the Complainant from Retaliation:			
Specific Steps to Be Taken to Protect the Complainant from Retaliation			
	Yes	10	9.2%
	No	99	90.8%

(continued)

**Table 3-20. Rights and Responsibilities of Complainants (“Whistleblowers”)
(continued)**

Characteristic	Present in Policy	Number	Percent
What Complainant Should Do if He/ She Experiences Retaliation			
	Yes	36	33.0%
	No	73	67.0%
Commitment to Respond to Retaliation, or to Take Action Against Retaliators			
	Yes	64	58.7%
	No	45	41.3%
Description of a Process for Responding to Allegations of Retaliation			
	Yes	11	10.1%
	No	98	89.9%
Specific Actions to be Taken Against Retaliators			
	Yes	2	1.8%
	No	107	98.2%
Institution’s Policy Mentions Allegations Not Made in Good Faith (e.g., “Bad Faith”)			
	Yes	95	87.2%
	No	14	12.8%
What Does the Policy Specify with Regard to Allegations Not Made in Good Faith			
Specifies Criteria for Determining When Allegations Are Not Made in Good Faith			
	Yes	23	21.1%
	No	86	78.9%
States that Action May Be Taken Against Those Not Making Allegations in Good Faith			
	Yes	79	72.5%
	No	30	27.5%
Specifies Action that may Be Taken Against Person Not Making Good Faith Allegations			
	Yes	8	7.3%
	No	101	92.7%

The institutions also vary in the number and types of complainant rights they include in their research misconduct policies. The complainant right mentioned most often in the institutions’ polices is the right to receive notification of the findings resulting from the investigation; slightly more than two-thirds (68.8%) specify the complaint has a right to be notified of the findings. Fewer than half (48.6%) of the policies include a statement that the complaint has a right to receive guidance or advice prior to making the allegation, and only a little more than one third (38.5%) state that the complainant has a right to be interviewed during the inquiry and investigation. Other complainant rights specified in these policies include the right to be notified of the process involved for making and following up on allegations of research misconduct (32.1%); the right to be notified of any significant new allegations or issues (22.9%); the right to receive a copy of the inquiry and investigation

reports (22.9%); the right to have counsel or an advisor (16.5%); and the right to present evidence (16.5%). Very few (8.3%) of the policies mention that the complainant has the right to present witnesses as this is most often thought of as one of respondents' key rights in the process of defending themselves.

The institutions all impose some obligations on complainants. Almost all (91.7%) of their policies state that the complainant must make the allegation in good faith and more than half (55.1% for each) state that the complainant is obligated to agree to be interviewed, furnish records as requested by the inquiry or investigation committees, and to generally cooperate with the inquiry and investigation. However, fewer than half specifically state that the complainant must maintain confidentiality about the allegation, and only one policy specifies the obligation to not speak with the press.

Despite the maintenance of confidentiality, the respondent may figure out who made the misconduct allegation and retaliate against the person. Most (87.2%) of the policies mention that the institution will protect complainants from retaliation, but few (9.2%) specify how they will go about doing it, or detail the process for responding (10.1%) to it, and only one-third (33.0%) describe what complainants should do if they feel they have experienced retaliation. Nevertheless, a little more than half of the policies (58.7%) indicate that the institution is committed to dealing with instances of retaliation and taking action against the person responsible for it. Again, very few policies (1.8%) describe what that action might be.

As with the statement that allegations must be made in good faith, a large proportion of policies (87.2%) make specific reference to allegations not made in good faith, and about three-quarters (72.5%) include a statement that action will be taken against those complainants who have not made their allegation in good faith. Even so, only about one-fifth (21.1%) include the criteria used to determine that an allegation was not made in good faith, thereby largely leaving this determination to the institution's discretion. Again, very few (7.3%) detail the specific actions the institution might take against a person who makes a bad faith allegation.

As shown in Table 3-21, of those policies that mention the complainants' rights, 87.1% include only about half of the nine complainants' rights we looked for in the policies, most of which are also specified in the ORI's model policy. We found only one policy that was so detailed as to include all of the complainant rights we had included in our code list.

Further, of those that specified the complainants' responsibilities when making an allegation, most (89.7%) mention only one of the five responsibilities of interest, and a few (7.9%) do not mention any at all. These policies are not particularly thorough in describing what the institution expects of the complainant who makes an allegation of research misconduct. Less than one-third (30.1%) of the policies include five of the six complainant obligations we were looking for, but about a quarter (25.2%) specified only one.

Table 3-21. Number of Complainants' Rights Specified in the Institutions' Policies

Characteristic	Frequency	Percent	Cumulative Frequency	Cumulative Percent
Number of Complainants' Rights Included in the Policy				
0	1	1.1%	1	1.1%
1	20	21.5%	21	22.6%
2	21	22.6%	42	45.2%
3	11	11.8%	53	57.0%
4	17	18.3%	70	75.3%
5	11	11.8%	81	87.1%
6	8	8.6%	89	95.7%
7	3	3.2%	92	98.9%
9	1	1.1%	93	100.0%
Number of Complainants' Responsibilities Included				
0	3	7.9%	3	7.9%
1	34	89.5%	37	97.4%
2	1	2.6%	38	100.0%
Number of Requirements the Institutions Impose on Complainants				
1	26	25.2%	26	25.2%
2	16	15.5%	42	40.8%
3	7	6.8%	49	47.6%
4	22	21.4%	71	68.9%
5	31	30.1%	102	99.0%
6	1	1.0%	103	100.0%
Number of Protections Institutions Provide to Complainants				
0	26	27.4%	26	27.4%
1	28	29.5%	54	56.8%
2	30	31.6%	84	88.4%
3	9	9.5%	93	97.9%
4	2	2.1%	95	100.0%
Number of Criteria for Determining When an Allegation Was Not Made in Good Faith				
0	14	14.7%	14	14.7%
1	56	59.0%	70	73.7%
2	21	22.1%	91	95.8%
3	4	4.2%	95	100.0%

The institutions' policies are also light on the protections they say they offer complainants. A majority (61.1%) of the policies describe one or two protections that they offer to complainants. Strikingly, a little more than a quarter (27.4%) do not indicate that the institution provides any protections at all. Finally, a majority (59.0%) outlines only one

specific action the institution will take against a person who makes an allegation in bad faith, and about 14.7% do not mention what will happen to such persons.

3.3.3.11 *Sanctions, Appeals, and Restoration of Respondents' Reputation*

We also reviewed policies to determine whether they include information on the sanctions institutions might impose for a finding of research misconduct. Additionally, we evaluated whether the policies contain detail on an appeals process, and if so, the extent of information and guidance on how to go about initiating an appeal. Restoration of respondents' rights is another issue that policies could address; therefore we coded them for the level of details contained with regards to this topic area as well.

As shown in Table 3-22, nearly all (98.2%) of the policies state that respondents who commit research misconduct may be sanctioned. Institutions might impose any number of sanctions upon an individual who commits research misconduct. More than two-thirds (68.8%) of the institutions' research misconduct policies provide examples of what those sanctions might be; however only about a third (30.3%) provide any indication of the factors, e.g., the severity of the offense, that might be considered in determining what sanctions will be imposed. In general the institutions' policies are clear on who – or what position within the institution - is responsible for imposing sanctions for research misconduct; just fewer than 90% include this information. Once a finding of research misconduct is made, the decision must be communicated, at a minimum, to those involved. Almost all (94.5%) of the policies reviewed articulate who within and outside the institution will be notified if there is a finding of research misconduct.

Table 3-22. Sanctions for Research Misconduct

Characteristic	Present in Policy	Number	Percent
Respondents Found Guilty of Research Misconduct May or Will Be Sanctioned			
	Yes	107	98.2%
	No	2	1.8%
Gives Examples of Sanctions that May Be Applied			
	Yes	75	68.8%
	No	34	31.2%
Factors Considered in Determining the Sanctions			
	Yes	33	30.3%
	No	76	69.7%
Who Decides Appropriate Sanctions			
	Yes	95	87.2%
	No	14	12.8%
Who Will or May be Notified of a Misconduct Finding			
	Yes	103	94.5%
	No	6	5.5%

In addition to abstracting information about sanctions from the policies, we also reviewed them to determine the extent to which there is any mention of an appeals process and what actions or decisions can be appealed. From Table 3-23 it is clear that more than half the policies discuss the topic. While we did not code the policies to determine whether any discussed grounds for appeals, we did code them to determine what decisions could be appealed. Almost all (94.5%) policies indicate that the decision to hold an inquiry can be appealed; however, very few (4.6%) make allowances for an appeal of the decision to conduct an investigation into the alleged misconduct. Only about one-third of policies (31.2%) indicate that the finding from an investigation can be appealed and even fewer (20.2%) say that sanctions can be appealed. However, almost one third (32.1%) of policies state there is a time limit on when appeals can be filed.

Table 3-23. The Appeals Process

Characteristic	Present in Policy	Number	Percent
Policy Mentions an Appeals Process			
	Yes	56	51.4%
	No	53	48.6%
Specifies Decision to Hold an Inquiry Can Be Appealed			
	Yes	103	94.5%
	No	6	5.5%
Specifies Decision to Hold an Investigation Can Be Appealed			
	Yes	5	4.6%
	No	104	95.4%
Specifies Finding from the Investigation Can Be Appealed			
	Yes	34	31.2%
	No	75	68.8%
Specifies Sanction Can Be Appealed			
	Yes	22	20.2%
	No	87	79.8%
Specifies Time Period for Filing an Appeal			
	Yes	35	32.1%
	No	74	67.9%

Table 3-24 shows the proportion of the policies that discuss restoration of the respondents' reputation. Almost all (96.3%) of the research misconduct policies include language on the restoration of respondents' reputation if the inquiry or investigation of the allegation finds no research misconduct occurred. However, the policies are not very specific in explaining whose responsibility it is in the institution to make sure this happens. Only a little more than half (56.9%) provide any information in that regard. Even fewer (45.9%) explain the steps that will or might be taken to accomplish restoration of the respondent's

reputation if the inquiry and investigation committees find no evidence of research misconduct.

Table 3-24. Restoration of Respondent's Reputation

Characteristic	Present in Policy	Number	Percent
Policy States Institution Is Responsible for Restoring the Respondent's Reputation			
	Yes	105	96.3%
	No	4	3.7%
Identifies Who Is Responsible for Efforts to Restore the Respondent's Reputation			
	Yes	62	56.9%
	No	47	43.1%
States Steps that Can be Taken to Restore Respondent's Reputation			
	Yes	50	45.9%
	No	59	54.1%

4. DEMOGRAPHIC AND PROFESSIONAL CHARACTERISTICS OF THE SURVEYED POPULATION

This study's surveyed population of medical school-based NIH-funded researchers (principal investigators) ranges in age from 19 to 99 years, with more than 98% falling between 36 and 78 years of age. As can be seen from the researchers' characteristics presented in Table 4-1, more than one-eighth (15.0%) of the population is under 45 years of age, more than two-fifths (41.2%) are between 45 and 54, nearly one-third (31.4%) is between 55 and 64, and one-eighth (12.5%) is 65 years of age or older. Males (71.6%) out-number females (28.4%) by more than two and half times.

Table 4-1. Demographic and Professional Characteristics of the Researchers

Researcher Characteristics	Weighted Number	Weighted Percent
Age Group		
Under 45 Years of Age	2,334	15.0%
45 To 54 Years of Age	6,415	41.2%
55 to 64 Years of Age	4,895	31.4%
65 Years of Age and Older	1,945	12.5%
Gender		
Male	11,257	71.6%
Female	4,460	28.4%
Highest Degree Earned		
MD-PhD	1,797	11.2%
MD	3,492	21.7%
PhD/ScD	10,624	66.2%
Other Doctorates	115	0.7%
Masters Degree	26	0.2%
Other Masters Degree	2	0.0%
Discipline		
Medicine	5,756	35.9%
Dentistry	25	0.2%
Pharmacy	121	0.8%
Public Health	268	1.7%
Nursing	13	0.1%
Social Science	982	6.1%
Basic/Natural Science	8,097	50.5%
Mathematics/Statistics	144	0.9%
Education	20	0.1%
Fine Arts	7	0.0%
Engineering	335	2.1%

(continued)

Table 4-1. Demographic and Professional Characteristics of the Researchers (continued)

Researcher Characteristics	Weighted Number	Weighted Percent
Theology	3	0.0%
Liberal Arts	98	0.6%
Social Work	25	0.2%
Administration	3	0.0%
Veterinary Science	69	0.4%
Other	8	0.1%
Allied Health (Speech-Language Pathology, Audiology, Movement, Exercise Physiology, Optometry)	73	0.5%
Ever Completed a Residency or a Post-Doctoral Training Appointment		
No, Neither	1,303	8.1%
Yes, a Residency Appointment	1,461	9.1%
Yes, a Post-Doctoral Appointment	9,960	62.1%
Yes, Both	3,320	20.7%
Current Institutional Title or Rank		
Research Associate	33	0.2%
Assistant Professor	1,451	9.1%
Associate Professor	4,376	27.6%
Full Professor	9,387	59.1%
Emeritus Professor	266	1.7%
Other	359	2.3%
Primary Appointment in this Medical School		
Yes	14,954	94.0%
No	951	6.0%
Years Employed with this Institution		
Under 5 Years	1,642	10.3%
Between 5 and 9 Years	3,367	21.2%
Between 10 and 14 Years	3,295	20.8%
Between 15 and 24 Years	4,572	28.8%
25 Years or More	3,001	18.9%
Years Conducting Biomedical Research		
Under 5 Years	37	0.2%
Between 5 and 14 Years	1,569	9.8%
Between 15 and 24 Years	6,315	39.4%
Between 25 and 34 Years	5,341	33.4%
35 Years or More	2,751	17.2%

(continued)

Table 4-1. Demographic and Professional Characteristics of the Researchers (continued)

Researcher Characteristics	Weighted Number	Weighted Percent
Characterization of Current Research Activity?		
Basic Science	12,210	76.4%
Clinical Research	3,771	23.6%
Does Your Research Activity Typically Require Submitting a Request for Review by your IRB?		
No	7,573	47.4%
Yes	8,402	52.6%
Number of NIH Research Project Grants Named as PI in the Past 10 Years?		
Fewer than 5 Grants	10,441	65.4%
From 5 to 9 Grants	4,510	28.3%
From 10 to 19 Grants	838	5.3%
20 or More Grants	169	1.1%
Approximate Total Award Value of the NIH Research Project Grants on Which Have Been PI in the Past 10 Years		
Less Than \$1,000,000	1,942	12.2%
From \$1,000,000 to Less Than \$5,000,000	9,477	59.6%
From \$5,000,000 to Less Than \$10,000,000	3,066	19.3%
\$10,000,000 or More	1,418	8.9%

Not unexpectedly, the vast majority (99.8%) of this population of medical school-based NIH-funded researchers has, as its highest achieved level of formal education, a doctoral degree of some kind. Just under two-thirds (66.2%) have a PhD, ScD, or the equivalent alone; slightly more than one-fifth (21.8%) has an M.D degree alone, and 11.2% has a joint MD-PhD degree. A very small percentage (0.7%) has some other type of doctoral degree that includes D.D.S., Dr.P.H., D.V.M., and Psy.D., and an even smaller percentage (0.2%) of the population of NIH grant principal investigators has a master's degree as their highest achieved level of formal education.

