
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, “*Publication.*” 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>.

Responsible Conduct of Research (RCR)

P.D. Magnus and Michael Kalichman,
September 2002

Publication

Background

In academic life, it is said, one must “publish or perish.” Indeed, publication is central to many disputes about responsible conduct of research. Publication facilitates the open exchange of information among researchers and exposes findings and methods to the scrutiny of the community. It also documents who is first with new ideas or discoveries, shows productive use of research funds, and provides a record by which a research career can be judged. For these latter reasons, publication has a prominent role in advancement, promotion, and continued research funding. Scientists are under considerable pressure to publish.

In pursuit of publication and, more specifically, of credit, prospective authors can have serious differences of opinion about when to publish, what to publish, and how credit should be apportioned. Some of these issues are discussed below. Authorship and peer review demand special attention and are included as separate topics. Ultimately, the centrality of publication in academic life means that it is implicated to some degree in nearly all aspects of the responsible conduct of research.

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 unwritten standards. Many professional societies, scientific journals, and institutions

have guidelines, the depth and scope of which are quite variable.

One of the most widely cited guidelines for publication is a document from the International Committee of Medical Journal Editors (ICMJE). In 1978, a group of medical journal editors met in Vancouver to establish guidelines for the format of manuscripts submitted to their journals. A product of that meeting was the ICMJE guidelines, Uniform Requirements for Manuscripts Submitted to Biomedical Journals, which have been expanded and revised to address ethical questions (ICMJE, 1997). These guidelines have been adopted by more than 500 biomedical journals.

Copyright law

Extensive international and U.S. copyright laws regulate protection for writings such as research publications. For most published articles and book chapters, authors are required to transfer the copyright to the publisher. In practice, this means that authors of a published paper are in violation of federal law, not just ethical standards, if they attempt to republish without first getting permission from the copyright holder, the publisher. Therefore, unless one is legally advised otherwise, it is best to assume that it is never acceptable to reproduce previously published work without permission from both the author(s) and the publisher.

Principles

Research is not complete until it has been reported

Research is no contribution to the scientific community until it is reported, whether through publication or some other means. Reports are a necessary first step in the dialog with other scientists about the approach and significance of the work. Unless research is reported, it is impossible for others to build on what has been learned.

Publication is not merely a matter of credit.

One may wish to publish so as not to perish, but this alone is not enough to justify a report's being published. Publications should present some substantive and new result or analysis, and should not serve merely to increase the author's number of publications.

Credit for important new contributions to the scientific literature is assigned to the authors. Along with the privilege of credit, however, authors assume a responsibility for the integrity of what is being published. By placing their names on a publication, authors are attesting that the work was done as described. If this is found not to be the case, for instance if some of the data are found to be falsified, then the names of all the authors will be associated with a fraudulent paper.

Authors have a responsibility for assuring not only that the paper is free of outright fraud, but for assuring generally that it is free of misrepresentation. Although errors can occur, authors should endeavor to publish an accurate, complete, clear, and unbiased representation of their work, including background for their work, the methods used, the findings, the significance and contributions of the work, and fair assignment of authorship and credit.

Guidelines

Contributions to the literature

Dividing research findings into the smallest publishable units might increase an investigator's total number of publications, but works against the interests of science. Minimally, this is an inefficient use of scarce resources, including space in journals and the time of authors, editors, and reviewers. Furthermore, fragmentation of one study into many small publications can give the false impression that a line of research has been extensively pursued. Even so, a scientist's reputation is likely to be more respected if based on a few widely respected studies rather than on many small, fragmentary reports. No simple formula can determine the point at which a body of data warrants publication, but scientific literature benefits from the publication of manuscripts that represent new and substantial findings.

Redundant publication

Publication of data in more than one location gives the findings more visibility, but it may also mislead readers into believing that the publications represent distinct data sets. In the case of clinical findings, this could contribute to a false impression that some greater number of patients has been studied. In the case of basic research, readers could be misdirected into thinking that the study had been successfully replicated. Any data set, either in whole or in part, should not be

published twice without making explicitly clear which of the data have been published previously and where and when the work was published.

Some exceptions to the injunction against redundant publication may be justified. It is acceptable to publish a paper that was published previously only as an abstract, although authors should disclose the prior publication and avoid the suggestion that the two represent distinct results. In some circumstances, the case can be made that two completely different audiences can be reached only by separate publications: for example, when a work warrants publication in two languages. Even in such cases, however, the editor and the publisher for both papers must approve the arrangement. In all of these cases, it is essential that the later publication make clear reference to the earlier work. Without such reference, the second publication constitutes a falsification of the research record.

For the submission of papers, most journals require that the work not be submitted simultaneously elsewhere for consideration. Submission of a paper is tantamount to provisionally giving the selected journal copyright to the work, and it initiates considerable expense of time and effort in reviewing the manuscript. Only when an article has been rejected by or withdrawn from consideration in one journal may it be submitted elsewhere.

