

ORI NEWSLETTER

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ORI ASSESSING ALLEGATIONS QUICKER, INCREASING CASE CLOSINGS

ORI has reduced the time it takes to assess allegations of scientific misconduct and significantly increased the number of misconduct cases closed annually between 1992 and 1995.

Preliminary data indicate that ORI has reduced the average time for assessing allegations from nearly 400 calendar days in 1992 to 58 days in 1995. However, 3, 11, and 28 allegations received in 1993, 1994, and 1995 respectively, remained to be assessed as of October 31, 1995. Assessment time was defined as the period between the date of receipt of the allegation to the date on which it was determined to open a case, refer the allegation to another office, or a decision was made that no further action was necessary.

The average assessment times shown in Table 1 are based on those allegations (about 60 percent of all allegations received by ORI) that required a thorough review to determine whether a formal case should be opened. The remaining allegations that clearly fell outside ORI jurisdiction, or could not be pursued because of insufficient information, were not included in calculating the average assessment time. ORI received over 675 allegations since it was established in June 1992.

Table I: Average Assessment Time for Allegations by Year of Receipt and Number of Allegations, 1992 - 10/95.

| YEAR | NO. ALLEGATIONS | AVG. ASSESSMENT TIME IN CALENDAR DAYS |
|------|-----------------|------------------------------------------|
| 1992 | 56 | 387 |
| 1993 | 118 | 232 |
| 1994 | 100 | 117 |
| 1995 | 69 | 58 |

As shown in Table II, the total number of cases processed by ORI in a calendar year has increased from 26 in 1992 to 49 (projected) in 1995. Forty-one cases were closed by October 31, 1995. ORI has reduced its inherited backlog, cases opened from 1989 to 1992, from 54 to 5 and expects to close the remainder by the end of 1995, excluding any hearings pending before the Departmental Appeals Board.

Table II: Total Cases Closed by Year, 1992-1995*

| YEAR | CASES CLOSED |
|------|--------------|
| 1992 | 26 |
| 1993 | 38 |
| 1994 | 44 |
| 1995 | 49* |

*Projected to end of 1995.

WIDESPREAD MISREPRESENTATION FOUND IN FELLOWSHIP APPLICATIONS

Widespread misrepresentation in cited publications and claimed research experience were found in a review of 236 applications for gastroenterology fellowships at the University of Pittsburgh School of Medicine. The review was reported by Drs. Gail Sekas and William R. Hutson in the *Annals of Internal Medicine* 123:1, pp. 38-41, July 1, 1995.

Sixteen of the 53 applicants (30.2 percent) who claimed published articles misrepresented them by reporting citations of nonexistent articles in actual journals, articles in nonexistent journals, or articles noted as "in press." Forty-seven of the 138 applicants (34.1 percent) who reported research experience during their residency in a U.S. training program misrepresented that experience.

Presentations at meetings claimed by 5 of 17 applicants (29.4 percent) could not be confirmed. Published abstracts reported by 14 of 40 applicants (35 percent) could not be found. However, the authors noted that some meeting programs containing the reported abstracts were not published in journals or deposited in libraries.

The authors further reported misrepresentation in a limited review of infectious disease fellowship applications. They "urged the academic community to begin to address and correct the serious situation of misrepresentation by trainees."

RESULTS OF 1994 ANNUAL REPORT ON POSSIBLE RESEARCH MISCONDUCT OUTLINED

Two hundred and fifty-seven institutions were removed from the ORI assurance database following completion of the 1994 Annual

Report on Possible Research Misconduct, thereby making those institutions ineligible to receive PHS research funds.

One hundred and eighty-six institutions became ineligible to receive PHS funds by failing to return their Annual Report form to ORI. Fifty-eight institutions were removed from the assurance database because they did not expect to apply for PHS funds, did not conduct research, merged with another institution, or no longer exist. Thirteen institutions were deleted because the Annual Report forms were undeliverable.

Another 273 institutions indicated they did not have policies or procedures for responding to allegations of scientific misconduct or failed to answer the pertinent question on the Annual Report form. ORI asked these institutions, except for 89 small businesses, to submit their policies and procedures for review within 60 days, or risk losing their eligibility to receive PHS research funds.

Annual Report forms were mailed in January 1995 to the 3,204 institutions that had an assurance on file with ORI as of November 1, 1994. Responses were received from 3,018 institutions for a response rate of 94.2 percent. However, only 70 percent of the institutions returned their Annual Reports by the March 1 deadline.

