
University of Arizona Program in Research Integrity Education Monthly Newsletter

A Federally Mandated Compliance Education Program

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New Personnel in the Office of Research Compliance & Policy

It is with great pleasure that we introduce you to the new *Training Coordinator* for the Office of Research Compliance & Policy, Tina Tarin. Below, Tina tells us a bit about herself.

Greetings to all of you! My name is Tina Tarin and I am the new Training Coordinator for the Office of Research Compliance & Policy. I have been on the university campus for 10 years as a student and an employee. Most recently I worked for the Campus Health Department as a Violence Prevention Specialist with the Oasis Program. I have experience in program development and training, and I look forward to working with all of you as we advocate towards excellence in compliance and responsible conduct of research. Please feel free to stop by and visit or call if you have any questions. Thank you!

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Study Finds Mismatch between Observing and Reporting Suspected Research Misconduct

A study of suspected research misconduct conducted by the Gallup organization in collaboration with ORI suggests there is a large discrepancy between the number of incidents of suspected research misconduct observed by researchers and the number of such incidents reported by institutions to ORI. At press time, the study findings were scheduled to be published in *Nature* on June 19, 2008, as a commentary by Sandra Titus, Director of Intramural Research, ORI; James Wells, former Study Director, Gallup; and Lawrence Rhoades, former Director, Division of Education and Integrity, ORI. The final report is on the ORI web site at <http://ori.hhs.gov/publications/studies.shtml>

This finding is based on the responses from 2,212 NIH-supported principal investigators (a 51-percent response rate) in 2,212 academic departments from

605 institutions in the United States. One hundred and sixty-four investigators (7.4 percent) indicated that they had observed or had direct evidence of researchers in their own department committing one or more incidents of suspected research misconduct (total incidents 201) in the past three academic years (2002-2004).

Titus said, "Two hundred and one cases observed by 2,200 respondents over three years is essentially three cases per 100 persons per year. Assuming that non-responders (roughly half our sample) did not witness any misconduct, we reduced the ratio to 1.5 cases per 100 persons. Applying that ratio to the 155,000 people supported by NIH extramural research grants in 2007 suggests that there could be 2,325 possible research misconduct observations per year. If 60% of these cases were reported to institutional officials as in our survey, approximately 1,350 would have been reported whereas 1,000 would likely be unreported to officials."

Chris Pascal, Director of ORI, added that institutions receiving PHS research support are required to report the number of allegations received in their Annual Report on Possible Research Misconduct to ORI. From 1993-2006, institutions reported receipt of 1,592 allegations (114 per year). This gives further evidence that there is institutional underreporting.

The commentary poses the question: How can there only be 24 institutional reports submitted to ORI if there are so many observations of suspected misconduct?

There are several ways to account for the disconnect: the researcher may fear he or she will look foolish if the allegation is not substantiated or assumes someone else will or should report the suspected misconduct; he or she may not want to be distracted from his or her research by becoming involved in an inquiry or investigation, or may fear possible retaliation. Institutional leaders may worry about the public image of their institution; they might fire the accused so that the problem goes away or not act in order to protect the revenue stream the accused generates; they may avoid doing an investigation primarily to save time, money, and effort.

The study responded to criticisms of earlier studies of research misconduct by using a specific definition of research misconduct (the federal definition), stipulating a time period in which the suspected misconduct occurred (three academic years), limiting the respondents to one per department to prevent duplicate reporting, using a large sample (4,298), covering a wide range of disciplines instead of a few, and focusing on suspected research misconduct rather than actual research misconduct because most research misconduct allegations are not substantiated.

The study also has limitations including the following: (1) one observer per department; (2) principal investigators primarily in the biomedical, behavioral, and life sciences as the only respondents; and (3) no data on the funding involved in the suspected research.

Six recommendations are made to institutions for fostering a culture of integrity: (1) adopt a zero tolerance for research misconduct, (2) protect whistleblowers, (3) implement a clear system for reporting alleged research misconduct, (4) increase mentors' awareness of their roles in establishing and maintaining research rules and minimizing opportunities to commit research misconduct, (5) develop continuing mechanisms for reviewing and evaluating the research and training environments, and (6) promote role models of ethical behavior.

