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# University of Arizona Program in Research Integrity Education Monthly Newsletter

*A Federally Mandated Compliance Education Program*

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December 1, 2007

Volume 7, No. 12

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This month the Program in Research Integrity Education (P.R.I.E.) newsletter focuses on the Responsible Conduct of Research (RCR) topic of *Authorship*. The following information was excerpted from the journal, *Science*, and may be found at: <http://www.thescientist.com/article/home/53743/>.

We trust you will determine this information to be helpful and informative.

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## AUTHORSHIP

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### Bringing Order to Authorship How to resolve authorship disputes – and avoid them altogether

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From *TheScientist.com*  
Volume 21 | Issue 11 | Page 91

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In August, the members of a US government interdisciplinary research group gathered behind closed doors to discuss a controversy that had been brewing in the lab. The group – which comprised chemists, biologists, toxicologists, and physicists – was discussing an author dispute that had arisen over a soon-to-be-published manuscript.



One of the life scientists in the lab (who asked to remain anonymous for fear of retribution) had directed a smaller project within his discipline, mentoring a postdoc throughout the conception and execution of the experiments, as well as compiling the paper, which the postdoc wrote. When this researcher returned from vacation and saw the final version of the paper, the postdoc was correctly listed as first author. However, the lab

director - not a life scientist - was listed as senior corresponding author. The postdoc's mentor was listed in the middle of the author list.

Over the course of the closed-door meeting, other life scientists in the lab argued on behalf of the researcher that since the lab director had no expertise in the paper's subject material, the first author's mentor should be the senior author. Voices were raised, tensions were high, but at the end of the meeting, nothing had changed, and the lab director remained the senior author. "It was as bad as anything I've ever seen and been a part of," says the postdoc's mentor. "Ultimately, it was take it or leave it."

Authorship is the currency of a scientist's career and research experience. Anita Sostek, divisional director at NIH's Center for Scientific Review, says a researcher's track record is extremely important to reviewers who decide to whom to award grants. "If you see somebody in the field a long time and they're always in the middle, it looks like they're not in the same leadership position as [people who are consistently] first or last authors."

In August and September we asked our online readers to share their stories of authorship nightmares, as well as their ideas for improving the system. In more than 60 comments, many readers noted that authorship disputes can be traumatic, and that an overhaul of the whole system would be a welcomed change. Although many labs have a streamlined system of authorship, adverse situations can arise for researchers, especially those just starting their scientific careers. So what can be done about it?

### More not always merrier

As collaborations become more common, deciding who gets credit for what can get complicated, causing turf battles over who really deserves prominent positions on author lists.

Frank Jenkins, a pathologist at the University of Pittsburgh, normally has no problems in his lab when it comes to authorship; the student or postdoc who does most of the work is the first author of the subsequent paper and Jenkins is the last.

Recently, however, he ran into problems while collaborating with another lab on a project. After someone in Jenkins' lab had collected most of the data, the collaborating principal investigator (PI) said that his postdoc should be the first author. "It's only when you start having collaborations with other labs that things can get dicey," says Jenkins. While the paper has yet to be published, the PIs agreed to have their postdocs alternate as first authors on subsequent papers from the same collaboration.

Authorship practice varies by field, making interdisciplinary collaborations and the subsequent author lists more complicated. In physics papers, senior and corresponding authors are listed at the beginning of the author list, whereas, in chemistry, the senior author is sometimes the first author on a paper, even if a postdoc completed the bulk of the work. In the life sciences, first listing is usually given to the researcher who did most of the work, both physical and intellectual, and last billing goes to the mentor or person who guided the project and whose grant money paid for the project - the PI. "This new movement toward group authorship ... can get very confusing," says Katrina Kelner, deputy editor for life sciences at *Science* magazine.

