ORI NEWSLETTER

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ORI DEVELOPS HANDBOOK FOR RESEARCH INTEGRITY OFFICERS

ORI has developed a handbook for the official in PHS awardee and applicant institutions who is responsible for creating and implementing policies and procedures required by the Federal regulation on handling allegations of scientific misconduct. The handbook will be sent to all institutions that have an active assurance on file with ORI, except small businesses.

ORI produced the *ORI Handbook for Institutional Research Integrity Officers* because the low frequency at which allegations of scientific misconduct occur and the high turnover rate in institutional officials responsible for misconduct policy (17 percent in 1994) make it difficult to develop the expertise required to respond to such allegations in an objective, thorough, and competent manner.

The handbook is divided into five sections: (1) Institutional Responsibilities; (2) Legal Rulings; (3) ORI Oversight; (4) ORI Outreach; and (5) Appendices.

The institutional responsibilities section describes the obligations that institutions assume by applying for or receiving PHS research funds: (1) Developing an administrative process for responding to allegations of scientific misconduct; (2) submitting an assurance; (3) keeping an assurance active; (4) responding to allegations of scientific misconduct; (5) restoring reputations of exonerated respondents; (6) protecting the positions and reputations of complainants; (7) cooperating with the ORI; (8) fostering research integrity; (9) informing scientific and administrative staff about the institution's policies and procedures for responding to allegations of scientific misconduct; and (10) implementing PHS/DHHS administrative actions.

The ORI oversight section covers: (1) ORI mission and structure; (2) PHS offices that handle research abuses; (3) oversight of institutional inquiries and investigations; (4) conduct of inquiries and investigations at institutions; (5) determinations of misconduct, administrative actions, and the hearing process; (6) assurance program; (7) Annual Report on Possible Research Misconduct; (8) institutional compliance reviews; (9) review of retaliation complaints; (10) implementation of PHS/DHHS administrative actions; (11) PHS ALERT system; and (12) defining plagiarism.

The ORI outreach section reports on informational and educational activities. The appendices contain important documents and forms.

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GUIDELINES PROVIDE OPTIONS FOR HANDLING RETALIATION COMPLAINTS

ORI has developed guidelines that suggest options which PHS applicant and awardee institutions may use to respond to whistleblower retaliation complaints, in conforming with the PHS regulation (42 C.F.R. Part 50, Subpart A) to protect good faith whistleblowers.

ORI Guidelines for Institutions and Whistleblowers: Responding to Possible Retaliation Against Whistleblowers in Extramural Research are recommendations which may serve as interim guidance until the regulation on the protection of whistleblowers mandated by the NIH Revitalization Act of 1993 becomes effective. The guidelines are available on the ORI home page on the World Wide Web (http://phs.os.dhhs.gov/phs/ori/ori_home.html).

Institutions that use these guidelines in handling whistleblower retaliation complaints will be considered by ORI to be in compliance with the current regulatory requirement for protecting whistleblowers. However, institutions are not required to adopt these procedures; they may devise their own procedures to satisfy their regulatory obligation.

Under the recommended guidelines, institutions must report all retaliation complaints to ORI within 10 working days of receipt, be responsive to any request for interim protections, and appoint a responsible official to handle whistleblower retaliation complaints.

The guidelines offer institutions two options for handling retaliation complaints--investigation or arbitration. If the whistleblower declines the option proposed by the institution, the institution is encouraged to propose the alternative option. If the institution offers either option, but the whistleblower declines, he or she may pursue any other legal remedies available to resolve the retaliation complaint. However, ORI will deem the institution to have met its regulatory requirement.

According to the guidelines, an investigation should be conducted by a panel of at least three persons who have the appropriate expertise and no conflicts of interest. Appropriate remedies must be adopted if retaliation is found and a report of the investigation must be sent to ORI. If the institution has

substantially conformed to the guidelines, ORI will not review the merits of the institutional determination.

