

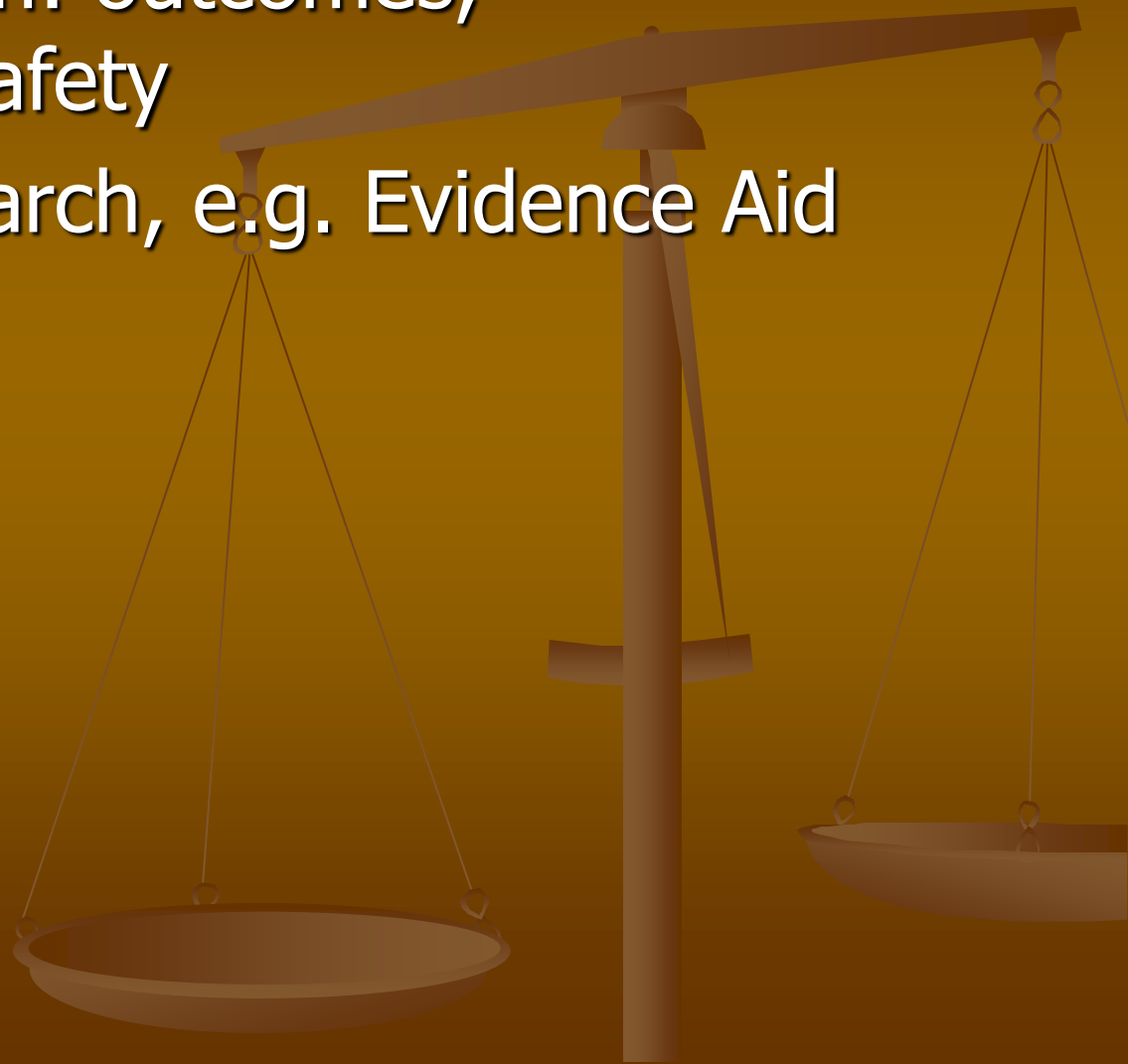
# Research ethics and Disasters

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# Research as an ethical imperative

- Primary research: outcomes, effectiveness, safety
- Secondary research, e.g. Evidence Aid



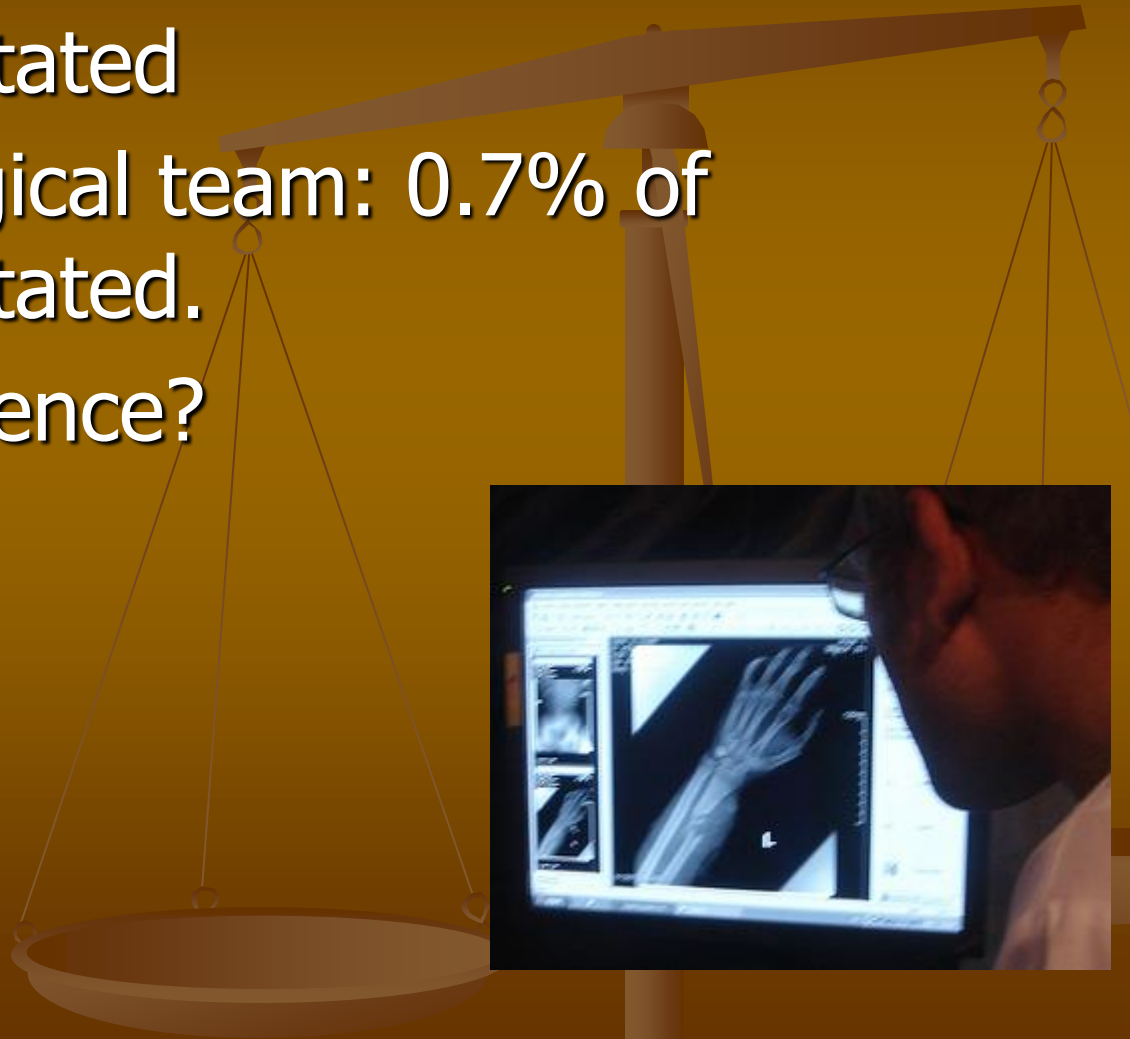
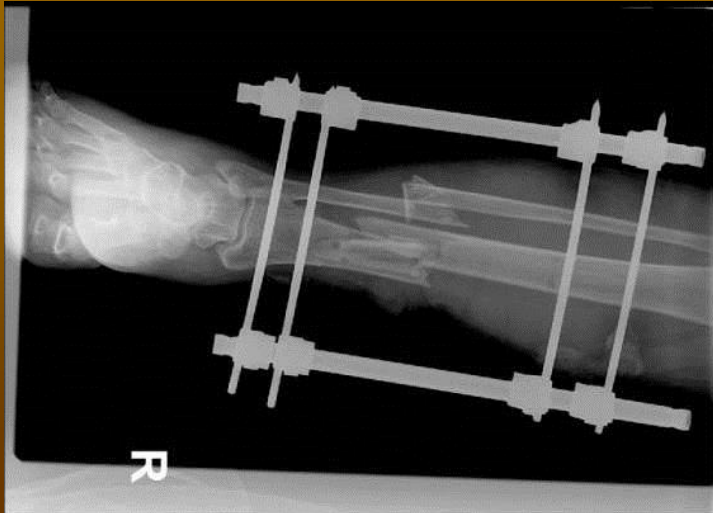
# Research ethics

