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# University of Arizona Program in Research Integrity Education Monthly Newsletter

## *A Federally Mandated Compliance Education Program*

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November 1, 2005

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

This month we highlight *Criteria for Authorship* as defined by the International Committee of Medical Journal Editors (ICMJE). To learn more about the Committee and ICMJE guidelines, you may access their website at <http://www.icmje.org/>.

### **About the International Committee of Medical Journal Editors (ICMJE)**

A small group of editors of general medical journals met informally in Vancouver, British Columbia, in 1978 to establish guidelines for the format of manuscripts submitted to their journals. The group became known as the Vancouver Group. Its requirements for manuscripts, including formats for bibliographic references developed by the National Library of Medicine, were first published in 1979. The Vancouver Group expanded and evolved into the International Committee of Medical Journal Editors (ICMJE), which meets annually. The ICMJE gradually has broadened its concerns to include ethical principles related to publication in biomedical journals.

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### **Criteria for Authorship**

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#### **Ethical Considerations in the Conduct and Reporting of Research Authorship and Contributorship**

*Byline Authors*

An "author" is generally considered to be someone who has made substantive intellectual contributions to a published study, and biomedical authorship continues to have important academic, social, and financial implications. (1) In the past, readers were rarely provided with information about contributions to studies from those listed as authors and in acknowledgments. (2) Some journals now request and publish information about the contributions of each person named as having participated in a submitted study, at least for original research. Editors are strongly encouraged to develop and implement a contributorship policy, as well as a policy on identifying who is responsible for the integrity of the work as a whole.

While contributorship and guarantorship policies obviously remove much of the ambiguity surrounding contributions, it leaves unresolved the question of the quantity and quality of contribution that qualify for authorship. The International Committee of Medical Journal Editors (ICMJE) has recommended the following criteria for authorship; these criteria are still appropriate for those journals that distinguish authors from other contributors.

- Authorship credit should be based on 1) substantial contributions to conception and design, or acquisition of data, or analysis and interpretation of data; 2) drafting the article or revising it critically for important intellectual content; and 3) final approval of the version to be published. Authors should meet conditions 1, 2, and 3.
- When a large, multi-center group has conducted the work, the group should identify the individuals who accept direct responsibility for the manuscript (3). These individuals should fully meet the criteria for authorship defined above and editors will ask these individuals to complete journal-specific author and conflict of interest disclosure forms. When submitting a group author manuscript, the corresponding author should clearly indicate the preferred citation and should clearly identify all individual authors as well as the group name. Journals will generally list other members of the group in the acknowledgements. The National Library of Medicine indexes the group name and the names of individuals the group has identified as being directly responsible for the manuscript.
- Acquisition of funding, collection of data, or general supervision of the research group, alone, does not justify authorship.
- All persons designated as authors should qualify for authorship, and all those who qualify should be listed.
- Each author should have participated sufficiently in the work to take public responsibility for appropriate portions of the content.

Some journals now also request that one or more authors, referred to as “guarantors,” be identified as the persons who take responsibility for the integrity of the work as a whole, from inception to published article, and publish that information.

Increasingly, authorship of multi-center trials is attributed to a group. All members of the group who are named as authors should fully meet the above criteria for authorship.

The order of authorship on the byline should be a joint decision of the co-authors. Authors should be prepared to explain the order in which authors are listed.

#### ***Contributors Listed in Acknowledgments***

All contributors who do not meet the criteria for authorship should be listed in an acknowledgments section. Examples of those who might be acknowledged include a person who provided purely technical help, writing assistance, or a department chair who provided only general support. Financial and material support should also be acknowledged.

Groups of persons who have contributed materially to the paper but whose contributions do not justify authorship may be listed under a heading such as “clinical investigators” or “participating investigators,” and their function or contribution should be described — for example, “served as scientific advisors,” “critically reviewed the study proposal,” “collected data,” or “provided and cared for study patients.”

Because readers may infer their endorsement of the data and conclusions, all persons must give written permission to be acknowledged.

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### **Two New Reports Related To Research Misconduct**

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Two new reports have been posted on the ORI home page that contain data related to research misconduct that could be useful in generating discussions in lab meetings, seminars, symposia, workshops or courses. The data may also be useful in generating research ideas.

