# **Scientific Misconduct Investigations**

## 1993-1997

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### Scientific Misconduct Investigations: 1993-1997

#### **EXECUTIVE SUMMARY**

This report presents an analysis of the 150 scientific misconduct investigations closed by the Office of Research Integrity (ORI) from 1993 to 1997. In that period, ORI received about 1,000 allegations that resulted in the opening of 187 cases and the closing of 218. ORI closed more cases than it opened because it inherited cases from a previous office. These 218 cases included 68 inquiries and 150 investigations. The 150 investigations resulted in 76 findings of scientific misconduct and 74 findings of no misconduct.

Ninety-three percent of the investigations involved extramural research, 7% involved intramural research. The primary responsibility of institutions to conduct the investigations was progressively affirmed during the period as the percent of extramural investigations conducted exclusively by institutions steadily rose from 64% to 96%. The primary site of the investigations was medical schools (68%) followed by hospitals (11%) and research institutes (10%). Twenty-one funding mechanisms supported the research under investigation with the traditional grant, the RO1, being most frequently involved.

Falsification was the most frequent type of misconduct that resulted in an investigation, it was involved in four of every five investigations either alone or in combination with other types of misconduct, especially fabrication. Fabrication was the second most frequent type of misconduct that resulted in an investigation, plagiarism was third.

Institutions imposed nine types of sanctions on respondents found guilty of scientific misconduct. The most frequent sanction was termination of employment. Institutions also imposed sanctions on respondents who were not found guilty of scientific misconduct under the Public Health Service (PHS) definition, but were found guilty by institutions under their own definition of academic or scientific misconduct or who failed to comply with other expected behaviors. The most frequent actions taken in these cases were reprimands.

The PHS imposed 170 administrative actions on the 76 respondents found to have committed scientific misconduct under its definition. Fifty-four respondents (71%) were debarred from receiving Federal funding for periods ranging from 18 months to 8 years. Other actions included prohibition from PHS advisory service, 91%, supervised research, 26%, certification of data, 13%, certification of sources, 9%, and correction or retraction of articles, 13%.

Respondents were primarily males holding a Ph.D. or M.D. degree. More than three-fourths of the allegations were made against associate professors, 27%, professors, 19%, postdoctoral fellows, 19%, and technicians, 13%. Fifty percent of the misconduct findings were made against postdoctoral fellows, 28%, and associate professors, 22%, while 59% of the no misconduct findings involved associate professors, 31%, and professors, 28%. Allegations were most frequently supported against students, 73%, postdoctoral fellows, 66%, and technicians, 62%,

and least frequently supported against professors, 19%, and assistant professors, 29%.

Like respondents, whistleblowers were primarily males holding a Ph.D. or M.D. degree. Senior personnel (deans, professors, associate professors) accounted for 47% of the whistleblowers, junior personnel, 21%. Data on about 30% of the whistleblowers were not available. The support rate for allegations made by whistleblowers in most academic ranks was about 50%. Students, however, had a support rate of 100% and technicians had a support rate of 20%.

Fifty-three percent of the inquiries were completed within the 60-day standard, 22% required twice the standard length, and 24% required more than twice the standard length. Inquiries that lasted beyond the standard length were more likely to be followed by an investigation that did not find misconduct. The most frequent size of inquiry panels that preceded investigations was three members. Inquiries conducted by a single person were most frequently (73%) followed by investigations that resulted in a misconduct finding, inquiries conducted by two persons were equally likely to be followed by investigations that found misconduct or no misconduct, while inquiries conducted by three or more persons were more likely to be followed by investigations that did not find misconduct (59%).

Thirty-two percent of the investigations were completed within the 120-day standard, 22% were completed within twice the standard period, and 38% lasted more than twice the standard period. Investigations completed within 180 days were more likely to result in a misconduct finding (61%) while investigations completed in more than 240 days were more likely to produce no misconduct findings (61%). The most frequent panel size in investigations, like inquiries, was three members. Investigations conducted by a single person were most likely to find misconduct (88%), investigations employing panels with two to four members were equally likely to find misconduct or no misconduct, while investigatory panels composed of five or more members were more likely to find no misconduct (66%).

## Scientific Misconduct Investigations: 1993-1997

### INTRODUCTION

The Office of Research Integrity (ORI) has annually published descriptive statistics on its scientific misconduct caseflow and closed investigations in the *ORI Annual Report* since 1993.<sup>1</sup> The descriptive statistics were based on data in the files and investigative reports. Caseflow statistics covered the number of allegations of scientific misconduct received and the number of cases opened and closed. Descriptive statistics were not provided on inquiries because institutions are required by the Public Health Service (PHS) regulation<sup>2</sup> to report an inquiry to ORI only when the inquiry concluded that an investigations, institutional settings, funding mechanisms, types of misconduct, administrative actions taken by institutions and the Federal government, the academic rank, highest degree and gender of respondents and whistleblowers, and panel size and length of inquiries and investigations. These annual statistics did not provide a dependable basis for making reliable statements about the misconduct investigations because of the variation from year to year. This report presents a cumulative 5-year statistical profile (1993-1997) on the caseflow and closed scientific investigations to provide a more dependable basis for making reliable statements about the misconduct investigations.

### CASEFLOW

This section describes the overall caseflow in ORI from 1993 to 1997 which eventually resulted in the closed investigations. It does not include the allegations of scientific misconduct or inquiries that were received by institutions but not reported to ORI because the institution decided that an investigation was unwarranted. When an allegation is made directly to ORI and ORI refers the allegation to an institution for review, ORI requires submission of an inquiry report even when the institution determines an investigation is unwarranted.

### **Allegations of Scientific Misconduct**

Almost 1,000 allegations of misconduct in PHS-supported extramural and intramural biomedical

<sup>&</sup>lt;sup>1</sup>In June 1992, ORI replaced two offices that were established in 1989 to respond to allegations of scientific misconduct in Public Health Service (PHS) supported research - the Office of Scientific Integrity (OSI) and the Office of Scientific Integrity Review (OSIR). ORI issued its first annual report in 1993.