More than one-third (35.9%) of the population identifies its primary discipline as medicine, whereas just over half (50.5%) identifies one of the basic or natural sciences as its primary discipline. Only 6.1% identifies its discipline as social science, and just 3.1% is involved in some other type of health-related field such as public health, dentistry, nursing, and allied health. Just 2.1% identifies their discipline as engineering. With respect to having received training and experience beyond their doctoral level education, only 8.1% indicate they have not had either a post-doctoral or residency appointment. Nearly two-thirds

(62.1%) report having completed a post-doctoral training appointment, 9.1% have completed a residency appointment, and 20.7% have completed both residency and post-doctoral training appointments.

The researchers in the population surveyed are not only highly educated and mature in terms of their ages, they are also quite high ranking in terms of their position in the medical school. Almost two-thirds (59.1%) identify themselves as full professors and just more than one-quarter (27.6%) are associate professors. There are fewer than one in ten in lower level academic positions such as research associate (0.2%) or assistant professor (9.1%). Only 2.3% are graduate students or post-graduate students. There is also a small percentage (1.7%) of emeritus professors.

As expected, the vast majority of researchers (94.0%) report that their primary academic appointment is in the medical school where we contacted them by e-mail. Only a small percentage of the medical school researchers are new to their positions, just 10.3% have been employed by their current medical school for less than 5 years. About double that percentage (21.2%) has been employed by their current medical school for between 5 and 9 years. About that same percentage has been employed in their medical school for between 10 and 14 years (20.8%) and for 25 years or more (18.9%). The largest percentage of researchers (28.8%) has seniority of from 15 to 24 years in their current medical school.

Further evidence of the seniority of this population as researchers is reflected in how long they report having been involved in the conduct of biomedical research. A negligible percentage (0.2%) has only been conducting biomedical research for less than 5 years. Nearly one in ten (9.8%) has been conducting it for from 5 to 14 years. However, nearly two-fifths (39.4%) indicate that they have been involved in this kind of research for from 15 to 24 years, and an additional one-third (33.4%) have been doing it for from 25 to 34 years. There is also a sizeable percentage (17.2%) who report having been involved in the conducted of biomedical research for 35 years or more.

Researchers were asked in the survey to characterize the nature of their research as being either basic science or clinical research. The researchers responded nearly three to one that they do basic science (76.4% vs. 23.6%). To further characterize whether there is human subject involvement in their research, we asked them whether their research typically had to undergo Institutional Review Board (IRB) scrutiny. More than half (52.6%) indicate that it does.

To assess the depth of their involvement in and dependence on outside research grant funding, researchers were asked to indicate to what extent their continued support from the medical school was contingent on continuing to obtain research project funding. Nearly one-fourth (23.6%) indicates that their position in the institution is fully dependent on continued research grant funding, but only 16.6% reports that their salary is not at all

dependent on continued research grant funding. However, another 23.6% responds they are dependent for less than half of their salary on continued research grant funding, but 36.3% reports that half or more of their salary is dependent upon continued research grant funding.

In addition, we asked the researchers on how many National Institutes of Health (NIH) research grants they have been the principal investigator (PI) in the past 10 years, and to estimate what the total award value of their NIH research awards was in the past 10 years as well. Nearly two-thirds (65.4%) reports having fewer than 5 NIH research grants on which they were PI in the past 10 years, and slightly more than one-quarter (28.3%) says they have been PI on from 5 to 9 NIH research grants. Only 6.3% have had 10 or more NIH awards in that time. With respect to the total award values of their NIH research grants over the past 10 years, only 12.2% reports having received less than one million dollars. Almost as many (8.9%) reports having received ten million dollars or more. The largest group (59.6%) reports its grants' worth to be from one to less than five million dollars for the past 10 years, followed by 19.3% who value their awards for the same time period at from five million dollars to less than ten.

To summarize, the survey was conducted among a largely middle-aged, well-educated group of NIH-funded researchers who are mostly male and trained in one of the basic sciences. They are quite experienced researchers who hold relatively high rank in their medical schools and have been employed in those institutions for a reasonably long period of time.

5. RESEARCHERS' CONTACT WITH RESEARCH MISCONDUCT POLICY AND PROCEDURES

We included a series of questions in the survey about the extent and nature of the researchers' involvement with allegations of research misconduct. We asked those who indicated some kind of experience what impact they thought it may have on their willingness to: a) make an allegation of research misconduct, or b) become involved as a witness or as a member of panel investigating alleged research misconduct. We also asked questions about what they thought are the most important considerations that a researcher takes into account when making a decision on whether or not to make an allegation of research misconduct.

5.1 Effect of Research Misconduct Experience on Willingness to Participate in the Future

From Table 5-1, it is clear that the vast majority (91.6%) of the population of researchers reports never having had an allegation of research misconduct made against them. Of the 8.4% of researchers who have been accused of research misconduct, slightly more than half (4.5%) report that the allegation of research misconduct was filed against them at their current institution. Nearly one-third of the researchers who have had an allegation of research misconduct made against them (2.7%) were accused at another institution, and 1.2% report having had an allegation filed against them at their current institution and elsewhere.

Among those who say they have had an allegation made against them, more than three-quarters (77.9%) reports that they believe that the experience has not affected their willingness to make an allegation of research misconduct against someone else. More than one-eighth (16.7%) indicate that they are less likely to make an allegation against someone else as a result of that experience, while only 5.4% say that they are more likely to make an allegation because of it.

Table 5-1. Researchers Experience with Research Misconduct Proceedings

Question/Responses	Weighted Number	Weighted Percent
Have you ever had an allegation of research misconduct made about your research at this institution or elsewhere?		
No, never	12,406	91.6%
Yes, at this institution	610	4.5%
Yes, elsewhere	366	2.7%
Yes, here and elsewhere	158	1.2%

(continued)

Table 5-1. Researchers Experience with Research Misconduct Proceedings (continued)

Question/Responses	Weighted Number	Weighted Percent
If Yes, did this experience affect your willingness to make an allegation of research misconduct against someone else?		
No	901	77.9%
Yes, I am less likely	194	16.7%
Yes, I am more likely	63	5.4%
Have you ever made an allegation of research misconduct about a colleague at this institution or elsewhere?		
No, never	12,026	88.9%
Yes, at this institution	755	5.6%
Yes, elsewhere	715	5.3%
Yes, here and elsewhere	39	0.3%
If Yes, did this experience affect your willingness to make an allegation of research misconduct against someone else?		
No	1,097	72.3%
Yes, I am less likely	287	18.9%
Yes, I am more likely	134	8.8%
Have you ever given testimony as a witness in an inquiry or investigation into an allegation of research misconduct, either at this institution or elsewhere?		
No, never	11,889	88.0%
Yes, at this institution	1,073	8.0%
Yes, elsewhere	480	3.6%
Yes, here and elsewhere	81	0.6%
If Yes, did this experience affect your willingness to give testimony as a witness in a research misconduct proceeding?		
No	1,343	81.1%
Yes, I am less likely	192	11.6%
Yes, I am more likely	122	7.3%
Have you ever been a member of an inquiry or investigation committee looking into an allegation of research misconduct, either at this institution or elsewhere?		
No, never	10,991	81.3%
Yes, at this institution	2,022	15.0%
Yes, elsewhere	425	3.1%
Yes, here and elsewhere	84	0.6%
If Yes, did this experience affect your willingness to serve as a member of an inquiry or investigation committee investigating an allegation of research misconduct?		
No	1,960	77.5%
Yes, I am less likely	184	7.3%
Yes, I am more likely	386	15.3%

Neither has the vast majority of researchers (88.9%) ever filed an allegation of research misconduct against a colleague. Half (5.6%) of the 11.2% of researchers in our study population who have filed an allegation of research misconduct against a colleague did so at their current institution. A very similar percentage (5.3%) says it filed an allegation against a colleague while at another institution. An even smaller percentage of researchers (0.3%) reports having filed an allegation against a colleague at both their current institution and elsewhere.

Of the subset of researchers who have filed an allegation of research misconduct against a colleague, nearly three-fourths (72.3%) indicate that they feel the experience did not affect their willingness to make a subsequent allegation of research misconduct. However, a sizeable percentage (18.9%) says that they are less likely to make an allegation against a colleague after having had the experience, but less than half that proportion (8.8%) says that they are more likely to make a subsequent allegation.

Approximately 88% of the researchers in our survey population report never having given testimony as a witness in an inquiry or investigation into an allegation of research misconduct. Of those who have given such testimony, 7.9% have done so at their current institution, 3.6% says they did it at another institution, and less than one in ten (0.6%) has done it at both their current institution and elsewhere.

Of the researchers who had experience as a witness in an inquiry or investigation into an allegation of research misconduct, more than four-fifths (81.1%) feel that the experience did not affect their willingness to give testimony as a witness in a future proceeding. Nearly one-eighth (11.6%) of those who served as a witness were less likely to provide testimony as a witness in the future, while 7.3% reports being more likely to provide testimony as a witness in a research misconduct proceeding in the future.

More than four-fifths (81.3%) of the researchers did not have experience as a member of an inquiry or investigation committee looking into an allegation of research misconduct. A sizeable percentage (15.0%) of researcher participated as an inquiry or investigation committee member at their current institution, 3.1% participated elsewhere, and less than one in ten (0.6%) of researchers has participated as an inquiry or investigation committee member at their current institution and elsewhere.

A majority of the researchers (77.5%) who served as members of an inquiry or investigation committee indicates that the experience has had no effect on their willingness to serve in the future as a member of an inquiry or investigation committee. Only 7.3% says that they are less likely to be willing to do so in the future, but 15.3% indicates that the experience has made them more willing to do so.

Regardless of the type of previous involvement with research misconduct proceedings, most researchers (72.3% to 81.1%) indicate that the experience has not had

any kind of impact on their willingness to participate in misconduct proceedings in the future. However, for those involved as respondents (the accused), complainants (the accuser), or as witnesses, from 11.6% to 18.9% indicate that as result of their of their prior experience, they are less willing to be involved in future research misconduct proceedings, whereas 15.3% of researchers serving as members of an inquiry or investigation committee say they are more willing to serve in the same way again. This reversal of the willingness to be involved suggests that the experience of researchers in the former roles is not as positive as the experience is for those involved on the committees adjudicating the allegations.

5.2 Importance of Considerations to Researchers about Whether or Not to Make an Allegation

In addition to assessing the researchers' involvement with the research misconduct process, we also asked their opinions about the importance of various considerations in the decision to report suspected research misconduct. From Table 5-2, we can see that the consideration which the largest percentage of researchers holds (79.3%) to be "very important" in the decision to report an allegation of research misconduct is confidence that the proceedings to resolve the allegation will be conducted fairly and justly. The consideration given the second highest percentage of "very important" responses is the belief that severe damage to the scientific record will occur if research misconduct is not halted (69.9%). Having first-hand evidence of the research misconduct receives the third highest number of responses that it is given (60.0%) "very important" consideration when making an allegation. The belief that research misconduct could potentially result in harm to people (58.8%) has only the fourth highest percentage of "very important" responses. Just over half of the researchers indicates that a belief that scientists are obliged to report misconduct (50.6%) is a "very important" consideration in the decision to make an allegation. The consideration of greatest overall importance in the decision to report suspected research misconduct is the confidence that the matter will be handled fairly and justly. Virtually all of the researchers (99.5%) deem this consideration either "very important" or "important".

Among the considerations researchers may make when deciding whether to make a research misconduct allegation that received the highest percentage of "not important" responses is maintaining the anonymity of the person (complainant or "whistleblower") making the report (12.8%). Knowing to whom reports of research misconduct should be made (12.7%) and the belief that research misconduct could result in potential harm to others (11.3%) are the considerations that have the second and third highest percentages of "not important" responses.

Table 5-2. Importance to Researchers of Considerations Affecting the Decision to Report Suspected Research Misconduct

Consideration/ Importance	Weighted Number	Weighted Percent
Research misconduct could result in people being hurt.		
Very important	7,907	58.8%
Important	4,022	29.9%
Not important	1,523	11.3%
The identity of the person making the report will remain anonymous.		
Very important	5,799	43.1%
Important	5,928	44.1%
Not important	1,718	12.8%
If research misconduct is not stopped, then the scientific record will be severely damaged.		
Very important	9,383	69.9%
Important	3,593	26.8%
Not important	456	3.4%
Having first-hand evidence of the research misconduct.		
Very important	8,067	60.0%
Important	4,883	36.3%
Not important	495	3.7%
Being confident that the matter will be handled fairly and justly.		
Very important	10,663	79.3%
Important	2,715	20.2%
Not important	69	0.5%
Knowing to whom reports of research misconduct should be made.		
Very important	5,276	39.2%
Important	6,466	48.1%
Not important	1,702	12.7%
The belief that all scientists are obliged to report research misconduct.		
Very important	6,807	50.6%
Important	5,896	43.9%
Not important	741	5.5%

The survey also asked researchers their opinion of the importance of considerations that may influence a researchers' decision to not report suspected research misconduct. Their responses are given in Table 5-3. The consideration receiving the largest percentage of "very important" and "important" responses (81.7%) is the fear of the potential damage that could befall ones personal reputation or career. Fear of retaliation by the person accused of the research misconduct has an almost equally large percentage of "very important" and "important" responses (80.6%). It is followed by the potential ostracism by colleagues with the third highest percentage (76.2%) receiving "very important" or "important" responses.

Table 5-3. Importance to Researchers of Considerations Affecting the Decision to Not Report Suspected Research Misconduct

Consideration/ Importance	Weighted Number	Weighted Percent
The fear of retaliation by the person accused of misconduct.		
Very important	4,071	30.5%
Important	6,694	50.1%
Not important	2,592	19.4%
The potential for ostracism by colleagues.		
Very important	3,597	27.0%
Important	6,575	49.3%
Not important	3,173	23.8%
Expectation that damage will result to one's own professional reputation and/or career.		
Very important	4,080	30.6%
Important	6,825	51.1%
Not important	2,449	18.3%
Not knowing what constitutes research misconduct at the institution.		
Very important	2,713	20.3%
Important	6,624	49.6%
Not important	4,017	30.1%
Spending too much time in the allegation resolution process.		
Very important	2,103	15.8%
Important	6,580	49.3%
Not important	4,658	34.9%
Not knowing to whom the misconduct is supposed to be reported.		
Very important	1,488	11.2%
Important	5,369	40.2%
Not important	6,489	48.6%

The consideration that received the largest percentage of “not important” responses and hence is the least important for **not** making an allegation is “not knowing to whom the misconduct should be reported.” The importance of not knowing to whom misconduct should be reported is split nearly 50/50 with 51.4% of researchers rating it as important/very important, and 48.6% rating it as not important. The considerations with the next highest proportion of “not important” as influences on the decision for not making an allegation are “spending too much time in the allegation resolution process” (34.9%), and “ambiguity of what constitutes research misconduct at the institution” (30.1%).