According to the guidelines, if the arbitration alternative is selected, the parties must sign an agreement that the retaliation dispute will be decided by final and binding arbitration and must identify the presiding arbitrator and designated arbitration association. The institution and the whistleblower must agree on the choice of arbitrator. The institution must send a copy of the final arbitration award to ORI.

In lieu of the two options, a settlement may be reached between the institution and the whistleblower at any time in the proceedings, even after an investigation or arbitration is underway. Settlement requirements are explained in detail in the guidelines. Whatever procedure is adopted, it should be completed within 180 days of the date the whistleblower retaliation complaint was filed.

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COMPLAINANT'S COURT CASE DISMISSED

A civil action against the ORI and Louisiana State University Medical Center (LSUMC) brought by a complainant in a closed case was dismissed on December 14. The U.S. District Court for the Western District of Louisiana ruled that Mr. Yoram Raz failed to exhaust his administrative remedies under the Federal Tort Claims Act and therefore precluded the Court from exercising jurisdiction over the claims. The Magistrate further ruled that, to the extent that Mr. Raz may have a contractual dispute with the U.S. Government, the proper forum for such a dispute is in the U.S. Court of Federal Claims.

Mr. Raz sought an injunction to reopen ORI's investigation into the scientific misconduct allegations previously raised. ORI had concurred with LSUMC's Inquiry Committee that no further investigation was warranted. He also sought damages for financial loss and damaged reputation because of ORI's alleged negligence in failing to assure fairness and objectivity in LSUMC's inquiry. Mr. Raz also claimed that he was a third-party beneficiary of a contract between ORI and LSUMC and that ORI had violated its contractual obligations by failing to pursue his scientific misconduct allegations adequately.

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COMPLAINANT FAILS TO PROVE ALLEGATIONS IN *QUI TAM* SUIT

A U.S. District Judge granted a motion for summary judgment

dismissing a *qui tam* suit under the False Claims Act because the complainant failed to provide any evidence of scientific fraud.

Walter E. Black, Jr., Senior Judge, U.S. District Court for Maryland, granted the summary judgment in a scientific misconduct case in which a former postdoctoral fellow alleged that an administrator, four researchers, and two institutions made false claims against the Federal government by making 48 false statements in 24 grant applications to the NIH from 1982 to 1989. A summary judgement is granted when there are no disputed issues of material fact for trial.

The False Claims Act permits private citizens to file suit on behalf of the Federal government against institutions and individuals who make false claims for payment. If successful, the complainant may receive up to 30 percent of the recovered funds.

Nine statements that were considered false by the complainant (because she believed the findings reported in the statements were untrue) prompted the Court to conclude that these allegations presented it "with a legitimate scientific dispute, not a fraud case. Disagreements over scientific methodology do not give rise to False Claim Act liability. Furthermore, the legal process is not suited to resolving scientific disputes or identifying scientific misconduct." The Court also found her claim that the defendant's practices deviated from scientific norms unsupported by any expert testimony.

Finally, the Court ruled that the complainant failed to show that any of the defendants "knowingly" submitted false claims to the government. The Court relied on the D.C. Circuit Court ruling that "the knowledge requirement of the False Claims Act has never required a higher standard than 'reckless disregard' or 'deliberate indifference' for the submission of false claims."

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BIVENS RETURES; PASCAL NAMED ORI ACTING DIRECTOR

Lyle W. Bivens, Ph.D., who held senior leadership positions in the PHS research integrity program since it was established in 1989, including directing ORI since January 1993, announced his retirement effective March 31, 1996, after 33 years of Federal service. Chris B. Pascal, J.D., Director, Division of Research Investigations (DRI), will serve as Acting Director until a replacement is appointed.

Under Dr. Bivens' direction, ORI instituted a case management

review and tracking system to expedite the processing of cases, began publicizing findings of scientific misconduct, developed model institutional policies and procedures for responding to allegations of scientific misconduct, established guidelines for responding to retaliation complaints from whistleblowers, initiated an annual report, began a systematic review of institutional policies and procedures, and issued instructions to PHS agencies on the handling of allegations of scientific misconduct in intramural research programs.