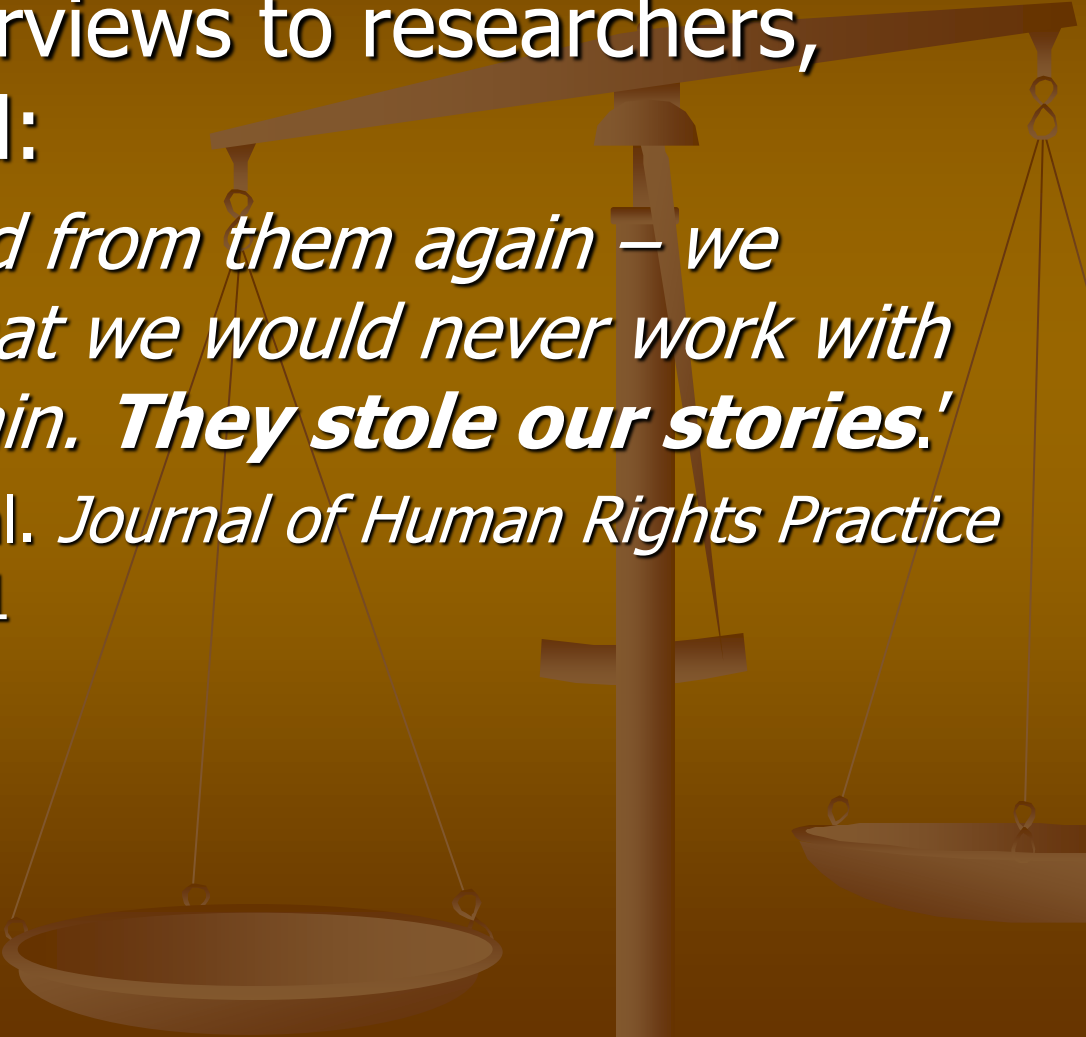
- Trovan meningitis experiments
- Post-Tsunami biological samples



# Haiti 2010: To amputate or not

- One university medical team: 7.7% of patients amputated
- One army surgical team: 0.7% of patients amputated.
- Why the difference?

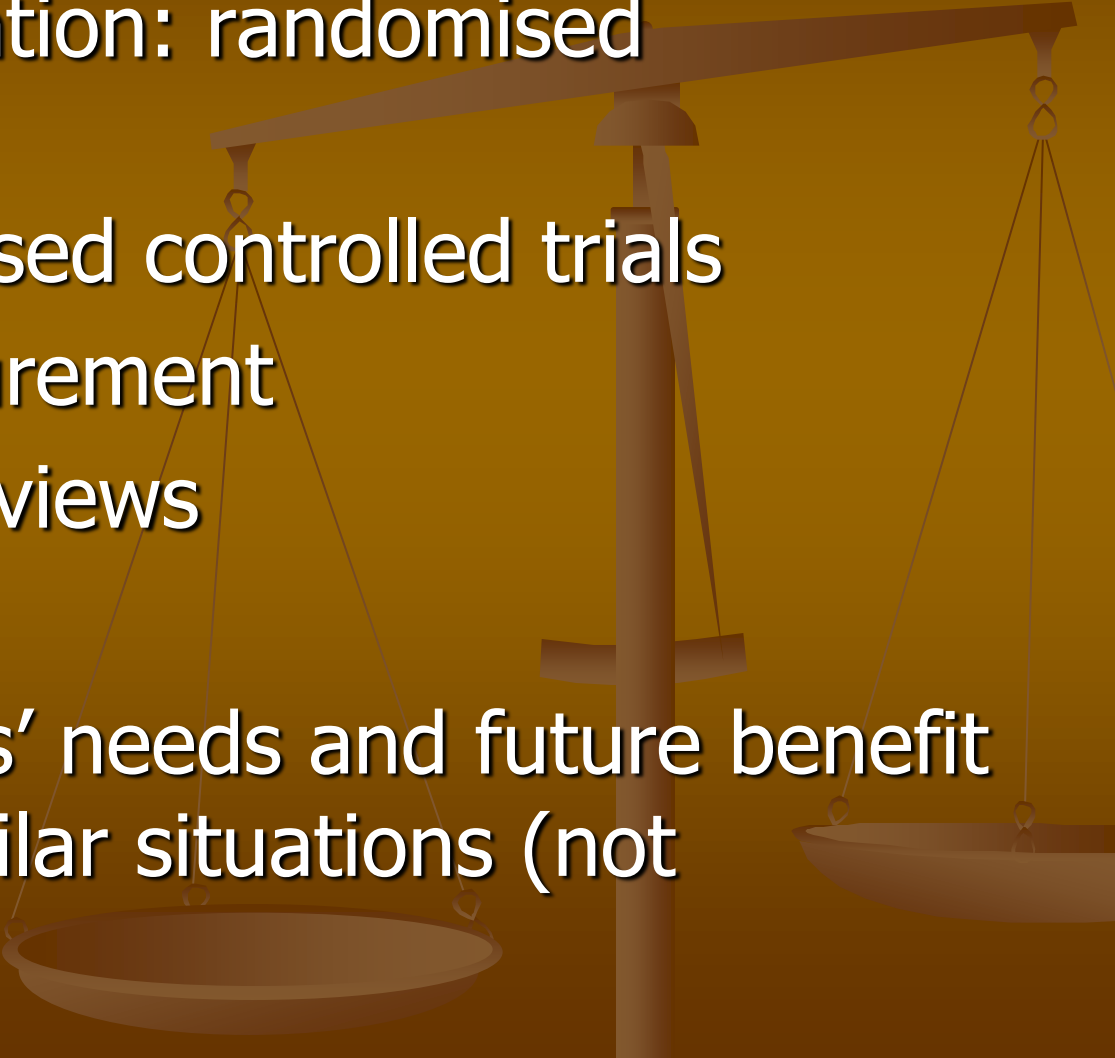


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- After giving interviews to researchers, women reported:
    - *'We never heard from them again – we decided then that we would never work with researchers again. **They stole our stories.'***
    - Pittaway E, et al. *Journal of Human Rights Practice* 2010;2:229-251

