



Bioethics Notes

March 2005

" There is no truth. There is only perception."

Gustave Flaubert (1821-1880)

Consult Services

We would like to remind you that the Bioethics Review and Advisory Committee in Danville provides ethics consultation services. We have an alphanumeric pager (2229). Anyone can request an ethics consultation. Page directly by phone, or leave a text message using the Infoweb Phone Directory. Enter "2229" in the Directory Search and then click on the "Quick Page" button.

Bioethics Committee

Co-chairs

Joel J. Berberich, MD, PhD
Robert B. Shabanowitz, PhD

Membership

Karen Adams, RN
Kristen Beech, JD
J. Brian Benestad, PhD
Gregory F. Burke, MD
Leann Crabb, RN, CCRN, TC
Lisa Eggleston, MD
Nancy Eisenhauer, MS, PA-C
Neil M. Ellison, MD
James R. Elmore, MD
Rev Stephen D. Engelhardt
Jill M. Gotoff, MD
Jane Hartman
John M. Hinson
Dona Leskuski, DO
Richard A. Martz
Rev MacKenzie Scott
Don Shifflett
Debbie Ulrich, RN
Jeffrey Whitman, PhD

Case Study

A 40 year old woman is unconscious at the scene of a motor vehicle accident. A helicopter arrives with a medical team to stabilize the patient prior to transportation to a medical center. Due to the extent of her injuries, the medical team decides that she qualifies for a study of the effectiveness of artificial blood substitutes and begins this therapy.

Although you will be hearing more about such studies in the future, we want to introduce some of the ethical aspects of studies conducted without **explicit informed consent**.

One of guiding principles of bioethics is respect for a person's autonomy. The [Belmont commission](#) summarized: "Respect for persons incorporates at least two ethical convictions: first, that individuals should be treated as autonomous agents, and second, that persons with diminished autonomy are entitled to protection."

This principle is actualized by individuals or by their surrogate when they consent to health care. Such consent recognizes a person's right to privacy and bodily integrity and that person's right of self determination.

However, there are legal exceptions to informed consent requirements, including medical emergencies. The standards for waiver of consent requirements for emergency research require that the risks associated with the research are reasonable in relation to what is known about the medical condition of the subject population, and require the balancing the risks and benefits of standard therapy versus the proposed intervention (Final Rules [21 CFR 50.24](#) and [45 CFR 46.101](#)).

As a result, these standards support the ethical principle of **non-maleficence**—not exposing the person to a greater risk of harm. More importantly, these standards recognize that there is a delicate balance between patient autonomy and **beneficence**. Most persons would consent to therapy that is potentially beneficial to themselves, or at least may lead to improved therapy for others.

In a recent survey of patients and families in an emergency department 70% of laypersons would not object to being entered into an emergency study without providing prospective informed consent ([McClure KB, Acad Emerg Med 10:352, 2003](#)). However, persons are willing to accept "voluntary" risks roughly 1000 times greater than "involuntary" risks (Starr C, Science 165 (September 19,1969) 1235, 1937).

Events

Join Us at Our Annual Bioethics Conference

April 13th, 2005

Hemelright Auditorium

[Pizza, Pens & Pills: The Ethics of the Pharmaceutical Industry in Healthcare](#)

e-mail

The Bioethics Review and Advisory Committee's address is:

bioethics@geisinger.edu

Visit

The Bioethics Review and Advisory Committee Homepage



Please visit our new web page, which includes frequent updates on ethical topics, links to selected bioethics websites, Geisinger ethics policies (under Bioethics Committee Resources), and past issues of **Bioethics Notes**

Preservation of the ethical values of respect for autonomy and non-maleficence is maximized by diligence of **Institutional Review Boards** in assessing risk and disseminating information to the community in advance of such studies to allow individuals who refuse to be subjects in a research study some method of indicating this refusal, such as wearing a colored wrist band. A recent excellent review summarizes the requirements for meeting ethical, legal and regulatory standards for conducting research without consent ([Biros MH, Ann Emerg Med 42:550, 2003](#)).

In her recent book, [Lesser Harms: The Morality of Risk in Medical Research](#), Sydney Halpern emphasizes that controlling the risks of human experimentation is one aspect of a larger social problem: how to handle the use of socially desirable but potentially hazardous technologies. Maximizing the morality of conducting research can be achieved by applying sociological understandings of the determinants of risk perception, of the cultural constructions of danger, of the social distributions of hazards and of social processes contributing to technological accidents.

Could the administration of an artificial blood substitute to this trauma victim without her consent be ethical? Yes, such emergency research without explicit consent clearly can meet ethical guidelines provided that risk is minimized and that individuals are afforded a means of withholding their consent to be a study subject. Moreover, such research may support the principle of beneficence: improving care for the person and for others.

Respectfully submitted,
Joel Berberich

The Bioethics Review and Advisory Committee gratefully acknowledges *The Degenstein Foundation*, whose funding helps support the educational activities of our committee. Feel free to forward *Bioethics Notes* to anyone interested. They can join by using the link below.

To join the list, send a blank email to List-Join:
<<mailto:join-bioethics@ghslistnt1.geisinger.edu>>