



Up date on research ethics in Africa

Achievements and challenges

4th EDCTP Annual Forum
Ouagadougou 22-24 October 2007

Dr Marie Charlotte Bouësseau
Ethics and Health (ETH)



Overview

1. Lessons learnt
2. New challenges
3. Towards a regional strategy to strengthen ethics of research for health

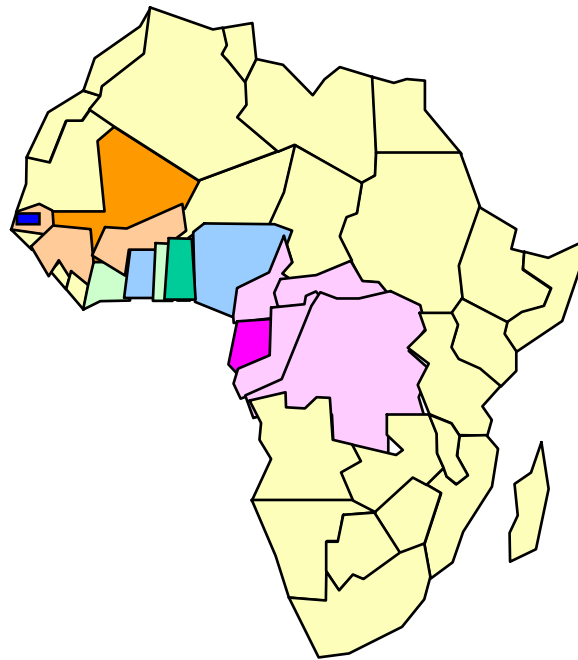
1. Lessons learnt

Networking for Ethics on Biomedical Research in Africa



Survey in 15 countries

- RECs,
- regulations
- resources and needs



Matrix for national strategic plans

Major Achievements

What should be avoided

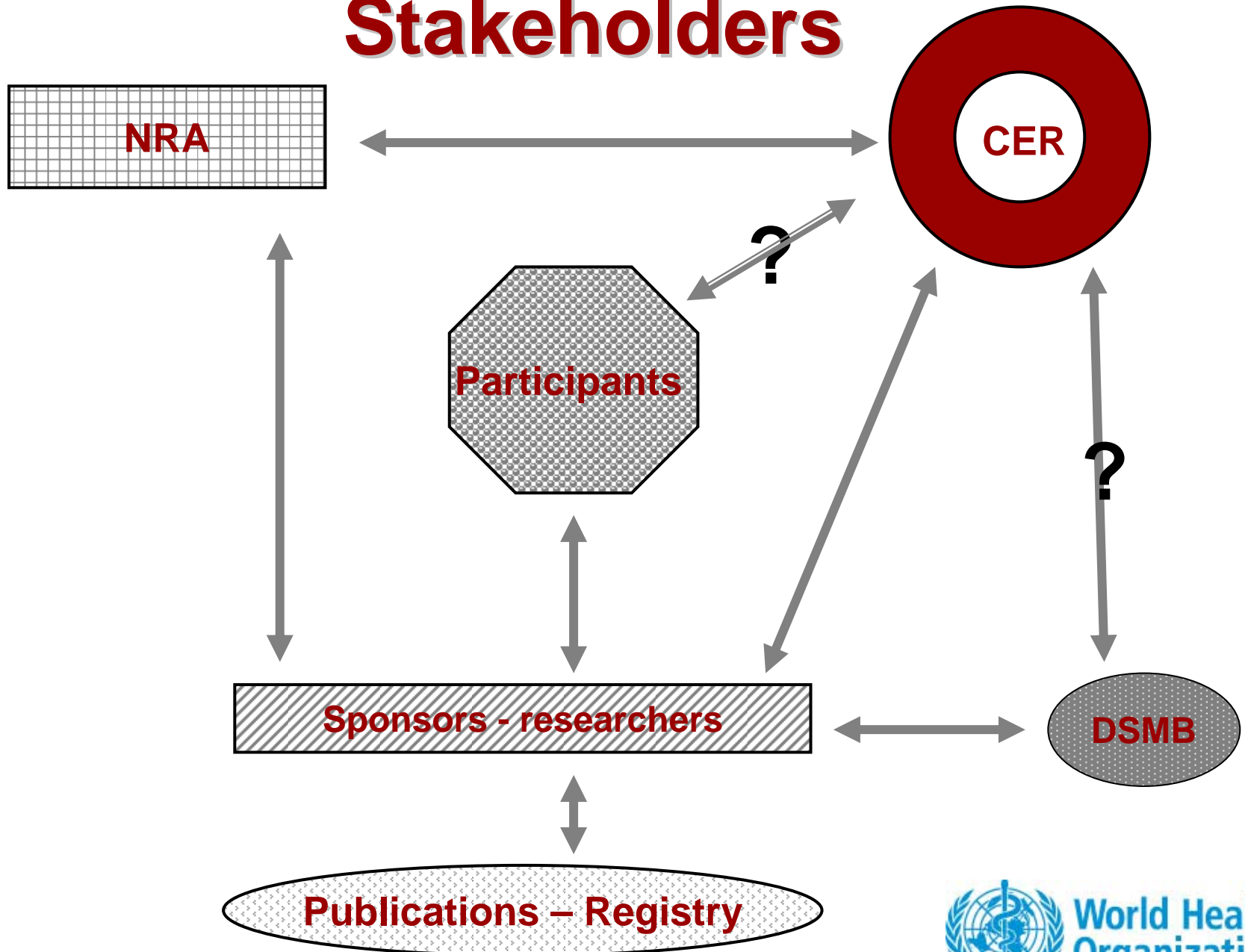
- **Awareness**
- **Capacity building**
 - **Training programmes**
(SARETI, West African Bioethics Training Programme, etc.)
 - **Training workshops**
 - **Distance learning tools**
(AMANET, TRREE for Africa)
- **International debate**
(critical analysis of concrete situations e.g. GFBR)
- **Networking initiatives**
(AMANET, PABIN, etc.)

