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# University of Arizona Program in Research Integrity Education Monthly Newsletter

*A Federally Mandated Compliance Education Program*

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This month the Program in Research Integrity Education (P.R.I.E.) newsletter focuses on the topic of, "Authorship." Each month we are continuing to highlight one of the nine core instructional areas in the Responsible Conduct of Research (RCR).

The information presented below is authored by Michael Kalichman and P. D. Magnus and may be viewed at the *RCR Education Resources* web site, which is: <http://rcrec.org/r/index.php>.

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## Responsible Conduct of Research (RCR)

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P.D. Magnus and Michael Kalichman,  
September 2002

### Authorship

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#### Background

Attribution of credit and responsibility is central to the structure of science. Authorship is the most visible form of credit, but credit in publications is also given in the form of acknowledgments or appropriate reference citations. Because credit for publication is so important to disputes and allegations of research misconduct, it is worth considering why credit is more than a matter of personal gratification. The framework of science depends in part on the ability of institutions, policy makers, and the public to identify who is responsible for the work and its interpretation. Funding agencies consider past success, as evidenced by authorship, in the allocation of research grants. Research institutions often use authorship as evidence of creative contributions that warrant promotion. Scientists themselves may use credit for past work as a mechanism to attract both new trainees and willing collaborators. Finally, in an era of increasing emphasis on commercialization, authorship and credit help to define intellectual property rights. These, and other reasons, explain both scientists' desire for the credit of authorship, but also why assigning authorship involves a certain weight of responsibility.

#### Rules and regulations

Other than copyright law and federal definitions of research misconduct, nearly all aspects of authorship and publication are covered only by guidelines and unspoken custom.

#### Principles

Authorship might be justified by significant contributions to the ideas that preceded the work, the design of the studies, execution of the study, analysis of the data, or drafting the manuscript. Yet some questions about who deserves authorship are not easily answered. Can simply performing the data collection ever be enough to justify authorship? Should every author be able to defend all aspects of a manuscript, or only some? Should all authors bear the same responsibility if any part of a manuscript is later found to depend on falsified or fabricated data? Because of questions like these, it is useful to explicate some core principles as a basis approaching these issues.

#### The credit of authorship is accompanied by responsibility for the work being published.

If the work is later found to be irresponsible or misrepresented, then all authors will have their name associated with it. Thus, all authors share responsibility for assuring that the studies and findings have been represented truthfully.

#### Authorship is an important sign to others in the scientific community.

Institutions, funding agencies, and researchers assess scientists in light of their publications. Thus, to include someone among the list of authors for a publication is to send a message to those groups.

#### The criteria for authorship should apply equally to everyone involved in the work.

If a researcher who gathered the raw data is included as an author, for instance, then all researchers who did comparable work should be included. Because authorship is a matter of public credit and responsibility, everyone who meets the accepted criteria for authorship should be included as authors.

#### Guidelines

##### Authorship criteria

Methods of assigning authorship vary greatly in academia, even within the same institution or discipline. While it is widely agreed that authorship should be based on a substantial contribution, reasonable people can differ considerably over the definitions of 'contribution' and 'substantial.' Some

emphasize the importance of having done the work as a criterion, or the only criterion, for authorship. Others put more emphasis on ideas, experimental design, and data interpretation. In some research groups, decisions about authorship are made solely at the discretion of the principal investigator, while in others decisions are made collectively by all who have had a significant role in the project. Some investigators expect authorship in return for providing access to key equipment, samples of an unusual reagent or cell line, or assistance with statistical methods or experimental design. Others argue that these contributions warrant only an acknowledgment not authorship.

Although criteria for authorship vary, an author ought at least minimally to have:

- made a substantial and new contribution to the research.  
*How new do substantial contributions need to be? They must add to the original scientific content of the research, to be sure, but how and to what degree is open to debate. Every scientist should give some consideration to this question of what counts as a new contribution.*
- agreed to take responsibility for at least some of the content of the manuscript, including a review of the relevant raw data.
- read and agreed to the manuscript before publication.
- agreed to be named as an author.

