ORI Newsletter

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RESEARCH CONFERENCE PLANNED; CALL FOR ABSTRACTS

ORI will convene a conference on "Research on Research Integrity" in the Washington metropolitan area on November 18-20, 2000, to discuss "emerging challenges for the responsible conduct of research."

Abstracts for papers and poster sessions are due by April 30, 2000. Preference will be given to research on research integrity, but interpretative literature reviews, theoretical papers, and identification of research areas with high potential for addressing (1) the responsible conduct of research, (2) the promotion of research integrity, (3) the prevention of misconduct, and (4) the handling of allegations of scientific misconduct are welcomed.

Areas of interest include, but are not limited to: data recording, data retention, data analysis, quality control, and the management of laboratories; authorship, plagiarism and publication practices; the detection, reporting, and investigation of alleged misconduct; respondents, whistleblowers, mentoring, postdocs, lab technicians and career pressures; confidentiality, retaliation, and the incidence of misconduct; the development of normative standards, responsible conduct of research training and elements of a research environment that promote integrity; the role of professional associations and scientific societies in promoting integrity; collaborative research; and the differential opportunity to commit research misconduct across scientific disciplines.

Abstracts for papers and poster sessions are welcomed on programs to promote research integrity, ways to improve programs and assess their effectiveness, and research opportunities related to such programs.

Plans for the conference were discussed during a meeting on November 18-19, 1999, in the Washington, D.C. area. Researchers from the following fields participated: management, biomedicine, organizational studies, deviant behavior, social psychology, and social studies of science. Also attending were senior staff from the Association of American Medical Colleges, the National Institutes of Health, and the Federation of American Societies for Experimental Biology.

Abstracts for the November 2000 conference must include a summary of the proposed presentation (including a bibliography) of no more than 1,000 words, and a résumé or biographical sketch not to exceed 100 words. Submissions by e-mail are strongly encouraged; if sent by regular mail please submit six copies. Abstracts will be refereed by a panel of reviewers. Successful applicants will receive a waiver of any registration fees. The deadline for abstracts is

April 30, 2000. Successful applicants will be notified by June 1, 2000.

Direct abstracts or other inquiries to: Nicholas Steneck, Ph.D., Office of Research Integrity, 5515 Security Lane, Suite 700, Rockville, MD 20852. Or e-mail: nsteneck@osophs.dhhs.gov.

For further background information about this project, see "Planning Meeting Held for Developing Research Agenda" on page 1 of the June 1999 issue of the *ORI Newsletter*.

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FINAL RESEARCH MISCONDUCT DEFINITION PROCEDURES DUE BY SPRING

The final government-wide definition of research misconduct and the procedures for responding to misconduct allegations are expected to be published in the *Federal Register* by spring. The 60-day comment period ended December 13, 1999.

All government agencies that fund research, intra- or extramural, will be expected to implement the definition and procedures either administratively or through regulatory change within a year of the publication date. The Office of Science and Technology Policy in the White House, which developed the definition and procedures with the National Science and Technology Council, will monitor implementation.

The final definition and procedures will most likely reflect only minor modifications if the opinions and comments voiced during the Town Meeting on Research Misconduct held at the National Academy of Sciences (NAS) on November 17, 1999, represented the views of all stakeholders. The original version of the definition and procedures, published in the *Federal Register* on October 13, 1999, is posted on the ORI web site under What's New at **http://ori.dhhs.gov**.

Among the concerns expressed by commentators were: including "omitting" data in the definition of falsification and "without giving appropriate credit" in the definition of plagiarism; the need for a more elaborate definition of what is NOT misconduct; the use of "preponderance of the evidence" as the standard of proof; specifying safeguards for respondents and whistleblowers; and excluding credentials and methodology from the definition because of the focus on data and the research record.

Federal officials endorsing the definition and procedures represented the National Institutes of Health, National Science Foundation, ORI, Department of Veterans Affairs, Department of Agriculture, Office of Naval Research, National Aeronautics and Space Administration, Department of Energy, the Environmental Protection Agency, and the National Oceanographic and Atmospheric Administration.
Other speakers commenting on the definition and procedures represented the Association of American Medical Colleges, the Association of American Universities, the National Association

of State Universities and Land Grant Colleges, the Federation of American Societies of Experimental Biology, the American Society for Microbiology, the American Society for Biochemistry and Molecular Biology, and the American College of Surgeons.

