
University of Arizona Program in Research Integrity Education Monthly Newsletter

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A Message from the Director *Thomas P. Davis, Ph.D.*

The following article addresses concerns of professional societies with the U.S. misconduct rules, and was reprinted from the June 22, 2004 issue of *"The Scientist."* We appreciate the use of this piece in the P.R.I.E. newsletter. You may view the article online at the following web site: <http://www.biomedcentral.com/news/20040622/03>.

US Misconduct Rules Examined **Professional Societies Express** **"Serious Concerns" Over** **Federal Research Regulations** *By Ted Agres*

While supporting most of the [proposed changes](#) to rules governing misconduct in federally sponsored research, representatives of professional research societies and US medical schools are expressing "serious concerns" and "strong objections" to several changes that would, among others, shift the burden of proof in investigations from institutions or the government to individual scientists.

For example, if records were missing, the scientist would have to prove that he or she did not commit misconduct. "We are concerned that the proposals are inconsistent with the presumption of innocence," Robert D. Wells, president of the Federation of American Societies for Experimental Biology (FASEB), wrote in [a letter to the Office Of Research Integrity](#) (ORI) in the Department of Health and Human Services (DHHS), which includes the National Institutes of Health and other research funding agencies. "This undercuts the protections for honest error. The burden of proof should remain the responsibility of ORI and not be shifted to the accused scientist."

In a [letter submitted collectively](#) to the ORI, four other associations representing US research universities, medical schools, and medical societies also objected to the proposed change.

"The institution should have the full burden of proving each and every element of research misconduct, including intent, recklessness, or knowing disregard of applicable standards," wrote the presidents of four organizations—the Association of American Medical Colleges, Association of American Universities, the Council on Governmental Relations, and the National Association of State Universities and Land-Grant Colleges.

DHHS [proposed the changes](#) to Public Health Service (PHS) regulations in April. The changes are intended to update and standardize the definition of misconduct and the process for investigating and adjudicating complaints, replacing regulations originally approved in 1989 and amended several times since. The ORI had been soliciting comments until June 15.

While continuing to define misconduct as "fabrication, falsification, or plagiarism," the rules would extend the government's reach to include scientists engaged in peer review for funding or publication in a scientific journal. But the research and academic organizations objected on grounds that to do so would exceed the scope of PHS authority. "Absent federal funding, those who engage in misconduct need to be punished by the journal or their home institution," wrote FASEB's Wells.

"We are truly grateful that they incorporated some of the key and fundamental pieces of the federal policy," said Carol Blum, an associate director at the Council on Governmental Relations. "But we were concerned that the PHS is extending or claiming jurisdiction or scope that's much broader than what we think is appropriate for a single federal agency," she told *The Scientist*.

The American Society for Microbiology (ASM) joined other organizations in expressing concern over a proposal to replace the three-member research integrity panel with a single administrative law judge to try misconduct cases. "This procedure would constitute a substantial

modification of the current process," ASM President Thomas Shenk wrote in a letter to the ORI. Scientific expertise is frequently needed in these hearings to determine if research misconduct had occurred, he said.

The organizations generally supported other proposals, including extending misconduct policy to research that is conducted under contract, setting a 6-year time limit on filing allegations of research misconduct, and clarifying the role of a [whistleblower](#) as that of a "complainant" who does not participate in the process beyond being a witness.

ORI Director Chris B. Pascal told *The Scientist* he would analyze the comments and present them to DHHS for consideration. Final regulations are expected to be published later this year.

Links for this article:

"Public health service policies on research misconduct," 42 CFR Parts 50 and 93, Federal Register, 20777-20803, April 16, 2004.
<http://a257.g.akamaitech.net/7/257/2422/14mar2001/0800/edocket.access.gpo.gov/2004/pdf/04-8647.pdf>

"RIN#0940-AA04 public health service policies on research misconduct," Letter to Chris B. Pascal from Robert D. Wells, June 10, 2004.
http://www.faseb.org/opa/news/docs/ORI_NPRM_letter_6x9x04.pdf

"RIN#0940-AA04 public health service policies on research misconduct," Letter to Chris B. Pascal from Jordan J. Cohen, Nils Hasselmo, Katharina Phillips, and C. Peter Magrath, June 15, 2004.
<http://www.aamc.org/advocacy/library/research/corrections/2004/061504.pdf>

T. Agres, "NIH misconduct rules reviewed," *The Scientist*, April 26, 2004.
<http://www.biomedcentral.com/news/20040426/04/>

L. DeFrancesco, "Researcher seeks whistleblower protection," *The Scientist*, November 1, 2002.
<http://www.biomedcentral.com/news/20021101/04/>