"If you see somebody in the field a long time and they're always in the middle, it looks like they're not in the same leadership position as [people who are consistently] first or last authors." – Anita Sostek

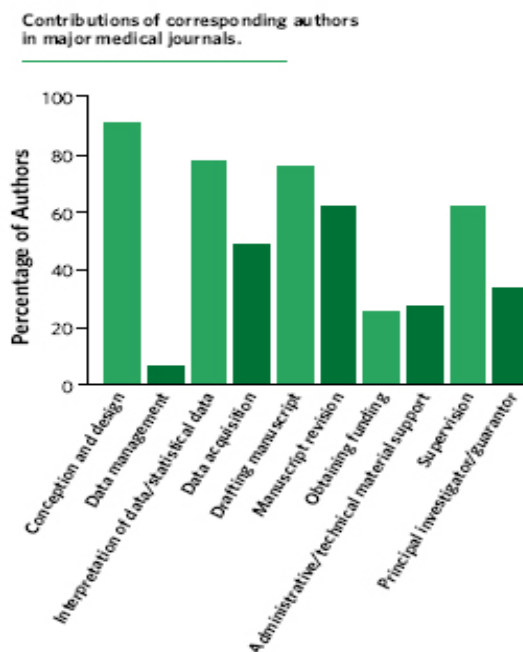
To ward off problems, Elaine Larson, director of the Center for Interdisciplinary Research on Antimicrobial Resistance at Columbia University, establishes a "communication plan" before or just as the writing of a paper begins. The group first decides the discipline and journal to which it will gear its manuscript; that decision helps to determine the first author and the order in which the other authors will be listed. For example, if the paper will be published in a chemistry journal, the senior chemist in the group will be first author. Once the first author is established, that person takes the role of identifying who else should be an author and in what order.

### Potential solutions

According to the guidelines of the International Committee of Medical Journal Editors (ICMJE), analyzing and interpreting data are the primary requirements for authorship, whereas acquiring funding, collection of data, and general supervision of research alone do not merit authorship. This method of deciding authorship is common,

according to Harvey Markovitch, chair of the Committee of Publication Ethics (COPE).

While some journals present their own guidelines and most go by ICMJE guidelines, there are no accepted standards about order of authors on a list, not to mention who should be on the list in the first place. Now, largely the only repercussion of authorship disagreements is rejection of a manuscript.



Source: *Journal of Investigative Medicine*, May 2007

When a consortium of authors submits a paper, Kelner and her colleagues at *Science* spend a great deal of time determining who is a bona fide author; even though *Science* provides its authors with guidelines on what constitutes authorship, individual authors often don't meet its requirements. In general, *Science* follows the ICMJE guidelines and checks that all authors on the list have made a substantial contribution to content of the paper. Soon *Science* will require that all authors of a paper (not just the corresponding author) register online and outline what they've contributed. *Science* would then approve the paper before it can be submitted.

The *Annals of Internal Medicine* requires each author to sign a document indicating that they've been involved in either the conception of the project, or analysis or interpretation of the data. By signing, they indicate they've been truthful and that every author has received due credit. If one author declines to sign the form, *Annals* returns the manuscript to the authors until they can work out their dispute.

Many online commenters suggested that absolute transparency in authorship is the only way to clear up disputes. Why not follow Hollywood's practice for bestowing credit on projects? Following each name in the top author list would be "dish washer," "provided funding," "collected samples," etc., depending on what each researcher contributed. Other commenters suggested that attaching an official document to each paper submission - which made them legally responsible for the paper and their own contributions - might prompt researchers to be more candid about their contributions, or lack thereof.

Some researchers and journals are handling the problem of authorship head-on, but invariably, problems will surface that don't have simple solutions. While the government investigators' closed-door meeting involving the postdoc, the postdoc's mentor, and the lab director seems to have resolved itself unfairly, the mentor (now in the middle of the author list) decided not to pursue the matter further. "Honestly, it would be career suicide to do something like that," he says.

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

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**Good Laboratory Practices (GLP)**

**Announcement of a Course: Laboratory  
Regulatory and Compliance Issues....  
Spring Semester PLS 4/595D  
2:00-3:15 PM Tues/Thurs**



This course, now in its fourth year, is designed and intended to provide students, lab managers, clinical studies coordinators, and faculty with an understanding of the scope and complexities of the regulatory and safety issues applicable to a wide range of environments.

