Chapter Four

The Importance of Ethical and Human Rights Issues in Global Health

The Importance of Ethical and Human Rights Issues in Global Health

- Failure to respect human rights is often associated with harm to human health
- Health research with human subjects puts people at risk for the sake of other people's health
- Health investments must be made in fair ways since resources are limited

The Foundations for Health and Human Rights

- Universal Declaration of Human Rights and other legally binding multilateral treaties
- Governments are obliged to respect, protect, and fulfill the rights they state

Selected Human Rights

The Rights-Based Approach

- Assess health policies, programs, and practices in terms of impact on human rights
- Analyze and address the health impacts resulting from violations of human rights when considering ways to improve population health
- Prioritize the fulfillment of human rights

Selected Human Rights

Limits to Human Rights

- Circumstances in which someone's rights may be temporarily suspended
- Suspension of rights should be as narrow as possible
- Suspension should be carried out with due process and monitored

Selected Human Rights

Human Rights and HIV/AIDS

- Health condition that is stigmatized and discriminated against
- Protecting the rights of people who are HIV-positive to employment, schooling, and participation in social activities
- Ensuring access to care
- Policies regarding testing
- Protection of confidentiality

Research on Human Subjects

- Most research studies don't benefit the people who participate in them
- Ethical concerns about putting participants at risk for the sake of other people's health

Key Human Research Cases

Nazi Medical Experiments

- Conducted experiments on euthanasia victims, prisoners of war, occupants of concentration camps
- International Scientific Commission investigated and documented abuses after war
- Questions over whether it is ethical to use data the Nazis generated

Key Human Research Cases

The Tuskegee Study

- US Public Health Service conducted a study on the natural history of syphilis in African American men
- Study went on for 40 years
- Subjects were never given treatment
- Eventually led to regulations for the protection of human research subjects

Key Human Research Cases

The "Short-Course" AZT Trials

- Trials of a "short-course" AZT regimen to prevent mother-to-child transmission of HIV
- Some people thought that poor people were being exploited since the trials were taking place in low-income countries
- Studies remain controversial

Research Ethics Guidelines

The Nuremberg Code

- First document to specify ethical principles that should guide physicians engaged in human research
- "Voluntary consent of the human subject is absolutely essential"

Table 4.1: The Standards of the Nuremburg Code

- Those who participate in the study must freely give their consent to do so. They must be given information on the "nature, duration, and purpose of the experiment." They should know how it will be conducted. They must not be forced or coerced in any way to participate in the experiment.
- The experiment must produce valuable benefits that can not be gotten in other ways.
- The experiment should be based on animal studies and a knowledge of the natural history of the disease or condition being studied.
- The conduct of the research should avoid all unnecessary physical and mental suffering and injury.
- The degree of risk of the research should never exceed that related to the nature of the problem to be addressed.
- The research should be conducted in appropriate facilities that can protect research subjects from harm.
- The research must be conducted by a qualified team of researchers.
- The research subject should be able to end participation at any time.
- The study will be promptly stopped if adverse effects are seen.

Source: Regulations and Ethical Guidelines—Directives for Human Experimentation—Nuremberg Code. Available at: http://ohsr.od.nih.gov/guidelines/nuremberg.html. Accessed August 3, 2006.

Research Ethics Guidelines

The Declaration of Helsinki

- Developed ethical principles to guide physicians conducting biomedical research on humans
- Principles apply equally to nonphysicians

Table 4.2: The Declaration of Helsinki: Key Principles

Scientific Validity

- Medical research involving human subjects must conform to generally accepted scientific principles and be based on a thorough knowledge of the scientific literature.

Fairness

- Populations that are underrepresented in medical research should be provided appropriate access to participation.
- Medical research involving a disadvantaged or vulnerable population or community is only justified if the research is responsive to the health needs and priorities of this population or community and if there is a reasonable likelihood that it stands to benefit from the results of the research.
- Study participants are entitled to be informed of the study's outcome and to share benefits that result from it, such as access to interventions identified as beneficial in the study.

Source: Adapted from World Medical Association. *Declaration of Helsinki*. Available at: http://www.wma.net/en/30publications/10policies/b3/index.html. Accessed August 16, 2010.

