Volume 5, No. 4, Office of Research Integrity, September 1997.

 Copies of this and other ORI publications are available on WWW of the Internet at http://phs.os.dhhs.gov/phs/ori/ori_home.html

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New Home Page Address: http://www.dhhs.gov/phs/ori

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1996 ANNUAL REPORT SETS RECORDS

The 1996 Annual Report on Possible Research Misconduct survey sent to 3,310 institutions in January was completed by March 31 with the highest response rate achieved to date by the survey.

"We appreciate the excellent cooperation institutions are giving to the Annual Report," said Chris Pascal, Acting Director, ORI, "because the collected information is shared with institutions to facilitate our collaborative effort to protect the integrity of research supported by the PHS."

The response rate for the 1996 Annual Report was 89 percent by the March 31 deadline, 4 percent higher than the previous year. Previous surveys were not completed until April, May or June.

Eighty-eight institutions reported they were responding to allegations of scientific misconduct received in 1996 or before. Of these institutions, 92 percent reported taking one or more actions to protect whistleblowers. Eighty percent indicated that they had taken steps to restore the position or reputation of exonerated respondents. Nonresponsive institutions will be contacted to determine whether they also took actions.

Three hundred and four assurances were inactivated; 267 because institutions did not submit their Annual Report; 67 because institutions withdrew their assurance. Institutions withdraw their assurances because they do not expect to apply for PHS funds, cease to exist, or merge with another institution.

Also, 342 institutions reported that they did not have an institutional policy (IP) or they failed to respond to the pertinent question. ORI has requested IPs from 179 of these institutions for review. ORI will send letters to the remaining 163 informing them that they have an IP on file with ORI. Two institutions reported conducting investigations not previously reported and were asked to submit their reports.

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APPEALS COURT SENDS BAYLOR CASE BACK TO TEXAS STATE COURT

The lawsuit filed against Baylor College of Medicine (BCM) and others who participated in an investigation into allegations of scientific misconduct will be heard in a Texas state court rather

than in a Federal court to which the BCM had initially succeeded in moving the case.

The U.S. Court of Appeals for the Fifth Circuit dismissed BCM's appeal of a remand order by the U.S. District Court for the Southern District of Texas that sent the lawsuit back to Texas state court. Besides remanding the case to the State court, the district court has also rejected arguments that BCM is entitled to immunity from such suits and that an exhaustion of administrative remedies is required. The appeal specifically sought to have the Fifth Circuit rule on the immunity issue. In dismissing the appeal, the Fifth Circuit held that appellate courts are precluded from reviewing orders of remand made pursuant to 28 U.S.C. 1447(c). However, the Fifth Circuit also held that the district court's determinations as to immunity and exhaustion were "jurisdictional in nature" and may be revisited by the Texas state court.

Kimon J. Angelides, Ph.D., a former research scientist at BCM, sued BCM, senior college officials, and members of the investigation committee in Texas state court for various acts arising out of the investigation, the finding(s) of misconduct, and subsequent dismissal. Dr. Angelides claimed that BCM had defamed him by reporting the misconduct finding to ORI, even though such notice is required by Federal regulations.

At the request of ORI and HHS, the Department of Justice (DOJ) had filed an *amicus* brief arguing that BCM and its employees are entitled to an absolute privilege from defamation claims because they were under a statutory and regulatory obligation to report misconduct findings to ORI. ORI and the Office of the General Counsel are now considering whether to recommend that HHS ask the DOJ to file another *amicus* brief in the State court proceedings.

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WORKSHOP FOR MISCONDUCT OFFICIALS DRAWS 76; MORE DISCUSSION WANTED

Seventy-six representatives from public and private universities and medical schools, research institutes, hospitals, state governments, and professional associations in 26 states, the District of Columbia, and Puerto Rico attended the first ORI Introductory Workshop for Institutional Misconduct Officials in the Natcher Conference Center at NIH on June 6.

"ORI may offer this workshop once or twice a year in different parts of the country because of the highly favorable evaluation it received from participants," Chris Pascal, Acting Director, ORI, said. "We may also adopt a two-day format or reduce the

number of topics covered because participants want more time for discussion with ORI staff and other participants."

