A variety of issues are emerging from inquiries and investigations conducted by institutions under their scientific misconduct assurance programs.

In this article, ORI presents the PHS position on four significant issues: (1) the categories of institutional personnel covered by the Federal regulation on misconduct in science; (2) the premature termination of investigations by "confessions" or "negotiated pleas;" (3) the use of an inappropriate standard of proof, and (4) the withholding of names of panel members.

These ORI responses deal only with scientific misconduct issues being addressed under the PHS assurance programs and are not necessarily applicable to independent determinations regarding an institution's own professional norms.

**Categories of Personnel Covered** - Inquiries and investigations required by the PHS assurance program must be conducted on any individual alleged to have committed PHS-related scientific misconduct, including postdoctoral fellows, residents, graduate students, undergraduate students, nurses, technicians and other staff members. Institutional policies and procedures may not be limited to faculty and professional staff. Nor may the policies provide for less rigorous inquiries or investigations for students and other nonprofessional staff. Policies and procedures which do not apply equally to all individuals alleged to have committed scientific misconduct do not meet the requirements of either the institution's assurance to ORI or the Federal regulations and put the institutional assurance in jeopardy.

**Confessions/Negotiated Pleas** - Occasionally, an institution has accepted a "confession" or "negotiated plea" in lieu of a full investigation -- especially when the respondent has left or offered to leave the institution as part of the "deal." Either of these actions may terminate prematurely an investigation and prevent the full extent of the misconduct to become known. Also, respondents have been known to withdraw or explain away their "confession" after the institutional report is forwarded to ORI. Negotiated pleas may solve an institution's immediate problems but they do not meet the institution's responsibilities under its assurance or the remedial concerns of ORI to protect PHS funds. Without the benefit of a full investigation, the ORI may be required under its oversight responsibilities either to request...
additional information that could require the institution to reopen or repeat an investigation or to initiate an ORI investigation.

- **Standard of Proof** - The ORI's evidentiary burden of proof is a "preponderance of the evidence" which is the Federal government standard for administrative law cases. While an institution may choose to use another standard for its internal actions, ORI cannot accept either a misconduct or no misconduct finding on any other standard. Consequently, an institution must base the investigation and findings forwarded to ORI on the preponderance of evidence standard.

- **Panel Members** - The names of the panel members in institutional inquiries and investigations must be included in the materials sent to the ORI with its report, because ORI has an oversight obligation to ensure that inquiries and investigations are free of conflicts of interest and bias and have appropriate expertise available. Also, panel members should be informed that their names could become available to the respondent and that they may be interviewed by ORI during its oversight process, an appeal by the respondent, or an institutional compliance review.

In each of these instances, to enable ORI to complete its oversight responsibilities, ORI may: 1) request additional information; 2) require the institution to reopen or repeat the investigation; 3) conduct an ORI investigation, or (4) conduct a review of the institution's compliance with its assurance.

**ORI SEEKS LITERATURE ON PROTECTIONS FOR WHISTLEBLOWERS**

Whistleblowers in all walks of life are sometimes subjected to harassment, loss of jobs, and even law suits as a result of filing a complaint or providing evidence. Unfortunately, this is true even in the scientific community. As a result, for the last several months ORI has been taking an increasingly proactive stance to protect good faith whistleblowers.

Current regulations provide that good faith whistleblowers should not suffer retribution as a result of their actions. Institutions conducting inquiries and investigations must undertake "diligent efforts to protect the positions and reputations of those persons who, in good faith, make allegations" of scientific misconduct. 45 C.F.R. §50.103(d)(13). Thus, the regulations provide protection for those who raise misconduct issues in good faith, as long as there is some basis for the allegations, even if, after investigation, the allegations are not proven.

ORI believes that making a "good faith" allegation of scientific misconduct is protected under Federal law. Therefore, when made to the proper institutional and Federal officials, these allegations would be privileged communications which would
provide the whistleblower with a defense to claims of libel or slander by the respondent. ORI is preparing a background paper on this issue and will announce its availability in this newsletter.

