ORI NEWSLETTER

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## ORI ISSUES ANNUAL REPORT; REDUCES CASELOAD IN 1996

In 1996, ORI closed 49 scientific misconduct cases and handled 196 allegations of misconduct. Seventeen cases concluded with a finding of misconduct and the imposition of 43 PHS administrative actions including 13 debarments. None of the 17 misconduct findings was appealed; all respondents signed voluntary exclusion or settlement agreements.

These are some of the facts published in the *ORI Annual Report - 1996* that was distributed in November to all institutions that have an active assurance on file with ORI except for small businesses.

At the end of the year, ORI had reduced its misconduct case load to an all time low--48 cases. ORI also reduced its compliance caseload from 16 to 10 in 1996. Currently, ORI's processing time for scientific misconduct cases averages 10-12 months.

The annual report includes standard features such as summaries of all ORI cases, both misconduct and no misconduct, a description of ORI educational activities, and a statement of activities at the institutional level. It also includes for the first time a summary of scientific misconduct-related litigation handled by ORI (11 cases) and a summary of whistleblower retaliation cases handled from 1994 to 1996 (16 cases).

The report also discusses major Federal policy issues, such as the potential liability of institutions and institutional officials for investigating and reporting allegations of misconduct to ORI.

The report is available from the ORI home page at http://www.dhhs.gov/phs/ori or in hard copy.

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## ORI SEEKS COLLABORATORS FOR CONFERENCES/WORKSHOPS

ORI is seeking proposals from institutions, professional associations and scientific societies that wish to collaborate with ORI in developing a conference or workshop that addresses either handling scientific misconduct allegations or the promotion of research integrity.

The proposed workshops would be held between September 1998 and December 1999. ORI intends to hold six or more conferences or workshops during this period in strategic locations around the country. The conferences and workshops would be jointly developed, presented and supported by ORI and collaborating organizations. The level of ORI support will be contingent on the availability of funds.

"We would like to hold two workshops on scientific misconduct and two workshops on research integrity issues," Chris Pascal, Acting Director, ORI, said. "The other workshops will depend on the nature of the proposals we receive."

Proposals for fall 1998 should be submitted by March 31, 1998; proposals for calendar year 1999 should be submitted by May 31, 1998. The proposal should include a rationale for the conference or workshop, a draft agenda and, if possible, potential speakers, the proposed length, date(s), location, estimated attendance, marketing plan, and name of the principal organizer. The proposal should be five pages or fewer.

"A conference or workshop may deal with a single topic in depth," Pascal said, "or consider several interrelated topics. In either case, the primary objective is to expand the knowledge base, provide new perspectives, and stimulate thinking and discussion. We want these conferences and workshops to move us forward."

Among the topics that might be considered for a scientific misconduct workshop are incidence, prevention, detection, definition, reporting allegations/misconduct findings, investigating, sanctions, restitution, rehabilitation, whistleblowers, respondents, institutions, professional associations, scientific societies, editors, and funding agencies.

Among the topics that might be considered for a research integrity conference are record keeping in research, data management, quality control, assignment of credit, intellectual property rights, mentoring, collaborative research, the principal investigator, the laboratory director, institutions, professional associations, scientific societies, editors, funding agencies, prevention of misconduct, and designing and implementing systems to promote research integrity.

ORI also is interested in hearing from institutions that would like to host the ORI Introductory Workshop for Institutional Misconduct Officials during the same period. For more information and materials on workshop planning, please call Dr. Alicia Dustira at (301) 443-5300.

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## UNIVERSITY PAYS $1.6 MILLION IN DAMAGES

After 7 years of court action and appeals, the University of Michigan paid $1.67 million in damages in July to a researcher who said her work had been stolen by her supervisor. According to the *New York Times*, the money went to Dr. Carolyn Phinney, a researcher in psychology, in a civil case that began in 1988.

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## INTRODUCTORY WORKSHOP HELD AT TUSKEGEE UNIVERSITY

ORI conducted its Introductory Workshop for Institutional Misconduct Officials at Tuskegee University in Alabama on November 13 in collaboration with university staff. Besides Tuskegee University staff, the 47 attendees represented institutions and organizations in Alabama, Georgia,

Mississippi, Arizona, New Jersey and Virginia.

