Empowering Stakeholders in Health Research

DEFINING STAKEHOLDER RESPONSIBILITIES TOWARD IMPLEMENTING A DUTY-BASED ETHICS

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Ethical principles underlying human research are generally considered to be universal
- Respect for persons
- Beneficence
- Justice

Ethical principles provide guidance for the decisions and actions of all stakeholders in the human research endeavor
Human Research—Ethical Foundations

- Ethical principles are derived from moral philosophy
- Application of different philosophies lead to adoption of different principles
- Ethical foundations of human research stem from several lines of philosophical thought
Deontological ethics or deontology

From Greek, *deon*, "obligation, duty"

An approach to ethics that focuses on the rightness or wrongness of intentions or motives behind action such as respect for rights, duties, or principles, as opposed to the rightness or wrongness of the consequences of those actions.
Human Research—Unethical from the Outset?

ontological Philosophy and the Categorical Imperative

“Act only according to that maxim whereby you can at the same time will that it should become a universal law.”

“Act in such a way that you treat humanity, whether in your own person or in the person of any other, always at the same time as an end and never merely as a means to an end.”

—Immanuel Kant, Metaphysics of Morals, 1797
Human Research—Ethical Foundations

Research with human beings is justified by the good that it brings to society. This is a utilitarian rationalization for allowing scientists to use others as a means to their ends. As a consequence, all parties to the human research endeavor have an ethical responsibility and moral duty to:

- Safeguard the safety, interests and well being of subjects
- Ensure the quality and integrity of the science
- Ensure that the benefits to society are realized
Stakeholder Roles and Responsibilities

**Individuals**
- Investigator
- Research coordinator
- Research nurse
- Research monitor
- Research administrator
- IRB member
- DSMB member
- Study participant
- Subject advocate
- Surrogate
- Statistician
- Author
- Reviewer

**Entities**
- Sponsor
- Contract research organization
- Site management organization
- Regulatory agency/oversight authority
- Research facility
- IRB/Ethics Committee
- Study coordinating committee
- Data/safety monitoring board
- Family members/support groups/communities
- Journals/editors
- Manufacturers
The individuals and entities engaged in human research constitute a matrix of overlapping roles and responsibilities that together serve to ensure that their duties are satisfied.

This matrix is like a finely woven silk cloth—
- A single broken thread causes a defect
- A single defect spoils the entire cloth
- A single hole can result in disaster
- A single disaster can shred the fabric of trust

It is our duty to protect not just research subjects, but to protect the integrity of science itself.
Within the duty-based ethical framework for human research, each participant, whatever one's role, bears responsibility, an imperative, to:

- Acquire the necessary knowledge and training to ensure that one's responsibilities are understood and fulfilled.
- Commit to conduct one's activities in an efficient and responsible manner according to the principles of respect for persons, beneficence and justice.
- Hold other stakeholders to the same high-level of excellence as they expect from themselves.
- Work together, collaboratively to achieve fulfill these goals and commitments.
Our Duty

“We should expect no more from others than we expect from ourselves--
We should expect no less from ourselves than the very best that we can do...
Anything less is just not good enough!”