

Report on 2001 Annual Report on Possible Research Misconduct

August 2002

Office of Research Integrity
Office of Public Health and Science
Department of Health and Human Services

<http://ori.hhs.gov>

Executive Summary

For the reporting year 2001, ORI conducted the second consecutive electronic Internet-based system to allow institutions to access their ORI assurance record for the purpose of updating institutional contact information and to electronically submit their annual report.

The amount of misconduct activity—receipt of an allegation or conduct of an inquiry or investigation—reported by institutions in their 2001 Annual Report on Possible Research Misconduct increased for the third consecutive year.

In 2001, 78 institutions reported misconduct activities. Sixty-one of these institutions opened 72 new cases; the other institutions were still responding to allegations received earlier. New cases were opened by 54 higher education institutions, 2 research organizations, 3 independent hospitals, 1 health organization, and 1 small business.

Institutions received 127 allegations. The number of allegations of fabrication and plagiarism decreased from 2001. One bad faith allegations was reported. The 72 new cases opened by the institutions resulted in 67 inquiries and 20 investigations. Some cases were closed following a preliminary assessment of the allegations or were received too late in the year to begin an inquiry.

Of the 4,074 annual reports for calendar year 2001 due for renewal, about 82 percent were returned by the March 31, 2002, deadline. This was up from about 77 percent reported for the 2000 submissions.

The effort to establish and utilize an e-mail network covering all institutions that have an active assurance continues to progress well. About 99 percent of the institutions have submitted e-mail addresses for their responsible official. The e-mail network enables ORI to quickly contact institutional officials individually or en masse. The e-mail system was utilized to send the initial notification of the submission of the annual report, as well as follow-up notices.

Ninety-nine percent of the responding institutions appear to have the required policy for handling allegations of scientific misconduct. Ninety-five percent of the responding institutions indicated that they have the required policies. Another 4 percent have policies on file with ORI even though they either indicated that they did not have such a policy or did not answer the pertinent question. The 32 institutions that reported they did not have the required policy were asked to establish one and send it to ORI for review.

The results of the 2001 Annual Report survey required considerable updating of the ORI assurance database which contains the names of all institutions that have an active assurance and therefore are eligible to receive PHS research support. Seven hundred and fifty-four assurances were considered delinquent, including 651 institutions that did not return their Annual Reports by the March 31 deadline, and 103 institutions that voluntarily withdrew their assurances rather than submit the Annual Report or submit a previously requested misconduct policy. Small businesses accounted for 61 percent of the inactivated assurances; higher education accounted for 17 percent.

The Annual Report survey continues to encounter problems with (1) the initial response rate, (2) erroneous or confusing responses regarding the availability of policies, (3) unanswered questions, and (4) ambiguous responses. ORI will address these problems through the *ORI Newsletter*, the ORI web site, the cover letter accompanying the Annual Report form, and the e-mail network.

Introduction

This report describes the conduct and results of the 2001 Annual Report on Possible Research Misconduct. It presents the regulatory basis for requiring institutions to submit the report, the report results, methodology employed, the follow-up actions taken, the problems encountered, and proposed solutions.

Requirements of Federal Regulation

The PHS regulation (42 CFR Part 50, Subpart A) on misconduct in science places several requirements on institutions receiving or applying for funds under the PHS Act. The institutional requirements are monitored by ORI's Assurance Program.

Section 50.103(a) of the regulation states: "Each institution that applies for or receives assistance under the Act for any project or program which involves the conduct of biomedical or behavioral research must have an assurance satisfactory to the Secretary that the applicant: (1) Has established an administrative process that meets the requirements of this Subpart, for reviewing, investigating, and reporting allegations of misconduct in science in connection with PHS-sponsored biomedical and behavioral research conducted at the applicant institution or sponsored by the applicant; and (2) Will comply with its own administrative process and the requirements of this Subpart."

Section 50.103(b) of the regulation states: "The institution's assurance shall be submitted to the [ORI], on a form prescribed by the Secretary . . . and updated annually thereafter . . . An institution shall submit, along with its annual assurance, such aggregate information on allegations, inquiries, and investigations as the Secretary may prescribe."

To fulfill this requirement, institutions must submit to ORI an Annual Report on Possible Research Misconduct (PHS form #6349).