In keeping with the spirit of the regulations, ORI has made declarations of the above policy available to some good faith complainants involved in civil suits over their actions as whistleblowers. Also, ORI has, in some instances, sent letters stating the above policy to institutions employing complainants and other potential witnesses in investigations. Institutions who either fail to protect or who permit retaliation against good faith complainants are in violation of their Federal assurance and may have their assurance compliance reviewed.

Congress has also expressed its concern for whistleblowers. As is discussed more completely elsewhere in this issue, Section 161 of the National Institutes of Health Revitalization Act of 1993 (Pub. L. 103-43) specifically amended section 493 of the Public Health Service Act to require HHS to publish new regulations, which include standards for preventing and for responding to the occurrence of retaliation against whistleblowers. Congress also instructed ORI to establish remedies for noncompliance which may include termination of and recovery of PHS funding from entities who violate these standards.

ORI is beginning to draft these regulations and, in preparation, would appreciate any comments, experiences, or other information such as state statutes, regulations, and attorney general opinions on whistleblowers. Please send your comments to Barbara Bullman, Division of Policy and Education, ORI.

NSF REPORTS ON MISCONDUCT CASES

The number of scientific misconduct cases being processed by the Office of Inspector General at the National Science Foundation rose from 60 on July 1, 1992 to 81 cases on June 30, 1993, according to the eighth OIG Semiannual Report to Congress.

During that 12-month period, NSF opened 55 cases and closed 34. The report did not contain information on the types of misconduct involved in the cases or on case outcome.

NIH REVITALIZATION ACT BECOMES LAW

The National Institutes of Health Revitalization Act of 1993, Pub. L. 103-43, was signed by President Clinton on June 10. Sections 161-163 of the Act amend section 493 of the PHS Act to establish a number of new mandates for the PHS Research Integrity Program. For purposes of explanation, the new law can be divided into three major sections: General Provisions, Commission on Research Integrity, and Whistleblower Protection.
General Provisions

The law strengthens the independence of the ORI by establishing it as an independent entity with the director reporting to the Secretary of Health and Human Services (HHS). It also replaces the term "scientific fraud" with "research misconduct"; ratifying the Department's prior use of the term misconduct in regulations and substituting "research" for "scientific" which is consistent with the PHS focus on research integrity.

Although all the following items noted in these "General Provisions" are already in place in some form under current regulations, Congress chose to establish explicit statutory mandates for them. This clearly strengthens the underlying authority for the specific requirements.

The new law ratifies and strengthens the general statutory authorities for research integrity by: (1) mandating that each entity applying for PHS funds for any project or program that involves the conduct of biomedical or behavioral research provide assurance that it has in place a process to review reports of research misconduct and report them to the Office of Research Integrity; (2) requiring that specific regulations be developed to govern the response to reports of research misconduct, the conduct of investigations, and the administrative actions to be taken when misconduct is found; and (3) mandating regulations be developed that establish monitoring procedures for assurances and investigations.

Commission on Research Integrity

The law requires the establishment of a Commission on Research Integrity. The purpose of the Commission is to make recommendations on the Research Integrity Program. These recommendations must be included in the report the Commission must provide to the Secretary of HHS, the House Committee on Energy and Commerce, and the Senate Committee on Labor and Human Resources.

The Commission is to be established within 90 days of the enactment of the Act. It replaces the PHS Advisory Committee on Research Integrity. The Commission report is due within 120 days of the establishment of the Commission.

This statute not only requires that the Commission be established, but it also contains explicit requirements for its membership. Specifically, the Commission must be composed of twelve members: three must be scientists with "substantial accomplishments in biomedical or behavioral research"; three must be individuals with "experience in investigating allegations of misconduct with respect to research"; three must represent institutions of higher education; of the three remaining members, one must be an ethicist and one must be an attorney. No more than three members of the Commission may be officers or employees
of the Federal Government.

