Micro Research

Google images

Basics of Research Ethics

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Objectives:

- Appreciate the historical context of research ethics
- Understand the basics for international standards for research ethics
- Identify concerns regarding risk
- Describe the differences that exist when vulnerable populations are participants.
- Define “Conflict of Interest” and describe some guiding principles

Basics of Research Ethics

Potential Competing Interests:

Name	Organization	Role
J Jones	WHO	Consultant
	University X	Assoc. Professor
	Hospital X	Clinician
	'X Company'	Consultant
S Smith	Institute	Director
	Drug Company A	Clinical Trial
	Drug Company B	Investor
	Drug Company C	Consultant

Conflict of Interest and Integrity in Research

One of the best definitions of conflict of interest was proposed by Denis Thompson.

"a conflict of interest is a set of conditions in which professional judgment concerning a primary interest (such as a patient's welfare or the validity of research) tends to be unduly influenced by a secondary interest (such as financial gain)"

NEJM, 1993.

Specific Conflicts of Interest (COI)

Role Confusion:
Caregiver vs. Researcher

- Clinicians doing research, have two goals,
  - to provide best care for the patient,
  - to acquire generalizable knowledge.
- The two goals can present a conflict.
- To be ethical, clinicians can't disadvantage research subjects, particularly when they are patients who come to them for care.

What can we learn from the past ?

- The history of politics, medicine, and business are rich and detailed.
- The history of Ethics is brief and short!

A Brief History of Human Research Ethics-1

Hippocratic Oath:

- ***….primum nil nocere…***

  ("I will prescribe regimens for the good of my patients according to my ability and my judgment and never do harm to anyone.")

A Brief History of Human Research Ethics-2

Nuremberg (Nürnberg) Code (1947)

As part of the verdict in the Nuremberg War Crimes Trials of 23 German doctors, the Court enumerated some rules for “Permissible Medical Experiments”, now known as the “Nuremberg Code”:

- *voluntary consent*
- *benefits outweigh risks*
- *ability of the subject to terminate participation*

A Brief History of Human Research Ethics-3

Declaration of Helsinki 1964…

Recommendation guiding doctors in Biomedical Research involving human subjects.

"*Concern for the interests of the subject must always prevail over the interests of science and society*"

World Medical Association Updates -2013 (Brazil)http://www.wma.net/en/30publications/10policies/b3/

A Brief History of Human Research Ethics- 4

Tuskegee incident

In 1972: revealed that for > 40 years

US Public Health Service-

performing studies on poor black men from Tuskegee, Alabama

all denied treatment for syphilis without ever consenting.

Awareness of these studies created a **scandal** --demand for more stringent regulations for informed and voluntary participation in human research.

What have we learned ?

- The Nuremberg Code prohibited most research involving children and many vulnerable populations e.g. pregnant women.
- The Declaration of Helsinki formally disallowed non-therapeutic research on non-consenting subjects.
- The codes present difficulties for those who want to advance the health of vulnerable people who do not have the capacity for consent.

The unexpected outcome !

Policy that strictly prohibits children and other vulnerable populations from participation in research may harm both individuals and the populations *en masse* by making them research "orphans."

- Overprotection can harm the ones you are trying to protect!

Overcoming the dilemma

- Ethics committees must examine studies for acceptable balance of risk and benefit.
- Principle of justice for a vulnerable and other populations means risk is distributed equally and benefits are accessible to everyone.

An ever-present tension for clinicians

Three Principles of Research Ethics

Principles:

- respect for persons,
- beneficence and
- justice.

Concept of non-malificence is complementary to beneficence:

- to do good and no harm,
- to maximize potential benefits,
- while ***minimizing risk***.

Concept of Minimal Risk

The US Federal Common Rule describes minimal risk as meaning that

"the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ***ordinarily encountered in daily life****."*

Equipoise, Risk and Therapeutic Procedures

- Equipoise “a state of uncertainty as to the relative superiority of two treatments”.
- Exposure to therapeutic risk may sometimes be acceptable if clinical equipoise exists.
- Children may be exposed to risk if there is equipoise: treatment A vs B.
  - This is the case in children with cancer in which death, secondary to toxicity of treatment, is a potential event with either.

Placebo Interventions

A placebo should ***only*** be allowed if there are valid reasons to use it rather than an active drug.

A placebo must satisfy one of these conditions:

- minimal risk,
- more than minimal risk but a direct benefit from the placebo
- a minor increase over minimal risk but the study is likely to produce knowledge of vital importance to the subject's own disease.

References: Research Ethics

Ethical and Scientific Implications of the Globalization of Clinical research.
http://content.nejm.org/cgi/content/full/360/8/816

Regulation of biomedical research in Africa.
http://www.bmj.com/cgi/content/full/332/7545/848?rss

The Declaration of Helsinki (Editorial)
www.bmj.com/cgi/content/full/335/7621/624?view=long&pmid=17901471

Interactive Research Training Curriculum,
www.fhi360.org/resource/research-ethics-training-curriculum-retc-second-edition

See chapter 1 Handbook: Basics in Research Ethics.

Local Ethics Process

forms, resources, advice….

Example:

West Africa 2014: Should the experimental drugs never tested in humans be given to Ebola cases?

MR Team Work Day 5 & Homework

1. Background should be well developed.
2. Research question/hypothesis clear
3. Method(s) selected – tasks assigned for completion of methods
4. MR team member selected to me budget manager – collect budget information, begin budget justification
5. Homework: complete methods work and firm up budget; start to think about presentation

Micro Research

Planning for Final Day Presentation

- Title Slide (1)
- List MR Team members, their background, COI (1)

- Background (3)
- Research Question(s) or Objectives (1)
- Method Slides (3)
- Budget (1)
- KT plan (1)
- Next steps (1)

Total= 10 slides (excludes title and team member slides)

Judges Evaluate

- Relevance: to local & the wider community *(35 points)*
- Feasibility: time, budget *(35 points)*
- Other *(10 points each)*
  - Importance to Africa
  - Novelty
  - Team participation