In administering the Assurance Program, ORI determines whether an institution has a current assurance on file so that PHS funds may be awarded, and reviews the information submitted on the Annual Report form to see whether the institution is complying with the regulation.

Results/Methodology

This section describes the results and methodology of the 2001 Annual Report under the following headings: (1) Electronic Reporting System; (2) Misconduct Activities Reported; (3) Availability of Policies and Procedures; (4) Bad Faith Allegations; (5) Data Collection; (6) Response Rate; and (7) Changes in Institutional Population.

Electronic Reporting System

The 2001 reporting year was the second year for the ORI electronic Internet-based system, which allowed institutions to access their ORI assurance record for the purpose of updating institutional contact information and to electronically submit their annual report.

Report on 2001 Annual Report on Possible Research Misconduct

Prior to the 2000 annual report ORI would prepare and mail a hard copy of the annual report to all institutions with active assurances, with instructions for those institutions to update their institutional profile (name, address, phone, fax and e-mail), and to report any misconduct activity that may have occurred in the reporting period. For the 1999 reporting period, ORI mailed nearly 3,800 annual reports. As these reports were returned, ORI updated its assurance program database to record any changes in the institutional profile, as well as any misconduct information that was reported.

The electronic system is designed to allow institutions to access and update their institutional assurance record at any time during the year, and allow them to complete the annual report on-line during the reporting period. The ORI assurance database can be automatically updated with the information submitted. In implementing this electronic system, ORI eliminated 1) the need to prepare and mail a hard copy report to all active institutions, and 2) the burden of updating each record with the information returned with the annual report. The system also reduced the burden on reporting institutions by providing them with a straightforward on-line reporting system that eliminated the need to prepare and return a hard copy of the annual report.

Over the past 3 years, ORI has been developing an e-mail network to allow it to disseminate information related to the ORI programs quickly and easily through the e-mail system. This e-mail network was also used as the primary means of notifying institutions of the new electronic annual reporting system. ORI requested and received e-mail addresses on approximately 99 percent of the institutions in the ORI assurance database, and these institutions were informed in the fall 2001 of the new electronic annual reporting system. In order to ensure that all institutions were informed of the new reporting system, facsimiles were sent to the remaining institutions that had not previously provided an e-mail address to ORI, as well as to those institutions whose current e-mail address in ORI's records was found to be undeliverable.

Consistent with the timing of notifications sent in past years, ORI sent an initial e-mail to institutions on January 14, 2002, notifying them of the requirement to submit an annual report to ORI, and instructions on accessing both their assurance record and the on-line instructions for completing the report. To ensure that all organizations were notified, instructions were also sent via facsimile to the approximately 1 percent of the organizations that had not previously provided ORI with a valid e-mail address. Only 2 institutions had not provided either an e-mail address or a facsimile number to ORI. Annual reports were mailed to these institutions. Of the 4,060 initial e-mail notices that were sent on January 14, 2002, only 15 were returned to ORI as non-deliverable, requiring the preparation and transmission of facsimiles to each of these institutions with the annual report instructions. An additional 14 institutional records, requiring the submission of an annual report, were added during the reporting period.

Also consistent with past practices, a second e-mail notice was sent in mid February to all organizations that had not yet submitted their 2001 Annual Report.

At the March 1, 2002, due date, it was noted that the response rates for the submission of the 2001 Annual Report was significantly less than in previous years, likely due to the changeover to the electronic system, and problems with the e-mail notification system. The due date was therefore extended to March 31, 2002, and all institutions were notified via e-mail. A final notice was sent by e-mail on March 14, 2002, to those institutions that had not yet submitted their annual report.

In analyzing the assurance database after the March 31, 2002, deadline, it was noted that a number of institutions had logged on to the system and made changes to their institutional profile, but had not submitted the annual report. Recognizing that this was likely an oversight on the part of these institutions, notices were sent to officials at 57 organizations with instructions on manually submitting the annual report to ORI.

Misconduct Activities Reported

In 2001, 78 institutions reported misconduct activities—the receipt of an allegation or conduct of an inquiry and/or investigation. Sixty-one institutions opened 72 misconduct cases in 2001 upon receipt of new allegations, 17 institutions were continuing to process allegations made in 2000, and 19 institutions were responding to allegations made both prior to and during 2001. The level of reported misconduct activity increased for the third consecutive year. See Table 1. Of the 61 institutions reporting new allegations in 2001, 54 were institutions of higher education, 2 were research organizations, 3 were independent hospitals, 1 was a health organization, and 1 was a small business.

