Ethical Considerations For Human Challenge Studies: The WHO perspective

World Health Organization

Dr. Abha Saxena
Coordinator, Global Health Ethics

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GLOBAL HEALTH ETHICS TEAM

World Health Organization

Working in the WHO and Beyond

- Supporting ethics within WHO
  - Research Ethics Review Committee - ERC
  - Public Health Ethics Consultative Group
  - Incorporating ethics in technical guidelines
  - Staff capacity strengthening – workshops, e-training
- Health ethics across the globe
  - Developing normative guidance
  - Training tools
  - Capacity strengthening workshops

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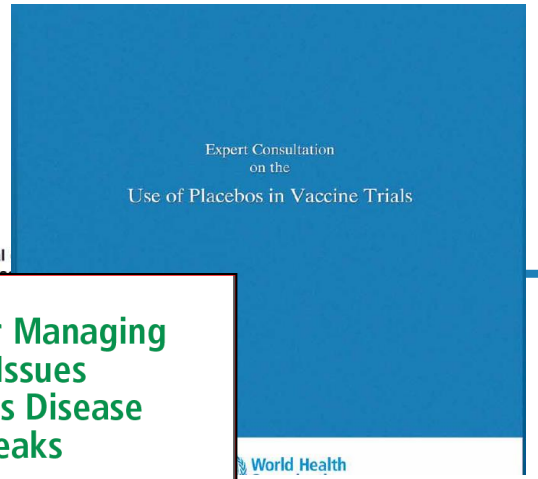
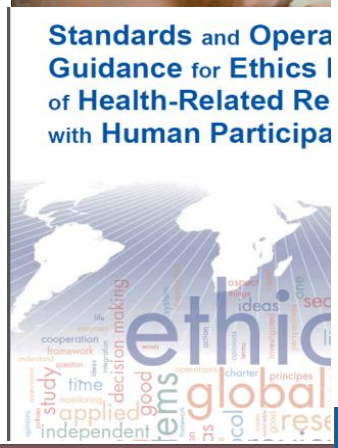
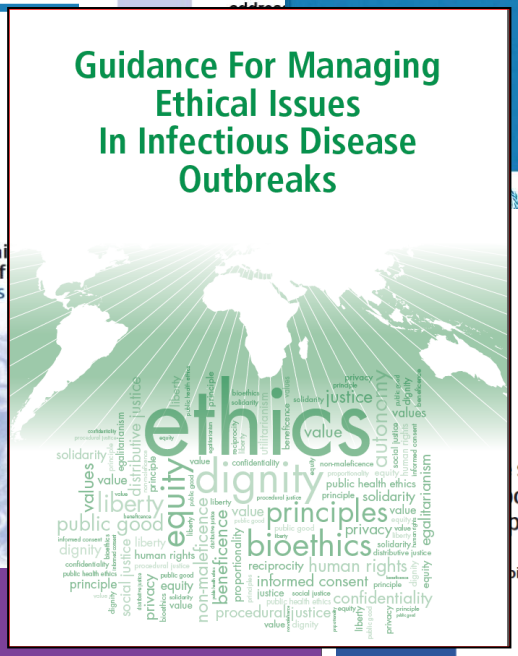
Why WHO ?

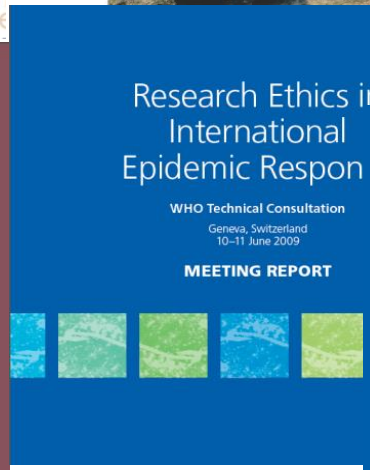
- Trusted, neutral partner
- Convening Power
- Developing countries look to WHO to provide advice, especially on contentious issues

