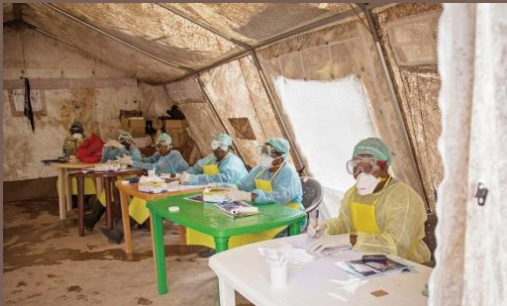


# REC AND THE DIVERSITY OF DISASTER RESEARCH: AN ETHICAL ASSESSMENT



Péter Kakuk  
University of Debrecen  
Hungary

COST IS1201 Disaster Bioethics, Workshop: Ethical Challenges of Research Conducted in Disaster Settings. February 08-09. 2015. Jagiellonian University, Krakow, Poland

# My approach

*To provide an ethical assessment on how disaster research diversity affects RECs.*

## Background sources:

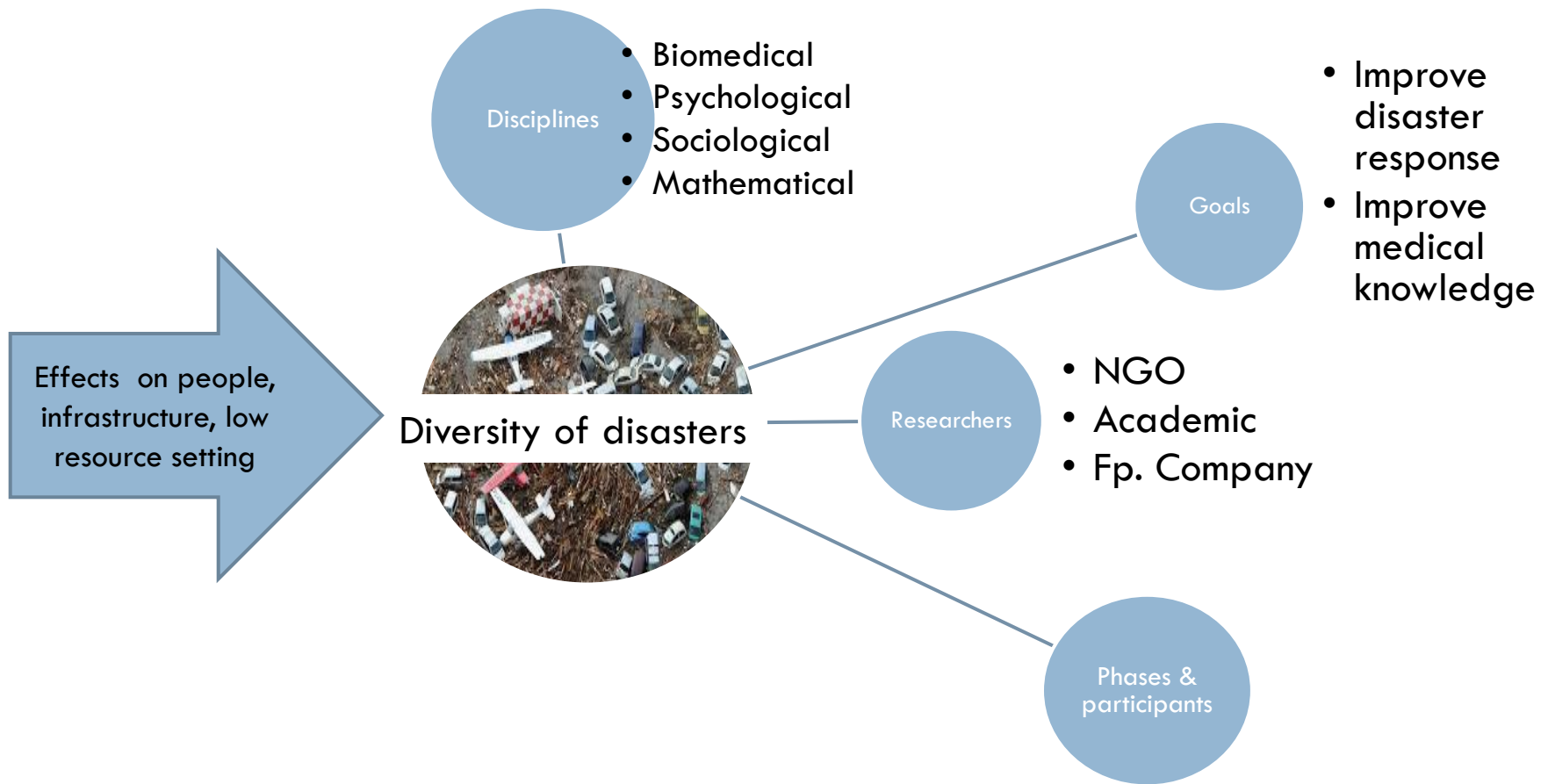
- Insights from the COST Disaster Bioethics project years.
- Interpret some results of our study on disaster research ethics guidelines
- Incorporate Hunt M. et al.'s results: „Ethical implications of diversity in disaster research”
- Interpret from a double perspective: I'm a member of the central REC in Hungary, but also an academic focusing on research ethics.
- I'm not an expert in the field of disaster research, but I regard disaster research ethics issues as important door that opens up unseen areas of research ethics, („ethical issues when nothing is normal”)