Topics include, but are not limited to, GLP, GCP, GMP regulations, SOP's Human Subjects, Re-search Integrity, Animal Welfare, Chemical and Biological Safety, HIPAA, Data Validation, Com-puter Based Lab Management Systems, and Per-sonnel Management.

Marilyn M. Marshall, SpM, Quality Assurance Officer  
Office of the Vice President for Research  
621-1469 (p), 621-1429 (f)



**News from HIPAA.....**

**HIPAA Authorization**

Regulation dictates the necessary information that must be disclosed in a HIPAA Authorization form. The following is a check list to assist you in always having HIPAA compliant forms:

**Regulatory Components:**

- + Identity of Party Authorizing Disclosure
- + Subject's Signature
- + Date of Signature
- + Personal Representative (if required)
- + Identity of Party/Parties Receiving Disclosure
- + Identity of Person(s) Who Provide PHI
- + Description of the Information to be Disclosed
- + Purpose of Disclosure
- + Expiration Date of Authorization
- + Right to Revoke
- + Treatment not conditioned on Signing of Authorization
- + Redisclosure Provisions
- + Publication Provisions
- + Copy of Signed Form to Subject

Jeniece Poole, Privacy Officer  
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[jpoole@email.arizona.edu](mailto:jpoole@email.arizona.edu)



**Radiation Control**



**Radioactive Material Security Rules**

The goal of the Radioactive Material (RAM) Security Rules is to restrict access to and prevent unauthorized use or removal of RAM. RAM security is the responsibility of all individuals who work in any radiation use area as a part of their employment. Such personnel include radiation workers, non-radiation workers, or others who frequent the radiation use lab, such as University support personnel.

**General Security Requirements**

Security of radioactive material that is not specifically accepted by these rules or by Committee approval, whether in sealed or unsealed form, must be accomplished by at least one of the following methods listed below.

- Keeping radioactive material under the constant “line of sight” surveillance by a radiation worker
  - A radiation worker providing line of sight surveillance of RAM inventory must belong to the Approval to which the RAM belongs
- Locking the RAM use or storage area/laboratory
- Placing RAM in locked storage, such as a cabinet or refrigerator with an installed lock or external lock and hasp within an approved RAM use or storage area/laboratory

Physical security must be complemented by challenging unauthorized entry into the lab. Visitors must be questioned as to their purpose for being in a radiation lab.

### ***Increased Security Requirements***

In addition to enacting one of the general security requirement methods listed above, the following RAM must be additionally secured in locked storage, such as a cabinet or refrigerator with an installed lock or external lock and hasp.

- All unsealed RAM belonging to an Approval that is authorized for unsealed radioactive material possession that exceeds 100 mCi of H-3 or a total of 50 mCi of all other radionuclides combined.
- All sealed sources not specifically described in the *Exceptions* section below.

### ***Exceptions***

Certain radioactive materials may be warranted by the Radiation Control Office (RCO) to require little or no security or control. Normal labeling and posting of rooms, areas and equipment usually offers sufficient hazard communication for these types of radioactive materials. These materials include:

- Naturally occurring or depleted radioactive material (uranium and thorium compounds),
- Quantities of material exempt from licensing (licensing status is determined by the RCO prior to ordering),
- Properly labeled RAM use equipment, such as pipettes, sinks, glassware, absorbents, tongs, etc.,
- Generally Licensed material (e.g. tritium exit signs, commercial smoke detectors, liquid scintillation counter internal and external check sources, and anti-static sources in balances),
- Sealed sources mounted in stationary equipment (security requirements for these sources must be specifically exempted by the RCO),
- Check sources attached to portable survey instruments,

- Properly labeled radioactive material, to include waste, that when summed for any designated RAM use area, from all approvals, is not in excess of 40  $\mu$ Ci. Typical waste and material in this category include analytical samples, dry waste, cell and tissue cultures, autoradiography and electrophoresis plates, animal related waste as well as liquid samples or wastes such as radioactive scintillation vials or chromatography cocktails.
  - Liquid RAM must either be placed in secondary containment or upon suitable absorbents to limit the spread of contamination. Security exemptions other than those listed above must be granted by the appropriate Radiation Safety Committee. The RCO must be notified prior to ordering any radioactive material to determine the licensing status of the material and associated security requirements.

