
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 “*Collaboration.*” 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

Collaboration

Background

Science increasingly depends on collaborations. This is reflected in the increased number of authors per publication. For example, a random sampling of 20 journal articles published in *Science* in 1966 had an average of 1.9 authors per article, with a maximum of 3 authors. By the year 2000, the average had more than doubled to 4.3, with a maximum of 12 authors. [Mussurakis, 1993, Khan et al., 1999] This increase reflects both larger research groups and collaboration between research groups. The rise in collaborations is a result of many factors. First, no single person has the skills, knowledge, and resources to address all research problems. A judicious choice of collaborators can save considerable time and money. Second, the funding and structure of science tend to favor programs in which recognized authorities are involved from each key area. Third, breakthroughs are often more likely to come from collaboration across disciplines than by adherence to tried and true methods. Fourth, collaboration between the private sector and academia is being encouraged by legislation (e.g., the Bayh-Dole Patent Reform Act of 1980 allowed universities to negotiate patent rights with industrial partners), industry (which recognizes the benefits of the expertise and reputation of academics), and academia (which can benefit from immediate and long-term sources of private funding). Finally, collaborations are easier than they were before.

With obvious improvements in communication (phone, fax, email), shipping (one-day delivery), and travel (to national and international conferences), potential collaborators are more likely to find each other and are more able to maintain their collaboration. Whatever the reason, collaborations are increasingly beneficial and possible.

Collaborations are a frequent source of problems, and this results in part because collaboration can take many different forms. It certainly implies two or more people having joined together for a common purpose, but this might involve almost any arrangement of shared time, work, resources, unique materials, data, ideas, or money. Once the work is completed, credit and responsibility can then be shared in a number of ways.

In some cases, collaborations may not even begin because of reluctance to share or work together [Cohen, 1995]. Once started, collaborations can be marred by misunderstandings of what is to be provided by each of the participants, unhappiness with a slow collaborator, disagreement about what and when to publish, or conflicts regarding authorship and credit. [Kahn et al., 2000; Wilcox, 1998].

Although there is no single panacea for such problems, it is evident that any solution needs to be based in improved communication.

Rules and regulations

The process of collaboration is regulated primarily at the institutional level, not by the public or private funders of research. The presumption is that the community is best served by minimal barriers to free and open collaboration. Nevertheless, the outcomes of collaboration, particularly patents and copyrights, are restricted by both public and private funders of research. Moreover, nearly all institutions have rules and guidelines governing collaboration. For example, most academic institutions have explicit rules governing ownership of the products of work done by employees of the institution, material transfer, and limitations on academic-industrial agreements that might compromise the institution's academic mission. Some institutions also have guidelines for issues such as sharing and ownership of data, assignment of authorship, and credit and responsibilities for authors [East-

wood et al., 2001]. In general, collaboration with someone outside of an institution cannot proceed without involving the institution.

Principles

The nature of collaborations is so variable that it is difficult to identify a comprehensive set of ethical principles; however, responsible collaborations are defined by openness and communication.

A number of professional societies and journals have also published guidelines that address various aspects of collaborations. In 1995, the American Academy of Microbiology published a document summarizing many of the important issues in collaborations plus suggested guidelines for successful collaboration (Macrina et al., 1995). Another report, with a focus on universities and industry, makes a variety of suggestions about how to overcome the existing barriers to collaboration (National Academy of Sciences etc., 1999).

Collaborators should be open about the research.

Science is a communal enterprise; both science and society are best served by collegiality and open collaboration. Collaborators should be clear with one another about the research to be undertaken, the methodology, the results, and so on.

Collaborators should be open and clear about the terms of the collaboration.

Collaboration is most likely to succeed if expectations are clearly communicated (and perhaps documented) before commitments are made. There should be a shared understanding of what is to be exchanged through the collaboration and how the products of the collaboration will be shared.

Guidelines

While successful collaborations depend on explicit communication, such communication is often difficult. In some cases, different cultural backgrounds are an impediment to understanding. The culture of the private sector emphasizes discovery and application of profitable products, for instance, while academics may be more interested in mechanisms and new discoveries. In international collaborations, participants may literally speak different languages. Even when a common language is available, participants may have very different styles and understandings of communication as well as different perspectives on sharing and ownership.

Different research disciplines can also be a source of miscommunication. Because of the nature of the work, some disciplines may have very different expectations about hours to be worked (e.g.,

many biochemical and molecular biological studies require long hours), standards of proof (e.g., different disciplines have developed different views about the need for statistical methods), or the pace of work (e.g., high quality electron microscopy can often be elusive and require many days or weeks of searching for acceptable images long after a study has been otherwise completed). Similarly, communication across disciplines can be impaired by different understandings about the science, vocabulary, or methods.

