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Science at the heart of medicine

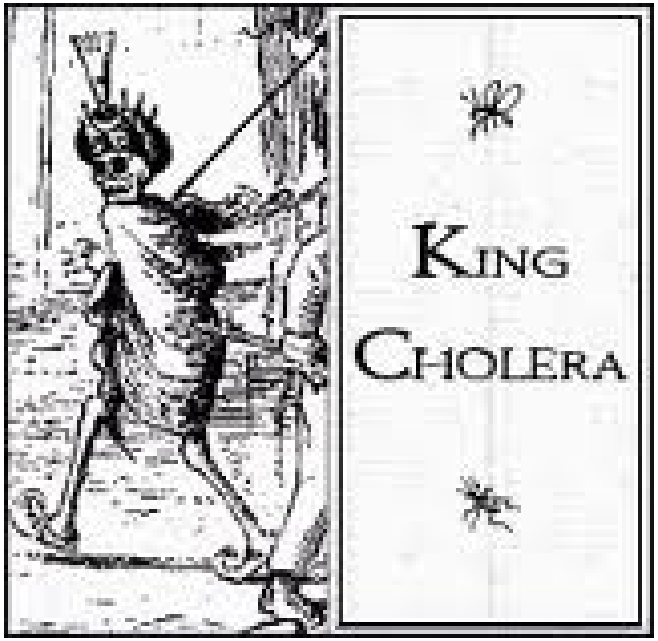
Research in Disasters

Studying Vulnerable Populations in the Context of Enhanced Vulnerability

Ruth Macklin, PhD

Disasters create vulnerability

- People are rendered vulnerable by
  - Injuries
  - Fear
  - Grief
  - Inadequate food and water
  - Loss of housing
  - Disease outbreaks
    - Cholera in Haiti following earthquake in 2010



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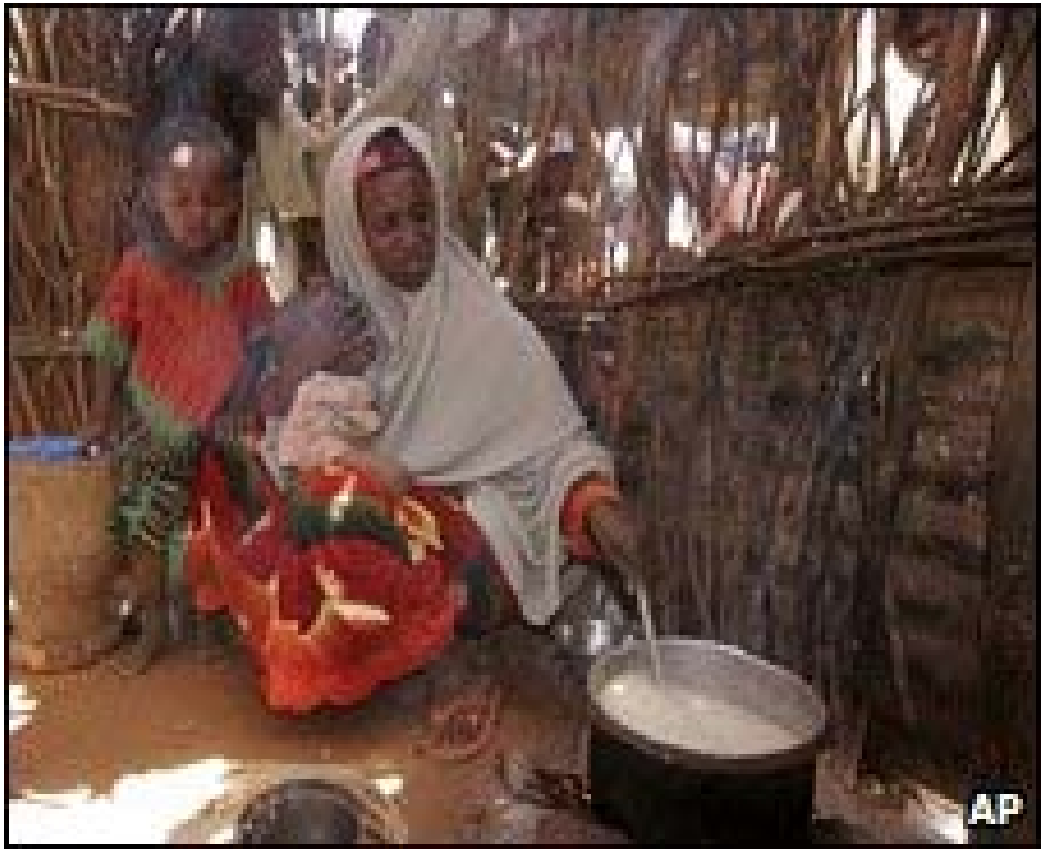
Vulnerable populations before disaster