# Psychological debriefing

- New York post 9/11: 9,000 debriefers
- Post Tsunami 2004: hundreds of trauma counsellors to Sri Lanka to deal with estimated PTSD rates of 50-90%.
- Actual rate: 1.7%
  - ❖ Rose SC, et al. Psychological debriefing for preventing post traumatic stress disorder (PTSD). *Cochrane Library* 2002; Issue 2.
- Psychologically, most (but not all) disaster survivors need 'practical help often learned better from grandmothers than from graduate training'
  - ❖ Gist & Devilly. Post-trauma debriefing. *Lancet* 2002;360:741-2.

# What sort of research?

- Medical intervention: randomised controlled trials
  - Cluster randomised controlled trials
  - Outcome measurement
  - Qualitative interviews
  - Surveys
  - Focus on victims' needs and future benefit to people in similar situations (not opportunism)
- 



# What sort of researcher?



MORAL SCIENCE  
Protecting Participants in  
Human Subjects Research

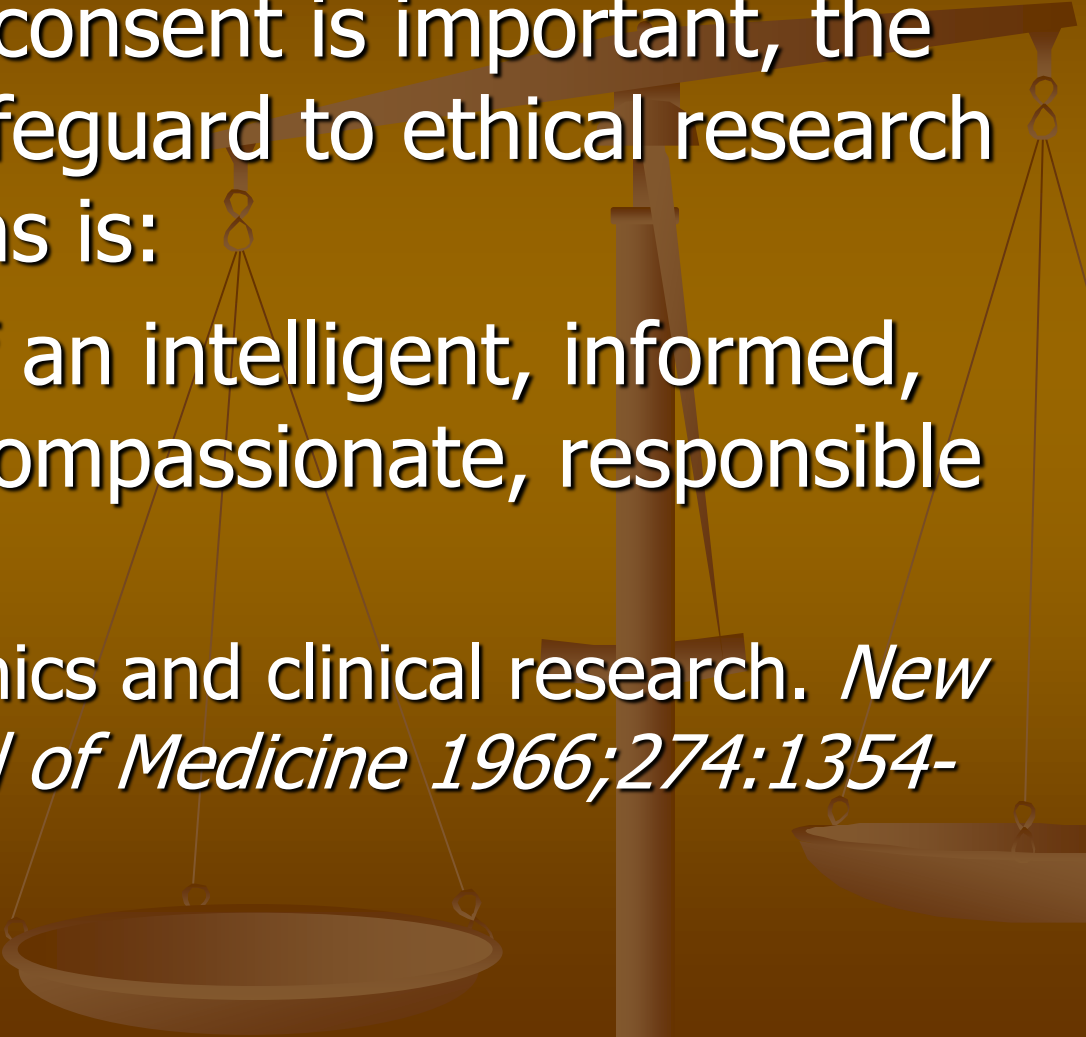
Presidential Commission  
*for the Study of Bioethical Issues*

December 2011



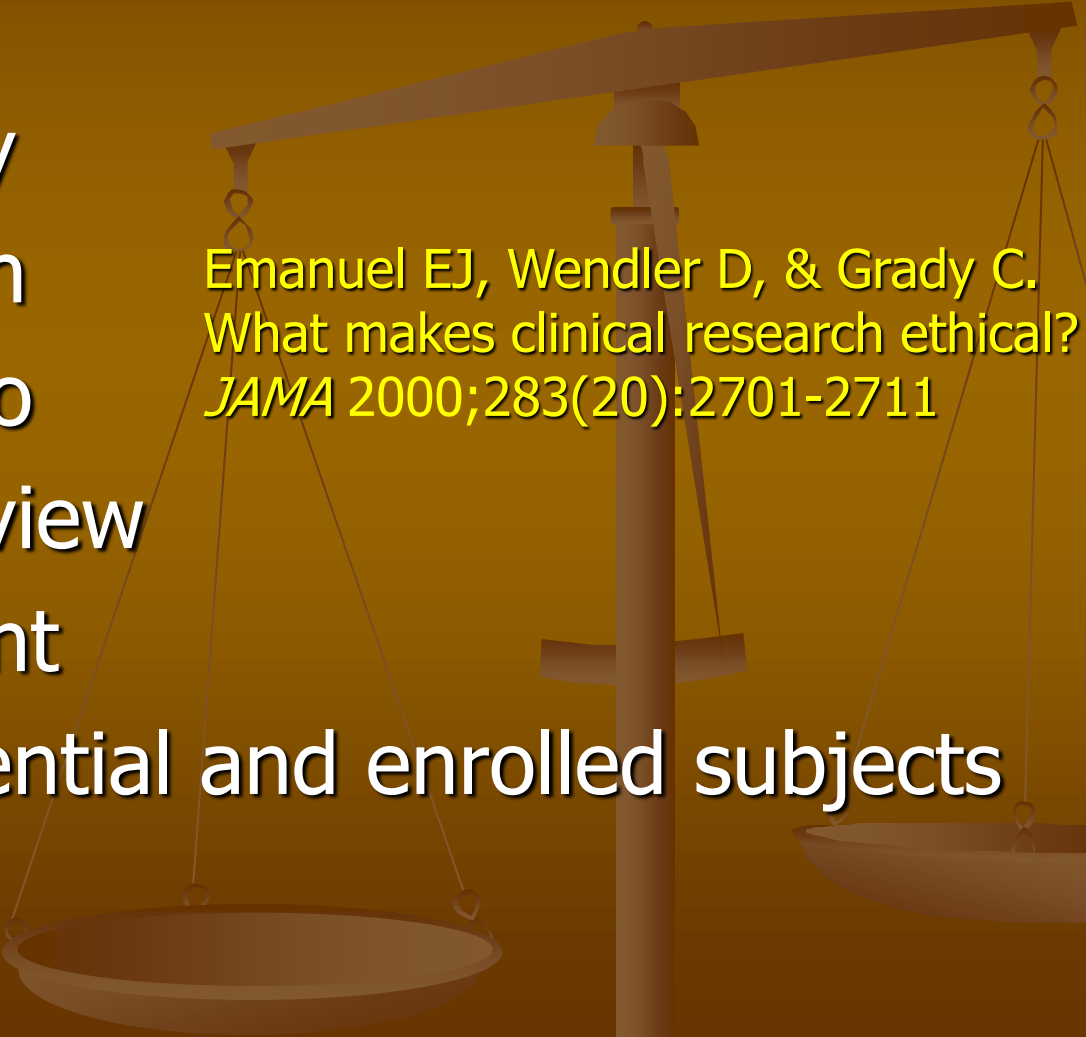
- “the virtuous researcher”
  - ◆ ‘a focus on the internal ethical motivation of individual investigators, not only the rules and regulations that externally motivate investigators toward compliance’ (p. 32)



