
University of Arizona Program in Research Integrity Education Monthly Newsletter

January 1, 2004

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A Message from the Director

Thomas P. Davis, Ph.D.

This month's newsletter focuses on *Promoting the Responsible Conduct of Research*. Chris B. Pascal, J.D., Director of the Office of Research Integrity (ORI), Department of Health and Human Services United States Public Health, is the author of the featured article. I trust you will read and appreciate the crucial nature of why this newsletter is distributed campus-wide each month for all employees of our University research community.

We would like to wish everyone a very healthy, prosperous, productive New Year.

Viewpoint:

From the President to the Principal Investigator: Promoting the Responsible Conduct of Research

By Chris B. Pascal, J.D., Director,
Office of Research Integrity

Reprint from the Association of
American Medical Colleges (AAMC) Reporter
November 2003 Issue

For several years, the Office of Research Integrity (ORI) has increasingly turned its resources and staff time to the promotion of research integrity and the responsible conduct of research (RCR). While responding to individual incidents of research misconduct remains a core part of ORI's mission, ORI recognizes the need to take affirmative steps, in collaboration with our research partners, to instill key principles of responsible research into the mission, culture, and curricula of research institutions. This expanded mission was announced by the Department of Health and Human Services (HHS) in 2000. At that time, HHS stated that ORI would oversee and direct the research misconduct and integrity activities of the office, including "education and training in the responsible conduct of

research, activities designed to promote research integrity and prevent misconduct, and research and evaluation programs." U.S. medical schools are the single largest source of biomedical research sponsored with Public Health Service funds. As a result, ORI relies heavily on AAMC's members to provide leadership in this area.

In ORI's view, responsible research practices are critical to the quality of research. Education in these practices is necessary to develop researchers' skills and competencies not only in integrity issues but also in the actual conduct of the research. Inability to distinguish between a legitimate exclusion of data because of problems with the study, such as a failed technique or an overly diluted catalyst, and the convenient exclusion of data to improve the reported results certainly affects the quality of the research and may lead to false, or falsified, results. Asserting improper authorship on a paper undercuts the common currency of a scientific career. Failure to disclose or manage an important conflict of interest may undermine public confidence in a study's results. All of these examples potentially lessen the quality of research, as well as its integrity. For these reasons, ORI recommends that academic institutions make RCR education a priority.

University leaders are uniquely able to promote system-wide RCR education and responsible research practices. They can show their commitment to research integrity by establishing effective, institution-wide RCR education programs, and demonstrating through their personal behavior the highest degree of integrity and intolerance for aberrant behavior in those under them. In this way, they set the moral tone for the institution. Department chairs can also play a significant role in promoting research integrity because RCR education appears to

be most effective when delivered by leaders closest to researchers. Chairs provide more immediate advocacy and feedback to departmental researchers on the importance of integrity issues and, perhaps, provide personal guidance on particular issues. In addition, deans and chairs can play an important role, through advocacy and example, in making sure the medical school and research departments provide formal RCR instruction.

Lab chiefs and principal investigators (PIs) are on the front lines and have the most direct influence on the research practices of other research staff in the lab. Clear guidance by the laboratory chief or PI on what the appropriate norms are for the discipline and how the research staff can navigate these concerns can make a great deal of difference in creating a positive laboratory climate for quality research. Senior investigators can also contribute to responsible research practices by teaching these issues in formal graduate training programs and other RCR courses and by demonstrating such practices in mentoring junior investigators.

To provide support to AAMC member institutions and their individual investigators in promoting RCR, ORI and AAMC have engaged in a number of fruitful collaborations, including co-sponsoring conferences and workshops, developing guidance documents, and addressing other issues related to research integrity. Under our current cooperative agreement with AAMC to fund research integrity activities of scientific and academic societies, 15 projects from 13 societies were funded in the past year. In addition, ORI has a small RCR resource development program to provide funds up to \$25,000 to research institutions to develop curricula materials on RCR topics. In the past two years, ORI has funded 28 projects from 27 different institutions. AAMC institutions and their investigators may apply for these awards.

ORI remains committed to fostering research integrity and RCR education in academic medical centers and relies heavily on institutional leaders to provide the ideas, energy, creativity, and commitment of the research community to make advances in this area viable and long lasting. As institutional leaders, you have an important role in

fostering integrity in biomedical research to the ultimate benefit of your institutions, departments, laboratories, students and colleagues, and the general public. ORI invites your further contributions in this area.

For more information, visit the [Office of Research Integrity Web site](#).

