
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 *Preventive Ethics*. We thank Professor Pimple from the Poynter Center in Indiana for providing this article.

Preventive Ethics

By Kenneth D. Pimple, Ph.D.
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<http://poynter.indiana.edu/tre4-3.html>

The 1997 University-Wide Symposium on Research Ethics, focused on “Preventive Ethics.” In a 1993 article in *The Journal of Clinical Ethics*, Lachlan Farrow, Robert M. Arnold, and Lisa S. Parker made a rough analogy between preventive medicine and what they called preventive ethics. The fundamental idea is simple: minor problems left unattended are likely to grow into major problems. This holds true in health care, in clinical ethics, and in the responsible conduct of scientific research.

People who have to deal with allegations of misconduct in science, including David E. Wright, MSU’s University Intellectual Integrity Officer, have observed that in most cases of unethical research, warning signs are visible early to the discerning observer. Cases involving intellectual property, for example, often become heated only after a long period of collaborators’ simmering over real or imagined disagreements or power struggles.

Imagine two collaborators with different work styles who want to take their research in different directions. Collaborator A, who tends to be more circumspect in drawing conclusions, is only willing to publish results after extremely careful consideration, and is really only interested in basic research. Collaborator B, on the other hand, wants to pursue an aggressive and fast-paced research agenda with a clear applied component and wants immediately to develop ties to industry.

Furthermore, A sees B as pushy and imperious, while B sees A as parochial and timid. If these differences are allowed to gnaw, a problem is likely to develop. B will accuse A of dragging things out; A will accuse B of sloppy science motivated by greed. One can easily imagine any

number of actions that either of the collaborators could take that would give rise to an accusation of research misconduct from the other.

If, however, the conflict is noticed early, it would probably be possible to forestall an ugly fight. It might be wise for these two not to work with each other at all. Or it might be possible for them to agree on an explicit research strategy for a specified period of time - say five years - with definite plans for how decisions will be made, credit shared, and the like, as well as specifications for how the collaboration will be dissolved or renewed.

Different styles can be an asset or a liability. If A and B try to keep quiet about their very real differences, perhaps grumbling to themselves that they wish the other would be “reasonable,” they are headed for trouble. But people with different work styles often complement and strengthen each other, making for a stronger team, if they acknowledge their differences and think carefully about how to manage disagreements.

Whenever people work together, as in science, competing interests are at stake. But within a given lab or department, science does not have to be a zero-sum game, where every win for one person involves a loss for another. “Preventive ethics” does not call for an assumption that your colleagues are likely to act unethically if given a chance; rather it calls for an awareness that minor conflicts are inevitable, but major conflicts can often be avoided if the minor ones are not allowed to fester.

Research Integrity Certificate Program Created by SRA International

A Research Integrity Certificate Program has been created by the Society of Research Administrators (SRA) International to provide its members with a foundation for identifying, understanding and addressing the complex ethical dimensions of research.

The certificate program is designed to provide a basic understanding of topics associated with research integrity—including cultural aspects, goals for facilitating research integrity, and strategies for creating an institutional culture that values ethical and responsible practices in research.

Basic requirements of the certificate program are attendance at a half-day or full-day workshop on research integrity that focuses on general aspects of research integrity or any specific area associated with research integrity and completion of at least one session from any five of the following six concentration areas: research integrity in general; research protections and compliance review boards (e.g., IACUC, IRB, ESCRO, bio-safety, conflicts of interest); data management (e.g., recordkeeping, data ownership, data sharing); social responsibility; authorship, publication, and/or peer review; and problem-solving skills, tools and resources to address problems in the research environment. Participants must complete requirements within three years. The certificate program is designed for research administrators, senior management, executives, and members of review boards who have interests and shared responsibilities associated with the ethical dimensions of research. The program is also recommended for investigators interested in addressing NIH, NSF and DOD requirements specific to research ethics education and training.