Plagiarism

Authors take responsibility for both the ideas and words in a publication. For this reason, copying an entire manuscript is a clear example of research misconduct. While taking credit for someone else's research findings is clearly a greater wrong than copying their methods section, both are examples of plagiarism – taking personal credit for someone else's words or ideas. To use the words of another author, either state where the original words can be found or reproduce the original text with clear and well-cited attribution to the original author. Even with proper citation, repeating the words of other authors is constrained by the fair use provisions of copyright law.

A difficult case of plagiarism is when it occurs between colleagues. When text has been co-authored, the question of ownership may be a matter of dispute. In some research groups, jointly written text is assumed to be shared prop-

erty available for use by any of the original authors. Opinions about the extent of collective ownership of jointly written materials vary and it may be impractical to determine when plagiarism has occurred (see the Office of Research Integrity, 1994). It should never be assumed that it is acceptable to take credit for words written by someone else, and this issue should be openly addressed among collaborators.

Citation

The references cited in a research publication form the path that connects new work with the work on which it is built. Just as a thorough reference search is the foundation for responsible research, appropriate reference citation is the foundation for responsible reporting. Because future readers will rely on the references listed, an author has responsibilities to assure the accuracy of each citation so that readers can locate the referenced work, to include adequate references that document the origins of ideas, to verify that referenced works are consistent with the ideas and information credited to them, and to cite original sources whenever possible.

Statistical methods

Statistical methods are often used to describe data samples, to summarize results and relationships, and to test hypotheses. Usually, readers will not have access to the raw data and, therefore, will base any conclusions on the outcome of the statistical analyses. Because the assumptions and meaning of statistical tests vary widely, simply reporting a final P value (the probability of a false positive) tells readers very little unless they also know the methods of data collection and analysis. For these reasons, it is essential that authors not only design and analyze experiments appropriately, but also that they clearly and openly describe their methods (American Statistical Association, 1999).

Errata, corrections, and retractions

The decision to submit a correction or retraction is not an easy choice to make, and all authors of the paper should be informed. Despite any perceived risks, there are also advantages to an appropriate correction or retraction. Admitting error is typically perceived as a sign of integrity and concern for the highest standards in work entered into the published record. Conversely, failure to admit to an error can be devastating if the problem with the manuscript is first discovered by others.

The integrity of the scientific literature is best served by rapid correction of misleading or mistaken information.

If errors are discovered after a manuscript has been published, then authors have several options, depending on the significance of the errors: (1) If minor errors are found to have been included in a manuscript, then a letter (singular erratum or plural errata) describing the errors should be submitted to the journal that published the article. (2) If unintentional errors are great enough to undermine part of a report, then the authors should submit a letter to the journal explaining the errors as a correction to the publication. (3) If unintentional errors are of such a magnitude as to invalidate or seriously undermine the entire report or if misconduct affecting the work on the part of one or more authors is found to have occurred, then the authors should retract the paper by writing to the editor of the publication.

Resources

Works cited

In addition to (ICMJE, 1997), other commonly cited guidelines are (NIH, 1997; Society for Neuroscience, 1999; Eastwood et al., 2001).

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- Eastwood S, Fike JR, Cogen PH, Rosegay H, Berens M (2001): BTRC Guidelines on Research Data and Manuscripts (Brain Tumor Research Center, University of California San Francisco, 1989). Revised and updated in 2000 and reprinted in Bulger RE, Heitman EE, Reiser SJ, eds.: The Ethical Dimensions of the Biological Sciences, 2nd ed. Cambridge University Press, New York.
- International Committee of Medical Journal Editors (1997): Uniform Requirements for Manuscripts Submitted to Biomedical Journals. JAMA 277:927-34. <http://www.icmje.org>
- NIH (1997): Guidelines for the Conduct of Research in the Intramural Research Programs at NIH. <http://www.nih.gov/campus/irnews/guidelines.htm>
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Further resources

- Asilomar Working Group on Recommendations for Reporting of Clinical Trials in the Biomedical Literature (1996): Checklist of information for inclusion in reports of clinical trials. *Ann Intern Med* 124:741-743.
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- Moher D, Schulz KF, Altman DG [for the CONSORT Group] (2001): The CONSORT statement: revised recommendations for improving the quality of reports of parallel group randomized trials. *JAMA* 285: 1987-1991. "[A] checklist and flow diagram to help improve the quality of reports of randomized controlled trials."