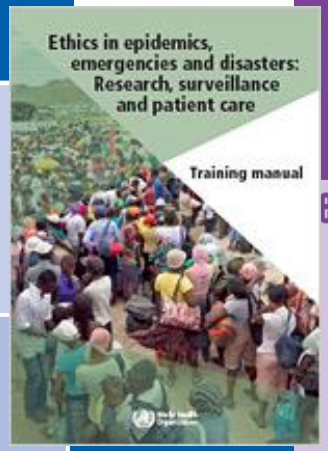


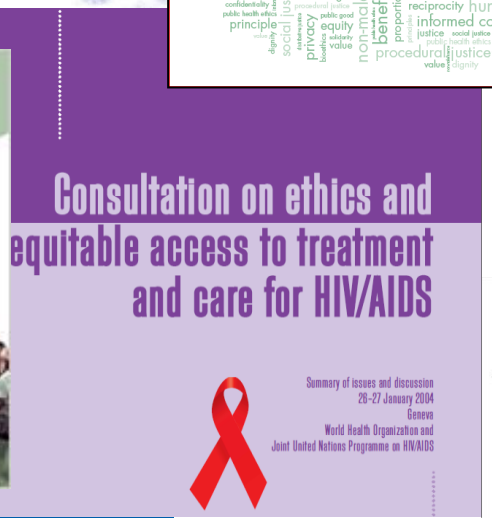


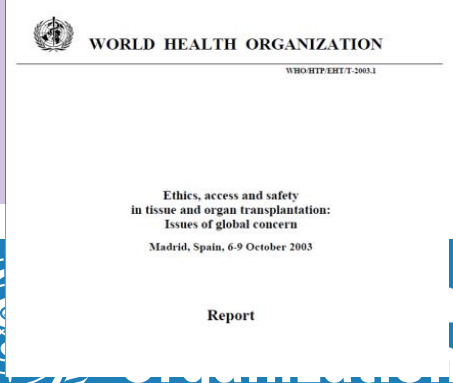


Research ethics committees
Basic concepts
for capacity-building



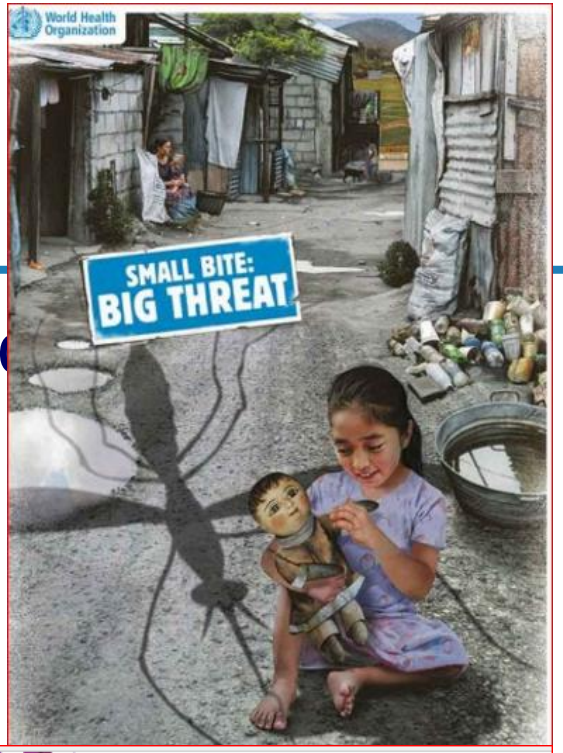


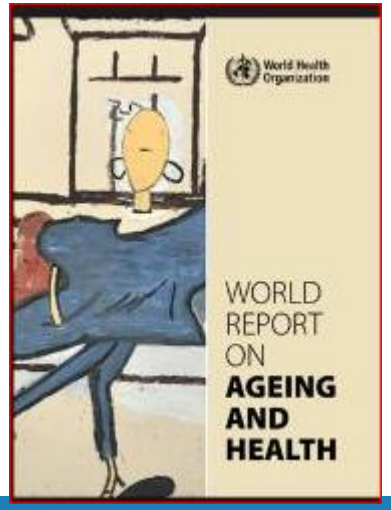




Current Activities

- Vector Borne Diseases and ethical implicati and treatment
- Healthy Ageing
- Antimicrobial Resistance