- Food insecurity
- Lack of potable water
- Inadequate health care
- At risk from endemic diseases



Criticisms of conducting research in disasters

- Disaster victims are rendered too vulnerable by the disaster
- Disasters in developing countries or other poor communities render the inhabitants more vulnerable
  - They need aid, not research
- People recruited for research by health workers may confuse research with treatment
  - The therapeutic misconception
- People caught in a disaster are too emotionally unstable to provide informed consent

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Criticisms of conducting research in disasters

- Even following a disaster, victims by be traumatized by interview or physical exams that cause them to recall terrible circumstances
- Conducting research in disasters may impede efforts to mitigate harm and can intrude into rescue operations
- There is insufficient time to prepare a research protocol and have it reviewed by a research ethics committee
  - Research subjects may lack adequate protection of their rights and welfare

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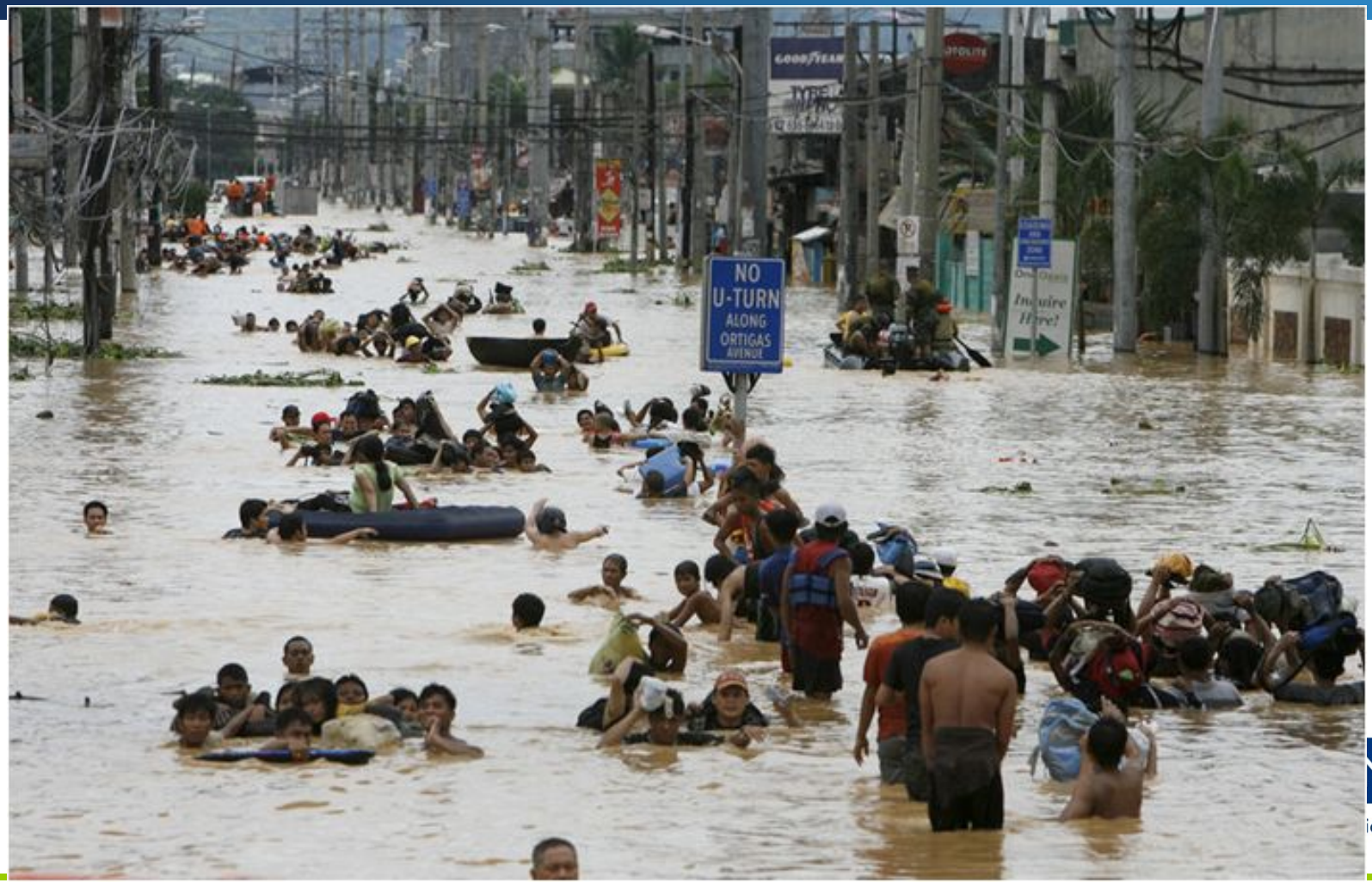
Protesting the Bhopal disaster