For more information, contact the Society of Research Administrators (SRA) Education and Professional Development Officer at (703) 741-0140. Email: info@srainternational.org.

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



Good Laboratory Practices (GLP)

**Best Practice Principles
for Individual Researchers**

Useful (good) research records explain:

- What you did,
- when you did it,
- why you did it,
- how you did it,
- who you are (the person creating the record),
- what project(s) it was a part of,
- who thought of it if not you,
- what special materials and instruments you used,
- where you obtained the materials and instruments,
- what happened and what did not happen (data),
- how you manipulated and analyzed the results,
- your interpretation (and the interpretations of others if important), and

- what will be the next steps in the project based on these results?

In addition, good research records:

- Are legible if handwritten,
- are recorded using reliable materials and tools,
- are well organized (e.g., well labeled, indexed, catalogued, etc.),
- are accurate and complete; they include (1) all original data and important study details (meta-data) and (2) successful and unsuccessful studies and activities,
- describe and date all alterations and changes in records,
- allow repetition of your procedures and studies by yourself and others,
- are accessible (physically and/or electronically) to others both short term and long term,
- are stored and backed-up properly for the short and long term (archiving),
- are witnessed where needed to protect intellectual property rights,
- are in compliance with departmental, institutional, and federal regulatory requirements, with special care given to human and animal research.

Source of the following information is from an article "Academic Research Record-Keeping: Best Practices for Individuals, Group Leaders, and Institutions" Alan A. Schreier, PhD, Kenneth Wilson, PhD, and David Resnik, PhD, JD published in *Academic Medicine*, Vol. 81, No. 1 / January 2006

**If it is not written down
it did not happen.....**

Marilyn M. Marshall, SpM, RQAP-GLP
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News from HIPAA.....

**HHS Adds New Enforcement Data to its
Web Site on HIPAA Privacy
Compliance and Enforcement**

May 9, 2008

In response to continuing interest in HHS enforcement of the HIPAA Privacy Rule, the Office for Civil Rights today made available to the public additional information about these activities.

OCR has added a new data section on its Compliance and Enforcement Web Site. The public

can now access enhanced information about several aspects of OCR's health information enforcement program:

- Charts showing state-specific case investigation results;
- Calendar-year enforcement-results graphs and charts;
- Calendar-year graph showing complaint receipts;
- Yearly variation in the issues in cases resolved through corrective action.

These charts and graphs augment the Web Site's comprehensive information about the Privacy Rule, which creates important federal rights and requirements to protect the privacy of personal health information.

You may access the new OCR data section at: <http://www.hhs.gov/ocr/privacy/enforcement/data.html>. The enhanced Compliance and Enforcement Web Site continues to provide information for consumers, health care providers, health plans, and others in the health care industry, and may be found at: <http://www.hhs.gov/ocr/privacy/enforcement>.

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University of Arizona – Animal Care



Quality Care for Research Animals

The BIO5 Animal Facility is nearing completion, with a projected turn-over date of early July. Once the building is released to UAC, there will be a 3-4 week start-up period by UAC to test equipment and clean and disinfect rooms. There is going to be an additional project in the BIO5—renovation of an animal room into a ABSL-3 suite to accommodate the Department of Immunobiology. Drs. Doetschman and Sanders, along with Tim Ruddy and Casey Kilcullen-Steiner did a noise simulation on the building to determine if the construction project should delay the opening of the animal facility. Noise was evident in the hallway near the cage washer, but noise could not be heard in the GEMM Core Suite or in the animal rooms, which will be commissioned first. Therefore, the decision was made to move animals as soon as possible following the testing phase by UAC.

UAC has submitted an NCCR Improving Institutional Animal Resources Grant, which would

provide for additional IVC caging (ventilated caging) for the BIO5 Animal Facility. If funded, 16 additional IVC units would be purchased for the BIO5 cage inventory.

