
University of Arizona Program in Research Integrity Education Monthly Newsletter

A Federally Mandated Compliance Education Program

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At the University of Arizona we continue to strive for success in educating our scientific community in the execution of ethical research. This newsletter is one avenue in which we instruct our research community regarding integrity in research. We trust you will find the following information enlightening and helpful.

What is Ethics in Research & Why Is It Important

by David B. Resnik, J.D., Ph.D.

Promoting Ethical Conduct in Science

Many of you may be wondering why you are being required to have training in research ethics. You may believe that you are highly ethical and know the difference between right and wrong. You would never fabricate or falsify data or plagiarize. Indeed, you also may believe that most of your colleagues are highly ethical and that there is no ethics problem in research.

If you feel this way, relax. No one is accusing you of acting unethically. Indeed, the best evidence we have shows that misconduct is a very rare occurrence in research. There have been 200 confirmed cases of misconduct in federally funded research in the last 200 years, which works out to a rate of 1 in 10,000 (or 0.01%). Of course, this estimate may be extremely low due to various biases related to under-reporting. Several studies have surveyed researchers to ask them whether they have observed misconduct or know about a case of suspected misconduct. There is a great deal of variation in these results, ranging from 3% to 12% who say they have observed misconduct or know about a case of suspected misconduct. These results, though much higher than 0.01%, still do not support the hypothesis that is common in science, especially when you consider these results in relation to the larger body of research. If 5-10% of drivers have witnessed a fatal traffic accident, this does not prove that fatal traffic accidents are common, if you consider this in light of total numbers of hours that people drive.

Clearly, it would be useful to have more data on this topic, but so far there is no evidence that science has become ethically corrupt. However,

even if misconduct is rare, it can have a tremendous impact on research. Consider an analogy with crime: it does not take many murders or rapes in a town to erode the community's sense of trust and increase the community's fear and paranoia. The same thing is true with the most serious crimes in science, i.e. fabrication, falsification, and plagiarism. However, most of the crimes committed in science probably are not tantamount to murder or rape. Most of the crimes in science, like most of the crimes in society, are probably the less serious but ethically significant misdeeds that are classified by the government as 'deviations.' Moreover, there are many situations in research that are genuine ethical dilemmas.

Will training and education in research ethics help reduce the rate of misconduct in science? It is too early to tell. The answer to this question depends on how one understands the causes of misconduct. There are two main theories about why researchers commit misconduct. According to the "bad apple" theory, most scientists are highly ethical. Only researchers who are morally corrupt, economically desperate, or psychologically disturbed commit misconduct. Moreover, only a fool would commit misconduct because science's peer review system and self-correcting mechanisms will eventually catch those who try to cheat the system. In any case, a course in research ethics will have little impact on "bad apples," one might argue. According to the "stressful" or "imperfect" environment theory, misconduct occurs because various institutional pressures, incentives, and constraints encourage people to commit misconduct. Often cited here pressures to publish or obtain grants or contracts, career ambitions, the pursuit of profit or fame, poor supervision of students and trainees, and poor oversight of researchers. Moreover, defenders of the stressful environment theory point out that science's peer review system is far from perfect and that it is relatively easy to cheat the system. Erroneous or fraudulent research often enters the public record without being detected for years. To the extent that research environment is an important factor in misconduct, a course in research ethics is likely to help people to get a better understanding

of these stresses, sensitize people to the various ethical concerns, and improve ethical judgment and decision making.

Misconduct probably results from environmental and individual causes, i.e. when people who are morally weak, ignorant, or insensitive are placed in stressful or imperfect environments. In any case, a course in research ethics could still be useful in helping to prevent deviations from norms even if it does not prevent misconduct. Many of the deviations that occur in research may occur because researchers simply do not know or have never thought seriously about some of the ethical norms of research. For example, some unethical authorship practices probably reflect years of tradition in the research community that have not been questioned seriously until recently. If the director of a lab is named as an author on every paper that comes from his lab, even if he does not make a significant contribution, what could be wrong with that? That's just the way it's done, one might argue. If a drug company uses ghostwriters to write papers "authored" by its physician-employees, what's wrong about this practice? Ghost writers help write all sorts of books these days, so what's wrong with using ghostwriters in research?

Another example where there may be some ignorance or at least some mistaken traditions is the problem of conflicts of interest in research. A researcher may think that a "normal" or "traditional" financial relationship, such as accepting stock or a consulting fee from a drug company that sponsors her research, raises no serious ethical issues. Or perhaps a university administrator sees no ethical problem in taking a large gift with strings attached from a pharmaceutical company. Maybe a physician thinks that it is perfectly appropriate to receive a \$300 finder's fee for referring patients into a clinical trial.

If "deviations" from ethical conduct occur in research as a result of ignorance or a failure to reflect critically on problematic traditions, then a course in research ethics may help reduce the rate of serious deviations by improving the researcher's understanding of ethics and by sensitizing him or her to the issues.

Finally, training in research ethics should be able to help researchers grapple with ethical dilemmas in that it introduces researchers to some important concepts, tools, principles, and methods that can be useful in resolving these dilemmas. In

fact, the issues have become so important that the NIH has decided that all intramural researchers should receive training in research ethics. We will try to make the process as painless and interesting as possible.

