

ORI Closed Investigations into Misconduct Allegations Involving
Research Supported by the Public Health Service: 1994-2003

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Introduction

From 1994 to 2003, research institutions and the Office of Research Integrity (ORI) conducted 259 formal investigations into allegations of research misconduct in biomedical or behavioral research, research training or related research activities supported by the Public Health Service (PHS). These investigations resulted from the implementation of the 1989 regulation that requires institutions that apply for or receive PHS support to establish procedures for responding to allegations of research misconduct that includes a two-stage process: (1) an inquiry to determine whether the allegation warrants an investigation and (2) an investigation to determine whether misconduct has occurred, and if so, by whom.¹

This report presents data from these investigations that broadly describe the implementation of the research misconduct regulation by institutions, PHS agencies and ORI.² The data address several questions related to research misconduct and the handling of such allegations:

- How frequently are research misconduct allegations made?
- Where are research misconduct investigations being conducted?
- What types of research misconduct are being committed?
- What is the outcome of research misconduct investigations?
- Who is being accused of research misconduct?
- Who is making the allegations of research misconduct?
- What administrative actions are imposed on individuals against whom research misconduct findings are made?
- How long does it take to conduct inquiries and investigations?
- Does the size of the inquiry or investigation panel affect the outcomes?

The data used in this descriptive analysis come from the largest database on research misconduct investigations in the world, the administrative case tracking system maintained by the Division of Investigative Oversight, ORI. This database was designed for monitoring the handling of

¹ Responsibility of PHS Awardee and Applicant Institutions for Dealing With and Reporting Possible Misconduct in Science. 42 CFR Part 50, Subpart A. Available on ORI web site at <http://ori.hhs.gov>.

² Also see *New Institutional Research Misconduct Activity: 1992-2001* at http://ori.hhs.gov/research/intra/studies_completed.shtml.

research misconduct allegations by extramural institutions, PHS agencies and ORI. The information in the database was extracted by ORI staff from reports on misconduct investigations conducted by research institutions and PHS agencies.

This report presents the data from three perspectives: the ten-year period, 1994-2003, a comparison of two five-year periods, 1994-1998 and 1999-2003, and the outcome of investigations. The data presented in this report are suggestive rather than definitive. More questions are raised than answers provided. Suggestions are made for further research.

Allegations of Research Misconduct

This section presents data on allegations of research misconduct received directly by ORI or indirectly through institutions and PHS agencies. Institutions and PHS agencies are not required to inform ORI about an allegation until they decide to open an investigation.³ Institutions report aggregate data on the number of allegations received and the number of inquiries and investigations conducted in their Annual Report on Possible Research Misconduct. This section presents data on (1) the disposition of allegations received by ORI, (2) the number of new cases opened annually by ORI, (3) the number of research misconduct findings made by PHS, and (4) the types of research misconduct committed .

Disposition of allegations

Over the ten-year period, ORI received 1,777 allegations. Nineteen percent (329) of these allegations resulted in new ORI misconduct cases because they met the three conditions required to establish PHS jurisdiction: (1) the alleged behavior fit the definition of research misconduct in the 1989 regulation; (2) the research involved was supported by the PHS; and (3) the allegation contained sufficient information to permit the allegation to be pursued. Twelve percent (218) were referred to other federal agencies that had jurisdiction over the alleged misconduct. No action was possible by ORI on the remaining allegations (69 percent) because they did not meet the conditions required to establish PHS jurisdiction. ORI also took no action on some allegations because they were handled by the National Institutes of Health (NIH).⁴ Annually, ORI received an average of 178 allegations; the median was 184 and the range 112-244.

³PHS agencies informed ORI about all allegations involving their intramural research programs until 2000 when the Assistant Secretary for Health assigned them the primary responsibility, like extramural institutions, to respond to allegations of research misconduct.

⁴The Assistant Secretary for Health assigned authority to NIH in 2000 to respond, jointly with ORI, to research misconduct allegations received directly from the NIH extramural programs.

Table 1: Disposition of research misconduct allegations received by ORI, 1994-2003.

Disposition	1994	1995	1996	1997	1998	1999	2000	2001	2002	2003	Total
Resulted in inq/inv	38	49	39	26	33	25	27	39	32	21	329
Referred to other agency	24	30	39	18	18	16	12	25	21	15	218
No action possible	123	165	118	122	61	89	133	135	137	147	1230
Total	185	244	196	166	112	130	172	199	190	183	1777

Overall, the number of allegations received between the comparison periods declined by 29 or 3 percent. More important, the percent of allegations that resulted in inquiries and/or investigations decreased from 21 to 17 percent and referrals decreased from 14 to 10 percent while allegations on which no ORI action was possible increased by 8 percent. The average number of allegations received in the first five years was 181 per year compared to 175 in the second five-year period.

Table 2: Disposition of allegations made to ORI, 1994-1998 and 1999-2003.

Disposition of allegations	1994-1998	1999-2003
Resulted in inq/inv	21% (185)	17% (144)
Referred to other agency	14% (129)	10% (89)
No action possible	65% (589)	73% (641)
Total	100% (903)	100% (874)

Number of new cases

The 1989 research misconduct regulation assigned primary responsibility for responding to research misconduct allegations to institutions but reserved the right of the Department of Health and Human Services (HHS) to conduct an investigation before, during, or after an institutional investigation. From 1989 to 2000, ORI

conducted research misconduct investigations into PHS intramural and extramural programs on behalf of HHS. In 2000, the Secretary of Health and Human Services assigned responsibility to conduct HHS research misconduct investigations to the Office of the Inspector General, HHS, in extramural research programs and to

PHS agencies in intramural research programs upon the recommendation of the HHS Work Group on Research Misconduct and Research Integrity.⁵

ORI opens a case when it determines that an allegation meets the conditions previously stated; those allegations may be made directly to ORI or an institution may inform ORI that it has opened an investigation. Over the ten-year period, ORI opened 338 new cases, an average of 34 per year. The median number of cases opened annually was 33.5; the range was 22 to 49. Institutions conducted 94 percent of the inquiries and 96 percent of the investigations in that period. ORI conducted its last inquiry in 1997 and its last investigation in 1999.

Table 3: Number of ORI cases opened by type, 1994-2003.

Case type	1994	1995	1996	1997	1998	1999	2000	2001	2002	2003	Total	%
Institutional inquiries	13	19	16	6	10	15	7	10	12	9	117	35
Institutional investigations	17	27	23	18	21	14	19	25	29	13	206	61
ORI inquiries	3	3	0	1	0	0	0	0	0	0	7	2
ORI investigations	5	0	0	1	1	1	0	0	0	0	8	2
Total	38	49	39	26	32	30	26	35	41	22	338	100

The decline noted between the comparison periods in the receipt of research misconduct allegations is repeated in the number of new cases opened. The total number of new cases opened declined by 30 (16 percent). The number of cases opened in each case type category declined, but the proportion of institutional investigations increased between the comparison periods.

The shift to institutional inquiries and investigations is quite evident. From 1994-1998, institutional inquiries and investigations accounted for 92% of the new cases; from 1999-2003, they accounted for 99 percent. Institutions conduct 90 percent of the inquiries and 94 percent of the investigations in the first five years compared to 100 percent of the inquiries and 98 percent of the investigations in the second five years. ORI opened an average of 37 new cases in the first period and 31 in the second period.

⁵Report of the HHS Work Group on Research Misconduct and Research Integrity. ORI web site at <http://ori.hhs.gov>.

Table 4: Number of ORI cases opened by type, 1994-1998 and 1999-2003.

Case type	1994-1998	1999-2003
Institutional inquiries	35% (64)	34% (53)
Institutional investigations	57% (106)	65% (100)
ORI inquiries	4% (7)	0 (0)
ORI investigations	4% (7)	1% (1)
Total	100% (184)	100% (154)

Number of research misconduct findings

Over the 10 years, 259 investigations resulted in 133 findings of research misconduct (51 percent) and 126 findings of no misconduct (49 percent). For misconduct findings, the annual average was 13, the median 13.5 and the range 8-24. For the no misconduct findings, the average was 13, the median 12 and the range 4-22.

Table 5: Outcomes of research misconduct investigations, 1994-2003.

Outcome	1994	1995	1996	1997	1998	1999	2000	2001	2002	2003	Total	%
Misconduct	11	24	16	14	9	12	8	14	13	12	133	51
No misconduct	15	17	22	15	12	12	7	4	10	12	126	49
Total	26	41	38	29	21	24	15	18	23	24	259	100

The comparative decline between the five-year periods in the number of allegations and the number of new cases is reflected in the number of findings made. There was a 33 percent decrease in total findings including a 20 percent decrease in misconduct findings and a 44 percent decrease in no misconduct findings. While the number

of findings plunged, the percentage of investigations that resulted in misconduct findings rose from 48 to 57 percent between the periods while the number of no misconduct findings decreased from 52 to 43 percent; a total shift of 18 percent toward misconduct findings.

