
University of Arizona Program in Research Integrity Education Monthly Newsletter

A Federally Mandated Compliance Education Program

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The article below was published in the journal *The Scientist* in February, 2006, and is entitled, “*Lies, Damn Lies...and Scientific Misconduct.*” The author is Glenn McGee*. We trust you will benefit from reading this timely piece.

Also featured are updates from the University of Arizona Research Support Services Group (RSSG) units. In addition, many research ethics training opportunities are provided.

Lies, Damn Lies... and Scientific Misconduct

It's time for a revolution
in the ethics of research

From *The Scientist*

Volume 20 | Issue 2 | Page 24

Author: Glenn McGee*

Merriam Webster reports that in 2005, “integrity” received more hits than any other word in their online dictionary. It’s not clear how many more hits scientific integrity can take: An MIT researcher is fired for fabricating a dozen papers. A pharmaceutical company omits data from key publications about side effects. A South Korean stem cell researcher admits to a stunned nation that, “blinded by work and a drive for achievement,” he submitted a “fake it before you make it” article to *Science*. It appears that research misconduct has taken its place among the epidemics that scientists need to worry about.

An aphorism attributed to Mark Twain holds that there are three kinds of lies: lies, damn lies, and statistics. At first the public points to a bad apple who paints mice, or switches out slides, and fumes if the researcher conspires to hide it. But it takes a village to do big science: authors, collaborators, students, sponsors, regulators; different languages, different countries, disparate goals. A lone scientist can offer mea culpa, but fraud on the scale of South Korea’s almost always involves collusion and conspiracy, hidden in the complexity of the research. It is a nightmare for scientific journals, but more than anything it terrifies the public.

Science depends on public support. Too often Hollywood sends the message to a fickle public that

scientists-cum-fundraisers cannot be trusted to make what Malcolm Gladwell calls “blink” judgments about recruitment of egg donors, or to review thousands of pages of data. In the wake of the Hwang scandal in Korea, stem cell researchers who had been worshipped as heroes scraping for support become “rogues blinded by ambition.” Those waging jihad against stem cell research talk about tangled webs, and they ask how far it is from an exaggeration of the results to an exaggeration of the benefits of embryonic cell research.

The solution to what the public – incorrectly – perceives as an epidemic of scientific misconduct is not obvious. Public relations is not the answer. Scientists who have spoken publicly about the Hwang matter have only made things worse. There are dozens of commissions on research ethics and programs to provide certification in it. There are conferences, journals, and agencies. Companies post ethics codes in hallways. Government pressure for compliance depends on funding, and in the United States, there’s scant funding for stem cell research.

The great hope lies in teaching new generations of scientists, yet there’s no evidence that it has an effect on the rate of misconduct. Scare tactics about the fate of Woo-suk Hwang will not transform those who enter graduate school ready to fabricate results, particularly when students report that their mentors could care less about the ethics course.

Nothing will prevent Dr. Jekyll from becoming Mr. Hyde, but mentors and oversight can help vulnerable newbies to science eschew bad habits. Researchers learn what is important by watching the boss; perhaps the boss should learn to teach the integrity course using lessons from the lab. Funding and institutional review-board approval should depend less on consent forms and more on ethics training and strategy. University compliance should emphasize remediation for those who play with matches rather than punishment for burning down the house.

Ultimately we don’t have any clue what works, but it’s a safe guess that the institutions that innovate in research ethics and study outcomes will be the ones that prevent misconduct. If we’re going to throw

buckets of money at frontier science, we'd better throw a little bit more at finding the best ways to help new scientists do it responsibly.

*Glenn McGee is the director of the Alden March Bioethics Institute at Albany Medical College, where he holds the John A. Balint Endowed Chair in Medical Ethics.

**UNIVERSITY OF ARIZONA
RESEARCH AND SERVICE GROUP (RSSG)**

**HUMAN SUBJECT
PROTECTION PROGRAM**

≡Highlights≡

**Banking of Human Biological
Materials for Research**

Researchers in the 21st century face many challenges not the least of which is learning to establish repositories or banks for human biological materials. This article describes basic information regarding the collection, storage and distribution of biological materials for research.