In summary, the considerations noted by researchers as being critical to pulling researchers to decide to make an allegation of research misconduct are first, confidence that the matter will be handled fairly and justly by the institution, followed next by the recognition that if the research misconduct is not stopped it could damage the research

record, and then third, having first-hand evidence of research misconduct. Maintaining the anonymity of the complainant was most often judged as an unimportant consideration in reporting an allegation, but only by a small proportion of the researchers. On the other hand, we found that the considerations judged of greatest overall importance to pushing researchers away from the decision to report research misconduct are first, the expectation of damage to one's professional reputation and/or career, followed closely by the fear of retaliation by the respondent, and then third, the potential for being ostracized by ones' colleagues. Not knowing to whom the research misconduct should be reported is viewed by the most researchers (almost half) as an unimportant consideration in why research misconduct does not get reported. Presumably, they could ask an administrator for such information so it should not be a deterrent to reporting misconduct.

6. RESEARCHERS' KNOWLEDGE OF THEIR INSTITUTIONS' RESEARCH MISCONDUCT POLICY AND PROCEDURES

We asked a series of questions in the survey pertaining to researchers' awareness of various aspects of their institutions' research misconduct policies and procedures, including: whether they have read the policy; how familiar they feel they are with it; whether they know the activities that are defined in the Federal regulations as research misconduct; are aware of the methods for reporting it; know the process by which a determination of research misconduct is made; are aware of protections from retaliation; are aware of institutional action against persons who knowingly make false allegations of research misconduct; and know the requirement for maintaining confidentiality.

6.1 Exposure to and Knowledge of Institutional Research Misconduct Policy

Approximately 9 out of 10 of the researchers in the population surveyed say they have read at least some part of their institution's research misconduct policy and procedures (Table 6-1). Fewer than half (44.3%) indicates that they have read the full policy and procedures. A similar percentage (46.0%) acknowledges that they have only read part of the institution's policy and procedures. Approximately one-tenth (9.8%) admit to not having read the policy at all.

Table 6-1. Exposure to Institution's Research Misconduct Policy and Procedures

<i>Question/Responses</i>	<i>Weighted Number</i>	<i>Weighted Percent</i>
Have you ever read your institution's research misconduct policy and procedures?		
Yes, I have read them fully	6956	44.3%
Yes, I have read them in part	7225	46.0%
No, I have not read them at all	1532	9.8%

We also asked the researchers to assess their knowledge of the institution's research misconduct policy and procedures on a continuum ranging from 0 (know nothing) to 10 (know everything). As can be seen in Table 6-2, one-fifth (20.4%) of the researchers rate their knowledge between 0 and 4. More than half (51.5%) of the researchers give themselves a rating of 7 or higher. Similar percentages describe their knowledge at the extremes with 2.1% indicating that they know nothing about their institution's research misconduct policy and procedures (rating of 0), and 2.5% indicating that they know everything (rating of 10).

Table 6-2. Researchers' Knowledge of Their Institution's Research Misconduct Policy and Procedures

Question/Responses	Weighted Number	Weighted Percent
On a scale from 0 to 10, how would you describe your knowledge of your institutions research misconduct policy and procedures?		
0= (Know Nothing)	335	2.1
1	313	2.0
2	600	3.8
3	1056	6.8
4	890	5.7
5	2649	16.9
6	1753	11.2
7	3261	20.9
8	2988	19.1
9	1406	9.0
10= (Know Everything)	393	2.5

The survey delved into greater detail about researchers' familiarity with specific issues that may or may not be covered in their institution's research misconduct policy and procedures, including: the Federal regulation's definition of activities that constitute research misconduct; to whom allegations of research misconduct should be officially reported; the type of information that should be included in an allegation of research misconduct; the process by which allegations of research misconduct are examined; and procedures for protecting "complainants" (whistleblowers) from retaliation.

As indicated in Table 6-3, more than four-fifths of researchers (85.1%) report being very or somewhat familiar with what the Federal regulations say constitutes research misconduct. More than half of the researchers (53.8%) say they are only somewhat familiar with what their institution's policy says about the definition of activities that constitute research misconduct according to the Federal regulations. Slightly less than one-third (31.3%) say they are very familiar with what their institution's policy says about the definition of research misconduct in the Federal regulations. Just 11.9% and 3.1% respectively say they are not very or at all familiar with what the Federal definition includes.

Table 6-3. Researchers' Familiarity with Specific Aspects of their Institution's Research Misconduct Policy

Question/Response	Weighted Number	Weighted Percent
How familiar are you with what your institution's policy says about:		
a. The Federal regulations definition of activities that constitute research misconduct?		
Very familiar	4835	31.3%
Somewhat familiar	8320	53.8%
Not very familiar	1835	11.9%
Not at all familiar	473	3.1%
b. To whom allegations of this kind of research misconduct should be officially reported?		
Very familiar	5310	34.4%
Somewhat familiar	7169	46.4%
Not very familiar	2384	15.4%
Not at all familiar	592	3.8%
c. What information should be included in an allegation of this kind of research misconduct?		
Very familiar	2669	17.3%
Somewhat familiar	7917	51.2%
Not very familiar	3978	25.7%
Not at all familiar	891	5.8%
d. The process by which allegations of this kind of research misconduct are examined?		
Very familiar	2907	18.8%
Somewhat familiar	7584	49.1%
Not very familiar	3985	25.8%
Not at all familiar	980	6.3%
e. Procedures for protecting "complainants" (whistleblowers) of this kind of research misconduct from retaliation?		
Very familiar	2407	15.6%
Somewhat familiar	7242	46.9%
Not very familiar	4456	28.8%
Not at all familiar	1351	8.7%

A similar large majority of researchers (80.8%) report that they are very or somewhat familiar with their institution's policy regarding to whom allegations of research misconduct should be officially reported. Fewer than half (46.4%) are only somewhat familiar with whom the policy directs that research misconduct allegations be made, and slightly more than one-third (34.4%) say they are very familiar with whom to make

misconduct allegations. Nearly one-fifth reports being not very (15.4%) or not at all familiar (3.8%) with their institution's policy on the matter.

When asked about what their institution's policy says about the type of information that should be included in an allegation of research misconduct, more than two-thirds of researchers (68.5%) say they are very (17.3%) or somewhat familiar (51.2%) with the types of information that should be included in an allegation. However, nearly one-third (31.5%) say they are not very familiar (25.7%) or familiar at all (5.8%) with the types of information that their institution's policy requests be in an allegation.

There is a very similar distribution of responses when we asked about participants' familiarity with their institution's process for handling allegations of research misconduct. Just about two-thirds (67.9%) say they are somewhat (49.1%) or very familiar (18.8%) with what their institution's policy says about the process by which allegations of research misconduct are examined. Roughly one-quarter (25.8%) report not being very familiar with the process described in their institution's policy, and 6.3% say they are not at all familiar with it.

Somewhat less than two-thirds of researchers (62.5%) say they are either somewhat (46.9%) or very familiar (15.6%) with their institution's procedures for protecting "complainants" (i.e., whistleblowers) from retaliation. A sizeable percentage (28.8%) reports that it is not very familiar with the protections for retaliation against complainants, and 8.7% say they are not at all familiar with the protections offered by their institution.

As this discussion reveals, researchers seem to report different levels of familiarity with different aspects of their institution's research misconduct policy. To get a better overall view of researchers familiarity with these five very important aspects of their institution's policy we assigned values to their responses (very familiar = 4, somewhat familiar = 3, not very familiar = 2, and not at all familiar = 1) and summed them across the five items. As can be seen from Table 6-4, there is considerable variation in the combination of responses researchers give to the question of their familiarity. However, it is encouraging that there are only 2.0% of researchers who say they are not at all familiar with any of the five key aspects of their institution's research misconduct policy we asked about, i.e., a score of 5. At the opposite end of the distribution, it is more encouraging that there are 8.4% who say they are very familiar with all five aspects, i.e., a score of 20.

Table 6-4. Index of Researcher Familiarity with Selected Key Aspects of Their Institution's Research Misconduct Policy

<i>Overall Index of Researcher Familiarity with Selected Key Aspects of Research Misconduct Policy</i>	<i>Weighted Number</i>	<i>Weighted Percent</i>
5	310	2.0%
6	70	0.5%
7	168	1.1%
8	189	1.2%
9	221	1.4%
10	1,004	6.5%
11	819	5.3%
12	1,043	6.8%
13	1,322	8.6%
14	1,264	8.2%
15	3,374	21.8%
16	1,463	9.5%
17	1,348	8.7%
18	937	6.1%
19	633	4.1%
20	1,292	8.4%

To get a better measure of how many researchers say they are very familiar with their institution's policy, we summed the number of items out of the five that researchers report being very familiar with, and present the resulting distribution in Table 6-5. This is a less encouraging picture of how well informed researchers are about key selected aspects of their institution's policy. The table clearly shows that more than half (54.2%) of the researchers do not judge themselves to be very familiar with any of the five very important aspects of their institution's policy that we asked about. Approximately one-fourth more (26.1%) say they are very familiar with only one or two of these policy areas. Fewer than one of ten researchers (8.4%) reports being very familiar with all five critically important aspects of the policy.

Table 6-5. Number of Aspects of Research Misconduct Policy with which Researchers Say They Are Very Familiar

<i>Number of Items with which Researchers Are Very Familiar</i>	<i>Weighted Number</i>	<i>Weighted Percent</i>
0	8,374	54.2%
1	2,347	15.2%
2	1,684	10.9%
3	1,087	7.0%
4	671	4.3%
5	1,292	8.4%

6.2 Knowledge of Activities that Federal Regulations Define as Research Misconduct

To explore how familiar researchers are with the research practices that the Federal regulations specify to define research misconduct, we asked the researchers to identify them from a list of 10 questionable or unethical practices (Table 6-6). The vast majority of researchers correctly identified the three activities defining research misconduct in the Federal regulations: falsification (91.2%), fabrication (88.0%), and plagiarism (83.1%). This means that nearly 20% of researchers did not correctly identify all three.

Further, it is discouraging that still substantial, albeit somewhat smaller, majorities incorrectly identified fraudulent use of research funds (81.5%), ignoring IRB requirements (76.3%), and financial conflict of interest (63.9%) as behaviors defined as research misconduct according to the Federal regulations. Three other activities also got a bare majority of researchers identifying them as constituting research misconduct according to the Federal regulations – not maintaining confidentiality (59.7%), embezzlement (57.3%), and violating research protocol (56.4%). It is interesting to note, however, that more than half of the researchers indicate that nine of the 10 activities listed are identified as research misconduct in their institution’s research misconduct policy and procedures. Only immoral behavior, the least frequently cited activity to be defined as research misconduct (29.9%) by the Federal regulations, is not mentioned by a majority of the researchers.

Table 6-6. Activities that Federal Regulations Specifically Define as Research Misconduct

Potential Research Misconduct Activities/Response	Weighted Number	Weighted Percent
Indicate which of the following are among the activities that Federal regulations define as research misconduct?		
Financial conflict of interest		
Yes	10,323	63.9%
No	5,836	36.1%
Falsification		
Yes	14,728	91.1%
No	1,431	8.9%
Fraudulent use of research funds		
Yes	13,168	81.5%
No	2,991	18.5%
Plagiarism		
Yes	13,428	83.1%
No	2,731	16.9%
Not maintaining confidentiality		
Yes	9,642	59.7%
No	6,517	40.3%
Ignoring IRB requirements		
Yes	12,330	76.3%
No	3,829	23.7%
Immoral behavior		
Yes	4,826	29.9%
No	11,333	70.1%
Violating research protocol		
Yes	9,111	56.4%
No	7,048	43.6%
Embezzlement		
Yes	9,253	57.3%
No	6,906	42.7%
Fabrication		
Yes	14,218	88.0%
No	1,941	12.0%

To get an overall sense of how well researchers could correctly identify which forms of bad research practice constitute research misconduct, we created a research misconduct definition score based on summation of their responses to the ten items. The score is a count of the number of behaviors correctly identified as research misconduct (up to 3) in the Federal regulations and the number of behaviors correctly not included as research misconduct (up to 7) in the Federal regulations and is presented in Table 6-7.

Table 6-7. Distribution of Correctly Identified Components of Research Misconduct

<i>Number of Research Misconduct Components Correctly Identified</i>	<i>Weighted Number</i>	<i>Weighted Percent</i>
1 and 2	112	0.7%
3	3,570	22.1%
4	2,651	16.4%
5	2,850	17.6%
6	2,221	13.8%
7	2,518	15.6%
8	882	5.5%
9	502	3.1%
10	852	5.3%

The most striking thing in the table is that only 5.3% of the researchers have answered all 10 of the items correctly in their effort to distinguish the activities that are specified in the Federal regulations as defining research misconduct from the other bad research practices. Even allowing for two errors, only 13.8% achieved a score of eight or more correct responses, and just over half (56.8%) got five of the answers correct, suggesting that many researchers are not aware of what the Federal regulations include as research misconduct.

6.3 Researcher Confidence in their Knowledge of Key Aspects of their Institution’s Research Misconduct Policy

The survey also asked researchers a series of six questions about specific important aspects of their institution’s research misconduct policy and procedures. The purpose of the questions was not to get an accurate description of the policy but rather to create a measure of how confident the researchers are of their knowledge. Researchers answering “don’t know” are considered less confident sure about their knowledge of the policy.

In the first question, researchers were asked about whether their institution’s research misconduct policy and procedures told whether allegations of research misconduct can be made anonymously. As indicated in Table 6-8, there is a nearly even split with 48.4% indicating that their institution’s policy and procedures does address whether allegations of research misconduct can be made anonymously, and 48.8% acknowledging that they do not know whether their institution’s policy and procedures address this issue. Only a very small percentage of researchers (2.8%) say that their institution’s policy and procedures address does not address whether allegations of research misconduct can be made anonymously or not.

Table 6-8. Does Policy Allow for Making Anonymous Allegations of Research Misconduct

<i>Question/Responses</i>	<i>Weighted Number</i>	<i>Weighted Percent</i>
No	428	2.8%
Yes	7,323	48.4%
Don't know	7,374	48.8%

The data in Table 6-9 are for the question that asks whether the researcher's institutional policy states that allegations of research misconduct can be reported orally. Fully two-thirds of the researchers (66.7%) don't know whether their institution's policy and procedures state that allegations of research misconduct can be reported orally or not (e.g., via phone, email, in-person). Almost thirty percent (29.5%) says that their policy does address allegations that are not reported in writing, and only 3.8% of researchers indicates that the policy does not.