ORI staff made presentations on the evolving approaches to scientific misconduct and research integrity, the maintenance of institutional eligibility for funding, the conduct of inquiries and investigations, Federal oversight of investigations, the protection of respondents and whistleblowers, the implementation of administrative actions, and the disclosure of case information. Tuskegee staff served as moderators of open discussion sessions and as panelists. Additionally, attendees from three institutions served as panelists.

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## FISHER CASE SETTLED

On August 27, 1997, five days before Dr. Bernard Fisher's suit against the University of Pittsburgh, HHS, NIH, NCI, ORI, and Secretary Shalala and others in their official capacities was scheduled to begin trial, all parties entered into a settlement agreement, and the court immediately dismissed the case with prejudice. The settlement was a full release of all Dr. Fisher's claims, and no government party admitted to any liability or violation of law. In his suit, Dr. Fisher had raised numerous charges challenging actions taken by the University of Pittsburgh, NIH, and ORI, which he claimed affected his reputation and position as the former director of the National Surgical Adjuvant Breast and Bowel Project. Dr. Fisher's claims against ORI focused on the ORI scientific misconduct investigation, which he suggested violated his due process rights and the safeguards set forth in the Federal regulations. ORI's report, issued Feb. 28, 1997, did not make a finding of scientific misconduct. A few months prior to the settlement, the court dismissed several Privacy Act claims raised by Dr. Fisher, as those claims had already been disposed of by the U.S. District Court for the District of Columbia when *Fisher* v. *NIH* was dismissed.

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## QUESTIONS ADDED TO 1997 ANNUAL REPORT FORM

Several questions added to the 1997 Annual Report on Possible Research Misconduct form will enable institutions to clarify their responses concerning the protection of whistleblowers and the restoration of reputations of exonerated respondents and provide data on bad faith allegations and institutional sanctions.

In addition, the e-mail address of the responsible official will be requested for the first time to facilitate communication between those officials and ORI.

The 1997 Annual Report form is scheduled to be mailed to institutions on January 12, 1998, with a submission deadline of March 2, 1998. However, at press time, the form was undergoing its tri-annual review by the Office of Management and Budget so the above content and dates may change.

Assurances for 304 institutions were inactivated as a result of the 1996 Annual Report survey.

ORI withdrew 267 because the institutions did not submit their reports by the deadline; 67 institutions withdrew their assurance and were no longer required to submit the report. An institution must have an active assurance to be eligible to receive PHS research support.

The additional questions concerning whistleblower protection ask for the number of cases in which an effort was made to protect the whistleblower and also provide an opportunity to explain why no action was taken in some cases.

The additional questions concerning the restoration of the reputation of exonerated respondents ask for the number of cases that are still ongoing, the number of cases in which no misconduct was found, and an explanation of why no action was taken in some cases.

The new question about the imposition of institutional sanctions asks for the number of cases in which misconduct was found and the sanctions imposed in each case. This question was added because many institutions do not describe the sanctions imposed on the respondent when misconduct is found. This omission may be due to institutional appeal processes or the decision to wait for the completion of the ORI oversight review before imposing sanctions.

The new question about bad faith allegations asks for the number of bad faith allegations received, and the actions taken against the whistleblower in each case. This question was added because of the concern in the research community about the incidence of bad faith allegations. Many institutional administrative policies permit disciplinary actions to be taken in such cases.

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## ORI REVIEWING PARENT/AFFILIATE INSTITUTIONS

ORI is reviewing the administrative policies established by 80 institutions to respond to allegations of scientific misconduct, which claim that their policies also apply to another 186 institutions that are affiliated with them.

The review is part of ORI's continuing program to review institutional policies for responding to allegations of scientific misconduct for compliance with the Federal regulation (42 C.F.R. Part 50, Subpart A) and to determine how well the parent/affiliate mechanism for establishing institutional policies is working.