Collection of biological materials

Human biological materials range from tissue samples to blood, sputum, urine, bone marrow, and cell aspirates. Commonly these materials are referred to as “specimens”.

Specimens may be in existence at the time of the research and archived for clinical purposes, obtained during a research study and stored for future use, or may need to be fresh and require prospective collection. Both existing and prospectively collected specimens can be stored in repositories or banks.

Repositories can vary in size from small collections under control of one or two individuals to large collections under the control of a department or large multi-site research project.

Storage of biological materials

One of the first recommendations for setting up a repository or bank is to establish policies that guarantee the security and confidentiality of specimens and any data associated with the samples. It is important to consider who will have access to the stored specimens and how identifiable information will be kept confidential. The researcher may want to consider obtaining a Certificate of Confidentiality as added protection for banked specimens.

Distribution of biological materials

Procedures should also be established for the distribution of specimens to other researchers. One recommendation is that specimens be anonymized

prior to their distribution. Anonymized means that specimens were originally collected with a direct identifier but that identifier has been irretrievably stripped away. Specimens can also be obtained in such a way that identifiable information was never collected. These types of specimens involve the lowest level of risk. Banked specimens may also be stored with codes or numbers attached which link them to identifiable data.

There is justification for use of tissues obtained **clinically** for research. However, unless a compelling rationale can be given by the researcher for the use of coded or linked specimens they should be anonymized prior to distribution.

Additionally, specimens may have been obtained during one research study, banked in a repository and are now being requested for use in another research project. It is important for the researcher to take a thorough look at the original consent form in order to comply with the wishes of the subject with regard to future use. These specimens may contain codes or numbers that link them to identifiable information. Prior to distribution for future research these biological materials should be anonymized.

After a repository has received review and approval by an Institutional Review Board (IRB), each subsequent study involving the specimens housed in the repository will require an independent review by the IRB. The researcher plays a critical role in ensuring that use of human biological materials are conducted in an ethical manner that protect the subjects from whom they were obtained.

*Sobel, M. & Hansen, K. (2005). Banking of Human Biological Materials for Research. In E. A. Bankert and R. J. Amdur (Eds.), Institutional Review Board Management and Function (pp. 433-437). Sudbury, MA: Jones and Bartlett.

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



Always keep the following tips in mind:

- It is best to keep research and office areas secured at all times.
- If you work in or around a research area, wear identification and be prepared to present it. If you see people in your research area not displaying an ID card, ask them if they need assistance.

- Non-staff people in a research area should be escorted by a staff member at all times.
- You know your work areas the best. Do not handle suspicious or unknown packages.
- Watch your area for strangers and unusual activity. If you see someone unknown to you in a research area, ask him or her if you can help.
- Be particularly aware of vehicles that have been left unattended near university buildings.
- Watch for doors or windows that have been propped open or marked with graffiti.
- Back-up valuable computer data and store it off site.
- Change the password on sensitive databases, using a combination of symbols and upper and lower case letters.
- Be cautious of unusual e-mail messages and do not open unfamiliar attachments.
- Monitor your web site for potential defacement.



News from HIPAA.....

Final HIPAA Enforcement Rule

The Final HIPAA Enforcement Rule (“Final Rule”) has been published, and may be accessed on the Office for Civil Rights (OCR) web site (<http://www.hhs.gov/ocr/hipaa/>) by clicking on “Final Enforcement Rule Published.” The Final Rule, which takes effect March 16, 2006, adopts unified enforcement procedures for the Privacy Rule and the other HIPAA Administrative Simplification rules, such as the Security Rule. In addition, the Final Rule establishes procedural and substantive requirements for the imposition of civil money penalties (“CMPs”) for violations of the HIPAA provisions. The adoption of the Final Rule completes the regulatory enforcement structure begun when the Privacy Rule was issued in 2000 and expanded by the interim final procedural enforcement rules issued in 2003.