Table 6: Outcomes of research misconduct investigations, 1994-1998 and 1999-2003.

Outcome	1994-1998	1999-2003
Misconduct	48% (74)	57% (59)
No misconduct	52% (81)	43% (45)
Total	100% (155)	100% (104)

Types of misconduct

Eighty-nine percent of the 133 research misconduct findings made over the entire period were based on falsification or fabrication singularly or in combination. Falsification accounted for 40 percent of the findings; fabrication for 22 percent, and the falsification and fabrication combination for 27 percent. Six percent of the findings were based on plagiarism alone; another 4 percent combined plagiarism with falsification. The most frequent type of research misconduct was falsification which alone or in combination with fabrication or plagiarism accounted for 71 percent of the findings.

Table 7: Types of misconduct involved in research misconduct investigations, 1994-2003.

Type of Misconduct	1994	1995	1996	1997	1998	1999	2000	2001	2002	2003	Total	%
Fabrication	2	5	3	4	4	3	1	2	4	1	29	22
Falsification	3	9	6	5	3	8	4	4	5	6	53	40
Plagiarism	1	3	1	1	0	0	0	2	0	0	8	6
Fabrication/falsification	5	7	4	4	2	1	2	4	3	4	36	27
Falsification/plagiarism	0	0	1	0	0	0	1	2	1	0	5	4
Other combinations FFP	0	0	1	0	0	0	0	0	0	1	2	1
Total	11	24	16	14	9	12	8	14	13	12	133	100

The frequency and proportion of two types of misconduct increased between the comparison periods; all other declined. The absolute number of falsification findings increased from 26 to 27 and the combination of falsification and plagiarism increased from 1 to 4. Proportionally, falsification increased from 35 percent to 46 percent and falsification/plagiarism increased from 1 percent to 4 percent between the comparison periods. The

frequency of falsification alone or in combination with other types rose from 66 to 77 percent between the comparison periods.

Table 8: Types of misconduct involved in research misconduct investigations, 1994-1998 and 1999-2003.

Type	1994-1998	1999-2003
Fabrication	25% (18)	19% (11)
Falsification	35% (26)	46% (27)
Plagiarism	8% (6)	3% (2)
Fabrication/ falsification	30% (22)	24% (14)
Falsification/plagiarism	1% (1)	7% (4)
Other FFP combinations	1% (1)	1% (1)
Total	100% (74)	100% (59)

Discussion

This section on allegations of research misconduct raises questions concerning (1) the decline in reported research misconduct activity, (2) the low percentage of allegations received by ORI that result in case openings, (3) the increasing percent of investigations that result in misconduct findings, and (4) the high percentage of misconduct findings based on falsification.

The decline in reported research misconduct activity occurred while the NIH research budget increased from \$9.9

billion in FY 1996 to \$21.6 billion in FY 2003.⁶ Studies and reports have suggested that a positive correlation may exist between increased funding and increased misconduct.⁷ The number of allegations received, the number of new cases opened, and the number of research misconduct findings have decreased while NIH support for biomedical and behavioral research increased at least 118 percent. What happened to the expected increase in research misconduct activity?

The low number of allegations received by ORI that result in case openings indicates that the reporting of research misconduct and other types of misconduct is not well understood within the research community. What are institutions doing to educate their faculty, staff, and students in these matters? Given the negative impact making an allegation may have on a research career, the percentage of allegations that are not substantiated needs explanation. What motivates an individual to make an allegation of research misconduct? Does the level of protection provided to whistleblowers prevent them from adequately confirming their suspicions before they make an allegation? Do institutional officials provide adequate guidance or advice to potential whistleblowers? Is confidential consultation available before formal allegations are made?

The increasing percent of investigations that are resulting in misconduct findings may indicate increased maturity in the implementation of the research misconduct regulation. Have institutions developed reliable criteria for deciding when to open an investigation? Are institutions developing greater expertise in investigating research misconduct allegations? Are institutions more willing to make misconduct findings?

The high frequency of falsification as the type of misconduct involved in PHS research misconduct investigations compared to fabrication and plagiarism also needs explanation. Research misconduct cases handled by the National Science Foundation deal primarily with plagiarism. Do the sciences differ in the opportunity structures they provide for deviant behavior? Do researchers believe they can get away with falsification more easily than fabrication or plagiarism? Is falsification considered a lesser evil than fabrication or plagiarism?

Future research

Has the implementation of the research misconduct regulation served as a deterrence to research misconduct?

⁶ These totals include research grants, research training, and intramural research reported in a table on the History of Obligations by Total Mechanisms FY 1996-FY 2005 on the NIH website. About 95 percent of the research misconduct cases opened by ORI involve support from NIH intramural and extramural programs. Other PHS agencies account for the remaining cases.

⁷ University Policies and Ethical Issues in Research and Graduate Education: Highlights of the CGS Deans' Survey. Judith P. Swazey, Karen Seashore Louis, and Melissa S. Anderson. *CGS Communicator*, V. 22, No. 3, March 1989. Top Funded Institutions Report Most Misconduct Activity. *ORI Newsletter*, V. 6, No. 3, June 1998.

Do researchers understand the policies and procedures adopted by their institutions for handling research and other misconduct allegations?

Why are so many allegations made that cannot be substantiated?

Are institutions developing greater expertise in handling research misconduct allegations?

Why is the frequency of falsification so much higher than fabrication or plagiarism?

Settings of Research Misconduct Investigations

This section looks at misconduct investigations from the perspectives of (1) extramural/intramural programs, (2) institutional settings and (3) funding mechanisms.

Extramural/intramural programs

Extramural research accounted for 97 percent of the research misconduct investigations in the 10-year period; intramural research, 3 percent.⁸ Extramural institutions conducted an average of 25 investigations per year; the median was 24, the range, 15 to 38. Intramural programs in PHS agencies averaged one investigation per year; the median was 0.5, the range, zero to 3.

Table 9: Research misconduct investigations by type of PHS research program, 1994-2003.

Program	1994	1995	1996	1997	1998	1999	2000	2001	2002	2003	Total	%
Extramural	25	38	38	28	19	24	15	18	21	24	250	97
Intramural	1	3	0	1	2	0	0	0	2	0	9	3
Total	26	41	38	29	21	24	15	18	23	24	259	100

The percentage of investigations conducted by extramural institutions increased from 95 percent to 98 percent between the comparison periods while the percentage of investigations conducted by intramural institutions decreased from 7 percent to 2 percent.

⁸Extramural research is conducted by non-federal employees in public or private institutions that receive grants or cooperative agreements. Intramural research is conducted in federal government facilities by federal employees or contractors that are supported by the PHS.

Table 10: Research misconduct investigations by type of PHS research program, 1994-1998 and 1999-2003.

Program	1994-1998	1999-2003
Extramural	95% (148)	98% (102)
Intramural	5% (7)	2% (2)
Total	100% (155)	100% (104)

Extramural institutions also made 97 percent of the ORI research misconduct findings in the 10-year period while the PHS intramural programs made 3 percent. Extramural institutions had a higher rate of research misconduct findings (52 percent) than the intramural programs (44 percent). The average number of misconduct findings made by extramural institutions per year was 13; the median, 13, and the range, 8 to 23. The average number of misconduct findings made by the intramural programs per year was 0.4; the median, zero, and the range zero to 2.

Table 11: Research misconduct findings by type of PHS research program, 1994-2003.

Program	1994	1995	1996	1997	1998	1999	2000	2001	2002	2003	Total	%
Extramural	10	23	16	14	9	12	8	14	11	12	129	97
Intramural	1	1	0	0	0	0	0	0	2	0	4	3
Total	11	24	16	14	9	12	8	14	13	12	133	100

Although the number of misconduct findings made by extramural institutions decreased by 21 percent between the comparisons periods, extramural institutions accounted for 97 percent of the research misconduct findings made in each period and the PHS intramural programs accounted for 3 percent.

Table 12: Research misconduct findings by type of PHS research program, 1994-1998 and 1999-2003.

Program	1994-1998	1999-2003
Extramural	97% (72)	97% (57)
Intramural	3% (2)	3% (2)
Totals	74	59

Institutional settings⁹

Medical schools were the primary sites for research misconduct investigations by an overwhelming margin accounting for 71 percent of the investigations conducted during the 10-year period. Colleges and universities were a distant second with 12 percent. Research organizations, institutes, laboratories, and foundations were in third place at 10 percent. The remaining investigations were conducted in PHS agencies or independent hospitals.¹⁰

Table 13: Research misconduct investigations by institutional settings, 1994-2003

Institutional Setting	1994	1995	1996	1997	1998	1999	2000	2001	2002	2003	Total	%
Medical school	20	27	32	19	12	16	12	12	15	19	184	71

⁹The institutional settings section was revised in April 2006 when a new categorization was adopted for institutional settings. Medical schools include their clinical facilities which were previously coded as independent hospitals. The addition of colleges and universities almost emptied the other category.