Different individuals can simply have very different standards and interpersonal styles. Some people consider a verbal agreement to be binding, while others prefer explicit, written contracts. Some favor rapid publication of each new finding; others prefer to amass a body of work for a single large publication. Some are convinced that authorship and credit should be reserved only for those who have made the most substantial contribution to the study; others are much freer in assigning credit. Some readily and clearly speak their minds; others are more withdrawn and will volunteer information only if asked.

Although guidelines or regulations do not explicitly cover all these aspects of collaboration, the goal should be communication that clarifies expectations of all parties involved. Although it may not be necessary to put everything in writing, attempts should be made to explicitly address relevant issues. Finally, it is important to keep in mind that although collaboration is in the best spirit of science, opening a collaboration can leave a scientist vulnerable to the actions, or inaction, of his or her collaborators. Therefore, choosing colleagues should be based not only on the science, but also on the likelihood of an amicable relationship in which lines of communication can be kept open.

Resources

Works cited

- Bayh-Dole Patent Reform Act (1980): Section 6, Patent and Trademark Amendment of 1980, PL 96-517; implementation by OMB Circular No. A-124 [superseded by PL 98-62 and 37CFR401, 1987]
- Cohen J (1995): Share and share alike isn't always the rule in science. *Science* 268:1715-1718.
- 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, Reiser SJ, eds.): *The Ethical*

Classification of Medical Devices*

This is one article in a series of articles regarding classification of medical devices. The regulations about medical devices are found in the Code of Federal Regulations Title 21, part 800-1050. The device regulations are similar in many ways to the drug regulations; however there are several distinctions. One difference is the definition of a medical device. A medical device is distinguished from a drug in that it cannot react chemically with the body and that it is being promoted or studied for a medical purpose. A combination device such as a pump or patch that delivers drug might be classified as either a drug or device depending on which part is investigational. In vitro diagnostic test kits are medical devices. Their regulatory status depends on their use. For example diagnostic test kits that are used for medical purposes are of interest to the FDA, unlike those kits that will not be used for a medical purpose. Radiologic products that introduce energy are also regulated as devices.

Historically, the Food and Drug Administration (FDA) did not have a mechanism for the review of medical devices. It wasn't until 1976 that the FDA conducted a review of medical devices and discovered that approximately 8,000 devices were available on the market. A literature review revealed that although many of these devices had not caused any harm, 10,000 injuries were reported during a 10-year time frame with 751 device-related fatalities.

With the Medical Device Amendment of 1976, the FDA established three classifications for devices. The classification was not intended as a measure of risk but was established in order to measure the level of regulation that would be required in order to verify safety and effectiveness.

During the next ten years, all 8,000 devices that were on the market as of May 26, 1976 were classified by discipline (cardiology, neurology, etc.) as either class I, II, or III. Class I devices have general controls. This means that these types of devices need little regulation in order to ensure safety and effectiveness. The only controls imposed by the FDA on these types of devices are manufacturing and claims made about the device. Examples of class I devices includes crutches, band-aids, and cast components.

- Dimensions of the Biological Sciences, 2nd ed. Cambridge University Press, New York.
- Khan KS, Nwosu CR, Khan SF, Dwarakanath LS, Chien PF (1999): A controlled analysis of authorship trends over two decades. American Journal of Obstetrics and Gynecology 181:503-7.
- Kahn JO, Cherg DW, Mayer K, Murray H, Lagakos S for the 806 Investigator Team (2000): Evaluation of HIV-1 Immunogen, an Immunologic Modifier, Administered to Patients Infected With HIV Having 300 to 549 X 106/L CD4 Cell Counts: A Randomized Controlled Trial. JAMA. 284:2193-2202.
- Macrina FL et al. (1995): Dynamic Issues in Scientific Integrity: Collaborative Research. American Academy of Microbiology, Washington, D.C.
<http://www.asmus.org/acasrc/aca1.htm>
- Mussurakis S (1993): Coauthorship trends in the leading radiological journals. Acta Radiologica 34:316-20.
- Wilcox LJ (1998): Authorship: the coin of the realm, the source of complaints. JAMA 280:216-7.
- National Academy of Sciences, National Academy of Engineering, Institute of Medicine, and National Research Council (1999): Overcoming Barriers to Collaborative Research. Report of a Workshop. National Academy Press, Washington, D.C. [the document is for sale, but there are links to free versions in pdf and html]
<http://www.nap.edu/catalog/9722.html>

Further resources

- International Committee of Medical Journal Editors (1997): Uniform Requirements for Manuscripts Submitted to Biomedical Journals. JAMA 277:927-34
<http://www.icmje.org>
- Korenman SG, Berk R, Wenger NS, Lew V (1998): Evaluation of the research norms of scientists and administrators responsible for academic research integrity. JAMA 279:41-7.
- Macrina FL (2000): Chapter 8: Collaborative research. In: (Macrina FL, ed.) Scientific Integrity: an Introductory Text with Cases. 2nd ed., ASM Press, Washington, DC, pp. 157-178.

