

Ethical Issues in International Human Research Protections

Daniel R. Vasgird, PhD, CIP
WVCTSI Ethics & Regulatory Knowledge
Services

West Virginia University
drvasgird@mail.wvu.edu

October 16, 2017

Robert K. Merton

- Stated that the disinterested pursuit of truth is the norm of science, expressed as:
 - Universalism
 - Communalism
 - Disinterestedness
 - Organized skepticism

Milton Friedman

Stated that the limits of the social responsibility of industrial corporations are “to make as much money for their stockholders as possible”.

What does this mean for science considering the scale of private research funding these days?

Consequences of Ambition

Perseverance and success,
but increased:

1. Risk for unintentional bias
2. Willingness to cut corners
3. Willingness to commit serious misconduct

Empathy

“The first step in the evolution of ethics is a sense of solidarity with other human beings.”

Albert Schweitzer

“Ethics primarily concerns the effects of our actions on others.”

Randy Cohen

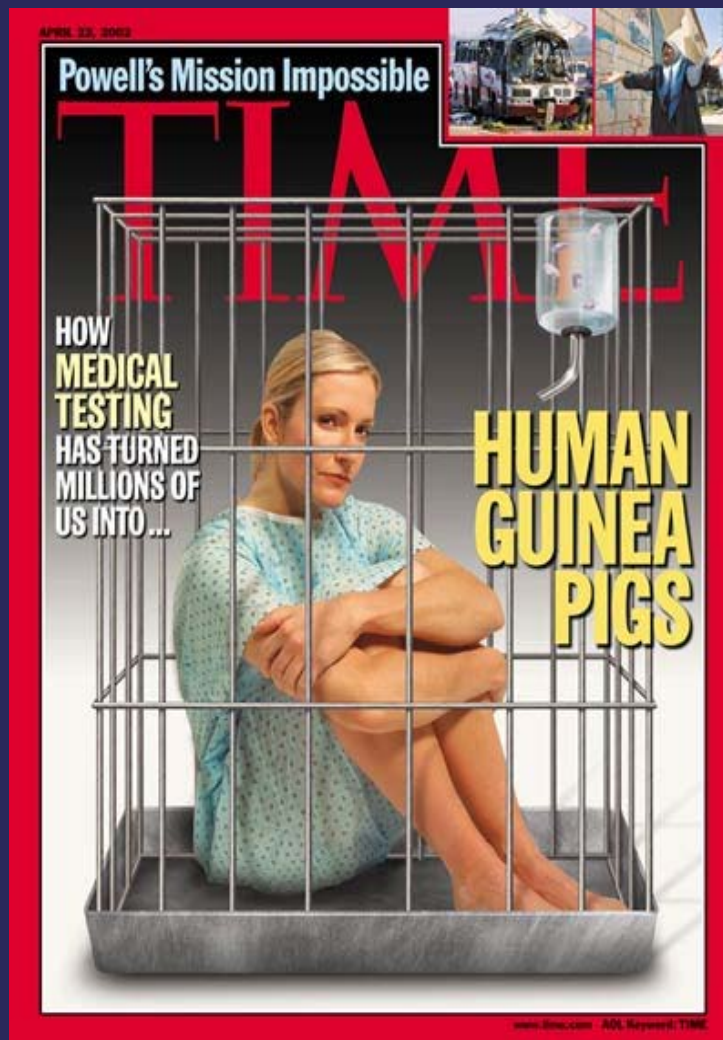
“Managing Externally Funded Research Programs: ...Effective Management Practices” -COGR

Research integrity is now listed as a basic principle of quality management, emphasizing that it is no longer enough for administrators to presume that it is being attended to informally.

RCR Core Areas

- Human Research Protections
- Research Protections for Animals
- Research Misconduct
- Conflict of Interest & Commitment
- Mentor/trainee Relationships
- Responsible Authorship
- Peer Review
- Data Management, Sharing and Ownership
- Collaborative Science
- Social Responsibility

Jesse Gelsinger





INTEGRITY
IN SCIENTIFIC RESEARCH

Creating an
Environment
That Promotes
Responsible
Conduct

INSTITUTE OF MEDICINE
NATIONAL RESEARCH COUNCIL
OF THE NATIONAL ACADEMIES

National Academy of Sciences

To maintain (public) **confidence and trust** in this (the scientific) enterprise, researchers must protect the *empirical objectivity* of research, the *unbiased reporting* of results and the *open sharing* of that information for the good of society.

International Research Ethics

- The term “international research” generally refers to research conducted in developing countries by researchers and sponsors from industrialized countries.

International Research Ethics

- Only recently has international research ethics begun to receive the benefit of widespread public discourse and debate

International Research

- Traditionally, industrialized countries set the research agenda and carry out research in developing countries.
- Research conducted in developing countries is increasingly becoming a collaborative effort between industrialized and developing countries.

International Research Ethics

- Fundamental ethical questions arise due, in large part, to the global imbalance of power and huge disparities in wealth and access to health care between developing host countries and industrialized countries that either conduct or sponsor research.

International Research Ethics

- In addition to economic-related conditions, historical, cultural, political, or legal factors that exist in a particular community or country can contribute to the difficulties of conducting research in developing countries.