At the completion of the Annual Report survey, the ORI assurance database contained 2,947 institutions including 750 higher education organizations; 281 research organizations, institutes, laboratories or foundations; 237 independent hospitals; 29 education organizations other than higher education; 392 other health, human resources, or environmental organizations; 1,258 small businesses. Seventeen percent of the institutions changed their responsible institutional official in 1994.

ORI BEGINS SYSTEMATIC REVIEW OF INSTITUTIONAL POLICIES AND PROCEDURES

ORI has initiated a systematic process for reviewing institutional policies and procedures for responding to allegations of scientific misconduct that have been established by institutions that apply for or receive PHS research funds in compliance with the Federal regulation (42 C.F.R. Part 50, Subpart A).

The annual process involves a five percent random sample of institutions that have an active assurance on file with ORI

declaring that they have established and will follow an administrative process for responding to allegations of scientific misconduct that complies with the Federal regulation.

Development of the process began in 1994 in anticipation of a recommendation made in the report on ORI by the Office of the Inspector General, Department of Health and Human Services. ORI previously reviewed institutional policies and procedures only for cause.

Under the new process, ORI requests policies and procedures from selected institutions during the first quarter of the year and reports the results of its evaluation to the institutions by the end of the year. When the evaluation is completed, ORI sends each institution a letter stating whether its policies and procedures are acceptable. If ORI finds that the policies and procedures are unacceptable, an accompanying report cites the provisions of the regulation that are not adequately reflected in the document. Institutions then have 90 days to submit their revised policies and procedures to maintain their eligibility for PHS research funding.

PUBLICATIONS

The Responsible Conduct of Research, compiled by Dr. Dore Beach, University of South Florida. A text for pre- and postdoctoral students planning careers in scientific research. Contact: Dr. Thomas Mager, VCH Publishing Division I, Physical Sciences, Editorial Dept., Pappelallee 3, D-69469 Weinheim, Germany. Phone: +49 (0) 6201/6060.

INSTITUTIONS ACT TO PROTECT COMPLAINANTS IN MISCONDUCT CASES

Institutions are developing a range of actions to protect individuals who make allegations of scientific misconduct in good faith, according to their 1994 Annual Report on Possible Research Misconduct.

Federal regulations require institutions that apply for or receive PHS funds to protect "to the maximum extent possible, the privacy of those who in good faith report apparent misconduct" and undertake "diligent efforts to protect the positions and reputations of those persons who, in good faith, make allegations." 42 C.F.R. §§ 50.103(d)(1) and (d)(11).

Among the actions reported by the institutions were

(1) protecting the identity of the complainant, (2) moving the complainant to another laboratory, (3) warning the accused against taking retaliatory actions, (4) investigating charges of retaliation, (5) monitoring for potential retaliatory action, (6) providing financial assistance to restore the complainant's research program, (7) publishing public letters from the president and provost in the university newspaper, and (8) informing appropriate officials that the allegation was made in good faith.

Additional actions are indicated in the following institutional reports:

● "Co-workers were cautioned to avoid negative behavior toward the complainant. They were told he was doing the 'right thing.' His identity has been protected except on a 'need to know' basis. The complainant left the . . . to go to another high quality academic experience elsewhere. He was assisted by the university."

● "In the one instance where such protection was required, the University prevented the attempt by the respondents to terminate the complainant, and the University continues to ensure the employment of this individual at another laboratory within the University."

● ". . . The Director of the Regulatory Compliance Office informed the complainant about state 'whistleblower statutes' and encouraged the complainant to maintain contact with the RCO, and the department chairman and college Dean were reminded of the protections afforded to the complainant."

● ". . . Special arrangements were made for the person who made the allegations (a postdoc) to use an alternate laboratory for completion of his experiments so as not to conflict with the person alleged to have committed scientific misconduct (the postdoc's supervisor). Finally, an administrative procedure was established for ensuring that the supervisor's letters of recommendation for the postdoc were not influenced by the postdoc's allegations of scientific misconduct."

ORI POSTS HOME PAGE ON WORLD WIDE WEB

ORI has developed its own home page on the World Wide Web of the Internet. The home page contains general information about ORI, telephone and fax numbers for the different divisions, copies of

selected publications, and brief descriptions of additional publications available from the office. Current and back issues of the *ORI Newsletter* and two ORI position papers are directly accessible from the home page. One position paper summarizes the PHS position on ten issues concerning allegations of misconduct in PHS-supported research; the other describes protections that are available for whistleblowers in defamation suits.