Source: Excerpted from the National Institute of Environmental Health Sciences - NIH (NIEHS) web site. You will find the complete article at: <http://www.niehs.nih.gov/research/resources/bioethics/whatis.cfm>

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



Good Laboratory Practices (GLP)

The start of the fall semester is an excellent time to discuss and review laboratory documentation with all new and continuing laboratory personnel.

Lab notebooks:

- Pages consecutively numbered
- All entries recorded in ink
- Entries should be legible
- Sign and date each page
- Notebooks should be reviewed by PI at prescribed intervals
- Corrections can be made by crossing out error and recording correct information, reason for correction, sign and date correction.

Checklists:

- Should be placed on freezers and refrigerators and temperatures recorded at least once a day
- Can be used for any procedure to document when and how data was acquired
- All boxes should be filled in or if no data was recorded, a line drawn through the data box
- Sign and date all checklists
- Archive all checklists in project file

Documentation is a continuous process designed to assure that raw data is recorded legibly, promptly and attributable for project excellence.

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



Radiation Control



New Radioactive Material Approval Forms

by Crystal Morris

In order to use Radioactive Material (RAM) at any University of Arizona facility you must first apply and receive permission from the Radiation Safety Committee. All protocols involving radioactive material are reviewed by a Radiation Safety Committee and the committee will grant an Approval for use as requested. The forms used to apply for an approval or amend an existing approval for RAM or sealed sources have undergone major revisions. The "Application for Radioactive Material Approval" form is now four, specific forms:

- Application for New Radioactive Material Approval (RC-010NR)
- Application for New Sealed Source Approval (RC-010NS)
- Application to Amend Radioactive Material Approval (RC-010AR)
- Application to Amend Sealed Source Approval (RC-010AS)

These forms have been updated to simplify and expedite the application process. The original form was separated into four new forms to be more specific to their use. This is congruent to the changing requirements of the application process. The changes also reflect updates being made in the radiation safety training courses. All the forms and their instructions can be found on the Radiation Control Office website www.radcon.arizona.edu. If you have any suggestions or comments on the use of the application forms, please contact Crystal Morris at 626-5099.



News from HIPAA.....

HHS, Providence Health & Services Agree on Corrective Action Plan to Protect Health Information

The U.S. Department of Health & Human Services (HHS) has entered into a Resolution Agreement with Seattle-based Providence Health & Services (Providence) to settle potential violations of the Health Insurance Portability and Accountability Act of 1996 (HIPAA) Privacy and Security Rules. In the agreement, Providence

agrees to pay \$100,000 and implement a detailed Corrective Action Plan to ensure that it will appropriately safeguard identifiable electronic patient information against theft or loss.

The Privacy and Security Rules are enforced by HHS' Office for Civil Rights (OCR) and the Centers for Medicare & Medicaid Services (CMS). The Privacy and Security Rules require health plans, health care clearinghouses and most health care providers (covered entities) to safeguard the privacy of certain individually identifiable health information and meet additional security standards for patient information maintained in electronic form. The Resolution Agreement relates to Providence's loss of electronic backup media and laptop computers containing individually identifiable health information in 2005 and 2006.

Winston Wilkinson, the director of the OCR, stated, "We are committed to effective enforcement of health information privacy and security protections for consumers. Other covered entities that are not in compliance with the Privacy and Security Rules may face similar action."

While OCR and CMS have successfully resolved over 6,700 Privacy and Security Rule cases by requiring the entities to make systemic changes to their health information privacy and security practices, this is the first time HHS has required a Resolution Agreement from a covered entity. Providence's cooperation with OCR and CMS allowed HHS to resolve this case without the need to impose a civil money penalty.

Director Wilkinson noted, "We commend Providence for their cooperation during the course of the investigation and for their voluntary implementation of comprehensive and system-wide improvements to protect individually identifiable health information."

The incidents giving rise to the agreement involved two entities within the Providence health system, Providence Home and Community Services and Providence Hospice and Home Care. On several occasions between September 2005 and March 2006, backup tapes, optical disks, and laptops, all containing unencrypted electronic protected health information, were removed from the Providence premises and were left unattended. The media and laptops were subsequently lost or stolen, compromising the protected health information of over 386,000 patients. HHS received over 30 complaints about the stolen tapes and disks, submitted after Providence, pursuant to state notification laws, informed patients of the theft. Providence also reported the stolen media to

HHS. OCR and CMS together focused their investigations on Providence's failure to implement policies and procedures to safeguard this information.

Under the Resolution Agreement, Providence agrees to pay a \$100,000 resolution amount to HHS and implement a robust Corrective Action Plan that requires: revising its policies and procedures regarding physical and technical safeguards (e.g., encryption) governing off-site transport and storage of electronic media containing patient information, subject to HHS approval; training workforce members on the safeguards; conducting audits and site visits of facilities; and submitting compliance reports to HHS for a period of three years.

