

Strengthening ethics review of research involving human participants

International round table

*Biomedical research in developing countries:
the promotion of Ethics, Human Rights and Justice*

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Historical background

Initiative launched in October 2002 by the Director General

- To provide a focal point for the examination of the ethical issues raised by activities throughout the organization, including the regional and country offices
- To develop activities regarding a wide range of global bioethics topics

e.g. research with human beings, fair access to health services, pandemic influenza planning

Previous to this initiative, HQ departments had been very active in research ethics

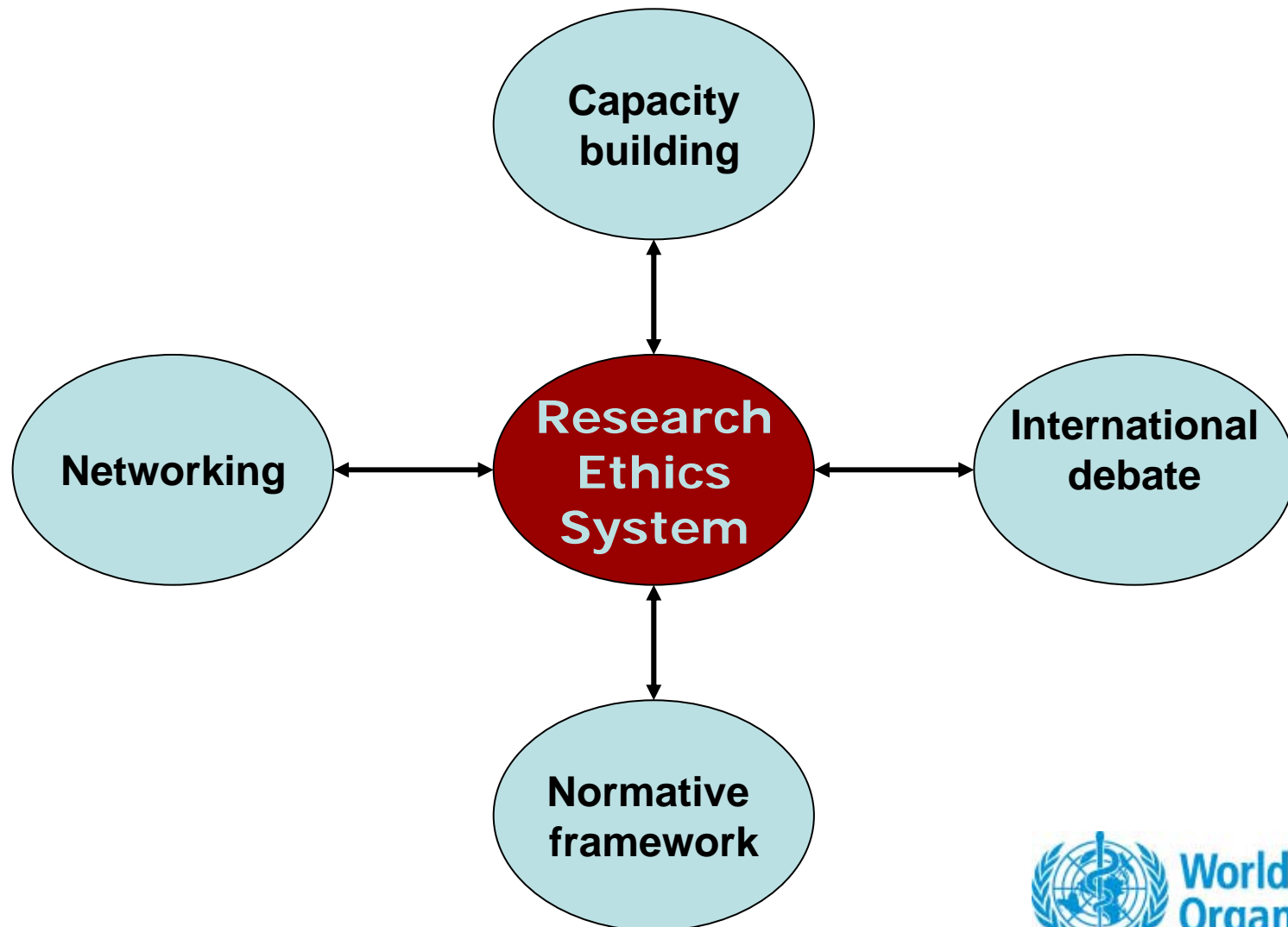
e.g. training activities, normative documents, ERC