<sup>&</sup>lt;sup>2</sup>Responsibility of PHS Awardee and Applicant Institutions for Dealing With and Reporting Possible Misconduct in Science, 42 C.F.R. Part 50, Subpart A.

and behavioral research were received by ORI during the 5-year period, ranging from 166 to 244 per year and averaging 197. About one in five allegations met the criteria for opening a formal case under the PHS regulation.<sup>3</sup> About one in seven allegations were referred to other offices or agencies because they concerned research that did not involve PHS funding or they alleged misconduct that did not fall under the PHS definition of scientific misconduct.<sup>4</sup> No action was possible on two-thirds of the allegations because they did not contain sufficient specific information to permit another disposition to proceed further, either the whistleblower was unknown or was unable or unwilling to provide additional data or another source of information was not available. The number of allegations received by ORI declined substantially in 1996 and 1997, however, this decline may appear more precipitous than it is because the number of allegations received in 1995 was abnormally high. See Table 1.

### New Cases

The allegations received during this 5-year period resulted in 187 new cases, ranging from 26 to 49 per year and averaging 37. Over the 5 years, 89% of the new cases were referred to institutions, 11% were handled by ORI. Beginning in 1995, there was a substantial shift in the assignment of cases between institutions and ORI resulting from an ORI policy decision to limit its investigations of extramural cases to special circumstances.<sup>5</sup> The PHS regulation assigns the primary responsibility for responding to allegations to institutions, but permits the Department of Health and Human Services (HHS) to conduct its own investigation.<sup>6</sup> In the 3-year period, 1995-

(2) The alleged misconduct meets the definition of scientific misconduct set forth in PHS regulation.

(3) There must be adequate information to proceed with an inquiry.

<sup>4</sup>Misconduct or Misconduct in Science means fabrication, falsification, plagiarism, or other practices that seriously deviate from those that are commonly accepted within the scientific community for proposing, conducting, or reporting research. It does not include honest error or honest differences in interpretations or judgments of data. 50.102.

<sup>5</sup>ORI may conduct the inquiry and/or investigation when the allegation involves multicenter clinical trials, when an institution is unwilling or unable to do so, or under other special circumstances.

<sup>6</sup>50.104 (a) (6).

<sup>&</sup>lt;sup>3</sup>Each allegation received by ORI is assessed against the criteria which must be met in order to open a case. These criteria are:

<sup>(1)</sup> The research in which the alleged misconduct took place must be supported by PHS funds or involve an application for PHS funds.

97, institutions responded to 96% of the cases, ORI responded to 4% compared to 1993-94 when institutions handled 79% of the cases and ORI, 21%. See Table 2.

### **Closed Cases**

ORI closed 218 cases during the 5-year period, ranging from 28 to 58 per year and averaging 44.<sup>7</sup> The closed cases included 68 inquiries and 150 investigations. Overall, institutions handled 83% of the closed cases, they conducted 91% of the closed inquiries and 79% of the closed investigations. As the investigations initiated by the Office of Scientific Integrity were closed, institutional inquiries and investigations became a greater portion of closed cases. Over the 5-year period, the number of cases forwarded to the next year declined from 72 to 35. The 218 closed cases resulted in 142 no misconduct findings (65%) and 76 findings of misconduct (35%). See Table 3.

### **CLOSED INVESTIGATIONS**

The PHS regulation requires institutions to notify ORI about a scientific misconduct allegation only when an investigation is warranted. For such investigations, institutions are required to submit a detailed report that demonstrates that the investigation was "performed in a timely manner and with sufficient objectivity, thoroughness and competence."<sup>8</sup> These detailed reports provided the data for the ORI database on investigations on which this analysis is based. ORI closed 150 investigations from 1993-1997, ranging from 16 to 41 per year with an average of 30.<sup>9</sup> The remainder of this analysis will focus on the closed investigations.

### **Final Disposition of Investigations**

The final disposition of investigations includes the results of ORI oversight reviews and appeals to the Departmental Appeals Board (DAB). As a result of its oversight reviews, ORI did not make a PHS finding of scientific misconduct in 10 instances where the institution did find scientific misconduct. In addition, five PHS findings of scientific misconduct were reversed by the DAB or were withdrawn by ORI after an appeal was filed. Prior to these adjustments, 91 investigations (61%) resulted in a finding of misconduct, 59 (39%) did not. After these adjustments, the final disposition of investigations resulted in an almost equal split between finding misconduct and finding no misconduct. Seventy-six investigations (51%) produced

<sup>&</sup>lt;sup>7</sup>ORI closed more cases than it opened during the period because 79 cases were carried into 1993 from 1992.

<sup>&</sup>lt;sup>8</sup>50.104 (a) (6).

<sup>&</sup>lt;sup>9</sup>Some of these investigations were based on allegations received prior to 1993. Some investigations based on allegations received during the 5-year period were not completed prior to 1997.

misconduct findings, 74 (49%) did not. The number of misconduct findings ranged from 10 to 24 per year with an average of 15. The number of no misconduct findings ranged from 6 to 21 per year with an average of 15. See Table 4.

### **PHS Research Program**

The investigations concerned research supported by PHS extramural and intramural research programs. One hundred and forty extramural and ten intramural investigations were conducted. The number of extramural investigations ranged from 11 to 38 per year with an average of 28. The number of intramural investigations ranged from none to five per year with an average of two. See Table 5. The extramural research program accounted for 93% of (1) the closed investigations, (2) the misconduct findings, and (3) the no misconduct findings. Although slightly higher, these findings are similar to the funding pattern for the programs. The NIH allocated 88% of its \$11.9 billion research budget to extramural research in 1997.<sup>10</sup>

### **Performer of Investigations**

The PHS regulation regarding scientific misconduct assigns the primary responsibility for responding to allegations of scientific misconduct to applicant or awardee institutions, but reserves to HHS "the right to perform its own investigation at any time prior to, during, or following an institution's investigation."<sup>11</sup> These provisions create three possible performers of extramural investigations: institutions, ORI, or an institution and ORI. Over the 5-year period, institutions exclusively conducted 83% of the investigations, the institution/ORI combination accounted for 8%, and ORI exclusively conducted 9%. The primary responsibility of institutions to conduct the investigations was progressively affirmed during the period as the percent of extramural investigations conducted exclusively by institutions steadily rose from 64% to 96%. See Table 6. ORI has reserved its involvement in extramural investigations to cases that involve exceptional circumstances.<sup>12</sup> Each of the performer categories produced an almost equal split between findings of misconduct and no misconduct.