Three discussion periods were included in the workshop to address (1) institutional experiences and perspectives on responding to allegations; (2) institutional experiences in protecting whistleblowers and respondents, and (3) approaches and experiences in resolving cases. Moderators were Charles A. Goeffrion, University of Arizona; Rebecca Dresser, Case Western Reserve University Law School; and Angelo M. Taveira-DaSilva, Georgetown University Medical Center, respectively.

The institutional perspective was further explored during the closing session that featured a panel discussion by institutional officials moderated by Barbara Mishkin, Hogan & Hartson. In that session, Barbara Starklauf, Assistant Dean, The Johns Hopkins University School of Medicine, summarized the institutional resources committed to the investigation phase in two cases. The first investigation conducted by 2 full professors and 1 associate professor, involved 25 3-hour meetings over a l0-month period and resulted in a 33-page report with 67 documents appended. The second investigation conducted by 3 full professors involved 16 meetings lasting 2.5 hours each over an 8-month period and resulted in a 35-page report with 35 documents appended.

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GERMANY, ENGLAND RESPONDING TO SCIENTIFIC MISCONDUCT CASES

Scientific misconduct cases in Germany and England are fueling efforts to develop research standards and establish policies and procedures for responding to allegations of misconduct in those countries.

The Deutsche Forschungsgemeinschaft (DFG), the main granting agency in Germany, has decided to establish an international commission composed of 7-10 prominent scientists to discuss research standards and scientific oversight procedures that may be adopted in Germany and internationally, according to *Science*.

In addition, the Max Planck Society for the Advancement of the Sciences, the premier scientific research organization in Germany, is developing new guidelines and procedures for detecting, assessing, and punishing research fraud, Science reports. The Max Planck Society has approximately 10,750 staff members, including about 2,750 scientists in 75 institutes and research facilities that are supported by the federal and state governments in Germany.

The German efforts were sparked by a major misconduct case that involved two investigations, three institutions, at least four published papers, and four investigative committees. One respondent has admitted fabricating the data; the other denies all charges. In another case last year, a German university withdrew the doctorate in chemistry that it had awarded to a researcher.

In England, the editors of nine prestigious British medical journals have formed a Committee on Publication Ethics to help each other deal with fraudulent papers submitted to their journals. One editor had four apparent misconduct cases in his first year. The editors will seek advice from the committee on how to handle alleged fraud cases. The committee may also draft guidelines on investigating complaints, promote research into publication ethics, and provide training in good practice, according to *ScienceNow* on the World Wide Web. In 1995, *Nature* reported that the Medical Research Council and the Royal College of Physicians were taking steps to combat scientific misconduct in medical research in England.

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NIH APPOINTS OMBUDSPERSON; CREATES COOPERATIVE RESOLUTION CENTER

The NIH has appointed an ombudsman and created a new center to serve as a neutral site for resolving disputes related to mentoring, authorship, reagent sharing, data management, and career advancement. NIH's Office of Equal Opportunity, Office of Human Resources Management, Office of Intramural Research, and Committee on Scientific Conduct and Ethics collaborated to launch the pilot project. The new Cooperative Resolution Center is being headed by ombudsman David Robinson, a senior intramural scientist. The pilot program involves five different NIH institutes and is expected to become NIH-wide after a year.

The Center will initially offer mediation, early neutral evaluation, and peer panel evaluation. Once the issues have been clarified and all parties agree, various forms of alternative dispute resolution will be possible.

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SOCIETY WORKSHOP EXPLORES USE OF MEDIATION

ORI will participate in a half-day workshop on the use of mediation to resolve research integrity and whistleblower retaliation issues during the 1997 Society of Research Administrators International meeting in Atlanta on October 4. Chris B. Pascal, J.D., Acting Director, ORI, and Thomas E. Walsh, Ph.D., Director of Sponsored Research, University of Florida,

will address the use of mediation from their perspectives during the workshop. The session organizer is Merritt Lee Murry, Esq., who specializes in alternative dispute resolution techniques.

Murry said, "This workshop will discuss research issues that do not rise to the level of scientific misconduct but have serious institutional and personal concerns that can be resolved through mediation rather than formal investigation or litigation." A role-play demonstration of mediation to resolve authorship/credit disputes, improper data handling, and whistleblower retaliation complaints will include the principal investigator and counsel, the postdoctoral candidate and counsel, the university counsel, and mediator.

