Research ethics in the context of humanitarian emergencies

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Ethics

- Ethics is the systematic study of concepts, principles and theories that address issues of right and wrong.
- Ethical virtues are the personal characteristics that impact ethical behaviour: courage, honesty, fidelity, etc.
‘If you are faced with a dilemma on what is the right thing to do, moral philosophy [ethics] will not find a decision for you. What it can do is remove some confusions and clarify some obscurities, so that the options stand out more plainly.’

“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)
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.’

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).
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: Trovan v Ebola
3. Subject selection

- Ought to be fair and just.
- Participants should be chosen because of the aims of the research 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. How will they benefit?
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.
  - Humanitarian aid worker or researcher?
  - Duty to sending agency or survivors?
  - Association with military, political, religious goals.

- Independent review tries to address potential conflicts of interest.
  - International and institutional
  - Local review – community involvement

- Thorough review balanced against urgent window of research ‘opportunity.’
- R2HC Ethical Framework: [http://www.elrha.org/R2HC](http://www.elrha.org/R2HC)
- MSF Ethics Review Board: [http://fieldresearch.msf.org/msf/handle/10144/11645](http://fieldresearch.msf.org/msf/handle/10144/11645)
- Working Group on Disaster Research and Ethics (WGDRE): [https://globalhealthtrials.tghn.org/articles/draft-statementguidelines-disaster-research/](https://globalhealthtrials.tghn.org/articles/draft-statementguidelines-disaster-research/)
6. Informed consent

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

- Nuremberg Code, 1947

A. Competence – impact of trauma

B. Information – plain language statement

C. Understanding – translation issues

D. Lack of coercion – can be subtle

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, family, religious aspects protected within the research?
Summary

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


- http://DisasterBioethics.eu