Before he headed the office, Dr. Bivens served as the Director of the Division of Policy and Education since ORI was created in May 1992 by merging the Office of Scientific Integrity Review (OSIR) and the Office of Scientific Integrity (OSI). From 1989 to 1992, he served as Director, OSIR within the Office of the Assistant Secretary for Health. Dr. Bivens received a PHS Special Recognition Award (1991) for his leadership in establishing the PHS research integrity program.

Mr. Pascal served as Chief, Research Integrity Branch, Office of the General Counsel, from 1992 to 1995 when he became Director, DRI. Previously, he served as legal advisor to the OSIR from 1989 to 1992 while he was Chief Counsel for the Alcohol, Drug Abuse, and Mental Health Administration, a position he held from 1982-1992.

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ADMINISTRATIVE ACTIONS: RANGE, RATIONALE, IMPLEMENTATION DESCRIBED

Individuals found to have committed scientific misconduct in PHS-supported research may have administrative actions imposed on them by the Department of Health and Human Services as well as by their institutions (42 C.F.R. 50.104(a)(7) and 50.103(d)(14)).

DHHS may impose administrative actions on a respondent: (1) when a settlement is reached through a Voluntary Agreement; (2) when the respondent does not request a hearing before a Research Integrity Adjudications Panel of the Departmental Appeals Board (Panel); or (3) when a Panel decision affirms the ORI misconduct finding.

One or more of the following administrative actions are most commonly imposed when a misconduct finding is final. ORI may also impose any other action on the respondent that is authorized by law and reasonably responds to the seriousness, extent, and type of scientific misconduct. Although the modal time period for the imposition of administrative actions is generally three

years, the time may be increased or decreased depending on the extent of the need to protect the Federal government in general and PHS programs in particular. Some of the considerations used in making this determination include the seriousness of the respondent's acts or omissions and any aggravating or mitigating factors. The effective time periods for PHS administrative actions are not retroactive, but begin when the administrative action is officially imposed.

Administrative actions are carried in the PHS ALERT System and on the PHS Administrative Actions Bulletin Board for the duration of the action.

Debarment
This action is intended to protect Federal funds by prohibiting the support or the involvement of debarred individuals in any capacity under a Federal grant, contract, or cooperative agreement, including serving as principal investigator, co-principal investigator, research associate, research assistant, technician, consultant, contractor, and participating in all other types of covered transactions as defined in 45 C.F.R. Part 76 and 48 C.F.R. Subparts 9.4 and 309.4 for a specified period of time.

Prohibition Against Advisory Service
This action is intended to protect the PHS advisory system by prohibiting individuals who have committed scientific misconduct from serving in any advisory capacity to the PHS including service as an initial review group member, an ad hoc reviewer, a consultant, or an agency, institute, center or division board or council member for a specified period of time.

Required Certification of Sources
For a specified period of time, an individual is required to certify in every PHS research application or report that all contributors to the application or report are properly cited or otherwise acknowledged. The certification by the individual must be endorsed by an institutional official. A copy of the endorsed certification must be submitted to ORI by the institution. This action is intended to protect the integrity of applications and reports submitted to PHS research programs by assuring that the words and ideas expressed are those of the individual (i.e., have not been plagiarized) and applies to all documents submitted to the PHS that involve the individual. These documents include new, renewal, and continuation applications, and progress and final reports.

Required Certification of Data

For a specified period of time, any institution employing the individual is required to submit, in conjunction with each application for PHS funds or report of PHS research in which the individual is involved, a certification that the data provided by the individual are based on actual experiments or are otherwise legitimately derived, and that the data, procedures, and methodology are accurately reported in the application or report. A copy of the certification must be submitted to ORI by the institution. This action is intended to verify the integrity of the data submitted by the individual to the PHS in applications and reports and covers new, renewal, and continuation applications, as well as progress and final reports.