Fundamental Premises of Conducting Research in Developing Countries

- #1- Research conducted by researchers and sponsors from industrialized countries in developing countries should be responsive to the health needs and priorities of the population on which it is conducted. But what does it mean to be “responsive?”

Fundamental Premises of Conducting Research in Developing Countries

- #2 - It is unethical to exploit vulnerable populations or individual participants in the conduct of research. But what constitutes exploitation?

Fundamental Premises of Conducting Research in Developing Countries

- #3 - It is unacceptable to lower the ethical standards adopted in the industrialized world when carrying out research in developing countries. But is a different standard necessarily a lower standard?

It certainly can be in some cases such as the use of prisoners in research in some developing countries. Could never be done in this country.

Awareness of the Context in which the Research will be Conducted

- Certain beliefs and values that exist in developing countries may conflict with fundamental ethical principles.
- There are 2 areas that should give one pause in that regard: informed consent and prior ethical review.

Informed Consent

- Research conducted in developing countries presents unique challenges during the informed consent process.

Informed Consent

- Literacy rates
- Language barriers unrelated to literacy
- Belief systems

Informed Consent

- Withholding key information
- Same problem where there is absolute trust in the physician to make decisions for patients

Informed Consent

- Significance given to “signing” a consent form
- Need for translators, not just straightforward interpreters

Informed Consent

- Ethical concerns may arise in developing countries where family or community members traditionally are involved in the consent process.
- Cultural accommodations should be made. In no case, however, should the permission of a family member or tribal or community leader serve as a substitute for individual voluntary informed consent.

Informed Consent

- Requirement of voluntariness is particularly troublesome in research conducted in developing countries.

Informed Consent

- A related concern about voluntariness arises when research subjects are recruited from developing country populations that are considered to be especially vulnerable.

Ethnographic Research

In a nutshell, researchers must make their research goals clear to the members of the community where they undertake their research and gain the informed consent of their consultants to the research beforehand. It is also important to learn whether the group would prefer to be named in the written report of the research or given a pseudonym and to offer the results of the research if informants would like to read it. Most of all, researchers must be sure that the research does not harm or exploit those among whom the research is done.

<http://www.aaanet.org/committees/ethics/ethics.htm>

Prior Ethics Committee Review

- In international research, prior review of research can occur:
 - In the sponsor's home country;
 - In the host country (local review);or
 - In many cases, in both countries.

Prior Ethics Committee Review

- It is generally agreed that there is a need to help build the capacity of developing countries to conduct ethical review of research.

New and Important Issues in International Research Ethics

- o Three new and important issues in international research ethics:
 - Post-trial benefits
 - Capacity building
 - Community consultation

Post-Trial Benefits

- Until recently, little attention has been paid to the provision of benefits to research subjects and host communities and countries after a study is completed.

Post-Trial Benefits

- When research is conducted in developing countries, the huge disparity in power between rich and poor nations manifests itself in two ways.
 - (1) In most cases, the industrialized world sets the research agenda and carries out the research. A gradual change is evident however.

Post-Trial Benefits

(2) Typically, the industrialized world receives the great majority of research benefits, but assumes very few of its burdens.

The obligation to provide post-trial benefits is based upon distributive justice.

Post-Trial Benefits: Biomedical Research

- Post-trial benefits for subjects are most typically an experimental intervention proven effective by the study but may also take the following forms:
 - Effective interventions;
 - Technology transfer (e.g., license to manufacture a drug);
 - Health services (e.g., maintenance of a primary care clinic);
 - Capacity building (applicable to most types of research); and
 - Researcher commitments.

Post-Trial Benefits

- Support for post-trial obligations is found in a number of international and national research ethics documents (biomedical).
- Even among those who agree that such an obligation exists, there is sharp disagreement about its nature and scope.
- New issue in international research called a "**Prior Agreement.**"

Capacity Building

- There is a need for researchers and sponsors from developed countries to help build the capacity of developing host countries for (1) designing and conducting research; (2) scientific and ethical review of research; and (3) implementing the results of research after the study is completed.

Capacity Building

- Capacity building objectives should be consistent with the expectations of subjects and communities.
- Examples: transfer of scientific knowledge and skills; provision of research facilities and equipment; development of ethics review capacity.

Community Consultation


- Consultation means that in some fashion the community role in research goes beyond simple participation such that community interests are discussed within the framework of the research project.

Community Consultation

- Designed to respect the culture and dignity of the community and achieve its full understanding and acceptance of the research.

Community Consultation

- There may be difficulty in defining the community for purposes of research.
- Process is especially important in research, such as genetic research, that may present risks to villages, communities, or racially or ethnically defined groups, particularly with regard to the publication of research results or the identification of the group or place in which research was conducted.



“Progress depends on extending our imaginative range, identifying with those who are unnecessarily suffering.”

George Scialabba

Resources: Fogarty International Center

- **Bioethics Resources for Teachers and Students:** One-stop on-line education and training resource including International Research Ethics courses, case studies and curricula:

<https://www.fic.nih.gov/ResearchTopics/Bioethics/Pages/teachers-students.aspx#online>