The review is guided by two questions: (1) Does the policy comply with the regulation? and (2) Does the policy provide an administrative process that is applicable to the affiliated institutions? An affiliate does not have an independent policy and, therefore, is eligible for funding only if the policy of the parent institution complies with the regulation and provides the affiliate with a workable administrative process for handling allegations. If the parent policy does not comply, the affiliate must submit its own policy to ORI.

A report will be prepared on each unit of analysis--a parent institution and its affiliates--

indicating whether the parent policy meets the regulatory requirements and is applicable to all affiliates. If not, the report will explain the regulatory provisions that are not adequately reflected and list needed changes to their policies.

Where applicable, institutions will be required to submit appropriate changes. Where problems are identified, ORI will offer technical assistance on making policy changes to improve coordination between entities.

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## MINNESOTA RULINGS CONCERN PHS AGENCY/INSTITUTION RELATIONSHIP

On July 23, 1997, a Federal district court in Minnesota issued two related rulings concerning the relations between institutions and PHS granting agencies. In the first case, *Regents of the University of Minnesota* v. *Shalala*, the court dismissed the University's lawsuit, which had alleged that NIH violated constitutional due process provisions and protections for States when it took administrative actions to increase oversight of grants administration activities at the University of Minnesota by designating the university as an "exceptional organization" and removing expanded authorities to transfer funds without prior approval from NIH. The court held that the Government's decision to impose conditions on a grant award is committed to agency discretion, and that such conditions do not violate the Tenth Amendment. The University appealed the dismissal, and oral arguments are anticipated in the Spring of 1998.

In *U.S. ex rel. Zissler* v. *Regents of the University of Minnesota*, the U.S. Government had claimed that the university violated the False Claims Act, the Federal Food, Drug, and Cosmetic Act, and Medicare statutes, and was thus liable under the False Claims Act and common law theories of unjust enrichment, payment by mistake, disgorgement of profits, and breach of fiduciary duty. Adopting a position contrary to other circuit courts, the Minnesota court dismissed those claims based on the False Claims Act because it determined that the Act did not clearly indicate that it applies to the States.

The court declined to dismiss the Government's common law claims against the university, concluding that it does have equitable powers to order restitution of funds to the Government based on unjust enrichment, payment by mistake, disgorgement of profits, and breach of fiduciary duty because the university failed to demonstrate that the Food, Drug and Cosmetic Act restricts the court's jurisdiction in equity, and it is not necessary for the statute to explicitly confer such authority.

More details and analysis of the cases may be found on ORI's home page.

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## ADMINISTRATIVE ACTIONS NEEDING DOCUMENTATION EXPLAINED

Several institutions have had questions recently about administrative actions imposed on respondents in scientific misconduct cases that require institutions to submit specified documents

to PHS funding agencies and copies of those documents to ORI.

Two administrative actions require institutional action; two require action by the respondent, and one requires action by the institution and the respondent.

When a certification of data is imposed on a respondent, the employing institution must certify that the data provided by the respondent are based on actual experiments or are otherwise legitimately derived, and that the data, procedures, and methodology are accurately reported in the grant application or report submitted to the agency. The statement of certification must accompany the grant application or report; a copy of the statement must be sent to ORI.

When a plan of supervision is imposed on a respondent, the institution which submits an application for PHS support for a research project on which the individual's participation is proposed or which uses the individual in any capacity on PHS-supported research, must submit with the grant application a plan of supervision that will ensure the scientific integrity of the individual's research contribution. The funding agency will determine the acceptability of the plan. A copy of the plan must be submitted to ORI.

When a respondent is required to submit a retraction or a correction of an article, the respondent must also send a copy of the retraction or correction letter to ORI. The respondent remains in the ALERT system until the letter is received.

When a certification of sources is imposed on a respondent, the respondent must submit with each application or report a statement of certification that is endorsed by an institutional official that all contributors to the application or report are properly cited or otherwise acknowledged. A copy of the statement must be sent to ORI.

