

Research Injuries and Compensation

Temidayo O Ogundiran
MBBS (Ibadan), MHSc (Toronto), FRCS (Edinburgh),
FWACS

Division of Oncology, Department of Surgery, University of Ibadan and University
College Hospital, Ibadan
West African Bioethics Programme, University of Ibadan, Nigeria

**Why do people participate in
research?**

Why do people participate in research?

- curiosity
- altruism
- sensation seeking
- desire for attention provided by physicians
- hope of personal therapeutic benefit
- financial

Are there risks in research?

Categories of risk

- Physical risk – the participant may suffer bodily harm which may be serious or minor, temporary or permanent, immediate or delayed as a result of research participation
- Psychological risk – participant may suffer affectation of perception of self, emotional suffering or induction of aberrations in thought or behavior
- Social risks – research findings or even participation may expose one to possibility of different forms of discrimination or stigmatization
- Economic risks – participants may directly or indirectly bear some financial costs related to participation

Research Injury

- injury that occurs to a subject as a result of research participation
- may be minor harms, major or catastrophic
- may require acute/short-term or chronic or continuing care

How often do research-related injuries occur?

- 1976: 331 researchers conducting research on 133,000 participants in 3 years recorded 4957 injuries. Most were trivial, 974 resulted in temporary disability, 57 injuries resulted in death or permanent disability
- Summary: 12 injuries/ 1000 subjects per year and a catastrophic injury rate of 14/100,000

How often do research-related injuries occur?...

- 1986 phase 1 drug trials: 1 death/27,000 subjects and 13 serious reactions; catastrophic injury rate of 4/100,000 participants

**Should research-related injuries be
compensated?**

Should research-related injuries be compensated?

- A spectrum of views from “yes” to “no”

USA

Europe

India

Nigeria

Ethical basis for compensation

- Beneficence

obligation to minimize the additional harms that may occur to the subject as a result of the injury

participants should be no worse off than they would be had they not participated in research

Ethical basis for compensation...

- Justice: fair distribution of benefits and burdens of research
 - if a research participant bears a heavy burden, such as an injury, fairness demands that he/she receive some form of medical treatment or compensation

Some issues in compensation

- Fair compensation system
- Resources for compensation

Resources

- David B. Resnik. Compensation for Research-Related Injuries: Ethical and Legal Issues. Journal of Legal Medicine 2006; 27: 263-87
- Bavdekar SB, Thatte UM. Compensation for research-related injury. J Postgrad Med 2009;55:87-8
- Nigerian National Code on Health Research Ethics
- Clement Adebamowo. Risk. West African Bioethics Programme