Table 1: Number of Institutions Reporting Misconduct Activities, Number of Institutions Reporting New Allegations, and Number of New Cases Opened, 1997-2001.

Annual Report	# of Institutions Reporting Activity	# of Institutions - New Allegations	# of New Cases Opened
2001	78	61	72
2000	82	60	62
1999	72	46	63
1998	67	41	54
1997	73	48	64

In their submissions, institutions report the receipt of an allegation of scientific misconduct, the type of misconduct, and the conduct of an inquiry and/or investigation. Reportable activities are limited to alleged misconduct involving PHS-supported research, research training, or other research-related activities.

For 2001, institutions reported receiving 127 allegations. The number of allegations for the categories of Falsification and Other increased from 2000, while Fabrication remained the same and Plagiarism experienced a slight decrease. See Table 2.

Table 2: Types of Misconduct and Total Number of New Allegations Reported, 1997-2001.

Annual Report	Fabrication	Falsification	Plagiarism	Other	Total
2001	37	46	17	27	127
2000	37	24	19	23	103
1999	21	37	13	18	89
1998	15	22	10	22	69
1997	26	34	8	24	92

The 72 new cases opened by the institutions in 2001 resulted in 67 inquiries and 20 investigations. Some cases were closed following a preliminary assessment of the allegation or were received too late in the year to begin an inquiry that year. The number of inquiries and investigations conducted in 2001 was more than reported during 1997 - 2000. See Table 3.

Table 3: Number of Inquiries and Investigations Conducted in Response to New Allegations, 1997-2001.

Annual Report	Inquiries	Investigations
2001	67	20
2000	59	18
1999	51	9
1998	38	7
1997	56	19

The 78 institutions reporting misconduct activity conducted a total of 67 inquiries and 20 investigations in 2001. These were in response to allegations made in 2001 and earlier. The number of inquiries conducted by an institution ranged from zero to three. The number of investigations conducted by an institution ranged from zero to two.

Availability of Policies and Procedures

Ninety-five percent (3,243) of the responding institutions indicated that they had the required policies for handling allegations of scientific misconduct. One hundred and eighty-five institutions (5 percent) indicated that they did not have the required policies. However, 153 of the institutions reporting that they did not have a policy do have a policy on file with ORI. The electronic reporting system provided a check box for institutions to indicate whether or not they had a misconduct policy, but the program was designed to default to a “no” answer if the question was not answered. It is evident that many institutions that do have policies either misunderstood the question, or failed to check the box.

Bad Faith Allegations

One bad faith allegation was reported by the 61 institutions that reported new misconduct activity on their 2001 Annual Report. The ORI Model Policy for Responding to Allegations of Scientific Misconduct states that “an allegation is not in good faith if it is made with reckless disregard for or willful ignorance of facts that would disprove the allegation.”

In the only incident of a reported bad faith allegation, no action was taken as the individual left the institution of his/her own accord prior to the conclusion of the assessment phase.

Data Collection

On January 14, 2002, notifications were sent to 4,060 institutions, including 219 foreign institutions that had an assurance on file with ORI as of December 31, 2001, informing them of their obligation to submit the 2001 Annual Report to ORI. A second notification was sent on February 15, 2002. During this reporting period, notification was sent to an additional 14 institutions that requested to re-establish their expired misconduct assurance by submitting the report for CY's 2000 & 2001. Table 4 shows that more than 52 percent of the forms went to small businesses; 37 percent went to organizations most likely to conduct research (codes 10, 20, 30), and the approximate 11 percent remaining went to miscellaneous organizations.

Table 4: Number of 2001 Annual Report Forms Mailed by Code and Type of Institution.

Code	Type of Institution	Number	Percent
10	Higher education	912	22.4
20	Research org., institute, lab, foundation	326	8.0
30	Independent hospital	273	6.7
40	Educational org. other than higher education	19	0.5
50	Other health, human resources, environ orgs.	400	9.8
90	Other (small business)	2,144	52.6
Total		4,074	100

Response Rate

Eighty-two percent (3,320) of the Annual Reports were submitted by the final deadline. The 2000 Annual Report survey resulted in a response rate of 77 percent by the March 31 deadline. Institutions submitted 68 percent (2,754) of the Annual Reports by the March 1, 2002, initial deadline. With the second notification, an additional 566 (14 percent) Annual Reports were submitted by March 31.