#### ***New Institutional Research Misconduct Activity: 1992-2001***

This report is based on the Annual Report on Possible Research Misconduct submitted by over 4,000 institutions and organizations worldwide that conducted research supported by the Public Health Service. Research misconduct activity is defined as the receipt of an allegation or the conduct of an inquiry and/or investigation into an allegation. Data are presented on the number of institutions

that have reported research misconduct activity, the frequency of such reports, the funding rank of the reporting institutions and the number of misconduct findings made.

#### ***ORI Closed Investigations into Misconduct Allegations Involving Research Supported by the Public Health Service: 1994-2003***

This report is based on 259 research misconduct investigations closed by ORI during a ten-year period. Data are presented on the academic rank, degree and gender of whistleblowers and respondents, the types of misconduct alleged, the institutional setting of investigations, the outcome of investigations, and the administrative actions imposed.

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### **VA Publishes Notice of Research Misconduct Policy**

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In the September 1, 2005 *Federal Register*, the Department of Veterans Affairs (VA) published a notice of the May 2005 action finalizing its Research Misconduct Policy (70 FR 52156). Issued as VAH Handbook 1058.2, the policy brings the VA into line with the December 2000 Office of Science and Technology Policy (OSTP) Federal Policy. As the Council on Government Relations (COGR) reported to the membership in June, the new VA policy describes universities and academic medical centers as external entities that may have concurrent or joint jurisdiction over the project and pledges to coordinate its response to allegations with the non-VA entities. The VA outlines five factors to be used in the “informal negotiations” that determine the lead organization. These factors include identifying the primary funding source; the entity that approved the underlying research; the primary employer; the facilities used in the research; and deciding which entity has the resources and personnel best suited to conduct the inquiry and investigation. This determination is important because the VA’s policy covers all employees including “without compensation” employees — often members of the staff of academic medical centers.

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### **UNIVERSITY OF ARIZONA RESEARCH AND SERVICE GROUP (RSSG)**

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#### **Course Offering in Regulatory Issues and Compliance**

This course was designed for students interested in laboratory management as a career, current laboratory managers, current researchers, or for

students who plan on academic, governmental or industry careers.

### ***PLS/PLP 495/595D — Regulatory Issues in Laboratory Management***

The primary objective of this course is to educate researchers on the myriad compliance issues involved in running today's laboratories, whether in the academic research or commercial arena. The course is intended to provide students, lab managers and faculty with an understanding of the scope and complexities of the regulatory and safety issues applicable to a wide range of environments.

Topics will include, but are not limited to, GLP, GMP and GCP regulations, SOPs, Human Subjects, Research Integrity, Animal Welfare, Chemical, and Biological Safety, DEA regulations, Computer Based Lab Management Systems, Data Validation and Personnel Management.

Professionals from each discipline provide theoretical grounding and practical applications for each of the areas of expertise.

### ***PLS 595d — Regulatory Issues in Laboratory Management***

Three credits, available Spring, 2006

Tues, Thurs 2:00-3:15 (1st Class in Marley 341H)

For more information, please see the course syllabus at <http://cals.arizona.edu/classes/pls595d/> or you may contact Lindy Brigham (626-8307, [lbrigham@ag.arizona.edu](mailto:lbrigham@ag.arizona.edu)).

## **HUMAN SUBJECT PROTECTION PROGRAM**

### **≡Highlights≡**

#### **Consent and Research With Cognitively Impaired Adult Participants\***

##### **What is cognitive impairment?**

Adults who are cognitively impaired may have a variety of conditions that affect their ability to reason and make competent decisions. The University of Arizona Human Subjects Protection Program Policy IV.D defines cognitive impairment as having a psychiatric disorder (e.g., psychosis, neurosis, personality or behavior disorder), an organic impairment (e.g., dementia) or a developmental disorder (e.g., mental retardation) that affects cognitive or emotional functions to the extent that capacity for judgment and reasoning is significantly diminished. Others, including individuals under the influence of or dependent on drugs or alcohol, those suffering from degenerative diseases affecting the brain, terminally ill patients,

and individuals with severely disabling physical handicaps, may also be compromised in their ability to make decisions that are in their best interest.