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- While informed consent is important, the most reliable safeguard to ethical research involving humans is:
  - 'the presence of an intelligent, informed, conscientious, compassionate, responsible investigator.'
    - ❖ Beecher HK. Ethics and clinical research. *New England Journal of Medicine* 1966;274:1354-1360

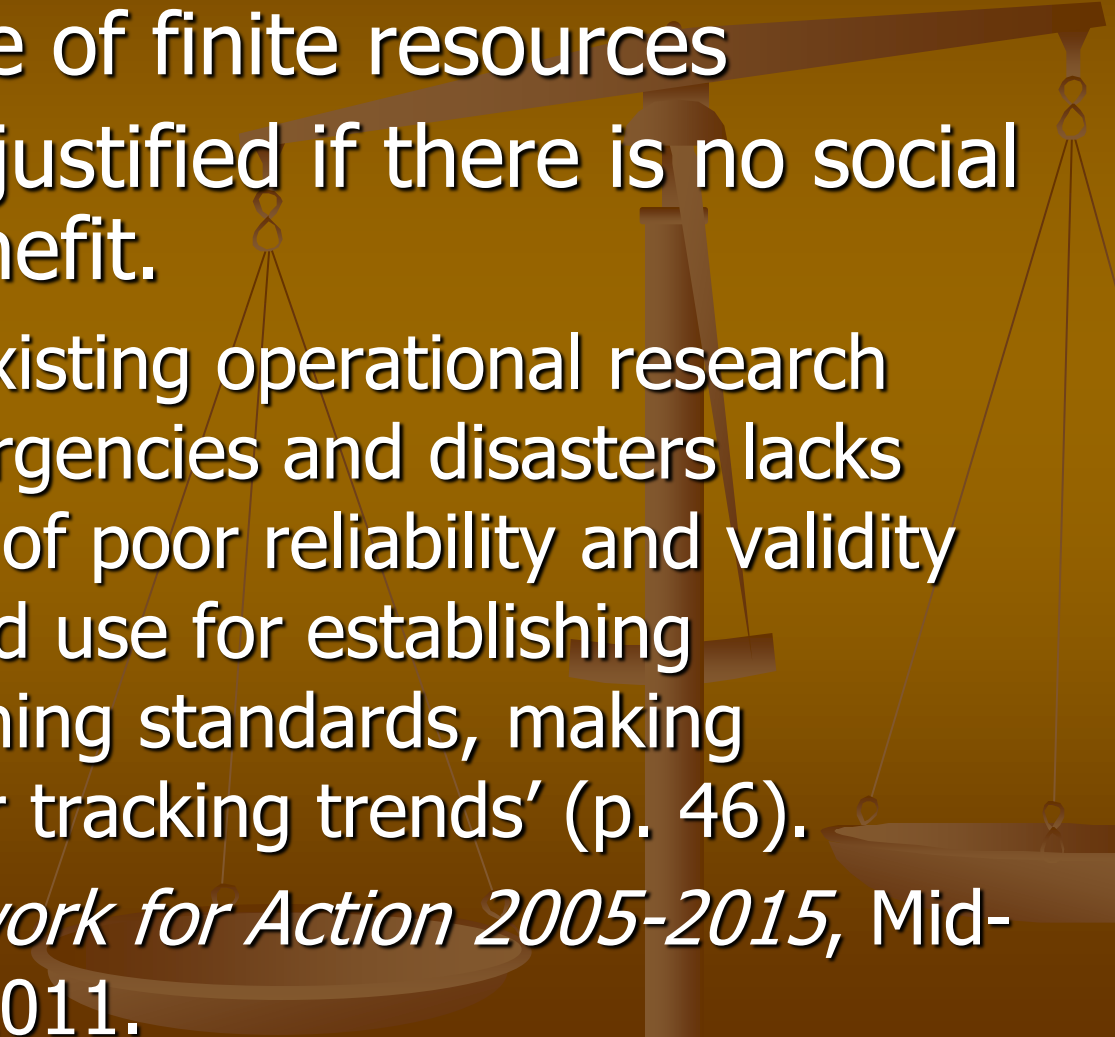
# General principles for Research ethics

- Value
- Scientific validity
- Subject selection
- Risk-benefit ratio
- Independent review
- Informed consent
- Respect for potential and enrolled subjects