*One definition of authorship accepted by many medical journals is that adopted by the International Committee of Medical Journal Editors (ICMJE) [1997]. Under this definition, someone is an author if and only if they have done all of the following:*

1. *made substantial contributions to conception and design, or acquisition of data, or analysis and interpretation of data;*
2. *drafted the article or revised it critically for important intellectual content;*
3. *approved of the final version to be published.*

*The ICMJE definition specifically excludes authorship for anyone whose contributions consist solely of arranging funding, collecting data, or supervising the research group. Although this definition is a valuable guideline because of its specificity, it is at odds both with common practice and with other views of authorship (Yank and Rennie, 1999).*

## **Transparency of authorship criteria**

Because criteria for authorship are not universally accepted, authorship is a frequent cause of disputes among scientists. The solution to such misunderstandings is for research groups and collaborators to be clear about the criteria and plans for authorship. For individual scientists, it is important to: discuss plans and criteria for authorship during the planning of any collaboration and to continue such discussion as the research project evolves. For the community of scientists, transparency could be accomplished by publishing the way in which individual authors contributed to the work.

*Such a model was proposed by an Authorship Task Force of the Council of Biology Editors (now the Council of Science Editors). In brief, the 'contributorship' model is less restrictive than the ICMJE model in defining authorship, but the contributions of each of the authors are to be identified to the journal and published with the manuscript (Horton and Smith, 1996; Smith, 1997; Rennie et al., 2000; Authorship Task Force, 2000). Several medical journals now use this model.*

## **Acknowledgments**

Many elements essential for a publication should be credited, but do not warrant authorship. People who provide facilities or resources, for instance, should be credited in the *Acknowledgments* section. Authors have the ethical responsibility to acknowledge all of those who made the research and manuscript possible. Because agreement with the contents of a manuscript might be inferred, it is good practice, and sometimes required, that anyone who is acknowledged has given his or her permission to be listed.

## **Resources**

### **Works cited**

- Authorship Task Force (2000): Is it time to update the tradition of authorship in scientific publications? Council of Science Editors (formerly Council of Biology Editors) <http://www.councilscienceeditors.org/services/ATF.shtml>
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#### Further resources

- Caelleigh AS (1991): Credit and responsibility in authorship. *Academic Medicine* 66: 676-677.
- Council of Science Editors (2000): Selected references on authorship. [http://www.councilscienceeditors.org/services\\_ATFReferences.shtml](http://www.councilscienceeditors.org/services_ATFReferences.shtml)
- Goodman NW (1994): Survey of fulfillment of criteria for authorship in published medical research. *British Medical Journal* 309: 1482.
- Hoey, John (2000): Who wrote this paper anyway?: The new Vancouver Group statement refines the definition of authorship. *Canadian Medical Association Journal* 163(6): 716-717. An interesting discussion of the way in which the ICMJE's guidelines would have affected the priority dispute surrounding the discovery of insulin.
- Huth EJ (1986): Guidelines on authorship of medical papers. *Annals of Internal Medicine* 104: 269-274.
- Relman AS (1990): Publishing biomedical research: Roles and responsibilities. *Hastings Cent Rep* 20:23-27.

Next month the featured RCR topic will be:  
"Peer Review"

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

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**HUMAN SUBJECTS  
PROTECTION PROGRAM**

≡ Highlights ≡

#### Research-Related Injuries\*

Current regulations do not mandate compensation for research-related injuries. Under the regulations, research institutions are only responsible for explaining whether or not medical treatments are available and/or whether compensation will be provided to the research participant in the event the individual is injured as part of his or her study part-

icipation [45 CFR 46.116(a)(6); 21CFR 56.116(a)(6)].

In addition to the regulations, the Nuremberg Code makes provision to address research related injury and states "the experiment should be so conducted as to avoid all unnecessary physical and mental suffering." The Belmont Report states that the ethical principles of **beneficence** and **justice** inform researchers of the responsibility to address the issue of research related injury and provides the argument for adequate compensation for human participants. The Office for Human Research Protection (OHRP) IRB Guidebook specifically states that "considerations (of the principles of **beneficence** and **justice**) may be appropriate to avoid the injustice that arises from social, racial, sexual, and cultural biases institutionalized in society."

The principle of **beneficence** requires that researchers take into account the well-being of human participants by reducing the risks involved in the research. When we fail to reduce the risks to human participants, the principle of beneficence is violated.

Participants may not fully understand the risk of their participation and with it their exposure to these risks. Consent forms are often filled with confusing scientific and medical jargon that is not understandable to the average individual. When individuals are recruited to participate in research, particularly high-risk research, it is imperative that they understand whether they will or will not receive compensation or medical care for injuries sustained as a result of their participation.

The lack of compensation for individuals who are injured as a result of their involvement in research is also ethically indefensible because of the ethical principal of **justice**. This is particularly important when an individual from a lower socio-economic status participates and does not have medical insurance. If there is no compensation for injury and these individuals are injured there may be no way for them to receive care for their research-related injuries.