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ANONYMOUS ALLEGATIONS PRODUCE VERY FEW MISCONDUCT CASES

Over 90 percent of the anonymous allegations received by ORI have been closed during the preliminary assessment stage because they do not contain the detail required to open a formal case or they do not fall within the jurisdiction of ORI.

ORI responds to anonymous allegations because it believes that allegations which have enough substance to be pursued without the involvement of the whistleblower should be investigated as far as possible, whether or not the identity of the whistleblower is known.

Nine percent of the 914 allegations of scientific misconduct received by ORI from 1993 through mid-1997 were anonymous, according to ORI's review of its records. Only 8.5 percent of these anonymous allegations resulted in a formal case. Only 1 of the 7 formal cases initiated by the 82 anonymous allegations received by ORI resulted in a finding of scientific misconduct--plagiarism. Five cases ended at the institutional inquiry stage and another institutional investigation did not find misconduct.

Altogether, anonymous allegations accounted for only 4 percent of the 351 formal cases opened by ORI and its predecessor since the PHS regulation was published in 1989. Many anonymous allegations are not pursued because the whistleblower only makes a single contact with ORI and does not provide a method for continuing contact that may produce needed information. In a few cases, this difficulty has been overcome because the whistleblower protected his or her identity by using a pseudonym, while giving ORI a telephone number or mailing address for future contacts. Others have used an attorney or an organization as an intermediary to ORI, while maintaining their anonymity. The key

issue for ORI is whether the whistleblower provides sufficient information on which ORI or a research institution can pursue an inquiry or investigation.

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DEBARMENTS/EXCLUSIONS: EFFECT ON INDIVIDUALS AND INSTITUTIONS

Debarments and exclusions are actions taken by the Federal government to protect itself and to ensure that it deals only with responsible persons. Persons may be debarred or voluntarily exclude themselves for several reasons, including a criminal conviction, fraud, or a history of unsatisfactory performance. Once debarred or excluded, a person may not receive any form of assistance, financial or nonfinancial, from the Federal government for a set period of time, usually 3 years. In this article, ORI answers some commonly asked questions regarding debarment and what an institution can do to protect itself when dealing with debarred persons. However, this article is intended only as a general discussion. Institutions and individuals should consult counsel with respect to the particulars of any debarment. For debarments based on findings of scientific misconduct, questions may also be directed to ORI counsel at (301) 443-3466. Regulations applicable to the U.S. Department of Health and Human Services are at 45 C.F.R. Part 76 (nonprocurement) and 48 C.F.R. Subparts 309.4 and 9.4 (procurement or FAR). For simplicity, we've used the term "debarment" to include any actions, including voluntary exclusions, which are listed in the General Services Administration's *List of Parties Excluded from Federal Procurement and Nonprocurement Programs* (GSA *List*).

Who can be debarred?
Both individuals and entities may be subject to debarment. In the area of grant and cooperative agreement supported research, this includes anyone who participates in the research: the principal investigators, researchers, contractors, students, and technical and support staff. To date, all ORI debarments have involved individuals, not institutions or other entities.

What types of assistance are barred?
With some exceptions, debarred persons may not receive *any* Federal assistance (nonprocurement) or contracts (procurement), financial or nonfinancial, under Federal programs and activities of Executive Branch agencies. This includes, but is not limited to, grants, cooperative agreements, subsidies, contracts, subcontracts, student loans, and other forms of Federal funding. For example, debarred persons may not be listed on a grant application for direct receipt of financial assistance in the form of a salary. Also, a debarred researcher may not receive

nonfinancial assistance by being allowed to use federally funded equipment, laboratory space, office personnel, and other resources. Physicians excluded under Medicare and Medicaid provisions are also considered to be debarred. Nor may institutions contract with, or solicit bids from, debarred businesses for amounts over $100,000 when payment is to be with Federal monies. However, since some exclusions are limited in scope or effect, an institution should check the actual terms of an exclusion.

How long is a debarment?
The usual term is three years. However, debarments may be for longer or shorter periods depending on the seriousness of the debarred person's actions.

What work can the debarred person do?
Many areas of employment are unaffected by debarment. For example, debarred persons may work as Federal government employees. They may work for state or local governments, universities, professional and trade organizations, or in the private sector as long as none of the assistance, benefits, or contracts they receive originates with Federal monies. Debarred researchers may continue to receive research grant support from nonfederal sources.