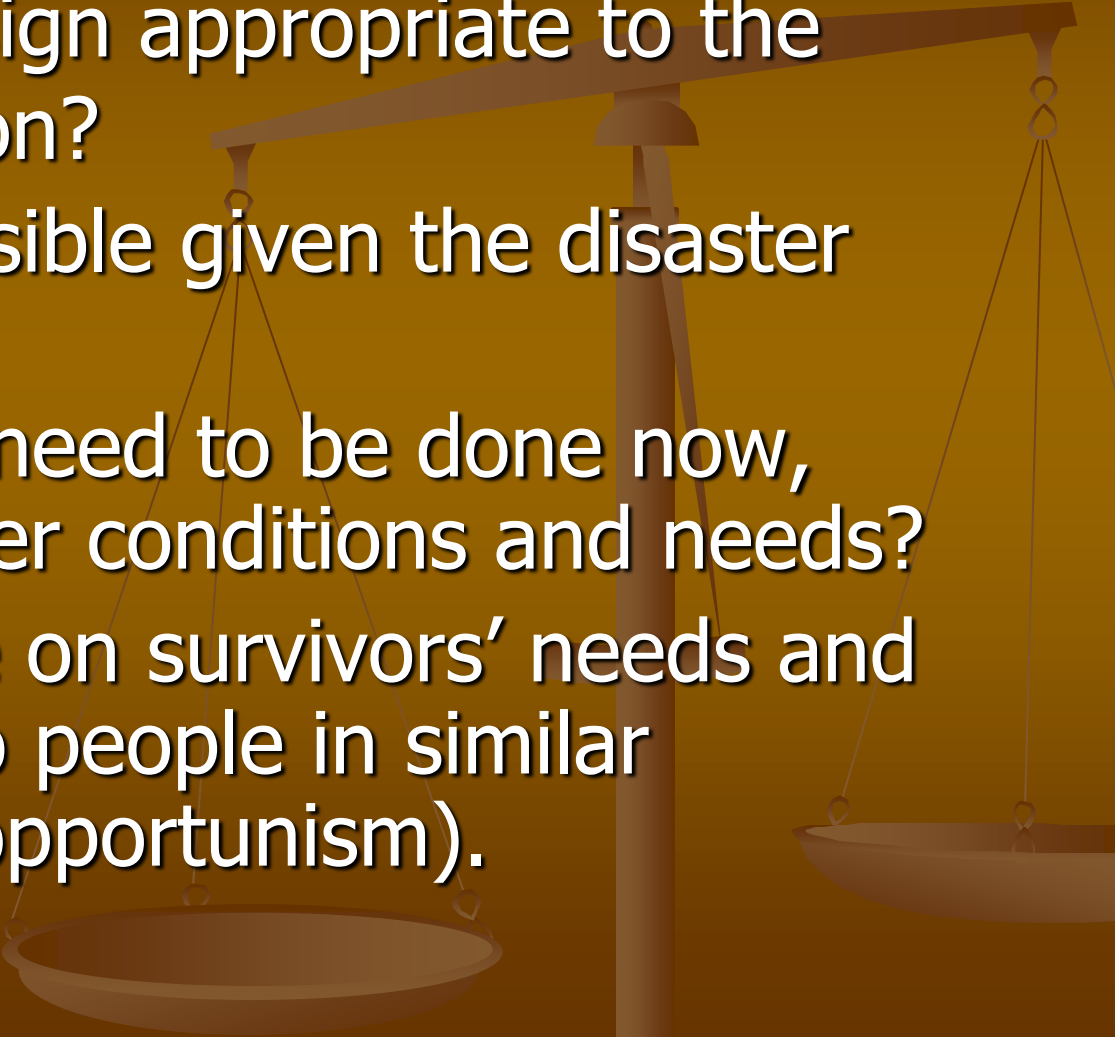


Emanuel EJ, Wendler D, & Grady C.  
What makes clinical research ethical?  
*JAMA* 2000;283(20):2701-2711

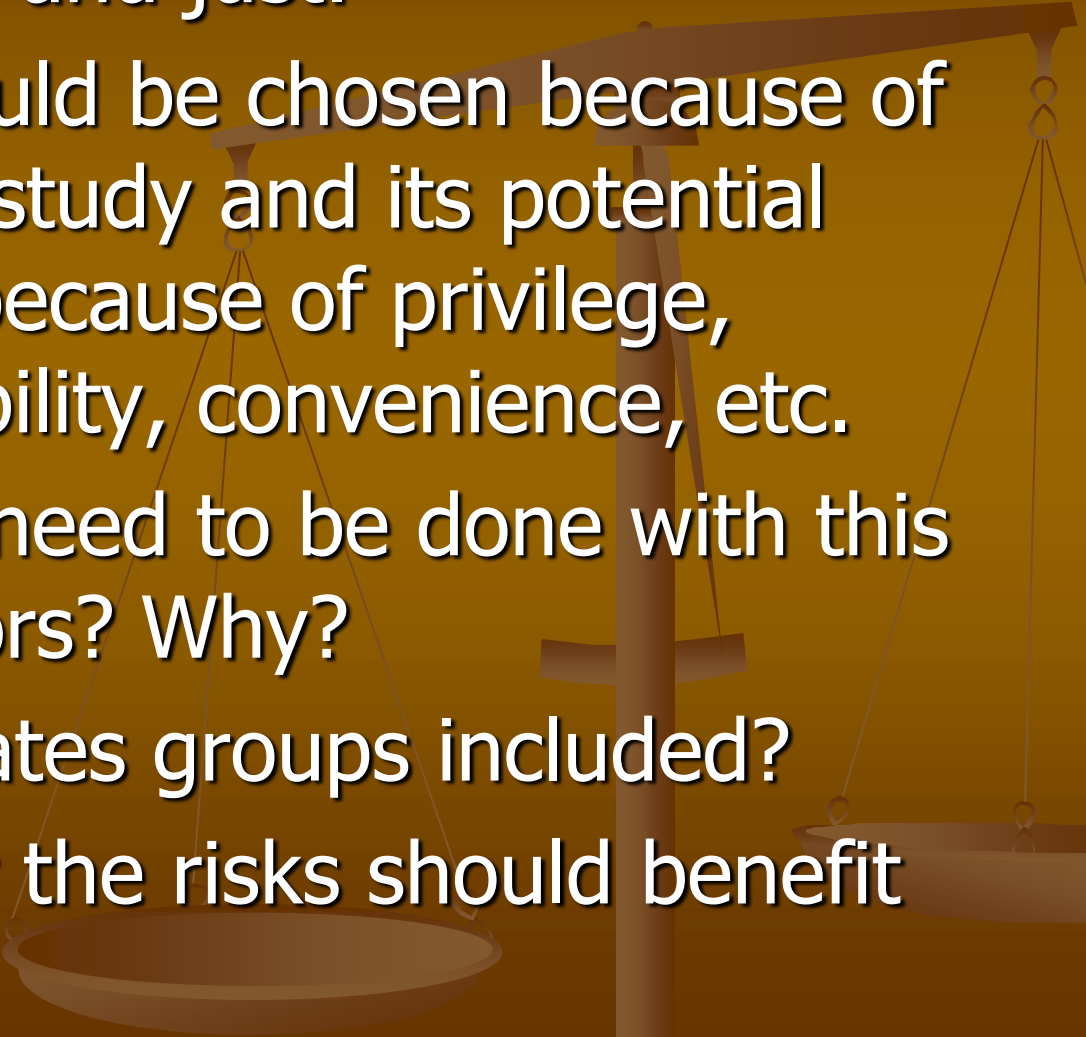
# 1. Value

- Ethical imperative for research
  - Responsible use of finite resources
  - Harms are not justified if there is no social or scientific benefit.
    - ❖ 'much of the existing operational research related to emergencies and disasters lacks consistency, is of poor reliability and validity and is of limited use for establishing baselines, defining standards, making comparisons or tracking trends' (p. 46).
    - ❖ *Hyogo Framework for Action 2005-2015, Mid-Term Review 2011.*
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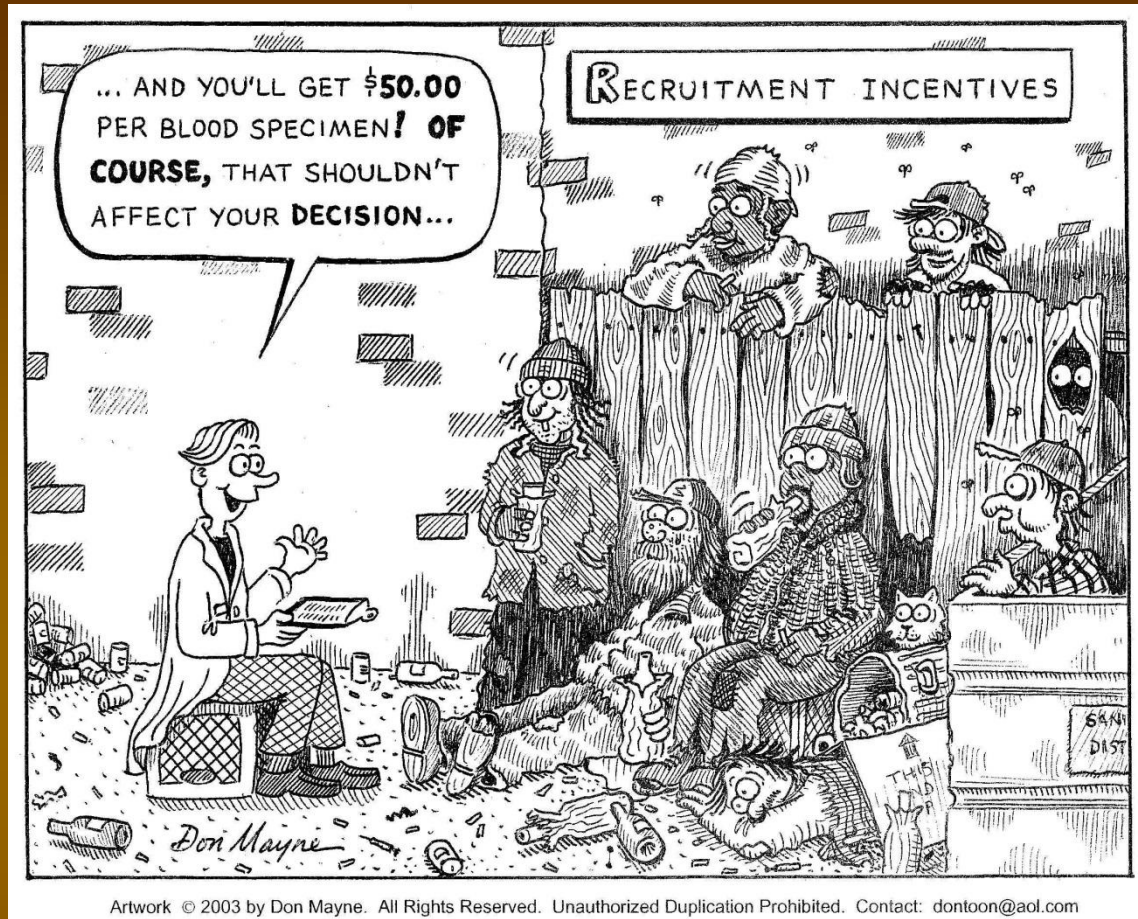
## 2. Scientific validity