Changes in Institutional Population

As of March 31, 2002, the assurances of 754 institutions were inactivated, including those for 651 institutions that did not submit their Annual Reports and 103 were removed from the ORI database because the institutions did not expect to apply for PHS funds, went out of business, merged with another institution, or did not submit their misconduct policies as requested. Small

businesses accounted for approximately 61 percent of the assurances inactivated for not returning their Annual Report or voluntarily withdrawing their assurance. See Table 5. Institutions of higher education accounted for approximately 17 percent of the assurances inactivated.

Table 5: Inactivation of Assurances by Institutional Code and Type and Cause, 2001.

Code	Institutional Type	No Report Submitted	Voluntary Withdrawal	Total
10	Higher Education	117 (18.0 %)	12 (11.7 %)	129 (17.1 %)
20	Research Org., Institute, Lab, Foundation	39 (6.0 %)	7 (6.8 %)	46 (6.1 %)
30	Independent Hospital	33 (5.0 %)	7 (6.8 %)	40 (5.3 %)
40	Educational Org., Other than Higher Education	4 (0.6 %)	0 (0.0%)	4 (.6 %)
50	Other Health, Human Res., Environmental Org.	62 (9.5 %)	12 (11.7 %)	74 (9.8 %)
90	Other (small businesses)	396 (60.9 %)	65 (63.0 %)	461 (61.1 %)
Total		651 (100%)	103 (100%)	754 (100%)

The inactivation of 754 assurances did not produce dramatic changes in the institutional population in the ORI Assurance Database. However, there were small percentage shifts among the types of organizations that comprise the total population. Rank order by size remained the same. See Table 6.

Table 6: ORI Assurance Database by Code, Type of Institution, Number of Institutions, Percent of Total, and Percent Change from 2000.

Code	Type of Institution	Number	Per-cent	% Change from 2000
10	Higher education	902	22.0	+ 0.3
20	Research org., institute, lab, foundation	325	7.9	- 0.1
30	Independent hospital	279	6.8	- 0.1
40	Education org. other than higher ed.	20	0.5	0.0
50	Other health, human res., environ. org.	398	9.7	+ 0.1
90	Other (small business)	2,181	53.1	- 0.2
Total		4,105	100	

The database query for Table 6 is the total number of records (active & inactive) on 3/31/02, and includes the initial assurances processed prior to 4/1/02.

Follow-up Actions

The follow-up actions required by the results of the 2001 Annual Report are described under the following headings: (1) Feedback to Institutions; (2) Requesting Policies and Procedures; (3) Notifying Institutions That They Have Policies; (4) Checking Reporting of Investigations; and (5) Updating Assurance Database.

Feedback to Institutions

This report on the 2001 Annual Report will be posted on the ORI home page and will be available in hard copy upon request. An article will be published in the *ORI Newsletter* in September 2002.

Requesting Policies and Procedures for Review

By the deadline, 185 institutions answered "no" to the question about whether the institution had a policy for responding to allegations of scientific misconduct, and ORI did not have their policy on file. However, of this number, 153 institutions had reported on previous Annual Reports that they did have misconduct policies. The 32 institutions, that may not have the required policies, were asked to submit their policies and procedures for review, or they would become ineligible to receive PHS research funding.

Notifying Institutions That They Have Policies

The 153 institutions that answered "no" to the question about the availability of an institutional policy will be notified that their institution does have a policy on file with ORI. Of this number, 74 have a Small Organization Statement and 79 have a more comprehensive institutional policy.

Checking Reporting of Investigations

The Annual Reports of all institutions that reported misconduct activity were forwarded to the Division of Investigative Oversight (DIO) to check on the reporting of investigations by those institutions. All new activity was properly reported by institutions submitting the 2001 Annual Report.

Updating Assurance Database

The Annual Report results required a major update of the ORI assurance database. By the deadline, 754 institutions had been inactivated.

Problems Encountered

This section describes the problems encountered during the conduct of the 2001 Annual Report survey under the following headings: (1) Electronic system; (2) Response Rate; (3) Erroneous Responses; and (4) Incomplete Reports.