Whistleblower Protection

The Secretary of HHS must establish in regulation standards for preventing and responding to occurrences of retaliation. These regulations would cover any entity applying for PHS biomedical or behavioral research funds. They would deal with retaliation against an employee who cooperated in an investigation or in good faith made an allegation that the entity, its agents, or officials engaged in or failed to adequately respond to an allegation of research misconduct.

In addition to establishing standards for entities to follow, the Secretary must establish in regulation monitoring systems and remedies for noncompliance. The remedies may include "termination of funding...for such project or recovery of funding..or other actions as appropriate."

The regulations mandated by the Act are due within 180 days of the enactment of the Act with the exception of the regulation encompassing the definition of "research misconduct" which is due 90 days after the submission of the report prepared by the Commission on Research Integrity.

9 of 22 Respondents Request Hearings

Nine of twenty-two respondents have taken the opportunity to request a hearing before the Departmental Appeals Board (DAB) since the process was initiated in November 1992. In four completed actions, the ORI findings and recommendations were upheld in three cases and overturned in the fourth.

One respondent requested a hearing only on the administrative actions proposed by ORI; the DAB upheld the three-year debarment. A second respondent appealed the finding and the proposed administrative actions; during preliminary proceedings, the respondent and the ORI entered into a Voluntary Exclusion and Settlement Agreement. Under the settlement, the respondent agreed to voluntarily exclude himself from applying for Federal funds and serving on PHS advisory committees and boards, both for a three-year period. These exclusions were effectively the same as the administrative actions proposed by ORI. The third respondent withdrew his request for a hearing.

In the fourth case, the DAB overturned an ORI finding of research misconduct. The DAB ruled that ORI failed to prove, by a preponderance of the evidence, that the false statements made by the respondent in two NIH grant applications were intentional [DAB Decision No. 1431 (August 6, 1993)].

Post-hearing briefs have been filed in another case. The DAB is expected to issue its finding this fall. The four remaining appeals were pending hearings at press time.
Legal rulings made by the Departmental Appeals Board (DAB) confirmed that the Department (HHS) has longstanding authority to investigate and impose administrative actions for scientific misconduct involving Federal funds. The DAB also ruled that PHS policies and procedures regarding scientific misconduct do not violate requirements of the Administrative Procedure Act (APA). These rulings sustain ORI's basic authority to continue investigating cases of scientific misconduct including those which arose prior to the adoption of the Federal regulation on misconduct in science in 1989.

The DAB issued these preliminary, legal determinations in response to briefs filed in three appeals. These rulings have import for the final outcomes of the three appeals, as well as for future cases.

As a general matter, the DAB ruled that HHS has discretionary authority to protect the Federal government's interest in the integrity of federally-funded research. This authority existed before PHS' scientific misconduct regulation (1989) and PHS Act § 493 (1985) ("Protection against scientific fraud"). Among the sources of HHS' authority, the DAB highlighted PHS Act § 301 (general authority to conduct intramural research and to make grants for research projects) and 42 C.F.R. Part 52 (governing grants for research projects under the PHS Act). Under these authorities, the Secretary has discretion to determine what projects will be funded and to place conditions on the funding.

The DAB also recognized that the PHS has maintained a consistent and longstanding interpretation of its authority as authorizing it to investigate and take appropriate actions against scientific misconduct. Both the HHS debarment regulations (1980) and the PHS "Policies and Procedures for Dealing with Possible Misconduct in Science" (1986) are examples of PHS' proper exercise of its pre-existing authority, the DAB stated.

Thus, the DAB ruled that the above-mentioned authorities provided adequate notice prior to the publication of the 1989 regulation that actions against scientific misconduct were within the Department's authority to protect its research programs. HHS need not rely on a specific scientific misconduct regulation to conduct such activities, the DAB concluded.

In addition, the DAB held that the 1986 and 1991 PHS scientific misconduct policies and procedures did not violate APA notice and comment requirements. The Board reasoned that PHS Act § 493 did not contemplate notice and comment rulemaking in relation to the agency process for handling scientific misconduct. Moreover, the DAB ruled the policies and procedures fell within the specific exceptions to the APA requirements as general statements of agency policy and rules of procedure.
In another ruling, the DAB stated that HHS has the authority to place conditions on future funding of applications or awards, a researcher's future employment by HHS, or service on peer review committees to deter scientific misconduct. The DAB further ruled that the Department's authority extends to both funded and unfunded grant applications.