Required Plan of Supervision
For a specified period of time, any 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 concurrently submit a plan for supervision of the individual's duties. The supervisory plan must be designed to ensure the scientific integrity of the individual's research contribution. A copy of the supervisory plan must be submitted to ORI by the institution. This action is intended to protect the integrity of the PHS research and covers new, renewal, and continuation applications.

Retraction of Article
The individual is required to submit a letter to a specified journal requesting retraction of a specified article within 30 days of notification of this action. This requirement is noted in the ALERT System until the individual sends a copy of the retraction letter to ORI. This action is intended to ensure the accurate reporting of research supported by PHS funds. ORI also notifies the relevant journal of this action.

Correction of Article
The individual is required to submit a letter within 30 days of notification of this action to a specified journal requesting correction of a specified article. This requirement is noted in the ALERT System until the individual sends a copy of the correction letter to ORI. This action is intended to ensure the accurate reporting of research supported by PHS funds. ORI also notifies the relevant journal of this action.

Institutional Actions
If appropriate for the particular circumstances of a specific case, ORI may accept the administrative actions already imposed on an individual by an institution. In these instances, ORI

considers whether the institutional actions are sufficient or whether additional administrative actions are needed to protect PHS research.

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CASE SUMMARIES

Daniel P. Bednarik, Ph.D., Centers for Disease Control and Prevention (CDC). Based on an investigation conducted by the Division of Research Investigations, ORI found that Dr. Bednarik, a former employee of the CDC, engaged in scientific misconduct by fabricating and falsifying research data in two scientific manuscripts that were submitted for publication. One paper, entitled "Expression of the human (cytosine-5) methyltransferase is regulated by alternative mRNA splicing," was not accepted and the other, entitled "Indirect evidence for an EBV-HIV hybrid virus: Human immunodeficiency virus type 1 and Epstein-Barr virus genome association," was withdrawn before review. Dr. Bednarik and ORI have entered into a Voluntary Exclusion Agreement where Dr. Bednarik has agreed not to appeal ORI's findings and has further agreed: (1) to exclude himself from any contracting or subcontracting with any agency of the Federal government and from eligibility for, or involvement in grants and cooperative agreements for a period of two years, beginning on October 30, 1995; (2) that any institution employing him be required to submit, in conjunction with each application for PHS funds or report of PHS-funded research in which he is involved, a certification that the data provided by him are based on actual experiments or are otherwise legitimately derived and that the data, procedures, and methodology are accurately reported in the application or report for a period of one year following his exclusion; (3) that any institution that submits an application for PHS support for a research project that proposes his participation or that uses him in any capacity on PHS-supported research must concurrently submit a plan for supervision of his duties, designed to ensure the scientific integrity of Dr. Bednarik's research, for a period of one year following his exclusion; and (4) to exclude himself from serving in any advisory capacity to PHS, including service on any PHS advisory committee, board, and/or peer review committee, or as a consultant for a period of three years, beginning on October 30, 1995.

Harry L. June, Ph.D., Indiana University-Purdue University at Indianapolis (IUPI). Based on an investigation conducted by IUPI, ORI found that Dr. June committed scientific misconduct by falsifying three letters of recommendation submitted with and in

support of a FIRST Award application to the PHS. Dr. June has entered into a Voluntary Exclusion Agreement with ORI in which he has accepted ORI's finding and has agreed to exclude himself voluntarily, for the three-year period beginning November 21, 1995, from serving in any advisory capacity to PHS, including service on any PHS advisory committee, board, and/or peer review committee, or as a consultant. In addition, Dr. June has voluntarily agreed to accept the administrative sanctions imposed by IUPI, which include requirements that Dr. June: (1) take a course in research ethics; (2) be supervised by a senior faculty member for not less than three years; and (3) submit all grant applications to his supervisor for review at least one month prior to the agency deadline and to the Dean's office at least two weeks prior to the agency deadline. No scientific publications were required to be corrected.

