
University of Arizona Program in Research Integrity Education Monthly Newsletter

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

This month's Program in Research Integrity Education (P.R.I.E.) newsletter focuses on an article which was published in the March 20, 2004 Ethics Resource Center issue of *Ethics Today*. It is entitled, "Bioethics," and it contains a multitude of information. You may access the *Ethics Today* web site at <http://www.ethics.org>. We appreciate being able to reproduce this article in our P.R.I.E. newsletter.

Bioethics

(Guest Column for *Ethics Today*)
Vincent Guss, Ethics Consultant
and Director of Pastoral Care
Inova Alexandria Hospital (2004-03)

An introduction to bioethics – a type of applied ethics that includes deliberation by all parties significantly affected by health care professionals, involving the perspectives and participation of all professionals representing pertinent disciplines.

Moral perplexity is evident in the practice of medicine with the awesome advance of biomedical and genetic research as attended by the resultant development of biomedical technology. There is renewed interest in promoting the rights and articulating the moral duties of health care professionals, researchers, and patients. Health care is delivered in the context of a multi-cultural and pluralistic society. These factors are largely responsible for the contemporary prominence of bioethics as a sub-discipline within the more general discipline of the study of morality known as "descriptive ethics." The goal of descriptive ethics is to attain empirical knowledge about morality. The practitioner of descriptive ethics is dedicated to describing existing moral views, and subsequently, explaining such views by advancing an account of their causal origin. Bioethics provides an approach for reflection, consultation, and articulation of the moral dilemmas that arise in the practice of medicine in an increasingly

complicated institutional setting of hospitals and other healthcare delivery systems.

There is a myriad of moral questions that arise in the context of health care delivery that present dilemmas that bioethics reflection address. For example, is a physician always morally obligated to tell a terminally ill patient that he or she is dying? Can a breach of medical confidentiality ever be morally defensible? Can euthanasia ever be morally justified? What ethical considerations must be addressed in surrogate motherhood and *in vitro* fertilization? Should research into cloning technology and genetic manipulation be promoted? When does aggressive medical care become futile treatment? Bioethics is a type of applied ethics that includes deliberation by all parties significantly affected by health care professionals, involving the perspectives and participation of all professionals representing pertinent disciplines, including medicine, nursing, pastoral care, social work, law, and other allied health professions.

In the past, the practice of medicine was largely confined within the bounds of the physician-patient relationship. However, now hospitals and other healthcare institutions are intimately intertwined with physicians and allied healthcare personnel in the delivery of medical care. There has been an extension of the consumer rights movement within the health-care arena, a heightened emphasis on the legal requirements of informed consent, and an accompanying escalation of concern within the healthcare community about legal liability. As a result, health-care professionals and institutions find it necessary to pay closer attention to the interplay among medical, legal, spiritual, social, and cultural ethical considerations. Moreover, as a society, there has come an increasing consciousness of issues of social justice. There is much consideration of "rights" to health care and the confrontation of the numerous problems of allocation of health care resources.

One prominent approach to addressing bioethical problems has been articulated by Tom L. Beauchamp and James F. Childress in *Principles of Biomedical Ethics*, originally published in 1979. The basic idea is that problems can be appropriately identified, analyzed, and resolved by reference to a set of four principles tailored specifically to be relevant to the field of bioethics: autonomy, nonmaleficence, beneficence, and justice. The principle of autonomy requires that health-care professionals respect and promote the effective exercise of patient choice, assuming informed consent. When patient choice is not possible, then consideration of the patient's values must be weighed heavily through "advanced directives" (if they exist) and the input of surrogate decision makers and/or significant others in the patient's life presumably reflecting those values, desires and "best-interest" of the patient. The principle of nonmaleficence requires that health-care professionals not act in ways that entail harm or injury to the patient. The principle of beneficence requires that the health-care professional act in ways to promote the patient welfare. The principle of justice requires that social benefits and social burdens be distributed in accordance with the demands of fairness and effective utility of those resources.