The DAB also delineated the burden of proof that rests on ORI during a hearing. In each hearing, the DAB would examine the researcher's particular conduct, the standards of conduct existing at the time of the conduct, and the appropriateness of the proposed administrative actions. The standard of proof employed by the DAB would be a preponderance of the evidence.

Regarding the applicable standards of conduct, ORI must show that the respondent's conduct violated standards applicable at the time of the conduct. The applicable standards are derived either from the relevant scientific community or from Federal requirements for applying for, conducting, or reporting federally-supported scientific research. The standards of conduct may vary according to the time period, location, and type of research involved.

Specifically, ORI must prove that the nature of the respondent's violation of the standards of conduct was such that any reasonable researcher in his or her position would have considered the action to constitute scientific misconduct at the time.

CASE SUMMARIES:
DATA FABRICATED BY GRADUATE STUDENT AND VISITING SCIENTIST

The ORI has issued final findings of scientific misconduct and has implemented administrative actions in the following cases:

Torrey Johnson, Tufts University. An inquiry and a subsequent investigation conducted by the University found that Mr. Johnson, a predoctoral graduate student in the Department of Biology, had fabricated research data on the genetic control of spermatogenesis. Mr. Johnson worked on a grant from the National Institute of Child Health and Human Development.

The university investigation concluded that Mr. Johnson's reports that he had extracted, purified, and characterized a transcription factor protein were fabricated. Mr. Johnson's notebooks provided no details on the purification procedures and he was unable to describe to his thesis committee the steps used to purify the protein. The investigation also concluded that it was likely that Mr. Johnson had used commercially-obtained human transcription factor instead of the protein claimed to have been purified from mouse testis.

The ORI concurred in the University's findings, and Mr. Johnson
has been debarred from receiving Federal grant or contract funds for a three-year period beginning May 14, 1993. For two years beyond the debarment period, any research institution which employs Mr. Johnson must provide the Public Health Service (PHS) a plan for the oversight of his scientific activities and certify the accuracy and integrity of information provided in PHS applications or in reports generated under a PHS award.

Two abstracts containing fabricated data were withdrawn: "Footprint analysis of the promoters of mouse and rat protamine 2 genes reveals difference in protein binding" XIth North American Testis Workshop, and "Protein binding to a conserved promoter element of the male germ cell specific mouse protamine 1 and 2 genes suppresses transcription in vitro in non-expressing tissues" J. Cell Biology Abstracts, 115:48a, 1991.

Fumihiko Sugata, M.D., National Institute of Allergy and Infectious Diseases (NIAID), National Institutes of Health (NIH). An inquiry conducted by NIAID and a subsequent investigation conducted by the Office of Research Integrity (ORI) found that Dr. Sugata, a Fogarty Visiting Scientist in the Laboratory of Infectious Diseases at the NIAID, had fabricated data in molecular biological research on the hepatitis virus. The inquiry and investigation found that there was no scintillation counter printout to support quantitative scintillation count data for one experiment recorded in Dr. Sugata's notebook. Dr. Sugata admitted that he had constructed the data from rough estimates based on autoradiograms, rather than from an actual scintillation counter run. He explained that he was under pressure from his professor in Japan to publish scientific papers, and that when he ran out of scintillation fluid he did not want to delay his project for the two or three weeks necessary to replenish the stock of fluid. The ORI concluded that the fabrication of data constituted scientific misconduct. Dr. Sugata has signed an agreement with the ORI that he will exclude himself for a two-year period beginning September 1, 1993 from any Federal grants or contracts, and from serving on any Public Health Service advisory committees for a three year period beginning on that date. Dr. Sugata also agreed that any applications for PHS support that he submits from September 1, 1995 to August 30, 1996 will be certified as to accuracy and reliability. The fabricated data did not appear in any scientific publications.

