ADVERSE EVENTS AND ETHICS IN RESEARCH

Professor A Dhai
Nelson R Mandela School of Medicine
University of KwaZulu-Natal
dhaia1@ukzn.ac.za
INTRODUCTION

• Issues – reconciling rights of individual persons with demands of scientific enterprise.

Intensified by laudable collective goal of medical research – to improve human well being, benefit people & society as whole

Interventional methods – hallmark of sound medical research – but not without cost
ADVERSE EVENTS IN
RESEARCH - DEFINITIONS

- ADVERSE EVENT – any untoward medical occurrence in the clinical trial participant where the contribution of the investigational product cannot be ruled out

MCC – SA. ADR reporting document May 03
ADVERSE EVENTS IN RESEARCH - DEFINITIONS

Serious Adverse Event – any untoward medical occurrence that in any dose:

- results in death
- Is life-threatening
- Requires patient hospitalisation or prolongation of existing hospitalisation
- Results in persistent or significant disability/ incapacity
- Is a congenital anomaly/ birth defect

MCC – SA. ADR reporting document May 03
ADVERSE EVENTS - WHOSE RESPONSIBILITY?

- During clinical trial
- After trial – long term surveillance
ADVERSE EVENTS - COMPENSATION

- SA Clinical Trials Guidelines 2000:

  “… are covered by comprehensive insurance for injury and damage …”

  “… sponsor should pay compensation to patients suffering bodily injury, including death …”

NIH – limited study funds available to cover cost for care for study related injury. No mechanisms for grantees to purchase insurance.
ADVERSE EVENTS - COMPENSATION

- "The US government should not sponsor or conduct clinical trials that do not, at a minimum, provide the following ethical protections . . . adequate care of and compensation to participants for injuries directly sustained during research . . ."”

National Bioethics Advisory Commission “Ethical and Policy Issues in International Research: Clinical Trials in Developing Countries” (2001)
CLINICAL TRIALS - SA

• Rich, unique environment for research - large number of vulnerable groups of poor populations

• Hence, many researchers drawn to SA
  - clinical trial industry increased by 40% in 1998
  - turnover for 2000 - approximately R billion
Some questionable factors for carrying out research in developing world:

- lower costs of the research,
- lower risks of litigation,
- availability of populations prepared to co-operate with any type of study,
- anticipated under-reporting of side effects - lower consumer awareness
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These views merely represent THE TRUTH.