ORI Newsletter

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RESEARCH CONFERENCE UPDATE; ABSTRACTS DUE APRIL 30

ORI will convene a conference on "Research on Research Integrity" (RRI) in Bethesda, Maryland, November 18-20, 2000, to discuss emerging challenges and research needs concerning the responsible conduct of research. See "Research Conference Planned," *ORI Newsletter*, 8(1), p. 1; Dec. 1999.

The purpose of this conference is to gather scholars in different disciplines together to share research results, discuss methods, and advise on future research directions. The latter are particularly important since ORI is planning to announce a new RRI research program this year, with funding to begin in 2001.

Over the last 2 decades, research integrity has been the focus of hundreds of policies and thousands of publications. Despite all the attention, surprisingly little research has been done on research integrity itself. Little is known about the best ways to promote integrity, the standards for normal practice, or the extent of misconduct in research. This makes it difficult for ORI--or any one else--to assure that the nation's investment in research is well managed or that appropriate steps are being taken to promote the responsible conduct of research.

As a ***research conference***, the November meeting will focus on raising and exploring evidence to answer key questions about research integrity. What, in practice as well as in principle, does "integrity in research" mean? Is research today being undertaken with appropriate integrity? Is research adversely affected by low or marginal integrity? How are standards for acceptable and unacceptable conduct conveyed? Are current approaches to teaching research ethics effective? How does the social environment in which research is undertaken affect research integrity?

Questions such as this are difficult, but not impossible, to answer. Survey research can help clarify attitudes toward accepted professional standards. Researchers, through their publications and lab notebooks, leave trails of evidence that can be studied to learn more about research practices. The careful study of decisionmaking can help elucidate assumptions and attitudes about the responsible practice of research, as can case studies, if undertaken with the objective of learning rather than instructing. Research is also not an entirely unique activity, and therefore understandings gained through the study of other professions can have relevance to the study of research and research integrity.

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 the following issues are welcomed:

- responsible conduct of research,
- promotion of research integrity,
- prevention of misconduct, and
- handling misconduct allegations.

For further information, see the ORI web site or send an e-mail message to the Conference coordinator, Nicholas Steneck, at: nsteneck@osophs.dhhs.gov.

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SCIENTIFIC ETHICS TRAINING REQUIRED BY CDC/ATSDR

All scientific staff and managers at the Centers for Disease Control and Prevention (CDC) and the Agency for Toxic Substances and Disease Registry (ATSDR) are required to pass a computer-based training program entitled "Scientific Ethics" to be eligible to conduct human subjects research in either agency.

In announcing the mandatory training in February 1999, Jeffrey P. Koplan, M.D., Director, CDC, and Administrator, ATSDR, said, "At the backbone of a strong public health science base is the practice of ethically responsible science . . . To help ensure that our public health research is ethically grounded, a new computer-based training program . . . has been developed . . . Upon completion of this training, CDC and ATSDR investigators will be better able to address ethical issues they encounter as they conduct research to improve the public's health."

All scientific staff and managers are required to complete the training within 6 months of its introduction to their respective CIO (center, institute, office). New staff members are required to complete the training before they conduct research at either agency. By mid-January 2000, the course had been taken by 880 persons and the certifying exam was passed by 667 persons who answered at least 80% of the questions correctly.

The training program contains five modules, each requiring 30-60 minutes to complete. The modules address the agencies' mission in science, the protection of human subjects, scientific integrity, science-related responsibilities, and cases studies. The modules may be taken in any order. At present, the training program must be completed only once, although discussions about the need for continuing education are ongoing.

The program familiarizes scientists and other public health professionals with basic ethical principles, policies, and procedures for the responsible conduct of science. As a self-directed learning opportunity, the program allows users to exit and re-enter at will, choose areas of greatest personal interest, and select levels of complexity through optional exercises.