**UNIVERSITY OF ARIZONA RESEARCH
AND SERVICE GROUP (RSSG)
Educational Opportunities**

**UNIVERSITY OF ARIZONA
OFFICE OF THE VICE PRESIDENT FOR RESEARCH
PRESENTS A ONE DAY SEMINAR
DATA INTEGRITY IN ANY LABORATORY
Emphasizing GLP / GCP Compliant Research**

**January 27, 2004
University Marriott Hotel**

PLAN TO ATTEND IF YOU ARE:

- *Considering future FDA or EPA studies*
- *Seeking to learn good practices for good science*

**Required to attend if you are doing FDA/
EPA studies for regulatory submission**

Dr. Belinda Lawler, Quality Assurance Officer for the Veterinary Diagnostic Laboratory, College of Veterinary Medicine, Iowa State University will conduct the seminar. Dr. Lawler has been a consultant to industry, contract testing laboratories, veterinary diagnostic labs and academic institutions. Her areas of expertise include GLP quality assurance, protocol review, contract laboratory inspection and set-up for regulated research trials and study monitoring.

The registration fee (including notebook, continental breakfast, break snacks and lunch) is:

- \$175 Per Individual
- \$125 Per Person (Three or more – same lab)
- \$200 Non University of Arizona personnel.

You may register on line at the VP Research website: <http://portal1.vpr.arizona.edu/register>.

All inquiries concerning the seminar may be directed to Marilyn M. Marshall, Quality Assurance Officer, 621-1469 or via email at marshalm@u.arizona.edu.

**University of Arizona
GRADUATE COURSE ANNOUNCEMENT
Spring Semester 2004**

**Scientific and Ethical Aspects
of Modifying Human Behavior**

Description:

Modern chemistry, biology and medicine in conjunction with the neuroscience revolution are providing tools which can modify basic

human behaviors (learning, addictive, aggressive, feeding, etc.). An examination of the scientific, cultural, religious and ethical issues related to this emerging science will be examined. Basic knowledge of chemistry and biology (two years of each) and of social sciences (psychology, philosophy, religious studies, etc.) are useful prerequisites or consent of instructor.

Units: 3

Place: Old Chem 126 (tentative)

Days & Time: T-Th 2-3:15 (tentative)

Course #: Chem 436/536

The tentative syllabus for this course is below.

Course Title: Scientific and Ethical Aspects of Modifying Human Behavior

Instructor: Victor J. Hruby
Regents Professor of Chemistry

I. Introduction

- A. Religious and Ethical Views of Human Behavior
- B. Scientific/Chemical-Biological Approaches to Human Behavior

II. Religious and Philosophical Views of Behavior

- A. Free Will/Agency
- B. The Dignity of Humans
- C. Religious Strictures of Behavior
- D. Law and Behavior
- E. Cultural Aspects

III. Science and Behavior

- A. Observations of Natural Behavior
- B. Relationships of Non-Human and Human Behavior
- C. Consciousness and Behavior

IV. Drugs and Drug Design of Compounds that Modify Behavior

- A. Ethical Considerations
- B. Scientific Considerations
- C. Science vs. Society - The Ethics of Biological Determinism
- D. Genetic Disease - Human Ethics
- E. Behavior/Sin/Science
- F. Who Will Decide - Science vs. Society
- G. Who Knows - Science vs. Religion
- H. Modifying Behavior – Cultural Dimensions, Society/ Theology/ Philosophy/Science

For more information, please contact Dr. Hruby at 621-6332 or hruby@u.arizona.edu.

ONLINE FELLOWSHIP IN PHYSICIAN ETHICS AND PROFESSIONALISM

Pursue an Ethics Fellowship...
from anywhere in the world.

Study at your own pace. Study in your own home. Learn online.

The Institute for Ethics at the American Medical Association (AMA), together with the [Medical College of Wisconsin's](#) (MCW) Graduate Program in Bioethics, now sponsors an Online Fellowship in Physician Ethics and Professionalism. This program is a unique opportunity for physicians on Institutional Review Boards, Privacy Boards, and ethics committees or for those who want to learn more about applied ethics.

Our online program is current, comprehensive, and convenient, with courses taught by expert faculty from the AMA, MCW, and around the world. Courses can be chosen to fit your specific interests.

Be a pioneer of online medical learning. Call today. [Get more detailed information on the fellowship.](#)

HIPAA VIDEOCONFERENCE TAPE AVAILABLE

The Society for Research Administrators (SRA) International Satellite Video-conference from January 23, 2003 is available on tape. It is three hours long, and contents are:

Part I: General Confidentiality Issues in Sponsored Agreements, and

Part II: Privacy/HIPAA Issues.