Is an institution that receives Federal funding required to discharge a debarred person?
No. Debarred persons are only prevented from receiving Federal assistance or working on projects that receive Federal assistance. Therefore, they can still participate in any nonfederally funded activities. Upon request, ORI will review the proposed or current work of researchers who have been debarred for scientific misconduct with respect to PHS-funded activities.

May an institution be held responsible for the conduct of its debarred employees?
Yes. An institution cannot knowingly allow a debarred person to participate in federally funded projects nor may it contract with or solicit bids from debarred persons for federally funded projects over $100,000. For example, if an institution knowingly permitted a debarred person to work on a federally funded project, it could result in a disallowance of costs, annulment or termination of an award, issuance of a work-stop order, debarment or suspension, or other administrative actions.

How can an institution know whether a person has been debarred?
All debarred persons are listed in the GSA *List*, which is available either through the U.S. Government Printing Office in

hard copy or electronically at www.ARNET.gov/epls/. Information on individuals debarred for PHS scientific misconduct is also available from the PHS Administrative Actions Bulletin Board which contains debarment information and other administrative actions of which an institution may need to be aware such as certification and supervision requirements. The bulletin board is available electronically at http://silk.nih.gov/public/cbz1bje.@www.orilist.html. More specific information on why individuals have been debarred may be found in summaries published by ORI in the *Federal Register*, the *ORI Newsletter* and in the *NIH Guide for Grants and Contracts*.

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SUIT BY ACCUSED SCIENTIST DISMISSED

In August, a U.S. appeals court upheld a lower court's dismissal of an accused scientist's challenges to the University of Pittsburgh's investigation procedures.

In an unpublished decision, the Court of Appeals for the Third Circuit affirmed the district court's summary judgment against Dr. Herbert Needleman, who had brought this action against Federal defendants, including ORI, and University defendants. Scientific misconduct allegations had been made against Dr. Needleman concerning a lead exposure study published in the *New England Journal of Medicine*. A University investigation found that the misrepresentations in the study did not rise to the level of scientific misconduct and ORI accepted the University's finding.

The litigation commenced in early 1992 when the University was still conducting an inquiry into the allegations. Dr. Needleman alleged in his suit that the university's procedures violated due process and that the definition of scientific misconduct was vague and overbroad, violating his First Amendment rights. On June 1, 1994, the district court granted the University's motion to dismiss the First Amendment claim. On November 23, 1994, the court granted the Federal defendants' motion to dismiss the entire complaint against them as moot, since ORI ultimately did not find misconduct. On May 22, 1996, the court granted summary judgment to the university defendants on all of the remaining claims against them.

Dr. Needleman appealed to the Third Circuit, citing only the district court's May 22, 1996, order. Thus, the court of appeals stated that it did not have jurisdiction over the First Amendment claim dismissed earlier. It agreed, nonetheless, that he failed to show that the University was an agent of the Federal government, thus defeating his First Amendment claim. Secondly,

the court agreed that the misconduct procedures provided sufficient due process because the University's hearing need not be elaborate and Dr. Needleman had had the "opportunity to present his side of the story." Finally, the Third Circuit affirmed the dismissal of the case against the Federal defendants on the grounds that Dr. Needleman's claims against the government were mooted by ORI's decision not to find misconduct.

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CASE SUMMARIES

Amitav Hajra, University of Michigan (UM): Based upon a report from UM, information obtained by the ORI during its oversight review, and Mr. Hajra's own admission, ORI found that Mr. Hajra, a former UM graduate student, engaged in scientific misconduct by falsifying and fabricating research data in five published research papers, two published review articles, one submitted but unpublished paper, in his doctoral dissertation, and in a submission to the GenBank data base. Mr. Hajra's doctoral training and research was supported by PHS grants, and his experiments were conducted at NIH's National Center for Human Genome Research (NCHGR).

Mr. Hajra began his graduate research at the University of Michigan with Dr. Francis Collins as his mentor. When Dr. Collins later accepted the position of director of the NCHGR and established a research laboratory at the NIH, Mr. Hajra continued his research on the NIH campus.