- Is the study design appropriate to the research question?
  - Is the study feasible given the disaster situation?
  - Does the study need to be done now, given the disaster conditions and needs?
  - Focus should be on survivors' needs and future benefit to people in similar situations (not opportunism).
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# 3. Subject selection

- Ought to be fair and just.
  - Participants should be chosen because of the aims of the study and its potential outcomes, not because of privilege, access, vulnerability, convenience, etc.
  - Does the study need to be done with this group of survivors? Why?
  - Are all appropriate groups included?
  - Those who bear the risks should benefit from the fruit.
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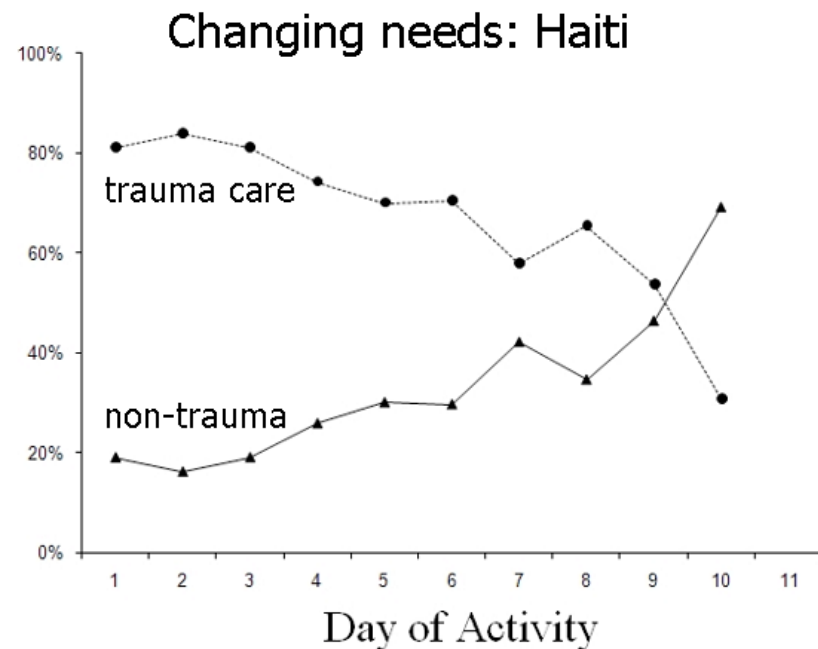
- Humanitarian misconception: how will you prevent participants thinking that research participation is required to receive humanitarian aid?

# 4. Risk-benefit ratio

## ■ Risks relate to:

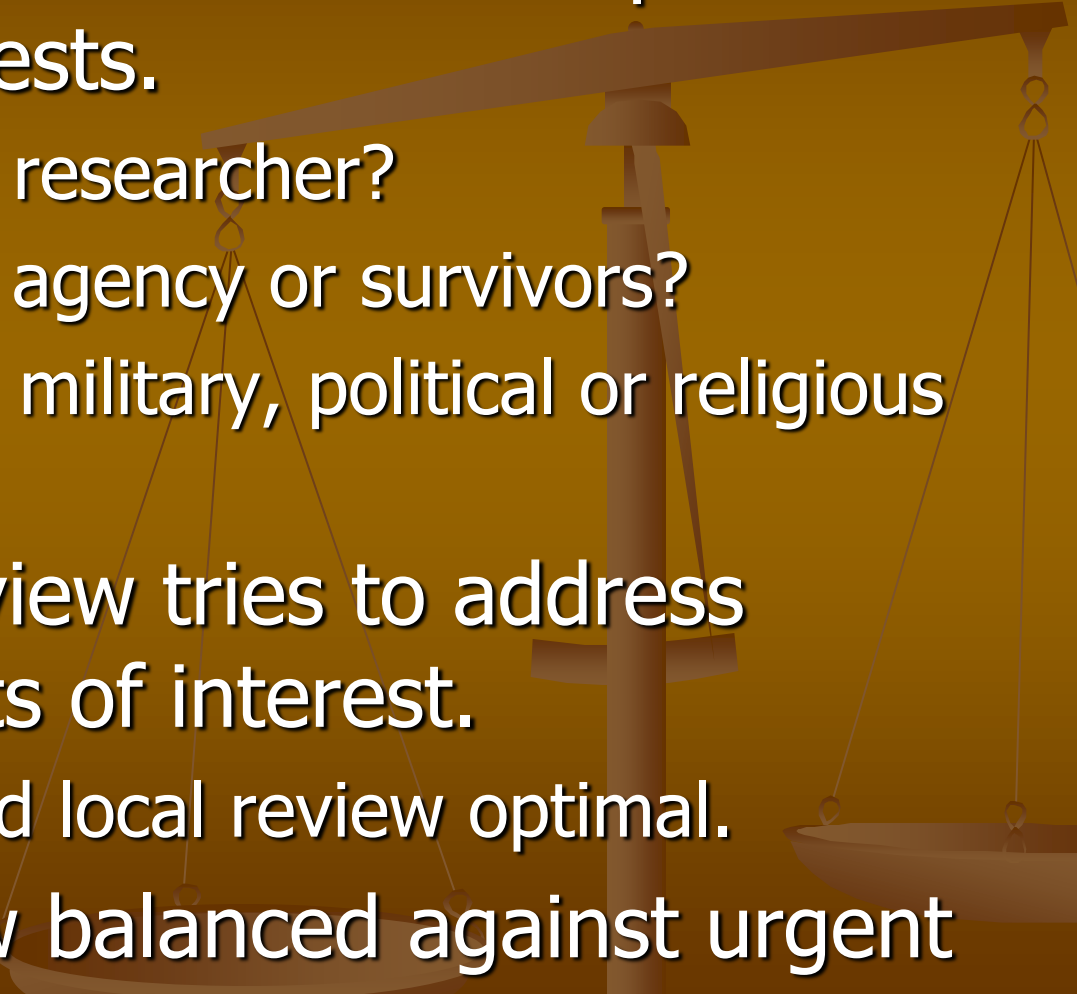
- ❖ participant group
- ❖ research methods (note psychosocial risks with qualitative research), and
- ❖ research topic (especially social science topics).