There will be more information on the “Final Rule” from Jeniece Poole, UA Privacy Officer, in the April, 2006 P.R.I.E. Newsletter. You may contact Jeniece at 621-1465, or by emailing her at: jpoole@email.arizona.edu.



Good Laboratory Practices (GLP)

Academic research record-keeping is the topic of an article in *Academic Medicine*¹ which states that **good record-keeping is central to the scientific process** and discusses.....*Best Practices for*

Individuals, Group Leaders, and Institutions.

Stated Problem.....

- Half the officials who reported experience with misconduct cases at their institutions also reported that they had been hampered in their inquires/investigations by **inadequate research records**.
- NIH funded studies investigators surveyed on the prevalence of questionable research practices noted that 27% of the 3,247 respondents admitted to “**inadequate record-keeping related to research projects.**”

The article presents a new synthesis of best practices to the research community as a potential aid in thinking about the challenges of record keeping in the first decades of the 21st century.

The article offers a guide in the development of better practices among research group leaders, as well as to encourage departments and institutions to adopt practices and policies that will aid research group leaders in their responsibility to keep good records.

¹ Academic Research Record Keeping: Best Practices for Individuals, Group Leaders, and Institutions. AL Schreier, K Wilson, and D. Resnik. *Academic Medicine*. Vol. 81, No1/January 2006/pages 42-47.



[Academic Research Record Keeping.pdf](#)

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Institutional Biosafety Committee



Bulletin



Calling all Researchers -
Have You Completed the
Annual Biosafety Declaration?

The Institutional Biosafety Committee (IBC) has recently launched a program known as the Annual Biosafety Declaration. This program requires *all* researchers who work with *biological material and/or toxins* to identify the level of biosafety they use within their laboratories. The form may be accessed at: <http://mua.abc.arizona.edu/declaration/>.

The biosafety levels are Biosafety Level One (BSL-1), Biosafety Level Two (BSL-2) or Biosafety Level Three (BSL-3). These specific biosafety levels are important, as they create varying levels of *institutional requirements* for both

laboratory practices and physical containment, based upon the actual risks of a laboratory acquired infection.

For more information, please contact Mark Grushka, Manager, Biosafety and Biosecurity at 621-5279, or email: mgrushka@u.arizona.edu.



Radiation Control

Reception Honoring Mel Young's Retirement

After 30 years of service, Dr. Melvin C. Young has decided to retire from The University on April 11, 2006. Dr. Young started his career with the Radiation Control Office in 1976. He has been instrumental in the development of the Radiation Safety Program.

We are grateful for Mel's contributions to the Radiation Control Office. Please join us in wishing Mel farewell at a reception/open house in his honor on Wednesday, April 5, from 12 pm to 2 pm at the Radiation Control Office, Babcock Building, Bldg. 1, Suite 1201.

Upcoming Conferences/Workshops

Promoting Research Integrity in Social and Behavioral Sciences Conference

Friday March 31, 2006
8:00 a.m. to 5:00 p.m.

At the University of Texas
at San Antonio Downtown Campus

The University of Texas at San Antonio (UTSA) is collaborating with the U.S. Office of Research Integrity (ORI) and the American Association of State Colleges and Universities to host a one-day conference on Promoting Research Integrity, targeting non-medical institutions and faculty in the social and behavioral sciences on March 31, 2006.

The conference is organized around a morning of federal speakers from The Office of Research Integrity, the National Institutes of Health (NIH), and the National Science Foundation (NSF).

The afternoon will focus on current practices at the institutional level and will be comprised of two tracks (for administrators and faculty, respectively), both of which are designed to promote vigorous audience participation.

On-line registration is available at:
<https://www.utsa.edu/research/ORIconference/registration.cfm>.

For more details about the UTSA/ORI conference, including hotel information and program agenda, please see the following web site:

<http://www.utsa.edu/research/ORIconference/index.cfm>.

