Ethical Issues in Human Subject Study : a view from four sides

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Ethical issues in human subject study : a view from IRB/IEC

1. Scientific value and Social value
    - Guideline 1 – CIOMS 2016
    - Sample size calculation not appropriate
    - Statistical analysis not correspond to research methodology
2. Informed consent process
    - no recruitment strategy mentioned, difficult to evaluate coercion or undue inducement
    - too much information, too long
    - difficult to comprehend especially clinical trials sponsored by pharmaceutical company (Google translate)
    - storage of biological materials for future use
    - physician-patient relationship
3. Compensation
    - no insurance coverage for research-related injury in investigator initiated protocol

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4. Safety
   - no data safety monitoring for investigator –initiated study
5. Subject Selection
   - exploitation of vulnerable population eg., nursing home,
6. Ethical guidelines
   - lack national guideline for studies involving food supplement, medical devices, cosmetics, biobank

Social value of research

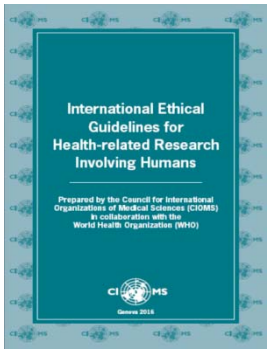
What does it mean?

- Nuremberg Code (1947) identifies “Social value” in second paragraph :-

  2. *The experiment should be such as to yield fruitful results for the good of society, unprocurable by other methods or means of study, and not random and unnecessary in nature*

Nuremberg Doctor’s Trial, BMJ 1996;313(7070):1445-75

Social value of research



What does it mean?

- International Ethical Guidelines for Biomedical Research Involving Human Subjects (CIOMS guidelines 2016):-
  Guideline 1:

The ethical justification for undertaking health-related research involving hyman is its scientific and ***social value*** *: the prospect of generating the knowledge and the means necessary to protect and promote people's health. Patients, health professionals, researchers, policy-makers, public health officials, pharmaceutical companies and others rely on the results of research for activities and decisions that impact individual and public health, welfare, and the use of limited resources. Therefore, researchers, sponsors, research ethics committees, and health authorities, must ensure that proposed studies are scientifically sound, build on an adequate prior knowledge base, and are likely to generate valuable information.*

Social value of research

What does it mean?

- International Ethical Guidelines for Biomedical Research Involving Human Subjects (CIOMS guidelines 2016):-
  Commentary on Guideline 1 :
  Social value.

  Social value refers to the importance of the information that a study is likely to produce. Information can be important because of its direct relevance for understanding or intervening on a significant health problem or because of its expected contribution to research likely to promote individual or public health. The importance of such information can vary depending on the significance of health need, the novelty and expected merits of the approach, the merits of alternative means of addressing the problem, and other considerations. For example, a well-designed, late phase clinical trial ***could lack social value*** *if its endpoints are unrelated to clinical decision-making so that clinicians and policy-makers are unlikely to alter their practices based on the study's findings.*

Social value of research

What does it mean?

- International Ethical Guidelines for Biomedical Research Involving Human Subjects (CIOMS guidelines 2016):-
  Commentary on Guideline 1 :
  Social value.

  Researchers, sponsors, research ethics committees and relevant health authorities, such as regulators and policy-makers, must ensure that a study has ***sufficient social value*** *to justify its associated risks, costs and burdens. In particular, there must be* ***sufficient social value to*** *justify risks to participants.*

Social value of research

Perceptions of social value of research*

- vary among careers
- public health workers – research should improve health and health care
- health managers – research outcome should improve health system, human resource development and capacity building for health workers
- most other researchers – research should benefit future persons and society arising from the research result**
- Emanuel included benefits such as capacity-building and infrastructure-development in accounts of social value***

*Lutge E, Slack C and Wassenaar D, Defining and negotiating the social value of research in public health facilities : perspections of stakeholders in a research-active province of South Africa, Bioethics 2017;31:128-35.
**King N., Defining and Describing benefit appropriately in clinical trials, J Law med Ethics 2000; 28: 332-43.
***Emanuel EJ et al What makes clinical research in developing countries ethical? The benchmarks of ethical research, J Infect Dis 2004;189:930-7.

Social value of research

- Habets et al :- social value can be seen as values shares by a community of individual; they are values held by society (value ***of*** society) and also can be values ***for*** society.(social value is an assigned predicate or property of an object, eg., research)
  - There is thus ***no standard*** to decide when an intervention of research has (enough) anticipated social value

Habets et al,: The social value of clinical research, BMC Medical Ethics 2014 **15**:66.

How can **IRB** handle **“ social value”** of research ?

- **no** standard solution
- take into consideration when review research protocol on human subject study –the “social value” that will be generated from the study.
- seriously assessing risk and benefit to participant that caused by participating in the research
- may add a section on “social value” of the study to the format of protocol that will be submit to IRB

Thank you