##### **Why is including cognitively impaired individuals a concern?**

The ethical principal of respect (informed consent) is important when considering whether to include adults with cognitive impairment as potential participants. One concern when mildly impaired adults are included in research studies is that these individuals may be more vulnerable to coercion. Those with more severe cognitive impairment may lack the capacity to provide informed consent.

##### **What are important things to consider for those participants who lack the capacity to consent?**

In instances where the participant is cognitively impaired, the Investigator must think about provisions for soliciting the assent of the participant when the subject is capable of providing assent as prescribed in 45 CFR 46, Subpart A. Otherwise, the Investigator may consider requesting a waiver of assent for those participants who are incapable of providing assent.

For research participants who are cognitively impaired, permission must be obtained from the individual's legally authorized representative, unless a waiver of informed consent has been granted by the IRB. Permission for the cognitively impaired individual to participate must be documented by the legally authorized representative's signature and date on the informed consent document.

##### **Who qualifies as a legally authorized representative?**

A legally authorized representative means an individual or judicial or other body authorized under Arizona law to consent on behalf of a prospective subject to participate in the procedure(s) involved in the research .

In the State of Arizona, for an adult subject who lacks the capacity to consent, the legally authorized representative is any of the following individuals when the research **involves** health care procedures:

- ✚ The participant's health care agent;
- ✚ The participant's legal guardian or conservator;
- ✚ Any of the individuals listed below in order of preference (as allowed by Arizona State law).

If the research **does not involve** health care procedures, the participant's legal guardian or conservator or any individual approved in consulta-

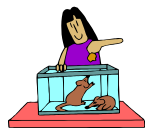
tion with the IRB Committee and the General Counsel's Office on a case-by-case basis may serve in this capacity. The State of Arizona also makes provisions for the following individuals to serve as legally authorized representatives:

- + Spouse (unless legally separated) – if the spouse declines to provide consent, then the next individual cannot be asked to give consent;
- + Adult child – if more than one child, consent from a majority of the children who are reasonably available;
- + Parent;
- + Domestic partner;
- + Sibling;
- + Close friend.

Research with individuals who are cognitively impaired is possible. However, these individuals are considered vulnerable and additional protection such as consent by the legally authorized representative may be required. Legally authorized representatives need to be informed about the study, and its implications for the participant. In addition, the legally authorized representative must understand his/her role in providing initial and ongoing consent and the ability to withdraw the participant when continued participation is no longer consistent with the participant's known wishes or is no longer in the best interest of the participant.

\*Delano, S. (2002). Research involving adults with decisional impairment. In R. J. Amdur and E. A. Bankert (Eds.), Institutional Review Board Management and Function (pp. 389-393). Sudbury, MA: Jones and Bartlett.

### University of Arizona – Animal Care Quality Care for Research Animals



## Animal Scoop

University Animal Care has a LISTSERV called "Animal Scoop." We invite you to [join](#) our LISTSERV for the purpose of quick notification of things that are of vital concern to your research, and to discuss issues that affect everyone involved in animal research here at the University.

University Animal Care is committed to provide the best service possible to our customers. We have had several in-house committee meetings to explore such things as improved communication, training and service to our investigators. One outcome of this committee is the "Alert" system wherein we can notify you of diseases, power outages or other emergency situations in a matter of minutes.

However, in the past, this had involved a lot of paperwork and the campus mail system, and was not adequate for the fastest notification in all cases.

We decided to utilize the University E-mail system which we feel is the best course wherein we could quickly send messages to many people through a LISTSERV. Thus, "Animal Scoop" was born.

We originally decided to set this list up as a quick medium to get word of facility emergencies to our investigators. We then expanded the idea to include the ability to discuss issues and share information. Among the topics that may be discussed are: technical information, resources, animal diseases, facility issues, etc.