Table 4.2: The Declaration of Helsinki: Key Principles (cont.)

Risks and Benefits

- The well-being of the individual research subject must take precedence over all other interests.
- The importance of the objective of a study must outweigh the risks to the research subjects.
- Physical, mental, and social risks must be minimized.

Placebos

- A new intervention must be tested against the best current proven intervention, except when:
  - No current proven intervention exists; or
  - Where for methodological reasons the use of placebo is necessary and subjects who receive placebo will not be subject to any risk of serious or irreversible harm.

Source: Adapted from World Medical Association. *Declaration of Helsinki*. Available at: http://www.wma.net/en/30publications/10policies/b3/index.html. Accessed August 16, 2010.

Table 4.2: The Declaration of Helsinki: Key Principles (cont.)

Consent

- Potential subjects must give voluntary, informed consent.
- For a potential research subject who is incompetent, the physician must seek informed consent from a legally authorized representative.
- Where possible, the physician must seek the assent and respect the dissent of an incompetent potential research subject.

Oversight and Accountability

- The research protocol must be submitted to an independent research ethics committee before the study begins.
- Every clinical trial must be registered in a publicly accessible database before recruitment begins.
- Authors have a duty to make publicly available the results of their research, including negative and inconclusive results.

Source: Adapted from World Medical Association. *Declaration of Helsinki*. Available at: http://www.wma.net/en/30publications/10policies/b3/index.html. Accessed August 16, 2010.

Research Ethics Guidelines

The Belmont Report

- US National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research
- Identified basic ethical principles
- Developed guidelines for research

Table 4.3: The Belmont Report

Basic Ethical Principle	Application of the Principle
Pespect for Persons: • Treat individuals as autonomous persons. • Protect individuals with diminished autonomy.	Informed Consent: • Individuals should be allowed to make an informed, voluntary decision about what happens to them. • Individuals whose capacity is limited should be given the opportunity to choose to the extent that they are able.
Beneficence: • Maximize possible benefits • Minimize possible harms	**Assessment of Risks and Benefits:** • A data-based risk/benefit assessment should be made. • Risks to subjects should be outweighed by the sum of the benefits to subjects and the benefit to society. The interests of the subjects should be given priority. • Risks should be reduced to those necessary to achieve the research objective.
Justice: • The benefits and burdens of research must be distributed fairly.	**Selection of Subjects:** • There must be fair procedures and outcomes in the selection of those participating in the research.

Source: U.S. National Institutes of Health, Office of Human Subjects Research. *The Belmont Report: Ethical Principles and Guidelines for the Protection of Human Subjects of Research.* Available at: http://ohsr.od.nih.gov/guidelines/belmont.html. Accessed September 9, 2010.

Evaluating the Ethics of Human Subjects Research

Clinical research protocol must satisfy six conditions:

- Social value
- Scientific validity
- Fair subject selection
- Acceptable risk/benefit ratio
- Informed consent
- Respect for enrolled subjects

Evaluating the Ethics of Human Subjects Research

Research in Low- and Middle-Income Countries

Important issues when the subjects are likely to be poor, under-educated and without access to good care:

- Standard of care
- Post-trial benefits
- Ancillary care

Evaluating the Ethics of Human Subjects Research

Human Subjects Research Oversight Today

- Ethical review by a research ethics committee
- Safeguard against exploitation
- Regulations vary from country to country

Ethical Issues in Making Investment Choices in Health

- Resources will always be fewer than needed to meet everyone's health needs
- Government ministries have tight budgets and need to decide how to allocate funds among options
- Better that the choices be made according to explicit, publicly justified criteria

Ethical Issues in Making Investment Choices in Health

Principles for Distributing Scarce Resources

Most plausible allocation proposals is justified by at least one of these ethical principles:

- Health maximization
- Equality
- Priority to the worst off
- Personal responsibility

Ethical Issues in Making Investment Choices in Health

Fair Processes

- Transparency about how decisions are made
- Representation from stakeholders affected
- Appropriate use of scientific data

Key Challenges for the Future

- Students of global health get insufficient exposure in their training to ethical issues
- No mechanisms of enforcement of humans rights
- Shortage of trained personnel for reviewing research
- Lack of reviews of how investments are made
- Unsolved ethical problems