The above article was taken from the June 2008 Office of Research Integrity Newsletter, Volume 16, No. 3 – <http://ori.hhs.gov>

**UNIVERSITY HANDBOOK FOR
APPOINTED PERSONNEL
THE UNIVERSITY OF ARIZONA**

You will find research related policies (2.13) in the University Handbook for Appointed Personnel, and the revised version of *The Policy and Procedure for investigations of misconduct in scholarly, creative, and research activities at the University of Arizona*, (2.13.09) approved by the Faculty Senate on April 2, 2007, at the following: <http://uhap.web.arizona.edu/chap2.html#2.13>

**UNIVERSITY OF ARIZONA
Office for Responsible
Conduct of Research**

The Research Compliance Program exists to facilitate the adherence of University research programs to the federally required compliance regulations and to act as a conduit for information that cuts across individual compliance areas in order to foster integrity in the scholarship and research carried out at the University.

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**UNIVERSITY OF ARIZONA
RESEARCH SUPPORT SERVICES GROUP
(RSSG)**



Radiation Control



[Online Registration](#) is now available for the "18th National Radon Training Conference", which is September 14-17, 2008, at Tuscany Suites and Casino, Las Vegas, Nevada.

Source: The Conference of Radiation Control Program Directors, Inc. (CRCPD) <http://www.crcpd.org/>



Good Laboratory Practices (GLP)

Save the following date for the Society of Quality Assurance 25th Annual Meeting, April 19-24 2009 - San Diego, CA.

More information is available from QAO....

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News from HIPAA.....

Safeguarding Protected Health Information

Are you using your personal computer for University of Arizona research related activities?

Are you removing hard copies of documentation that contains the names, addresses, phone numbers, medical record numbers, dates of birth, diagnosis or other research related data from the University of Arizona?

Are you storing information related to a research study in your home office?

Are you keeping study related data on a flash drive that you take with you?

If you answer yes to any of these questions, you need to take appropriate measures to ensure that the information is protected from inadvertent disclosure.

If it is necessary to remove data to an offsite location, it is your responsibility to protect the information. Computers and flash drives must be password protected and if possible, encrypted.

Hard copy documents should be contained in a locked briefcase or other secure file. As a security measure, enclose the documents in an envelope marked "Confidential, to be opened by addressee only." Address the envelope to the receiving party or to yourself.

Most of all, consider the location where the information will be stored when it is taken offsite from the University of Arizona. Is it secure?

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University of Arizona – Animal Care



Quality Care for Research Animals

UAC is initiating a seminar series for UAC – and the research community is invited to attend, as well. On August 29th, 2008, Dr. Andrew Comrie, Associate Vice President for Research will be speaking regarding the future of biomedical research at the UA. The seminar is from 1-2 PM in room 5403 of the AHSC.

The seminar schedule will be posted soon to the UAC web site.

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HUMAN SUBJECTS PROTECTION PROGRAM

≡Highlights≡

Continuing Review – How Can We Make It Work?

The Institutional Review Board (IRB) responsible for the oversight of a research project involving human subjects is charged with con-

ducting "continuing review of research at intervals appropriate to the degree of risk, but no less than once per year . . ." [45 CFR 46.109(e)] The Office of Human Research Protections (OHRP) states that, "Continuing review of research must be substantive and meaningful" and that the continuing review process is intended to maintain the same level of review as was performed at initial review/approval of the project. [Guidance on Continuing Review, issued 7/11/02, rev. 1/15/07]

The **Continuing Review Guidelines, Form and Report template** are provided to assist Investigators, HSPP Staff, and the IRB in understanding what has happened over the life of a project and during the current reporting period. These documents are only as valuable as the information provided by the Investigator. The IRB may request additional information from sources other than the Investigator (e.g., subjects, sponsors, research staff, consultants, observation of the consent process by a third party) to verify the conduct or status of the study.