© Photo courtesy of Australian Broadcasting Corporation



Justification for conducting research in disasters

- "To ensure effective and equitable responses to future disasters, we need to study what works and what doesn't work in present disasters"
  - This statement is true, but need exists to devote attention to ethical concerns just mentioned
- Threshold question
  - Are victims of disasters too vulnerable to permit their inclusion in research?
- **Who is vulnerable?**

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Declaration of Helsinki

- "Some research populations are particularly vulnerable and need special protection. These include those who cannot give or refuse consent for themselves and those who may be vulnerable to coercion or undue influence."
  - Too narrow, too brief
    - What "special protections" are appropriate or necessary?
    - What specific features determine the ability to give or refuse consent?
    - What sort of coercion might be present?

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CIOMS International Ethical Guidelines for Biomedical Research

- "Special justification is required for inviting vulnerable individuals to serve as research subjects and, if they are selected, the means of protection their rights and welfare must be strictly applied."
- "Vulnerable persons are those who are relatively (or absolutely) incapable of protecting their own interests. More formally, they may have insufficient power, intelligence, education, resources, strength, or other needed attributes to protect their own interests."
  - "Limited freedom to consent or to decline to participate in research"

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CIOMS: specific groups that may be vulnerable

- Subordinate members of hierarchical groups; elderly persons with dementia or residents of nursing homes; people receiving welfare benefits or social assistance; other poor people and the unemployed; patients in emergency rooms; some ethnic and racial minority groups; homeless persons; nomads, refugees or displaced persons, prisoners, patients with incurable disease; individuals who are politically powerless; members of communities unfamiliar with modern medical concepts.
  - No mention of victims of disasters

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Who isn't vulnerable?

- Skepticism and backlash against overuse of concept of vulnerability
  - "So many categories of people are now considered vulnerable that virtually all potential human subjects are included."
- How to counter this skepticism and render the concept of vulnerability meaningful, especially in the context of research in disasters?