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Supported by

- Global network of WHO Collaborating Centres
- Regional focal points,
- Interns

General email:
ct_ethics@who.int

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Ethical Criteria for Human Challenge Studies in Infectious Diseases

Ben Bambery*, Monash University
Michael Selgelid, Monash University
Charles Weijer, Western University
Julian Savulescu, University of Oxford
Andrew J. Pollard, University of Oxford

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Ethical Framework

- Risks (and benefits)
- Social Value
- Compensation for research related injury
- Vulnerable populations
- Right to withdraw
- Community Engagement

The WHO perspective

- Priority Setting
- Conditions to be satisfied for CHIM studies
- Trust Building
- Benefit Sharing
- Capacity Strengthening

Priority setting

- At least 14 pathogens for which discussions on CHIMs is taking place

- Criteria should be established for prioritising endemic pathogens in developing countries for the establishment of human challenge studies for elucidating the pathogenesis or for development of vaccines
  - Norovirus or shigellosis, or salmonella?
  - Intestinal parasites?
  - Zika?
  - All?

- Criteria for defining the problem statements

Conditions to be satisfied before undertaking Human Challenge studies

- Establishing risk criteria?
  - Would I do this on my blood relatives?
  - Risk of harm is reversible, non fatal, treatable
  - An upper limit of risk?

  Furthermore, risk comparisons must not be made to activities that pose unacceptable risks themselves, or in which people choose to participate because of the associated benefits (some sporting activities, for example, are thrilling precisely because they involve an elevated risk of harm).

- Availability of ‘clean’ knowledge …….Knowledge for the sake of knowledge – “you can do fantastic immunology…”?

Building and Maintaining Trust

- Increasing accountability
  - global database/registry of all CHIM studies
  - Global registry of all possible adverse events?
- What do we know about experiences of volunteers who have participated in human challenging studies conducted in developing countries?
- How are CHIM studies viewed by the public in countries in which they are undertaken? What is being done to understand the views of the populations?
- What is being done to increase understanding of the popular media for these studies?

Benefit sharing (CIOMS Guideline 2)

- Research conducted in low resource settings **must**
  - ensure that the research is responsive to the health needs or priorities of the communities or populations where the research will be conducted.
  - make every effort to make available as soon as possible any intervention or product developed, and knowledge generated, for the population or community in which the research is carried out,
  - assist in building local research capacity
  - consult with and engage communities in making plans for any intervention or product developed available, including the responsibilities of all relevant stakeholders.

This applies especially to CHIM studies

Role of Local and national ethics committees

- "…. Risks must be analysed by ethics committees"
- This is a complicated area – ethics committees – even in developed countries may not be best placed to evaluate the risk benefit ratio - requires a very good understanding of the science
  - Independent scientific review coordinated by the ethics committees
  - Advisory (global) ethics committee whose expertise could be tapped into
- Role of National Bioethics Committees – could contribute to building trust

Capacity Strengthening

- For research ethics Committees, and regulators.
- For public and the media
- Researchers and Research centres from developing countries
  - Controlled human infection model (CHIM) studies have pivotal importance in vaccine development, being useful for proof of concept, pathogenesis, down-selection and immunogenicity studies. Few have been carried out in low and middle income countries (LMIC), which is where the greatest burden of vaccine preventable illness is found
  - at the next IABS conference, I look forward to hearing more from investigators from developing countries leading research in their institutions.