### **Institutional Setting**

Medical schools, the primary extramural location for the conduct of biomedical research in the United States, were the most frequent institutional setting for investigations accounting for 68% of the investigations and 58% of the misconduct findings over the 5-year period. Other

<sup>11</sup>50.104 (a) (6).

<sup>&</sup>lt;sup>10</sup>NIH Extramural Data, FY 1997, NIH Web Page.

<sup>&</sup>lt;sup>12</sup>ORI has occasionally become involved in an extramural investigation when it concerned multi-institutional clinical trials, the institution requests assistance, or the institution appears unwilling or unable to conduct the investigation.

prominent sites were hospitals and research institutes. Hospitals accounted for 11% of the investigations and 15% of the misconduct findings. Research institutes conducted 10% of the investigations and produced 11% of the misconduct findings. See Tables 7 and 8. In 1997, NIH awarded about 50% of its extramural research funds to medical schools, 11% to research institutes, and 8% to hospitals. Within institutions, the investigations involved numerous departments including anatomy, anesthesiology, biochemistry, biology, cardiology, cell biology, dermatology, digestive diseases, gene therapy, gerontology, immunology, internal medicine, medicine, microbiology, molecular biology, molecular endocrinology, neurology, neurology, obstetrics and gynecology, oncology, ophthalmology, otolaryngology, pathology, pediatrics, pharmacology, physiology, psychology, psychiatry, radiology, surgery, and urology.

#### **Funding Mechanisms**

Twenty-one funding mechanisms have supported research under investigation. The dominant category of funding mechanisms involved were those classified as research - the "R", "P" and "M" series. This category accounted for 81% of the 202 support mechanisms cited in the investigations. See Table 9. The most prevalent single mechanism was the RO1, the traditional grant, which constituted 59% of the mechanisms. Other notable mechanisms were program projects (PO1) 6%, specialized centers (P50) 3%, and first independent research support and transition (FIRST) awards (R29), 3%. The notable mechanism for funding research training was the institutional national research service award (T32), 4%. The cooperative clinical research (U10) awards accounted for 3%.

#### **Type of Misconduct**

Falsification was the most frequent type of alleged misconduct that resulted in an investigation, it was involved in four out of every five investigations that were conducted between 1993-97. By itself, falsification accounted for 43% of the investigations. In combination with fabrication and/or plagiarism, falsification was involved in an additional 36% of the cases. Fabrication came in a distant second. Fabrication accounted for 12% of the investigations by itself and another 33% in combination with other types of misconduct for a total of 45%. Plagiarism was involved in 5% of the investigations itself and another 8% in combination with other types of misconduct for a total of 13%. The controversial "other practices" clause in the definition was involved in five cases (3%), one case by itself and four cases in combination with other types of misconduct. Falsification and fabrication, singularly or as a combination, accounted for 86% of the investigations and 91% of the misconduct findings. No finding of misconduct was based on the "other practices" clause of the PHS definition of scientific misconduct. See Table 10.

#### **Institutional Actions**

The PHS regulation on misconduct in science requires institutions to impose appropriate sanctions on individuals when the allegation of misconduct has been substantiated. In some cases, however, institutions impose sanctions on respondents who are not found guilty of scientific misconduct under the PHS definition because the respondents have violated a broader

institutional definition of academic misconduct or failed to appropriately comply with other expected behaviors. Many institutions, however, do not report the sanctions they have taken against a respondent in their investigation reports. The actions taken against respondents found guilty of scientific misconduct reported in Table 11 cover 41 of the 71 extramural misconduct findings (58%). Institutions also reported taking actions against 19 of the 69 extramural respondents (28%) against whom no finding of misconduct was made by ORI (Table 12). A few institutions imposed more than one action on a respondent.

Institutions imposed nine types of sanctions on individuals who were found guilty of scientific misconduct. The most frequent action was termination of employment, either voluntary or involuntary, taken against 30 respondents. Other actions imposed on more than one respondent were reprimands, supervised research, ethics training, and dismissal from school. In one case a research fellow was required to repay his fellowship funds to the university.

Institutions took ten types of sanctions on individuals who were not found guilty of scientific misconduct under the PHS definition, but may have been found guilty under the institutional definition or failed to comply with other expected behaviors. Reprimands were the most frequent action taken. Other actions imposed on more than one respondent included termination of employment, supervised research, and the correction or retraction of articles.

### **Government Actions**

The PHS regulation on misconduct in science also recognizes the authority of HHS to impose administrative actions of its own on investigators and institutions for violating the regulation. The PHS imposed 170 administrative actions on the 76 respondents (2.2 per respondent) found to have committed scientific misconduct. See Table 13. Fifty-four respondents (71%) were debarred from receiving Federal funding for periods ranging from 18 months to 8 years. Sixty-nine respondents (91%) were prohibited from PHS advisory service for periods ranging from 2 to 10 years. Institutions employing 20 respondents (26%) were required to submit to the funding agency and ORI a plan for supervising the participation of the respondents in any PHS-supported research for 1 to 3 years. Ten respondents (13%) were required to retract or correct articles. Six other respondents voluntarily withdrew manuscripts or retracted articles. In some cases, the administrative actions began after the debarment period ended.

#### **RESPONDENT AND WHISTLEBLOWER PROFILES**

These profiles are based on three characteristics of respondents and whistleblowers that were consistently reported in investigation reports or files: academic rank, highest degree, and gender.<sup>13</sup> These data are more complete on respondents, they are missing for 30% of the whistleblowers. Data on other characteristics of respondents and whistleblowers were not

<sup>&</sup>lt;sup>13</sup>In a few non-academic cases, the organizational rank of the individual was converted to an academic rank.

included in the database because they were not consistently available in investigative reports or ORI files.