### ***Facilities and equipment management by University employees or outside contractors***

UA Facilities Management (FM) personnel are trained by the RCO to report abnormal conditions in radioactive material labs. Although recommended, FM personnel are not required to be accompanied when working in a radioactive materials lab. Visitors and outside contractors shall be under constant supervision by a radiation worker when in radiation use areas. Such personnel do not need to be supervised if all RAM has been secured and if all RAM work areas are found to be free of contamination via a comprehensive, documented survey.

### ***Loss or Theft of Radioactive Material***

Any known or suspected loss or theft of radioactive material shall be reported immediately to the Radiation Control Office. The RCO may be reached via University of Arizona Police Department outside of normal business hours.

### ***Enforcement***

RCO staff members shall take every opportunity to verify compliance with these RAM security rules. Rooms found unoccupied with unsecured material will be in violation of the RAM security rules. Willful violation or repeated violation of the security rules will be reported to the appropriate radiation safety committee and may result in suspension or revocation of the Approval to possess and use radioactive materials.

Source:

<http://www.radcon.arizona.edu/RAM%20Security%20Rules.pdf>

## Institutional Biosafety Committee



### Bulletin



#### Frequently Asked Questions....

**Question:** Where can I get additional IBC assistance?

**Answer:** The administrative offices of the Institutional Biosafety Committee are located at 1230 North Park/Suite 205.

Margaret Stalker, Program Coordinator, Senior, is available to answer procedural questions on MUA submissions and review processes. Her phone number is 621-3441.

Mark Grushka, Manager of Biosafety and Biosecurity, can provide information on specific research biosafety questions. His phone number is 621-5279.

Margaret and Mark are the primary contacts for Proposal Routing Sheet signatures; however, any IBC Committee member can be contacted in the event Margaret or Mark are unavailable. In addition, IBC Staff can also provide the NIH Guidelines and the CDC-NIH Handbooks on Biosafety in Microbiological and Biomedical Laboratories (BMBL).

If you have questions regarding University of Arizona IBC forms you can contact the IBC staff at 621-3441 or 621-5279. Office hours are Monday through Friday 8a-5p.

The IBC FAX number is 621-6159.

## University of Arizona – Animal Care



### Quality Care for Research Animals

#### **Pathology Services Offers Hematology and Blood Chemistry Testing For Research Projects by Jessie Loganbill, MT, RLATg**

The UAC Pathology Services Laboratory offers hematology and blood chemistry testing on laboratory animals to support research projects. To ensure consistency, accuracy, and confidence in the results, we follow standard operating procedures, use equipment that has been calibrated with validated reagents, and perform routine, documented maintenance on the equipment used. In addition, all laboratory results are reviewed by the laboratory director (Dr. David Besselsen, DVM, PhD, DACLAM, DACVP) and/or laboratory supervisor prior to reporting. Jessie Logan-

bill, a research specialist principal and certified medical technologist, supervises and oversees the daily activities of the laboratory. She is assisted by two research technicians, Chris Brownlee and Justin Towne, both of whom have B.S. degrees in the biological sciences.

For hematology, complete blood counts (CBC's) are performed using the HEMAVET Multispecies Hematology Analyzer by Drew Scientific. It is a quantitative, automated multispecies hematology analyzer for *in-vitro* diagnostic use. It can determine a variety of hematological parameters on multiple species including dog, cattle, mouse, rat, primate, and sheep. Other species with anuclear red blood cells may also be tested. Blood smears are made and examined for cell morphology. A CBC requires about 80 ul unclotted, EDTA anticoagulated blood. Clotted or heparinized blood is not acceptable and cannot be tested. For optimum results samples should be submitted to the lab the same day they are obtained. If this is not possible samples may be refrigerated or kept at room temperature for up to 24 hours. Never place whole blood samples on ice or in the freezer. This destroys the blood cells and makes analysis impossible. The price for a CBC is \$15.00 each.