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- Hudson-Jones A, McLellan F, eds (2000): Ethical Issues in Biomedical Publication. Johns Hopkins University Press, Baltimore, 374 pp.
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- Lafollette MC (1996): Stealing into Print: Fraud, Plagiarism, and Misconduct in Scientific Publishing. University of California Press.
- Woodford FP with Goode ME and Gastel B (1999): How to Teach Scientific Communication. A Council of Biology Editors Manual. Council of Biology Editors, Inc., Bethesda, 199 pp. [Available from: Council of Science Editors, 11250 Roger Bacon Drive, Suite 8, Reston, VA 20190; fax 703-435-4390].
- Woolf PK (1987): Ensuring integrity in biomedical publication. *JAMA* 258:3424-3427.

Next month the featured RCR topic will be:

"Authorship"

HUMAN SUBJECTS PROTECTION PROGRAM

≧Highlights≦

Research and the Internet*

Increased use of the Internet for conducting research (both biomedical and behavioral) presents new challenges and concerns for protecting human subjects.

What are the concerns related to subjects participating in Internet research activities?

One concern specific to Internet usage is the risk related to exposure to certain questions. Although most Internet research is relatively harmless, certain types of questions may illicit an adverse reaction. Since there is usually no contact with participants, it is not likely that the researcher would know about an adverse reaction, much less the extent of the reaction. Generally it is not possible to provide debriefing to participants and if provided, it is difficult to know whether participants accessed the information. Because of these issues, collection of sensitive information may not be appropriate.

Another concern with Internet research is with privacy and confidentiality. Privacy issues include if the activity identifies the participant, and whether the activity is considered private or public. Many Internet activities involve the use of a pseudonym. However, this does not mean the individual is anonymous. Additionally, although most online activity is considered "public," federal regulations define private information as an individuals' "reasonable expectation of privacy." For example, although a chat room may be publicly available, it is not usually expected that conversations in a chat room would be monitored by an investigator and used for research purposes.

Breach of confidentiality is another potential risk to individuals participating in Internet research. Although anonymity is the most protective measure, anonymity is not easy to achieve. For example, data transmitted via email cannot be anonymous without additional steps, as email usually contains the sender's email address. Investigators wanting to use email as a mode of data transmission must provide an additional third step – a site that removes the sender's email address. Anonymity can also be achieved if software is used to store the information in a database that does not include identifiers and/or items that might identify the participant.

Is electronic informed consent possible?

Another issue of concern to Investigators is that of informed consent and documentation of informed consent. Although obtaining informed consent can be achieved through the Internet, documentation of consent can be troublesome since the technology for digital signatures is not yet widely available. One mechanism for obtaining voluntary consent is to present the participant with the required information and then ask them to click on an "I agree" button. This would satisfy the requirements for minimal risk research. Documentation of consent is more problematic. However, not all research needs documentation of informed consent and the IRB can waive this requirement when the research meets waiver requirements. When documentation of consent is required, the participant can sign a downloadable consent form and submit the signed consent to the Investigator. Once received, the investigator can send the participant a password to gain access to the on-line research project.

Use of the Internet is becoming a commonly accepted practice among researchers. Although a challenge, researchers can provide protection to participants while at the same time increase efficiency and gain access to greater numbers of potential participants.

J. M. Cohen. (2006). Internet research: A brief guide for institutional review boards. In E. A. Bankert and R. J. Amdur (Eds.), Institutional Review Board Management and Function (pp. 394-396). Sudbury, MA: Jones and Bartlett.



Addition to the Human Subjects Protection Program Web Site "Tip of the Week"

Located at the Human Subjects Protection Program (HSPP) web site, you will find a new addition, the "Tip of the Week." These tips are designed to help the research community learn about the Human Subjects Protection Program policies and procedures. Following is the "tip" for October 11, 2006.

"DID YOU KNOW..."

...that the project you submit to the Human Subjects Protection Program (HSPP) may receive a review by the convened Institutional Review Board (IRB) more than once? [HSPP Policy III.B]

When a project is initially reviewed at a convened meeting of the IRB, approval may be deferred. Approval is deferred if the study does not meet the criteria for approval as defined in 45

CFR 46.111 or if the IRB recommends substantial revisions to the IRB Application, Sponsor's Protocol, informed consent document(s), or other pertinent documents. When substantial revision is necessary, the risk-benefit ratio cannot be properly assessed. Once the investigator's response letter and revised documents are received, project approval is reconsidered at the next available Committee meeting." (<http://www.irb.arizona.edu>)



News from HIPAA.....

The National Institutes of Health (NIH) is proposing policies for Genome – Wide Association Studies (GWAS) that would involve data sharing, but would address the protection of research participants, according to a notice in the August 30th *Federal Register*. NIH's goal is to identify common genetic factors that influence health and disease for better understanding of "basic biological processes affecting human health," the notice explains. "It is critically important that the privacy and confidentiality of the participants be protected," the agency says. Protections will include submission of data without identifiable information and through the use of a "random, unique code," NIH says. Public comments on this policy will be taken through October 31, 2006. To read the notice, go to AIS's (Atlantic Information Services, Inc.) Government Resources at the Compliance Channel at www.AISHealth.com; click on "2006 *Federal Register*."

