



# CIOMS ethical guidelines for Biomedical Research

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# THIS TALK

- What is CIOMS?
- The CIOMS guidelines: an international standard
- Do these guidelines adequately guard the health and well-being of participants in scientific studies?
  - What went wrong in Guatemala?
  - CIOMS guidelines on these issues
- Conclusion



# What is CIOMS?

- An NGO: international, non-governmental, non-profit organization
- Forum to consider and prepare advice on contentious issues in research ethics and safety of pharmaceuticals...
- ... for WHO, public health authorities, academia, pharmaceutical industry and others.
- Established 1949 by WHO and UNESCO
- Offices located in Geneva c/o WHO, Switzerland



# Who is CIOMS?

## Members:

- 48 international member organizations, representing many of the biomedical disciplines
- 18 national members mainly representing national academies of sciences and medical research councils
- Executive committee:
  - 10 member organizations



# CIOMS' main fields of interest

1. Drug safety and drug development

2. Bioethics

- 1970s: newly independent WHO members set up health care systems
- Ethics was too sensitive for WHO
- CIOMS was asked to indicate how the Helsinki declaration (revised in 1975) could be applied, particularly in developing countries
- 1982: guidelines on biomedical research published
- Revision: 1993, 2002, 2011 (start of process)



# CIOMS BM research ethics guidelines

- Purpose: indicate how fundamental ethical principles and Declaration of Helsinki can be applied effectively in medical research world-wide in different:
  - cultures, religions, traditions, socioeconomic circumstances;
  - with special attention for developing countries.
- Content: 21 guidelines plus commentaries (!)
- Use: 2002 Guidelines have been widely used, notably in developing countries.
  - Indication: translation into several languages, including French, Spanish, Portuguese, Chinese, Arabic, Czech, and Vietnamese.



# What went wrong in Guatemala?

- Respect for persons
  - Participants were merely used as a means to further science
  - No informed consent was sought
  - Deception
- Beneficence
  - Participants were deliberately harmed (inoculation)
- Justice
  - No fair subject selection (participants were “the available and contained”)
  - No fair share of benefit (on individual level)



# CIOMS guidelines on these issues

- Respect for persons
  - Respect for autonomy: Informed consent (gln 4-7)
  - Protection of non-autonomous (gln 13-15)
- Beneficence
  - Balance between risks and benefits (gln 8-9)
- Justice
  - Responsiveness to health needs (gln 10)
  - Reasonable availability (gln 10)
  - Choice of control (gln 11)
  - Equitable distribution of burdens and benefits over groups (gln 12)



# Continued discussion

- Respect for persons
  - How can we improve the informed consent process (make it evidence based)?
  - What level of risk is acceptable in non-therapeutic research with non-autonomous participants
- Beneficence
  - Continued discussion on R/B assessment



# Continued discussion (ctnd)

## Justice

- Before actual start of study
  - When is a study responsive to health needs?
  - What is a equitable choice of population?
- During study
  - How much ancillary care?
- After completion of study
  - What is a fair share of benefit?
  - Is substitution fair? Who should benefit?
  - How much effort in capacity building is required?



# Conclusion

So can we rest reassured?

- No absolute safeguards, lot of open-ended terms with different interpretations
- Tendency to emphasize interests of community more, absolute supremacy of individual interests (cf DoH gln 6) is sometimes questioned
- But RECs attempt to minimize risk through reasoned deliberation
- Have to acknowledge: ‘by placing some people at risk of harm for the good of others, clinical research has the potential for exploitation’ (Emanuel et al)