### **Respondent Profile**

### Academic Rank

More than three-fourths of the allegations (78%) were consistently made against individuals in four academic ranks: associate professor, 27%, professor, 19%, postdoctoral fellows, 19%, and technicians, 13%. Two-thirds of the misconduct findings were made against postdoctoral fellows (28%), associate professors (22%), and technicians (17%) while 59% of the no misconduct findings involved associate professors (31%) and professors, (28%). Allegations were most frequently supported against students, 73%, postdoctoral fellows, 66%, and technicians, 62%, and least frequently supported against professors (19%) and assistant professors (29%). Senior ranks (professor and associate professor) account for 46% of allegations, 30% of misconduct findings, and 60% of no misconduct findings. Allegations against the senior ranks were supported 30% of the time. See Tables 14 and 15.

### Academic Degree

Respondents held a variety of academic degrees from doctorate to bachelor, but doctorates were predominant. The most frequent doctorate was the Ph.D. (44%) followed by the M.D. (32%). Only one respondent held the M.D./Ph.D. Respondents also held three other doctorates - D.D.S., D.V.M., and Ed.D. Nine percent of the respondents held bachelor degrees, 3% held master degrees. Respondents with a Ph.D. accounted for most (42%) of the misconduct findings and most (46%) of the no misconduct findings. Respondents with an M.D. accounted for 22% of the misconduct findings and 40% of the no misconduct findings. Allegations against respondents with a bachelor's or a master's degree were supported 80% of the time, against respondents with doctorates 39%. See Tables 16 and 17.

### Gender

Males are accused of scientific misconduct considerably more often than females. See Tables 18 and 19. The percentage of respondents, however, who were male declined over the 5-year period while the percentage of respondents who were female increased. Nevertheless, 73% of the respondents were male, 26% were female. The gender of one respondent was unknown. Seventy percent of the misconduct findings were made against male respondents as were 75% of the no misconduct findings. Allegations against female respondents, however, were supported more often than allegations against males (52% versus 44%).

### **Whistleblower Profile**

### Academic Rank

Almost half of the whistleblowers (45%) were in two academic ranks: professor, 29%, and associate professor, 16%. Senior personnel accounted for 47% of the whistleblowers, junior personnel, 21%. The academic rank of the whistleblower could not be determined for 30% of the investigations. Allegations by senior personnel (dean, professor, associate professor) resulted in 47% of the misconduct findings and 48% of the no misconduct findings. Allegations by junior personnel accounted for 17% of the misconduct findings and 25% of the no misconduct findings. The support rate for allegations made by whistleblowers in most academic ranks was about 50%. Students, however, had a support rate of 100%, assistant professors, 25%, and technicians, 20%. The support rate for the unidentified whistleblowers was 58%. See Tables 20 and 21.

### Academic Degree

Like respondents, whistleblowers held a variety of academic degrees ranging from doctorate to bachelor. Almost three-fourths (72%) of the whistleblowers held doctorates. The most frequent doctorate was the Ph.D. (42%) followed by the M.D. (29%). One whistleblower held a J.D. Only one whistleblower held a master's degree and seven (4%) held bachelor's degrees. The academic degree was not available for 22% of the whistleblowers. Whistleblowers with a Ph.D. accounted for most (37%) of the misconduct findings and most (47%) of the no misconduct findings. Whistleblowers with an M.D. accounted for 33% of the misconduct findings and 25% of the no misconduct findings. Allegations made by whistleblowers with a bachelor's degree were most frequently supported (86%) followed by whistleblowers holding an M.D. 56% and Ph.D. 44%. See Tables 22 and 23.

### Gender

Like respondents, whistleblowers were predominantly males (66% vs. 14%). The gender of whistleblowers could not be identified 20% of the time. Allegations made by male whistleblowers were more frequently supported (50%) than allegations made by female whistleblowers (42%). See Tables 24 and 25.

### INQUIRIES AND INVESTIGATIONS

The PHS regulation requires institutions to go through a two-step process in responding to allegations of scientific misconduct. The first step is the inquiry which determines "whether an allegation or apparent instance of misconduct warrants an investigation."<sup>14</sup> The second step is an investigation which involves "the formal examination and evaluation of all relevant facts to

<sup>14</sup>50.102.

determine if misconduct has occurred."<sup>15</sup> This section presents data on the length of inquiries and investigations and the size of panels that conducted inquiries and investigations.

### Inquiries

### Length

According to the PHS regulation, institutions are required to complete an inquiry "within 60 calendar days of its initiation unless circumstances clearly warrant a longer period." When a longer period is required, the circumstances warranting the longer period must be included in the inquiry report. However, the regulation does not stipulate the starting and ending points of an inquiry. In Tables 26 and 27, the length of the inquiry was measured from the date on which the inquiry panel held its first meeting to the date of the inquiry panel report. On this basis, 53% of the inquiries were completed within the 60-day standard, 22% required twice the standard length, and 24% required more than twice the standard length. Inquiries completed within the standard length were followed by 59% of the investigations that resulted in misconduct findings and 47% of the investigations that resulted in no misconduct findings. Inquiries that lasted beyond the standard length were more likely to be followed by an investigation that did not find misconduct.

### Panel Size

The PHS regulation requires institutions to secure necessary and appropriate expertise to carry out a thorough and authoritative evaluation of the relevant evidence in any inquiry. The purpose of the inquiry is to make a preliminary evaluation of the available evidence and testimony of the respondent, whistleblower, and key witnesses to determine whether there is sufficient evidence of possible scientific misconduct to warrant an investigation. Seventy-five percent of the inquiries were conducted by panels composed of three or fewer members. Twenty-seven percent of the inquiries were conducted by a single person. The most frequent size of inquiry panels was three members. See Table 28. Inquiries conducted by a single person were most frequently (73%) followed by investigations that resulted in a misconduct finding, inquiries conducted by two persons were equally likely to be followed by investigations that found misconduct or no misconduct, while inquiries conducted by three or more persons were more likely to be followed by investigations that found misconduct or no misconduct, while inquiries conducted by three or more persons were more likely to be followed by investigations that found misconduct or no misconduct, while inquiries conducted by three or more persons were more likely to be followed by investigations that found misconduct or no misconduct, while inquiries conducted by three or more persons were more likely to be followed by investigations that found misconduct or no misconduct (59%). See Table 29.