A passing score on the certifying exam triggers the program to print a personalized certificate to

which a unique identifier is assigned. Currently, a protocol will not be accepted for IRB review within the agencies unless the cover sheet shows the unique identifier for each agency co-investigator listed on the protocol. The unique identifier may be adopted later as a clearance requirement for manuscripts and presentations.

For more information, contact Frances Sanden at Tel: 404-639-7249; Fax: 404-639-7341; E-mail: flr1@cdc.gov.

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PRIVATE FIRM INVESTIGATES MISCONDUCT IN ENGLAND

A private investigative agency has been responding to allegations of scientific misconduct committed by medical practitioners conducting clinical research in the United Kingdom since 1996 in lieu of professional, academic, and scientific organizations and government agencies.

"In Britain we seem to be leaving it to pharmaceutical companies, a private agency, and the media to discover most cases. Cases that emerge from investigations held by medical schools or royal colleges are vanishingly rare," wrote Richard Smith, editor, *British Medical Journal*, in the 1998 Annual Report of the Committee on Publication Ethics.

In December 1997, the Medical Research Council (MRC), the leading research agency on human health in England, issued a policy and procedure for inquiring into allegations of scientific misconduct made against personnel in its intramural program. Institutions receiving MRC grants also are expected to comply with the policy and procedure.

MedicoLegal Investigations, a private agency, was founded by Peter Jay, a retired detective chief inspector for Scotland Yard and former senior investigator for the General Medical Council (GMC) Solicitors, and Frank Wells, M.D., former Director of Medical Affairs for the Association of the British Pharmaceutical Industry. The GMC is the governing body of the medical profession and is empowered to take disciplinary actions.

Jay and Wells have investigated cases involving 52 studies and 16 doctors since 1996. Twelve cases in which prima facie evidence of fraud/misconduct has been found were forwarded to GMC for processing. Two of these cases have been completed, each doctor being found guilty of serious professional misconduct and having his name erased from the Medical Register. Three additional cases involving 25 studies are currently under investigation.

Cases are referred to Jay and Wells primarily by pharmaceutical companies; other sources are universities, health authorities, research ethics committees and individual whistleblowers. Although most of their cases involve clinical research, they have also investigated allegations involving the use of animals and basic laboratory research. Funding is provided mainly by the pharmaceutical industry.

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CONFERENCE PROCEEDINGS AVAILABLE FROM SIGMA XI

Proceedings are available for the workshop on "Ethical Challenges and Practical Solutions for Managers in Research" held last September in Albuquerque under the joint sponsorship of Sigma Xi, The Scientific Research Society, and ORI.

The proceedings contain an executive summary, the presentations of five speakers, a discussion of the new Sigma Xi publication, *The Responsible Researcher*, and a panel discussion on institutional and government interactions. Discussion following each presentation is also included.

The 75-page proceedings are available from Sigma Xi, The Scientific Research Society, P.O. Box 13975, Research Triangle Park, NC 27709. Phone: 919-549-4691 or 800-243-6534. Cost per copy is $6.00.

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E-MAIL ADDRESSES PLEASE!

ORI will switch to the electronic submission of the Annual Report on Possible Research Misconduct beginning with the calendar year 2000 report.

To permit the system to operate effectively, ORI must have the e-mail address of the responsible official at each of the nearly 4,000 institutions that have an active assurance on scientific misconduct. Currently, ORI has such addresses for 80% of those officials.

If you have not included your e-mail address on the 1999 Annual Report form, please send it today to dbrown@osophs.dhhs.gov.

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ORI OFFERS RAPID RESPONSE FOR TECHNICAL ASSISTANCE TO INSTITUTIONS

The Office of Research Integrity (ORI) has created a new program to provide early and direct assistance to institutions responsible for assessing research misconduct allegations. Although this program was originally designed to be helpful to institutions with little or no experience in handling cases, experienced institutions can benefit from ORI's assistance in certain situations.