- **Table 6-9. Does Policy Allow for Orally Reported Allegations of Research Misconduct**

<i>Question/Responses</i>	<i>Weighted Number</i>	<i>Weighted Percent</i>
No	574	3.8%
Yes	4,442	29.5%
Don't know	10,040	66.7%

The survey also asked whether researchers' institutional research misconduct policy and procedures describe the process by which a determination of whether research misconduct actually occurred is made (Table 6-10). A large majority of researchers (70%) indicated that the process is described in their institution's policy and procedures. However, more than one-quarter did not know whether the policy and procedures outlined this process. Only 1.3% indicates that the process is not included within their institution's policy and procedures.

Table 6-10. Does Policy Discuss Process for Determining Whether Research Misconduct Actually Occurred

<i>Question/Responses</i>	<i>Weighted Number</i>	<i>Weighted Percent</i>
No	186	1.3%
Yes	10,481	70.1%
Don't know	4,277	28.6%

We also asked researchers if their institution's research misconduct policy addresses what actions the institution will take to protect persons from retaliation if they make a good faith allegation of research misconduct (Table 6-11). More than half of the researchers (55.2%) acknowledged that the institution's policy and procedures explain the actions that the institution will take to protect persons making allegations in good faith from retaliation. However, a sizeable percentage of researchers (41.6%) say they do not know if such actions are included in the institution's policy and procedures. A very small percentage (3.2%) indicates that their institution's policy and procedures does not discuss the actions that the institution will take to protect persons making allegations in good faith from retaliation.

Table 6-11. Does Policy Discuss Institutional Actions to Protect Complainants from Retaliation

<i>Question/Responses</i>	<i>Weighted Number</i>	<i>Weighted Percent</i>
No	480	3.2%
Yes	8,210	55.2%
Don't know	6,196	41.6%

The survey also asked whether researchers were familiar with whether their institution's policy and procedures discuss how the institution will respond to those who knowingly make false accusations of research misconduct. As seen in Table 6-12, nearly one-third (32.8%) said that their institution's policy and procedures do discuss how the institution will handle persons who knowingly make false accusations. However nearly double (62.2%) that percentage say they don't know, while 5.0% say that that the policy and procedures do not discuss the institutional process for handling such persons.

Table 6-12. Does Policy Discuss Institutional Response to Those Who Knowingly Make False Accusations of Research Misconduct

Question/Responses	Weighted Number	Weighted Percent
No	746	5.0%
Yes	4,871	32.8%
Don't know	9,231	62.2%

Regarding assurance and protection of the confidentiality of information (Table 6-13), more than half of the researchers (57.4%) indicates that their institution's research misconduct policy and procedures describes the protocol for protecting information obtained from research misconduct inquiries and investigations. A considerable percentage of researchers (40.1%), however, does not know whether their policy and procedures described such a protocol. Only 2.6% said that the policy does not address the process for assuring/protecting the confidentiality of this type of information.

Table 6-13. Does Policy Discuss Institutional Protocol for Assuring/Protecting Confidentiality of Information Obtained from Inquiries/Investigations

Question/Responses	Weighted Number	Weighted Percent
No	377	2.6%
Yes	8,465	57.4%
Don't know	5,917	40.1%

The issue about which there seems to be the most widespread belief by far that it is being discussed in the institution's research misconduct policy is the process for determining whether research misconduct actually occurred (71.4%). Only 28.6% say they don't know to this item. However, there are two issues about which substantial majorities say they don't know whether the issues are discussed in the policy: whether the institution allows allegations to be made orally (66.7%), and what the institutional response is to persons knowingly making a false allegation (62.2%).

The previous six tables provide a view of how many researchers say that they know or don't know whether each of a number of important issues associated with research misconduct is discussed in their institution's policy and procedures. To assess the number of researchers who repeatedly say they don't know whether the issues are discussed in the policy, we have created a measure to summarize the number of issues across the six items

for which researchers responded “don’t know” (Table 6-14). Only 14.8% feel knowledgeable enough about their institutional research misconduct policy to not answer any of the items about what’s covered in the policy with a “don’t know” response. At the other end of the distribution there are 16.3% who respond “don’t know” to all six items. More than one-third of researchers (36.8%) respond to the items with more “don’t know” responses than yes or no responses combined.

Table 6-14. Number of Items about which Researchers Indicated They Did Not Know Whether the Issue Was Discussed in the Institution’s Policy

Number of Policy Items to which Answered Don’t Know	Weighted Number	Weighted Percent
0	2,176	14.8%
1	2,176	14.8%
2	2,774	18.8%
3	2,186	14.8%
4	1,547	10.5%
5	1,475	10.0%
6	2,409	16.3%

7. INSTITUTIONAL DISSEMINATION OF RESEARCH MISCONDUCT POLICY AND PROCEDURES TO RESEARCHERS

The survey also explored how researchers in medical schools learn about their institutions' research misconduct policy and procedures. Approximately half of researchers (49.9%) indicate that new research faculty and staff are typically exposed to institutional research misconduct policy and procedures in the first few days (14.7%), within the first month of employment (23.7%), or within the first year (11.6%). More than one-third respond that they don't know (39.8%) during what time period newly hired faculty and staff are exposed to the policy and procedures. Less than one in ten of researchers indicate that (8.4%) new hires are never formally exposed to the institution's research misconduct policy and procedures, and (1.9%) respond other.

The survey proceeded to ask about the context in which the research misconduct policy and procedures are typically first presented to new research faculty and staff. Researchers were presented with the options listed below (Table 7-1) and asked to check all that applied to their institution. Attending a new employee group orientation is the most often cited response (34.7%), followed by e-mails with a URL to visiting a website (28.5%), distribution of a printed or electronic document (27.2%), through a Responsible Conduct of Research (RCR) program (24.9%), by means of IRB continuing educational activities (24.4%), by meeting new grant award requirements (16.7%), and least often through an all hands meeting on the policy (2.7%).

To follow up on the question about the format typically used to present the institution's research misconduct policy and procedures for the first time, researchers were presented with the options listed in Table 7-2 and asked to provide a single response. Slightly more than one-third of researchers (34.3%) say that their institution's policy and procedures are first typically presented as part of a printed or electronic version of the faculty manual. More than one-quarter of those who responded (28.1%) say they don't know the format in which it is first typically presented at their institution. Nearly one-quarter (24.6%) indicate an on-line course, and slightly more than one in ten respond (11.0%) that the research misconduct policy is first typically presented in a live group or workshop setting. Live one-on-one discussions are rarely used (0.6%). Most of the formats used do not usually permit immediate question and answer exchanges.

Table 7-1. Context in Which Research Misconduct Policy and Procedures are Typically First Presented to New Research Faculty and Staff

Context in which first presented/Response	Weighted Number	Weighted Percent
As part of new employee group orientation		
Yes	5,615	34.7%
No	10,544	65.3%
To meet new grant award requirements		
Yes	2,703	16.7%
No	13,456	83.3%
As part of the IRB's continuing educational activities		
Yes	3,944	24.4%
No	12,215	75.6%
In a Responsible Conduct of Research (RCR) program		
Yes	4,016	24.9%
No	12,143	75.1%
In an "all hands" meeting on the topic		
Yes	429	2.7%
No	15,730	97.3%
By means of a general distribution of the document (printed or electronic)		
Yes	4,399	27.2%
No	11,760	72.8%
Through an e-mail notice and referral to a web site		
Yes	4,598	28.5%
No	11,561	71.5%

Table 7-2. Format Typically Used to First Present the Institution's Research Misconduct Policy and Procedures

Format in which Typically Presented	Weighted Number	Weighted Percent
As part of a printed faculty manual	2,056	15.6%
As an electronic version of a faculty manual	2,471	18.7%
As an on-line course	3,245	24.6%
In a live group/workshop setting	1,447	11.0%
In a one-on-one discussion	73	0.6%
Don't Know	3,705	28.1%
Other	195	1.5%

The survey also asked questions about the accessibility of the research misconduct policy and procedures. Approximately half of the researchers (48.1%) indicate that research faculty and staff have an opportunity to attend a workshop, class, or other live presentation to obtain clarification or answers to questions about their institution's research misconduct policy and procedures. An almost equal percentage (42.2%) does not know whether research faculty and staff have such opportunities. When asked whether the policy and procedures are included in a printed handbook that is readily available to faculty and staff in a library or other public location, more than half of the researchers (55.1%) say yes, 41.2% do not know, and 3.8% indicate that the research misconduct policy and procedures are not readily available. The majority of researchers (73.7%) say that the institution's research misconduct policy is readily available on the institution's website. More than two-fifths of researchers (41.4%) said that the policy and procedures are available only on their institution's internal website, 4.3% say that they are available on the institution's external website, and 28.1% note that they are available on both websites. One-quarter of researchers (25.4%) do not know whether the policy and procedures are readily available on the internal or external website.

We asked researchers whether they were required to certify on a regular basis that they have reviewed the institution's research misconduct policy. Slightly less than one-third of the researchers (31.4%) say that they are required on an annual or biannual basis to certify that they have reviewed the institution's research misconduct policy and procedures. A similar percentage (31.0%) say do not know whether their institution requires that research faculty and staff periodically certify that they have reviewed the policy and procedures. More than one-quarter of researchers (27.9%) indicate that they either provided a one-time acknowledgement or have no requirement to periodically certify that the policy has been reviewed. The smallest percent of researchers either have to review the policy when applying for or awarded grants (7.7%) or have to do it less frequently than every year (2.1%).

In addition to asking about periodic certification requirements, the survey also asked whether researchers have *ever* been required to review their institution's research misconduct policy and procedures. Nearly half of researchers (47.1%) have never been required to review the policy and procedures, but 42.7% have been required to review them, and 10.3% say they don't know.

The presence of Responsible Conduct of Research (RCR) training is another topic explored in the survey. More than half of the researchers (56.8%) acknowledge having an RCR training program at their institution. A sizeable percentage of researchers (37.6%) say they do not know whether such a program exists at their institution. Only 5.7% say that their institution does not have an RCR training program. Nearly half of the researchers (47.0%) say they have participated in RCR training. A similar percentage of researchers (44.0%) say they have not, and 9.0% say they do not know if they have. Among those who

participated in the training, nearly all (96.9%) say that the training discussed research misconduct.

Another way of disseminating the institution’s research misconduct policy is through mentoring young investigators by more senior investigators. When asked, “Do you have responsibility for overseeing the research of one or more doctoral degree students, post doctoral fellows, or otherwise mentoring new investigators in your institution?”, 91.4% respond that they do. The majority (69.8%) say they are responsible for overseeing/mentoring between one and five students/researchers, 14.1% are responsible for overseeing the research of six to ten students/researchers, while 6.5% mentor or oversee more than ten.

Of those who are responsible for overseeing or mentoring students/researchers, 58.6% acknowledge that they sometimes talk with their students, post docs, or mentees about issues related to research misconduct. Nearly one-quarter say that they never (1.9%) or rarely (21.6%) discuss issues pertaining to research misconduct, whereas 17.8% note that they often discuss such issues with their students, post docs, or mentees.

The survey asked which of a variety of important research misconduct related topics these mentors discussed. The frequency with which each of these topics is discussed by the research mentors is presented in Table 7-3.

Table 7-3. Aspects of Research Misconduct Discussed by Mentors

Aspects Discussed/Response	Weighted Number	Weighted Percent
Maintaining Proper Records and Documents		
Yes	11,805	93.9%
No	771	6.1%
Responsibility to Report Alleged Misconduct		
Yes	5,208	41.4%
No	7,368	58.6%
Repercussions on Career of Making Misconduct allegation		
Yes	3,736	29.7%
No	8,840	70.3%
To Whom to Report Misconduct		
Yes	3,306	26.3%
No	9,270	73.7%
Process to Resolve Misconduct		
Yes	2,137	17.0%
No	10,439	83.0%
Evidence to Support Allegation of Misconduct		
Yes	2,191	17.4%
No	10,385	82.6%
Potential Response of Colleagues to Your Making Allegation		
Yes	1,502	11.9%
No	11,074	88.1%

(continued)

Table 7-3. Aspects of Research Misconduct Discussed by Mentors (continued)

Aspects Discussed/Response	Weighted Number	Weighted Percent
Time and Energy Involved in Making Allegation of Misconduct		
Yes	1,057	8.4%
No	11,518	91.6%
How to Report Research Misconduct		
Yes	1,628	13.0%
No	10,947	87.1%
Activities that Constitute Research Misconduct		
Yes	9,209	73.2%
No	3,367	26.8%
What It Means that Every Research Report Is Expected to Be Honest		
Yes	8,710	69.3%
No	3,866	30.7%
How Allegations of Misconduct Made in Good Faith May be Erroneous.		
Yes	2,697	21.4%
No	9,879	78.6%

As reported by the researchers who say they mentor post-doctoral and graduate students or new researchers, the research misconduct related topics discussed most often include: maintaining proper records and documentation (93.9%), activities that constitute research misconduct (73.2%), honest reporting of research findings (69.3%), and the responsibility to report alleged misconduct (41.4%).

As a follow-up question, the survey asked in which of several selected contexts these discussions of research misconduct issues typically occur. The frequency with which the contexts are mentioned is presented in Table 7-4. According to the researcher's responses, discussions about research misconduct most frequently occur in the context of discussions about research methods (72.9%); report, proposal, and manuscript preparation (68.6%); and when stories concerning research misconduct appear in the popular press (43.3%) or in professional journals (38.5%). Such discussions least typically arise as topics in seminars or other formal didactic settings (14.0%).

Table 7-4. Contexts in which Research Misconduct is Discussed

Context in which Discussed/Response	Weighted Number	Weighted Percent
Seminar on Topic		
Yes	1,758	14.0%
No	10,817	86.0%
Discussion of Research Methods		
Yes	9,165	72.9%
No	3,411	27.1%
During Report, Proposal, or Manuscript Preparation		
Yes	8,623	68.6%
No	3,953	31.4%
With the Appearance of Research Misconduct Articles in Journals		
Yes	4,836	38.5%
No	7,740	61.5%
When Stories of Research Misconduct Appear in the Popular Press		
Yes	5,441	43.3%
No	7,135	56.7%

The survey also asked researchers an open ended question about advice they would give graduate and post-doctoral students, new researchers, and mentees who believe they have witnessed research misconduct and are considering making a formal allegation to an institutional official (Table 7-5). The majority (71.5%) of researchers are generally supportive of reporting the allegation of misconduct. Approximately one-quarter of researchers (24.3%) say they would suggest having evidence and documentation available to back up their allegation.

Only a few researchers (0.4%) admit that they are generally unsupportive of reporting potential research misconduct to any institutional official, and there are a few who expressed no confidence in their institution's ability to handle such an allegation properly (0.1%). However, there is a greater percentage of researchers who say they do not know what advice they would give (0.6%), than the percentage of researchers who are generally unsupportive of reporting suspected research misconduct (0.5%). Other suggested actions include: attempting to communicate with the suspected wrongdoer (1.5%), discussing the potential for retaliation and other adverse consequences that may occur as a result of filing an allegation (0.8%), seeking the advice of others (0.1%), and reporting the alleged misconduct to the project's PI or the accused person's supervisor or department chairperson (0.3%).