### Investigations

### Length

According to the PHS regulation, an investigation should ordinarily be completed within 120 days of its initiation. This includes conducting the investigation, preparing the report of findings, making that report available for comment by the subjects of the investigation and submitting the

<sup>&</sup>lt;sup>15</sup>50.102.

report to the ORI. If additional time is needed, the institution is required to request an extension from ORI. However, the regulation does not stipulate a starting point for investigations. In Table 30, the length of the investigation was measured from the date of the first meeting of the investigation committee to the date ORI received the report. Thirty-two percent of the investigations were completed within the 120-day standard, 22% were completed within twice the standard period, and 38% took more than twice the standard period. Investigations completed within the 120-day standard resulted in 41% of the misconduct findings and 23% of the no misconduct findings. Investigations completed within 180 days appear more likely to result in a misconduct finding (61%) while investigations completed in more than 240 days are more likely to produce no misconduct findings (61%). See Table 31.

### Panel Size

The PHS regulation requires institutions to secure necessary and appropriate expertise to carry out a thorough and authoritative evaluation of the relevant evidence in any investigation. The purpose of the investigation is to explore in detail the allegations, to examine the evidence in depth, and to determine specifically whether misconduct has been committed, by whom, and to what extent. Compared to inquiries, a considerably smaller percentage (20%) of investigations were conducted by panels composed of one or two members. Sixty-five percent of the investigations, like inquiries, was three members. See Table 32. Investigations conducted by a single individual were most likely to find misconduct (88%), investigations employing panels with two to four members were equally likely to find misconduct or no misconduct, while investigatory panels composed of five or more members were more likely to find no misconduct (60%). See Table 33.

#### CONCLUSION

Most allegations of scientific misconduct do not result in inquiries or investigations because they do not contain sufficient information to proceed or do not meet the criteria for PHS jurisdiction. About two-thirds of the allegations that result in formal cases are not sustained. However, when a case proceeds to a full investigation, PHS scientific misconduct is found about half of the time.

Allegations of scientific misconduct may be made at any type of institution against any member of the research team supported by any type of funding mechanism. Medical schools are the prime source of allegations, but other sources include hospitals, research organizations, institutes and laboratories. Allegations primarily concern falsification and fabrication of data which directly question the integrity of PHS-supported research. These allegations are made by and against professors, associate professors, assistant professors, research instructors, postdoctoral fellows, research associates, students and technicians. Males with Ph.D. or M.D. degrees are the predominant participants but a sizeable number of females and other degree holders are involved. The RO1 grant is the funding mechanism most frequently implicated, but program, center, and training grants, and cooperative agreements are also involved. ORI hopes that this report will provide useful descriptive data to the scientific community concerning scientific misconduct investigations involving PHS-sponsored research.

#### TABLES

#### 1993 1994 1995 1996 1997 Disposition Total 35 38 49 20% 39 20% 187 19% Resulted in inq/inv 18% 21% 26 16% Referred to other agency 29 15% 24 13% 30 12% 39 20% 18 11% 140 14% 122 No action possible 132 67% 123 66% 165 68% 118 60% 73% 660 67% 100% 100% Total 196 185 100% 244 196 100% 166 100% 987 100%

### Table 1: Disposition of Allegations to ORI, 1993-1997

### Table 2: Number of Cases Opened by Case Type, 1993-1997

Case Type	19	993	19	994	19	95	19	96	19	97	То	otal
Institutional Inquiries*	14	40%	13	34%	19	39%	16	41%	6	23%	68	36%
Institutional Investigations	14	40%	17	45%	27	55%	23	59%	18	69%	99	53%
ORI Inquiries	1	3%	3	8%	3	6%	0	0%	1	4%	8	4%
ORI Investigations	6	17%	5	13%	0	0%	0	0%	1	4%	12	7%
Total	35	100%	38	100%	49	100%	39	100%	26	100%	187	100%

\*Only includes inquiries that did not recommend an investigation.

### Table 3: Number of Cases Closed by Case Type, 1993-1997

Case Type	19	993	199	94	19	95	19	96	19	97	То	otal
Institutional Inquiries*	12	43%	17	39%	14	24%	10	21%	9	23%	62	28%
Institutional Investigations	7	25%	18	41%	32	55%	34	69%	27	69%	118	54%
ORI Inquiries	0	0%	1	2%	3	5%	1	2%	1	3%	6	3%
ORI Investigations	9	32%	8	18%	9	16%	4	8%	2	5%	32	15%
Total	28	100%	44	100%	58	100%	49	100%	39	100%	218	100%

\*Only includes inquiries that did not recommend an investigation.

Outcome	19	993	199	94	19	95	19	96	19	97	Тс	otal
Misconduct	10	63%	11	42%	24	59%	17	45%	14	48%	76	51%
No Misconduct	6	37%	15	58%	17	41%	21	55%	15	52%	74	49%
Total	16	100%	26	100%	41	100%	38	100%	29	100%	150	100%

Table 4: Final Disposition of Closed Investigations, 1993-1997

### Table 5: Closed Investigations by Type of PHS Research Program, 1993-1997

Research Program	1	993	19	94	19	95	19	96	19	97	То	otal
Extramural	11	69%	25	96%	38	93%	38	100%	28	97%	140	93%
Intramural	5	31%	1	4%	3	7%	0	0%	1	3%	10	7%
Total	16	100%	26	100%	41	100%	38	100%	29	100%	150	100%

### Table 6: Closed Extramural Investigations by Performer of Investigation, 1993-1997

Performer	19	993	19	94	1	995	19	96	1	.997	Тс	otal
Institution	7	64%	17	68%	32	84%	34	90%	27	96%	117	83%
Institution/ORI	0	0%	7	28%	2	5%	2	5%	0	0%	11	8%
ORI	4	36%	1	4%	4	11%	2	5%	1	4%	12	9%
Total	11	100%	25	100%	38	100%	38	100%	28	100%	140	100%

### Table 7: Closed Extramural Investigations by Institutional Settings, 1993-1997

Institutional Setting	19	993	19	94	1	995	19	96	1	.997	Т	otal
Medical schools	7	64%	21	84%	19	50%	30	79%	18	64%	95	68%
Hospitals	0	0%	1	4%	8	21%	5	13%	1	4%	15	11%
Research institutes	0	0%	2	8%	6	16%	3	8%	3	11%	14	10%
Other	4	36%	1	4%	5	13%	0	0%	6	21%	16	11%
Total	11	100%	25	100%	38	100%	38	100%	28	100%	140	100%