"The protection of patient information is a top priority for Providence Health & Services," stated Providence's Chief Information Security Officer Eric Cowperthwaite. "Since these incidents occurred, we have reinforced our security protocols and implemented new data protection measures. Under the terms of the agreement, we will continue to implement appropriate policies, procedures and training."

Kerry Weems, the acting administrator of CMS, commented, "This resolution confirms that effective compliance means more than just having written policies and procedures. To protect the privacy and security of patient information, covered entities need to continuously monitor the details of their execution, and ensure that these efforts include effective privacy and security staffing, employee training and physical and technical features."

The Resolution Agreement and Corrective Action Plan can be found on the OCR Web site at <http://www.hhs.gov/ocr/privacy/enforcement/>.

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University of Arizona – Animal Care



Quality Care for Research Animals

Brief Update:

UAC:

The BIO5 Animal Facility is expected to open in September. Initially, once turned over to UAC, a testing period of approximately three-four

weeks will be conducted. All animal rooms will have to be stocked with supplies and equipment, and all areas must be disinfected. The cage wash facility will have to be stocked and tested. Equipment for outfitting the rooms and cage wash is on order. A meeting has been held to determine the operating procedures for the building and will shortly be available to all researchers.

IACUC:

The IACUC Office is being supported by Mary Durham and Andrea Mitchell. These individuals can be contacted at 621-9305 or email to iacuc@email.arizona.edu.

A number of changes have been made in the operation of the IACUC and these will be shared in the next newsletter.

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HUMAN SUBJECTS PROTECTION PROGRAM

≧Highlights≦

Evaluating Study Design*

Questions frequently arise as to the Institutional Review Board's (IRB) authority to evaluate study design and study quality. For example, is it appropriate for the IRB to vote not to approve a study because previously completed research has answered the research question? Or, should the IRB question the statistical power calculation used to determine the number of subjects in a study? Many members of the research community believe it is not the role of the IRB to routinely evaluate the quality of the science of a research project.

This article will explain the role of the IRB in evaluating study design. The IRB acts in accordance with federal regulations and makes decisions that support the ethical principles found in the Belmont Report. The ideas presented in the Belmont Report emphasize that (a) the study is designed so that the risks to subjects are minimized, and (b) the potential benefits of the research justify the potential risks.

Additionally, several sections of the Nuremberg code (1949) address scientific quality/design and risk/benefit. According to point 3 of Nuremberg "the experiment should be so designed and based on the results of animal experimentation and a knowledge of the natural history of the disease or other problem under study that the

anticipated results will justify the performance of the experiment.” The Declaration of Helsinki (2000) also addresses specific aspects of study design and IRB review. The Department of Health and Human Services (DHHS) and the Food and Drug Administration (FDA) regulations require that the Institutional Review Board (IRB) will determine that the study is designed so that risks to subjects are minimized and justified by potential benefits (45 CFR 46.111).

If revising the study design will meaningfully decrease risk to subjects then the IRB should recommend to the Principal Investigator that the design be altered. There are also situations where the study should not be approved. Examples include research where the design is so detrimental to subjects that the value of the study results will be almost zero. Or, when the question to be answered by the study is not important or has already been answered.

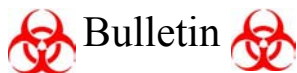
It is important to remember that in institutions where student research is conducted, the design may not always be optimal. However, in these cases, the risk to subjects is often zero. The IRB might wish to recommend revisions to the study design. However, in the absence of risk, there is really no ethical justification for the IRB to make such revisions a requirement for IRB approval.

The IRB is under federal regulation and ethical requirements to evaluate study design and other aspects of the quality of the study because quality of the study design affects the rights, safety and welfare of the study subjects.

***Amdur, R. (2002). Evaluating Study Design and Quality. In R.J. Amdur and E. A. Bankert (Eds.), Institutional Review Board: Management and Function (pp. 152-153) Sudbury, MA: Jones and Bartlett.**

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Institutional Biosafety Committee



Biosafety in Microbiological and Biomedical Laboratories (BMBL) 5th Edition

U.S. Department of Health and Human Services
Centers for Disease Control and Prevention
and National Institutes of Health
Fifth Edition, Feb 2007

US Government Printing Office
Washington: 2007

Complete 5th Edition of BMBL (All Sections)



(PDF - 2.4 MB)

NOTE: - Printed booklets, HTML and Spanish versions not yet available

Source:

<http://www.cdc.gov/OD/OHS/biosfty/bmb15/bmb15toc.htm>

Upcoming Conferences/Workshops

September 14-17, 2008

18th National Radon Training Conference

Theme: Growing Radon Leaders

<http://www.crcpd.org/2008RnMtg.asp>

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

October 19-24, 2008

IRPA 12 – Buenos Aires, Argentina

October 19-24, 2008

13th Annual Congress of the International Radiation Protection Agency (IRPA)

<http://www.irpa12.org.ar/index.php>

May 15-17, 2009

Fifth Biennial Research Conference on Research Integrity
Niagara Falls, NY

Co-Sponsor: University of Minnesota

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Words of Wisdom:

"Fairest of the months!

Ripe summer's queen

The hey-day of the year

*With robes that gleam with
sunny sheen*

Sweet August doth appear."

~ R. Combe Miller