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Intrinsic and extrinsic vulnerability

- Intrinsic vulnerability
  - Factors such as increased age, being very young, reduced cognitive ability, psychosis
- Extrinsic vulnerability
  - Circumstances such as hospitalization, imprisonment, or financial capacity
- Large majority—if not all—people in a disaster share the characteristic of “extrinsic vulnerability”
- Elderly, children, people with physical or mental disabilities are “intrinsically vulnerable”

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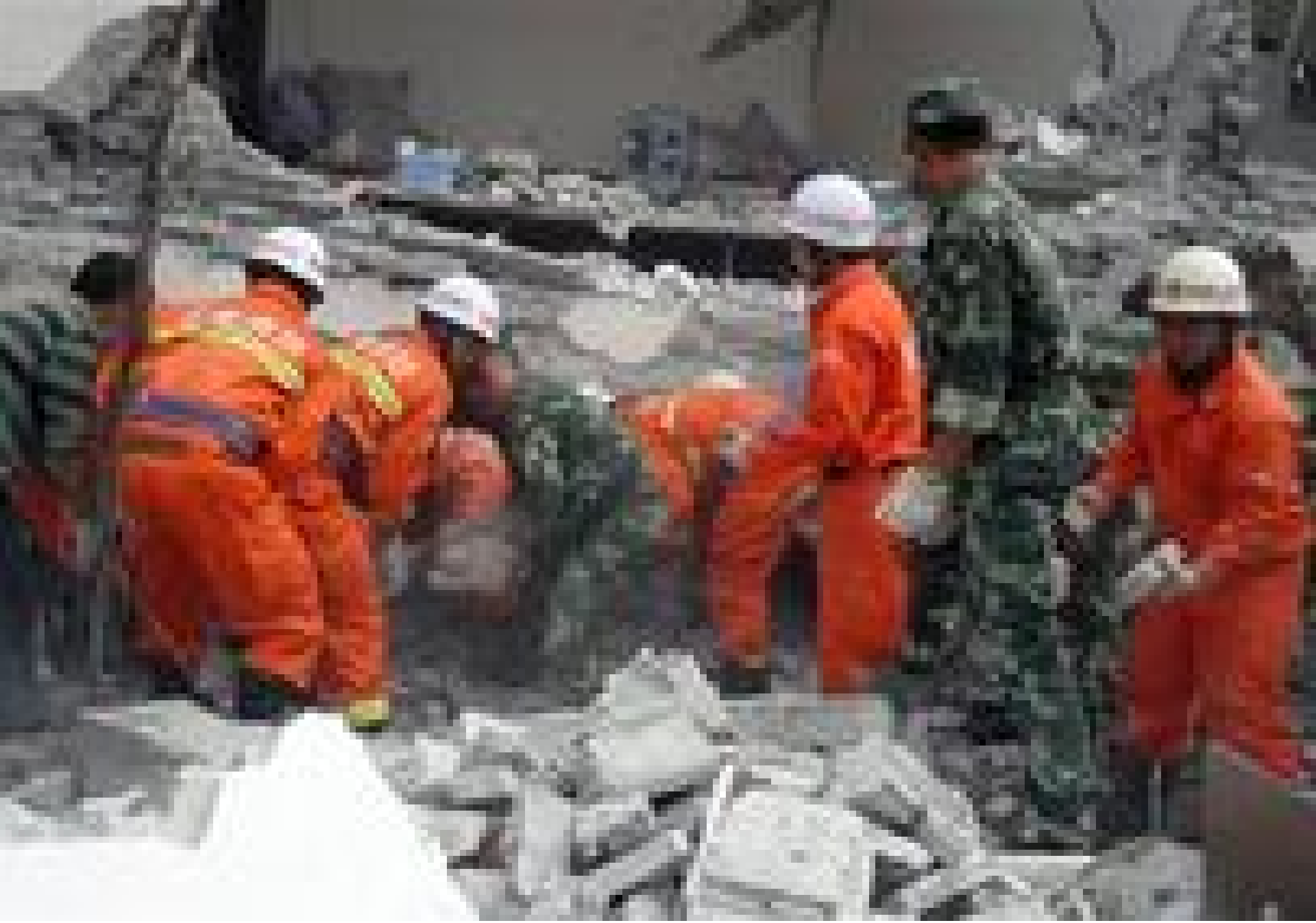