In conclusion, the injustice related to lack of coverage can be prevented by researchers and sponsors accepting the responsibility of compensation for research related injury. As researchers, it is important to realistically appraise the degree of possible risk of harm to the participant and provide compensation for injury in circumstances where there is risk to the participant.

\*Vasgird, D. (2006). Research-related injuries. In E. A. Bankert and R. J. Amdur (Eds.), Institutional Review Board Management and Function (pp. 229-231). Sudbury, MA: Jones and Bartlett.

 **Good Laboratory Practices  
(GLP)**

**Clinical Studies Review Program  
Pilot Announcement**

In its continuing commitment to research compliance, the Office of the Vice President for Research, Graduate Studies, and Economic Development is initiating a pilot Clinical Studies Review Program (CSRP) in January 2007. The CSRP will focus on assessing the level of regulatory compliance of individual investigators at the University of Arizona. Reviewers will measure compliance according to federal regulations for Good Clinical Practice, the Health Insurance Portability and Accountability Act (HIPAA), and other applicable regulations or guidance pertaining to a particular project.

The Director of Research Compliance, Alice Langen, will notify the Study Director/Principal Investigator of each project selected for review approximately two weeks before scheduling a date. At that time a review checklist will be sent as a guide for the investigator to follow.

The Director of Research Compliance and the Quality Assurance Officer, Marilyn Marshall, will be responsible for the scheduling, performance, and reporting associated with the CSRP. They will meet with the Study Director/PI to discuss the review report, and completed reports will be archived at the Quality Assurance Office. Reports will be available to the Director of Research Compliance, the Quality Assurance Officer, the Vice President for Research, and the Study Director/PI.

While the CSRP is an effort centered on Quality Improvement and Quality Assurance, there is the possibility that reviewers will discover issues of non-compliance during the review process. Should this occur, a copy of the CSRP report will be forwarded to the Director, Human Subjects Protection Program.

The assessments will be another way of assisting the University in fulfilling its responsibility for improving the integrity of research. The data gathered via the CSRP will also provide vital information about areas of research practice

in need of enhancement and assist in better focusing training efforts on subject matter particularly useful for PI's and other study personnel.

An evaluation of the CSRP's effectiveness will occur after six months. At that time the Quality Assurance Officer will seek feedback from Study Director's/PI's who have been reviewed by the program.

If you have questions about the Clinical Studies Review Program (CSRP) please contact Alice Langen ([langena@email.arizona.edu](mailto:langena@email.arizona.edu)) or Marilyn Marshall ([marsalm@u.arizona.edu](mailto:marsalm@u.arizona.edu)).

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

**HIPAA Regulations Regarding Decedents**

HIPAA regulations include the continued protection of Personal Health Information (PHI) of decedents. Information contained in a medical record or as part of payment can not be shared without permission of a personal representative or next of kin. The HIPAA regulations safeguard PHI in the past, present and future.

Should a participant die while enrolled in a research study, the study records and all PHI related to this subject need to be handled in a manner consistent with the information of the other study participants.

If you wish to use PHI of the deceased for research purposes, HIPAA regulations do not require covered entities to obtain Authorizations from the personal representative or next of kin, a waiver or an alteration of the Authorization, or a data use agreement. However, the covered entity must obtain from the researcher who is seeking access to decedents' PHI (1) oral or written representations that the use and disclosure is sought solely for research on the PHI of decedents, (2) oral or written representations that the PHI for which use or disclosure is sought is necessary for the research purposes, and (3) documentation, at the request of the covered entity, of the death of the individuals whose PHI is sought by the researchers.

Jeniece Poole, Privacy Officer  
Office of the Vice President for Research  
[jpoole@email.arizona.edu](mailto:jpoole@email.arizona.edu)

## Institutional Biosafety Committee



### Frequently Asked Questions....

**Question:** What types of research must be submitted to the Institutional Biosafety Committee for review?

**Answer:** The Committee provides expert review of research projects to ensure compliance with all relevant biosafety guidelines. Researchers working with recombinant DNA, microbial pathogens, or implementing human gene therapy projects must submit a Memorandum of Understanding and Agreement (MUA) form to the IBC. In this form researchers describe the nature of the research and specific biosafety practices and containment that will be used during the course of the research. The Committee reviews all proposed research projects regardless of funding status.

In May, 1995 the IBC initiated biosafety reviews of the UofA courses involving recombinant DNA, microbial pathogens (including human blood, fluids, tissues, or bone), and field trips. These reviews are annual and updated teaching forms are required only when changes to the course are made that necessitate additional biosafety practices.