The possibility that data had been fabricated or falsified first came to the attention of Dr. Collins when an editor informed him that reviewers of a manuscript had questioned the authenticity of a figure. When intervening events and a survey of laboratory notebooks and other data confirmed deep concerns, Dr. Collins confronted the student who admitted to fabricating major portions of his dissertation research and related research publications. The UM, NIH and ORI were notified. Dr. Collins also submitted retractions and corrections of the relevant publications and databases. ORI asked the UM, where Mr. Hajra was completing his final year of medical school, to conduct a formal investigation.

The following research reports (1-5) and review articles (6-7) contained falsified and fabricated data:

(1) Hajra, A., Collins, F.S. "Structure of the leukemia-associated human CBFB gene." *Genomics* 26(3):571-579, 1995. Retraction published in *Genomics* 38:107,1996.

(2) Hajra, A., Liu, P.P., Speck, N.A., Collins, F.S. "Overexpression of core-binding factor (CBF) reverses cellular transformation by the CBFß-smooth muscle myosin heavy chain chimeric oncoprotein." *Molecular and Cellular Biology* 15(9):4980-4989, 1995. Retraction published in *Molecular and Cellular Biology* 16:7185, 1996.

(3) Hajra, A., Liu, P.P., Wang, Q., Kelley, C.A., Stacy, T., Adelstein, R.S., Speck, N.A., and Collins, F.S. "The leukemic core binding factor ß-smooth muscle myosin heavy chain (CBFß-SMMHC) chimeric protein requires both CBFß and myosin heavy chain domains for transformation of NIH 3T3 cells." *Proc. Natl. Acad. Sci. USA* 92(6):1926-1930, 1995. Retraction published in *Proc. Natl. Acad. Sci. USA* 93:15523, 1996.

(4) Wijmenga, C., Gregory, P.E., Hajra, A., Schröck, E., Ried, T., Eils, R., Liu, P.P., and Collins, F.S. "Core binding factor ß-smooth muscle myosin heavy chain chimeric protein involved in acute myeloid leukemia forms unusual nuclear rod-like structures in transformed NIH 3T3 cells." *Proc. Natl. Acad. Sci. USA* 93(4):1630-1635, 1995. Correction published in *Proc. Natl. Acad. Sci. USA* 93:15522, 1996.

(5) Liu, P.P., Wijmenga, C., Hajra, A., Blake, T.B., Kelley, C.A., Adelstein, R.S., Bagg, A., Rector, J., Cotelingham, J., Willman, C.L., and Collins, F.S. "Identification of the chimeric protein product of the CBFB-MYH11 fusion gene in inv(16) leukemia cells." *Genes, Chromosomes, and Cancer* 16:77-87, 1996. Correction published in *Genes, Chromosomes, and Cancer* 18:71, 1997.

(6) Hajra, A., Liu, P.P., and Collins, F.S. "Transforming properties of the leukemic Inv(16) fusion gene CBFB-MYH11." in "Molecular Aspects of Myeloid Stem Cell Development." in L. Wolff and A.S. Perkins, eds. *Current Topics in Microbiology and Immunology* ("*Current Topics*"), volume 211: *Molecular Aspects of Myeloid Stem Cell Development*, Springer-Verlag, Berlin and New York, 1996. pp. 289-298. The *Current Topics* volume has no mechanism for publishing retractions but the series editor has been notified.

(7) Liu, P.P., Hajra, A., Wijmenga, C., and Collins, F.S. "Molecular pathogenesis of the chromosome 16 inversion in the M4Eo subtype of Acute Myeloid Leukemia." *Blood* 85: 2289-2302, 1995. Correction published in *Blood* 89:1842, 1997.

Mr. Hajra submitted a fabricated nucleotide sequence: U22149, "Human leukemia-associated core binding factor subunit CBFbeta (CBFB) gene, promoter region and partial CDS." GenBank (NCBI,

NLM, NIH). This database entry was removed in Sept. 1996. The majority of data reported in Mr. Hajra's dissertation, "Transformation properties of the leukemic CBFß-SMMHC chimeric protein," was fabricated. He also fabricated and falsified original research data in a manuscript submitted for publication to *Oncogene* but withdrawn prior to publication.

Mr. Hajra was found to be solely responsible for the data falsification and fabrication and no patients were involved in the research. Mr. Hajra has accepted the ORI finding and has entered into a Voluntary Exclusion Agreement in which he has agreed, for the 4-year period beginning July 7, 1997, to exclude himself from any Federal grants, contracts or cooperative agreements and to exclude himself from serving in any advisory capacity to the PHS.