Linda Musgrave, IACUC Coordinator is leaving the university after nineteen years of outstanding service to the IACUC and research community. Linda is getting married and moving to Oregon. Please join us in wishing Linda well in her new life. Next month, an update regarding changes in the IACUC will be provided in the Newsletter.

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Institutional Biosafety Committee



Institutional Biosafety Committees (IBCs) are the cornerstone of institutional oversight of recombinant DNA research. The following information and resources are provided to help IBCs perform this critical role, as well as to inform others about the roles and responsibilities of these important committees.

Meetings and Conferences

- **Upcoming Workshops and Training Sessions** – The NIH Office of Biotechnology Activities (OBA) conducts workshops, training sessions, and presentations throughout the year. Come back frequently to this site for the latest information on upcoming events.

Frequently Asked Questions (FAQs) of Interest to IBCs

- [Key Definitions and Acronyms](#)
- [NIH Guidelines for Research Involving Recombinant DNA Molecules](#)
- [IBC Roles and Responsibilities](#)
 - [Preparation of, and Access to, Minutes \(May 14, 2004\)](#)
 - [Further Guidance on Preparation of Minutes \(Feb. 23, 2007\)](#)
- [Committee Membership](#)
- [Submitting Committee Information to the NIH Office of Biotechnology Activities](#)
- [Incident Reports](#)
- [Major Actions - Genetic Transfer of Antibiotic Resistance Traits](#)

OBA_NEWS Listserv

- [Subscribe now!](#) Subscribe or browse archives for updates on current initiatives, policies, and news from the OBA.

Questions?

- If you have questions about OBA's activities, interpretations of the *NIH Guidelines*, upcoming meetings, or related matters, do not hesitate to contact OBA staff by [email](mailto:oba@od.nih.gov) at oba@od.nih.gov, or by phone at 301-496-9838.

Links of Interest to IBCs

- [American Biological Safety Association](#)
 - [Biosafety Discussion List](#)
- [American Society for Microbiology](#)
- [American Society of Gene Therapy](#)
- [Association for Assessment and Accreditation of Laboratory Animal Care International](#)
- [Association for the Accreditation of Human Research Protection Programs](#)
- [Biosafety in Microbiological and Biomedical Laboratories \(CDC and NIH\)](#)
- [Centers for Disease Control and Prevention](#)
 - [Select Agent Program](#)
- [Department of Health and Human Services](#)
 - [Secretary's Advisory Committee on Xenotransplantation \(DHHS\)](#)
 - [Office of Human Research Protections \(DHHS\)](#)
- [Federal Register On-line](#)
- [National Science Advisory Board on Biosecurity \(NSABB\)](#)
- [National Institutes of Health](#)
 - [Office of Biotechnology Activities \(Home page\)](#)
 - [Biosafety Considerations for Research with Lentiviral Vectors](#)
 - [Human Gene Transfer Protocol List \(OBA\)](#)
 - [NIH Guidelines for Research Involving Recombinant DNA Molecules](#)
 - [Safety Considerations in Recombinant DNA Research with Pathogenic Viruses](#)
 - [Office of Laboratory Animal Welfare \(NIH\)](#)
- [Risk Group Classification for Infectious Agents \(ABSA\)](#)
- [USDA Animal and Plant Health Inspection Service](#)

Source:

<http://www4.od.nih.gov/oba/IBC/IBCindexpg.htm#O.%20Meetings%20and%20Conferences>



Radiation Control



Radioactive Labeled Equipment

By Crystal Morris

The Radiation Control Office has had several incidences where equipment labeled as radioactive is loaned out to non radiation use labs or is shipped to surplus. Equipment, such as refrigerators, freezers, incubators, or centrifuges, has the potential to be contaminated when using radioactive material. This equipment must be labeled with a radioactive material sticker or tape. After the equipment is no longer needed for use with radioactive material the equipment should be surveyed, clean of any radioactive contamination, and the labels removed. Be sure to discard the radioactive material labels in the radioactive material trash or deface them before putting them in the regular trash. Radioactive Material Approval Holder's must survey and remove radiation labels from any equipment before relinquishing it back to their department or sending it to surplus. If equipment is transported by a vehicle or a non-radiation worker, it must be surveyed and have the labels removed or covered. If you do not have a radioactive material approval and receive equipment labeled radioactive, prior to using it, please contact the Radiation Control Office at 626-6850 or rcohelp@u.arizona.edu.