- **Duplication of activities and lack of information**
- **Inflation of norms**
- **Lack of clarity concerning responsibilities of the different stakeholders**
- **Lack of coordination between NRAs and RECs**

2. New challenges

- Child mortality, maternal health, HIV-AIDS, malaria (MDGs) require research for health in low and middle incomes countries (see Bamako forum)
- Research raises complex and controversial ethical questions:
 - *How to share benefits?*
 - *What level of care and treatment should be provided to trials participants?*
 - *Is the research related to health priorities (10/90 gap)?*
 - *Is new knowledge incorporated in decision making processes?*
- Strong RECs
- Clear responsibilities shared between all stakeholders

Stakeholders



RECs

- **Diversity** of systems should be respected
(different kinds of RECs: IRBs, national, etc.)
- **Clarification** of functions, coordination with NRAs
- **Legitimacy** of RECs
(training, institutional recognition, human and financial resources, etc.)
- **Harmonization** of existing initiatives / quality improvement of RECs
- Information about **training resources** and measurement of **long term impact**

Capacity strengthening

- Avoid conflicts of interests
(sponsoring of research / training of RECs)
- Collect and disseminate information about workshops and distance learning courses
- Provide tools for trainers in ≠ languages
- Evaluate long term impact

Quality assurance

Objective:

To ensure that research *for* health protects human participants respecting international ethical standards and local values.

Questions:

- What are the criteria and modalities of evaluation?
- How is responsible?

National regulations

- **Harmonization** of norms (without uniformity)
- **Dissemination** of existing procedures and regulations (website)
- **Enforcement** of domestic laws and regulations
- **Collaboration between countries** sub regional networks