Reprinted from the October 2006 issue of
REPORT ON PATIENT PRIVACY.

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Institutional Biosafety Committee



Frequently Asked Questions....

Question: What is the Institutional Biosafety Committee (IBC)?

Answer: The Institutional Biosafety Committee was formed October, 1976, per a national directive from the National Institutes of Health (NIH). The initial purpose of the IBC was to review all research with recombinant DNA on the University of Arizona campus, subject to rule provided by the Office of Recombinant DNA Research at NIH. Later, a similar set of rules governing recombinant DNA research in agriculture was provided by the U.S.

Department of Agriculture (USDA). At that time, the Committee began to work closely with the Animal and Plant Health Inspection Service (APHIS) Office of the USDA and with the Arizona Department of Agriculture and Horticulture. In the fall of 1988, in response to local needs and federal regulations, the Committee expanded its role to include the review of research involving microbial organisms pathogenic to plants, animals and humans. In February 1991, the Committee agreed to review research protocols involving biohazards submitted by the Tucson Veterans Affairs Medical Center.





 **Good Laboratory Practices (GLP)**

Study Director GLP Roles and Responsibilities

Key Principle of GLP:

The Study Director is the single point of control

The Study Director has overall responsibility for technical conduct of study according to the FDA and EPA regulations:

-  Analysis
-  Documentation
-  Interpretation
-  Reporting of results

Study Directors/Principal Investigators whether required by federal regulations or not....good practices in the laboratory will result in good science. The Quality Assurance Office is here to encourage and help with training on good record keeping and documentation or other laboratory issues to enhance research capabilities.

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

University of Arizona – Animal Care
Quality Care for Research Animals



We're moving ever closer to going live! Draft protocol manuals have been written for the PI, IACUC Staff and IACUC Committee members. Draft animal requisition manuals for the PI and UAC staff are also ready. Pertinent manuals will be placed on the UAC web page by December 2006.

In September, the IACUC office mailed lists of active protocol personnel to the PI's for revision and eSirius access assignment. A second mailing will go out towards the end of the year to pick up staffing additions that have occurred since the beginning of September. This data will be used to

populate the contact and access lists in eSirius. The eSirius Access Request form is currently available on the UAC page <http://www.ahsc.arizona.edu/uac/> under the forms section if you wish to add **non protocol** related personnel to the eSirius access list established in September. After eSirius goes live, the eSirius Access Request form will be used to request access to eSirius for all personnel, including new PIs.

A migration of test data from our existing system Sirius into eSirius is scheduled to occur in late September to early October. The test migration allows us our first look at how the data transfers and what we can expect when we make our final migration into a production environment prior to going live.

We hope to make the final Sirius to eSirius data transfer in early December and at that time the IACUC office staff as well as the UAC Husbandry Purchasing and Bar Code staff will use eSirius exclusively to enter protocols, animal orders and perform bar code census related activities. Training will be offered to everyone affected by the switch to eSirius in December. This includes PIs and their staff, IACUC committee members, adjunct protocol reviewers and UAC administrative staff.

January 1, 2007 is our projected go live date for eSirius. At that time the research community will use eSirius to enter protocols and animal orders. Prescheduled and on-demand training will continue to be offered after we go live.

As we currently lack the online invoicing component of eSirius (should be out at the end of this year), we anticipate going live with eSirius invoices later in the spring.

Please contact Andi at 626-8332 or mitchela@u.arizona.edu if you have any questions about the eSirius implementation.

**OPPORTUNITIES FOR
ON-LINE ETHICS TRAINING**

**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.

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.

Upcoming Conferences/Workshops

November 15-18, 2006

2006 Annual HRPP Conference...*A Commitment to Ethical Research: Advancing the Mission of Human Research Protection Programs*
broskin@primr.org

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.

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.



“Integrity” is the 2005 Word of the Year

About 200,000 individuals looked up the definition of the word “integrity” on the Merriam-Webster online dictionary site making it the most frequently looked up word in 2005 and earning the word “integrity” the title—Word of the Year.

The Merriam-Webster site defines integrity as firm adherence to a code of especially moral or artistic values: **incorruptibility**; an unimpaired condition: **soundness**; and the quality or state of being complete or undivided: **completeness**. The synonym for integrity is **honesty**.

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

Words of Wisdom:

“The mere formulation of a problem is far more essential than its solution, which may be merely a matter of mathematical or experimental skills. To raise new questions, new possibilities, to regard old problems from a new angle requires creative imagination and marks real advances in science.”

——— *Albert Einstein*