To request use of the tape, please contact *Alice Langen*, Director, Research Standards & Compliance, Office of the VP for Research (621-5196) or langena@u.arizona.edu.

Also, after viewing the video, please notify the P.R.I.E. office (Ruth Daniels at 626-6282) to receive a *Certificate of Completion* for your files and grant submissions.

NIH HUMAN PROTECTIONS COURSE AVAILABLE

A free web-based course that will enable physicians, biomedical and behavioral researchers, nurses, and data managers to satisfy the NIH requirements for training about the rights and welfare of human participants in research studies is available at <http://cme.nci.nih.gov>.

The NIH Course on Human Research Protections utilizes interactive modules, case studies, and exercises to cover the following topics: roles and responsibilities of researchers and their key personnel, guiding ethical

principles for research, federal regulations, informed consent, institutional review boards, ongoing protections throughout the course of study, data and safety monitoring, reporting of adverse events, privacy and confidentiality, and historical events that have impacted policy and legislation.

ON-LINE MODULE OR SHORT COURSE IN THE ETHICS OF RESEARCH WITH HUMAN SUBJECTS

The Least of My Brothers

Funded by the [National Institutes of Health](#)
(Grant Number 1 T15 AI07601)

The Least of My Brothers is an on-line module or short course in the ethics of research with human subjects. Content for the module was developed by the Poynter Center for the Study of Ethics and American Institutions at Indiana University-Bloomington (Kenneth D. Pimple, Project Director; Julia A. Pedroni, Co-Director; Victoria Berdon, Graduate Assistant) in collaboration with WisdomTools, Inc., which also provided the technical realization of the course. The module is now ready for use by interested teachers and researchers.

For complete information and to review the module at no charge, you may contact <http://poynter.indiana.edu/sas/lb/>. You may also contact Kara Lochridge at: (812) 856-4968, or klochrid@indiana.edu.

UPCOMING CONFERENCES/WORKSHOPS

March 19-20, 2004

Promoting the Responsible Conduct of Research: What it Means to the Research Enterprise

Winston, NC

Co-sponsors: Winston-Salem State University, Wake Forest University School of Medicine

http://ori.dhhs.gov/html/programs/conf_workshops_2004.asp

March 22, 2004

Does Funding Source Influence Research Integrity?

Baltimore, MD

Co-Sponsor: Society of Toxicology

http://ori.dhhs.gov/html/programs/conf_workshops_2004.asp

April 13-14, 2004

Responsible Conduct of Research in Psychological Science

Washington, DC

Co-Sponsor: American Psychological Association

http://ori.dhhs.gov/html/programs/conf_workshops_2004.asp

April 22-25, 2004

American College of Physicians Annual Session 2004: Ethics and Human Rights Offerings

New Orleans, LA

<http://www.acponline.org/ethics/as2003-04.htm>

May 19-22, 2004

Eleventh Annual Teaching Research Ethics Workshop

Indiana University Bloomington/Poynter Center

<http://poynter.indiana.edu/tre/workshop.shtml>

June 21-22, 2004

The RCR Summit: A National Dialogue on Future Directions of RCR

East Lansing, MI

Co-Sponsor: Michigan State University

http://ori.dhhs.gov/html/programs/conf_workshops_2004.asp

October 14-15, 2004

Research Integrity and Financial Conflicts of Interest in Clinical Research: Legal Issues and Regulatory Requirements

Charlottesville, VA

Co-Sponsor: University of Virginia School of Medicine, Center for Biomedical Ethics

http://ori.dhhs.gov/html/programs/conf_workshops_2004.asp

October 23-27, 2004

RCR Expo

Salt Lake City, UT

Co-Sponsor: SRA International

http://ori.dhhs.gov/html/programs/conf_workshops_2004.asp

November 12-14, 2004

ORI Research Conference on Research Integrity – 2004

San Diego, CA

Co-Sponsor: University of California – San Diego

http://ori.dhhs.gov/html/programs/conf_workshops_2004.asp

December 1-3, 2004

Developing Policy on Institutional Conflict of Interest

Las Vegas, NV

Co-Sponsor: University of Nevada – Las Vegas

http://ori.dhhs.gov/html/programs/conf_workshops_2004.asp

December 8, 2004

Ethics and Responsible Conduct of Research Workshop

Washington, DC

Co-Sponsor: Council of Graduate Schools

http://ori.dhhs.gov/html/programs/conf_workshops_2004.asp

University of Arizona Program in Research Integrity Education staff:

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The P.R.I.E. newsletter is compiled by Ruth Daniels.

Words of Wisdom: "Shelving hard decisions is the least ethical course."

— *Adrian Cadbury*