Layers of vulnerability

- Vulnerability is a relational concept
  - Concerns relation between a person or group and the circumstances or the context
  - Not to be understood as a permanent and categorical condition
    - "Layers, not labels"
      - Florencia Luna
- "Layers" approach useful in determining vulnerability of people in disasters
  - The more intrinsic and external factors, the more layers, the greater the vulnerability

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Comparison with research involving patients

- Investigations of new drugs or experimental use of existing medications in disasters illustrates “layers” approach
  - Subjects are sick and debilitated from exposure to toxic or lethal substances
  - Medical intervention carries risk of harm and unanticipated adverse events
- This is no different, in principle, from much biomedical research
  - Many patients are severely ill or debilitated
  - Drugs may be toxic with severe effects

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Research in disasters in developing countries

- Governments are poor, possibly corrupt
- Fewer skilled medical personnel than in industrialized countries
- Poor countries and communities take longer to recover and resume services
- However, the need for financial, medical, and other forms of aid should not be in competition with the conduct of research
  - > Sources of research funding differ from those for aid
  - > Researchers often not the same people as providers of emergency care

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Distinguishing disaster research from public health practice

- Both research and public health response require gathering data from people caught in disasters
- Both activities might involve blood drawing for detection of infection or radioactive material
- Both situations could involve administering an antidote or medication and studying its effectiveness

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Why distinguish between research and practice?

- Internationally accepted requirements for research
  - Submission of a protocol for prior review by duly constituted, independent research ethics committee
  - Obtaining voluntary, informed consent from research subjects
    - Explain purpose, procedures, risks, benefits, and alternatives to participating
- Response to disaster by Ministry of Health requires no prior committee review and no formal consent process for surveys or interviews

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Attempts to define ‘research’

- US Code of Federal Regulations
  - “*Research* means a systematic investigation, including research development, testing and evaluation, *designed to develop or contribute to generalizable knowledge*.”
- US Centers for Disease Control and Prevention
  - “If the primary intent is to prevent or control disease or injury or to improve a public health program, and no research is intended at the present time, the project is non-research.”
    - Criterion is “primary intent” of the activity

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Problems with the definitions

- What is learned in the course of the investigation may lead to generalizable knowledge, even if that was not the initial intent of the activity
- The intent of an investigation is rarely specified in advance
  - This would imply the existence of independent bodies or agencies capable to record expressed intents ahead of the implementation of activities, a rather unrealistic proposal when applied to fast evolving emergency settings

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Additional problems

- An emergency response often contains elements of research in addition to the primary intent
  - A questionnaire accompanied by drawing blood from people who become sick and those who remain well during a disease outbreak
    - Researchers seek to determine whether any biological, genetic, or life style factors caused some people to get sick while others did not
  - This situation is common when biological samples are stored for dual use during a disease outbreak, resulting in a mix of research and non-research

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Possible solutions

- RECs could establish a policy for disease outbreak investigations
  - A short statement of purpose and procedures of the investigation can be prepared and submitted for expedited, or quick review by the committee chair or other designated member
  - Best practice for research conducted during emergency is to establish the basic research design for various categories of research prior to the emergency
    - CIOMS Epi Guidelines

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Need for research in disasters

- Enhanced likelihood of accidental radiation exposure
- Increasing use of nuclear technology in power production and possibility of nuclear terrorism or war

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Need for research on sex and gender differences

- "There is a general lack of research on sex and gender differences in vulnerability to and impact of disasters"
  - » World Health Organization
  - > Evidence of greater vulnerability of women than men when disasters strike
    - Women and girls more vulnerable to sexual abuse in disaster situations
    - Sex industry often becomes part of the interaction between refugee or displaced population and local community

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Conclusions

- Victims of disasters have a layer of vulnerability in addition to whatever other factors may make them vulnerable
- Being vulnerable does not imply that risks of research are any greater than for less vulnerable individuals
- Yet all the usual precautions should be in place to
  - minimize risks
  - end an interview if it is too stressful
  - Make provision for medical care or counseling if needed
  - Treat participants with respect for their

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Amateur Japan and Indonesia Tsunami Footage