
University of Arizona Program in Research Integrity Education Monthly Newsletter

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A Message from the Director **Thomas P. Davis, Ph.D.**

I am pleased to present the article below, “*Setting the Stage for Modeling Ethical Behavior*,” by Jerry Brown, Programs Manager at the Ethics Resource Center (ERC) located in Washington, D.C. The ERC is a nonprofit, nonpartisan educational organization whose **vision** is a world where individuals and organizations act with integrity. This is a very worthwhile and timely vision.

The internet web address for the ERC is: <http://www.ethics.org/>. I urge you to visit this web site as it has been a great source of information for the Program in Research Integrity Education.

Setting the Stage for Modeling Ethical Behavior

By: *Jerry Brown*
Ethics Resource Center 2003

Modeling is a powerful leadership strategy where you show your employees through your own behavior how you want them to behave with others. This article includes some practical tips for modeling ethical conduct.

A standard refrain heard often when business conduct is discussed is that leaders need to model ethical behavior for their employees.

Modeling is a powerful leadership strategy where you show your employees through your own behavior how you want them to behave with others. It has been used successfully to demonstrate flexibility, politeness, decisiveness, compassion, sharing and numerous other desirable traits. It also works extremely well as an ethics-teaching tool.

In fact, one of the principal findings of the Ethics Resource Center's 2000 National Business Ethics Survey was that the modeling of ethical behavior by organizational leaders, managers, supervisors and coworkers sets a good example for desired business behavior. When employees perceive formal and informal leaders are ethical, they:

- Feel less pressure to compromise ethical standards;
- Observe less misconduct on the job;
- Are more satisfied with their organization overall; and,
- Feel more valued as employees.

In other words, organizational ethics become real for employees when they see good ethics being applied.

The problem with modeling is that all too often the audience present when ethical dilemmas arise is small, and the modeled behavior is **missed** by the majority of employees who are engaged with activities elsewhere. So, how can a leader multiply the effectiveness of modeling? Set the stage in advance and then make sure you discuss observed behavior that models good ethical conduct.

Make it acceptable to talk about ethics. As a topic, ethics has taken on a negative patina. The multitude of scandals and ethical shortcomings reported in the press paint a depressing picture of individuals who skirt their responsibilities or ignore conduct guidelines to the detriment of their organizations. Sadly, there are countless examples of modeled behavior of good ethical conduct that never see the light of day.

- Take time during a staff meeting or other group event to commend someone on demonstrated ethical conduct;
- Talk about ethical conduct routinely and encourage your employees seek guidance whenever they question whether or not an act is ethical;
- Keep the lines of communication open. When someone wants to talk about an ethical issue, the time to talk about it is then.... not at some future date. Pushing the discussion off to later diminishes the importance you are trying to place on ethics.

Create a habit of repeating organizational lore. In every organization, there are stories of individuals who have gone the extra mile to accomplish a seemingly impossible task. Stories also exist in every organization of how someone chose to do something right even though it may have been painful to do so.

- Capture organizational stories of proper conduct and use them to illustrate desired behavior;
- Write the stories down so they can be passed on to future employees;
- Use organizational newsletters and other publications to spread the word about ethical successes.

Include ethical conduct as a measure on performance evaluations. People do what is rewarded or measured. If the emphasis is on proactive, ethical behavior, you'll see more of it. If it a measurable objective, employees will think more about it.

- Make your expectations for ethical conduct well known;
- Capture live examples of ethical conduct to use when delivering a performance evaluation;
- Provide some award or incentive for ethical performance (one organization awarded certificates titled "*Caught you...doing something good*" that were delivered along with a gourmet cookie. Another presented small Corporate Commitment Plaques for ethical conduct).

Make ethics more important than just annual coverage. Talk about ethics often and at all levels. Ask employees what they like and dislike about their jobs. Inquire if there is anything that they have to do at work that makes them uncomfortable or that seems to them to be a compromise of their own personal ethics. Listen to what they have to say.

When you reach the point of talking about ethics routinely and your team knows where you stand on the need for good conduct and behavior, you'll be surprised how easy it becomes to ask someone for an example of observed ethical conduct on the job and how fast your stockpile of ethics lore grows.

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](#)
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The Least of My Brothers is an on-line module (or short course) in the ethics of research with human subjects. Please contact the following web site: <http://poynter.indiana.edu/sas/lb/>. 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)

Background

As an Agency of the U.S. Department of Health and Human Services (HHS), the Health Resources and Services Administration (HRSA) has certain responsibility for the protection of participants in human research studies.

