



# Elements of Research Ethics Review II

Social Value

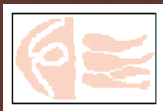
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1. Social or Scientific value
2. Scientific validity
3. Fair subject selection
4. Favourable risk-benefit ratio
5. Independent review
6. Informed consent
7. Respect for potential and enrolled subjects



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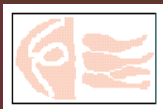
“To be ethical, clinical research must be valuable...”

– *E. J. Emanuel et al*



“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”

– *The Nuremberg Code*



“Medical research is only justified if there is a reasonable likelihood that the population in which the research is carried out stand to benefit from the results of the research”

– *Declaration of Helsinki*



## Corollary - 1

Clinical research without possible social or scientific value is a waste of resources and unnecessary exposure of human beings to potential harm

## Corollary - 2

Badly planned and poorly designed research that causes inconvenience to participants with possible risks will not produce useful or valid results is considered unethical



# Assessment of value - 1

Will the proposed treatment or diagnostic intervention being evaluated lead to improvement in health and well being?

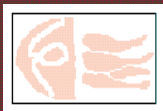
# Assessment of value - 2

Is the research a study of etiological or epidemiological factors that could lead to innovative therapeutic or diagnostic interventions?

# Assessment of value - 3

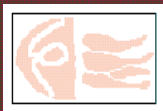
Is the research one that could generate new knowledge about the structure or function of human biological systems?

(Even if that knowledge does not have immediate practical applications)



# Assessment of value - 4

- Would the results be generalizable?
- Is the hypothesis being tested trifling or weighty?
- Are the answers being sought already available – in their entirety or in large measure?



# Assessment of value - 5

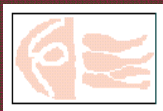
- Would the results of the research be adequately and appropriately disseminated?
- Is there a plan for dissemination of the results?



# International Collaborative Research -

- Share fairly financial and other rewards
- Who are the beneficiaries of the research?
- Assess the importance of the health systems being investigated and the prospective value of the research for each of the beneficiaries

continued



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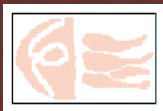
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# International Collaborative Research - continued

- Enhancing value for each of the beneficiaries: dissemination of knowledge, product development, long term research collaboration, health system improvement
- Prevent undermining the existing health system infrastructure and services

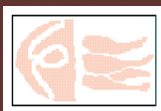
- *Ethical principles and benchmarks for multinational research*

Emanuel *et al* -



# Practical Problems - 1

- Determining social value can be uncertain: requires judgements
- Research results can be imperfectly incorporated into the healthcare system

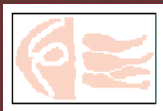




# Practical Problems - 2

How stringently should these requirements be applied?

- Research as a training requirement
- Undergraduate research



**END**