Table 7-5. Advice Given by Researchers to Persons Who Have Witnessed Research Misconduct and Are Considering Making an Allegation

Type of Advice Offered by Mentor	Weighted Number	Weighted Percent
Generally supportive of reporting allegation	8,132	71.5%
Urged to have evidence and documentation available if making an allegation	2,764	24.3%
Would discuss the potential for retaliation and other adverse consequences that may result from filing an allegation	87	0.8%
Stressed the importance of maintaining confidentiality/anonymity	42	0.4%
Suggested making an attempt to communicate with the accused person about it prior to filing an allegation	168	1.5%
Expressed mistrust of the institution to properly handle an allegation of research misconduct	16	0.1%
Generally unsupportive of reporting potential research misconduct to institutional officials.	49	0.4%
Don't know	64	0.6%
Recommend reporting it to the project's principal investigator or the accused person's supervisor or department chairperson	30	0.3%
Seeking advice from others	16	0.1%

8. PERCEPTIONS OF THE INSTITUTION'S EFFORTS TO EDUCATE ABOUT MISCONDUCT AND INTEGRITY

One way to evaluate how well an institution is doing at educating its workforce is to ask the persons who are presumably the target of the institution's educational efforts. We asked the medical schools' researchers a series of 10 questions to obtain their views of the effort being put forth by their medical school to familiarize them with the school's policy and procedures regarding how it handles allegations of research misconduct. The questions consist of a mix of general items about the extent of the efforts of the institution and items that focus on specific topic areas on which the institution's efforts could have been focused. The researchers were asked to respond to each of the items by saying they either strongly agree, agree, disagree, strongly disagree, or did not know. In this section of the report we review how they responded to each separate item and then discuss our effort to create a summary measure across all 10 of the items.

8.1 Researcher Perceptions of the Effectiveness of Specific Areas of Institutional Efforts to Educate about Research Misconduct

Table 8-1 presents the 10 statements about the institutions' effort and researchers' responses to them. The first item probes whether, in the researchers' opinion, the institution does all it can to make researchers familiar with its policy and procedures governing research misconduct. More than two-thirds either strongly agree or agree (15.6% and 53.6%, respectively) that it does. Less than one-fourth strongly disagrees or disagrees (23.4%), and only 7.5% says they do not know.

Table 8-1. Researchers' Perceptions of the Effectiveness of Their Institution's Effort to Educate Research Staff on Research Misconduct

Statement/Responses	Weighted Number	Weighted Percent
This institution does all it can to assure that members of the research faculty and staff are familiar with the policy and procedures governing research misconduct		
Strongly Agree	2,121	15.6%
Agree	7,282	53.6%
Disagree	2,836	20.9%
Strongly Disagree	337	2.5%
Don't Know	1,015	7.5%
This institution has made a concerted effort to educate research faculty and staff about what constitutes research misconduct		
Strongly Agree	2,587	19.1%
Agree	7,579	55.8%
Disagree	2,197	16.2%
Strongly Disagree	284	2.1%
Don't Know	931	6.9%

(continued)

Table 8-1. Researchers' Perceptions of the Effectiveness of Their Institution's Effort to Educate Research Staff on Research Misconduct (continued)

Statement/Responses	Weighted Number	Weighted Percent
The climate at this institution makes research faculty and staff feel comfortable and ethically responsible reporting potential research misconduct to the appropriate official		
Strongly Agree	3,132	23.1%
Agree	7,903	58.2%
Disagree	968	7.1%
Strongly Disagree	269	2.0%
Don't Know	1,301	9.6%
There is a need for more opportunities for research faculty and staff to learn what they should do when they have evidence of research misconduct		
Strongly Agree	1,142	8.4%
Agree	6,111	45.0%
Disagree	4,716	34.8%
Strongly Disagree	718	5.3%
Don't Know	879	6.5%
This institution has made a concerted effort to educate research faculty and staff about whom to report allegations of research misconduct		
Strongly Agree	1,493	11.0%
Agree	7,100	52.4%
Disagree	3,185	23.5%
Strongly Disagree	312	2.3%
Don't Know	1,462	10.8%
Persons who make allegations of research misconduct at this institution need not fear that they will be ostracized or marginalized by colleagues		
Strongly Agree	2,185	16.1%
Agree	6,938	51.2%
Disagree	1,438	10.6%
Strongly Disagree	377	2.8%
Don't Know	2,623	19.3%
This institution takes appropriate measures to protect persons who make allegations of research misconduct from being the objects of retaliation		
Strongly Agree	1,981	14.6%
Agree	6,600	48.7%
Disagree	506	3.7%
Strongly Disagree	211	1.6%
Don't Know	4,248	31.4%
The personnel at this institution who are responsible for reviewing allegations of research misconduct are trained and prepared to arrive at a fair and impartial judgment		
Strongly Agree	3,122	23.0%
Agree	6,592	48.7%
Disagree	696	5.1%
Strongly Disagree	256	1.9%
Don't Know	2,883	21.3%

(continued)

Table 8-1. Researchers' Perceptions of the Effectiveness of Their Institution's Effort to Educate Research Staff on Research Misconduct (continued)

Statement/Responses	Weighted Number	Weighted Percent
This institution could do more to make everyone feel obliged to report misconduct when they suspect it may have occurred		
Strongly Agree	533	3.9%
Agree	3,715	27.4%
Disagree	6,119	45.2%
Strongly Disagree	1,104	8.2%
Don't Know	2,073	15.3%
Persons who are considering making allegations of research misconduct at this institution should seriously consider the impact it will have on their professional career opportunities		
Strongly Agree	781	5.8%
Agree	3,601	26.6%
Disagree	5,733	42.3%
Strongly Disagree	1,660	12.3%
Don't Know	1,771	13.1%

In the second item, researchers are asked whether they believe the institution has made a concerted effort to educate its researchers about what constitutes research misconduct. Nearly three-fourths either strongly agrees or agrees (19.1% and 55.8%, respectively) that it is doing so. Only 18.3% disagrees or strongly disagrees, and just 6.9% does not know.

The next item inquires about whether the climate at the institution makes researchers feel comfortable and responsible by reporting research misconduct to the designated official. More than 80% either strongly agrees or agrees (23.1% and 58.2%, respectively) that it does. Less than one-tenth (9.1%) of researchers disagrees or strongly disagrees and just about the same percentage (9.6%) indicates they do not know.

In the fourth item, we changed the directionality of the question by asking whether the researchers feel there is a need to have more opportunities to learn what they should do when they have evidence of research misconduct. More than half again strongly agrees or agrees (8.4% and 45.1%, respectively), but this time with regard to being somewhat critical of its institution's efforts rather than supportive. Just about 40% disagrees or strongly disagrees (34.8% and 5.3%, respectively), thereby resulting in the smallest margin of support for the institution's effort to this point, and there are 6.5% who indicates they don't know.

In the next item, we ask whether the institution has made a concerted effort to educate researchers about the person to whom they should report allegations of research misconduct. Again a majority of almost two-thirds responds with strongly agrees or agrees

to this item (11.0% and 52.4%, respectively) in support of the institution's efforts. Just over one-fourth (25.8%) disagrees or strongly disagrees with the statement about the institution's effort, and 10.8% say they do not know.

The sixth item focuses on how effectively the institution has allayed fears that persons who make an allegation of research misconduct will be ostracized or marginalized by their peers and colleagues. Two-thirds of researchers strongly agree or agree (16.1% and 51.2%, respectively) that "whistleblowers" need not fear experiencing these responses to their making an allegation. Only about one-eighth of the researchers disagree or strongly disagree (10.6% and 2.8%, respectively), but nearly one-fifth (19.3%) say they do not know.

The next item is focused on whether the institution takes the appropriate actions to protect persons filing allegations of research misconduct from becoming objects of retaliation. Again, nearly a two-thirds majority of the researchers strongly agree or agree (14.6% and 48.7%, respectively) that the institution's efforts to protect "whistleblowers" are effective. Only a very small percentage says it disagrees or strongly disagrees (5.3%), but for this item, nearly one-third (31.4%) says it does not know. This large percentage may have occurred because research misconduct proceedings are supposed to occur in strict confidentiality and therefore little is known about how often such actions are needed and the nature of actions that have been taken to protect complainants.

The eighth item asks about whether the researchers believe that the persons at their institutions entrusted to carry out the process and procedures for dealing with allegations of research misconduct are trained and able to arrive at a fair and impartial judgment. Almost three-fourths of the researchers either strongly agree or agree (23.0% and 48.7%, respectively) with that statement, the largest level of agreement and endorsement of the institutions' efforts yet. Only a small percentage (6.0%) disagrees or strongly disagrees with the statement in support of the institution, but 21.3% say they do not know. It could be that this large percentage is a result of a lack of knowledge regarding the identity of the persons handling the institutions' misconduct proceedings.

The last two items represent a reversal in the direction of the question about the institutions' efforts such that agreement with them does not support the effectiveness of the institutions' educational efforts. Item 9 suggests that the institutions could do more than they do to make researchers feel obliged to report research misconduct when they suspect it has occurred. Nearly one-third responds that they strongly agree or agree (3.9% and 27.4%, respectively) with the item. A bare majority either disagrees or strongly disagrees (45.2% and 8.2%, respectively), in support of the medical schools' efforts to educate researchers about their responsibility with respect to reporting research misconduct, but an additional 15.3% say they do not know.

In the final item, we ask researchers whether persons contemplating making an allegation of misconduct at the institution should seriously consider the adverse impact that doing so could have on ones' career opportunities. Nearly one-third responds strongly agree or agree (5.8% and 26.6%, respectively) that despite efforts of the institution, that potential "whistleblowers" need to be wary of the potential adverse effect of making an allegation of research misconduct would have on their career opportunities. Again, a bare majority responds disagree or strongly disagree (42.3% and 12.3%, respectively) supporting the effectiveness of the institutions' efforts in sheltering "whistleblowers" from suffering adverse career impacts. However, 13.1% say they do not know.

8.2 Researcher Perception of the Overall Effectiveness of Their Institutions' Educational Efforts

In an effort to represent the overall perception of researchers about how effective they thought their institution was in educating its researchers regarding an assortment of key issues often addressed in research misconduct policies, we sought to create a single composite scale score based on the responses to the 10 items. To create the scale, responses to each item were considered equally important and hence were equally weighted. Responses that supported the effectiveness of the institutions efforts were given higher scores, those responses that did not support the effectiveness of the institutions' efforts were given lower scores, and don't know responses were given a middle value score. Because there were five response categories, the following values were assigned to them: strongly agree = 5, agree = 4, don't know = 3, disagree = 2, and strongly disagree = 1. However, the scoring of questions 4, 9 and 10 was reversed to more properly represent the direction of the perception being reported, i.e., not supporting the effectiveness of the institutions' educational efforts. The scale scores ranged from 10 (perceived as not being very effective) to 50 (perceived as being very effective). The grouped distribution in approximate quartiles is presented in Table 8-2.

Table 8-2. Distribution of Scale of Researchers' Perception of the Effectiveness of Their Institutions' Research Misconduct Policy Educational Effort

Perceived Effectiveness of Institutional Educational Effort	Weighted Number	Weighted Percent
Grouped Scale Scores		
10-31 Low	3,411	25.2%
32-35 Medium Low	3,040	22.5%
36-39 Medium High	3,361	24.8%
40-50 High	3,715	27.5%

To ensure that we were justified in combining the 10 items into a single overall scale, we measured the internal consistency of the 10 items. To measure how closely related the

set of 10 items are as a group to our presumed underlying construct (perceived institutional research misconduct policy education effectiveness), we calculated Cronbach's Alpha. Our proposed scale achieved an Alpha of 0.84, considered a reasonably high coefficient supporting our decision to combine the 10 items to form an overall scale of the researchers' perception of the effectiveness of the institution's efforts to educate its researchers about research misconduct.

9. RESEARCHER WILLINGNESS TO REPORT SUSPECTED RESEARCH MISCONDUCT TO AN INSTITUTIONAL OFFICIAL

In the survey, we presented researchers with a series of four statements that differed with respect to whom the researcher would go if research misconduct was suspected and how assured the researcher would have to be of his or her suspicion to go to an institutional official. We asked them to indicate whether they strongly agree, agree, disagree, or strongly disagree with each of the statements. The statements were prepared with the intent of combining the responses to create an index of the researchers' propensity to report suspected research misconduct to an appropriate institutional official as stated by the Federal regulations. The statements and responses are presented in Table 9-1.

Table 9-1. Researchers' Inclinations to Report Potential Research Misconduct to Institutional Officials

Statement/Responses	Weighted Number	Weighted Percent
I would have to be absolutely sure that the behavior of one of my colleagues represented research misconduct before I would make such an allegation to an institutional official.		
Strongly Agree	6,707	49.6%
Agree	5,640	41.7%
Disagree	1,144	8.5%
Strongly Disagree	46	0.3%
I would raise the possibility of misconduct with the person I suspected in order to give that person the a chance to correct the situation before making an allegation to an institutional official.		
Strongly Agree	2,465	18.3%
Agree	7,217	53.5%
Disagree	3,467	25.7%
Strongly Disagree	344	2.6%
I would discuss my suspicions with other colleagues and get their perspectives before I decided whether or not to report a colleague I suspected of research misconduct to an institutional official.		
Strongly Agree	2,067	15.3%
Agree	7,159	53.0%
Disagree	3,545	26.2%
Strongly Disagree	344	5.5%
I would immediately report a colleague to an institutional official if I had the slightest suspicion that the person was involved in research misconduct.		
Strongly Agree	148	1.1%
Agree	668	4.9%
Disagree	6,843	50.6%
Strongly Disagree	5,867	43.4%

The first statement asked whether a researcher would have to be absolutely sure that a colleague had committed research misconduct before he or she would make an allegation about the colleague's research activity to an institutional official. The vast majority agree with the statement. Almost half (49.6%) strongly agree with the statement

and another 41.7% just agree it with setting the bar at absolute certainty before making a formal allegation to an official of the medical school. Only 8.8% say they disagree or strongly disagree.

In the second statement, the possibility of discussing one's suspicion with the colleague who is suspected of misconduct is raised as a preliminary step to going to an institutional official. Such action would accord the colleague an opportunity to correct an error or a misperception, but it would also provide a warning that someone suspected something and give the colleague an opportunity to better cover up the wrongdoing. While a majority of the researchers still agree with the statement, fewer of them do and they do so less strongly. Only 18.3% strongly agree with the statement and 53.5% just agree with it. More than a quarter disagree or strongly disagree (27.2%) with the statement, possibly because they recognize the risk of triggering a cover up of the misconduct by raising the issue with the colleague rather than allowing an institutional official trained to address such issues do it.