ORI usually enters into lengthy interactions with the institution only after the institution has filed a report. With its new Rapid Response for Technical Assistance (RRTA) program, ORI provides

assistance to help resolve issues much earlier in the process.

Situations critical to the outcome of a case often present themselves very early in the process and institutions may miss issues which are relevant to PHS concerns, resulting in significant delays.

Examples of assistance available from ORI are:

- providing a rapid review of the institution's procedures to alert officials to potential problem areas;
- assisting in the sequestration, inventory, categorization, and plans for analyses of physical evidence;
- briefing institutional officials and committees on planning, implementation, and potential legal issues in inquiries and investigations;
- advising committee members on investigational goals and techniques;
- alerting officials of PHS issues and providing copies of grant applications and grant reports;
- providing advice on handling computer files;
- providing advice on analytical techniques for image enhancement and statistical analyses of data (e.g., digit analysis);
- handling evidence from human subjects or samples;
- suggesting collateral evidence to confirm or refute claims;
- providing advice on missing records;
- providing advice on forensic expertise and interpreting opinions received;
- assisting in locating outside experts;
- assisting in developing strategies to prevent incomplete and withdrawn admissions;
- identifying the need for notification of other Federal agencies;
- assisting in notification or requests for help from other institutions or organizations;

- sharing ORI experience on difficult legal issues;

- advising on potential whistleblower and confidentiality issues, including referring whistleblower issues promptly.

Some particularly challenging issues are voluminous or missing evidence, multi-center sites, involvement of outside parties, and premature admissions.

ORI staff may provide advice on the telephone, arrange a conference call, or travel on-site. If an institution requests on-site assistance, ORI may provide expertise very quickly with an array of materials and tools to assist the institution tailored to the specific requirements of the case.

ORI's intent for this program is to facilitate high quality and well-documented investigations and help resolve scientific misconduct cases promptly. To discuss any of these possibilities, please call Dr. Alan Price, Acting Director, DRI, or Dr. Barbara Williams, Acting Deputy Director, DRI, at 301-443-5330.

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RESEARCH INTEGRITY AGENDA DUE FOR SCIENTIFIC SOCIETIES

An agenda for action and research on the role and activities of scientific societies in promoting research integrity is expected to be available by August 2000. The agenda will be based on meeting discussions and a survey that the American Association for the Advancement of Science (AAAS) conducted prior to the ORI/AAAS conference that will be held on April 10-11, 2000, in Washington, D.C.

See ORI web site for details at **http://ori.dhhs.gov**.

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ORI SEEKS STUDENT INTERNS AND FACULTY FELLOWS

ORI is seeking interns and fellows from various academic disciplines including English, journalism, communication, science, social science, computer science, information science, psychology, political science, law, sociology, and education to contribute to its research, educational, and outreach efforts. Interns and Fellows will work in a professional environment under the guidance of ORI staff.

Applications for fellowships are invited from postdoctoral candidates and faculty and will be awarded to those interested in devoting 6 months to 1 year on projects or research related to research integrity or misconduct issues in science. Applicants are expected to have a doctorate or a professional postgraduate degree. Faculty interested in spending a sabbatical conducting research are also invited to apply.

Applications for internships are invited from undergraduate or graduate students and range from 3 months to 1 year. ORI is willing to work with your academic institution to provide college/university credit.

ORI developed these two programs to attract members of the scientific community who are willing to use their expertise to further PHS efforts to promote research integrity and prevent scientific misconduct. ORI has sponsored summer fellows and interns in past years, and has been quite pleased with the quality of researchers and students the program has attracted.

Send résumé and letter to Dr. Mary D. Scheetz, ORI. E-mail: mscheetz@osophs.dhhs.gov.

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NOTABLE QUOTE

"An environment that protects and nurtures research integrity is one in which questions can be freely raised. All individuals actually or potentially involved in maintaining scientific integrity need the security of knowing that open-mindedness and fair procedures are ensured." Report of the Commission on Research Integrity, p. 24. Department of Health and Human Services, 1995.