CONFERENCE DESCRIBES COMPLEXITIES OF PLAGIARISM

Investigating allegations of plagiarism may not be as simple as it initially appears because of the unexpected twists and turns that occur in such cases, the ambiguities surrounding the attribution of sources and the ownership of ideas in joint efforts, and the emergence of electronic publishing.

That is the thrust of the presentations made during the
Conference on Plagiarism and Theft of Ideas held June 21-22 at the National Institutes of Health. Co-sponsored by the American Association for the Advancement of Science (AAAS) and the ORI, the conference was attended by 150 persons.

Plagiarism accounted for about 25 percent of the allegations received by the ORI in the last three years and about 60 percent of the allegations received by the National Science Foundation during the same period. Dr. Marcel LaFollette, George Washington University, warned that the acceptance of plagiarism as the status quo will affect not just the self-identity of the plagiarized and the plagiarist but also science's self-identity, its image of seeking for and speaking the truth.

Investigations of allegations of plagiarism are not always straightforward; first impressions can be deceiving, and twists and turns do occur. Ms. C.K. Gunsalus, Esq., University of Illinois, observed that a surprising number of plagiarism allegations turn out to be misunderstandings or a dereliction of mentoring or supervisory responsibility. Dr. R. Douglas Wilkerson, Medical College of Ohio, told how a plagiarism investigation expanded to include fabrication when the respondent fabricated a document to show he did not commit plagiarism. Mr. James Meeks, Esq., Ohio State University, recounted a case where the respondent took responsibility for the plagiarism but claimed the plagiarism was done by a former student whom he would not name. Dr. Nelson Kiang, Massachusetts Institute of Technology, discussed multi-cultural aspects of plagiarism investigations, the difficulties in understanding the reactions of certain non-native scientists because of their heritage, and the need to educate American and foreign students that plagiarism and cheating are unacceptable.

Ambiguities surrounding the attribution of sources and the ownership of ideas in joint-efforts are major hurdles in investigations of plagiarism. Ms. Gunsalus found that the definition of appropriate attribution varied considerably. She further noted ambiguity surrounding the ownership of jointly-authored works and grant proposals and the responsibility for text in a multi-authored document. Dr. Alan Price, conference organizer, ORI, stated that plagiarism is particularly difficult or impossible to determine when people have worked together as collaborators, student-mentor, or investigator-coinvestigator.

Dr. Mark Wiser, Tulane University, proposed criteria for judging the seriousness of the complaint: (1) the extent and frequency of the plagiarism (how much material was copied, the whole paper or one paragraph or sentence); (2) the intent of the respondent (to defraud others, as a malicious intent to steal ideas); (3) previous evidence of plagiarism by this same respondent (including examination of the sentences and figures of other papers that were cited in the allegedly plagiarized paper); (4) the rank and level of training of the author (the more senior and experienced, the less credible their excuses); and (5) the nature
of the source material (from notes or from a published article or proposal). Ms. Gunsalus described the use of a computer program that had been developed by Mr. Walter Stewart and Dr. Ned Feder at the National Institutes of Health, to evaluate the extent of plagiarism and look for patterns in non-PHS cases, by attempting to quantitate the extent of common use of phrases between two or more questioned documents. She felt that the program was extremely useful for both confirming and disconfirming alleged plagiarism.

Dr. Edward Huth, Editor of The Online Journal of Current Clinical Trials, and Dr. Lorrin Garson, American Chemical Society, described some of the possibilities that electronic publishing offers. They concluded that, although electronic publishing offers a certain degree of threat of abuse, it also offers methodology to counteract the threat. Dr. Paul Anderson, editor of the Journal of Histochemistry and Cytochemistry, demonstrated technology for modification and creation of images for publication, citing the current dangers of computer-based plagiarism or falsification of images.