The third statement suggests discussing the suspicion with other colleagues to get other perspectives to consider before deciding on whether or not to report the suspected colleague to an institutional official. The response of researchers was only a little less in agreement with this statement than with the second statement. This may be because some researchers recognized that discussing it with colleagues, some of whom did not maintain strict confidentiality, could lead to leaks to the suspected wrongdoer with a resulting effort to cover up, as well as be seen as a violation of the pledge of confidentiality that is supposed to surround allegations of research misconduct. Just 15.3% of researchers strongly agree with the statement and 53.0% just agree with it. Nearly one-third of researchers disagree or strongly disagree (31.8%) with the statement.

The final statement demonstrates the most commitment to immediately reporting suspected research misconduct to an institutional official. This was by far the strongest statement of action to be taken when misconduct is suspected. As might have been expected from the responses to the first statement requiring absolute certainty about the misconduct as a condition of going to the officials, only a very small number of researchers (6.0%) strongly agree or just agree with this statement that has even the slightest suspicion as the trigger to report the colleague to institutional officials. Just about half disagree with the statement (50.6%), and 43.4% strongly disagree.

We created an index to summarize the researchers' inclination to report possible research misconduct based on their responses across these four different statements on how they would respond to the situation they faced. The index was formed by scoring the responses as strongly agree = 1, agree = 2, disagree = 3, and strongly disagree = 4, and summing across the four items. The scoring on the fourth item was reversed to be consistent with the others, e.g., with the low score showing greater inclination to not report

misconduct to an institutional official. Table 9-2 shows that the index scores range from 4 to 16, with almost half (47.1%) scoring 7 or less, and 52.9% scoring 8 or more.

Table 9-2. Index of Researcher Inclination to Report Allegation of Research Misconduct to the Designated Institutional Official.

Inclination To Report Research Misconduct Index Score	Weighted Number	Weighted Percent
4 (Low)	636	4.7%
5	994	7.4%
6	1,807	13.4%
7	2,911	21.6%
8	3,302	24.5%
9	2,177	16.2%
10	1,040	7.7%
11	402	3.0%
12	156	1.2%
13	32	0.2%
14 – 16 (High)	22	0.1%

10. ABILITY TO IDENTIFY AND WILLINGNESS TO REPORT LIKELY RESEARCH MISCONDUCT

One way to gauge how effectively the medical school has been in carrying out its responsibility under the Federal regulations requiring it to educate its researchers in what constitutes research misconduct is to assess how well researchers are able to recognize likely or possible research misconduct and how willing they are to report it to the appropriate person. These are after all the ultimate goal of the institution's research misconduct policy educational effort.

To do this, we worked with our consultant to create nine brief scenarios which were intended to represent a mix of bad research practice and research misconduct. We expected researchers who were well versed in the Federal regulations that define research misconduct, would be able to distinguish the situations representing bad practice from the ones illustrating likely research misconduct. Based on the information we provided, in only four of the nine scenarios was research misconduct in line with the Federal definition being represented. In this section of the study report, we review the scenarios and how the researchers responded to them (Table 10-1).

We conclude with a discussion of an index that we propose to represent the overall knowledge level reflected in the responses of researchers to all nine of the scenarios (Table 10-2). The index is based on the correct identification of each scenario as either representing likely research misconduct or not. In addition, we also review the researchers willingness to report likely research misconduct to the designated institutional official when they do correctly identify a scenario as likely research misconduct (Table 10-3).

10.1 Scenarios to Gauge Recognition of Likely Research Misconduct

In the first scenario, the person monitoring the store of radioactive materials becomes aware that a colleague is reporting in a research report more persons receiving doses of radioactivity in an experiment than would be possible with the amount of material available for use. We intended this to be an example of likely research misconduct (falsification) because the person monitoring the radioactive material knew how much radioactive material would have been needed for the number of persons presumably doses. Half (50.7%) of the researchers agree that it represents likely research misconduct. There seems to be general agreement that it is not likely research misconduct (6.7%). However, a large percentage says they don't know (42.6%). While it could represent an error on the report author's part, making an allegation could work to clear that up, since honest errors, unlike an intentional deception, do not result in any sanctions being applied.

Table 10-1. Researchers Identification of Likely Research Misconduct in Scenarios

Scenario Number/Response	Weighted Number	Weighted Percent
<p>1. You are responsible for tracking the radioactive materials received in the labs. It is normal procedure for your colleagues to circulate all manuscripts to lab staff for review and comments. In your review of a colleague's manuscript, you notice that there are more subjects involved in experiments using radioactive iodine than were discussed in the lab meeting. You also know that no radioactive stocks have come into the laboratory during the proceeding weeks. You calculate the quantity of radioactive iodine that would have had to be used with the subjects in the experiments and conclude that this was not possible.</p>		
Likely Research Misconduct	6,657	50.7%
Not Likely Research Misconduct	879	6.7%
Don't Know If Research Misconduct	5,590	42.6%
<p>2. A colleague is clinical investigator on a drug trial sponsored by a pharmaceutical firm. The drug appears to show some efficacy but also has some potentially serious side-effects. A resident tells you that your colleague is recruiting patients into the trial without disclosing to them the existence of a consulting contract with the firm.</p>		
Likely Research Misconduct	9,568	73.0%
Not Likely Research Misconduct	1,421	10.8%
Don't Know If Research Misconduct	2,117	16.2%
<p>3. A colleague of yours is doing a study involving guinea pigs. You know that the Institutional Animal Care and Use Committee discussed the study at length because it potentially involved inflicting some serious pain and suffering on the animals. The Committee approved the study after your colleague agreed to procedures that would substantially minimize pain and suffering. You've learned that your colleague is not actually using these procedures.</p>		
Likely Research Misconduct	10,730	82.1%
Not Likely Research Misconduct	1,084	8.3%
Don't Know If Research Misconduct	1,264	9.7%
<p>4. You are working on a series of related neurophysiology studies in a research group led by a more senior investigator. At a series of group meetings, the group leader assigned leadership and authorship for each of the studies and the expected resulting manuscripts. The group leader then confirmed the assignments with an e-mail to the group. You were assigned one set of experiments and first authorship on the two manuscripts expected to result from them. You conduct the experiments, draft both manuscripts, and send them to the group leader for review. In return, the group leader tells you that he has decided to be first author on both manuscripts despite being only minimally involved in conducting the experiments and writing the manuscripts.</p>		
Likely Research Misconduct	5,592	43.0%
Not Likely Research Misconduct	4,673	35.9%
Don't Know If Research Misconduct	2,738	21.1%
<p>5. A colleague of yours learned that a technician made up test results and combined them with some legitimate data to make the table in a grant proposal more convincing. The colleague dismissed the lab technician, but because the grant application was due the next day, submitted the grant application as it was with the intention of correcting it later.</p>		
Likely Research Misconduct	11,178	86.2%
Not Likely Research Misconduct	570	4.4%
Don't Know If Research Misconduct	1,225	9.4%

(continued)

Table 10-1. Researchers Identification of Likely Research Misconduct in Scenarios (continued)

Scenario Number/Response	Weighted Number	Weighted Percent
<p>6. You head a central data storage and analysis center serving a number of departments. You notice that the statistical tables for two different experiments included in a colleague's manuscript look identical. You point that out to him. He says it was the result of a file error and that he will fix it. Several months later you happen to see the actual publication and the tables for the two experiments have been substantially changed. Curious, you look to see what data files for this work your colleague has sent recently to the data storage facility. There are none that look like those in the publication, and the files you previously found problematic have been deleted.</p>		
Likely Research Misconduct	7,855	61.0%
Not Likely Research Misconduct	457	3.6%
Don't Know If Research Misconduct	4,566	35.5%
<p>7. You and a colleague have been working together on a clinical trial. As you are writing up the results, you find you have a major disagreement with how your colleague plans to interpret the data. You strongly believe that your colleague is wrong, even misleading, and that her interpretation should not be published because it could lead other researchers down a useless path and give false hopes to patients. Your colleague tells you that she intends to publish the data and her interpretation, and since you disagree, you are welcome to do the same.</p>		
Likely Research Misconduct	861	6.7%
Not Likely Research Misconduct	10,029	78.1%
Don't Know If Research Misconduct	1,944	15.2%
<p>8. You have recently initiated a working relationship with a new collaborator. One day, as you enter the collaborator's lab, you overhear his two post-docs talking about your joint research project. They sound defeated and annoyed. One says "This study is no different than all the others we have done. Again, we need to figure out how to get the results he wants to demonstrate." The other responds, "We just will have to figure out what data points to omit so that he gets the results he wants. I really thought this time it would be different because his new collaborator is so well respected by his post-docs."</p>		
Likely Research Misconduct	9,830	76.7%
Not Likely Research Misconduct	774	6.0%
Don't Know If Research Misconduct	2,221	17.3%
<p>9. You are the principal investigator on an NIH-funded study to examine the incidence of a serious communicable disease in minority sub-populations in several cities. In examining your data set it appears that one of the project's interviewers is very productive and is conducting more interviews than the interviewers in the other four sites. You do a random audit of that interviewer's work and discover that, although the interviews had only recently been conducted, one address is an abandoned house, several phone numbers are either not working or not correct, and in six repeat interviews you are told that the respondent never talked with an interviewer.</p>		
Likely Research Misconduct	12,003	94.0%
Not Likely Research Misconduct	205	1.6%
Don't Know If Research Misconduct	563	4.4%

Scenario two states that a colleague has presumably failed to reveal a potential conflict of interest to participants in a clinical trial being conducted for a pharmaceutical company. A large majority (73.0%) of the researchers indicate that it represents research

misconduct and only 16.2% say they do not know if it does. Conflicts of interest are considered unethical behavior by most institutions, and may be prohibited by medical school policy, but it is not research misconduct according to Federal regulations. Only 10.8% of researchers correctly report that it is likely not research misconduct.

The third scenario depicts a situation in which it becomes known that a colleague performing an experiment that potentially will cause pain and suffering to laboratory guinea pigs is not adhering to the procedures prescribed by the Institutional Animal Care and Use Committee as a condition of its approval to conduct the experiment. An even larger majority than for scenario two (82.1%) say that this scenario portrays likely research misconduct. Very few (8.3%) indicate that it does not likely represent research misconduct, and a similarly small percentage say they don't know. Despite the large percentage of researchers judging this scenario to portray research misconduct, it does not meet the Federal definition. However, it is unethical behavior and quite likely in violation of institutional rules as it violates the conditions for conducting the research established by the institution and agreed to by the colleague, but it is not defined as research misconduct.

In scenario four, there is an authorship dispute between a senior researcher leading a research group and someone more junior working on the same research project. The senior researcher assigned primary authorship and manuscript preparation responsibilities to the more junior colleague for two manuscripts and then, after the writing was completed, decided to be credited as the first author. There is a fairly close split between the researchers who indicate this represents likely research misconduct (43.0%) and those who say that it is not likely to be research misconduct (35.9%). More than one-fifth (21.1%) says they do not know whether it is. This scenario also does not constitute research misconduct according to the Federal regulations. Admittedly, this bait and switch behavior is not a good way to treat colleagues or gain the allegiance and respect of more junior colleagues. Institutions (and journals as well) often have authorship determination guidelines that may be applied to situations such as this.

In the fifth scenario, a colleague submits a grant proposal knowingly containing made up test results because there was not time before the deadline to correct it. While the colleague dismissed the person who fabricated the data and intended to correct the table with the made up data, submitting the proposal represents research misconduct ("fabrication") according to the Federal regulations. A large majority of the researchers (86.2%) correctly identified this behavior as representing research conduct, and only a very small percentage (4.4%) indicate that it is not likely to be. Somewhat more (9.4%) say they do not know whether it constitutes research misconduct.

The sixth scenario revolves around a person who works in a central data and analysis center. This person notices that two different tables in a colleague's manuscript look identical. The colleague says it was a file error and that he will fix it, but when the

publication comes out both tables are substantially different. A check of the data files does not reveal any tables like those in the publication and the files that produced the presumable “erroneous” tables are missing. We developed this scenario to represent likely research misconduct (“fabrication”) according to the Federal regulations. A full 61.0% report that this scenario is an example of likely research misconduct, and only 3.6% say it is not likely to be research misconduct. However, more than one-third (35.5%) indicate that they do not know whether it is likely research misconduct.

In scenario seven, two research colleagues are working on an experiment together. When it comes time to report the results, they have a major disagreement on the interpretation to be given to the data. Both believe that the other’s interpretation is wrong and that its publication will lead researchers down the wrong path, yet they both intend to publish the results with their own interpretation. The vast majority of researchers (78.1%) correctly recognize this scenario as a situation that is not likely to be research misconduct. Honest disagreement on the meaning of research results does not constitute research misconduct according to the Federal regulations. Only a small percentage (6.7%) indicates it is likely research misconduct, and 15.2% says they don’t know whether it represents research misconduct.

Scenario eight involves a researcher who overhears a discussion between post-docs complaining about one of the researcher’s new collaborators. From the sound of the discussion, this collaborator may have in the past pressured the post-docs to alter data to give her the results she wanted. They were regretful that, despite the researcher’s good reputation, that the new collaborator may be expecting the post-docs to alter the data to give her the results she wants again. While this may sound like research misconduct, the alteration of data has not yet occurred. More than three-quarters (76.7%) of the researchers mistakenly indicate that this scenario illustrates likely research misconduct, only 6.0% indicate that it is not likely research misconduct, and 17.3% say they do not know if it is or isn’t. If there was an allegation being made about something that happened then it would represent falsification which is research misconduct according to the Federal regulations, but it has not happened, at least not yet.

The ninth and final scenario involves a situation in which a field interviewer for a public health study is exceptionally productive. Upon closer review and audit, the interviewer is found to not have spoken with persons presumably interviewed and presumably interviewed persons in what was an abandoned dwelling. The vast majority of researchers (96.0%) correctly recognized this as an example of research misconduct (fabrication). Only a very small percentage (1.6%) mistakenly report it as not likely research misconduct, and nearly as few (4.4%) say they don’t know if it is or is not research misconduct.

10.2 Creation of an Index to Measure Identification of Likely Research Misconduct

To create a variable reflecting how accurately researchers are able to distinguish between research misconduct as defined in the Federal regulations and just plain bad scientific practice and other forms of misconduct, we created an index based on their responses to the nine items. The index was created by summing the number of items correctly identified as likely research misconduct or not likely research misconduct for the researchers who answered all nine items. Don't Know responses were always treated as incorrect. The index scores ranged from 0 to 9. At the high end of the index scores (7, 8 or 9), only 5.5% correctly distinguished between research misconduct and other bad research practices. Another 12.5% achieved an index score of 6 correct choices, while 26.1% more have an index score of 5 correct choices.

Returning to the low end of the index score range (0, 1, or 2) shows it represented by 8.3% of researchers. An additional 18.6% scored 3 correct specifications out of the 9 items, and 28.9% had 4 correct responses. Splitting the bell-shaped distribution of index scores at between 4 and below (55.8% forming the low group) and 5 and above (44.2% comprising the high scoring group) is as close to a median split dichotomy as possible.