3. Towards national strategies

Quantitative and qualitative indicators

Output

- Guidance documents, laws
- Educational programs
- Web site, seminars

Processes

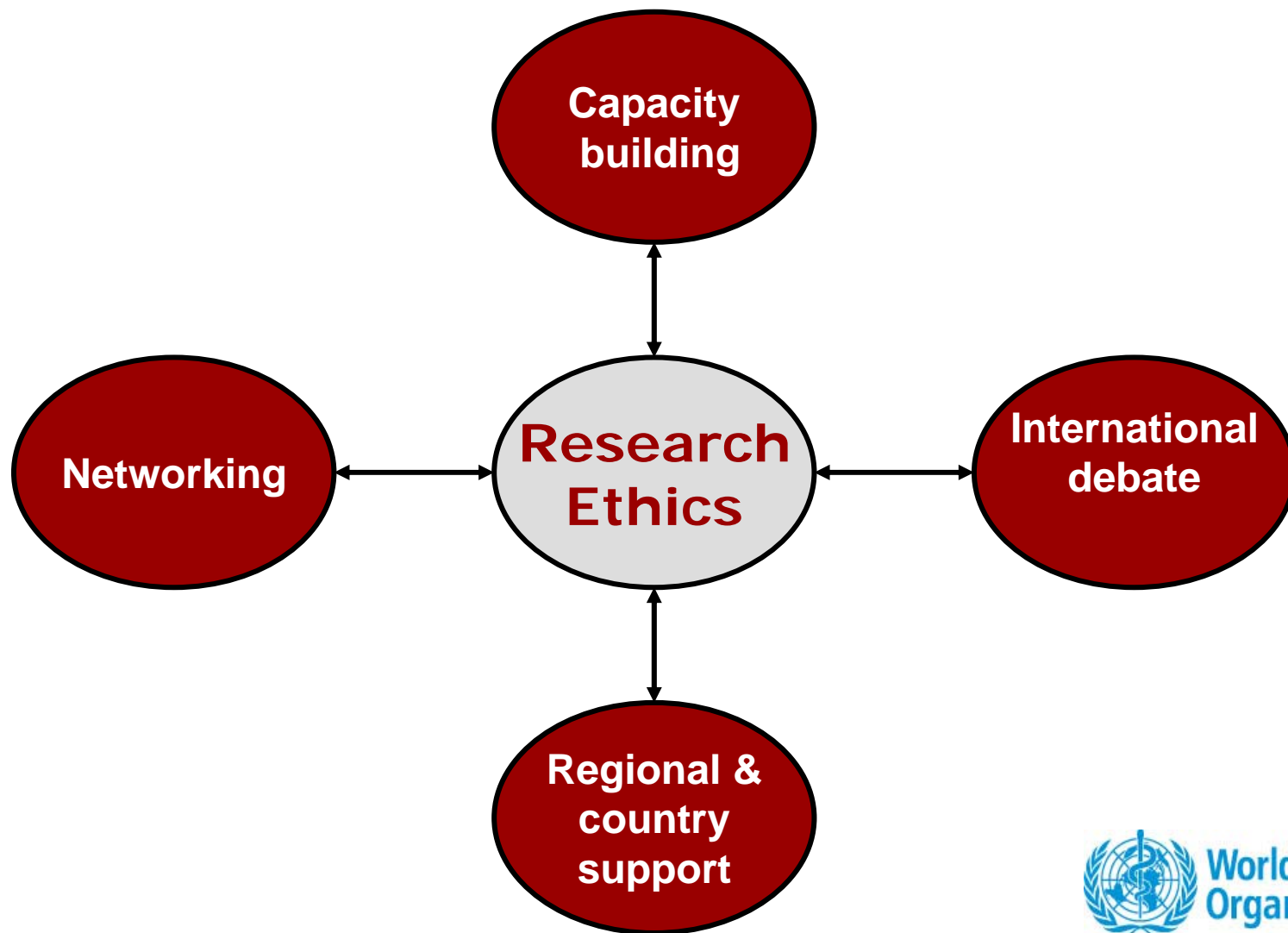
- National regulation
- Capacity building
- Networking

Input

- Human resources
- Financial resources
- Infrastructures

ethical review process

Collaboration within and outside WHO





Capacity building

- Ibadan (Feb 07) - EDCTP
- Tunis (March 07) – collaboration with RHR
- Ouagadougou (July 07) – PATH and RHR
- Gabon (07) – EDCTP

TRREE for Africa – EDCTP

- » To increase knowledge and skills /research ethics and strengthen partnership
- » Training material available in November 2008

http://trree.org/site/en_tree_home.phtml



International debate

- A venue for delegates from developing and developed countries to debate the ethical issues surrounding international collaborative research
- A discussion is based on concrete cases
- Last forum took place in June 2007 and focussed on :
 - Fostering the research ethics infrastructure in the developing world / transition societies
 - Ethical aspects of mental health research
- More information on next forum on <http://www.gfbronline.com>

Synthesis

a) Three pillars

- Strong RECs
- Clear regulations
 - harmonized ≠ uniform
 - enforced
- Active networks
 - debate
 - exchange of experiences
 - dissemination of up dated information

b) Five characteristics

- Feasible
- Sustainable
- Transparent
- Inclusive
- Accountable



***"Science and ethics tell us what
we must do"***

Margaret Chan to the World Health Assembly

November 2006