Dr. Drummond Rennie, West Coast Editor, Journal of the American Medical Association, directed attention to some responsibilities of editors and publishers. He argued that each revised chapter of a previously published edition of a book should state clearly its provenance; scientist authors and editors must have the courtesy and common sense to ensure that the authors of previous versions are acknowledged freely in the revised text (even though they have signed away prior copyright). He further asserted that journal editors have a duty to publish retractions, prominently and appropriately labeled, not just a weak letter to the editor. While he felt editors are powerless to investigate, when editors receive reports they must cooperate by publishing the results of investigations into the misconduct that affected their journal's pages, as well as retractions.

Dr. Mark S. Frankel, conference organizer, AAAS, recognized the importance of responding effectively to cases of plagiarism, not only to redress individual grievances, but also to protect the integrity of science and to fulfill a central responsibility to those who seek self-governance for their work and an accountability to the larger society.

The ORI is preparing a report on the conference. Its availability will be announced in this newsletter.

ANNUAL REPORT FORM MAILING SET FOR JANUARY

Forms for the ORI Annual Report on Possible Misconduct in Science for calendar year 1993 will be mailed on January 14, 1994, to all organizations with active scientific misconduct assurances.

These annual reports are required by the Federal regulation that initially established the institutional misconduct assurance
requirements. In the reports, institutions identify the official responsible for scientific misconduct policy, report changes in their misconduct policies and procedures, and summarize the year's activities associated with research misconduct allegations, inquiries and investigations.

The return date for submitting these annual reports will be March 1, 1994. Institutions that fail to return their annual reports by that date will become ineligible to receive PHS research funding because their scientific misconduct assurance will be inactivated. If you have any questions related to the Assurance Program requirements, please contact the ORI Assurance Program staff at (301) 443-5377.

PUBLICATIONS


*The AG Bioethics Forum* - An interdisciplinary newsletter in agricultural bioethics. To be placed on mailing list contact The AG Bioethics Forum, 403 Ross Hall, Iowa State University, Ames, Iowa 50011.


*Beyond the "Framework": Institutional Considerations in Managing Allegations of Misconduct in Research* - Provides practical advice to institutions on handling allegations of research misconduct. Single copy free. Association of American Medical Colleges, Division of Biomedical Research, 2450 N Street, N.W., Washington, D.C. 20037-1126.

*Responsible Science: Ensuring the Integrity of the Research Process*, Volume 1. Reports a two-year study by the National Academy of Sciences that comprehensively reviewed the factors that influence the integrity of the research process. Paperback
CALL FOR PAPERS

Ethics & Behavior - This relatively new journal solicits manuscripts in such areas as (1) fraud in the management or reporting of scientific research, (2) ethical dilemmas or professional misconduct in health and human service delivery, (3) public policy issues involving ethical problems, (4) the conduct of research involving human and animal participants, and (5) the exercise of social and ethical responsibility in human behaviors. Contact the editor: Gerald P. Koocher, Department of Psychiatry, Children's Hospital, 300 Longwood Avenue, Boston, MA 02115.

Association for Practical and Professional Ethics - Annual meeting. February 24-26. Stouffer Tower City Plaza Hotel, Cleveland. Papers on such ethical issues as confidentiality, conflict of interest, professional-client relationships, plus the teaching of ethics and curriculum development. Deadline October 30. Contact: Brian Schrag, Executive Secretary, APPE, 410 North Park Ave., Bloomington, IN 47405. Phone (812) 855-6450.

MEETINGS

November 3-4 - "Ethics and Politics in Clinical Trials." A short course on ethical issues and public policy dilemmas involved in clinical trials. Sponsored by the Johns Hopkins Center for Clinical Trials. Contact Office of Continuing Education, Johns Hopkins Medical Institutions at (410) 955-2959.


November 21 - Session on "Tales from the Front: Telling Stories about Scientific Misconduct." Society for the Social Studies of Science. Annual meeting. Purdue University. Contact: Tom Gieryn, Dept. of Sociology, Indiana Univ., Bloomington, IN 47405.
Please Duplicate and Circulate this Newsletter to Offices, Departments, Committees, and Labs. Thank You.

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