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Shoushu Jiao, M.D., University of Wisconsin (UW): Based upon reports from UW, as well as information obtained by ORI during its oversight review, ORI found that Dr. Jiao, former Research Associate, Department of Pediatrics, UW, engaged in scientific misconduct by falsifying and creating laboratory records while conducting biomedical research. The data in these records were reported in a National Institute of Neurological Disorders and Stroke (NINDS) grant application to support a request for PHS funding. Based on the factual findings in the reports, the following article has been retracted: Jiao, S., Gurevich, V., & Wolff, J.A. "Long-term correction of rat model of Parkinson's disease by gene therapy." *Nature* 362:450-453, 1993.

Dr. Jiao has entered into a Voluntary Exclusion Agreement with ORI in which he has voluntarily agreed, beginning August 8, 1997, (1) to exclude himself from any Federal grants, contracts or cooperative agreements for 3 years, (2) to exclude himself from serving in any advisory capacity to the PHS for 4 years, and (3) that any institution that submits an application for PHS support for a research project on which Dr. Jiao's participation 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 1 year following the 3-year exclusion. The supervisory plan must be designed to ensure the scientific integrity of Dr. Jiao's research contribution. The institution also must submit a copy of the supervisory plan to ORI.

Christopher Leonhard, Dartmouth College (DC): Based upon an investigation conducted by DC, information obtained by ORI during its oversight review, and his own admission, ORI found that Mr. Leonhard, a former graduate student in the Department of Psychology, DC, engaged in scientific misconduct in biomedical research supported by two grants from the National Institute of Mental Health.

Specifically, Mr. Leonhard fabricated experimental records and falsely represented them to his supervisor as being results obtained from multiple electrophysiological screening sessions conducted on eight animals, and fabricated two surgical records as evidence of experimental preparations (implantation of indwelling electrodes) on two animals, which in fact had not been done. The experimental records did not appear in any publications.

Mr. Leonhard has accepted the ORI finding and has entered into a Voluntary Exclusion Agreement with ORI in which he has voluntarily agreed, for the 3-year period beginning September 8, 1997, to exclude himself from serving in any advisory capacity to the PHS, and that any institution that submits an application for PHS support for a research project on which his partici-pation is proposed or which uses him in any capacity on PHS supported research or that submits a report of PHS-funded research in which he is involved, must concurrently submit a plan for supervision of his duties to the funding agency for approval. The supervisory plan must be designed to ensure the scientific integrity of Mr. Leonhard's research contribution. The instiution must submit a copy of the plan to ORI.

Jill A. London, Ph.D., University of Connecticut Health Center (UCHC): Based upon a report from the UCHC, as well as information obtained by ORI during its oversight review, ORI found that Dr. London, former Assistant Professor, Department of Biostructure and Function, School of Dental Medicine, UCHC, engaged in scientific misconduct by intentionally falsifying data in conjunction with applying for and reporting research supported by the National Institute of Neurological Disorders and Stroke (NINDS) and the National Institute on Deafness and Other Communication Disorders (NIDCD).

Specifically, ORI found that Dr. London's grant applications and articles contained numerous falsifications:

(1) Figures 6, 7, and 8 in a paper (London, J.A. & Cohen, L.B. "High time resolution, multi-site optical measurement of vertebrate somatosensory cortex during epileptiform discharges and vertebrate gustatory cortex." *Optical Methods in Neurobiology*, pp. 61-78, 1988.) prepared for the 11th Annual Meeting of the European Neuroscience Association (hereafter

referred to as the European Neuroscience paper) that cited support by NINDS, NIH grants R01 NS08437 and P01 NS16993;

(2) Figure 1A in a paper (London, J.A., "Optical recording of activity in the hamster gustatory cortex elicited by electrical stimulation of the tongue." *Chemical Senses* 15:137-143, 1990.) that cited support by NINDS, NIH grants R01 NS08437 and P01 NS16993; Figure 1A was found to be very similar or identical to Figure 7 of the European Neuroscience paper in #1 above;