About 175 individuals attended the meeting which was supported by ORI to promote discussion of the proposed definition and procedures. A live Webcast enabled others to access the discussion via the Internet and to submit questions. Audio files were on the NAS web site during the comment period.

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ORI PRODUCES GUIDANCE FOR EDITORS ON MANAGING MISCONDUCT ALLEGATIONS

ORI will issue a document in early 2000 that provides guidance to journal editors and their staffs on reporting suspect manuscripts, facilitating the investigation of misconduct allegations, improving the correction of the literature, and promoting research integrity.

Managing Allegations of Research Misconduct: A Guidance Document for Editors will be distributed extensively to journals, professional associations, scientific societies, and commercial publishers. The document also will be posted on the ORI web site at **http://ori.dhhs.gov**.

"We prepared this document because we wanted journal editors and publishers to know that ORI is committed to working with them to address research misconduct detected in manuscripts and published articles," Chris Pascal, Acting Director, ORI, said. "We expect this document to evolve as the collaborative effort between editors and ORI matures."

Since ORI was established in 1992, 78 publications involving scientific misconduct findings have required corrections or retractions of text, data, figures, or the entire article. Editors have requested assistance from editorial groups and ORI in addressing possible research misconduct in submitted manuscripts.

In the document, ORI urges editors to contact ORI or the institution(s) of the author(s) when research misconduct is suspected. ORI offers to provide assistance to editors in determining whether the suspected misconduct falls under the Federal definition and in identifying officials at institutions and other Federal agencies that should be contacted.

The document further states that ORI may ask editors to assist in an investigation by providing relevant data and/or by identifying the reviewer who alleged the misconduct (with the reviewer's consent). ORI notifies editors when an article published in their journal was involved in a finding of misconduct.

ORI suggests that editors consider taking preventive steps to protect themselves from legal

actions that may result from reporting suspect manuscripts by placing a notification in the journal's "Instructions to the Authors." The Editorial Policy Board of the Council of Biology Editors recently drafted the following statement for that purpose: "Should possible scientific misconduct or dishonesty in research submitted for review by the journal be suspected or alleged, the journal reserves the right to forward any submitted manuscript to the sponsoring or funding institution or other appropriate authority for investigation. The journal recognizes the responsibility to ensure that the question is appropriately pursued, but does not undertake the actual investigation or make determinations of misconduct."

Other steps include developing policies or guidelines concerning: reporting suspect manuscripts; handling suspect manuscripts; obtaining coauthor signatures on manuscripts; submitting data; retaining or circulating copies of manuscripts under review; and publishing corrections and retractions.

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ORI ADDS CHIEF COUNSEL, EDUCATION SPECIALIST

A litigator from the Department of Justice joined ORI as its Chief Counsel in October along with an educational specialist experienced in the development of multimedia instructional materials including CDS, videos, and interactive courses.

Caroline Gosse Elmendorf, J.D., replaced Marcus H. Christ, Jr., who moved to the Health Care Financing Division, OGC. Gail Gibbons, J.D., who was serving as Acting Chief Counsel, resumed her position as Deputy Chief Counsel.

Anita L. Ousley, Ph.D., is serving as a Program Analyst in the Division of Policy and Education where her primary responsibility is the development of instructional materials for a distant learning program on the responsible conduct of research, prevention of misconduct, promotion of research integrity, and handling allegations of scientific misconduct.

As a trial attorney, Ms. Elmendorf handled more than 100 cases under the National Childhood Vaccine Injury Act of 1986, litigating 10 appeals to the U.S. Court of Federal Claims and 5 appeals to the Federal Circuit. Prior to entering government service in 1991, she was a law clerk and associate at Linowes and Blocher and a legal assistant at Pepper, Hamilton & Scheetz, both in the Washington, D.C. area.
Ms. Elmendorf received her law degree in 1988 from the George Washington University Law School and received her bachelor's degree in 1984 from Princeton University.
Previously, Dr. Ousley worked for the Center for Nondestructive Evaluation at Iowa State University since 1993. In that position, she created educational materials on the nondestructive evaluation inspections of aircraft for employees of the Federal Aviation Administration and worked with community colleges and high schools to encourage students to pursue careers in math and science. Dr. Ousley received her doctorate in education with a specialty in higher

education from Iowa State University in 1995. She also holds a master's and a bachelor's degree in business administration from Iowa State.

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ANNUAL REPORT FORM SIMPLIFIED AND SHORTENED

A simplified and shorter Annual Report on Possible Research Misconduct form for calendar year 1999 will be mailed to institutional officials by January 10, 2000. A replacement copy should be requested from ORI if the form is not received by January 31, 2000.

