Respecting the Rights of Subjects in Disaster Research

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How we think.
Therapeutic/Disaster Illusion

- research is treatment
- researcher is your physician
- subject is a patient
“Ordinary patients [disaster victims] will not knowingly risk their health or life for the sake of ‘science.’ Every experienced clinical investigator [disaster responder] knows this.”

Henry Beecher, 1966
Emergency Medicine

• in an emergency, treat first and ask legal questions later.

• why? consent presumed? implied? NO

• physicians are privileged to treat in these circumstances
FDA Rules on Emergency Research

- life-threatening situation
- available treatments unproven or unsatisfactory
- need scientific evidence to determine safety and efficacy
- informed consent NOT FEASIBLE because:
  - subjects not able to consent
  - consent from another not feasible
- research holds prospect of direct benefit to subjects

IRB, DSMC, & COMMUNITY CONSULTATION
Justifications (Fost, 1998)

- democratic
- informed consent is not an end in itself
- carefully monitored by IRB and DSMC
- need new treatments
- people would consent if they could
- treatment today unsatisfactory
- save future lives
- i.e. utilitarian ethics are OK
FDA is NOT the final word on ethics or human rights

- First Gulf War and consent waivers
- Afghanistan War
- Preemption
- Pfizer in Nigeria
- Nuremberg Code
- Terrorism and “Ticking Bomb”
- Emergency Research
THE BOY WHO KICKED THE HORNET’S NEST
DEALING WITH JULIAN ASSANGE AND HIS SECRETS.
BY BILL KELLER
The Nuremberg Code

• Consent of Subject: *Voluntary, Competent, Informed and Understanding*

• Right to Withdraw *at any time*

• 8 Welfare Provisions *relating to protecting the interests of subjects and requiring application of scientific methods in research in which risks to subjects are outweighed by benefits*
UNIVERSAL DECLARATION OF HUMAN RIGHTS 1948–1998
International Covenant on Civil and Political Rights

Art. 7: No one shall be subjected to cruel, inhuman or degrading treatment or punishment. In particular, no one shall be subjected without his free consent to medical or scientific experimentation.
Siracusa Principles

Nonderogable rights:
58. No state party shall, even in time of emergency threatening the life of the nation derogate from the Covenant’s guarantees of...freedom from torture, cruel, inhuman or degrading treatment or punishment, and from medical or scientific experimentation without free consent...
save lives
Facts should matter

- blood substitute studies (& their sponsors)
- saline studies
- resuscitation studies
Blood Substitute Studies

- Based on 16 RCTs of 5 homoglobin-based blood substitutes [in 3711 subjects], their “use is associated with a significantly increased risk of death and MI [heart attack]” [164 deaths vs. 123 deaths]

Page 27,655: “Eventually we all die...”
“There’s got to be a better way.”...