Ruth Lupu, Ph.D., Georgetown University Medical Center (GUMC). Based on an investigation conducted by GUMC, ORI found that Dr. Lupu committed scientific misconduct by submitting a false letter of collaboration in an unfunded application to the PHS. Letters of collaboration are a significant factor in the evaluation of applications. Dr. Lupu has entered into a Voluntary Exclusion Agreement with ORI in which she has accepted ORI's finding and has agreed to exclude herself voluntarily, for the period beginning December 6, 1995, and ending January 30, 1997, from serving in any advisory capacity to PHS, including service on any PHS advisory committee, board, and/or peer review com-mittee, or as a consultant. In addition, Dr. Lupu has voluntarily agreed to accept the administrative sanctions imposed by GUMC, which include requirements that: (1) a letter of reprimand be issued and retained in her personnel file for two years; and (2) her future grant applications, proposals, and other publications be subject to special monitoring and review for two years. No scientific publications were required to be corrected.

Tetsuya Matsuguchi, M.D., Ph.D., Dana-Farber Cancer Institute/Harvard Medical School (DFCI/HMS). Based on an investigation conducted by DFCI/HMS, ORI found that Dr. Matsuguchi, formerly a Harvard Medical School Research Fellow at the DFCI, committed scientific misconduct by intentionally falsifying data by artificially darkening one band each on two autoradiographs in figures that he had prepared for a presentation at an intramural research seminar and by altering three bands on the print of an immunoblot included in Figure 2A of a paper published in the *EMBO Journal*. This research was supported by a PHS grant. Dr. Matsuguchi has entered into a Voluntary Exclusion Agreement with ORI in which he has accepted

ORI's finding and has agreed to exclude himself voluntarily, for the three-year period beginning November 3, 1995, from: (1) any contracting or subcontracting with any agency of the United States Government and from eligibility for, or involvement in, Federal grants and cooperative agreements; and (2) serving in any advisory capacity to PHS, including service on any PHS advisory committee, board, and/or peer review committee, or as a consultant. The above voluntary exclusion, however, shall not apply to Dr. Matsuguchi's future training or practice of clinical medicine whether as a medical student, resident, fellow, or licensed practitioner unless that practice involves research or research training. Dr. Matsuguchi has agreed to submit a letter to the *EMBO Journal* requesting correction of the article entitled "Tyrosine phosphorylation of p85Vav in myeloid cells is regulated by GM-CSF, IL-3, and Steel factor and is constitutively increased by p210BCR/ABL" (*EMBO Journal* 14:257-265, 1995).

Durga K. Paruchuri, Ph.D., University of North Carolina, Chapel Hill (UNC). Based on an investigation conducted by UNC, and information obtained during its oversight review, the ORI concluded that Dr. Paruchuri committed scientific misconduct by falsifying research records and falsely reporting to her supervisor and in a grant application submitted to the PHS that she had produced a clone of meningococcal bacteria transferrin binding protein 1, labeled "pUNCH 701," and used it to obtain a second clone, "pUNCH 702." Furthermore, ORI accepted the UNC finding that Dr. Paruchuri falsified research records at the Lineberger Cancer Research Center oligonucleotide synthesis facility in an attempt to support her false claim. Dr. Paruchuri accepted the ORI findings and agreed to exclude herself voluntarily for a period of two years beginning December 21, 1995, from any contracting or subcontracting with any agency of the Federal government and from eligibility for grants and cooperative agreements. Dr. Paruchuri further agreed that for a period of one year, in addition to and immediately following the two-year exclusion period, any institution which submits an application for PHS support for a research project on which Dr. Paruchuri's participation is proposed, or which uses Dr. Paruchuri in any capacity on PHS-supported research, or which submits a report of PHS-funded research in which Dr. Paruchuri is involved, must concurrently submit a plan of supervision and certification of data accuracy. Dr. Paruchuri also agreed to exclude herself voluntarily from serving in any advisory capacity to the PHS for a period of three years beginning December 21, 1995.