Whether one utilizes a "principle-based" approach to bioethics, or takes other competing approaches, it is important to be able to define the parameters, meaning, and substance of those principles by identifying the values of the patient, family members, health care staff, the institution, and the community itself. These values are influenced by philosophy, culture, religion, and historical backgrounds of all significant persons and institutions involved. The task of bioethical reflection is to resolve ethical problems associated with medicine and biomedical research in the context of dialogue with those of differing and possibly conflicting ethical values and perspectives. How does that "ethical resolution" occur? Is a particular medical practice right or wrong? Is it morally justifiable? In applied bioethics, the concern is not so much to establish the "correct" ethical or moral view. The mission is not even necessarily aimed at achieving "consensus" or "agreement" to the proper way to proceed with medical treatment. The goal is to provide a process, a forum, a way of describing a range of ethical options for health care that is reflective of the values and moral perspectives

articulated by those significantly affected (primarily the patient and/or research subject and/or the community).

The enterprise of bioethics reflection often occurs in the context of a hospital's interdisciplinary bioethics committee or institutional review boards. It can be provided through the employment of clinically trained bioethics consultants. It can be evident through public forums, the media, and the bioethics literature. Representatives from all the relevant health-care disciplines and medical specialties, from faith communities and specific cultural groups, from government, social service agencies and the law, and from lay-people in the community itself must be involved to give a holistic and balanced character to the quality of the reflection and consultation. Bioethics has at its heart the underlying premise of respect for human dignity, and as such, respect for the varying points of view, values, and philosophic, spiritual, and cultural perspectives of every one affected by the health-care decisions that are made to contribute to the well-being of the patient and of the whole community. When this form of "applied ethics" is operative when health-care decisions are being made, medical outcomes are generally improved and those affected by those outcomes are more satisfied because their input into making such decisions has been enhanced and valued.

Good Laboratory Practices Universal Precautions

- ❖ Always wear gloves when handling human blood, tissue or body fluids.
- ❖ Always wear a lab coat or gown in the laboratory.
- ❖ Do not smoke, eat, drink or apply cosmetics in the laboratory.
- ❖ Do not touch your skin or handle clean surfaces, material, or equipment while wearing gloves.
- ❖ Use mechanical pipetting devices – never pipette by mouth.
- ❖ Avoid the use of needles when working with potentially infectious materials.
- ❖ Avoid procedures that may cause aerosols or droplets to form – use containment for all such procedures.
- ❖ Decontaminate all work surfaces with a tuberculocidal disinfectant or sodium hypochlorite solution (10% dilution of household bleach) following any spill and following completion of work.

- ❖ Human blood, tissue and other potentially infectious materials should be transported in capped containers which are placed in a second impervious container, appropriately labeled.
- ❖ Discard all non-sharp material contaminated with blood, body fluids, or tissue into biohazard bags.
- ❖ Discard all sharps into approved sharps containers. Sharps containers must be located in the immediate vicinity of sharps use.
- ❖ Never bend, break, recap, or otherwise manipulate needles. Don't remove needles from syringe by hand. If removal is necessary, use a hemostat, forceps, or sharps containers equipped with a needle-removing device on its lid.
- ❖ Dispose of sharps containers when they are ¾ full. Do not allow containers to overfill. Never reach inside or attempt to force items into a sharps container.
- ❖ Discard gloves, remove laboratory clothing and wash hands before leaving the laboratory.
- ❖ Wear gloves consistently and wash hands frequently. The use of gloves should not be considered a substitute for careful hand washing after working with infectious material.

The above was found at the following web site:
www.yale.edu/oehs/PDF_files/UNIPRE.PDF.



News from HIPAA.....

Frequently asked questions on Privacy.....

Question:

Who must comply with these new HIPAA privacy standards?

Answer:

As required by Congress in HIPAA, the Privacy Rule covers:

- + Health plans;
- + Health care clearinghouses;
- + Health care providers who conduct certain financial and administrative transactions electronically. These electronic transactions are those for which standards have been adopted by the Secretary under HIPAA, such as electronic billing and fund transfers.

These entities (collectively called “covered entities”) are bound by the new privacy standards even if they contract with others (called “business associates”) to perform some of their essential functions. The law does not give the Department of Health and Human Services (HHS) the authority to regulate other types of private businesses or

public agencies through this regulation. For example, HHS does not have the authority to regulate employers, life insurance companies, or public agencies that deliver social security or welfare benefits. See the fact sheet and frequently asked questions (at www.hhs.gov/) about the standards on “Business Associates” for a more detailed discussion of the covered entities’ responsibilities when they engage others to perform essential functions or services for them.