Institutional Setting	Misco	onduct	No Mi	sconduct	То	otal
Medical schools	41	58%	54	78%	95	68%
Hospitals	11	15%	4	6%	15	11%
Research institutes	8	11%	6	9%	14	10%
Other	11	15%	5	7%	16	11%
Total	71	99%	69	100%	140	100%

 Table 8: Outcome of Extramural Investigations by Institutional Settings, 1993-1997

#### Table 9: Closed Extramural Investigations by Funding Mechanism, 1993-1997

Funding Mechanism	19	993	19	94	1	995	19	96	1	.997	То	otal
Research*	9	82%	35	85%	40	83%	46	82%	33	72%	163	81%
Research Training**	0	0%	2	5%	1	2%	6	11%	7	15%	16	8%
Coop Agreement***	2	18%	1	2%	2	4%	2	4%	4	9%	11	5%
Other****	0	0%	3	7%	5	11%	2	4%	2	4%	12	6%
Total	11	100%	41	100%	48	100%	56	101%	46	100%	202	100%

\*RO1, RO3, R10, R22, R29, R37, R43, R44, PO1, P10, P30, P50, MO1

\*\*F32, KO2, KO8, T32

\*\*\*UO1, U10

\*\*\*\*NO1, SO7

### Table 10: Closed Investigations by Type of Misconduct, 1993-1997

Type of Misconduct	19	993	199	94	19	995	19	96	19	997	То	tal
Fabrication	2	13%	3	11%	6	15%	3	8%	4	14%	18	12%
Falsification	5	31%	12	46%	17	41%	18	47%	12	41%	64	43%
Plagiarism	0	0%	1	4%	3	7%	1	3%	3	10%	8	5%
Fab/Falsification	7	44%	7	27%	12	29%	13	34%	8	28%	47	31%
Falsification/Plagiarism	0	0%	2	8%	1	2%	2	5%	1	3%	6	4%
Fab/Fals/Plagiarism	0	0%	0	0%	1	2%	0	0%	1	3%	2	1%
Fab/Plagiarism/Other	1	6%	0	0%	0	0%	0	0%	0	0%	1	1%
Plagiarism/Other	1	6%	1	4%	0	0%	1	3%	0	0%	3	2%
Other	0	0%	0	0%	1	2%	0	0%	0	0%	1	1%
Total	16	100%	26	100%	41	98%	38	100%	29	99%	150	100%

Institutional Action	1993	1994	1995	1996	1997	Total
Terminated employment*	6	4	9	8	3	30
Dismissed from school	0	0	1	0	1	2
Repayment of Funds	1	0	0	0	0	1
Suspension with pay	0	0	0	0	1	1
Supervised research	0	0	2	1	1	4
Reprimand	1	1	3	0	0	5
Retraction/correction	0	0	1	0	0	1
Ethics training	0	1	0	0	1	2
Community service	0	1	0	0	0	1
Total	8	7	16	9	7	47

Table 11: Institutional Actions Taken Against Respondents in Closed Investigations that Found Misconduct, 1993-1997

\*Includes resignations

### Table 12: Institutional Actions Taken Against Respondents in Closed Investigations that Did Not Find Misconduct, 1993-1997

Institutional Action	1993	1994	1995	1996	1997	Total
Terminated employment*	0	0	0	2	2	4
Removed from admin post	0	0	0	1	0	1
Pay increase withheld	0	1	0	0	0	1
Suspension with pay	0	1	0	0	0	1
Grant withdrawn	0	0	0	0	1	1
Supervised research	0	0	2	1	1	4
Prohibit serving on review committees	0	0	0	1	0	1
Reprimand	1	2	2	2	1	8
Retraction/Correction	0	0	0	1	1	2
Counseling	0	0	0	0	1	1
Total	1	4	4	8	7	24

\*Includes resignations

Government Action	1993	1994	1995	1996	1997	Total
	N=10	N=11	N=24	N=17	N=14	N=76
Debarment	80%	82%	67%	76%	57%	71%
Prohibition from service on advisory committees	80%	91%	88%	100%	93%	91%
Supervised research	0%	9%	25%	47%	36%	26%
Certification of data	40%	0%	4%	18%	14%	13%
Certification of sources	10%	9%	8%	6%	14%	9%
Retraction/Correction	0%	18%	21%	6%	14%	13%

 Table 13: Percent of Respondents by Government Actions in Closed Investigations, 1993-1997

Table 14: Closed Investigations by Academic Rank of Respondent, 1993-1997

Academic Rank	19	93	19	94	19	995	19	96	19	997	То	tal
Professor	2	13%	3	12%	7	15%	8	18%	11	34%	31	19%
Associate professor	6	38%	12	46%	15	32%	10	23%	2	6%	45	27%
Assistant professor	0	0%	0	0%	8	17%	2	5%	4	13%	14	8%
Research instructor	0	0%	0	0%	1	2%	0	0%	0	0%	1	1%
Postdoctoral fellow	4	25%	4	15%	5	11%	13	30%	6	19%	32	19%
Research asst/assoc	0	0%	0	0%	2	4%	0	0%	3	9%	5	3%
Student	2	13%	3	12%	1	2%	3	7%	2	6%	11	7%
Technician	2	13%	3	12%	8	17%	8	18%	0	0%	21	13%
None	0	0%	1	4%	0	0%	0	0%	4	13%	5	3%
Total	16	101%	26	101%	47	100%	44	101%	32	100%	165	100%

Academic Rank	Misc	onduct	No Mi	sconduct	То	otal
Professor	6	8%	25	28%	31	19%
Associate professor	17	22%	28	31%	45	27%
Assistant professor	4	5%	10	11%	14	8%
Research instructor	1	1%	0	0%	1	1%
Postdoctoral fellow	21	28%	11	12%	32	19%
Research assoc/asst	3	4%	2	2%	5	3%
Student	8	11%	3	3%	11	7%
Technician	13	17%	8	9%	21	13%
None	3	4%	2	2%	5	3%
Total	76	100%	89	98%	165	100%