Quality Assurance Professionals in Good Laboratory, Good Clinical and Good Manufacturing Practices

Please join us for the 22nd SQA Annual Meeting and Preconference Training

Sunday - Thursday, 23 - 27 April 2006
Pointe South Mountain Resort, Phoenix, AZ

Preliminary Registration is now available!
Please visit the [Registration](#) page for details!
Register by **27 March 2006** and save \$60 - \$220!

Teaching Research Ethics – Thirteenth Annual Workshop at Indiana University, May 10-13, 2006

The thirteenth annual Teaching Research Ethics Workshop will be held at Indiana University from May 10-13, 2006. Session topics include an overview of ethical theory, trainee and authorship issues, conflicts of interest, using human subjects in clinical and non-clinical research, and responsible data management. Information and registration are available at: <http://poynter.indiana.edu/tre>.

OPPORTUNITIES FOR ON-LINE ETHICS TRAINING

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. You may view more course information at the following web address: <http://poynter.indiana.edu/sas/lb/>. You may also contact Kara Lochridge by calling: (812) 856-4968, or via email at: klochrid@indiana.edu.

Online Educational Resources from the American Medical Association

The AMA's national initiative on *The Communication of Ethical Guidelines for Gifts to Physicians from Industry* offers 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.

The four free modules include:

1. Overview of Ethical, Professional, and Legal Issues for Physicians' Relationships with Industry

[Online self-study](#) [Downloadable resources for educators](#)

2. Physicians' Expectations of Industry and Sales Personnel

[Online self-study](#) [Downloadable resources for educators](#)

3. Professionalism and Gifts to Physicians from Industry

[Online self-study](#) [Downloadable resources for educators](#)

4. American Medical Association Ethical Guidelines on Gifts to Physicians from Industry

[Online self-study](#) [Downloadable resources for educators](#)

The 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.

Physicians can earn AMA PRA category 1 credit for the online self-study version. Local sites can issue CME credit for the classroom version of the downloadable educational modules.

Visit the following web address for more details: <http://www.ama-assn.org/ama/pub/category/8405.html>.

Fellowships Available

**Teaching Survival Skills and Ethics -
Travel Fellowships**

The 12th Annual Conference on Teaching Survival Skills and Ethics is offering travel fellowships to support the attendance of individuals at the 12th Annual Conference on Teaching Survival Skills and Ethics to be held June 11-16, 2006, in Snowmass, Colorado. This 5-day trainer-of-trainers conference, which is funded by the National Institutes of Health, is designed to prepare faculty and administrators to establish or improve instruction in the responsible conduct of research and in professional development (e.g., writing research

articles and grant applications; making oral presentations and teaching; funding employment; hiring, supervising, and mentoring).

There are a number of conference fellowships available, which cover travel, lodging, food, and all but \$350 of the registration fee.

For more information, please contact Beth A. Fischer or Michael J. Zigmond, Co-directors, Survival Skills and Ethics Program, University of Pittsburgh; Phone: 412-578-3716, FAX: 412-578-3790, survival@pitt.edu.

RRI Conference Abstract Due April 28, 2006

ORI is planning to hold the 4th Research Conference on Research Integrity from December 1-3, 2006, in Tampa, FL.

The biennial conference provides researchers with an opportunity to discuss crucial research problems, explore research methods, and to share research integrity and deterring research misconduct.

Preference will be given to original investigators that open research areas, use new research methods, or provide new insights into recognized research problems. Proposals for theoretical or methodological presentations, historical analyses, and interpretive literature reviews will also be considered.

Abstracts for papers, poster sessions, panel discussions, and working groups should be submitted electronically by April 28, 2006. Please see the ORI web site for details on submitting abstracts and conference schedule as it develops at <http://ORI.hhs.gov>. Questions should be sent to Nick Steneck at nsteneck@umich.edu.

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

Words of Wisdom:

"The most exciting phrase to hear in science, the one that heralds new discoveries, is not 'Eureka!' ('I found it!') but rather 'hmm....that's funny...'"

— Isaac Asimov