Several sections of the Continuing Review Report have generated a number of questions from both researchers and Committee members, sometimes delaying project re-approval. The suggestions below target the areas that have most often caused delays.

Sections 4 and 8 (summaries of local and non-local unanticipated problems involving risk to subjects or others):

- ❖ **Event descriptions:** Sufficient information must be provided for an understanding of the seriousness of the event and its impact on the subject.
- ❖ **Causality:** For non-local events, differences of opinion between the reporting Principal Investigator (PI), the sponsor, or the local PI, should be included in the causality column of the report (attribute each assessment as necessary).
- ❖ **Impact on Consent Instruments:** If the local PI has determined that there is no impact on the Consent Form, the specific rationale must be provided.
 - Examples may include: the event is directly related to drug but all local subjects have completed treatment; it is the first report of this event and causality is unclear; while the event may be related to study drug, concomitant drugs or underlying condition may have contributed to the event.

Section 13 (Investigator's review of relevant recent literature):

- ❖ Providing the **search engine** and **search terms** used to complete this section best demonstrates that the scope of the search was consistent with assessing whether any changes to the study procedures or documents are needed.
- ❖ A **summary** of the Investigator's review of the literature review results must be included. Include an overview of the published information and its impact on the local research endeavor, study participants and study documentation.
- ❖ **For behavioral studies:** Most often the scope of the successful literature review will focus on the methodology being employed to collect, store, and analyze data. Often the greatest risks to subjects involve breach of confidentiality or emotional distress. Methods for securing data (electronic as well as hard copy) are rapidly changing and should be addressed in the Investigator's assessment of the results of the literature review.
- ❖ **For biomedical studies:** The scope of the successful literature review will focus not only on procedures and the specific drug or device being studied, but also on the **drug/device class or sub-class** and whether the **standard of care** for a particular patient population has changed.

Expiration of project approval: If project approval expires and the discontinuation of the project would negatively impact currently enrolled subjects, a letter must be submitted to HSPP which lists each subject, procedures that should be continued under the protocol, AND the reason that continuation is **in the best interest of each subject**. Approval of the IRB Chair or Committee must be obtained prior to continuation of study procedures when project approval has expired.

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Institutional Biosafety Committee



**Laboratory Biosecurity:
Build Security into
Good Laboratory Practices**

On-line Course

This training describes key principles for securing biological agents in research laboratories

and biomedical facilities where loss, theft, release or intentional misuse of the agent might have significant public health or economic consequences. This training defines the term bio-security, delineates differences and similarities between biosafety and biosecurity, and discusses components of a laboratory biosecurity program.

Successful biosecurity programs should have full support from all levels of management, be site-specific, and be based on an understanding of facility assets and needs. Identifying which agents and infrastructure need to be protected is an individual organization's management decision. Biosecurity programs should apply corresponding security measures by using a graded approach to reduce risk to an acceptable level.

Source:

http://www.cdc.gov/OD/OHS/biosecurity_training/page1024.html

Upcoming Conferences/Workshops

September 14-17, 2008

18th National Radon Training Conference
Theme: Growing Radon Leaders
<http://www.crcpd.org/2008RnMtg.asp>

September 17, 2008

[A Research Integrity Education Conference for the Federal Nursing Community](#)
Bethesda, MD
Co-Sponsor: Uniformed Services University

October 2-3, 2008

Fostering International Research Collaborations
Co-Sponsor: University of Minnesota
Minneapolis, MN

October 19-14, 2008

IRPA 12 – Buenos Aires, Argentina
October 19-24, 2008
13th Annual Congress of the International Radiation Protection Agency (IRPA)
<http://www.irpa12.org.ar/index.php>

May 15-17, 2009

Fifth Biennial Research Conference on Research Integrity
Niagara Falls, NY
Co-Sponsor: University of Minnesota

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Words of Wisdom:

"All labor that uplifts humanity has dignity and importance and should be undertaken with pains-taking excellence."

~ Martin Luther King, Jr.