 Table 15: Outcome of Investigations by Academic Rank of Respondent, 1993-1997

### Table 16: Closed Investigations by Highest Degree of Respondent, 1993-1997

Degree of Respondent	19	93	19	94	19	995	19	96	1	997	То	otal
Ph.D.	5	31%	8	31%	18	38%	26	59%	16	50%	73	44%
M.D.	7	44%	10	38%	16	34%	10	23%	10	31%	53	32%
M.D./Ph.D.	0	0%	1	4%	0	0%	0	0%	0	0%	1	1%
D.D.S.	0	0%	0	0%	0	0%	1	2%	0	0%	1	1%
D.V.M.	0	0%	0	0%	0	0%	1	2%	0	0%	1	1%
Ed.D.	0	0%	0	0%	1	2%	0	0%	0	0%	1	1%
M.S.	0	0%	1	4%	0	0%	0	0%	0	0%	1	1%
M.A.	0	0%	0	0%	0	0%	2	5%	2	6%	4	2%
B.S.	2	13%	2	8%	4	9%	0	0%	0	0%	8	5%
B.A.	1	6%	3	12%	0	0%	0	0%	3	9%	7	4%
Unknown	1	6%	1	4%	8	17%	4	9%	1	3%	15	9%
Total	16	100%	26	101%	47	100%	44	100%	32	99%	165	101%

Highest Degree	Misc	onduct	No Mi	sconduct	To	otal
Ph.D.	32	42%	41	46%	73	44%
M.D.	17	22%	36	40%	53	32%
Other doctorates	2	3%	2	2%	4	2%
Master	4	5%	1	1%	5	3%
Bachelor	12	16%	3	3%	15	9%
Unknown	9	12%	6	7%	15	9%
Total	76	100%	89	99%	165	99%

 Table 17: Outcome of Investigations by Highest Degree of Respondent, 1993-1997

### Table 18: Closed Investigations by Gender of Respondent, 1993-1997

Gender of Respondent	199	93	1994		19	1995		1996		1997		tal
Male	13	81%	22	85%	35	74%	27	61%	23	72%	120	73%
Female	3	19%	4	15%	12	26%	16	36%	9	28%	44	26%
Unknown	0	0%	0	0%	0	0%	1	2%	0	0%	1	1%
Total	16	100%	26	100%	47	100%	44	99%	32	99%	165	101%

### Table 19: Outcome of Investigations by Gender of Respondent, 1993-1997

Gender of Respondent	Misconduct		No Mi	sconduct	То	otal
Male	53	70%	67	75%	120	73%
Female	23	30%	21	24%	44	26%
Unknown	0	0%	1	1%	1	1%
Total	76	100%	89	100%	165	100%

Academic Rank	19	93	19	94	19	995	19	96	19	997	То	tal
Dean	0	0%	2	7%	1	2%	1	2%	0	0%	4	2%
Professor	6	38%	9	31%	9	21%	11	24%	13	39%	48	29%
Associate professor	1	6%	4	14%	9	21%	7	16%	6	18%	27	16%
Assistant professor	0	0%	0	0%	4	9%	5	11%	3	9%	12	7%
Research instructor	0	0%	0	0%	0	0%	0	0%	0	0%	0	0%
Postdoctoral fellow	3	19%	1	3%	1	2%	3	7%	2	6%	10	6%
Research asst/assoc*	1	6%	1	3%	1	2%	0	0%	0	0%	3	2%
Student	0	0%	1	3%	1	2%	3	7%	0	0%	5	3%
Technician	1	6%	3	10%	1	2%	0	0%	0	0%	5	3%
None	0	0%	0	0%	2	5%	0	0%	0	0%	2	1%
Unknown	4	25%	8	28%	14	33%	15	33%	9	27%	50	30%
Total	16	100%	29	99%	43	99%	45	100%	32	100%	166	99%

Table 20: Closed Investigations by Academic Rank of Whistleblower 1993-1997

\*Includes nurse

### Table 21: Outcome of Investigations by Academic Rank of Whistleblower, 1993-1997

Academic Rank	Misconduct			sconduct	Total		
Dean	2	2%	2	2%	4	2%	
Professor	24	29%	24	29%	48	29%	
Associate professor	13	16%	14	17%	27	16%	
Assistant professor	3	4%	9	11%	12	7%	
Postdoctoral fellow	5	6%	5	6%	10	6%	
Research asst/assoc*	0	0%	3	3%	3	2%	
Student	5	6%	0	0%	5	3%	
Technician	1	1%	4	5%	5	3%	
None	1	1%	1	1%	2	1%	
Unknown	29	35%	21	25%	50	30%	
Total	83	100%	83	99%	166	99%	

\*Includes nurse

Degree of Whistleblower	19	93	19	94	19	95	19	996	19	97	То	otal
Ph.D.	7	44%	8	28%	17	40%	21	47%	17	52%	70	42%
M.D.	5	31%	11	38%	8	19%	13	29%	11	33%	48	29%
J.D.	0	0%	0	0%	1	2%	0	0%	0	0%	1	1%
M.S.	0	0%	1	3%	1	2%	0	0%	0	0%	2	1%
B.S.	0	0%	2	7%	2	5%	0	0%	0	0%	4	2%
B.A.	0	0%	0	0%	0	0%	3	7%	0	0%	3	2%
None	0	0%	0	0%	0	0%	1	2%	1	3%	2	1%
Unknown*	4	25%	7	24%	14	33%	7	15%	4	12%	36	22%
Total	16	100%	29	100%	43	101%	45	100%	33	100%	166	100%

Table 22: Closed Investigations by Highest Degree of Whistleblower, 1993-1997

\*Includes nurse

### Table 23: Outcome of Investigations by Highest Degree of Whistleblower, 1993-1997

Highest Degree	Misco	onduct	No Mi	sconduct	Total		
Ph.D.	31	37%	39	47%	70	42%	
M.D.	27	33%	21	25%	48	29%	
J.D.	0	0%	1	1%	1	1%	
Master	0	0%	2	1%	2	1%	
Bachelor	6	7%	1	1%	7	4%	
No degree	1	1%	1	1%	2	1%	
Unknown*	18	21%	18	22%	36	22%	
Total	83	99%	83	98%	166	100%	