as well as RO

e.g. Programme on Bioethics in PAHO since 1994



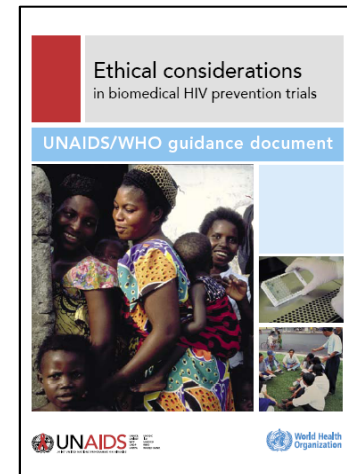
Strengthening research ethics systems



Guidance and normative documents

- WHO-UNAIDS

Ethical considerations in biomedical HIV preventive trials



- CIOMS

International ethical guidelines for epidemiological studies

- WMA

Declaration of Helsinki



Training and tools

- Training workshops
 - introduction to ethical review
 - ethical issues related to specific areas of research (reproductive health, HIV, etc.)
- Toolkit / local trainings on research ethics
- Distance learning tools
 - e.g. TRREE for Africa (EDCTP)
- PAHO working group on research ethics
- Task force on TB
- Other collaborations
 - e.g. CDBI manual



Networking

- Follow up of NEBRA project implemented in 15 African countries (EU)
- EMRO forum on research ethics
(WHO-EMRO/UNESCO joint meeting)
- Collaborating centers
 - U. Toronto, Miami, Chile, Espace Ethique Paris
 - 2 others in the process of recognition

International debate

Global Forum on Bioethics in Research

- A collaboration between several institutions (Fogarty, MRC UK, WT, WHO, COHRED, FLACSO, AKU, etc.)
- A venue for delegates (around 120) from developing and developed countries to debate the ethical issues surrounding international collaborative research
- The discussion is focused on specific issues e.g. research with indigenous and vulnerable populations (Auckland 2008), conflicts of interests (Santiago 2010) and based on concrete cases

Synthesis

- Collaboration with
 - WHO technical departments
 - WHO regional offices
 - other organizations (UNIACB)

in order to create more synergies and avoid duplication of work

- **Focus on**
 - implementation of principles, ensuring research activities follow the highest ethical standards
 - ethical issues raised by specific areas of research
 - emerging questions
 - definition of level of care and treatment provided to trials participants
 - improving equitable access to the benefits of research
 - improving transparency in research activities
e.g. International Clinical Trial Registry Platform
 - improving coordination between NRAs with RECs

What is needed?

– Accreditation / recognition process of RECs

Need for common criteria

e.g. FERCAP, national systems of accreditation

– Networking activities

- Exchange and analysis of RECs experiences

- Sub regions, ≠ languages

– Global registry of RECs and national regulations

Need for common platform

e.g. OHRP compilation, Global Research Ethics

Map Harvard School of Public Health, UNESCO

GEOPS



What is needed?

(2)

- Guidance documents
 - Harmonized (national / international) ≠ uniform
- Mapping of activities
 - Need for information concerning training workshops, educational program, online courses, networking activities, etc.
 - e.g. UNESCO GEOPS, EDCTP
- Accreditation of training programs

Bamako call for action on research for health

- *"To develop set and enforce standards regulations and best practices for fair, accountable and transparent research processes including those related to ethical review and conduct"*
- *"To strengthen research capacity and build a critical mass of young researchers by developing and including curricula on research methods and research ethics (...)"*



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