The form is simplified because it only asks for the following information: name and address of the institution, availability of an institutional policy for responding to allegations of scientific misconduct, the number of allegations received and inquiries and investigations conducted, the number of bad faith allegations received, the name of the responsible official, his/her phone and fax numbers, and his/her e-mail address.

Submission of the e-mail address for the responsible official on the 1999 form will be extremely important because ORI expects to move to the electronic transmission of the Annual Report for calendar year 2000.

Misconduct activity reported in the Annual Report must meet two criteria: the alleged misconduct must fall under the PHS definition of scientific misconduct and the questioned research must be funded by the PHS.

To assist institutions in maintaining confidentiality in misconduct cases, neither the PHS funding source nor the number of the grant involved in a case will be requested. Institutions will only be asked to furnish the ORI case number if one has been assigned.

The form is shorter because questions are no longer asked about the protection of whistleblowers, the restoration of reputations, and the sanctions imposed by institutions.

ORI hopes for a 90% response rate by the March 1 deadline, so that a second request will be unnecessary.

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WEB SITE IMPROVEMENTS PLANNED

ORI contracted with 3HTechnology to redesign and update its existing web site, which is expected to be operational in early spring. The URL for the ORI web site is **http://ori.dhhs.gov**.

The ORI web site will be visually appealing as well as easier to navigate and maintain. The refurbished site will have improved navigation, structural flow, content organization, and technical utility for users. Color-coded sections will make it easier to determine one's location

within the site. New graphics and short cuts make it easier to find other materials.

"We wanted to develop a web site that offers the best possible information about research integrity and scientific misconduct for the research community and for the public and are interested in feedback from site users," Chris Pascal, Acting Director, ORI, said.

Comments on the redesign are welcome, and may be e-mailed to the webmaster directly from the site or by sending a message to adustira@osophs.dhhs.gov.

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RIO ROLE DISCUSSED AT UPDATE WORKSHOP

The role of Research Integrity Officers (RIOs) in their institutes or centers was explored for the first time during the annual update workshop for NIH RIOs in November.

To facilitate the discussion, the first part of the workshop was held in conjunction with a meeting of the NIH Extramural Program Management Committee which is composed of officials from each NIH institute.

ORI staff later discussed the proposed common Federal misconduct definition and procedures, the recommendations of the HHS Review Group on Research Misconduct and Research Integrity, the new computer bar on awards to institutions that do not have an assurance, the operation of the PHS Administrative Actions Bulletin Board, the ORI workshops planned for the calendar year 2000, the studies currently funded by ORI, and the proposed ORI research program on research integrity. Staff from the Office of the General Counsel addressed various legal issues relevant to the handling of allegations.

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VISIT ORI TABLE AT AAAS MEETING

ORI will have a display table at the AAAS annual meeting in Washington, D.C., February 18-21, 2000, in Exhibit Hall C in the Marriott Wardman Park Hotel. ORI staff will be present to discuss the proposed research conference and program, collaborative workshops and conferences, the intern and fellows programs, the recommendations of the HHS review group on research misconduct and research integrity, the proposed Federal definition and procedures, the handling of allegations of misconduct, the review of institutional policies, current studies underway, and the assurance program. Stop by and say hello!

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REVIEW GROUP RECOMMENDATIONS BEING RAPIDLY IMPLEMENTED

Actions are being taken quickly to implement the 14 recommendations made by the HHS

Review Group on Research Misconduct and Research Integrity to improve the quality, effectiveness and efficiency of the system for responding to allegations of research misconduct and promoting research integrity in PHS extramural and intramural research programs.

Secretary Donna E. Shalala announced on October 22, 1999, that she has accepted the recommendations of the HHS Review Group. The announcement followed publication of the common Federal misconduct definition and procedures on October 14, 1999. See ORI web site What's New section for the complete documents.

Seven of the fourteen recommendations have been or soon will be implemented through published policy statements or *Federal Register* notices. Three other recommendations will require issuing one or more Notices of Proposed Rule Making (NPRMs) in calendar year 2000. Three recommendations do not require action because they reaffirm existing policy. The final recommendation requires no immediate action; it calls for an evaluation of the new system 3 years after it has been in operation.

In addition to the 14 recommendations, Secretary Shalala accepted 2 additional actions: (1) publication of an NPRM on the protection of whistleblowers, and (2) extension of the training requirement on the responsible conduct of research to all persons engaged in research or research training supported by PHS funds.