These responsibilities are mandated under HRSA's [Federalwide Assurance \(FWA\)](#) with the [HHS Office for Human Research Protections \(OHRP\)](#) as well as the Agency's own policy: [Program Protection of Human Subjects Participating in Research Programs Conducted or Supported by HRSA](#). The protections apply to studies conducted internally by HHS staff, as well as to external studies conducted by grantees and contractors.

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.

Getting Started

The HRSA Center for Quality and OHRP are pleased to provide you with this special training series.

The entire training should take you about 90 minutes to complete; however, you can complete each module independently of the others. Module 1 is 22 minutes. Module 2 is 28 minutes and Module 3 is 36 minutes.

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.

Ethical Guidelines for Gifts to Physicians from Industry
Free educational modules now available

The AMA's 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.

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.

These modules are for educational purposes only, and do not constitute legal advice. Laws that are referred to in these modules are subject to change and federal and state agencies are constantly updating their interpretive guidance concerning the pharmaceutical industry and its relationship with physicians. For further information, please consult with qualified legal counsel to ensure compliance with appropriate legal requirements.

For more information visit the following site:
<http://www.ama-assn.org/ama/pub/category/8405.html>.

Online Fellowship in Physician Ethics and Professionalism

The Institute for Ethics at the American Medical Association (AMA), together with the [Medical College of Wisconsin's](#) (MCW) Graduate Program in Bioethics, now sponsors an *Online Fellowship* in Physician Ethics and Professionalism. [You may get more detailed information on the fellowship.](#)

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

**UA HUMAN SUBJECT
PROTECTION PROGRAM**

≧Highlights≦

Policies and Procedures*

The University of Arizona Human Subjects Protection Program (HSPP) has developed a *draft* of policies and procedures. These documents are currently under review by a sub-committee comprised of members from the three IRBs (Behavioral Science Committee, Biomedical Committee and Continuing Review Committee). Once this sub-committee has completed its review and has determined that the HSPP policies meet federal regulations and institutional requirements, they will be signed off by the Vice President for Research, Graduate Studies and Economic Development.

Written procedures are required by federal regulation. This requirement is listed in the federal regulations 45 CFR 46.103(b)(4) and (b)(5) and is among the requirements for a federal assurance (see July 2004 issue of the Program in Research Integrity Education newsletter for information regarding assurances). The Office of Human Research Protections (OHRP) lists the lack of such documents as a deficiency (Common Findings No. 64, updated 07/10/20).

OHRP strongly recommends that institutions develop and distribute detailed information to investigators that includes the following:

- IRB roles and responsibilities;
- Requirements and procedures for initial and continuing IRB review and approval of research;
- Rationale and procedures for proposing that the research may meet the criteria for expedited review;
- Requirements and procedures for verifying that research is exempt from IRB review;
- Responsibilities of investigators during the review during the review and conduct of research;

- Requirements and procedures for notifying the IRB of unanticipated problems or events involving risks to the subjects or others, as well as any other expected or unexpected adverse events;
- Explanation of the distinction between FDA requirements for emergency use of test articles versus HHS regulation
- Examples and user-friendly forms for providing information to the IRB;
- Copies of the institution's Federal-Wide Assurance, HHS regulations (45 CFR Part 46), and the Belmont Report.

The Food and Drug Administration (FDA) regulations require written procedures when auditing a human subjects program. Recent FDA audit reports have sanctioned IRBs not only for failing to have written procedures but for failing to follow written procedures in accordance with 21 CFR 56.108.

Accreditation standards also require that an institution develop written policies and procedures for IRB functioning. According to the Association for the Accreditation of Human Research Protection Programs (AAHRPP), organizations must follow written policies and procedures governing all research involving human subjects. The policies and procedures must also specify to whom they apply, and that they are to be reviewed periodically.

Producing, maintaining, and using written procedures for the IRB, its administrative staff and researchers are obligatory. *Not* having written policies and procedures is contrary to federal regulations and can result in sanctions against the institution.

*Walker, C. S. (2002). IRB Policies and Procedures. In R. J. Amdur and E. A. Bankert (Eds.), Institutional Review Board Management and Function (pp. 43-49). Sudbury, MA: Jones and Bartlett.



Marilyn Marshall, SpM, Quality Assurance Officer for the Research Compliance Office, will be speaking at the upcoming 21st Annual Meeting and Pre-conference Training of the Society of Quality Assurance (SQA) in Orlando, Florida, on February 20-24, 2005. (Please see “[Upcoming Conferences/ Workshops](#)” on the last page of this newsletter). SQA is the professional organization committed to quality in research. Attendees will be comprised of individuals who promote and advance the principles and knowledge of quality

assurance essential to human, animal, and environmental health worldwide.