¹⁰In 2000 the Secretary of Health and Human Services permitted PHS agencies to conduct their own investigations. Prior to that time, the PHS agencies conducted the inquiries and ORI conducted the investigations.

College/Univ	4	1	4	6	1	6	1	4	4	1	32	12
Independent Hospital	0	3	1	1	2	0	0	0	0	3	0	7
Research org	1	7	1	2	4	2	2	2	1	4	26	10
PHS agency	1	3	0	1	2	0	0	0	2	0	9	4
Other	0	0	0	0	0	0	0	0	1	0	1	0
Total	26	41	38	29	21	24	15	18	23	24	259	100

A comparison of the two five-year periods indicates that most investigations were held in medical schools over the entire 10-year period. The largest percentage increase between the two periods was in the college and university category. The largest percentage decrease came in the independent hospital and PHS agency categories.

Table 14: Research misconduct investigations by institutional settings, 1994-1998 and 1999-2003.

Setting	1994-1998	1999-2003
Medical school	71% (110)	71% (74)
College/University	10% (16)	15% (16)
Independent Hospital	5% (7)	0% (0)
Research org	9% (15)	11% (11)
PHS agency	5% (7)	2% (2)
Other	0% (0)	1% (1)
Total	100% (155)	100% (104)

Independent hospitals had the highest rate of research misconduct findings (86 percent) followed by colleges and universities at 75 percent. PHS agencies had the lowest percentage of misconduct findings (44 percent) followed by research organizations, laboratories and foundations (46 percent) and medical schools (47 percent).

Table 15: Percent of investigations resulting in research misconduct findings by institutional settings, 1994-2003.

Setting	Misconduct Findings	Number of Investigations	Percent of investigations making misconduct findings
Medical school	86	184	47
College/University	24	32	75
Hospital	6	7	86
Research org	12	26	46
PHS agency	4	9	44
Other	1	1	100
Total	133	259	51

Medical schools and colleges and universities accounted for 83 percent of the misconduct findings and 84 percent of the no misconduct findings. Medical schools made 65 percent of the misconduct findings and 78 percent of the no misconduct findings. Colleges and universities made 18 percent of the misconduct findings and 6 percent of the no misconduct findings.

Table 16: Number and percent of misconduct and no misconduct findings by institutional setting, 1994-2003.

Setting	Misconduct		No Misconduct	
	Number	Percent	Number	Percent
Medical school	86	65	98	78
College/Univ	24	18	8	6
Independent hospital	6	4	1	1
Research org	12	9	14	11
PHS agency	4	3	5	4
Other	1	1	0	0
Total	133	100	126	100

Funding mechanisms

Research misconduct investigations have focused on research funded through research and research training grants, cooperative agreements, and other funding mechanisms. The research grant category is the most frequent funding mechanism involved in research misconduct investigations accounting for 73 percent of the investigations over the 10-year period. Cooperative agreements are the second most frequent funding

mechanism with 9 percent, followed by research training grants, 8 percent, other mechanisms, 7 percent, and intramural funding, 3 percent.

Table 17: Research misconduct investigations by funding mechanisms, 1994-2003.

Mechanism	1994	1995	1996	1997	1998	1999	2000	2001	2002	2003	Total	%
Research *	21	19	30	18	13	23	12	16	18	20	190	73
Research training **	1	8	5	1	1	0	0	0	1	3	20	8
Coop agreement ***	2	6	3	3	3	1	2	0	1	1	22	9
Intramural	1	3	0	1	2	0	0	0	2	0	9	3
Other ****	1	5	0	6	2	1	0	2	1	0	18	7
Total	26	41	38	29	21	25	14	18	23	24	259	100

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

** F32, KO2, KO8, T32

***UO1, U10

****NO1, SO7

A comparison of the five year periods indicates that the funding mechanisms involved in investigations is shifting substantially toward the research category and away from the other funding mechanisms. The percentage of investigations involving the research category rose 20 percent between the comparison periods while the percent of investigations involving every other funding mechanism declined.

Table 18: Research misconduct investigations by funding mechanisms, 1994-1998 and 1999-2003.

Mechanism	1994-1998	1999-2003
Research*	65% (101)	85% (89)
Research training**	10% (16)	4% (4)

Cooperative agreements***	11% (17)	5% (5)
Intramural	5% (7)	2% (2)
Other****	9% (14)	4% (4)
Total	100% (155)	100% (104)

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

** F32, KO2, KO8, T32

***UO1, U10

****NO1, SO7

Discussion

This section on the setting of research misconduct investigations raises questions concerning (1) the disparity between the number of research misconduct investigations and findings between the extramural and intramural programs; (2) the increasing concentration of research misconduct investigations in medical schools; and (3) the increasing concentration of research misconduct investigations from research funded through grants.

The NIH allocated about 88 percent of its research budget to extramural research and about 12 percent of its research budget to intramural research from FY 1996 to FY 2003. The extramural program accounted for 97 percent of the research misconduct investigations and 97 percent of the research misconduct findings. The comparative data indicates that the percentage of research misconduct investigations occurring in the extramural program is rising while it is dropping in the intramural program. Are there differences between the extramural and intramural programs that can explain these findings?

In FY 2002, NIH awarded 50.6 percent of its extramural research funds to medical schools, 9.6 percent to research organizations, institutes, laboratories and foundations, 7.8 percent to independent hospitals, and 32.2 percent to other types of institutions. Medical schools are the primary sites for the conduct of research misconduct investigations accounting for 71 percent of the investigations over the 10-year period. Medical schools have made the most findings - misconduct and no misconduct. What accounts for the differences in research misconduct activity in the various institutional settings?

Within institutions, numerous departments have been involved in research misconduct investigations including anatomy, anesthesiology, biochemistry, biology, cardiology, cell biology, dermatology, digestive diseases, gene therapy, gerontology, immunology, internal medicine, medicine, microbiology, molecular biology, molecular endocrinology, nephrology, neurology, obstetrics and gynecology, oncology, ophthalmology, otolaryngology, pathology, pediatrics, pharmacology, physiology, psychology, psychiatry, radiology, surgery, and urology. Do opportunity structures for committing research misconduct differ by departments?

Most of the NIH extramural support is provided through research grants (67 percent), especially the RO1 (47 percent). Ten percent of the funds are awarded through cooperative agreements; 4 percent through research training awards,

and 7 percent through other mechanisms. Funding mechanisms may establish very different research environments and opportunity structures for committing research misconduct. Seventy-three percent of the investigations involved research support by the research grant funding mechanism. The comparative data indicate that research misconduct investigations are increasingly focused on the research grant funding mechanism. The research grant category, however, contains 10 funding mechanisms that require very different organizational structures to conduct the research. Research misconduct has occurred in research supported through all of the funding mechanisms except for RO3, R22, R37, and P10. How does the organization of research differ by funding mechanism?

Future research

How do extramural and intramural research environments differ?

Why is the conduct of research misconduct investigations concentrated in medical schools?

Are some departmental structures more susceptible to research misconduct than others?

Do funding mechanisms provide different opportunity structures for engaging in research misconduct?

Respondents

Respondents are the individuals who are accused of research misconduct. This section will present data on their (1) academic rank, (2) highest degree and (3) gender. Data will also be presented on the investigation outcomes by the academic rank, highest degree and gender of the respondents.

Two hundred and seventy-four respondents were involved in the 259 investigations conducted over the 10-year period. Research misconduct appears to be a solitary activity for 95 percent of the investigations had only one respondent. No research misconduct investigation involved more than 3 respondents. The number of respondents declined 38 percent between the comparison periods from 170 to 104.

Academic rank

Persons accused of research misconduct cover the academic ranking structure from top to bottom. The most frequent academic ranks of respondents were associate professor, 20 percent; technician, 17 percent; postdoctoral fellow, 16 percent, and professor, 15 percent. The faculty ranks (professor, associate professor, assistant professor) accounted for 46 percent of the respondents while non faculty ranks accounted for 49 percent. The academic rank of the remaining respondents is unknown.

Table 19: Academic rank of respondents in research misconduct investigations, 1994-2003.

Academic Rank	1994	1995	1996	1997	1998	1999	2000	2001	2002	2003	Total	%
Professor	3	5	7	10	4	5	2	0	2	2	40	15
Associate professor	14	15	9	3	1	1	5	1	4	2	55	20

Assistant professor	0	10	3	4	1	4	1	5	0	2	30	11
Postdoctoral fellow	3	5	12	6	3	1	3	2	5	4	44	16
Research associate/assistant	0	2	1	4	3	4	2	1	2	3	22	8
Student	3	1	3	3	2	1	1	3	4	1	22	8
Technician	3	8	4	0	5	6	1	5	5	10	47	17
None/unknown	0	0	5	2	3	2	0	1	1	0	14	5
Total	26	46	44	32	22	24	15	18	23	24	274	100

The number of respondents declined from 170 to 104 (39 percent) between the comparison periods. A major shift occurred in the academic rank of respondents between the comparison periods. While the faculty ranks accounted for 52 percent of the respondents from 1994-1998, they accounted for 34 percent from 1999-2003. Respondents in the non faculty ranks increased from 48 to 66 percent between the comparison periods. Between the two periods, respondents who were professors decreased 7 percent; associate professors, 13 percent, but assistant professors increased 2 percent. In the non faculty ranks, technicians increased 14 percent; research associates/assistants, 6 percent, and students, 3 percent, but postdocs decreased 3 percent, and unknowns decreased, 2 percent.