Click here to join Animal Scoop 



## News from HIPAA.....

**What does the term "Review Preparatory to Research" refer to with respect to in the HIPAA regulations?**



"Review preparatory to research" is the mechanism by which an investigator may access Public Health Information (PHI) for the purpose of designing a research study, generating a research hypothesis, or to assess the feasibility of conducting a study (e.g. to see if there are enough potential subjects, etc.). In order to review PHI preparatory to research, the PI must be able to establish that:

- PHI is necessary for the research
- PHI will not be used for any other purpose
- PHI will not be removed from the premises
- PHI is not recorded in any format

The physician of record, as indicated in the patient's medical record, may contact the prospective research participant on behalf of the PI to inform him/her of a research study that may be of interest.



## Good Laboratory Practices (GLP)

### Don't fool with the FDA....

The following is an excerpt from *FDA News* . . .

#### ***"United States Marshals Seize Violative Infusion Pumps Made by Baxter Healthcare Corporation"***

At the request of the U.S. Food and Drug Administration (FDA), on October 12, 2005, the

U.S. District Court for the Northern District of Illinois issued a warrant for seizure of three types of infusion pumps manufactured by Baxter Healthcare Corporation because FDA inspections revealed that the firm has continually failed to follow medical device manufacturing requirements.

The seized products are: SYNDEO PCA Syringe Pumps, Colleague Volumetric Infusion Pumps, and Colleague CX Volumetric Infusion Pumps. Baxter has distributed these products worldwide. Infusion pumps are electronic devices intended to control delivery of solutions and medications to patients. Pump shutdown could result in serious injuries or death to critically ill patients who depend on continuous infusion medications and/or life-sustaining medications.

“This case demonstrates that the FDA will take the necessary steps to protect America's public health,” said Margaret O’K. Glavin, FDA Associate Commissioner for Regulatory Affairs. “Today's notification shows our commitment to informing the public about important safety issues . . .”

All University of Arizona units planning to submit manufactured products or laboratory and research grant data to the FDA or EPA should contact Marilyn M. Marshall, Quality Assurance Officer prior to submission to help assure full compliance with federal regulation governing Good Laboratory Practices, Good Manufacturing Practices and Good Clinical Practices. Public health and the University’s research integrity are at stake.

Marilyn M. Marshall  
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[marshalm@u.arizona.edu](mailto:marshalm@u.arizona.edu)



## **Radiation Control** **UMC/Clinical**

The Radiation Control Office provides comprehensive radiation safety services to University Medical Center (UMC). These services provide for the protection of health and safety of all persons who may be exposed to radiation on UMC premises, and to ensure that all applicable regulations are followed.

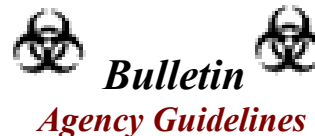
[Physicians \(working with radioactive materials or diagnostic x-rays\)](#)

[Diagnostic Radiology \(Technologist and Support Staff\)](#)

[Nuclear Medicine \(Technologist and Support Staff\)](#)  
[Radiation Oncology \(Technologist and Support Staff\)](#)  
[Perioperative Services \(Nurses and Support Staff\)](#)  
[Nursing 3NE](#)

If you are not sure of what you need please contact us at 626-6850 or [rcohelp@u.arizona.edu](mailto:rcohelp@u.arizona.edu)

## **Institutional Biosafety Committee**



The following links connect you to the most current version of the NIH Recombinant DNA Guidelines from the CDC Biosafety in Microbiological and Biomedical Laboratories Handbook.

You should refer to both the NIH Guidelines and the CDC Handbook to complete the University of Arizona IBC Memorandum of Understanding and Agreement Form. The USDA Guidelines may be useful in completing MUA's for research pertaining to plants and plant pathogens.

- [NIH Recombinant DNA Guidelines](#)
- [CDC Handbook](#)
- [USDA Guidelines](#)

If you are conducting field work or may potentially handle wild rodents, please review the [CDC recommendations for Hantavirus](#)

If you are using microbial pathogens go to the [Health Canada](#) homepage to obtain a Material Data Safety Sheet for the pathogen you use.

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*The P.R.I.E. newsletter is researched  
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### *Words of Wisdom:*

*“No legacy is so rich as honesty.”*

*William Shakespeare (1564 - 1616),*

*"All's Well that Ends Well",*

*Act 3, Scene 5*