Next month the featured RCR topic will be:

"Mentoring"

Knowing the history and rationale behind devices will enable researchers to better understand the device regulations, how they differ from the drug regulations and the critical role the FDA plays in the regulations of medical devices.

*Heath, E. J. (2006). Research Involving a Medical Device. In E. A. Bankert and R. J. Amdur (Eds.), Institutional Review Board Management and Function (pp. 434-440). Sudbury, MA: Jones and Bartlett.

See next month's review of class II devices

Good Laboratory Practices (GLP)

Pre-Clinical Studies and Good Laboratory Practices (GLP)

Good Laboratory Practices (GLP) under 21 CFR 58 applies to nonclinical laboratory studies (safety studies) that are intended to support applications for research and marketing permits including Investigational Device Exemption and Premarket Approval applications. Compliance with this part is intended to ensure the quality and integrity of safety data obtained from animal studies submitted to FDA.

If information on nonclinical laboratory studies is provided in the IDE application as part of the report of prior investigations, a statement that all such studies have been conducted in compliance with applicable requirements in the good laboratory practice regulations in part 58 must be provided. If any study was not conducted in compliance with the GLP regulations, a brief statement of the reason for the noncompliance must be provided. [§812.27]

If you would like to read more, please go to: www.fda.gov/cdrh/devadvice/ide/related.shtml.

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News from HIPAA.....

The Center for Medicare and Medicaid Services (CMS) recently released guidance on how Covered Entities under the Health Insurance Portability and Accountability Act (HIPAA) can protect electronic protected health information (EPHI) when it is being accessed or used outside of the entity's physical location. This guidance is in response to the many security incidents related to the use of laptop computers and other portable devices that are used to store or access EPHI, CMS says.

You may access the guidance by following this link:

www.cms.hhs.gov/SecurityStandard/Downloads/SecurityGuidanceforRemoteUseFinal122806.pdf

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



The triennial site visit by our accrediting agency AAALAC International has been scheduled for February 12-14, 2007. The site visit will include visits to all animal facilities, farms and laboratories where animals are kept for 12 hours or more. All survival surgical areas will also be visited. During the next two weeks, researchers who will be affected by the site visit will receive a call to schedule a time for the site visitors to inspect laboratories and satellite facilities. Site visitors will inspect control drug logs and drugs, including controlled drugs, antibiotics, and others. Please go through your pharmaceutical agents and be sure that all expired drugs are removed and disposed of.

As soon as we have further details, including the names of our site visitors, we will post the information to Animal Scoop, the UAC-Researcher listserv.



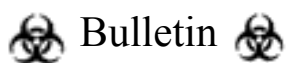
Radiation Control

Institutional Support Personnel In-Services:

Institutional support personnel that have limited exposure to radiation or have limited access to radiation-restricted areas have once-only in-service requirement, although they are not designated as radiation workers and are not required to complete an RC-088. Each department is responsible for ensuring that untrained personnel do not work in radiation-restricted areas. These in-services are offered routinely and are directed to individuals from the following units:

- UA Police
- UMCC Security
- UA/UMCC Environmental Services Support
- UA/UMCC Facilities Management crafts shops
- University Animal Care
- UA/UMCC Shipping/Receiving
- Risk Management and Safety

Institutional Biosafety Committee



Frequently Asked Questions....

Question: How often does the Institutional Biosafety Committee meet?

Answer: The Biosafety Committee meets once a month September through June. Committee meetings are a luncheon format at which time specific projects are reviewed in detail. Biosafety level 1 (BL1) projects are reviewed in depth by the IBC staff before being placed on the monthly agenda. Committee members are provided the opportunity to examine individual BL1 projects at the time of the meeting.

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>.

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

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.

March 29-30, 2007

Data Fabrication and Falsification: How to Prevent, Detect and Evaluate

Boston, MA

Co-sponsors: Harvard Medical School, Harvard School of Public Health, and Harvard Teaching Hospitals

May 15-18, 2007

14th Annual Teaching Research Ethics Workshop

Indiana Memorial Union, Bloomington, IN

[Register](#) now for the Fourteenth Annual [Teaching Research Ethics Workshop](#).

May 31 – June 1, 2007

Costs and Benefits of Responsible Conduct of Research Education Programs

Minneapolis, MN

Co-sponsor: University of Minnesota

September 17-19, 2007

First World Conference on Research Integrity

Lisbon, Portugal

Co-sponsor: European Science Foundation

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and compiled by Ruth Kurash Daniels.*

Words of Wisdom:

*"Love is the master key which opens the
gates of happiness."*

————— *Oliver Wendell Holmes*