Table 20: Academic rank of respondents in research misconduct investigations, 1994-1998 and 1999-2003.

Rank	1994-1998	1999-2003
Professor	17% (29)	10% (11)
Associate professor	25% (42)	12% (13)
Assistant professor	10% (18)	12% (12)
Postdoctoral fellow	17% (29)	14% (15)
Research assoc/asst	6% (10)	12% (12)

Student	7% (12)	10% (10)
Technician	12% (20)	26% (27)
None/unknown	6% (10)	4% (4)
Total	100% (170)	100% (104)

Respondents in non faculty ranks were more likely to have a misconduct finding made against them (66 percent vs 34 percent) than respondents in the faculty ranks. Research associates and assistants had the highest rate of misconduct findings (77 percent) made against them, followed by students (68 percent), and postdoctoral fellows (61 percent). The lowest rate of misconduct findings was against professors (15 percent).

Table 21: Percent of respondents against whom research misconduct findings were made by academic rank, 1994-2003.

Rank	Misconduct findings	Number of respondents	Percent of misconduct findings
Professor	6	40	15
Associate professor	24	55	44
Assistant professor	13	30	43
Postdoctoral fellow	27	44	61
Research associate/asst.	17	22	77
Student	14	22	68
Technician	31	47	51
None/unknown	1	14	7
Total	133	274	49

The highest number of misconduct findings was made against technicians (31) followed by postdoctoral fellows (27) and associate professors (24). These three academic ranks accounted for 62 percent of the misconduct findings. Professors had the least misconduct findings made against them (6). Faculty ranks constituted 31 percent of the misconduct population; non faculty ranks, 68 percent. No misconduct findings were most frequently made in investigations involving professors (34) and associate professors (31). Faculty ranks accounted for 58 percent of the no misconduct findings; non faculty ranks, 33 percent. The academic rank of the remaining 9 percent is unknown.

Table 22: Number and percent of misconduct and no misconduct findings by academic rank of respondents, 1994-2003.

Rank	Misconduct		No misconduct	
	Number	Percent	Number	Percent
Professor	6	5	34	24
Associate professor	24	16	31	22
Assistant professor	13	10	17	12
Postdoctoral fellow	27	20	17	12
Research associate/assistant	17	13	5	4
Student	14	11	8	6
Technician	31	24	16	11
None/Unknown	1	1	13	9

Total	133	100	141	100
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Highest degree

The highest degree held by respondents ranged from a bachelor's degree to a doctorate. Seventy-six percent of the respondents held advanced degrees, 70 percent held doctorates. Forty-five percent held Ph.D. degrees; 23 percent held M. D. degrees, and two percent held other doctorates including D.D.S., D.V.M., and Ed.D. Six percent had a master's degree. Another 12 percent held bachelor's degrees. The highest degree of the remaining respondents is unknown.

Table 23: Highest degree of respondents in research misconduct investigations, 1994-2003

Highest Degree	1994	1995	1996	1997	1998	1999	2000	2001	2002	2003	Total	%
Ph.D	7	21	27	16	8	11	8	7	11	8	124	45
M.D.	10	14	9	10	2	4	4	1	3	5	62	23
Other doctorates*	0	1	2	0	0	0	0	1	0	1	5	2
Masters	1	0	1	2	5	2	0	2	3	1	17	6
Bachelors.	8	4	3	3	4	3	2	2	2	1	32	12
Unknown	0	6	2	1	3	4	1	5	4	8	34	12
Total	26	46	44	32	22	24	15	18	23	24	274	100

*Includes 1 D.D.S., 3 D.V.M., 1 Ed.D

The percent of respondents holding a master's degree was the only category to increase between the first and second five-year periods (5 to 8 percent). Respondents with M.D. degrees showed the largest decrease from 26 to 16 percent. The Ph.D. degree was the most frequent highest degree held by respondents even though it declined slightly between the comparison periods from 47 to 43 percent.

Table 24: Highest degree of respondents in research misconduct investigations, 1994-1998 and 1999-2003.

Degree	1994-1998	1999-2003
Ph.D.	47% (79)	43% (45)
M.D.	26% (45)	16% (17)
Other doctorates	2% (3)	2% (2)

Master	5% (9)	8% (8)
Bachelor	13% (22)	10% (10)
Unknown	7% (12)	21% (22)
Total	100% (170)	100% (104)

Respondents who did not have a doctorate were more likely to have a misconduct finding made against them (61 percent) than those that had a doctorate (42 percent). The misconduct rate for respondents who had a master's degree was 65 percent, bachelor's degree was 59 percent. The misconduct rate for respondents who had Ph.D. degrees was 45 percent. The lowest misconduct rate was for respondents who held M.D. degrees at 34 percent.

Table 25: Percent of respondents against whom research misconduct findings were made by highest degree, 1994-2003.

Degree	Number of misconduct findings	Number of respondents	Percent of misconduct findings
Ph.D.	56	124	45
M.D.	21	62	34
Other doctorates	3	5	60
Masters	11	17	65
Bachelors	19	32	59
Unknown	23	34	68
Total	133	274	49

Sixty percent of the misconduct findings were made against respondents with doctorates, including Ph.Ds. (42 percent), M.Ds. (16 percent) and other doctorates (2 percent). Respondents without doctorates accounted for 22 percent of the misconduct population including 8 percent with master’s degrees and 14 percent with bachelor’s degrees. The highest degree for 18 percent of the respondents was unknown; the majority probably did not hold doctorates.

Seventy-nine percent of the no misconduct findings involved respondents with doctorates, including Ph.Ds. (48 percent), M.Ds. (29 percent) and other doctorates (2 percent). Respondents without doctorates accounted for 13 percent of the no misconduct population including 4 percent with master’s degrees and 9 percent with bachelor’s degrees. The highest degree for the other 8 percent was unknown; the majority probably did not hold doctorates.

Table 26: Number and percent of misconduct and no misconduct findings by highest degree of respondent, 1994-2003.

Degree	Misconduct		No Misconduct	
	Number	Percent	Number	Percent
Ph.D.	56	42	68	48
M.D.	21	16	40	29
Other doctorates	3	2	3	2
Masters	11	8	6	4
Bachelors	19	14	13	9
Unknown	23	18	11	8
Total	133	100	141	100

Gender

Respondents were overwhelmingly male (70 percent) over the 10-year period. Male respondents outnumbered female respondents in every year except 1998. The average number of male respondents each year was 19, the median was 18, the range 10 to 34. The average number of female respondents each year was 8, the median was 8.5, and the range, 2 to 16.

Table 27: Gender of respondents in research misconduct investigations, 1994-2003.

Gender	1994	1995	1996	1997	1998	1999	2000	2001	2002	2003	Total	%
Male	21	34	27	23	10	16	13	13	20	14	191	70
Female	5	12	16	9	12	8	2	5	3	9	81	29
Unknown	0	0	1	0	0	0	0	0	0	1	2	1
Total	26	46	44	32	22	24	15	18	23	24	274	274

The percent of respondents who were male increased from 68 to 73 percent between the two five-year periods. The percent of female respondents dropped from 32 to 26 percent between the comparison periods. The gender of the remaining one percent of respondents is unknown.

Table 28: Gender of respondents in research misconduct investigations, 1994-1998 and 1999-2003.

Gender	1994-1998 N	1999-2003 N
Male	68% (115)	73% (76)
Female	32% (54)	26% (27)
Unknown	0% (1)	1% (1)
Total	100% (170)	100% (104)

The rate of misconduct findings against female respondents (51 percent) was a little higher in comparison with male respondents (48 percent).

Table 29: Percent of respondents against whom research misconduct findings were made by gender, 1994-2003.

Gender	Number of misconduct findings	Number of respondents	Percent of research misconduct findings
Male	91	191	48
Female	41	81	51
Unknown	1	2	50
Total	133	274	49

Males comprised 68 percent of the respondent population against whom misconduct findings were made; females comprised 31 percent. Males accounted for 71 percent of the respondent population against whom no misconduct finding was made; females accounted for 28 percent.

Table 30: The number and percent of misconduct and no misconduct findings by gender of respondents, 1994-2003.