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



The triennial inspection of *The University of Arizona Animal Care and Use Program* by the Association for Assessment and Accreditation of Laboratory Animal Care International will take place in the first quarter of 2007. This comprehensive review of our animal care program includes inspection of all animal facilities, farms, and most laboratories where animals are used. The IACUC, Animal Hazard Program and other animal-related programs are also reviewed. UAC and the IACUC will be visiting laboratories and facilities prior to the inspection, as needed, to assure readiness for the site visit. As soon as dates have been allocated for the site visit, UAC will inform researchers who may be impacted by the site visit. If you have questions or concerns

related to the site visit, please contact Susan Wilson-Sanders at 626-1066 or via email at [wilson-s@u.arizona.edu](mailto:wilson-s@u.arizona.edu).



## Radiation Control

### Sealed Sources and Devices

An 'Approval to Use Radioactive Materials' is granted to a particular professor or researcher after the Radiation Safety Committee reviews and approves the application. The application ([RC-010](#)) specifies what radionuclides will be used, the activity, the chemical forms, the protocols, and the rooms where the material will be used and stored. An Approval is granted by the Radiation Safety Committee based on this information. Any changes to the Approval require an amendment that must be submitted for review by the Radiation Safety Committee prior to beginning the work.

[Form RC-088](#), Radiation Worker Data Sheet & Training Record must be completed by each person who is going to work with radioactive materials before such work begins. All employees and students who work with sealed sources are required to attend the Radiation Source Protection Course ([RSPC](#)) prior to beginning work. Approval Holders are not required to attend the RSPC, but are required to attend an Approval Holder Orientation (AHO) prior to beginning work with sealed sources.

During initial training with the Approval Holder, it is essential to become familiar with the characteristics and the safe handling of the sealed source(s) you will be using. At any time you need information about a sealed source, the Radiation Control Office (RCO) is available as a resource. Information about any source currently in use is available from the RCO upon request during this course. Additionally, the following subjects will be reviewed:

1. Sealed source ordering and shipping is initiated through the RCO.
2. Leak test certificates and information about sealed sources must be provided to the RCO for all incoming sources. Leak test certificates and information about sealed sources is provided by the RCO for all outgoing sources.
3. In the event, a sealed source may be donated to the University of Arizona, the request must be routed through the RCO prior to any receipt or acceptance of a sealed source.

Questions regarding sealed sources can be directed to the RCO at 626-6850 or [rcohelp@u.arizona.edu](mailto:rcohelp@u.arizona.edu).

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## OPPORTUNITIES FOR ON-LINE ETHICS TRAINING

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### 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. For more information, please visit the following internet web site: <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 on-line 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).

### Human Subjects Research Online Training, "Protecting Human Subjects" From the Department of Health and Human Services

This educational training series is designed to provide you with: Historical background for behavioral and biomedical research; Ethical principles for human subject research; Case studies; Information on the role of an Institutional Review Board (IRB). If you are a HRSA staff member, researcher, grants and contracting official, grantee or someone outside the agency (including institutional officials, reviewers, students, investigators, or IRB members), you will find information provided in this training valuable.

**Module 1:** "EVOLVING CONCERN: Protection for Human Subjects"

**Module 2:** "THE BELMONT REPORT: Basic Ethical Principles and Their Application"

**Module 3:** "BALANCING SOCIETY'S MANDATES: Criteria for Protocol Review"

If you are interested in additional resources, you may find the [OHRP Institutional Review Board Guidebook](#) helpful.

The 1993 Guidebook is designed to assist IRB members research, and institutional administrators in fulfilling their responsibilities for protecting the rights and welfare of human subjects as defined in the HHS regulations (45 CFR 46) entitled "Protection of Human Subjects," revised June 18, 1991.

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## Upcoming Conferences/Workshops

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**December 1-3, 2006**

[Research Conference on Research Integrity](#)

Tampa, FL

Co-sponsors: Association of American Medical Colleges, American Association for the Advancement of Science

To obtain a conference schedule:

<http://ORI.hhs.gov>.

Questions should be addressed to Nick Steneck at [nsteneck@umich.edu](mailto:nsteneck@umich.edu).

**February 16, 2007**

American Association for Laboratory Animal Science (AALAS) Symposium

Embassy Suites Hotel, Phoenix, AZ

[Submit your abstract form](#) for your paper or poster by November 15, 2006.

Address questions to: Grace Aranda at 621-3931, or email [www.azaalas.org](http://www.azaalas.org).

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*The P.R.I.E. newsletter is researched  
and compiled by Ruth Kurash Daniels.*

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*Words of Wisdom:*

*"Blessed is the season which engages the  
whole world in a conspiracy of love."*

— Hamilton Wright Mabie