Benefit and Harm Assessment in Healthcare Research and Practice in Disaster Settings

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Both Views Cannot be Right

War is a Perfect Laboratory for Research

War is the Worst Environment for Research
The world would only be one fact and one great truth for whoever knew how to embrace it from a single perspective. (J. D 'Alembert, 1753)

The world is...too complicated and too tragic...Most crises require weighing unknowns against unknowns, and choosing between competing evils.
Research: Exploring the Unknown
Rules for Ethical Research

• Informed Consent; (respect for persons)
• IRB determination that Risk/benefit is favorable; (Nonmaleficence)
• A determination that subjects bears a fair share of burdens and benefits (Justice)
Nuremberg Code:
The informed consent of the subject is absolutely essential
Nuremberg Code

- The experiment should be such as to yield fruitful results for the good of society; (rule 2)

- The degree of risk to be taken should never exceed that determined by the humanitarian importance of the problem to be solved by the experiment. (rule 6) (proportionality of harm/benefit)
Nuremberg Code
Helsinki Declaration
Good Clinical Research Practice
US federal Research Regulations

got ethics?

Ethics Template
Benefit And
Risk
Go Ahead - Take Risks
The research project must be responsive to the health conditions or needs of vulnerable subjects; Research done in developing countries, people of these countries must directly benefit from the fruits of that research.
Good Clinical Research Practice Guidelines.

- Foreseeable risks and any anticipated benefits for the individual subjects and society should be identified before research is initiated.

- Though the benefits of the result of the study to science and society should be taken into account, the most important considerations are those related to the rights, safety and well-being of the subjects.
US Federal Research Regulations

#1.

- Define **minimum** risks to mean that the probability and magnitude of risks anticipated in the research are not greater, in and of themselves, than those ordinarily encountered in daily life.
• Prior review of research protocols by the IRB. However, IRB should only consider those risks and benefits that may result from the research.

• IRB should not consider possible long-range effect of the research as among those risks that fall within the purview of its responsibility.
• The benefit ...must accrue directly and temporally to the actual subjects ...the risks to the subjects, their community and their future security must be kept to an absolute minimum and ...all anticipated risks should be identified and monitored...
Research we can do
Investigators will continue to believe in the green light of the orgiastic future brought by research.
It eludes them...but that's no matter...
tomorrow they will run faster, stretch out their arms farther...
and so the beat goes on....