Table 10-2. Researchers Ability to Distinguish Bad Research Practice from Likely Research Misconduct

Likely Research Misconduct Index Score	Weighted Frequency	Weighted Percentage
0	80	0.6%
1	174	1.4%
2	802	6.3%
3	2,368	18.6%
4	3,672	28.9%
5	3,318	26.1%
6	1,590	12.5%
7	503	4.0%
8	187	1.5%
9	15	0.1%

10.3 Reporting Likely Research Misconduct to the Institutionally Designated Official

In an effort to gauge the propensity of researchers to make research misconduct allegations (presumably to a person that ORI would typically refer to as the research integrity officer or RIO), we asked everyone who correctly identified one of the four items representing research misconduct according to the Federal regulations what they would do in that situation. They could respond: talk to the alleged wrongdoer, talk to the alleged wrongdoer's supervisor, report the allegation to the designated institutional official, or do

nothing. The response of researchers who correctly identified the scenario as representing likely research misconduct is reported for each of the four items.

For Scenario 1, the majority of researchers (58.4%) say they would talk with their colleague while another 32.5% say they would talk with the colleague’s supervisor. A remarkably small 9.0% of the researchers who correctly identified the behavior represented as likely research misconduct according to Federal regulations indicate they would make an allegation to the designated institutional official.

Table 10-3. Researchers’ Responses to Correctly Identifying Research Misconduct.

What Would You Do In Response to This Scenario?	Weighted Number	Weighted Percentage
Scenario 1		
Talk to colleague	3,904	58.4%
Talk to colleague’s supervisor	2,174	32.5%
Report to designated official	601	9.0%
Nothing	3	<0.1%
Scenario 5		
Talk to colleague	5,467	48.9%
Talk to colleague’s supervisor	2,440	21.8%
Report to designated official	2,873	25.7%
Nothing	396	3.5%
Scenario 6		
Talk to colleague	2,406	30.6%
Talk to colleague’s supervisor	2,307	29.3%
Report to designated official	3,101	39.4%
Nothing	54	0.7%
Scenario 9		
Talk to interviewer	2,953	24.6%
Talk to interviewer’s supervisor	4,997	41.7%
Report to designated official	4,034	33.6%
Nothing	6	0.1%

In response to Scenario 5, a somewhat larger percentage of researchers (25.7%) say they would make a research misconduct allegation to the designated institutional official. However, almost a majority (48.9%) would again opt to talk with the colleague while 21.8% say they would speak to the colleague’s supervisor.

For Scenario 6, the largest percentage (39.4%), but far from a majority, indicates that they would make an allegation of research misconduct to the designated institutional official. The percentages indicating they would opt to talk with the colleague or the colleague’s supervisor are very similar (30.6% and 29.3%, respectively).

In Scenario 9, more than one-third (33.6%) indicate that they would make the report of research misconduct to the designated institutional official, while almost one-

quarter (24.6%) say they would talk with the interviewer. The largest proportion (41.7%) says they would talk with the interviewer's supervisor. While the percent that would go the designated institutional official is never the majority of researchers but varies widely from scenario to scenario, it is encouraging to note that the percent who say they would do nothing in the face of witnessing likely research misconduct is uniformly very small, ranging from 0.1 % to 3.5%.

We also created an index to reflect the likelihood of researchers who correctly identified scenarios representing likely research misconduct to say they would report it to the designated institutional official. The index scores range from 0 (would report none) to 4 (would report all four).

Table 10-4. Number of Times that Researchers Who Correctly Identify Likely Research Misconduct in Scenarios Say They Would Report It to the Designated Institutional Official

Number of Correctly Identified Research Misconduct Scenarios Researchers Say They Would Report to the Designated Institutional Official	Weighted Number	Weighted Percent
0	6,713	52.2%
1	3,115	24.2%
2	1,903	14.8%
3	871	6.8%
4	269	2.1%

Only a very small percentage (2.1%) of researchers say they would report all four likely research misconduct scenarios to the designated institutional official and just slightly more (6.8%) say they would report three of the four. On the other hand, more than half of the researchers (52.2%) indicate that, despite recognizing up to four scenarios as representing likely research misconduct, they would report none of them to the designated institutional official. In addition, almost one quarter (24.2%) say they would only report one of the likely research misconduct scenarios to the designated institutional official, and another 14.8% say they would report only two.

In summary, researchers seem to have a more expansive view of the Federal regulations' definition of research misconduct than is the reality. While reasonably large percentages correctly identify research misconduct according to the Federal regulations, large percentages also mistakenly identify as likely research misconduct what is admittedly bad research behavior that is not defined as research misconduct by the Federal regulations. When asked about what they would do upon correctly identifying likely research misconduct, fairly consistently, the vast majority of researchers say they would talk with the alleged perpetrator or the perpetrator's supervisor rather than reporting it to the institutional official designated to handle allegations of research misconduct. Such actions

could result in the unintended consequence of having the likely research misconduct covered-up rather than resolved according to institutional policy.

11. ASSOCIATIONS AMONG RESEARCHER KNOWLEDGE, EXPOSURE TO POLICY, PERCEPTIONS OF THE INSTITUTION'S EFFORT, AND ACCESS TO AND THOROUGHNESS OF THE INSTITUTION'S RESEARCH MISCONDUCT POLICY

11.1 Objective

To this point in the study we have examined the demographic and professional characteristics of researchers in US medical schools as well as how they say researchers learn about their institutions' research misconduct policy and procedures. We also probed how much they know about their institution's research misconduct policy and procedures and elements of the Federal definition of research misconduct. In addition, we have examined the extent of involvement that researchers have had with actual misconduct proceedings in a variety of possible roles as well as the perceptions researchers have about the effectiveness of the effort that their institutions have put into administering their research misconduct policy and educating their research staff about research misconduct (e.g., what it is, how to identify it, and when to report it to a designated institutional official). We have also looked at how able researchers are to recognize likely research misconduct and distinguish it from bad or unethical research activity. In addition, we have also described characteristics of the institution's research misconduct policy that is posted on the internet, and the intensity of its NIH research grant activity. In this section we have examined the extent to which there are associations between these different measures and researchers being more positive in their perceptions of the efforts of their institution to meet their legislative obligations.

11.2 Conceptual Approach

We chose to collect data in the survey on how researchers in medical schools learn about their institution's research misconduct policy because we anticipated that the amount and type of exposure to the policy would have an impact on the amount of knowledge they have of their institution's research misconduct policy and procedures, their own ability to identify research misconduct when they see it, as well as their perception of the institution's efforts to administer and impart its research misconduct policy to its research staff. Further, we expected that more effective types of exposure would be associated with a fuller understanding of research misconduct and a greater knowledge of key aspects of the institution's misconduct policy. We expected that a greater capability and willingness on the part of researchers to identify and report suspected research misconduct would also be associated with how the researchers perceived their institution's efforts to disseminate its policy. We anticipated that knowing more about the institution's policy and the meaning of research misconduct would contribute to a more positive perception of the effectiveness of the institution's efforts to administer its policy and educate its researchers.

11.3 Analytic Approach

To assess the impact of the institution’s efforts, we divided the perceived effectiveness of institutional efforts scale into high and low halves as close as possible to the median scale score. Then we specified a logistic regression statistical model to predict whether the researcher’s perception of their institution’s effort was in the high or low half of the scale score range. Our predictors included selected demographic, professional and other person-specific characteristics as control variables or co-variates. This was an effort to control on the effects, if any, of variables not amenable to policy manipulation by the institution. Then we specified a set of exposure, knowledge, research misconduct experience, and other predictor variables that we felt were more open to policy changes that could actually influence researchers to perceive the efforts of their institution in a more positive light. We also included how well researchers were able to identify likely research misconduct as a predictor in the model, on the expectations that being able to do it would be evidence of the effectiveness of the institution’s effort. In addition, we included some measures of the institutional context or environment. Table 11-1 specifies the variables that we included in the initial model that was tested. In the final step of the modeling, we removed the effects of variables that were not significant, one at a time, parsing until only significant predictors remained.

Table 11-1. Variables Included in the Initial Logistic Regression Model

Variable Names	Response Categories	Unweighted Number	Percentage
Researcher Demographic and Professional Characteristics			
Age Group	<45 Years	722	14.7%
	>= 45 <55	2,005	40.7%
	>= 55 <65	1,576	32.0%
	>=65	618	12.6%
Gender	Male	3,548	71.5%
	Female	1,415	28.5%
Current Research Activity	Basic Science	3,943	78.2%
	Clinical Research	1,099	21.8%
	Ass’t/Assoc		
Academic Rank	Professor	1,809	36.6%
	Full or Emeritus		
Time Worked at Institution	Professor	3,129	63.4%
	<5 Years	511	10.2%
	>=5-9 Years	1,107	22.1%
	>=10-14 Years	1,033	20.6%
	>=15-24 Years	1,435	28.6%
Participated in Responsible Conduct of Research (RCR) Training	>= 25 Years	924	18.4%
	No	2,046	45.5%
	Yes	2,058	45.8%
	Don’t Know	388	8.6%

**Table 11-1. Variables Included in the Initial Logistic Regression Model
(continued)**

Variable Names	Response Categories	Unweighted Number	Percentage
Number of Research Grants Has Been a Principal Investigator	<5	3,352	66.6%
	>=5 and <10	1,387	27.5%
	>=10	296	5.9%
Dependence of Position on Research Grant Funding	Not at All	934	18.7%
	Dependent for less than half of Salary	1,289	25.8%
	Dependent for Half my Salary	1,709	34.2%
	Salary is Fully Dependent	1,064	21.3%
Predisposition to Report Misconduct	Low 4-6	1,076	25.2%
	Medium 7-8	1,953	45.7%
	High 9-16	1,237	29.0%
Predictor Variables-Behaviors Associated with the Extent and Nature of Exposures to the Policy			
Read Research Misconduct Policy and Procedures	Yes, read them fully.	2,212	44.6%
	Yes, read them in part.	2,238	45.1%
	No, have not read them at all.	509	10.2%
Familiarity with 5 Aspects of Institution's Policy	Low 5-13	1,626	33.3%
	Medium 14-16	1,900	38.9%
	High 17-20	1,356	27.8%
Correctly Identified Elements of Definition of Research Misconduct	Low 1-4	1,993	39.1%
	Medium 5-6	1,617	31.7%
	High 7-10	1,490	29.2%
When Researchers First Exposed to Policy	First Days	674	14.5%
	First Month	1,057	22.8%
	Within First Year	535	11.5%
	Never Formally	409	8.8%
	Don't Know or Time Not Specified	1,963	42.3%
Doesn't Know if Issues Covered in Policy	Low 0-2	2,237	48.0%
	High 3-6	2,424	52.0%

**Table 11-1. Variables Included in the Initial Logistic Regression Model
(continued)**

Variable Names	Response Categories	Unweighted Number	Percentage
Format Used to First Expose Researchers to Policy	Printed Faculty Manual	662	16.0%
	Electronic Faculty Manual	820	19.8%
	On-Line Course	945	22.8%
	Live Group Discussion/ Workshop/ One on One	492	11.9%
	Don't Know	1,222	29.5%
Context Researchers are Exposed to the Policy: Group Orientation	Yes	1,746	34.2%
	No	3,354	65.7%
Upon Award of New Grant	Yes	833	16.3%
	No	4,267	83.7%
IRB Continuing Education	Yes	1,214	23.8%
	No	3,886	76.2%
RCR Course	Yes	1,175	23.0%
	No	3,925	77.0%
All Hands Meeting	Yes	112	2.1%
	No	4,988	97.8%
Distribution of Printed Policy on Paper or Electronically	Yes	1,374	26.9%
	No	3,726	73.1%
E-mail Notice and Referral to a Website	Yes	1,370	26.9%
	No	3,730	73.1%
Ever Required to Review Policy	No	2,198	48.7%
	Yes	1,864	41.3%
	Don't Know	449	10.0%
Annually Certify Policy Review	No	1,766	39.2%
	Yes	1,374	30.5%
	Don't Know	1,365	30.3%
Policy Available on Website	Yes	3,297	72.7%
	No/ Don't Know	1,239	27.3%
Policy Available in Library or Public Location	No	179	3.9%
	Yes	2,480	54.5%
	Don't Know	1,889	41.5%
Opportunity to Attend Workshop, Class, or Live Presentation to Clarify or Ask Questions about Policy	No	434	10.7%
	Yes	1,911	46.9%
	Don't Know	1,726	42.4%
Been a Respondent	No	3,918	91.4%
	Yes	367	8.6%
Been a Complainant	No	3,793	88.5%
	Yes	491	11.5%

Table 11-1. Variables Included in the Initial Logistic Regression Model (continued)

Variable Names	Response Categories	Unweighted Number	Percentage
Been a Witness	No	3,757	87.8%
	Yes	524	12.2%
Been a Committee Member	No	3,468	81.0%
	Yes	812	19.0%
Research Misconduct Index from Nine Brief Scenarios	Low 0-4	2,234	55.6%
	High 5-9	1,781	44.4%
Institutional Environment Measures			
Number of NIH Research Grants in 2005-06	Low <=250	1,119	22.3%
	High >50	3,892	77.7%
Number of Minutes to Locate Policy Online	Low < 3	2,439	50.8%
	High >=3	2,363	49.2%
Breadth and Depth of Information included Online	High Breadth and High Depth	2,308	48.1%
	High Breadth and Low Depth	314	6.2%
	Low Breadth and High Depth	364	7.6%
	Low Breadth and Low Depth	1,816	37.8%

The demographic, professional, and other potentially important researcher characteristics we had in the initial model as control variables or co-variates include: age group, gender, whether conducts basic science or clinical research, academic rank, how long has been working at the institution, whether ever participated in a responsible conduct of research (RCR) course, the number of research grants on which has been the principal investigator during the past 10 years, dependence of position on research grant funding, and predisposition to report misconduct to institutional officials.

The predictor variables that we have selected from the researcher survey to represent behaviors associated with the extent and nature of exposure to the institutions' research misconduct policy and procedures include: how fully the policy was read, the self-reported level of familiarity with five specific aspects of the institution's research misconduct policy, the level of knowledge of the elements constituting the Federal definition of research misconduct, the number out of six specific elements about the institution's research misconduct policy that researchers say they don't know, how quickly researchers are introduced to the institution's research misconduct policy, the format through which new researchers are typically first exposed to the policy, the context in which researchers are exposed to the institution's policy, whether the researchers have ever been told that they must review the policy, whether researchers must certify annually that they have reviewed the policy, whether researchers say that the policy is available on the internet or in a

printed handbook available in a public place like a library, whether researchers have an opportunity to attend a live meeting about the institution's policy where they are able to ask questions and get clarification of it, whether the researcher has ever been involved in any way in a research misconduct proceeding (e.g., as a respondent, complainant, witness, or committee member), and how many out of nine scenarios researchers were able to distinguish likely research misconduct from bad or unethical research conduct.