Gender	Misconduct		No Misconduct	
	Number	Percent	Number	Percent
Male	91	68	100	71
Female	41	31	40	28
Unknown	1	1	1	1
Total	133	100	141	100

Administrative actions

Administrative actions were imposed by the federal government and by institutions on respondents against whom research misconduct findings were made. Institutions also imposed administrative actions on some respondents against whom no finding of research misconduct was made because the investigation discovered other inappropriate behavior or poor management practices.

HHS imposes one or more of six administrative actions on respondents against whom research misconduct findings are made: (1) debarment from receipt of federal funding; (2) prohibition from serving the PHS in an advisory capacity; (3) supervision of research; (4) retraction or correction of publications; (5) certification of data provided in proposals to the PHS, and (6) certification that sources from which theories, ideas, data, findings, methodology and so on were properly acknowledged in PHS proposals and publication of research results. The administrative actions were imposed for periods ranging from one to 10 years.

HHS imposed an average of 2.3 administrative actions on each of the 133 persons against whom research misconduct findings were made. The most frequently imposed administrative action (95 percent) was prohibition from serving the PHS in an advisory capacity. Debarment from the receipt of federal support, the action that may have the most severe impact on a research career, was imposed on 65 percent of the respondents. The percent of respondents on whom the other administrative actions were imposed were supervised research, 36 percent; requiring the retraction and/or correction of publications, 16 percent; certification of data submitted in proposals to the PHS, 11 percent, and certification that sources of information were appropriately acknowledged, 5 percent.

Table 31: Administrative actions taken by federal government in research misconduct investigations, 1994-2003.

Government Action	1994	1995	1996	1997	1998	1999	2000	2001	2002	2003	Total
Number of Respondents	11	24	16	14	9	12	8	14	13	12	133
Prohibited from serving as an advisor to PHS	10	21	17	13	9	12	6	13	13	12	126
Debarment from receipt of federal support	9	16	13	8	4	6	6	9	8	7	86
Supervision of research	1	6	8	5	6	8	2	4	3	5	48

Retraction/correction of publications	2	5	1	2	1	2	1	2	3	2	21
Certification of data	0	1	3	2	0	1	1	4	1	2	15
Certification of sources	1	2	1	2	0	0	0	0	0	0	6
Total	23	51	43	32	20	29	16	32	28	28	302

The percent of respondents who were debarred or required to certify their sources declined 7 and 8 percent respectively between the comparison periods. Certification of data (which generally is imposed when plagiarism is found) was not imposed in the second five-year period. The use of three other administrative actions increased: certification of data, 7 percent; supervised research, 2 percent, and retractions and corrections, 2 percent.

Table 32: Administrative actions taken by federal government in research misconduct investigations, 1994-1998 and 1999-2003.

Government action	1994-1998	1999-2003
Prohibited from serving as an advisor to PHS	95% (70)	95% (56)
Debarment from receipt of federal support	68% (50)	61% (36)
Supervision of research	35% (26)	37% (22)

Retraction/correction of publications	15% (11)	17% (10)
Certification of data	8% (6)	15% (9)
Certification of sources	8% (6)	0% (0)
Total administrative actions	169	133
Total respondents	74	59
Actions per respondent	2.3	2.3

Data on institutional actions against respondents who had research misconduct findings made against them are incomplete because institutions are not required to report their actions to ORI. Institutions, however, did expand the list of administrative actions taken against respondents by the federal government, particularly in the 1999-2003 period. Termination of employment was the most frequently reported institutional action. Other actions were reprimands, ethical training, rescission of degree, formal apology, suspension with pay, community service, notifying the new employer, probation, and withholding pay.

Institutions also reported imposing actions on respondents against whom no ORI research misconduct finding was made but other behaviors were discovered that violated the standards of the institutions. Again, more institutional actions were reported in the second five-year period than in the first. Termination of employment was the most frequently reported action. Other actions included reprimands, supervised research, retractions/corrections, probation, ethical training, prohibition from serving in an advisory capacity to the PHS, grant withdrawal, withholding pay increases, removal from an administrative position, barred from human research, suspension with pay, formal apology, withheld pay, community service, and rescinding principal investigator status for one year.

Discussion

The section on respondents raises questions concerning the (1) shift in the academic rank of respondents; (2) the decline in respondents holding doctorates; (3) the differences between male and female respondents; and (4) the imposition of PHS administrative actions.

The data show that respondents cover the academic ranks from technician to professor. The academic rank of respondents, however, appears to have undergone considerable change during the 10-year period. From 1994-1998, 52 percent of the respondents came from the faculty ranks (professor, associate professor, assistant professor), but faculty representation among respondents dropped to 34 percent from 1999-2003. In addition, misconduct findings were returned in 34 percent of the investigations involving respondents in the faculty ranks compared to 66 percent of the investigations involving non faculty respondents. What accounts for these differences?

Researchers holding Ph.Ds. are more frequently supported by the PHS than researchers holding any other degree, so it is not surprising that respondents hold Ph.Ds. more often than any other degree. What is surprising is the

decrease in the number of respondents holding an M.D. between the two comparison periods. Overall, respondents who held doctorates comprised 75 percent of the respondents from 1994-1998, but only 61 percent from 1999-2003. Misconduct findings were returned in 61 percent of the investigations involving respondents without doctorates compared to 42 percent of the investigations involving respondents with doctorates. Do misconduct cases involving respondents who are non faculty and do not hold doctorates differ from cases involving respondents who are faculty and hold doctorates?

Seventy percent of the principal investigators supported by NIH are males; 24 percent are females; the gender of the remaining 6 percent is unknown. Seventy percent of the respondents are male; 29 percent female; the gender of 1 percent is unknown. How do male and female respondents differ?

The imposition of PHS administrative actions on research careers has not been explored. The administrative actions vary in severity and potential impact. Debarment may end a research career while supervised research and certification of data permit rehabilitation. Most administrative actions require the cooperation of the employing institution for implementation. The effectiveness of PHS administrative actions needs study.

Future research

What accounts for the changing composition of the respondent population?

What explains the rates of misconduct findings by academic rank and/or highest degree of respondents?

How do male and female respondents differ?

What effect does PHS administrative actions have on respondents and institutions?

Whistleblowers

Whistleblowers are the individuals who make allegations of research misconduct. Whistleblowers are essential to the reporting and investigation of research misconduct for two reasons. First, individuals rarely report their own misconduct. Second, whistleblowers become valuable witnesses in investigations. This section will present data on the (1) academic rank, (2) highest degree, and (3) gender of the whistleblowers. In addition, data will be presented on outcomes of the investigation initiated by the allegations made by the whistleblowers.

There were 289 whistleblowers in the 259 investigations that occurred in the 10-year period. Whistleblowers like respondents generally appear to act alone. Only 18 of the 259 investigations involved more than one whistleblower; 11 of those 18 investigations returned misconduct findings.

Contrary to popular belief, most whistleblowers were in the faculty ranks rather than the non faculty ranks over the 10-year period. The faculty ranks (dean, professor, associate professor, assistant professor) accounted for 57 percent of the whistleblowers while the non faculty ranks (postdoctoral fellows, research associates/assistants, students,

technicians) accounted for 19 percent of the whistleblowers. The percentage of whistleblowers that came from the non faculty ranks might increase substantially if the academic rank of the anonymous or confidential whistleblowers (25 percent) was known. The academic ranks that contributed the most whistleblowers were professors (30 percent) and associate professors (16 percent).

Table 33: Academic rank of whistleblowers in research misconduct investigations, 1994-2003.

Academic Rank	1994	1995	1996	1997	1998	1999	2000	2001	2002	2003	Total	%
Dean	2	1	1	0	0	0	0	0	0	0	4	1
Professor	8	9	15	11	11	7	3	1	8	13	86	30
Associate professor	4	9	9	5	2	2	1	7	3	5	47	16
Assistant professor	0	5	9	4	1	4	3	1	1	0	28	10
Postdoctoral fellow	1	1	3	3	2	0	1	1	2	0	14	5
Research associate/assistant	0	1	0	1	3	4	1	0	0	1	11	4
Student	2	1	3	0	0	0	1	1	2	2	12	4
Technician	4	1	0	2	2	0	0	3	1	1	14	5
Anon/confid/unknown	8	15	8	6	5	8	5	5	8	5	73	25
Total	29	43	48	32	26	25	15	19	25	27	289	100

The number of whistleblowers decreased from 178 to 111 (38 percent) between the comparison periods. Whistleblowers from the faculty ranks declined from 57 to 53 percent while whistleblowers in the non faculty ranks increased from 17 percent to 19 percent. The unknown group increased from 24 to 28 percent. The distribution of whistleblowers across the academic ranks was fairly stable over the 10 year period. The percentage of whistleblowers coming from five academic ranks declined; two academic ranks showed increases and one academic rank remained the same. The largest percentage change was in the anonymous/confidentiality/unknown category.

Table 34: Academic rank of whistleblowers in research misconduct investigations, 1994-1998 and 1999-2003.