In-house clinical chemistries are performed using the Endocheck Plus Chemistry Analyzer by Hemagen Diagnostics, Inc. It is a compact, micro-processor controlled, photometer used for analyzing components of animal serum or plasma. Testing includes liver, kidney, and multi-organ function, as well as other clinical chemistries. Reagents for each test come prepackaged and ready to use as individual tests or profiles. Sample requirements are serum or heparinized plasma. The volume needed varies depending on which test or profile is performed. Prices range from \$3.50 for an individual test to \$30 for a comprehensive panel (12 tests).

Investigators planning to submit samples for analysis must schedule the submission with the laboratory at least 2 days in advance for hematology submissions, at least 1 week in advance for serum chemistry submissions (due to the need to order reagents), and preferably as soon as the submission date for the samples is known.

Results are generally reported within 24 to 48 hours after submission and are distributed via email or campus mail. Detailed blood collection information, test availability, and required sample volume is available on our website at: <http://www.uac.arizona.edu/invest/pathservices.shtml>.

You may also call the laboratory directly for assistance at 626-7661 or email us at [uacpath@mail.arizona.edu](mailto:uacpath@mail.arizona.edu). Please visit our website or call the laboratory for more information.

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## HUMAN SUBJECTS PROTECTION PROGRAM

### ≧Highlights≦

#### Revisions to an Approved Study\*

Last month's article addressed **minor revisions** to an already approved study or consent form. This month's article will review **major revisions** to an already approved study or consent form.

As a reminder, following the initial review and approval of a study, the need for a change to the consenting documents or study often becomes apparent to the Principal Investigator, study personnel, or study sponsor. This need may arise after the study has started when recruitment, enrollment, or procedural issues are identified.

Review of changes to the study or consent form is required under federal regulations. The Food and Drug Administration (FDA) regulations state that the IRB shall follow written procedures "for ensuring prompt reporting to the IRB of changes in research activity and for ensuring that changes in approved research during the period for which IRB approval has already been given may not be initiated without IRB review and approval except where necessary to eliminate apparent immediate hazards to the human subjects".<sup>[Sec.108(a)(3)]</sup> The Department of Health and Human Services (DHHS) regulations have similar wording.<sup>[Sec.102(b)(4)(iii)]</sup>

Revisions are usually one of three types:

- Informational revisions
- Minor revisions
- **Major revisions**

Major revisions involve changes to the study that may impact the participants and may significantly increase the risks to participants. Examples include change in the investigational drug or inclusion of an additional study arm. A form is used to submit the request. The **Request for Amendment Form** to document the changes can be found at <http://www.irb.arizona.edu/system/files/Amendment+Form.doc> on the HSPP website. The completed Request for Amendment Form should have attached copies of documents that are affected by the change (e.g.,

consent form, recruitment material, questionnaire).

It is important for researchers to understand that federal regulations require IRB approval prior to **major revisions** made to a study or consent document. Understanding the rationale behind the requirement is the first step towards better protection of study participants and compliance with federal regulations.

\*Bye, S. (2002). Revisions of an Approved Protocol. In R. J. Amdur and E. A. Bankert (Eds.), Institutional Review Board Management and Function (pp. 289-291). Sudbury, MA: Jones and Bartlett.

Rebecca Dahl, Ph.D.

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### OPPORTUNITIES FOR ON-LINE ETHICS TRAINING

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#### Data Management Video Available on ORI Web Site

<http://ori.dhhs.gov/>

A video-based resource for data management is now available on the ORI website. This product contains 10 video vignettes that address data sharing, technology transfer, data storage, data falsification, data ownership, sharing of resources, and collaboration.

These vignettes address several gray areas. When is it appropriate to share data? Are you allowed to share the research protocol with other universities? Under what circumstances is it appropriate to remove lab books from the lab?