\*Includes nurse

### Table 24: Closed Investigations by Gender of Whistleblower, 1993-1997

Gender of Whistleblower	199	93	19	994	19	995	1	996	19	97	То	otal
Male	11	69%	15	52%	26	60%	31	69%	26	79%	109	66%
Female	3	19%	7	24%	5	12%	6	13%	3	9%	24	14%
Unknown	2	13%	7	24%	12	28%	8	18%	4	12%	33	20%
Total	16	101%	29	100%	43	100%	45	100%	33	100%	166	100%

Gender of Whistleblower	Misco	onduct	No Mi	sconduct	То	otal
Male	54	65%	55	66%	109	66%
Female	10	12%	14	17%	24	14%
Unknown	19	23%	14	17%	33	20%
Total	83	100%	83	100%	166	100%

 Table 25: Outcome of Investigations by Gender of Whistleblower, 1993-1997

### Table 26: Closed Investigations by Length of Inquiry, 1993-1997

Length of Inquiry	199	93	19	94	19	995	19	996	19	997	То	tal
0-60 days	7	44%	15	58%	24	59%	19	50%	15	52%	80	53%
61-90 days	2	13%	4	14%	4	10%	4	11%	2	7%	16	11%
91-120 days	6	38%	2	8%	1	2%	4	11%	4	14%	17	11%
121-150 days	0	0%	1	4%	5	12%	1	3%	3	10%	10	7%
Over 150 days	0	0%	4	15%	7	17%	9	24%	5	17%	25	17%
Unknown	1	6%	0	0%	0	0%	1	3%	0	0%	2	1%
Total	16	101%	26	100%	41	100%	38	102%	29	100%	150	100%

### Table 27: Outcome of Investigations by Length of Inquiry, 1993-1997

Length of Inquiry	Misco	onduct	No Mi	sconduct	То	otal	
0-60 days	45	59%	35	47%	80	53%	
61-90 days	7	9%	9	12%	16	11%	
91-120 days	8	11%	9	12%	17	11%	
121-150 days	4	5%	6	8%	10	7%	
Over 150 days	10	13%	15	20%	25	17%	
Unknown	2	3%	0	0%	2	1%	
Total	76	100%	74	99%	150	100%	

Size of Inquiry Panel	19	93	19	94	19	995	19	96	19	997	То	tal
One	5	31%	9	35%	8	20%	7	18%	11	38%	40	27%
Two	1	6%	2	8%	6	15%	4	11%	5	17%	18	12%
Three	3	19%	7	27%	17	41%	20	53%	7	24%	54	36%
Four	4	25%	5	19%	5	12%	3	8%	3	10%	20	13%
Five	0	0%	2	8%	2	5%	3	8%	0	0%	7	5%
Six or more	3	19%	1	4%	3	9%	1	3%	3	10%	11	7%
Total	16	100%	26	101%	41	102%	38	101%	29	99%	150	100%

Table 28: Closed Investigations by Size of Inquiry Panel, 1993-1997

### Table 29: Outcome of Investigations by Size of Inquiry Panel, 1993-1997

Size of Inquiry Panel	Misco	onduct	No Mi	sconduct	То	otal
One	29	38%	11	15%	40	27%
Two	9	12%	9	12%	18	12%
Three	24	32%	30	41%	54	36%
Four	7	9%	13	18%	20	13%
Five	3	4%	4	5%	7	5%
Six or more	4	5%	7	9%	11	7%
Total	76	100%	74	100%	150	100%

### Table 30: Closed Investigations by Length of Investigations, 1993-1997

Length of Investigation	199	93	19	94	19	995	19	96	19	997	То	otal
0-120 days	5	31%	9	35%	10	24%	13	34%	11	38%	48	32%
121-180 days	1	6%	3	12%	10	24%	10	26%	7	24%	31	21%
181-240 days	1	6%	3	12%	4	10%	2	5%	2	7%	12	8%
241-300 days	0	0%	2	8%	5	12%	4	11%	4	14%	15	10%
Over 300 days	7	44%	9	35%	12	29%	9	24%	5	17%	42	28%
Unknown	2	13%	0	0%	0	0%	0	0%	0	0%	2	1%
Total	16	100%	26	102%	41	99%	38	100%	29	100%	150	100%

Length of Investigation	Misco	onduct	No Mi	sconduct	To	otal	
0-120 days	31	41%	17	23%	48	32%	
121-180 days	17	22%	14	19%	31	21%	
181-240 days	6	8%	6	8%	12	8%	
241-300 days	5	7%	10	14%	15	10%	
Over 300 days	17	22%	25	34%	42	28%	
Unknown	0	0%	2	3%	2	1%	
Total	76	100%	74	101%	150	100%	

 Table 31: Outcome of Investigations by Length of Investigations, 1993-1997

#### Table 32: Closed Investigations by Size of Investigation Panel, 1993-1997

Size of Investigation Panel	19	993	19	994	19	95	19	96	1	997	То	otal
One	1	7%	5	19%	3	7%	1	3%	6	21%	16	11%
Two	0	0%	4	15%	4	10%	3	8%	3	10%	14	9%
Three	4	25%	6	23%	13	32%	21	55%	9	31%	53	35%
Four	3	19%	5	19%	4	10%	4	11%	4	14%	20	13%
Five	4	25%	4	15%	8	20%	6	16%	4	14%	26	17%
Six or more	4	25%	2	8%	9	22%	3	8%	3	10%	21	14%
Total	16	101%	26	99%	41	101%	38	101%	29	100%	150	99%

### Table 33: Outcome of Investigations by Size of Investigation Panel, 1993-1997

Size of Investigation Panel	Misc	onduct	No Mi	sconduct	Total	
One	14	18%	2	3%	16	11%
Two	7	9%	7	9%	14	9%
Three	26	34%	27	36%	53	35%
Four	10	14%	10	14%	20	13%
Five	11	14%	15	20%	26	17%
Six or more	8	11%	13	18%	21	14%
Total	76	100%	74	100%	150	99%