The NPRM on whistleblower protection is expected to be published in the *Federal Register* in 2000. Development of a regulation on the protection of whistleblowers was mandated by the NIH Revitalization Act in 1993 and was delayed pending resolution of issues addressed in the HHS Review Group report and development of government-wide Federal policies announced by the Office of Science and Technology Policy (OSTP). Extension of the training requirement on the responsible conduct of research was recommended by the Commission on Research Integrity and endorsed by an HHS workgroup that reviewed Commission recommendations for the Secretary, the Office of Public Health and Science, and NIH. See related article in this issue, “PHS Agencies to Conduct Inquiries and Investigations.”

"These recommendations and related actions strengthen the Department's response to misconduct and the ORI mission," Chris Pascal, Acting Director, ORI, said. "The expanded focus of ORI on the responsible conduct of research, the promotion of integrity, and the prevention of misconduct gives ORI additional opportunities to build partnerships with the research community to promote research integrity and strengthen the research enterprise."

The HHS Review Group report is available on the ORI web site at **http://ori.dhhs.gov**. Progress in the implementation phase will be reported in this newsletter and on the ORI web site in the What's New section.

Recommendation 1: Definition. The Department will adopt the government-wide definition of

research misconduct when it is finalized by OSTP. The new definition will be included in an NPRM revising 42 C.F.R. Part 50, Subpart A.

Recommendation 2: Human and animal subjects. The new definition of research misconduct does not cover protections for human subjects and animal welfare. Confirms current HHS policy and no action is necessary.

Recommendation 3: Other misconduct in research. Forms of misconduct not covered under the definition will be covered by other mechanisms. Confirms current HHS policy and no action is necessary.

Recommendation 4: Institutions are primarily responsible for responding to allegations. Primary responsibility for responding to allegations of scientific misconduct rests with research institutions. PHS intramural programs are included within the definition of research institutions and will conduct their own investigations. See related article in this issue, "PHS Agencies to Conduct Inquiries and Investigations." ORI will offer on-site technical assistance to buttress the ability of institutions to conduct their own investigations.

Recommendation 5: Development of consortia. A contract is expected to be awarded in January 2000 to study the feasibility of developing consortia to assist institutions that do not have adequate capacity to conduct inquiries and investigations. The study is expected to take about a year. See related article in this issue, "Feasibility Study Focuses on Development of Consortia."

Recommendation 6: OIG to conduct Federal fact-finding. The policy statement which assigns responsibility for HHS investigations involving research misconduct to the Office of Inspector General, HHS, is available on the ORI web site. See related article in this issue, "OIG Investigations Viewed as Last Resort."

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Recommendation 7: Separation of fact-finding from adjudication. Final decisions regarding ORI proposed findings of research misconduct and PHS administrative actions will be assigned to the Assistant Secretary for Health (ASH). A *Federal Register* notice covering this change is being developed.

Recommendation 8: Timely processing of allegations. A target timeline of 480 days has been established for completing misconduct cases, including the institutional inquiry and investigations, ORI oversight, and the ASH decision. The policy statement is available on the ORI web site. See related article in this issue, "Timeline Established for Completing Misconduct Cases."

Recommendation 9: Role of whistleblower in misconduct cases. The policy statement clarifying the role of the whistleblower in misconduct cases, as a witness, is available on the ORI web site. See related article in this issue, "Policy Clarifies Complainant Role As Witness in Misconduct Cases."

Recommendation 10: Preponderance of the evidence. The preponderance of the evidence standard for determining whether research misconduct has occurred will be included in a revision of 42 C.F.R. Part 50, Subpart A, subject to final adoption of the standard in the Federal policy. See related article in this issue, "Preponderance Recommended as Standard of Proof."

Recommendation 11: ORI mission. The Review Group recommended that the role, mission, and structure of ORI be changed to emphasize preventing misconduct and promoting research integrity in addition to its oversight responsibilities. The new role, mission, and structure of ORI is described in a *Federal Register* notice that is expected to be published soon. See related article in this issue, "Reorganized ORI Focuses on Oversight, Integrity, Prevention."

Recommendation 12: Qualified immunity. A bill providing qualified immunity for institutions and staff involved in responding to allegations of scientific mis-conduct in PHS-supported research is being drafted and is expected to be submitted to OMB in 2000.

Recommendation 13: Departmental Appeals Board (DAB) hearings. A notice providing up to two scientists on DAB hearing panels is expected to be published soon. An NPRM on regulations for DAB hearing procedures is expected sometime in 2000.