EXHIBIT SPACE FREE AT RCR (Responsible Conduct of Research) EXPO 2004

The RCR Expo 2004 will be held October 25th and 26th in conjunction with the Society of Research Administrators (SRA) International 2004 Annual Meeting in Salt Lake City, Utah. The Expo will be held in the luxurious Grand America Hotel, situated in a high-traffic space within the conference area. With over 1,200 top research administrators attending the SRA meeting, this event will be an excellent opportunity for institutes and businesses to showcase their RCR educational materials, videos, training tools, web sites, and/or programs.

Exhibit space is free to the 25 exhibitors selected to participate. Those interested in becoming an exhibitor at the RCR Expo 2004 should contact Loc Nguyen-Khoa (LNguyen-Khoa@osophs.dhhs.gov) and include your name, institution, and description of your product or program.

For more information about the Society of Research Administrators International 2004 Annual Meeting, visit <http://www.srainternational.org>.

INTRO RCR TEXT MAILED; REVISION UNDERWAY

Single copies of the ORI Introduction to the Responsible Conduct of Research were mailed in January 2004 to the responsible institutional official at the 4,000 institutions that have a misconduct policy assurance on file with ORI.

The publication is currently being revised because some illustrations, case studies, and the ISBN number were dropped, and format and style errors were made during the production process of the initial printing. Publication content, however, is accurate. A PDF version of the missing material is available on the ORI web site at <http://ori.hhs.gov>.

The revised publication is expected to be available for purchase from the Government Printing Office this Spring. Please see <http://bookstore.gpo.gov>. It will be posted on the ORI web site later this year for on-line reading or downloading.

RCR SUMMIT SET FOR MICHIGAN STATE UNIVERSITY IN JUNE

Responsible conduct of research (RCR) instructors and program coordinators are urged to participate in a national dialogue on future directions in RCR education that will be held at Michigan State University (MSU) on June 28-29, 2004.

A web site for *The RCR Summit: A National Dialogue on Future Directions of RCR* will be available shortly on the MSU and ORI web sites. "We would like to see a substantial turnout for this conference," Larry Rhoades, Director, Division of Education and Integrity, ORI, said, "because we would like to begin developing a collaborative effort that would be helpful to us all."

The conference will develop basic information on the structure of RCR programs created across the country, discuss the content and pedagogical approaches being used, and suggest directions for the further development of the RCR education program.

CONFERENCE, WORKSHOP, AND MEETING PROPOSALS DUE OCTOBER 1, 2004

ORI is seeking proposals from institutions, scientific societies, and professional associations that wish to collaborate with ORI in developing conferences, workshops, symposia, colloquiums, seminars, and annual meeting sessions that address the responsible conduct of research, research integrity, or research misconduct. ORI will provide up to \$20,000, depending on the event proposed.

The next target date for receipt of application is October 1, 2004. Proposal instructions and an application form are available on the ORI web site at <http://ori.dhhs.gov/html/programs/conf-workshops.asp>.

Please submit your proposal electronically to cfassi@osophs.dhhs.gov. Dr. Carolyn Fassi may be reached at 301-443-5300.

UA Human Subjects Program

≧Highlights≦

Human Subjects Protection Program Reporting Requirements

During the life of a research project, certain events/occurrences need to be reported to the Institutional Review Board (IRB). The following is a reminder list for investigators:

Submit for IRB Approval

- ✓ Changes to study procedures/materials (protocols/grant proposals, subject population, consent instruments [including translated forms], recruitment procedures/materials, data collection instruments, adverse events and Investigator's Brochure updates impacting risk/benefit ratio, etc);
- ✓ Change in sponsor;
- ✓ Changes in study status (closed to new subjects, data analysis only, concluded, withdrawal of project, etc.);
- ✓ Changes in personnel.

Submit for IRB Review

- ✓ Adverse events (investigator-generated and sponsor-generated);
- ✓ Investigator's Brochure updates (no change in risk/benefit ratio);
- ✓ Progress reports submitted to, or received from, sponsor;
- ✓ Protocol deviations;
- ✓ Site Authorizations.