Marilyn's presentation, “*A University's Response to a Compliance Issue*,” will cover the University of Arizona's experience related to the FDA/EPA Regulations for Good Laboratory Practices (GLP). After a *Warning Letter* was issued to the University of Arizona in 2001, the Office of Vice President for Research took steps to increase awareness of regulatory issues with policies and procedures to ensure that University GLP studies were in compliance.

If you would like more information about the Society for Quality Assurance (SQA) Meeting, please visit the following web address: http://www.sqa.org/gqac/forms/GGAC_Reg_Form.pdf.



News from HIPAA.....

Frequently asked questions on Privacy.....

Question: Does the HIPAA Privacy Rule strictly prohibit the use, disclosure, or request of an entire medical record? If not, are case-by-case justifications required each time the entire medical record is disclosed?

Answer: No. The Privacy Rule does not prohibit the use, disclosure, or request of an entire medical record; and a covered entity may use, disclose, or request an entire medical record without a case-by-case justification, if the covered entity has documented in its policies and procedures that the entire medical record is the amount reasonably necessary for certain identified purposes. For uses, the policies and procedures would identify those persons or classes of person in the workforce that need to see the entire medical record and the conditions, if any that are appropriate for such access. Policies and procedures for routine disclosures and requests and the criteria used for non-routine disclosures and requests would identify the circumstances under which disclosing or requesting the entire medical record is reasonably necessary for particular purposes.

The Privacy Rule does not require that a justification be provided with respect to each distinct medical record.

Finally, no justification is needed in those instances where the minimum necessary standard does not apply, such as disclosures to or requests by a health care provider for treatment purposes or disclosures to the individual who is the subject of the protected health information.



Radiation Control
Institutional Biosafety Committee



"IBC Basics" Workshop

The National Institute of Health (NIH), Office of Biotechnology Activities (OBA) is partnering with Public Responsibility in Medicine and Research (PRIM&R), the Applied Research Ethics National Association (ARENA), and the NIH Office of Laboratory Animal Welfare in sponsoring a one-day educational workshop on the roles and responsibilities of Institutional Biosafety Committees (IBCs). The workshop, titled "IBC Basics: An Introduction to the NIH Guidelines and the Oversight of Recombinant DNA Research," will take place on March 13, 2005 prior to the PRIM&R and ARENA Annual Institutional Animal Care and Use Committee (IACUC) Conference. The venue for the meeting will be the Town and Country Resort Hotel in San Diego, California.

"IBC Basics" is intended for IBC members and staff who have an interest in the oversight of recombinant DNA research, as well as research administrators, biological safety officers, regulatory affairs officers, and the members and staff of other institutional oversight committees such as IACUCs.

To view registration information and more workshop information, please visit: http://www.primr.org/education/2005_IACUC/program_IA05.html. If you have questions about the program, you may also contact Kathryn Harris, Ph.D., Senior Outreach and Education Specialist (Contractor), NIH OBA, at 301-435-2195.

University Animal Care
Quality Care for Research Animals



University of Arizona Animal Care

Frequently asked questions...

Question: How can research results derived from animal testing be extrapolated to humans?

Answer: There are striking similarities between the physiological systems of humans and various species of animals. For example, much of what we know about the immune system has come from studies with mice, and much of what we know about the cardiovascular system has come from studies with dogs.

Research results from animals also provide the information necessary to design human trials that must be completed for legal approval of new devices, drugs or procedures. It is important to be able to gauge how a new drug or procedure will affect a whole biological system before using it on humans. This is critical for scientific as well as ethical reasons. Laboratory animals are an integral part of the research process. In fact, virtually every major medical advance of the last century is due, in part, to research with animals.

UPCOMING
CONFERENCES/WORKSHOPS

February 20-24, 2005

1st Global Quality Assurance Conference and, 21st Society of Quality Assurance (SQA) Annual Meeting – “Committed to Quality in Research”

Orlando, FL

<http://www.sqa.org/gqac/index.asp>

February 24-27, 2005

Fourteenth Annual Meeting

Association for Practical and Professional Ethics

San Antonio, TX

<http://www.indiana.edu/~appe/program.html>

May 12-14, 2005

Twelfth Annual Teaching Research Ethics Workshop

Indiana Memorial Union

Bloomington, IN

<http://poynter.indiana.edu/tre/workshop.shtml>

June 9-10, 2005

Ethics and Social Responsibility in Engineering and Technology

Linking Workplace Ethics Education

Los Angeles, CA

<http://www.gonzaga.edu/Academics/Continuing+Education/Curent+Programs/Engineering+Ethics/default.htm>

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The P.R.I.E. newsletter is compiled by Ruth Daniels.

Words of Wisdom:

Determine never to be idle... It is wonderful how much may be done if we are always doing.

— *Thomas Jefferson*