HUMAN SUBJECTS PROTECTION PROGRAM

⇒Highlights⇐

Expedited Review*

This article is the last of three articles that focus on expedited review procedures. As previously presented, the Department of Health and Human Services (DHHS) and The Food and Drug Administration (FDA) acknowledge that not all research with humans requires review by a Full Committee. Regulations allow the review of minimal risk research to be conducted by the Institutional Review Board (IRB) Chair or another board member designated by the IRB Chair.

The list of nine categories eligible for expedited review are briefly summarized as follows:

- (1) Clinical studies of drugs and medical devices only when (a) research on drugs for which an investigational new drug applica-

tion is not required; or (b) research on medical devices for which an investigational device exemption application is not required or the medical device is cleared/approved for marketing and the medical device is being used in accordance with its cleared/approved labeling.

- (2) Collection of blood samples by finger stick, heel stick, ear stick, or venipuncture (must meet collection criteria).
- (3) Prospective collection of biological specimens for research purposes by noninvasive means.
- (4) Collection of data through noninvasive procedures (not involving general anesthesia or sedation) routinely employed in clinical practice, excluding procedures involving x-rays or microwaves. Where medical devices are employed, they must be cleared/approved for marketing.
- (5) Research involving materials (data, documents, records, or specimens) that have been collected for any reason or will be collected solely for nonresearch purposes (such as medical treatment or diagnosis).
- (6) Collection of data from voice, video, digital, or image recordings made for research purposes.
- (7) Research on group characteristics or behavior (including but not limited to, research on perception, cognition, motivation, identity, language, communication, cultural beliefs or practices and social behavior) or research employing survey, interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies.
- (8) Continuing review of research previously approved by a convened IRB as follows (a) where the research is permanently closed to the enrollment of new subjects, all subjects have completed all research-related interventions; and the research remains active only for the long term follow-up of subjects; or have been identified or when the remaining research activities are limited to data analysis.
- (9) Continuing review of research not conducted under an investigational new drug application or investigational drug exemption where categories 2 through 8 do not apply but the IRB has determined and documented at a convened meeting that the research

involves no greater than minimal risk and no additional risks have been identified.

The website found at <http://www.hhs.gov/ohrp/humansubjects/guidance/expedited98.htm> gives additional information and guidance regarding the nine categories mentioned above. Whether or not the research meets the criteria for an expedited review is determined by application of the regulations as well as whether ethically based standards are met.

***Oki, G. & Zaia, J. (2002). Expedited IRB Review. In R.J. Amdur and E. A. Bankert (Eds.), Institutional Review Board: Management and Function (pp. 114-117) Sudbury, MA: Jones and Bartlett.**

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Upcoming Conferences/Workshops

June 8-13, 2008

<http://www.survival.pitt.edu/events/trainer.asp>
14th Annual Trainer-of-Trainers Conference
Teaching Survival Skills and Ethics
Silvertree Hotel
Snowmass, Colorado

July 23, 2008

[Public Service, Public Trust: Deepening the Experience of Research Integrity for Medical Scientists and Clinicians](#)
Bethesda, MD
Co-Sponsor: Uniformed Services University

September 17, 2008

[A Research Integrity Education Conference for the Federal Nursing Community](#)
Bethesda, MD
Co-Sponsor: Uniformed Services University

October 2-3, 2008

Fostering International Research Collaborations
Co-Sponsor: University of Minnesota
Minneapolis, MN

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Words of Wisdom:

“My father didn't tell me how to live; he lived, and let me watch him do it.”

— Clarence B. Kelland