



Challenges in ethics review process of research in disaster settings: results from a qualitative review of guidelines

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Search strategy

Identification of guidelines for research ethics in disaster settings by a tree-tiered search strategy:

- 1) search in two databases: PubMed and Google Scholar,
- 2) Internet search (Google),
- 3) search by screening references of included documents.

Search terms: *guidelines AND "research ethics" AND (disaster OR emergency OR crisis).*

Inclusion criteria:

- ▶ meet the definition of research ethics guidelines (systematically developed statements to assist responsible conduct of researchers and other stakeholders in the process of planning, conduct, and reporting of research)
- ▶ issued by an international or national organization/ institution/meeting or proposed by individual researchers/ a group of researchers
- ▶ research ethics in disaster settings is addressed in the whole document or at least in one part/chapter
- ▶ the document covers at least one of the following types of human subject research: clinical drug research/ biomedical research involving physical interventions/ research on health data and biological material/ psychology or social sciences research

Results

- ▶ As a result of consensus 14 full text guidelines were included in analysis as documents meeting the inclusion criteria
- ▶ The included guidelines cover the period 2000-2014
- ▶ There is a peak in number of documents in the 2008-2010 (8 out of 14 guidelines are published in this period of time)

Analysis

All included guidelines were analyzed in two levels:

1. In the first step the year of publication; authors and issuing organizations are analysed
2. In the second step each guideline is analyzed qualitatively to identify particular categories describing scope, target group and content of each guideline
3. The guidelines are reviewed in each category and the main characteristics are summarized

Qualitative analysis

- ▶ constant comparative method
- ▶ inductive category coding and a simultaneous comparison of all obtained units of meaning
- ▶ each new unit of meaning is compared to all other units and subsequently grouped – categorized and coded
- ▶ in the process of coding initial categories and subcategories were changed, merged and omitted when necessary, as well as new categories were generated

Categories

- ▶ Social value of research
- ▶ Interests and rights of research subjects
- ▶ Experience and awareness of researchers
- ▶ Organization of review
- ▶ Problems in the review process

Social value of research

- ▶ potential of application in future disaster situations
- ▶ direct or indirect benefit to individuals or community
- ▶ research cannot be pursued in non-disaster context
- ▶ not draining away recourses for relief
- ▶ involvement of local researchers and/or community
- ▶ post-research obligations

Social value of research

(in yellow: draft version of CIOMS)

- ▶ potential of application in future disaster situations
 - ▶ studies are designed so as to yield scientifically valid results under the challenging and often rapidly evolving conditions of a disaster
- ▶ direct or indirect benefit to individuals or community
 - ▶ researchers, regulators, research ethics committees, and sponsors must ensure that proposed studies are scientifically sound, build on an adequate prior knowledge-base, and are likely to generate valuable information (guideline1)
- ▶ research cannot be pursued in non-disaster context
 - ▶ the research is responsive to the health needs or priorities of the disaster victims and cannot be conducted outside a disaster situation

Social value of research

- ▶ not draining away resources for relief
 - ▶ The conduct of research must not unduly compromise the response to the victims of a disaster. *Humanitarian workers, researchers and sponsors must be aware of these conflicts and ensure that their studies do not unduly compromise the disaster response. Researchers and sponsors should also aim to add to the infrastructure for the humanitarian response.*
- ▶ involvement of local researchers and/or community
 - ▶ communities are actively engaged in study planning, while recognizing the associated practical challenges and ensuring cultural sensitivity
- ▶ guideline 7
- ▶ post-research obligations
 - ▶ guideline 2, guideline 24

Interests and rights of research subjects

- ▶ balancing need for evidence and possible harm
- ▶ minimal risk requirement
- ▶ justice in selection of participants
- ▶ potential for overburdening of research subjects
- ▶ provisions for confidentiality and privacy protection
- ▶ regulation of transfer of biological material
- ▶ application of standard of care

Interests and rights of research subjects

- ▶ balancing need for evidence and possible harm
 - ▶ The risks and potential benefits of experimental interventions are assessed realistically especially when they are in the early phases of development. [...] *It is essential that researchers and sponsors realistically assess the potential benefits and risks of experimental interventions and communicate these clearly to potential participants and individuals at risk.*
- ▶ minimal risk requirement
 - ▶ -
- ▶ justice in selection of participants
 - ▶ participants are selected fairly and adequate justification is given if particular populations (for example health workers) are targeted

Interests and rights of research subjects

- ▶ potential for overburdening of research subjects
 - ▶ burdens and benefits in the selection of groups of subjects as well as the possible benefits of the research are equitably distributed
- ▶ provisions for confidentiality and privacy protection
 - ▶ guideline 4
- ▶ regulation of transfer of biological material
 - ▶ guideline 11
- ▶ application of standard of care
 - ▶ guideline 5

Experience and awareness of researchers

- ▶ cultural sensitivity of researchers
- ▶ awareness of impact of research
- ▶ conflicts of interest
- ▶ training in research ethics
- ▶ professional competence of researchers

Experience and awareness of researchers

- ▶ cultural sensitivity of researchers
 - ▶ engaging local communities about the research is essential for maintaining public trust and ensuring that studies are conducted in a culturally sensitive manner
- ▶ awareness of impact of research
 - ▶ because disasters often lead to vulnerability and fragile political and social situations, engaging local communities about the research is essential for maintaining public trust

Experience and awareness of researchers

- ▶ conflicts of interest
 - ▶ guideline 25
- ▶ training in research ethics
 - ▶ guideline 1
- ▶ professional competence of researchers
 - ▶ guideline 1

Organization of review

- ▶ centralization of review
 - ▶ research ethics committees or a specialist ethics committee (perhaps on a national or regional level) may conduct an initial accelerated review of study protocols and continue oversight if studies raise significant ethical concerns
- ▶ conditions for full and expedite review
 - ▶ the disaster situation can require modifying standard procedures so that the ethical principles can be upheld in the most expedient way possible [..] accelerated ethical review during disasters may be necessary to ensure that valuable ethical studies can begin as soon as possible

Organization of review

- ▶ alternative review mechanisms
 - ▶ health officials and research ethics committees must develop procedures to ensure appropriate, timely and flexible mechanisms and procedures for ethical review and oversight
- ▶ «just-in-case» protocols
 - ▶ research ethics committees could pre-screen study protocols in order to facilitate and expedite ethical review in a situation of crisis
- ▶ proportionality of review
 - ▶ research ethics committees or a specialist ethics committee (perhaps on a national or regional level) may conduct an initial accelerated review of study protocols and continue oversight if studies raise significant ethical concerns

Problems in the review process

- ▶ risk of bureaucracy of the review process
- ▶ lack of guidelines for research in disaster settings
- ▶ distinction between research and non-research

Conclusions

- ▶ Some subcategories discovered in the review are not covered or are partially covered by draft version of CIOMS guidelines
- ▶ One of essential requirements is to ensure appropriate dissemination of information about ongoing research and research results among researchers to share information, avoid duplication of efforts and overburdening of research subjects
- ▶ There is need for a discussion on lack of empirical evidence supporting statements and requirements included in guidelines, e.g. effects of alternative approaches in organization of review; risk of re-traumatization, evaluation of risks,



Thank you!