

# Empowering Stakeholders in Health Research



## **DEFINING STAKEHOLDER RESPONSIBILITIES TOWARD IMPLEMENTING A DUTY- BASED ETHICS**

**GREG KOSKI, PHD, MD  
HARVARD MEDICAL SCHOOL**

**CHAIR, SIDCER ADVISORY BOARD**

# Human Research—Ethical Foundations



- **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

# Human Research—Ethical Foundations



## **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?



### **Deontological 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. ”

# 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 end

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

# Stakeholder Roles and Responsibilities



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



# Stakeholder Roles and Responsibilities



Within the duty-based ethical framework for human research, each participant, whatever ones role, bears responsibility, an imperative, to

Acquire the necessary knowledge and training to ensure that ones responsibilities are understood and fulfilled

Commit to conduct ones 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!”**