# Some introductory comments on the academic literature of disaster research ethics

Disaster research is a wide and overlapping concept:

- Research in public emergency
  - Clinical research conducted on emergency patients,
  - Research in undeveloped countries, resource poor settings.
  - Disaster research v. research in disasters
- To improve disaster management we need evidence...

# Diversity of disasters and disaster research



Where? When? Who? What? How? Why?

# Disaster research ethics: is it something special?

*Should we treat disaster research as an exception to our common research ethics framework?*

- It might be special, because:
  - Normal REC procedure is not adequate
  - Higher vulnerability of participants
  - Higher risk of therapeutic misconception
  - Conflicting priorities between Care v. Research
  - Non-local researchers, foreign institutions
    - ▣ New ethical issues? Partly yes
    - ▣ New ethical principles? No
    - ▣ New procedure for ethics review? Yes
      - **RECs should be prepared on how to proceed in such situations**

# Core ethical requirements for clinical trials

+ collaborative partnership in developing country trials

1. **Social value**
2. **Scientific validity**
3. **Selection of subjects**
4. **Risk-benefit ratio**
5. **Independent review**
6. **Informed consent**
7. **Respect for subjects**

**Table 2.** Seven Requirements for Determining Whether a Research Trial Is Ethical\*

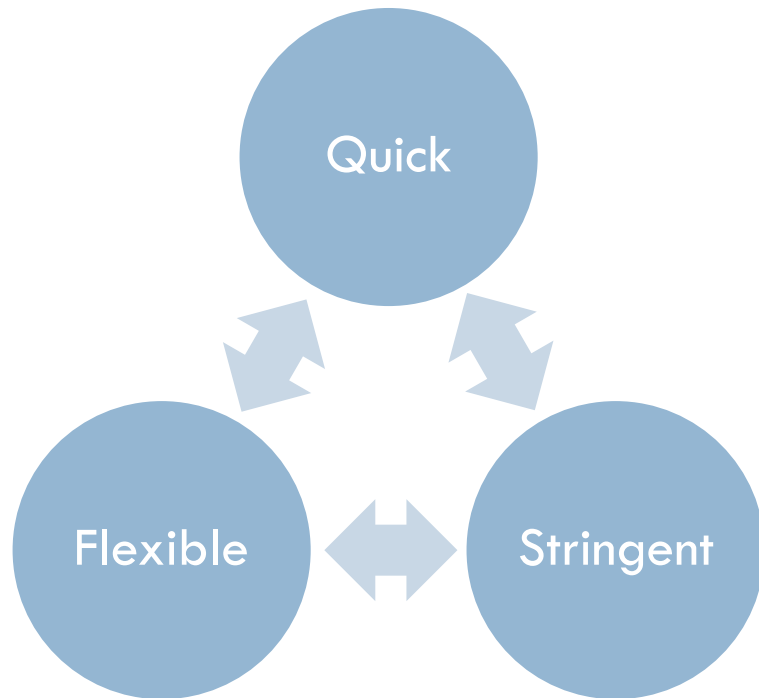
Requirement	Explanation	Justifying Ethical Values	Expertise for Evaluation
Social or scientific value	Evaluation of a treatment, intervention, or theory that will improve health and well-being or increase knowledge	Scarce resources and nonexploitation	Scientific knowledge; citizen's understanding of social priorities
Scientific validity	Use of accepted scientific principles and methods, including statistical techniques, to produce reliable and valid data	Scarce resources and nonexploitation	Scientific and statistical knowledge; knowledge of condition and population to assess feasibility
Fair subject selection	Selection of subjects so that stigmatized and vulnerable individuals are not targeted for risky research and the rich and socially powerful not favored for potentially beneficial research	Justice	Scientific knowledge; ethical and legal knowledge
Favorable risk-benefit ratio	Minimization of risks; enhancement of potential benefits; risks to the subject are proportionate to the benefits to the subject and society	Nonmaleficence, beneficence, and nonexploitation	Scientific knowledge; citizen's understanding of social values
Independent review	Review of the design of the research trial, its proposed subject population, and risk-benefit ratio by individuals unaffiliated with the research	Public accountability; minimizing influence of potential conflicts of interest	Intellectual, financial, and otherwise independent researchers; scientific and ethical knowledge