We have also included several variables that we propose represent aspects of the institutional environment. One that is intended to represent the intensity of the biomedical research environment of the institution is based on the number of research grants awarded to principal investigators from the institution. Two others are based on information gleaned from the research misconduct policies we located and abstracted from the internet. One of these is an indicator of ease of access to the policy on-line, i.e., the number of minutes it took the abstractor to locate the policy. We also wanted to investigate whether the breadth and depth of the information included on the policies posted on-line were associated with how well disposed researchers are toward their institution's efforts. Because these variables were very highly correlated, we cross-tabulated them and created a four cell typology of these two dimensions to examine any association of these categorical types with researcher perception of the effectiveness of the institution's policy implementation and education efforts.

11.4 Results of the Analysis

The results of the logistic regression model parsed of non-significant predictors and covariates are presented in Table 11-2. The overall model is highly significant (Wald F test = 23.40, df = 23, p-value = 0.0000) and the pseudo-R² = 0.215. This means that the variables in the model reduce errors in the prediction of whether researchers assess the effectiveness of their institution's effort to implement and propagate its research misconduct policy to be among those rated in the top half rather than the bottom half of scale values by 21.5%.

Only one of the covariates representing a characteristic of medical school researchers – academic rank – is significant and remains in the model. The odds ratio of 1.50 can be interpreted to mean that the odds of a researcher at the rank of full or emeritus professor perceiving the efforts of the institution to administer and promote its research misconduct policy to be in the high half of the distribution are 50% higher than the odds of the same perception occurring among researchers at the assistant or associate professor level. A number of other researcher characteristics including age, research grant success, and gender are modestly associated with rank and are at least partially controlled for in the model with this variable.

Table 11-2. Statistically Significant Variables Remaining in the Final Parsed Logistic Regression Model

Variable Names/ Response Categories	Odds Ratio (95% Confidence Interval)	Wald F-Test	P-Value
Researcher Demographic and Professional Characteristics			
Academic Rank		10.53	0.0000
Assistant/Associate Professor	1.00		
	1.50		
Full/Emeritus Professor	(1.26-1.79)		
	1.05		
All Other Positions	(0.55-2.02)		
Researchers' Reported Familiarity with, Exposure to, and Availability of Institutional Policy			
Index of Familiarity with Institution's Policy (5 items)		21.63	0.0000
Low (5-13)	1.00		
	1.56		
Medium (14-16)	(1.27-1.92)		
	2.26		
High (17-20)	(1.77-2.88)		
Index of Don't Know Policy Items (6 items)		32.24	0.0000
Low (0-2)	1.00		
	0.60		
High (3-6)	(0.50-0.71)		
When Researchers First Exposed to Policy		15.48	0.0000
	1.53		
First Few Days of Work	(1.17-2.00)		
	1.68		
First Month of Work	(1.34-2.09)		
	1.34		
In First Year of Work	(1.02-1.75)		
	0.42		
Never Formally Exposed	(0.30-0.59)		
Don't Know/No Time Specified	1.00		
Ever Been Required to Review Policy		4.02	0.0180
No	1.00		
	1.31		
Yes	(1.09-1.57)		
	1.08		
Don't Know	(0.81-1.43)		
Annually Certify Have Reviewed Policy		12.29	0.0000
No	1.00		
	1.67		
Yes	(1.35-2.07)		
	1.41		
Don't Know	(1.14-1.73)		
Policy on Web Site		14.19	0.0002
	1.48		
Yes (internal or external or both)	(1.21-1.81)		
No or Don't Know	1.00		

Table 11-2. Statistically Significant Variables Remaining in the Final Parsed Logistic Regression Model (continued)

Variable Names/ Response Categories	Odds Ratio (95% Confidence Interval)	Wald F-Test	P-Value
Policy in Printed Handbook and Readily Available			
	0.46 (0.29-0.75)	14.62	0.0000
No			
Yes	1.37 (1.16-1.63)		
Don't Know	1.00		
Can Attend Live Policy Presentation			
	0.73 (0.53-1.00)	16.41	0.0000
No			
Yes	1.51 (1.26-1.80)		
Don't Know	1.00		
Ever Been A Complainant			
No	1.00	16.56	0.0000
Yes (This Place, Elsewhere, or Both)	0.59 (0.46-0.76)		
Measures of Medical School Context			
Policy Breadth/Depth Typology		7.93	0.0000
High Breadth and High Depth	1.00		
High Breadth and Low Depth	0.60 (0.42-0.86)		
Low Breadth and High Depth	0.62 (0.46-0.86)		
Low Breadth and Low Depth	1.17 (0.98-1.40)		

The largest block of significant variables in the model is associated with measures of the researchers' level of familiarity, experience, and exposure to the policy. The first of these is the five item index score based on researchers self-reported level of familiarity with key aspects of their institution's research misconduct policy. The 1.56 odds ratio for the medium scoring group of researchers means that they have 56% higher odds than the group scoring low to perceive the effectiveness of their institution's effort as being in the high half of the distribution. Researchers whose level of familiarity with the same five items of the policy is high have an odds ratio of 2.26. This indicates that they have 126% higher odds than the low familiarity group of perceiving the effectiveness of their institution's effort as being in the high half of the distribution. Much the same situation is represented by the index based on the number of their institution's policy items that the researchers say they do not know, with the higher score reflecting greater policy ignorance. Hence, the 0.60 odds ratio means that researchers scoring high on the number of don't know responses have 40% lower odds of perceiving their institution's efforts as being in the high half of the distribution as researchers scoring in the low end of the index.

The earlier researchers are first exposed to the institution's research misconduct policy – first days at work, first month and first year -- the higher the odds (by from 34% to 68%) that they will perceive their institution's effort to be in the higher half of the scale score distribution as compared to researchers who don't know when that exposure occurs. On the other hand, researchers who report that new researchers are never formally exposed to the policy have 58% lower odds of perceiving their institution's effort in the high half of the distribution as compared to researchers who say they don't know when researchers get their first policy exposure.

Researchers who say that they have at some time been directed by their institution to review the research misconduct policy have an odds ratio of 1.31. This indicates that they have 31% higher odds of perceiving the effectiveness of their institution's efforts to implement and disseminate their research misconduct policy to be in the high half of the score distribution than is true for those who have never been directed to review it. The impact of having to annually certify that one has reviewed the policy is even greater. Researchers who say they are required to certify annually they have reviewed the policy have an odds ratio of 1.67, indicating that they have 67% higher odds of perceiving their institution to be in the high half of the scale score distribution than researchers who are not required to certify that they have reviewed the policy annually.

Researchers who are aware of having the research misconduct policy on the institution's web site have 48% higher odds of perceiving their institution's efforts in the high half of the scale score distribution as compared to those who don't know or say it is not on the web site. Researchers who state that their institution has a printed copy of the policy in a handbook and readily available in a library or other public space have 37% higher odds of perceiving their institution's efforts as belonging in the higher half of scale scores than researchers who say they don't know whether this is true of their institution. On the other hand, researchers who say their institution does not have a printed copy of the policy in a handbook that is readily available have 54% lower odds of placing their institution in the high half of the scale score. In addition to having the policy available on the institution's web-site and printed and available, researchers who report that they can attend a live presentation of the policy where they can ask questions and get clarification of the institution's research misconduct policy have an odds ratio of 1.51. This means they have 51% higher odds of perceiving their institution's efforts as being in the high score half of the scale score distribution than is true of persons who say they don't know whether they can attend a live interactive presentation of the policy. It should be noted that the odds ratio for researchers who say they do not have the option of attending a live presentation of the policy is 0.73. This means they have 27% lower odds of perceiving their institution's efforts in the high half of the distribution than researchers who say they don't know.

The final significant variable is whether a researcher has ever been a complainant (“whistleblower”). Rather than the first hand experience of the process providing greater confidence in and support for the efforts of the institution, the odds ratio of 0.59 suggests just the opposite impact. Researchers who have been complainants have 41% lower odds of assessing their institution’s efforts as being in the high end of the scale score distribution as compared to researchers who have never been a complainant.

The final significant variable to discuss is the only significant institutional level variable in the model. It is the product of a cross-tabulation of two measures derived from the abstraction of the medical school research misconduct policies that were found on line and abstracted representing policy breadth (topic areas covered) and depth (details provided). Two of the four cells of the typology are significant in the model. When compared to researchers whose institution’s breadth and depth scores were both in the high half of those measures, only the two cells in which the breadth and depth scores are discrepant – one is high and the other is low – is the odds ratio significant. They are both similar in that they have 40% (high and low cell) and 38% (low and high cell) lower odds of perceiving their institution’s efforts to implement and disseminate their policy as being in the high end of the scale score as is true for the cell where both dimension are high.

In summary, we performed a multivariable analysis employing logistic regression to model a dichotomous measure of how favorably researchers perceive the institution’s efforts to implement and disseminate their research misconduct policy. The variables in the model improve the prediction of the researcher’s perception of their institution’s efforts to implement its policy, as well as to have its researchers know the policy, by more than 21%. The results indicate that researchers who: are in higher ranks, are very familiar with their institution’s policy, are exposed to the institution’s policy early in their employment, have been directed to review the policy, have had to certify to that annually, indicate that their institution makes the policy available on its web-site, makes a printed copy of the policy available in its handbook, gives researchers the opportunity to attend a policy presentation where they can ask questions about and get clarification of the policy are all associated with having higher odds of perceiving the institution’s efforts favorably. On the other hand, not knowing selected aspects of the policy, having been a complainant at some time, and being in an environment where the research misconduct policy available on its web site is either long on policy breadth but short on depth or long on depth and short on breadth are associated with having lower odds of perceiving the institution’s odds favorably.

12. CONCLUSIONS, LIMITATIONS, AND RECOMMENDATIONS

12.1 Conclusions

There are no established standards against which to gauge whether research institutions' efforts are effective for administering their research misconduct policy and to disseminate its research misconduct the policy to its researchers as required by the Federal regulations. In light of this, we undertook to assess how well researchers in institutions were able to do what the institution's policy and its dissemination efforts are supposed to do and to collect researchers' views. We have opted to use two measures as indicators of institutional effectiveness – how well researchers can identify likely research misconduct, and the perception of researchers of their institution's efforts to disseminate its research misconduct policy – in order to explore what factors are associated with these outcomes.

In the process of conducting this study, we have described key demographic and professional differences among the researchers. In addition, we have described the extent to which researchers have experienced the research misconduct process first hand and its impact on their willingness to participate further. We also have described differences in the extent to which researchers have read the institution's research misconduct policy, know key aspects of the policy, and are able to define what is meant by research misconduct. And, we have also described differences in the way researchers report that they are exposed and given access to the institution's research misconduct policy.

From the survey that was conducted, we find that only 44% of the researchers have read their institution's research misconduct policy and procedures in its entirety and that 10% have not read it at all. In response to our request to indicate their level of knowledge of their institution's research misconduct policy and procedures on a continuum running from 0 (know nothing) to 10 (know all) 21% give responses below the midpoint of 5. In response to a query to indicate their level of familiarity (very, somewhat, not very, not at all) with five specific aspects of their institution's policy, 54% say they are not very familiar with any and 81% respond they are very familiar with two or fewer out of the five. In another effort to assess researchers' knowledge of key aspects of the policy, we asked them to identify from a list of ten activities, the ones that constitute research misconduct according to the Federal regulations. More than 20% did not correctly identify falsification, fabrication and plagiarism. When all ten items were scored as correctly identified according to Federal regulations as research misconduct or not research misconduct, 57% have correctly identified half or fewer. In a final effort to gauge researchers' familiarity with their institution's policy, we asked whether the policy addressed six basic issues to which they could reply no, yes, or don't know. We summed the number of don't know responses and found that 52% respond don't know to half or more of the items.

To measure the perception of researchers about the effectiveness of their institution's efforts to administer and disseminate its research misconduct policy to researchers, we prepared ten statements about the adequacy of institution's efforts. We asked researchers to respond whether they strongly agree, agree, don't know, disagree, or strongly disagree. Pretty much across the board for every item, there are at least 30% of researchers who respond in ways that indicate that they do not perceive that the institution's efforts have been adequate to effectively achieve their objective.

To measure whether the researchers are able to discriminate between research misconduct and other improper or unacceptable research behavior, we prepared nine brief scenarios, some of which were made to represent likely research misconduct. We asked researchers to indicate whether they thought each scenario represented likely research misconduct, not likely research misconduct or don't know. For each scenario identified as likely research misconduct, we also asked what action the researcher would take. For the four scenarios correctly identified as likely research misconduct, the percentages saying they would report an allegation to the institutionally designated official to assess (the correct action according to most policies) ranged from only 9% to 39%.

Based on the lack of knowledge of the policy demonstrated by large proportions of researchers, their own perceptions of how effective their institution's efforts have been, and their inability to correctly distinguish between likely research misconduct and other inappropriate research activity, we conclude that the efforts of the institutions have not been adequate to achieve an acceptable level of knowledge about the research misconduct policy.

12.2 Limitations

As with many surveys, the response rate fell short of what we had expected, but only by a couple of percentage points (48% vs. 50%). There were 177 sampled researchers for whom we did not have an e-mail address who never had a chance to respond and were not included in our analysis. We used weights to more fully represent the population of medical school researchers and to accommodate the different levels of non-response from each of the institutions. Because our sampling frame lacked information beyond the school name, post-stratification weighting according to demographic or other characteristics was not possible. Finally, for a few questions in the questionnaire, the item non-response rate approached 20%. Since all derived variables were only calculated for respondents with all needed data present, there are respondents who did not get scored on some variables and who, therefore may not have been included in analyses using that item.

As we noted in the report, there were six institutions whose research misconduct policy we could not access on the internet. Thus they are not included among the medical schools whose policies we abstracted. There were in addition eight other medical schools

whose research misconduct policy did not get abstracted because they did not receive at least 10 NIH research grant awards during FYs 2005 and 2006 combined and hence had no researchers selected for inclusion in the web-based survey.

12.3 Recommendations

12.3.1 Recommendations to the Institutions

Update the policy in areas as directed by a revised model policy from ORI. Incorporate more examples of what actions institution could take under specified circumstances. Want to make complainants comfortable and secure feeling, but also want to be realistic for complainants.

Require researchers to read and certify that they have read the policy upon being hired, thereafter have them annually certify they have reviewed or taken a course or workshop that reviews and tests comprehension of the material.

Make policy more available in printed form and on external internet.

Make more different ways of receiving policy available, including especially face to face small group sessions where scenarios could be discussed and questions could be asked about policy.

Need to take actions to counteract the perception that bad things happen to complainants.

12.3.2 Recommendations to the Office of Research Integrity

Update model policy specifying areas to be enriched so there is more detail on what the institution will do and balance between the treatment of respondent and complainant. Try to make policies more uniform from place to place, but allow for differences in institutions size and structure.

Require institutions to have new researchers read and certify they have read the policy.

Annually require that researchers reread or take a course that will review and test key points of policy.

Investigate why the experiences of respondents, complainants and witnesses are so much negative impact on future willingness to participate than is true for members of the committee doing the inquiry/investigation. Also investigate why complainants have such negative perceptions of their institutions' efforts.

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