(3) Figures 10 to 13 in grant application 2 P50 DC00168-14, "Connecticut Chemosensory Clinical Research Center," submitted to NIDCD, NIH on January 28, 1994; these figures also appear as Figures 4 to 7 in grant application 2 P50 DC00168-14A1, submitted to NIDCD, NIH on September 28, 1994;

(4) Figures 2, 8, and 9 in grant application 1 R01 DC01752-01, "Optical recording of hamster gustatory cortex activity," submitted to NIDCD, NIH on January 29, 1992; these figures were the same as Figures 11, 12, and 13, respectively, in grant application 2 P50 DC00168-14 (see #3 above);

(5) figures supplied for Figures 1 and 3 in grant application 1 F32 NS09601-01, "Modular response patterns in hamster gustatory cortex," submitted to NINDS, NIH on August 3, 1993; these figures were the same as Figures 10 and 11, respectively, in grant application 2 P50 DC00168-14 (see #3 above);

(6) Figure 3 of a handout that Dr. London provided during an NIH site visit on April 25, 1994, conducted in conjunction with the review of grant application 2 P50 DC00168-14; the top and bottom portions of Figure 3 of the site visit handout were very similar or identical to Figures 6 and 7, respectively, of the European Neuroscience paper (see #1 above), and approximately 115 of the 125 traces appearing in each of the figures showed identities, with one or two "active" traces being identical;

(7) Figures 1, 2, and 3 in a paper (London, J.A. & Wehby, R.G. "Classification of inhibitory responses of hamster gustatory cortex." *Brain Research* 666:270-274, 1994.) that cited support by NIDCD, NIH grants P50 DC00168 and T32 DC00025; and

(8) nine figures included in a manuscript (London, J.A. & Wehby, R.G. "Excitatory neural responses in the hamster gustatory cortex." Submitted to *Brain Research*, 1996.) that cited support by NIDCD, NIH grants P50 DC00168 and T32 DC00025.

Dr. London has accepted the ORI finding and has entered into a Voluntary Exclusion Agreement with ORI in which she has agreed, for the 5-year period beginning August 8, 1997, to exclude herself from any Federal grants, contracts or cooperative agreements and to exclude herself from

serving in any advisory capacity to the PHS.

Dr. London is required to submit a letter to:

*Chemical Senses* requesting a retraction of the following article: London, J.A. "Optical recording of activity in the hamster gustatory cortex elicited by electrical stimulation of the tongue." *Chemical Senses* 15:137-143, 1990;

*Brain Research* requesting a retraction of the following article: London, J.A., & Wehby, R.G. "Classification of inhibitory responses of the hamster gustatory cortex." *Brain Research* 666:270-274, 1994; and

*Optical Methods in Neurobiology* requesting a retraction of Section V, Results -- Hamster of the following article: London, J.A., & Cohen, L.B. "High time resolution, multi-site optical measurement of vertebrate somatosensory cortex during epileptiform discharges and vertebrate gustatory cortex." *Optical Methods in Neurobiology*, pp. 61-78, 1988, prepared for the 11th Annual Meeting of the European Neuroscience Association.

Xiaomin Shang, Ph.D., University of Texas Southwestern Medical Center (UTSMC): Based upon a report from the UTSMC, information obtained by ORI during its oversight review, and his own admission, ORI found that Dr. Shang, a former postdoctoral fellow student in the Department of Obstetrics and Gynecology, UTSMC, engaged in scientific misconduct arising out of certain biomedical research supported by a training grant from the National Institute of Child Health and Human Development (NICHD). Specifically, Dr. Shang fabricated a chemiluminescent film of a Western blot by using a physical mask to alter the prior results showing lack of antibody specificity to a human steroid metabolizing isozyme, rather than replicating an experiment as requested by his mentor. The fabricated data were not published.

Dr. Shang has accepted the ORI finding and has entered into a Voluntary Exclusion Agreement with ORI in which he has voluntarily agreed, for the 3-year period beginning September 29, 1997, to exclude himself from serving in any advisory capacity to the PHS, and that any institution that submits an application for PHS support for a research project on which his participation is proposed or which uses him in any capacity on PHS-supported research or that submits a report of PHS-funded research in which he is involved must concurrently submit a plan for supervision of his duties to the funding agency for approval. The supervisory plan must be designed to ensure the scientific integrity of Dr. Shang's research contribution. The institution also must submit a copy of the supervisory plan to ORI.