Rank	1994-1998	1999-2003
Dean	2% (4)	0% (0)
Professor	30% (54)	29% (32)

Associate professor	16% (29)	16% (18)
Assistant professor	11% (19)	8% (9)
Postdoctoral fellow	6% (10)	4% (4)
Research assoc/asst	3% (5)	5.5% (6)
Student	3% (6)	5.5% (6)
Technician	5% (9)	4% (4)
Anon/confid/unknown	24% (42)	28% (31)
Total	100% (178)	100% (111)

Allegations made by research associates resulted in the highest rate of misconduct findings (64 percent) followed by students (58 percent), professors (55 percent), and associate professors (51 percent). Allegations made by technicians resulted in the lowest rate of misconduct findings (29 percent) followed by postdoctoral fellows (36 percent).

Table 35: Percent of substantiated allegations by academic rank of whistleblowers, 1994-2003.

Rank	Number of whistleblowers whose allegations were substantiated	Total number of whistleblowers	Percent of substantiated allegations
Dean	2	4	50
Professor	47	86	55
Associate professor	24	47	51
Assistant professor	12	28	43

Postdoctoral fellow	5	14	36
Research assoc/asst	7	11	64
Student	7	12	58
Technician	4	14	29
Anon/confid/unknown	40	73	55
Total	148	289	51

Allegations made by whistleblowers in the faculty ranks resulted in 57 percent of the misconduct findings compared to 16 percent for the non faculty whistleblowers and 27 percent for the unknowns. Allegations made by professors and associate professors accounted for nearly half of the misconduct findings (48 percent).

Allegations made by whistleblowers in the faculty ranks resulted in 56 percent of the no misconduct findings compared to 20 percent for whistleblowers in the non faculty ranks and 24 percent for the unknown whistleblowers. Allegations made by professors and associate professors accounted for 44 percent of the no misconduct findings.

Table 36: The number and percent of misconduct and no misconduct findings by academic rank of whistleblowers, 1994-2003.

Rank	Misconduct		No Misconduct	
	Number	Percent	Number	Percent
Dean	2	1	2	1
Professor	47	32	39	28
Associate professor	24	16	23	16
Assistant professor	12	8	16	11

Postdoctoral fellow	5	3	9	6
Research associate/assistant	7	5	4	3
Student	7	5	5	4
Technician	4	3	10	7
Anon/confid/unknown	40	27	33	24
Total	148	100	141	100

Highest degree

Sixty-seven percent of the whistleblowers held doctorates; 45 were Ph.Ds. and 22 percent were M.Ds. Non doctorates accounted for 7 percent of the whistleblowers. The highest degree of 26 percent of the whistleblowers is unknown.

Table 37: Highest degree of whistleblowers in research misconduct investigations, 1994-2003.*

Highest Degree	1994	1995	1996	1997	1998	1999	2000	2001	2002	2003	Total	%
Ph.D	8	17	24	13	13	12	8	11	10	14	130	45
M.D.	7	8	13	11	6	4	3	1	5	6	64	22
J.D.	0	1	0	0	0	0	0	0	0	0	1	0
Master	3	1	0	0	0	0	0	1	1	1	7	2
Bachelor	2	2	5	0	0	0	0	2	1	1	13	5
Unknown	9	14	6	8	7	9	4	4	8	5	74	26
Total	29	43	48	32	26	25	15	19	25	27	289	100

A major shift occurred among whistleblowers who held doctorates between the comparison periods. The percent of whistleblowers with Ph.Ds. increased from 42 percent to 49 percent while the percent of whistleblowers with M. Ds. decreased from 25 percent to 17 percent. Researchers with Ph.D. degrees dominate whistleblowing.

Table 38: Highest degree of whistleblowers in research misconduct investigations, 1994-1998 and 1999-2003.

Degree	1994-1998	1999-2003
Ph.D.	42% (75)	49% (55)

M.D.	25% (45)	17% (19)
J. D.	1% (1)	0% (0)
Master	2% (4)	3% (3)
Bachelor	5% (9)	4% (4)
Unknown	25% (44)	27% (30)
Total	100% (178)	100% 111

Allegations made by whistleblowers with bachelor degrees resulted in the highest rate of research misconduct findings (62 percent) followed by whistleblowers with M. D. degrees (53 percent) and Ph.D. degrees (50 percent). Whistleblowers with master degrees had the lowest percent of substantiated allegations (29 percent).

Table 39: Percent of substantiated allegations by highest degree of whistleblower, 1994-2003.

Degree	Number of whistleblowers whose allegations were substantiated	Total number of whistleblowers	Percent of substantiated allegations
Ph.D.	65	130	50
M.D.	34	64	53

J. D.	0	1	0
Master	2	7	29
Bachelor	8	13	62
Unknown	39	74	53
Total	148	289	51

Allegations made by whistleblowers holding the Ph.D. degree initiated investigations that produced 44 percent of the research misconduct findings. Allegations made by whistleblowers with M.D. degrees resulted in 23 percent of the research misconduct findings..

Allegations made by whistleblowers holding the Ph.D. degree also produced 46 percent of the no misconduct findings. Allegations made by whistleblowers with M.D. degrees accounted for 21 percent of the no misconduct findings. Allegations made by whistleblowers holding the Ph.D. or M.D. degree accounted for 67 percent of the misconduct findings and 67 percent of the no misconduct findings.

Table 40: Number and percent of misconduct and no misconduct findings by highest degree of whistleblowers, 1994-2003.

Degree	Misconduct		No Misconduct	
	Number	Percent	Number	Percent
Ph.D.	65	44	65	46
M.D.	34	23	30	21
Other doctorates	0	0	1	1
Masters	2	1	5	4
Bachelors	8	6	5	4
Unknown	39	26	35	24
Total	148	100	141	100

Gender

Like respondents, whistleblowers were predominately males (56 percent) over the 10-year period. Females accounted for 23 percent of the whistleblowers and unknowns the remaining 21 percent.

Table 41: Gender of whistleblowers in research misconduct investigations, 1994-2003.

Gender	1994	1995	1996	1997	1998	1999	2000	2001	2002	2003	Total	%

Male	14	25	33	23	13	16	8	11	9	11	163	56
Female	7	5	8	3	9	1	3	5	11	13	65	23
Unknown	8	13	7	6	4	8	4	3	5	3	61	21
Total	29	43	48	32	26	25	15	19	25	27	289	100

A major shift occurred in the gender of whistleblowers between the comparison periods. The percent of male whistle whistleblowers declined from 61 to 49 percent while the percent of female whistleblowers increased from 18 to 30.

Table 42: Gender of whistleblowers in research misconduct investigations, 1994-1998 and 1999-2003.

Gender	1994-1998	1999-2003
Male	61% (108)	49% (55)
Female	18% (32)	30% (33)
Unknown	21% (38)	21% (23)
Total	100% (178)	100% (111)

Allegations made by male whistleblowers resulted in a higher rate of research misconduct (54 percent) than those made by female whistleblowers (45 percent). The rate of research misconduct findings for whistleblowers whose gender was unknown was 51 percent.

Table 43: Percent of whistleblowers whose allegations were substantiated by gender, 1994-2003.

Gender	Number of whistleblowers whose allegations were substantiated	Total number of whistleblowers	Percent of substantiated allegations
Male	88	163	54
Female	29	65	45
Unknown	31	61	51
Total	148	289	51

Male whistle lowers were involved in 59 percent of the investigations that found research misconduct followed by the unknowns at 21 percent and female whistleblowers at 20 percent. Male whistleblowers were also involved in 53 percent of the investigations that did not find research misconduct followed by female whistleblowers at 26 percent and the unknowns at 21 percent.

Table 44: Number and percent of misconduct and no misconduct findings by gender of whistleblowers, 1994-2003.

Gender	Misconduct		No Misconduct	
	Number	Percent	Number	Percent
Male	88	59	75	53
Female	29	20	36	26
Unknown	31	21	30	21
Total	148	100	141	100

Discussion

This section raises questions concerning the (1) academic rank of respondents, (2) the highest degree held by whistleblowers, (3) the gender of whistleblowers, (4) the success rate of whistleblowers, and (5) the relationship between the whistleblowers and the respondents.

Contrary to popular belief, allegations of research misconduct are most frequently made by professors and associate professors rather than postdocs, graduate students or technicians. Are professors and associate professors making allegations against colleagues or subordinates? Do their allegations originate from their mentoring or supervisory responsibilities? Why did the number of professors and associate professor making allegations decrease so dramatically between the comparison periods?

The most successful whistleblowers seem to be the least qualified persons to make allegations - research associates/assistant's and students. Successful being defined as making allegations that are substantiated in investigations. The rate of misconduct findings for research associate/assistants and students was 64 and 58 percent respectively. Professors and associate professors who should be most qualified to recognize research misconduct

when they see it have rates of misconduct findings of 55 and 51 percent respectively. The least successful are postdoctoral fellows (36 percent) and technicians (29 percent). Why? This pattern continues when whistleblowers are categorized by their highest degrees. Whistleblowers with bachelor's degree have a 62 percent success rate while the success rate for whistleblowers with M.D. or Ph.D. degrees is 53 and 50 percent respectively.