After viewing each 10 second video, the learners are presented with a question to see what action they would take in response to the situation. Consequences for each action are given to allow users immediate feedback about their decision making process.

The product was created by Syracuse University with funding from the ORI RCR Resource Development Program.

#### Contemporary Science, Values and Animal Subjects in Research

<http://ori.hhs.gov/education/products/ncstate/index.htm>

This site, developed at North Carolina State University, is an Office of Research Integrity (ORI) sponsored project. It is intended to be both a learning tutorial and a clearing house. Ethics and the use of animals in research is an enormous topic: this site is an introduction both to the central issues and the information re-sources available. The format is the same throughout each

Tutorial; an essay with numerous links to further websites. Think of the essay as an extended annotated bibliography, with the written text suggesting connections between the online materials. Study Questions found at the end of each Tutorial or section of a Tutorial in Part I: Ethics and Part III: Mini-Lessons are intended either for self study or for group or class/lab use at your institution.

### Online Research Ethics Course

This course was developed through the Practical Ethics Center at the University of Montana with Office of Research Integrity support during the 2002-03 academic year. Six course sections include: *Session One* (Ethical Issues in Research); *Session Two* (Interpersonal Responsibility); *Session Three* (Institutional Responsibility); *Session Four* (Professional Responsibility); *Session Five* (Animals in Research); *Session Six* (Human Participation in Research).

The following web address contains more information regarding this valuable online course: [http://ori.hhs.gov/education/products/montana\\_round1/research\\_ethics.html](http://ori.hhs.gov/education/products/montana_round1/research_ethics.html)

### Ethical Guidelines for Gifts to Physicians from Industry

*Free educational modules now available*

The American Medical Association's (AMA) 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.

These 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 (ABMS).

For more information, you may visit the following internet web address: <http://www.ama-assn.org/ama/pub/category/8405.html>.

### 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 online module (or short course) in the ethics of research with human subjects. For more details and course information,

please access the following internet web address: <http://poynter.indiana.edu/sas/lb/>, or you may also contact Kara Lochridge at: (812) 856-4968, or [klochrid@indiana.edu](mailto:klochrid@indiana.edu).

### Online Study Guide University of New Hampshire Responsible Conduct of Research

[http://ori.hhs.gov/education/products/unh\\_round1/www.unh.edu/rcr/index-2.html](http://ori.hhs.gov/education/products/unh_round1/www.unh.edu/rcr/index-2.html)

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## Upcoming Conferences/Workshops

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**January 14-18, 2008**

[Course Fees and Registration](#) ➤

*Principles and Practices of Biosafety*

Sponsored by: American Biological Safety Association  
Sheraton Austin Hotel, Austin, TX

**February 8, 2008**

<http://www.hhs.gov/ohrp/education/conference.html#upcoming>

OHRP – Research Community Forum

*Thinking Outside the Box: Addressing the Challenges of*

*Human Subject Research in 2008*

Sacramento, CA

**April 4, 2008**

<http://www.hhs.gov/ohrp/education/conference.html#upcoming>

OHRP – Research Community Forum

*From the Past to the Future: Protecting Research Subjects as Times Change*

New Orleans, LA

**April 17-19, 2008**

[First Biennial ORI Conference on Responsible Conduct of Research \(RCR\) Education, Instruction, and Training](#)

Co-Sponsor: Washington University

St. Louis, MO

**May 13-16, 2008**

Fourteenth Annual *Teaching Research Ethics Workshop*

Indiana Memorial Union, Bloomington, Indiana

See [Teaching Research Ethics Overview](#) for the agenda.

For registration and fee information, see:

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

**October 2-3, 2008**

Fostering International Research Collaborations

Co-Sponsor: University of Minnesota

Minneapolis, MN

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### University of Arizona Program in Research Integrity Education staff:

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*Words of Wisdom:*

*“Perhaps the best Yuletide  
decoration is being wreathed in  
smiles.”*

— Unknown