Recommendation 14: Evaluation of Departmental system. An evaluation of the new Departmental system on research misconduct and research integrity is to be made by an independent organization "at the end of the third year of operation under the system." A transition period of 1-2 years is anticipated. No immediate action is necessary.

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PHS AGENCIES TO CONDUCT INQUIRIES AND INVESTIGATIONS

Primary responsibility for responding to allegations of research misconduct and promoting research integrity in PHS intramural research programs was assigned to PHS agency heads by the Assistant Secretary for Health (ASH). Previously, agencies conducted inquiries and submitted their reports to ORI for review, and investigations were conducted by ORI. In November, the ASH directed the PHS agency heads to implement the recommendations of the HHS Review Group on Research Misconduct and Research Integrity by taking the following actions by the start of FY 2001:

- Establish an agency policy for responding to allegations of research misconduct that complies

with the common Federal procedures published in the *Federal Register* on October 14, 1999, and the PHS regulation (42 C.F.R. Part 50, Subpart A), and submit it to ORI for review.

- Conduct inquiries and/or investigations into allegations of research misconduct and submit a report on any investigation conducted to ORI for review.

- Establish a training requirement in the responsible conduct of research for all staff at institutions that are engaged in research or research training under PHS grants, contracts, and cooperative agreements.

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OIG INVESTIGATIONS VIEWED AS LAST RESORT

Federal investigations of allegations of misconduct in research supported by the PHS will be conducted by the HHS Office of Inspector General (OIG) to separate Federal investigations from any part of the Federal adjudication process.

In making this recommendation, the HHS Review Group on Research Misconduct and Research Integrity emphasized "that an OIG investigation should be necessary only in very unusual instances" because institutions have the primary responsibility for responding to allegations.

"Any awardee institution that cannot or will not conduct the fact-finding process should be assisted to develop its own capacities or to affiliate with an entity or consortium that can do the work," the Review Group report stated. ". . . an institution that fails to discharge its responsibility to perform fact-finding, refuses to perform fact-finding, or fails to conduct the process in an acceptable manner after receiving technical assistance should be reviewed to determine its suitability for continuing eligibility to receive awards."

A policy statement adopted by ORI and OIG to implement this recommendation states that "ORI will continue to receive and assess allegations of research misconduct . . . and determine whether the allegation falls under the PHS definition of research misconduct . . . and whether the matter falls under PHS jurisdiction."

ORI will refer cases to OIG only "in rare instances" where Federal criminal misconduct is alleged, the institution cannot discharge its obligation to perform the fact-finding, or when ORI and OIG jointly decide that referral of the case to the research institution would be inappropriate. Except for criminal misconduct, ORI will refer the case to OIG only if the consortia-based approach cannot be used in the case.

When ORI refers a case to OIG, the policy states, "OIG will maintain its independent authority to determine whether there is sufficient evidence to justify conducting an investigation. ORI staff will provide assistance to OIG staff in identifying the type of scientific or technical

expertise needed and, if requested, ORI will assist OIG in providing names or contacting potential experts. HHS will provide scientific experts as needed by OIG to conduct a thorough and competent investigation."

The policy further states, "If OIG declines to open an investigation, then OIG will inform ORI of the reasons for the declination. If ORI continues to believe that the case warrants HHS investigation, ORI will request a meeting with OIG and the ASH to determine whether such an investigation should be done and by whom."

"In cases in which OIG has conducted an investigation, OIG will decide whether and when to refer its factual findings to prosecutorial authorities for criminal or civil action, or to ORI or to other appropriate offices for administrative action. In cases where OIG refers to ORI its investigative findings, ORI will make its own determination on the PHS issues of research misconduct for possible PHS administrative action." The complete policy is available on the ORI web site.

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REORGANIZED ORI FOCUSES ON OVERSIGHT, INTEGRITY, PREVENTION

The reorganized ORI will place greater emphasis on preventing misconduct and promoting research integrity through education and training in the responsible conduct of research, activities designed to promote research integrity and prevent research misconduct, and research and evaluation programs.

The HHS Review Group on Research Misconduct and Research Integrity recommended that "the role, mission, and structure of ORI change to become one of preventing misconduct and promoting research integrity principally through oversight, education, and review of institutional findings and recommendations." Therefore, ORI will rename the Division of Policy and Education as the Division of Education and Integrity and the Division of Research Investigations as the Division of Investigative Oversight.

The new organization and functions of ORI will be described soon in a *Federal Register* notice.