Like respondents, whistleblowers are predominately males but females seem to be increasing their participation. Are female whistleblowers similar to their male counterparts? Does the increasing participation of females as whistleblowers reflect their growing presence in biomedical research as principal investigators?

Another area of research that may be worthwhile pursuing is the relationship between whistleblowers and respondents. In other words, who accuses whom. Does it make any difference in the outcome whether a professor accuses another professor, postdoctoral fellow, or technician? Or if a postdoctoral fellow accuses a professor, research associate or student? Or a technician accuses a graduate student, associate professor or another technician?

Like respondents, the consequences of whistleblowing for whistleblowers are relatively unexplored.¹¹ Do the consequences depend on whether the allegation is substantiated? What happens if the allegation is deemed to have been made in bad faith? Was the whistleblower protected by the institution? Were retaliators disciplined? Whistleblowers have not been asked to evaluate the process employed by their institution to handle their allegations of research misconduct.

Future research

Why are so many allegations of research misconduct made by professors and associate professors?

Why do allegations of research misconduct made by research associates/assistant's and students have a higher success rate than those made by professors and associate professors?

Do female whistleblowers differ from male whistleblowers? Do female whistleblowers differ from female respondents?

Does who accuse whom affect the success rate of allegations of research misconduct?

What consequences does whistleblowing have on the careers of whistleblowers?

Institutional Responses to Allegations

The misconduct regulation requires institutions to go through a two-step process in responding to allegations of research misconduct. The first step is the inquiry which determines "whether an allegation or apparent instance of

¹¹ Consequences of Whistleblowing for the Whistleblower in Misconduct in Science Cases. Washington, D.C.: Research Triangle Institute, 1995. Available on the ORI web site at <http://ori.hhs.gov>.

misconduct warrants an investigation.”¹² The second step is an investigation which involves “the formal examination and evaluation of all relevant facts to determine if misconduct has occurred.”¹³ This section presents data on (1) the length of inquiries and investigations, (2) the size of panels that conducted inquiries and investigations, and (3) whether the inquiries and investigation resulted in findings of research misconduct. The data on the inquiries are limited to those inquiries that preceded an investigation.

Inquiries

Length

According to the PHS misconduct regulation, institutions should complete an inquiry “within 60 calendar days of its initiation unless circumstances clearly warrant a longer period.”¹⁴ When a longer period is needed, the circumstances warranting the longer period must be included in the inquiry report. The regulation, however, does not stipulate the starting and ending points of an inquiry. In this report, 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. Over the 10-year period, 59 percent of the inquiries were completed within the 60-day standard and 41 percent were not. Twelve percent took 61-90 days; 8 percent, 91-120 days; 6 percent, 121-150 days, and 15 percent, more than 150 days.

Table 45: Length of inquiries that resulted in research misconduct investigations, 1994-2003.

Length	1994	1995	1996	1997	1998	1999	2000	2001	2002	2003	Total	%
0-60 days	15	24	19	15	15	16	10	12	16	10	152	59

¹² Responsibility of PHS Awardee and Applicant Institutions for Dealing With and Reporting Possible Misconduct in Science, 42 CFR Part 50, Subpart A. Available on ORI web site.

¹³ Responsibility of PHS Awardee and Applicant Institutions for Dealing With and Reporting Possible Misconduct in Science, 42 CFR Part 50, Subpart A. Available on ORI web site.

¹⁴ Responsibility of PHS Awardee and Applicant Institutions for Dealing With and Reporting Possible Misconduct in Science, 42 CFR Part 50, Subpart A. Available on ORI web site.

61-90 days	4	4	4	2	2	2	3	2	2	5	30	12
91-120 days	2	1	4	4	3	3	0	1	1	3	22	8
121-150 days	1	5	1	3	1	2	0	1	2	0	16	6
More than 150 days	4	7	9	5	0	1	2	2	2	6	38	15
Unknown	0	0	1	0	0	0	0	0	0	0	1	0
Total	26	41	38	29	21	24	15	18	23	24	259	100

The comparison data suggest a tendency toward shorter inquiries. The percent of inquiries completed within the 60-day standard increased from 57 to 62 percent and the inquiries lasting 61-90 days increased from 10 to 13 percent. All other categories show a slightly lower percent between the comparison periods.

Table 46: Length of inquiries that resulted in research misconduct investigations, 1994-1998 and 1999-2003

Length	1994-1998	1999-2003
0-60 days	57% (88)	62% (64)
61-90 days	10% (16)	13% (14)
91-120 days	9% (14)	8% (8)
121-150 days	7% (11)	6% (5)
More than 150 days	16% (25)	12% (13)
Unknown	1% (1)	0% (0)
Total	100% 155	100% (104)

Fifty-six percent of the inquiries that lasted 121 days or more were followed by investigations that resulted in research misconduct findings. Fifty-three percent of the inquiries completed within the 60-day standard preceded investigations that found research misconduct. Forty percent of the inquiries completed in 61-120 days were followed by investigations that resulted in research misconduct findings.

Table 47: Number and percent of inquiries that preceded investigations that made research misconduct findings by length of inquiries, 1994-2003.

Length	Number of misconduct findings	Total number of inquiries	Percent of inquiries leading to misconduct findings
0-60 days	81	152	53
61-90 days	11	30	37
91-120 days	10	22	45
121-150 days	9	16	56
More than 150 days	21	38	55
Unknown	1	1	100
Total	133	259	51

Seventy-six percent of the investigations that found research misconduct were preceded by inquiries that were completed within the 60-day standard (60 percent) or lasted more than 150 days (16 percent). Seventy-one percent of the investigations that did not make a research misconduct finding were preceded by inquiries that were completed within the 60-day standard (56 percent) or lasted between 61-90 days (15 percent)

Table 48: Outcomes of research misconduct investigations by length of inquiry, 1994-2003.

Length	Misconduct		No misconduct	
	Number	Percent	Number	Percent
0-60 days	81	60	71	56
61-90 days	11	8	19	15
91-120 days	10	8	12	10
121-150 days	9	7	7	6
More than 150 days	21	16	17	13
Unknown	1	1	0	0
Total	133	100	126	100

Panel size

The PHS misconduct regulation requires institutions to secure necessary and appropriate expertise to carry out a thorough and competent evaluation of the relevant evidence in any inquiry. The misconduct regulation, however, does

not require or recommend a specific number of persons. Over the 10-year period, the number of persons used to conduct an inquiry ranged from one to six or more. The most frequent number of persons used to conduct an inquiry was three (36 percent) followed by one person (22 percent), two persons (14 percent) and four persons (12 percent).

Table 49: Panel size in inquiries that resulted in research misconduct investigations, 1994-2003.

Size	1994	1995	1996	1997	1998	1999	2000	2001	2002	2003	Total	%
One	9	8	7	11	3	7	4	4	5	0	58	22
Two	2	6	4	5	6	2	2	3	5	1	36	14
Three	7	17	20	7	4	7	6	8	5	11	92	36
Four	5	5	3	3	4	2	0	1	4	5	32	12
Five	2	2	3	0	3	2	2	2	3	5	24	9
Six or More	1	3	1	3	1	4	1	0	1	2	17	8
Total	26	41	38	29	21	24	15	18	23	24	259	100

The comparison data suggest a slight trend toward inquiry panels composed of five or more members. From 1994-1998, panels composed of five or more members accounted for 12 percent of the inquiries; from 1999-2003, they accounted for 21 percent of the inquiries. A comparable decrease occurred in the use of one and two person panels. Three person panels were most frequently used to conduct inquiries throughout the 10-year period. The use of five-person panels increased from 6 to 13 percent between the comparison periods while the use of a single person to conduct an inquiry declined from 25 to 19 percent.

Table 50: Panel size of inquiries that resulted in research misconduct investigations, 1994-1998 and 1999-2003.

Size	1994-1998	1999-2003

One	25% (38)	19% (20)
Two	15% (23)	12% (13)
Three	35% (55)	36% (37)
Four	13% (20)	12% (12)
Five	6% (10)	13% (14)
Six or More	6% (9)	8% (8)
Total	100% (155)	100% (104)

Seventy-two percent of the inquiries that were conducted by one person were followed by investigations that made research misconduct findings. The percent of investigations that resulted in research misconduct findings declined as the size of the inquiry panels increased, except for five- member panels. Inquiry panels with six or more members were followed by the least percent of investigations (12 percent) that made research misconduct findings.

Table 51: Number and percent of inquiries that preceded investigations that made research misconduct findings by inquiry panel size, 1994-2003.