## ■ Risk 'calculation' is particularly complex and highly variable in disasters.





# 5. Independent review

- Researchers often have real and perceived conflicts of interests.
    - ❖ Relief worker or researcher?
    - ❖ Duty to sending agency or survivors?
    - ❖ Association with military, political or religious goals.
  - Independent review tries to address potential conflicts of interest.
    - ❖ International and local review optimal.
  - Thorough review balanced against urgent window of research 'opportunity.'
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# Conflict of interest

- Therapeutic misconception
- Financial, e.g. Trovan
- Cultural
- Military



# Ethical oversight

- Médecins Sans Frontières  
*Ethics Framework for Medical Research*
- Scientific merit
- Ethical justification
- Judged by international standards
- Cultural sensitivity
- Respect for research subjects



# 6. Informed consent

- *The voluntary consent of the human subject is absolutely essential.*

Nuremberg Code, 1947

A. Competence

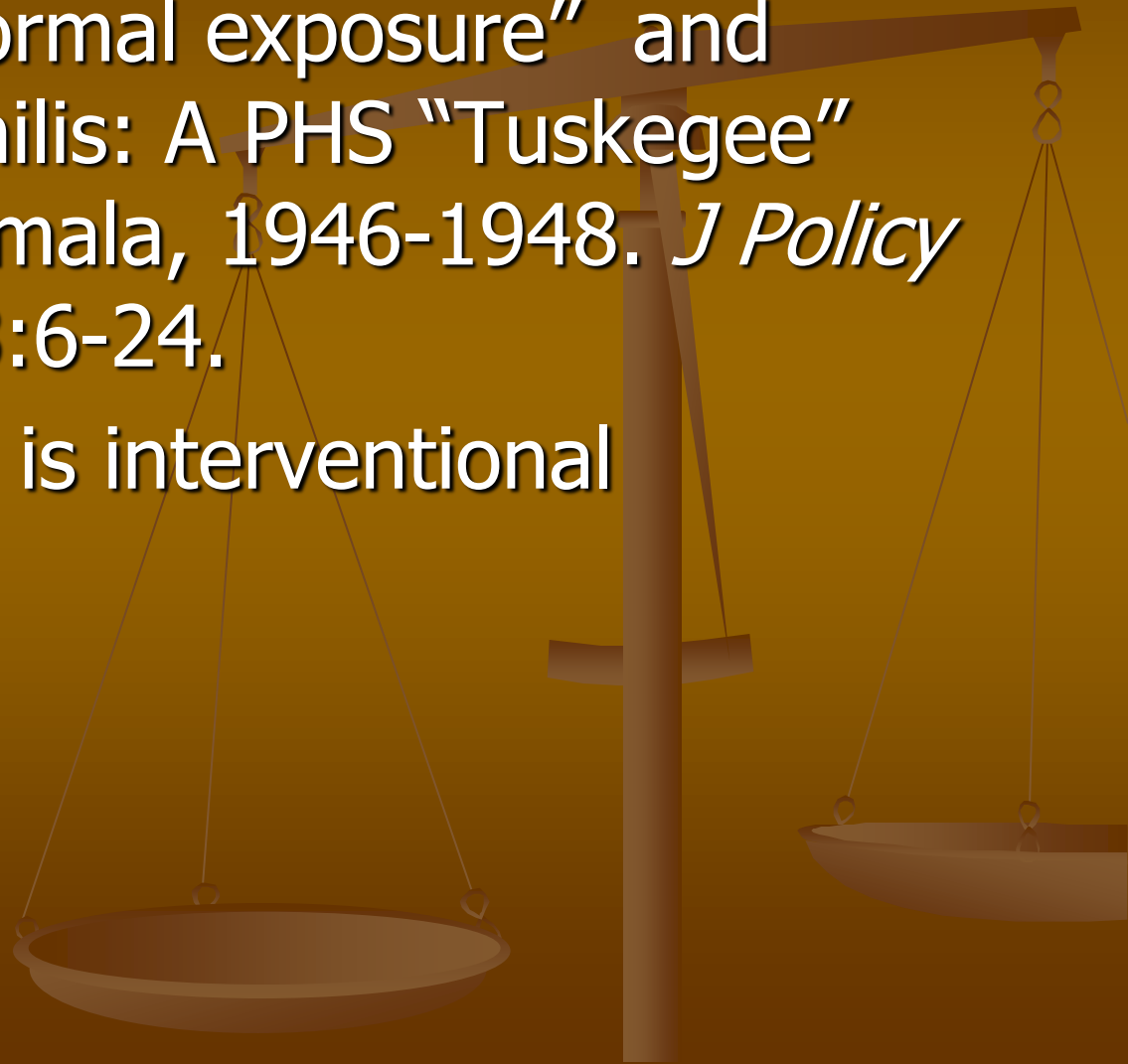
B. Information – **plain** language statement

C. Understanding – translation issues

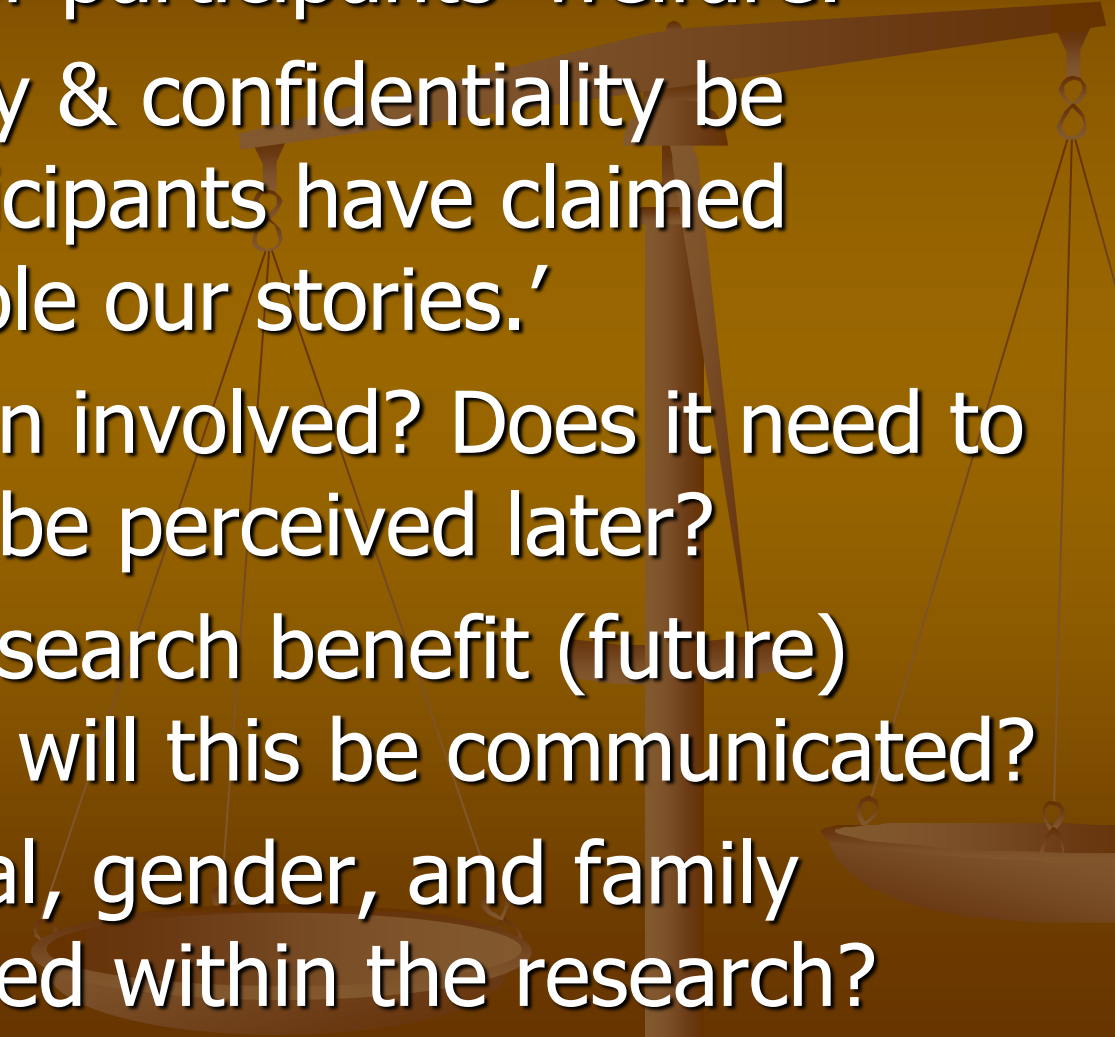
D. Lack of coercion – can be subtle

E. Authorisation – Who? When? Where?

- Reverby SM “Normal exposure” and inoculation syphilis: A PHS “Tuskegee” doctor in Guatemala, 1946-1948. *J Policy History* 2011;23:6-24.
- Not all research is interventional