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POLICY CLARIFIES COMPLAINANT ROLE AS WITNESS IN MISCONDUCT CASES

After the initial allegation of misconduct is filed, a complainant (whistleblower) should participate in a scientific misconduct case only "as a witness" according to a recommendation made by the HHS Review Group on Research Misconduct and Research Integrity.

The recommendation states, "Once the complainant has made a formal allegation that research misconduct has occurred, that person should not participate in the fact-finding phase, or in any

other aspect of the determination of misconduct, other than as a witness."

To implement this recommendation, ORI has adopted the following policy on "The Complainant's Role in an Inquiry, Investigation, or Hearing."

"The Office of Research Integrity (ORI) encourages complainants to cooperate fully with ORI and the institution conducting the investigation and to provide them with all information that may be relevant to the allegations. Often, the resolution of a scientific misconduct allegation is dependent on the complainant's continued cooperation. However, it is the responsibility of the investigative body and ORI, not the complainant, to ensure that the allegation is thoroughly and competently investigated to resolution. See 42 C.F.R. 50.103(a) and 50. 104(a)(6). Therefore, once the allegation is made, the complainant assumes the role of a possible witness in any subsequent inquiry, investigation, or hearing. For purposes of the scientific misconduct proceedings, the complainant is not the equivalent of a 'party' in a private dispute between an 'accuser' and 'accused.' The complainant does not control nor direct the process, have access to evidence, except as determined by ORI or the investigative body, nor act as a decision maker in the proceeding's outcome. If there is a formal hearing related to the proceedings, the complainant may be asked by the research institution, if the hearing is at the institutional level, or ORI, if the hearing is at the federal level, to serve as a witness, just as he or she would in a court of law. In some cases, the complainant may even be a key witness, and therefore, the research institution or ORI may rely heavily on the witness in presenting evidence. In other instances, however, the complainant may have a much more limited role.

Several sections of Public Health Service regulations acknowledge the importance of the role of the individual who brings forward allegations. For example, institutions are to undertake diligent efforts to protect the position and reputation of the complainant, protect the complainant's privacy to the maximum extent possible, and provide the complainant with those portions of the investigation report that address his or her role and opinions. See 42 C.F.R. 50.103(d)(2) and (13) and 50.104(a)(2), respectively. However, these provisions do not imply additional rights or privileges in directing the course of the proceedings.

ORI understands that being a complainant is often difficult, particularly if the complainant has been involved in the research under question and believes that his or her reputation is also at stake. Nevertheless, it is extremely important that the investigative body and ORI maintain objectivity during the proceedings, and, therefore, the role of the complainant must be strictly limited to that of a witness."

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TIMELINE ESTABLISHED FOR COMPLETING MISCONDUCT CASES

A target timeline of 480 days has been adopted for completing misconduct cases that involve research supported by the PHS in response to a recommendation made by the HHS Review

Group on Research Misconduct and Research Integrity.

"Several problems associated with the present process stem from the inordinate amount of time that has been taken to address allegations from start to finish," the Review Group stated. "Timely conduct of the inquiry, investigation, and adjudication phases must be a clear commitment among Federal and institutional partners."

The timeline begins with the initiation of an institutional inquiry and concludes with review by the Assistant Secretary for Health (ASH), thereby, establishing guidelines for government oversight for the first time. Not included in the timeline are cases that are appealed to the Departmental Appeals Board (DAB) or investigated by the Office of Inspector General (OIG). The DAB regulation establishes 9 months as a goal for completion of a hearing. By statute, the OIG is independent from Departmental supervision and thus exempt from the timeline.

The timeline is broken down as follows:

Inquiry	60 days
Investigation	120 days
ORI Oversight Review	240 days
ASH Review	60 days
Total	480 days

Extensions continue to be permitted at each step of the process for reasonable cause which must be documented. The full timeline policy is available on the ORI web site.

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PREPONDERANCE RECOMMENDED AS STANDARD OF PROOF

Preponderance of the evidence, rather than clear and convincing, is the standard of proof recommended by the HHS Review Group on Research Misconduct and Research Integrity for determining whether research misconduct has occurred in PHS-supported research.

The standard is consistent with government-wide debarment and suspension regulations and the proposed common Federal procedures for responding to allegations of research misconduct. See the ORI web site.