The home page also provides instructions for retrieving several larger ORI publications from the OASH Bulletin Board. These documents include ORI's model policy and procedures for extramural institutions, back issues of ORI's Annual Reports, and the report on the 1993 ORI/AAAS Conference on Plagiarism and Theft of Ideas. Additional publications are also listed along with information on how to request them. ORI's home page address is http://phs.os.dhhs.gov/phs/ori/ori_home.html.

GAO REPORT: APPROVES PROCEDURES,
CRITICIZES DELAY IN PROCESSING CASES

In August 1995, the Government Accounting Office issued a report on ORI operations, based on a study requested by Congress, which largely focused on ORI investigative practices and procedures for handling cases and the timeliness of ORI's response. The GAO made the following general conclusions:

ORI has "developed and implemented procedures for handling misconduct cases, which we believe conform to established federal standards for investigations." Based on a review of 30 initial allegations and 10 investigations, the report found "few concerns about the [ORI] techniques used in handling cases." The report criticized ORI's backlog of cases and continuing delay in processing new allegations.

Progress made by ORI in assessing allegations, reducing its case backlog, and increasing the number of cases closed annually is reported on page one.

DEPARTMENTAL PANEL REVIEWING COMMISSION REPORT

A high-level departmental panel is reviewing the recommendations made by the Commission on Research Integrity for possible implementation by the Department of Health and Human Services.

The panel was established in November by the Secretary of Health and Human Services upon the recommendation of the Assistant

Secretary for Health.

The panel includes senior representatives from PHS research agencies and the offices of the Secretary, Assistant Secretary for Planning and Evaluation, General Counsel, Inspector General, and Research Integrity. William Raub, Science Advisor, Office of the Assistant Secretary for Planning and Evaluation, chairs the panel. Its report is expected in early 1996.

Copies of the Commission report were scheduled to be sent in December 1995 to all institutions that have an assurance on file with the ORI, PHS agencies, university libraries, professional and scientific associations, and the media.

Individuals desiring a copy of the report should contact Henrietta Hyatt-Knorr at ORI for information on the availability of the report. E-mail: hhyatt@osophs.ssw.dhhs.gov. Fax: (301) 443-5351. Phone: (301) 443-3400. Comments on the report may be sent to Ms. Hyatt-Knorr.

CORRECTION

In the September 1995 *ORI Newsletter* (Vol. 3, No. 4), the last sentence in **Complainant Wins Suit** on page 2 should have read "In 1993, a lawsuit involving allegations of fraud and retaliation . . ."

CASE SUMMARIES

DAB PANEL RULES PHS REGULATION APPLIES TO FOREIGN INSTITUTIONS

Catherine Kerr, St. Mary's Hospital. ORI conducted an investigation into possible scientific misconduct on the part of Ms. Kerr while she was a data coordinator at St. Mary's Hospital, Montreal, Quebec, and concluded that she committed scientific misconduct by falsifying and fabricating the dates of tests or examinations required prior to study entry for one woman entered in the Breast Cancer Prevention Trial (BCPT) and fabricated laboratory results and falsified dates of laboratory tests used to follow the progress of another woman entered in the trial. The BCPT is coordinated by the National Surgical Adjuvant Breast and Bowel Project and supported by the National Cancer Institute and the National Heart, Lung, and Blood Institute. Because the BCPT is still in progress, no conclusions or results have been published and no clinical recommendations have been based on the

results of the study. Based on its conclusions, ORI recommended institutional supervision of Ms. Kerr for three years in any PHS-supported research project and that she be prohibited from serving on PHS advisory committees, boards, and peer review groups for the same period.

On May 24, 1995, Ms. Kerr requested a *de novo* hearing of ORI's findings and recommended administrative actions against her before a Research Integrity Adjudications Panel of the Departmental Appeals Board (Panel). Prior to the hearing Ms. Kerr, through her attorney, made a motion before the Panel challenging ORI's jurisdiction over her. On August 16, 1995, the Panel denied Ms. Kerr's motion.

Specifically, the Panel rejected Ms. Kerr's assertion that, as a Canadian citizen and under the principles of international law, ORI did not have jurisdiction to make its findings and take the recommended actions against her. The Panel ruled that all institutions and individuals who apply for or receive PHS research funds, regardless of where they are physically located or where the PHS-supported research was conducted, are subject to the scientific misconduct regulations.