Ms. Victoria Santa Cruz, University of Arizona (UA). Based on an

investigation conducted by the institution, ORI found that Ms. Santa Cruz, former Program Coordinator, College of Nursing, UA, engaged in scientific misconduct by fabricating interview data on a questionnaire intended for use in two studies funded by two PHS grants. Ms. Santa Cruz did not contest the ORI findings or administrative actions, which require that, for a period of three years, any institution that proposes her participation in PHS-supported research must submit a supervisory plan designed to ensure the scientific integrity of her contribution. Ms. Santa Cruz is also prohibited from serving in any advisory capacity to PHS, including service on any PHS advisory committee, board, and/or peer review committee, or as a consultant for a period of three years, beginning December 14, 1995. Because the studies involved are ongoing, no publications were affected by the fabricated data, and no clinical treatment has been based on the results of the studies.

Weishu Y. Weiser, Ph.D., Brigham & Women's Hospital/Harvard Medical School (BWH/HMS). ORI found that Dr. Weiser, formerly of BWH/HMS, com-mitted scientific misconduct by falsifying data in biomedical research supported by two PHS grants. She entered into a Voluntary Exclusion Agreement with ORI in which she accepted ORI's finding and has agreed to exclude herself voluntarily for the three-year period beginning October 19, 1995, from: (1) participating in any Federal contracts or subcontracts and from eligibility for or involvement in grants and cooperative agreements, and (2) serving in any advisory capacity to PHS, including but not limited to service on any PHS advisory committee, board, and/or peer review committee, or as a consultant. She has agreed to retract the articles entitled "Human recombinant migration inhibitory factor activates human macrophages to kill Leishmania donovani" (*Journal of Immunology* 147:2006-2011, 1991), "Recombinant migration inhibitory factor induces nitric oxide synthase in murine macrophages" (*Journal of Immunology* 150:1908-1912, 1993), and "Recombinant human migration inhibitory factor has adjuvant activity" (Proceedings of the National Academy of Sciences 89:8049-8052, 1992).

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ORI CLOSES, OPENS RECORD NUMBER OF CASES

ORI increased its misconduct case closings by 32 percent in 1995, closing 58 cases compared to 44 in 1994, and reduced by 75 percent its pre-1993 case backlog by closing 9 of 12 cases.

ORI increased its compliance case closings by 40 percent in 1995, closing 14 cases compared to 10 in 1994. Nine compliance cases

closed in 1995 involved allegations of retaliation against whistleblowers; those closed in 1994 were all compliance reviews.

Forty-nine misconduct cases were opened in 1995 compared to 38 in 1994, an increase of 29 percent. Thirteen compliance cases (including 8 involving retaliation) were opened in 1995 compared to 19 (including 9 retaliation complaints) in 1994, a decrease of 32 percent. ORI began 1995 with 67 misconduct and 17 compliance cases; it carried 58 misconduct and 16 compliance cases into 1996.

The number of queries received by ORI concerning possible incidents of scientific misconduct jumped 32 percent, from 185 in 1994 to 244 in 1995. By the end of the year, 210 queries had been assessed and 31 new cases resulted.

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MEETINGS

May 2-5, 1996. "The Conduct of Science: Keeping the Faith" is being sponsored by the Keystone Symposia on Molecular and Cellular Biology in Keystone, CO. Information is available from Keystone Symposia, Drawer 1630, Silverthorne, CO 80498; tel: (800) 253-0685 or (970) 262-1230; Fax: (970) 262-1525.

May 30 - June 1, 1996. "Ethical Issues of Animal Research" conference at Indiana U., Bloomington. Contact Kenneth Pimple, Poynter Center for the Study of Ethics and American Institutions, Indiana U., 410 North Park Ave., Bloomington, IN 47405; tel: (812) 855-0261; Fax: (812) 855-3315.

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