"Debarment and other sanctions are taken to protect the public's and the Federal Government's interests, not for purposes of punishment," the Review Group report stated. "The debarment regulations appropriately adopt an evidentiary standard of preponderance of the evidence, the usual standard of proof in civil actions." The more rigorous standard, clear and convincing, was

considered by the Review Group because of significant reputational interests at stake for scientists found to have engaged in research misconduct, but was not recommended.

"Because the government's purpose in imposing debarment or other sanctions is to protect its interest in conducting business only with responsible persons, the Review Group concluded that the application of a more demanding evidentiary standard before sanctions for research misconduct could be imposed would not adequately serve the government interest," the Review Group report stated.

Consistent with prior ORI policy, institutions may apply a different standard of evidence in making internal decisions on misconduct, but must apply the preponderance standard in reporting cases to ORI.

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FEASIBILITY STUDY FOCUSES ON DEVELOPMENT OF CONSORTIA

ORI will commission a study to determine the feasibility of organizing consortia to assist institutions, especially small- to middle-sized, to conduct inquiries and/or investigations and further reduce any need for Federal fact-finding in extramural misconduct cases.

The HHS Review Group on Research Misconduct and Research Integrity recommended that "HHS should encourage the formation of consortia that can conduct the fact-finding process when establishment of an individual institutional or organizational process is impractical."

"Consortia may be groups of awardee institutions; groups formed by professional organizations; or mixed groups formed for the specific purpose of providing for the conduct of fact-finding processes on behalf of awardee institutions," the HHS Review Group stated. "The key is that the consortium will be organized to assist a responsible awardee institution that otherwise cannot properly conduct fact-finding."

The study will seek to (1) determine the interest in developing consortia among institutions and professional organizations, (2) assess the expected utilization of consortia, its cost, and methods for cost reimbursement, (3) stipulate the principles for organizing consortia, (4) suggest steps HHS may take to encourage the development of consortia, (5) determine whether the ORI on-site technical assistance program can be an effective means of assisting institutions in conducting their own fact-finding processes, and (6) determine whether the desired assistance could be provided through other mechanisms.

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CASE SUMMARY

Karrie Recknor, University of Washington (UW): Based on a report dated January 27, 1999,

by the UW, Ms. Recknor's admission, and information obtained by ORI during its oversight review, ORI found that Ms. Karrie Recknor, former Graduate Research Assistant, Department of Psychology, University of Washington, engaged in scientific misconduct arising out of certain biomedical research supported by a National Institute of Allergy and Infectious Diseases grant. Specifically, Ms. Recknor admitted to falsifying electronic mail responses presented to the Principal Investigator as part of a project, "Prognosis of Chronic Fatigue Syndrome." Ms. Recknor was responsible for conducting interviews on the impact of life events for six subjects and for assigning preliminary Brown and Harris' Life Events and Difficulties Schedule (B&H) scores to each interview. Ms. Recknor was required to send the interview notes and preliminary scores to a collaborator. The collaborator was to reassess the scores and e-mail the corrected scores or an agreement statement back to Ms. Recknor. Ms. Recknor failed to send the interview notes and preliminary scores for these six interviews to the collaborator for evaluation and instead falsified electronic mail responses to indicate that the collaborator's evaluation had been conducted. Ms. Recknor entered these scores into the research database for the above-mentioned project. The falsified scores did not appear in any publications.
Ms. Recknor accepted the ORI finding and entered into a Voluntary Settlement Agreement with ORI in which she has voluntarily agreed, for the 2-year period beginning August 19, 1999, to exclude herself from serving in any advisory capacity to the Public Health Service (PHS), and any institution that submits an application for PHS support for a research project on which her participation is proposed or which uses her in any capacity on PHS supported research, or that submits a report of PHS-funded research in which she is involved, must concurrently submit a plan for supervision of her duties to the funding agency for approval. The supervisory plan must be designed to ensure the scientific integrity of Ms. Recknor's research contribution. The institution must submit a copy of the supervisory plan to ORI.

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NEEDS ASSESSMENT UNDERWAY FOR ORI EDUCATIONAL PROGRAM

The Center for Health Policy Studies is conducting a needs assessment to determine the types of educational strategies ORI should pursue to assist the research community in preventing scientific misconduct, promoting the responsible conduct of research, and responding to allegations of misconduct.

In its report, approved by the Secretary of Health and Human Services, the HHS Review Group on Research Misconduct and Research Integrity recommended that "the role, mission, and structure of ORI change to become one of preventing misconduct and promoting research integrity principally through oversight, education, and review of institutional findings and recommendations."