Informed consent	Provision of information to subjects about purpose of the research, its procedures, potential risks, benefits, and alternatives, so that the individual understands this information and can make a voluntary decision whether to enroll and continue to participate	Respect for subject autonomy	Scientific knowledge; ethical and legal knowledge
Respect for potential and enrolled subjects	Respect for subjects by (1) permitting withdrawal from the research; (2) protecting privacy through confidentiality; (3) informing subjects of newly discovered risks or benefits; (4) informing subjects of results of clinical research; (5) maintaining welfare of subjects	Respect for subject autonomy and welfare	Scientific knowledge; ethical and legal knowledge; knowledge of particular subject population

\*Ethical requirements are listed in chronological order from conception of research to its formulation and implementation.

©2000 American Medical Association. All rights reserved.

(Reprinted) JAMA, May 24/31, 2000—Vol 283, No. 20 2703

# Issues to consider for RECs n.1



**Proper review procedure  
in disaster research: FQS**

*n1. Reconsider the  
national/international REC system:*

- Do we have an plan for emergency review?
- Is it legally recognized?
- Does it have enough felxibility?
- Do we have clear and easily applicable *hierarchical risk categorization* for research studies?

# Issues to consider for RECs n.2.

*n.2. Reconsider the available and potential REC procedure modalities:*

- *How they might serve FQS ethical review?*
- *How some sample disaster research scenarios would fit into the available REC procedures?*
- *The case of prefab ethics review: Generic research protocol? Pre-approval review?*





# Issues to consider for RECs n.3.

## *N.3. Available guidelines & recommendations:*

- Tri-Council Policy Statement (Canada, 2010). Ethical conduct for research involving humans. Research ethics review during publicly declared emergencies.
- WGDRE (2007): Statement on ethical issues in disaster related research – a developing world perspective
- Schopper D, Upshur R, Matthys F, Singh JA, Bandewar SS, et al. (2009) Research Ethics Review in Humanitarian Contexts: The Experience of the Independent Ethics Review Board of Médecins Sans Frontières. PLoS Med 6(7).
- Tansey CM et al. (2010) A framework for research ethics review during public emergencies. CMAJ, Oct. 5. 182(14).
- Update on the CIOMS, guidelines (2016?)

# Issues to consider for RECs n.4.

## *n.4. Disaster research participants & the concept of vulnerability:*

- Guidance documents
- Legal requirements
- Research approval limited
- Extra justification is needed
  - **Inflation of vulnerability might result in decreasing disaster research.**
  - Cautious and reflective understanding of vulnerability in disaster settings.



Our STSM & disaster research ethics guidelines team

**Thank you for your attention!**