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## SYMPOSIUM ON MISCONDUCT SLATED FOR AAAS ANNUAL MEETING

A half-day symposium, "Misconduct in Science: A Decade of Progress or Merely Years of Controversy?" will be part of AAAS' Annual Meeting and 150th anniversary celebration

February 13, 1998, in Philadelphia. Alicia Dustira, Deputy Director, Division of Policy and Education, ORI, and Barbara Mishkin, an attorney with Hogan & Hartson, are co-organizers.

The session will open with Dr. Nickolas Steneck, University of Michigan, providing perspectives on the ways in which scientists, the Federal government, and research institutions have dealt with cases of misconduct in science in the past, and discuss the evolution of the definition and protection of whistleblowers. Then, Dr. Sybil Francis from the White House Office of Science and Technology Policy will explain the difficulties of developing a common definition and common policies for handling allegations of research misconduct for all the scientific research funded by the Federal government. Next, Mr. Samuel Crocker, a former university attorney, will discuss lawsuits and criminal investigations that are widely covered by the popular and scientific press.

While there is plenty of anecdotal evidence on how whistleblowers and respondents in misconduct cases have been treated, Dr. James Lubalin, the director of two special surveys done for ORI, will report on the consequences of being involved in a misconduct case. Finally, Ms. Mishkin will discuss some of the important outcomes that have resulted from past cases and provide a preview of what to expect in the future.

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## ORI PLANS THREE REGIONAL CONFERENCES FOR 1998

ORI will co-sponsor a conference on February 10-11, 1998, with the University of Michigan (UM) in Ann Arbor on managing integrity in research. The conference will focus on building a culture of ethical conduct within research institutions as well as handling allegations of research misconduct or other abuses of the research process. For additional information, check the UM Research Responsibility Website for up-to-date-information on the conference: http://www.responsibility.research.umich.edu or contact Alicia Dustira, ORI, (301) 443-5300 or Judy Nowack, UM, (313) 768-1289.

ORI and the University of North Carolina (UNC) at Chapel Hill are jointly sponsoring a regional workshop on scientific integrity on May 18-19, 1998. For information call Alicia Dustira, ORI, (301) 443-5300 or Robert Lowman, UNC-Chapel Hill, (919) 962-0656.

ORI and the University of Arizona will hold a "Conference on the Management of Biomedical Research Laboratories" from October 1-3, 1998, in Tucson. The format will promote discussion on the role of the laboratory director, the development and management of a research agenda, data management, quality control, collaborative research, mentoring, and the assigning of credit for productivity. Institutions that have guidance documents in these areas are asked to submit copies to ORI for possible use in the conference. For information call Larry Rhoades, ORI, (301) 443-5300 or Alice Langen, University of Arizona, (520) 621-5196.

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## KAROLINSKA INSTITUTE DISCLAIMS ARTICLES

The Swedish research institute that awards Nobel prizes in medicine and physiology announced that it cannot validate about 20 articles on gene amplification in breast and bladder cancer published by Ulf Lonn, a former researcher at the institute. However, it did not make a finding of misconduct, according to *Nature*. Lonn denied the charge and considers himself legally cleared. His lawyer said Lonn was not given a fair chance to defend himself and indicated that the matter may end up in court.

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ORI REGIONAL CONFERENCES - 1998

February 10-11, Ann Arbor, MI, University of Michigan, Managing Integrity in Research

May 18-19, Chapel Hill, NC, University of North Carolina at Chapel Hill, Workshop on Research Integrity

October 1-3 Tucson, AZ, University of Arizona, Management of Biomedical Research Laboratories

For details, see ORI PLANS THREE REGIONAL CONFERENCES <U>supra</U> or call ORI (301) 443-5300.

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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 and PHS agencies to facilitate pursuit of a common interest in handling allegations of misconduct and promoting integrity in PHS-supported research.

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