Reporting Requirement Reminder to Advisors/Investigators:

- ✓ All IRB-approved projects require continuing review at least annually (see project approval letter for review interval). For completed projects, where all data collection and analysis is finished, a concluding Periodic Review Form must be submitted to the IRB to officially conclude the project. Please see information at: www.irb.arizona.edu/continuerreview.html.

UNIVERSITY OF ARIZONA RESEARCH AND SERVICE GROUP (RSSG) Educational Opportunities

OPPORTUNITIES FOR ON-LINE ETHICS TRAINING

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.](#)

NIH Human Protections Course Available

A free web-based course that will enable physicians, researchers, nurses, and data managers to satisfy the NIH requirements for training about

the rights and welfare of human participants in research studies is available. More information is at the following web site: <http://cme.nci.nih.gov>.

**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. For complete information please contact the following: <http://poynter.indiana.edu/sas/lb/>. You may also contact Kara Lochridge at: (812) 856-4968, or klochrid@indiana.edu.



More Educational Opportunities

PHCL 595b
(PS 595b, BME 595b, CBIO 595b)

**Scientific Writing Strategies
and Ethics**

Course Coordinators:

W. Daniel Stamer, Ph.D. – 626-7767 –
dstamer@eyes.arizona.edu, and

Thomas P. Davis, Ph.D. – 626-7643 –
davistp@u.arizona.edu

*This course satisfies the requirement for
research ethics training by the N.I.H./N.S.F.*

Please contact Dr. Stamer for more details:
dstamer@eyes.arizona.edu or call 626-7767.

**HIPAA VIDEOCONFERENCE
TAPE AVAILABLE**

The Society for Research Administrators (SRA) International Satellite Videoconference from January 23, 2003 is available on tape. It is three hours long, and contents are:

Part I: General Confidentiality Issues in
Sponsored Agreements, and,

Part II: Privacy/HIPAA Issues.

To request use of the tape, please contact *Alice Langen*, Director, Research Standards & Compliance, Office of the VP for Research (621-5196) or langena@u.arizona.edu.

Also, after viewing the video, please notify the P.R.I.E. office (Ruth Daniels at 626-6282) to receive a *Certificate of Completion* for your files and grant submissions.

**UPCOMING
CONFERENCES/WORKSHOPS**

May 19-22, 2004

Eleventh Annual Teaching Research Ethics Workshop
Indiana University Bloomington/Poynter Center
<http://poynter.indiana.edu/tre/workshop.shtml>

June 21-22, 2004

**The RCR Summit: A National Dialogue on Future Directions
of RCR**

East Lansing, MI

Co-Sponsor: Michigan State University

http://ori.dhhs.gov/html/programs/conf_workshops_2004.asp

June 28-29, 2004

**The RCR Summit: A National Dialogue on Future Directions
of RCR**

East Lansing, MI

Co-Sponsor: Michigan State University

October 14-15, 2004

**Research Integrity and Financial Conflicts of Interest in
Clinical Research: Legal Issues and Regulatory
Requirements**

Charlottesville, VA

Co-Sponsor: University of Virginia School of Medicine, Center
for Biomedical Ethics

http://ori.dhhs.gov/html/programs/conf_workshops_2004.asp

October 23-27, 2004

RCR Expo

Salt Lake City, UT

Co-Sponsor: SRA International

http://ori.dhhs.gov/html/programs/conf_workshops_2004.asp

November 12-14, 2004

ORI Research Conference on Research Integrity – 2004
San Diego, CA

Co-Sponsor: University of California – San Diego

http://ori.dhhs.gov/html/programs/conf_workshops_2004.asp

December 1-3, 2004

Developing Policy on Institutional Conflict of Interest
Las Vegas, NV

Co-Sponsor: University of Nevada – Las Vegas

http://ori.dhhs.gov/html/programs/conf_workshops_2004.asp

December 8, 2004

Ethics and Responsible Conduct of Research Workshop
Washington, DC

Co-Sponsor: Council of Graduate Schools

http://ori.dhhs.gov/html/programs/conf_workshops_2004.asp

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

Words of Wisdom:

Indecision is often worse than wrong action.

— *Gerald Ford*