

RESEARCH ETHICS INVOLVING THE MILITARY

Lt. Col. (Dr.) A. Balasuriya

Dean, Faculty of Allied Health
Sciences, KDU

Member, KDU ERC & FERCSL

Why research in the military?

- Generally, follow traditions
- Evidence base is needed for improvement
- New inventions, technologies & methodologies will improve productivity and give cutting edge advantage
- Directorates of Research and Development established in all 3 services

Issues with military research

- Security and
- Hierarchical structure
- Therefore, obtaining permission
- Authorship
- Data collection
- Accusations of torture

Nuremberg trial



10 points of the Nuremberg code

- Voluntary consent of the human subject is absolutely essential
- Should ... yield fruitful results for the good of society, and not random and unnecessary
- Designed based on knowledge or evidence
- Avoid all unnecessary physical and mental suffering and injury
- Do not perform if death or disabling injury will occur

10 points of the Nuremberg code

- Degree of risk ... should never exceed the humanitarian importance of the problem (risk vs. benefit)
- Preparations and adequate facilities to protect the subjects against even remote possibilities of injury, disability or death
- Conducted only by scientifically qualified persons
- Should be at liberty to bring the experiment to an end
- Be prepared to terminate at any stage

Data collection issues

- Human rights
- Autonomy
- Risk to benefit ratio
- Justice

Ethical acceptability of a research

- Measures to ensure protection of vulnerable populations

WHO, 2011. Standards and operational guidance for ethics review of health-related research with human participants. WHO, Geneva.

Vulnerable (research) participants

- Those who are relatively (or absolutely) incapable of protecting their own interests
- May have insufficient power, intelligence, education, resources, strength, or other needed attributes to protect their own interests
- a substantial incapacity to protect own interests owing to such impediments as ... being a junior or subordinate member of a hierarchical group

Hierarchical relationship

- Individuals whose willingness to volunteer in a research study may be unduly influenced by the expectation, whether justified or not, of benefits associated with participation, or of a retaliatory response from senior members of a hierarchy in case of refusal to participate may also be considered vulnerable

Examples

- Members of a group with a hierarchical structure, such as medical, pharmacy, dental, and nursing students, subordinate hospital and laboratory personnel, employees of the pharmaceutical industry, members of the armed forces, and persons kept in detention

Others

- Patients with incurable diseases, people in nursing homes
- Unemployed or impoverished people, patients in emergency situations
- Ethnic minority groups, homeless people, nomads, refugees, minors and
- Those incapable of giving consent

Research involving vulnerable persons

- Special justification is required for inviting vulnerable individuals to serve as research subjects and, if they are selected, the means of protecting their rights and welfare must be strictly applied

How to justify?

- Study cannot be done in any other group
- Benefit the vulnerable group
- Benefits/ products of study available to them
- Risk benefit analysis

CIOMS guidelines

- junior or subordinate members of a hierarchical group
- agreement to volunteer may be unduly influenced, whether justified or not, by the expectation of preferential treatment if they agree or by fear of disapproval or retaliation if they refuse

Council for International Organizations of Medical Sciences 2002.
*International Ethical Guidelines for Biomedical Research
Involving Human Subjects. CIOMS, Geneva.*

Voluntary consent

- Voluntary consent absolutely essential
- Legal capacity to give consent
- Able to exercise free power of choice, without force, fraud, deceit, duress, over-reaching, or other ulterior form of constraint or coercion
- Sufficient knowledge & comprehension of the nature, duration & purpose; method & means; inconveniences & hazards reasonable to be expected; effects upon health
- Personal duty and responsibility of the individual who initiates, directs or engages in the experiment