Size	Number of misconduct findings	Total number of inquiries	Percent resulting in misconduct findings
One	42	58	72
Two	20	36	56
Three	44	92	48
Four	14	32	44
Five	11	24	46
Six or more	2	17	12
Total	133	259	51

Eighty percent of the investigations that produced misconduct findings were preceded by inquiries conducted by three persons or less. Inquiry panels with five or more members were followed by the least number of investigations (9 percent) that produced research misconduct findings. Sixty-four percent of the investigations that did not find misconduct were preceded by inquiries conducted by three or fewer persons.

Table 52: Outcomes of research misconduct investigations by size of inquiry panels, 1994-2003

Size	Misconduct		No Misconduct	
	Number	Percent	Number	Percent
One	42	32	16	13
Two	20	15	16	13
Three	44	33	48	38
Four	14	11	18	14
Five	11	8	13	10
Six or more	2	1	15	12
Total	133	100	126	100

Investigations

Length

According to the PHS research misconduct 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 report to the ORI. If additional time is needed, the institution is required to request an extension from ORI. The regulation, however, does not stipulate the starting and the ending points of an investigation. In this report, the length of an investigation was measured from the date of the first meeting of the investigation committee to the date ORI received the report of the investigation.

The percent of investigations (34) completed within the 120-day standard is considerably lower than the percent of inquiries (59) completed within the 60-day standard. Sixty-six percent of the investigations exceeded the 120-day standard. Thirty-two percent of the investigations last more than twice the 120-day standard.

Table 53: Length of research misconduct investigations, 1994-2003.

Length	1994	1995	1996	1997	1998	1999	2000	2001	2002	2003	Total	%
0-120 days	9	10	13	11	5	5	8	12	10	6	89	34
121-180 days	3	10	10	7	7	6	0	2	4	2	51	20
181-240 days	3	4	2	2	4	5	3	2	4	7	36	14
241-300 days	2	5	4	4	3	4	2	1	3	6	34	13
More than 300 days	9	12	9	5	2	4	2	1	2	3	49	19
Total	26	41	38	29	21	24	15	18	23	24	259	100

The percent of investigations completed within 120 days increased from 31 to 39 percent between the comparison periods. Investigations lasting from 181 to 300 days also increased while investigations lasting from 121-180 and over 300 days decreased.

Table 54: Length of research misconduct investigations, 1994-1998 and 1999-2003.

Length	1994-1998	1999-2003
0-120 days	31% (48)	39% (41)
121-180 days	24% (37)	14% (14)
181-240 days	10% (15)	20% (21)
241-300 days	11% (18)	15% (16)
More than 300 days	24% (37)	12% (12)
Total	100% (155)	100% (104)

Investigations completed within the 120-day standard had the highest rate of misconduct findings (57 percent). Investigations finished between 121 and 300 days were evenly divided between misconduct and no misconduct findings. The lowest percent of investigations that produced misconduct findings lasted more than 300 days (45 percent).

Table 55: Percent of investigations that made research misconduct findings by length of investigations, 1994-2003.

Length	Number of investigations making misconduct findings	Number of investigations	Percent of investigations making misconduct findings
0-120 days	51	89	57
121-180 days	25	51	49
181-240 days	18	36	50
241-300 days	17	34	50
More than 300 days	22	49	45
Total	133	259	51

Of the 133 investigations that resulted in research misconduct findings, 38 percent were completed within 120 days; 62 percent exceeded that standard. Of the 126 investigations that did not find research misconduct, 30 percent were completed within 120 days; 70 percent exceeded that standard.

Table 56: Number and percent of research misconduct investigations resulting in misconduct and no misconduct findings by length of investigations, 1994-2003.

Length	Misconduct		No misconduct	
	Number	Percent	Number	Percent
0-120 days	51	38	38	30
121-180 days	25	19	26	21
181-240 days	18	14	18	14
241-300 days	17	13	17	13
More than 300 days	22	16	27	22
Total	133	100	126	100

Panel Size

The PHS research misconduct regulation requires institutions to secure necessary and appropriate expertise to carry out a thorough and competent evaluation of the relevant evidence in any investigation. The purpose of the investigation is to explore the allegations, to examine the evidence in depth, and to determine specifically whether misconduct has been committed, by whom, and to what extent and significance. The most frequent panel size used in investigations over the 10-year period was three (36 percent) followed by five (16 percent).

Table 57: Size of panels in research misconduct investigations, 1994-2003.

Size	1994	1995	1996	1997	1998	1999	2000	2001	2002	2003	Total	%
One	5	3	1	6	0	2	1	4	3	0	25	10
Two	4	4	3	3	4	1	1	1	5	1	27	10
Three	6	13	21	9	9	5	5	9	5	11	93	36
Four	5	4	4	4	4	4	1	1	4	5	36	14
Five	4	8	6	4	2	4	4	0	5	5	42	16
Six or More	2	9	3	3	2	8	3	3	1	2	36	14
Total	26	41	38	29	21	24	15	18	23	24	259	100

Panel size in investigations remained fairly stable between the comparison periods. The use of panels with five or more members slightly increased while panels composed of two or three members slightly decreased. The use of one and four persons remained the same.

Table 58: Size of panels in research misconduct investigations, 1994-1998 and 1999-2003.

Size	1994-1998	1999-2003
One	10% (15)	10% (10)
Two	12% (18)	9% (9)
Three	37% (58)	34% (35)
Four	14% (21)	14% (15)
Five	15% (24)	17% (18)
Six or more	12% (19)	16% (17)
Total	100% (155)	100% (104)

An increase in panel size appears to be related to a decrease in the percent of research misconduct findings made. The percent of investigations conducted by one person that found research misconduct is extraordinarily high (92 percent) compared to investigations conducted by larger panels (47 percent).

Table 59: Percent of investigations that made research misconduct findings by size of panels, 1994-2003.

Size	Number of misconduct findings	Number of investigations	Percent of investigations resulting in misconduct findings
One	23	25	92
Two	15	27	56
Three	47	93	51
Four	18	36	50
Five	16	42	38
Six or more	14	36	39
Total	133	259	51

Of the 133 investigations that found research misconduct, 35 percent had a panel of three members followed by a panel of one (17 percent). Three member panels also accounted for 36 percent of the investigations that did not find misconduct followed by five-member (21 percent) and six or more members (17 percent). Investigations conducted by one person accounted for only 2 percent of the investigations that did not find misconduct.

Table 60: Number and percent of research misconduct investigations resulting in misconduct and no misconduct findings by size of investigation panels, 1994-2003.

Size	Misconduct		No Misconduct	
	Number	Percent	Number	Percent
One	23	17	2	2
Two	15	11	12	10
Three	47	35	46	36
Four	18	14	18	14
Five	16	12	26	21
Six of More	14	11	22	17
Total	133	100	126	100

Discussion

This section raises questions concerning (1) the length of inquiries and investigations, (2) the size of panels in inquiries and investigations, and (3) the relationships between length, panel size and outcomes.

Both inquiries and investigations vary considerably in length. The length of inquiries ranged from less than 60 days to more than 150 days. The length of investigations ranged from less than 120 days to more than 300 days. Fifty-nine percent of the inquiries were completed within the regulatory standard of 60 days; 34 percent of the investigations were completed within the 120-day standard. What accounts for these variations? Are the variations in length due to variations in complexity and difficulty of cases or respondents and their attorneys? Or is the variation due to inefficient management of inquiries or investigations? Do actions by whistleblowers, respondents, or witnesses prolong inquiries and investigations? Does panel size affect length? Are institutions conducting investigations under the guise of an inquiry to avoid reporting the allegation to ORI until they are sure misconduct occurred? What is the relationship between length of inquiries and length of investigations?

The size of inquiry and investigation panels range from one to six or more members. Inquiry panels are generally smaller than investigation panels. Seventy-two percent of the inquiries had panels composed of three or fewer members while 56 percent of the investigations had panels of three or fewer members. Inquiry panels were most frequently composed of three members (36 percent) or one member (22 percent); investigation panels were most frequently composed of three members (36 percent) or five members (16 percent). What accounts for these variations? What criteria do institutions use in deciding the size of panels in inquiries and investigations? Do the complexity and difficulty of a case impact panel size? Is the panel size affected by who is accusing whom? Can a panel of one or two members in an

inquiry or investigation contain the necessary and appropriate expertise to carry out a thorough and authoritative evaluation of the relevant evidence? Does panel size affect findings?

The data suggest a relationship between length, panel size and outcomes of inquiries and investigations. Fifty-three percent of the inquiries completed in the 60-day standard were followed by investigations that made research misconduct findings compared to 48 percent of the inquiries that exceeded the standard. Fifty-seven percent of the investigations completed in the 120-day standard produced research misconduct findings compared to 48 percent of the investigations that exceeded the standard. Are these differences due to the variations in the complexities of the case or to variations in the management of the process?

Future Research

What accounts for the variation in length of inquiries and investigations?

What accounts for the variations in panel size in inquiries and investigations?

What panel size is required to secure necessary and appropriate expertise?

What is the relationship between length, panel size and outcome in inquiries and investigations?