Electronic System

During the reporting period, ORI was contacted by many organizations that had questions related to the system or had problems accessing it. In most cases, the issues and questions raised were covered in the instructions, such as the institutions identification number and password. This problem was further complicated by the fact the electronic button to be used to give the user their password did not work. The major problem, however, was created by the ORI e-mail system (Outlook). During the first e-mail notification attempt ORI was unaware that a high percentage of the original notifications were not delivered. It wasn't until the second mailing, in mid-February that the problem became apparent. From the original 4,000 institutions ORI received approximately 3,500 - 4,000 e-mail inquiries and another 1,000 - 1,500 telephone calls. This overwhelming response created a giant backlog on a returned ORI response. Many officials called and left multiple voice-mail messages while also sending e-mail inquiries. On March 14, 2002, the third notification was sent using the NIH LISTSERV. Another problem was an issue related to the compatibility of the institution's computer system with the ORI system. While such conflicts are inevitable when dealing with over 4,000 independent systems, the most consistent problem involved difficulties of Macintosh users accessing the system. Also, an issue that was frequently raised concerned the lack of clear acknowledgment once the report had been transmitted to ORI and the incapability of the institution to print a copy of their submitted annual report.

Response Rate

Although the institutions were alerted to the Annual Report survey by the December 2001 *ORI Newsletter* article and by the cover letter accompanying the report form which emphasized the submission deadline, only 68 percent (2,754 of 4,074) of the Annual Reports were received by the March 1 deadline. This is up from the 68 percent received by the same date last year. Another 566 were submitted after the second notification.

Erroneous Responses

One hundred and fifty-three institutions responded that they did not have an institutional policy for responding to allegations of scientific misconduct when their policy was, in fact, on file with ORI.

Incomplete Reports

The number of incomplete responses is declining. Eleven institutions which did not report any misconduct activity did not check the box indicating that they did not have any misconduct activity to report. This number decreased by 28 from last year.

Proposed Solutions

Solutions to the problems encountered in the 2001 Annual Report are presented under the following headings: (1) Electronic System; (2) Response Rate; (3) Erroneous Responses; and (4) Incomplete Reports.

Electronic System

ORI is addressing the issue of Macintosh® compatibility with the system designer. The system designer will also be asked to modify the system to provide a printable acknowledgment to the user when the annual report has been successfully transmitted. Further, the electronic button, which is suppose to give the user their password, will also have to be in working order.

In an attempt to prevent another e-mail delivery problem we will use the NIH system, LISTSERV, for future mailings.

Response Rate

The major area for improvement is the total response rate. The conversion to an e-mail notification system and problems with the e-mail delivery system likely contributed to the still low response rate of 82 percent for the year. Efforts will be made to improve the accuracy and completeness of the e-mail records within the ORI system. Over the next few years, an effort will be made to raise the initial response rate to 90 percent. While some organizations will choose not to submit their annual reports electronically and will have to receive a hard copy of the annual report, ORI will strive to minimize that number.

Several steps taken previously will continue to be taken to increase the initial response to the 2002 Annual Report survey. An article will be published in the December 2002 issue of the *ORI Newsletter* calling attention to the initial submission deadline and the electronic submission. Detailed instructions and answers to frequently asked questions will be posted on the ORI web site. In addition, e-mail reminders regarding the Annual Report due date, will be sent to non-responsive institutions in mid-February and mid-March.

Erroneous Responses

As indicated previously, institutions that reported they did not have an administrative policy for responding to allegations of scientific misconduct when they do have a policy on file with ORI will be so notified.

Incomplete Reports

Incomplete reports will continue to be addressed in the Annual Report form instructions. These instructions will call attention to the question on availability of an administrative policy and will point out that the small organization statement qualifies as such a policy.

Conclusion

Once again the Annual Report has demonstrated that it is an essential mechanism for maintaining ORI's compliance and assurance programs. The results of the 2001 Annual Report identified 754 institutions that were inactivated from the assurance database and 32 institutions that may not have the required policies and procedures for handling allegations of scientific misconduct. The survey also collected information on misconduct activities at institutions during the year, and on institutional efforts to comply with provisions of the regulation addressing bad faith allegations received and the availability of policies to deal with misconduct

allegations. Finally, this Report highlights the need for follow-up actions and identifies problems in the reporting process for which solutions are proposed.