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MICROBIOLOGY ACADEMY OFFERS GUIDANCE ON COLLABORATIVE RESEARCH

Collaborative research may contribute to significant scientific advances that further scientific careers or it can generate conflicts or allegations of scientific misconduct that disrupt research projects and stall career mobility.

Guidance in managing the problematic nature of collaborative research is presented in a report, "Dynamic Issues in Scientific Integrity: Collaborative Research," issued by The American Academy of Microbiology. See complete report on line at [http://www.asmusa.org/acasrc/aca1.htm].

"If the (interdisciplinary) collaboration is to be fruitful," the report states, "the researchers must be prepared to understand the implications that the problems and solutions of one discipline hold for the problems and solutions of the other and to address the problems appropriate to their own discipline."

The need to consider the structure of a collaborative project explicitly is inherent in such arrangements because "when individuals working under different constraints and in different environments collaborate, their expectations and assumptions may be so divergent that it does not occur to the participants to discuss them."

According to the report, the major issues that collaborators should discuss include:

- "agreeing upon the goal of the collaboration, including expectations for outcomes or products;
- establishing and maintaining effective communication and making assumptions as clear as possible;
- defining the expected contributions each participant can make;
- allocating responsibilities;
- estimating an initial time frame for the collaboration;
- articulating the legal obligations of each party, especially with respect to intellectual property requirements and regulatory compliance;
- specifying the process and criteria by which authorship and credit will be assigned; and
- recognizing accountability to research institutions, funding agencies, the profession, and the public."

Discussion of these issues becomes extremely important in interdisciplinary research because "collaborations involving scientists from disparate fields of study can be especially complicated, because the parties may not have common vocabularies, compatible working styles, or shared assumptions about the collaboration."

"When and how information will be released are items that should be addressed and resolved among collaborators because colleagues may have very different expectations about how long information will be kept confidential," the report continues.

Additional issues occur in cross-sector collaborations between academic and industrial scientists according to the report:

- "standard operation procedures in each researcher's environment;
- special obligations of confidentiality and restrictions on release of information that apply to each collaborator;
- understandings about sharing materials and resources;
- authorship and patenting issues;
- concerns unique to graduate students (thesis topics, etc.); and
- whether additional participants figure in the collaboration (e.g., lawyers, patent officers, marketing officers, sponsored research officials, etc.)."

Collaborators must also be prepared to deal with allegations of irregularities and scientific misconduct. The report advises, "If there is an allegation of irregularities in a joint study, scientists should immediately inform all other members of the team and the appropriate authorities in their research institutions and funding agencies. If misconduct is found to have occurred in published research, coauthors have individual and collective responsibility to correct the published record of their work."

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CASE SUMMARY

John L. Ho, M.D., Cornell University (CU): Based on a report dated June 16, 1999, by CU (Report), as well as information obtained by ORI during its oversight review, ORI found that Dr. John Ho, Associate Professor, Department of Medicine and Department of Microbiology at CU Medical College, engaged in scientific misconduct by reporting falsified and fabricated research results in a National Heart, Lung, and Blood Institute, National Institutes of Health, grant application. Specifically, ORI found that Dr. John Ho committed scientific misconduct in connection with the data contained in Figure 10 of the application that purportedly demonstrated cytokine production heterogeneity. Dr. John Ho falsified the text describing Panel 2 of Figure 10 by representing that the interferon values reflected data from 25 donors when values from only 4 donors had been obtained. In addition, he falsified the data entries for Panels 1 and 3 of Figure 10 by representing that approximately 19 and 25 donor samples, respectively, were studied when only 3 and 6 genuine values were obtained, the remaining symbols reflecting fabricated results.