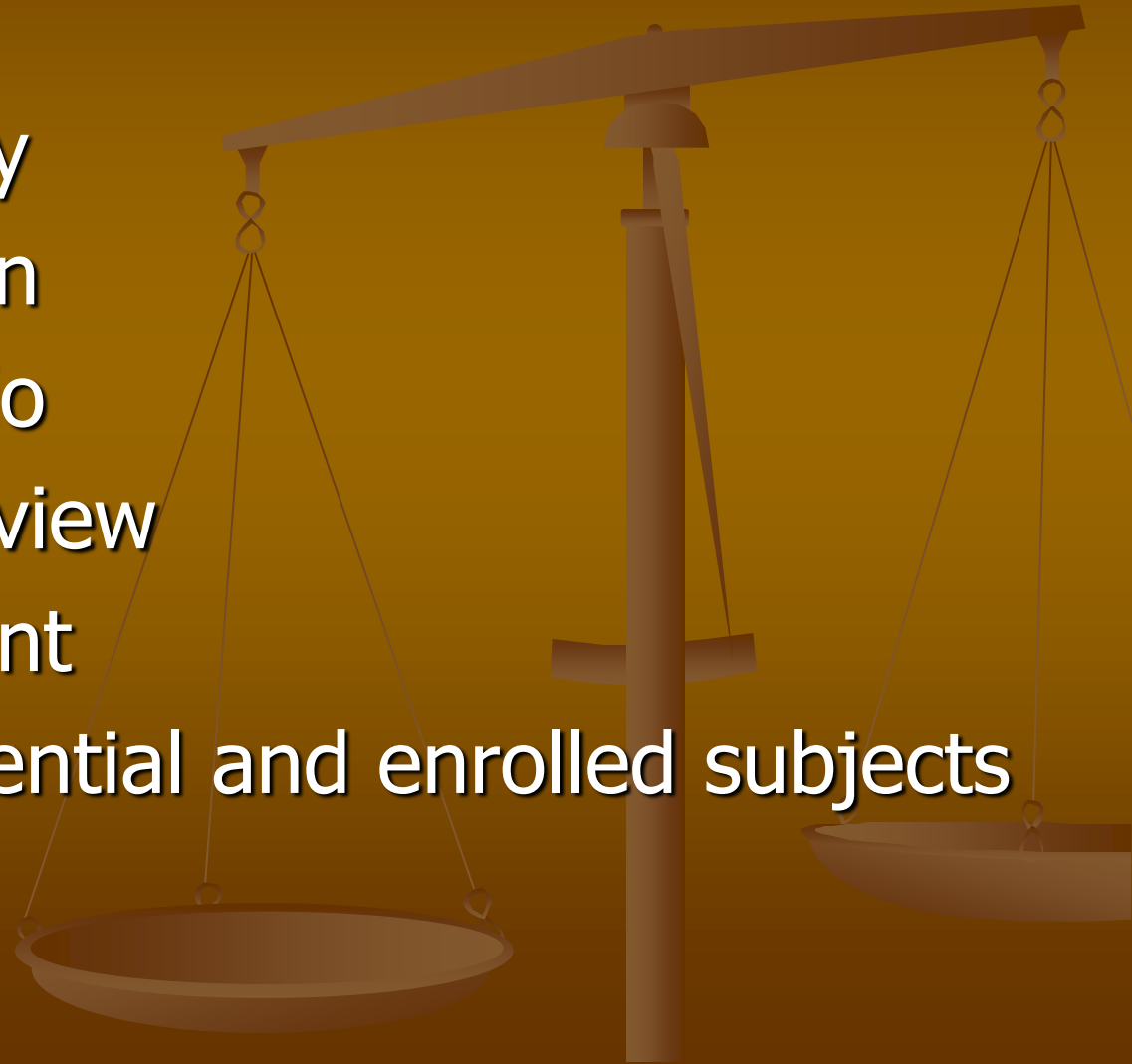


# 7. Respect for participants

- Need to monitor participants' welfare.
  - How will privacy & confidentiality be protected. Participants have claimed researchers 'stole our stories.'
  - Is any deception involved? Does it need to be? How will it be perceived later?
  - How can the research benefit (future) survivors? How will this be communicated?
  - How are cultural, gender, and family aspects protected within the research?
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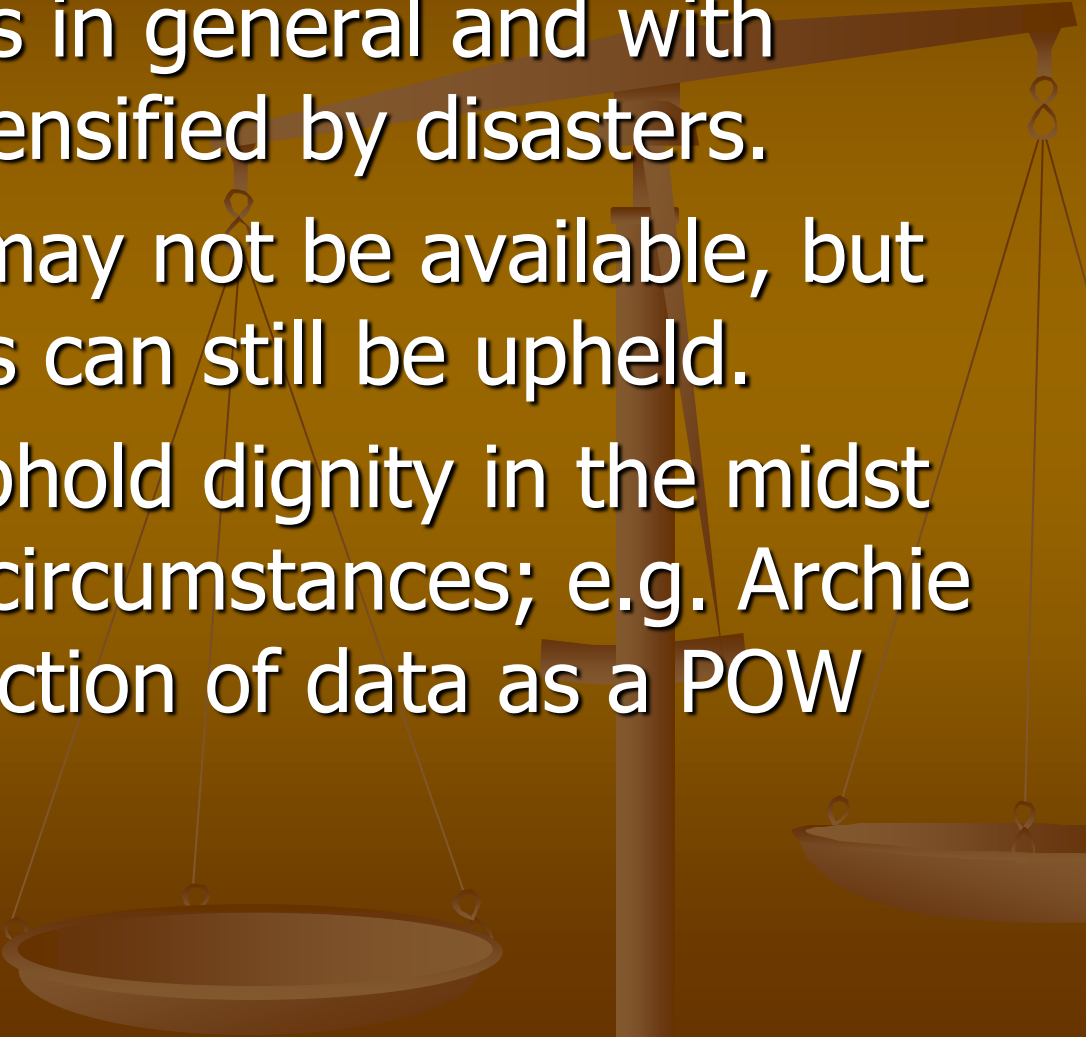
# Summary

- Value
- Scientific validity
- Subject selection
- Risk-benefit ratio
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# Conclusion

- Ethical dilemmas in general and with research are intensified by disasters.
  - Ideal solutions may not be available, but ethical principles can still be upheld.
  - Research can uphold dignity in the midst of undignifying circumstances; e.g. Archie Cochrane's collection of data as a POW (1941-1945).
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# Ethics with 'dirty hands'

- Ritchie, J. What counts as a 'dirty hand' death? 2011