The Panel also found that Ms. Kerr's due process rights were not violated during ORI's investigation as she had alleged. The Panel noted that she had received legally adequate notice that she was a potential respondent in the case, and that she had a right to obtain counsel. Moreover, the Panel ruled that Ms. Kerr was afforded ample due process even though she was not offered the opportunity to confront witnesses during the ORI investigation. If ORI finds that a respondent has committed scientific misconduct, the right to confront witnesses is available at a Panel hearing.

Lastly, the Panel agreed with ORI that Ms. Kerr's role as a data manager for the BCPT was covered by the scientific misconduct regulations as she was responsible for the reporting of research data. The Panel affirmed that, under the regulations, the potential for misconduct in science is not narrowly limited to "researchers" or "scientists," but extends to all employees or persons within a covered institution's control.

On August 30, 1995, Ms. Kerr withdrew her request for review of ORI's findings. Thus, those findings now constitute a final agency action and the proposed administrative actions have been implemented.

Alan L. Landay, Ph.D., Rush-Presbyterian, St. Luke's Medical

Center. Based on an investigation conducted by the institution, ORI found that Dr. Landay engaged in scientific misconduct involving two instances of plagiarism in publications related to two PHS grants. Dr. Landay has entered into a Voluntary Settlement Agreement with ORI in which he has accepted ORI's finding and, for the two year-period beginning August 8, 1995, has voluntarily agreed to (1) exclude himself from serving in any advisory capacity to PHS, including but not limited to service on any PHS advisory committee, board, and/or peer review committee, or as a consultant, and (2) certify in every PHS research application or report that all contributors to the application or report are properly cited or otherwise acknowledged. The certification by the respondent must be endorsed by an institutional official. A copy of the endorsed certification is to be sent to ORI by the institution. ORI acknowledges that Dr. Landay cooperated with the institutional investigation and the ORI review, accepted responsibility for his actions, and appropriately corrected the scientific literature. The two published papers (Coon, J.S., Landay, A.L., & Weinstein, R.S. "Advances in flow cytometry for diagnostic pathology." *Laboratory Investigations* 57:453-479, 1987; and Landay, A., Hennings, C., Forman, M., & Raynor, R. "Whole blood method for simultaneous detection of surface and cytoplasmic antigens by flow cytometry." *Cytometry* 14:433-440, 1993) that contained plagiarized text have been corrected (Landay, A. Correspondence. *Laboratory Investigations* 70:134, 1994; and Landay, A., Jennings, C., Forman, M., & Raynor, R. Correction. *Cytometry* 14:698, 1993).

Nicholas Y. Lorenzo, M.D., Mayo Foundation. ORI found that Dr. Lorenzo, formerly of the Mayo Foundation, committed scientific misconduct by falsifying and fabricating data incorporated into an abstract submitted for presentation at a professional meeting; the research was supported by a PHS grant. Dr. Lorenzo has entered into a Voluntary Exclusion Agreement with ORI in which he has accepted ORI's finding and has agreed to exclude himself voluntarily, for the three-year period beginning October 16, 1995, from (1) applying for or receiving any Federal grant or contract funds, and (2) serving in any advisory capacity to PHS, including but not limited to service on any PHS advisory committee, board, and/or peer review committee, or as a consultant. The voluntary exclusion, however, shall not apply to Dr. Lorenzo's future training or practice of clinical medicine whether as a medical student, resident, fellow, or licensed practitioner unless that practice involves research or research training. The abstract was withdrawn prior to publication, and thus, no correction of the literature is required.

Oscar R. Rosales, M.D., Yale University School of Medicine. ORI found that Dr. Rosales, Assistant Professor of Medicine (Cardiology) at the Yale University School of Medicine, committed scientific misconduct by plagiarizing and intentionally misrepresenting research in an application for PHS funding. Dr. Rosales has entered into a Voluntary Settlement Agreement with ORI in which he has accepted ORI's finding and, for the three year period beginning August 2, 1995, has voluntarily agreed to (1) exclude himself from serving in any advisory capacity to the PHS, including but not limited to service on any PHS advisory committee, board, and/or peer review committee, or as a consultant, and (2) certify in every PHS research application or report that all contributors to the application or report are properly cited or otherwise acknowledged. This certification must be endorsed by an institutional official, and the institution must send a copy of the certification to ORI.