Dr. John Ho has accepted the ORI finding and entered into a Voluntary Exclusion Agreement with ORI in which he has voluntarily agreed to comply with all terms and conditions of the plan for remedial training and scientific and administrative oversight imposed by CU. Pursuant to the Cornell Plan, Dr. John Ho can return to work at CU only after it receives written confirmation from Dr. David Ho that he has successfully completed a program of remedial training of at least 1 year's duration at the Aaron Diamond Foundation (ADF). Under the Cornell Plan, Dr. John Ho will be subject to 2 years of scientific and administrative oversight of his research upon his return to CU from the ADF.

Dr. John Ho agreed to exclude himself from serving in any advisory capacity to PHS or as a consultant for 3 years beginning December 28, 1999. He also agreed 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 to PHS and ORI a plan for supervision of his duties to ensure the scientific integrity of his research contribution; and a certification that the data provided are based on actual experiments or are otherwise legitimately derived, and that the data, procedures, and methodology are accurately reported in the application or research report.

Further, if he obtains a new employer during the 3-year period, he will notify ORI in writing of the name and address of his new employer, and give his new employer a copy of the Agreement and the CU Plan.

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CONSENSUS CONFERENCE IN UK DEFINES MISCONDUCT, GOOD RESEARCH

PRACTICES

A Joint Consensus Conference on Misconduct in Biomedical Research whose participants represented 10 medical councils, professional societies, foundations and industry in the United Kingdom produced a broad definition of research misconduct and enumerated the characteristics of a research environment that promote good research practice.

Research misconduct is "behaviour by a researcher, intentional or not, that falls short of good ethical and scientific standards" according to the consensus statement developed during the conference that was held last October in Edinburgh, Scotland. "The definition should not be read as being restricted to fabrication, falsification of data and plagiarism," the statement continued, "It is intended to cover the whole range of research misconduct."

According to the consensus conference, good research practice is promoted:

- "By affirming a culture through example in which honesty and integrity is expected of every individual and misconduct is not tolerated.
- Through education, training and vigilance from the outset, starting with undergraduate entry and continuing through lifelong learning.
- By ensuring formal training of all supervisors of research.
- By establishing effective and efficient mechanisms for monitoring, auditing and ethical review, appropriate to the design of the study.
- By provision of expert advice, guidance and training for ethics committees.
- By respecting consent and confidentiality.
- By having a framework for and promulgating written guidance on good research practice including publication policy and dissemination of results.
- By designing procedures to ensure that funds are only allocated within a framework for good research practice and when local systems for managing allegations of research misconduct are shown to be established and effective.
- By investigating all allegations of research misconduct firmly, fairly and expeditiously.
- By developing effective and impartial local systems for employers (the universities, NHS, industry, and research institutes) to manage allegations of research misconduct, including reference to disciplinary procedures or referral for criminal investigation.
- By providing access to appropriate support for whistleblowers and researchers."

The consensus conference recommended the establishment of a national panel with public representation to "develop and promote models of good practice for local implementation, provide assistance with the investigation of alleged research misconduct, and collect and collate information on incidents of research misconduct."

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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 ranges from $5,000 to $20,000. ORI intends to hold four to six regional conferences or workshops each year in strategic locations around the country.

June 1, 2000, is the next target date for the receipt of applications. Proposal instructions and an application form are available on ORI's home page (**http://ori.dhhs.gov**), by calling 301-443-5300, or by e-mail to requests@osophs.dhhs.gov.

For questions about the application process, to discuss a possible proposal, or to work with ORI staff in planning an event, contact Dr. Dustira at ORI.

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UPCOMING MEETINGS

The Role of Scientific Societies in Promoting Research Integrity
April 10-11, 2000
Washington, D.C. *See page 4.*

Practicum on Responding to Allegations of Research Misconduct
June 4-5, 2000
St. Charles, IL *See ORI web site.*

Research on Research Integrity
November 18-20, 2000
Bethesda, MD *See page 1.*

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