Fugang Li, Ph.D., University of Oklahoma Health Sciences Center (UOHSC): Based upon a report from the University of Oklahoma, information obtained by ORI during its oversight review, and Dr. Li's own admission, ORI found that Dr. Li, a former postdoctoral fellow in the Department of Biochemistry and Molecular Biology, UOHSC, engaged in scientific misconduct by fabricating and falsifying data in conducting and reporting research supported by a grant from NIH's National Heart, Lung and Blood Institute. Specifically, Dr. Li fabricated and falsified data in a study involving the characterization of glycoprotein binding to P-selection on the surface of human leukocytes. The questioned data were included in a manuscript that was withdrawn prior to publication. Dr. Li has accepted the ORI finding and has entered into a Voluntary Exclusion Agreement with ORI in which he has agreed, for the 3-year period beginning June 3, 1997, to exclude himself from any Federal grants, contracts or cooperative agreements and to exclude himself from serving in any advisory capacity to the PHS. No scientific publications were required to be corrected as part of this Agreement.

David N. Shapiro, M.D., St. Jude Children's Research Hospital (SJCRS): Based upon a report from SJCRS as well as information obtained by ORI during its oversight review, ORI found that Dr. Shapiro, former faculty member, SJCRS, engaged in scientific misconduct by falsifying the authorship of five publications listed in his biographical sketches in several NIH grant applications. Specifically, Dr. Shapiro listed himself as an author when he was not. Dr. Shapiro also fabricated data for Figures 5 and 7 in the following publication: Sublett, J.E., Jeon, I.S., & Shapiro, D.N. "The aveolar rhabdomyosarcoma PAX3/FKHR fusion protein is a transcriptional activator." *Oncogene* 11:545-552, 1995. Dr. Shapiro has submitted a letter to

Oncogene requesting retraction of these figures. Dr. Shapiro has accepted the ORI finding and has entered into a Voluntary Exclusion Agreement in which he has voluntarily agreed that beginning July 29, 1997, to: (1) exclude himself from any Federal grants, contracts or cooperative agreements for 2 years; (2) exclude himself from serving in any advisory capacity to the PHS for 3 years; and (3) that any institution that submits an application for PHS support for a research project on which his particpation is proposed or that uses him in any capacity on PHS-supported research must concurrently submit a plan for supervision of his duties to the funding agency for approval for 1 year following the 2-year exclusion. The supervisory plan must be designed to ensure the scientific integrity of Dr. Shapiro's research contribution. The institution also must submit a copy of the supervisory plan to ORI.

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ORI CONDUCTS TRAINING COURSE FOR NIH EXTRAMURAL STAFF

More than 70 NIH extramural program staff attended a continuing education course on "Scientific Misconduct: Who Does What?" on July 28. ORI speakers briefed participants on the office's current caseload, oversight activities, and educational programs. Participants also heard the latest developments in the lawsuit concerning institutional immunity in misconduct cases.

Other subjects discussed in the half-day session included the role of NIH extramural staff in reporting allegations and implementing administrative actions, and how NIH staff will be notified about the resolution of cases. ORI staff also reviewed the compliance requirements for extramural institutions and reiterated the need for confidentiality in misconduct cases.

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WORKSHOP PLANNING BEGINS FOR 1998-99 ACADEMIC YEAR

ORI invites proposals from institutions, associations, societies, and organizations interested in co-sponsoring workshops on responding to scientific misconduct or promoting research integrity during the 1998-99 academic year. ORI also invites requests for the organization of sessions at professional/scientific meetings and for individual speakers.

ORI has completed its workshop program for the 1997-98 academic year with the scheduling of five workshops. Requests for the organization of sessions and individual speakers will still be considered for this academic year. See December issue for further details.

The ORI Newsletter is published quarterly by the Office of Research Integrity, Office of the Secretary of Health and Human Services, and distributed to applicant or awardee institutions to facilitate pursuit of a common interest in handling allegations of misconduct and promoting integrity in PHS-supported research.

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*Lists of Meetings and Publications are neither exhaustive nor all inclusive. Nor should any of the items listed or described be even remotely construed as being favored or endorsed by the Government.

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