"We are very interested in finding out what educational resources the research community needs to promote research integrity, effectively train staff in the responsible conduct of research, and prevent research misconduct," Chris Pascal, Acting Director, ORI, said. "What educational

strategies are most likely to meet those needs; what resources, services or products should be produced, and what mechanisms should be used to make them available."

The needs assessment will employ focus groups and a survey. The study population will be composed of researchers, research administrators, institutional research integrity officers, professional association/scientific society executives, and training grant directors. Study results, expected in December 2000, will be incorporated into the 5-year strategic plan for the ORI education program.

Meanwhile, please forward any suggestions for educational resources related to the topics cited above to Dr. Anita Ousley at ORI. Tel: 301-443-5300; Fax: 301-443-5351.E-mail: aousley@osophs.dhhs.gov.

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ORI IS CO-SPONSORING THREE NATIONAL CONFERENCES IN SPRING 2000

March 24, 2000
Live Satellite Video Conference on Making the Right Moves in Handling Misconduct Allegations

ORI is co-sponsoring a national teleconference with the National Council of University Research Administrators (NCURA) on March 24, 2000, that will focus on the fundamental procedures and processes for managing allegations of misconduct in research. The purpose of the teleconference will be to provide basic training in assessing allegations of research misconduct and conducting inquiries to the individuals at universities who are the initial points of contact for allegations. Contact: Dr. Stephen Hansen, Dean, Graduate Studies, Southern Illinois University at Edwardsville, Edwardsville, IL; Tel: 618-650-3018; FAX: 618-650-3523; E-mail:shansen@siue.edu or Kathleen Larmett, Executive Director, NCURA, One Dupont Circle, N.W., Suite 220, Washington, DC 20036; Tel: 202-466-3894; FAX: 202-223-5573; E-mail: larmett@ncura.edu

April 10-11, 2000
The Role and Activities of Scientific Societies in Promoting Research Integrity, Washington, D.C.

ORI and the American Association for the Advancement of Science (AAAS) are convening a conference on "The Role and Activities of Scientific Societies in Promoting Research Integrity" on April 10-11, 2000, in Washington, D.C. Issues likely to be explored include: What ethics standards and policies are currently in place in professional societies and how do the societies communicate these standards to members and students? What range of professional conduct is covered by the standards? How do/should members use the standards or policies in their work? Or in training new or future members? What support structures (e.g., ethics committees,

hotlines) do/should professional societies employ to promote research integrity? How effective are the standards and support structures? What factors (e.g., law, resources, internal pressures) constrain or facilitate action by societies? Contact Sanyin Siang, AAAS, 1200 New York Ave., N.W., Washington, D.C. 20005; Fax (202) 289-4950; Email: societies@aaas.org

June 4-5, 2000
Practicum on Responding to Allegations of Research Misconduct, St. Charles, IL

ORI and AAAS are co-sponsoring a one-and-a-half day practicum June 4-5, 2000, on responding to allegations of research misconduct: Inquiry, investigation, and outcomes. Recent changes in Federal policies governing research misconduct will be examined as well as what to do when someone brings an allegation of research misconduct, who should be involved, what evidence needs to be gathered, how to secure and retain records, how to conduct an inquiry and investigation, how institutional regulations relate to those of the Federal government, and who to inform of the outcome. For further information, contact, Rachel Gray, Scientific Freedom, Responsibility and Law Program, AAAS, 1200 New York Ave., N.W., Washington, D.C. 20005; Tel: 202-326-7016, Fax: 202-289-4950; E-mail: rgray@aaas.org.

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CONFERENCE PROPOSALS DUE JUNE 1

ORI is seeking proposals from institutions, professional associations, and scientific societies that wish to collaborate with ORI in developing a conference or workshop on promoting research integrity or handling scientific misconduct allegations. The amount of funding available generally would be from $5,000 to $20,000.

Proposals are welcome any time, with June 1, 2000, serving as the next target date for the receipt of applications. Proposal instructions and an application form are available on ORI's web site (**http://ori.dhhs.gov**), by calling (301) 443-5300, or by sending e-mail to adustira@osophs.dhhs.gov.

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SCIENTIFIC MISCONDUCT: INTERNATIONAL PERSPECTIVES

A special issue featuring international perspectives on scientific misconduct will be published in *Science and Engineering Ethics* in January 2000. Representatives from Denmark, France, Germany, Poland, Sweden, the United Kingdom, and the United States describe the efforts underway in their countries to respond to scientific misconduct and promote the responsible conduct of research. The papers were originally presented during a conference at The Medical University of Warsaw in November 1998.

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