Good Laboratory Practices

**A Message from Marilyn Marshall
Quality Assurance Officer
University of Arizona**

As Quality Assurance Officer at the University of Arizona, I would like to share the following with the Campus-wide University Research family. The World Health Organization (WHO)

published a draft document in 2001 for Quality Standards in Basic Biomedical Research. The conclusions read... "The need for quality standards in biomedical research at the drug discovery stage has been articulated through several meetings under the auspices of WHO. It is indisputable that selection of successful drug candidates for further development must be based on reliable data obtained by using sound scientific research principles. **The proper organization of resources, writing of study plans and SOPs, education and training, documentation and supervision is the hallmark of universally acceptable, high quality and reliable data.**

The University of Arizona, Office of the Vice President for Research established the position of Quality Assurance Officer (QAO, Marilyn M. Marshall), one year ago. One of the major responsibilities is to assure that all University of Arizona research conducted under Good Laboratory Practices [GLP] will fully comply with 21 CFR 58 [FDA] and 40 CFR 120 [EPA] regulations. However, **basic principles** of GLP can be **applied to all research laboratories**. The WHO draft report is most specific about how **basic biomedical research can and should meet the challenge for reliable data**. You may view the draft document of the *Quality Standards in Basic Biomedical Research Handbook* at the following:



[WHO QstdBasicBiomedRes1.pdf](#)

If you have questions or comments, or for suggestions for "good practices that help achieve good science," please contact me at 621-1469 or via email at marshalm@u.arizona.edu.



News from HIPAA.....

Frequently asked questions on Privacy.....

Question:

What is the difference between "consent" and "authorization" under the HIPAA Privacy Rule?

Answer:

The Privacy Rule permits, but does not require, a covered entity voluntarily to obtain patient consent for uses and disclosures of protected health information for treatment, payment, and health operations. Covered entities that do so have complete discretion to design a process that best suits their needs.

By contrast, an “authorization” is required by the Privacy Rule for uses and disclosures of protected health information not otherwise allowed by the Rule. Where the Privacy Rule requires patient authorization, voluntary consent is not sufficient to permit a use or disclosure of protected health information unless it also satisfies the requirements of a valid authorization. An authorization is a detailed document that gives covered entities permission to use protected health information for specified purposes, which are generally other than treatment, payment, or health care operations, or to disclose protected health care information to be used and disclosed, the person authorized to make the use of disclosure, the person to whom the covered entity may make the disclosure, expiration date, and, in some cases, the purpose for which the information may be used or disclosed. With limited exceptions, covered entities may not condition treatment or coverage on the individual providing an authorization.

**EXHIBIT SPACE FREE AT RCR
(Responsible Conduct of Research)
EXPO 2004**

The RCR Expo 2004 will be held October 25th and 26th in conjunction with the Society of Research Administrators (SRA) International 2004 Annual Meeting in Salt Lake City, Utah. The Expo will be held in the Grand America Hotel, situated in a high-traffic space within the conference area. With over 1,200 top research administrators attending the SRA meeting, this event will be an excellent opportunity for institutes and businesses to showcase their RCR educational materials, videos, training tools, web sites, and/or programs.

Exhibit space is free to the 25 exhibitors selected to participate. If you are interested in becoming an exhibitor contact Loc Nguyen-Khoa (LNguyen-Khoa@osophs.dhhs.gov), and include your name, institution, and description of your product or program.

For more information about the Society of Research Administrators International 2004 Annual Meeting, visit <http://www.srainternational.org>.

**INTRO RCR TEXT MAILED;
REVISION UNDERWAY**

Single copies of the ORI Introduction to the Responsible Conduct of Research were mailed in January 2004 to the responsible institutional official at the 4,000 institutions that have a misconduct policy assurance on file with ORI.

The publication is currently being revised because some illustrations, case studies, and the ISBN number were dropped, and format and style errors were made during the production process of the initial printing. Publication content, however, is accurate. A PDF version of the missing material is available on the ORI web site at <http://ori.hhs.gov>.

The revised publication is expected to be available for purchase from the Government Printing Office this Spring. Please see <http://bookstore.gpo.gov>. It will be posted on the ORI web site later this year for on-line reading or downloading.

**CONFERENCE, WORKSHOP,
AND MEETING PROPOSALS
DUE OCTOBER 1, 2004**

ORI is seeking proposals from institutions, scientific societies, and professional associations that wish to collaborate with ORI in developing conferences, workshops, symposia, colloquiums, seminars, and annual meeting sessions that address the responsible conduct of research, research integrity, or research misconduct. ORI will provide up to \$20,000, depending on the event proposed.

The next target date for receipt of application is October 1, 2004. Proposal instructions and an application form are available on the ORI web site at <http://ori.dhhs.gov/html/programs/conf-workshops.asp>.

Please submit your proposal electronically to cfassi@osophs.dhhs.gov. Dr. Carolyn Fassi may be reached at 301-443-5300.

UA Human Subjects Program

≧Highlights≦

**Human Subjects Protection Program
Assurances***

What is an assurance?

An assurance is a type of contract obtained by an institution like the University of Arizona with a federal governmental agency. This contract establishes the standards for research conduct and in reality is the commitment of the institution to comply with the federal regulations governing human subjects research. In addition, the institution certifies that the research has been reviewed and approved by an Institutional Review Board.