Jose R. Sotolongo, Jr., M.D., Mount Sinai Medical Center. ORI found that Dr. Sotolongo, formerly of Mount Sinai Medical Center in New York, committed scientific misconduct by falsifying research involving guanabenz treatment of spinal cord injured cats presented in a PHS grant application. Dr. Sotolongo has entered into a Voluntary Exclusion Agreement with ORI in which he has accepted ORI's finding and has agreed to exclude himself voluntarily, for the three-year period beginning July 3, 1995, from (1) applying for or receiving any Federal grant or contract funds; and, (2) serving in any advisory capacity to the PHS, including but not limited to service on any PHS advisory committee, board, and/or peer review committee, or as a consultant. The above voluntary exclusion, however, shall not apply to Dr. Sotolongo's future training or practice of clinical medicine as a licensed practitioner unless that practice involves research or research training. No scientific publications were required to be corrected as part of this Agreement.

Richard Thwaites, University of North Texas Health Science Center at Fort Worth. Based on an investigation conducted by the institution, ORI found that Mr. Thwaites, a former medical student, engaged in scientific misconduct by fabricating data in a clinical trial study supported by a PHS grant. Mr. Thwaites has entered into a Voluntary Exclusion Agreement with ORI in which he has accepted ORI's finding and, for the three-year period beginning October 3, 1995, has voluntarily agreed to exclude himself from (1) applying for or receiving any Federal grant or contract funds, and (2) serving in any advisory capacity to PHS, including but not limited to service on any PHS advisory committee, board, and/or peer review committee, or as a

consultant. No scientific articles were published that relied on the fabricated data.

John J. Tomasula, Mount Sinai Medical Center. ORI found that Mr. Tomasula, formerly of the Mount Sinai Medical Center in New York, committed scientific misconduct by falsifying research involving guanabenz treatment of spinal cord injured cats reported in a PHS grant application. Additionally, ORI found that Mr. Tomasula had falsified his credentials on three PHS grant applications in which he claimed to have a Ph.D. degree from North-western University when, in fact, he had obtained a mail-order degree from Northwestern College of Allied Sciences in Oklahoma, an unaccredited, now defunct "institution." Mr. Tomasula has entered into a Voluntary Exclusion Agreement with ORI in which he has accepted ORI's finding and has agreed to exclude himself voluntarily, for the three-year period beginning June 29, 1995, from (1) applying for or receiving any Federal grant or contract funds and (2) serving in any advisory capacity to the PHS, including but not limited to service on any PHS advisory committee, board, and/or peer review committee, or as a consultant. No scientific publications were required to be corrected as part of this Agreement.

ORI MEETS WITH NIH INTEGRITY OFFICERS

ORI met with Research Integrity Officers (RIOs) representing the NIH extramural research programs on October 5 to discuss the RIOs' role in the PHS Research Integrity Program.

Under the PHS Research Integrity Program, RIOs are responsible for establishing an administrative process within their organizational unit to (1) report allegations of research misconduct received or identified, (2) cooperate with ORI reviews or investigations of extramural allegations concerning research misconduct, (3) implement administrative actions imposed on researchers found to have committed research misconduct, (4) verify the eligibility of institutions to receive funding under the PHS Act, and (5) promote research integrity.

ORI staff outlined the RIOs expected role during queries, preliminary assessments, inquiries, investigations, oversight reviews, and hearings. In addition, RIOs were informed about provisions of the Federal regulation which obligate institutions applying for or receiving PHS funds to (1) file an assurance, (2) submit the Annual Report on Possible Research Misconduct, (3) protect complainants, (4) restore the reputation of

exonerated respondents, and (5) implement PHS/DHHS administrative actions imposed on individuals found to have committed scientific misconduct. Mechanisms for keeping RIOs informed about the status and disposition of cases involving their organizational units were discussed along with the PHS Administrative Action Bulletin Board, PHS ALERT System, and ORI assurance database.

ORI and NIH attorneys discussed confidentiality in responding to allegations, Privacy Act limitations placed on information dissemination, conditions under which recovery of funds may occur, and the frequency of *qui tam* lawsuits.

WHISTLEBLOWER STUDY AVAILABLE FROM ORI

Single copies of the report on the study of the "Consequences of Whistleblowing for the Whistleblower in Misconduct in Science Cases" conducted by the Research Triangle Institute for ORI may be obtained from the Division of Policy and Education, ORI.

The report is available in hard copy or diskette. Please specify the format preference for your diskette: WordPerfect 5.1 or 6.1 or ASCII. A summary of the study results was published in the September 1995 *ORI Newsletter*.

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