Why does the University of Arizona need an assurance?

In order for an institution to receive federal funding for research involving human subjects, the institution must have on file an approved assurance with the Office of Human Research Protections (OHRP).

What happens if we have a federally funded project and the work includes another site that does not have an assurance?

If the other site is not “engaged” in the research project and they do not have an assurance, they do not need to have their own assurance. If they are “engaged,” they will need to contact the Human Subjects Protection Program for assistance in acquiring an assurance from OHRP.

How do I know if the other site is “engaged?”

OHRP has written guidance on whether a site is considered “engaged” or not. Generally sites become “engaged” when their employees:

- Intervene or interact with living individuals for research purposes;
- Obtain or access individually identifiable information for research purposes;
- Release individually identifiable private information, or permit investigators to obtain individually identifiable private information, without subjects’ explicit written permission.

The University of Arizona has a Federal-Wide Assurance (FWA) with OHRP formalizing our commitment to protect human subjects and we are held responsible for all research involving human subjects covered under this assurance. Therefore, it is essential that the University of Arizona informs the research community about and understands the commitments made in our FWA.

*Cohen, J. M. (2002). OHRP Federal-Wide Assurance. In R. Amdur & E. Bankert (Eds.), Institutional review board: Management and function (pp. 313-315. Sudbury, MA: Jones and Bartlett.

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

**National Center for Ethics in Health Care
Veterans Health Administration
Integrated Ethics Program (IEP) Project**

The IEP project is a major Center initiative that targets key institutional processes to improve the effectiveness of ethics programs at the facility level. The project aims to inspire systems change by applying principles of continuous quality improvement to better integrate clinical and organizational ethics “from the bedside to the boardroom.”

The IEP project provides facility teams with educational resources they need to achieve four goals:

- create an environment that supports ethical practices;
- improve the quality of ethics case consultation;
- systematically address recurring ethical problems;
- use evaluation tools to foster improvement.

These resources include training materials, video and online courses, monthly process improvement tasks, a virtual community (IEP listserve), other web-based tools, and technical support.

More information on the IEP will be coming soon and may be viewed at the following web site: (http://www1.va.gov/VHAETHICS/education_1.cfm).

**OPPORTUNITIES FOR
ON-LINE ETHICS TRAINING**

**Ethical Guidelines for
Gifts to Physicians from Industry**
Free educational modules now available

The AMA’s national initiative on *The Communication of Ethical Guidelines for Gifts to Physicians from Industry* is now offering four free online modules for CME credit.

Each educational module is available in two formats:

- Online self-study for CME credit; and
- Downloadable resources educators can use to build one-hour learning experiences.

The four free modules include:

1. ***Overview of Ethical, Professional, and Legal Issues for Physicians’ Relationships with Industry***
[Online self-study](#) [Downloadable resources for educators](#)
2. ***Physicians’ Expectations of Industry and Sales Personnel***
[Online self-study](#) [Downloadable resources for educators](#)
3. ***Professionalism and Gifts to Physicians from Industry***
[Online self-study](#) [Downloadable resources for educators](#)
4. ***American Medical Association Ethical Guidelines on Gifts to Physicians from Industry***
[Online self-study](#) [Downloadable resources for educators](#)

The educational modules will help satisfy Accreditation Council for Graduate Medical Education (ACGME) requirements for education on professionalism and industry professional relationships as well as similar requirements by the American Board of Medical Specialties.

Physicians can earn AMA PRA category 1 credit for the online self-study version. Local sites can issue CME credit for the classroom version of the downloadable educational modules.

These modules are for educational purposes only, and do not constitute legal advice. Laws that are referred to in these modules are subject to change and federal and state agencies are constantly updating their interpretive guidance concerning the pharmaceutical industry and its relationship with physicians. For further information, please consult with qualified legal counsel to ensure compliance with appropriate legal requirements.

For more information visit the following site:
<http://www.ama-assn.org/ama/pub/category/8405.html>.

Online Fellowship in Physician Ethics and Professionalism

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. [You may get more detailed information on the fellowship.](#)

NIH Human Protections Course Available

A free web-based course that will enable physicians, 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. More information can be accessed at the following web site:
<http://cme.nci.nih.gov>.

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. For complete information please contact the following web site:
<http://poynter.indiana.edu/sas/lb/>. You may also contact Kara Lochridge at: (812) 856-4968, or klochrid@indiana.edu.

Reminder

HIPAA VIDEOCONFERENCE TAPE AVAILABLE

The Society for Research Administrators (SRA) International Satellite Videoconference 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.

UPCOMING CONFERENCES/WORKSHOPS

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 2-3, 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

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

Words of Wisdom:

“If I understood too clearly what I was doing, where I was going, then I probably wasn't working on anything very interesting.”

— *Peter A. Carruthers (physicist) UofA*