Up date on research ethics in Africa
Achievements and challenges

4th EDCTP Annual Forum
Ouagadougou 22-24 October 2007

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Overview

1. Lessons learnt

2. New challenges

3. Towards a regional strategy to strengthen ethics of research for health

1. Lessons learnt
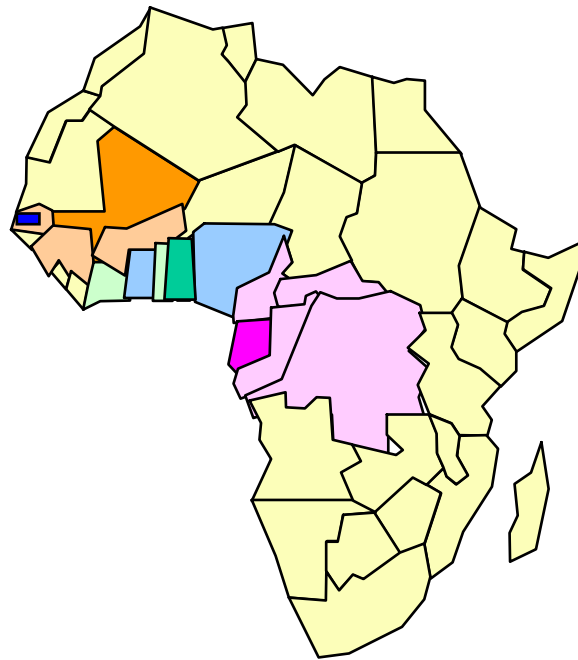
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Networking for Ethics on Biomedical Research in Africa

NEBRA
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SCIENCE and SOCIETY

Survey in 15 countries

Matrix for national strategic plans

- RECs,
- regulations
- resources and needs

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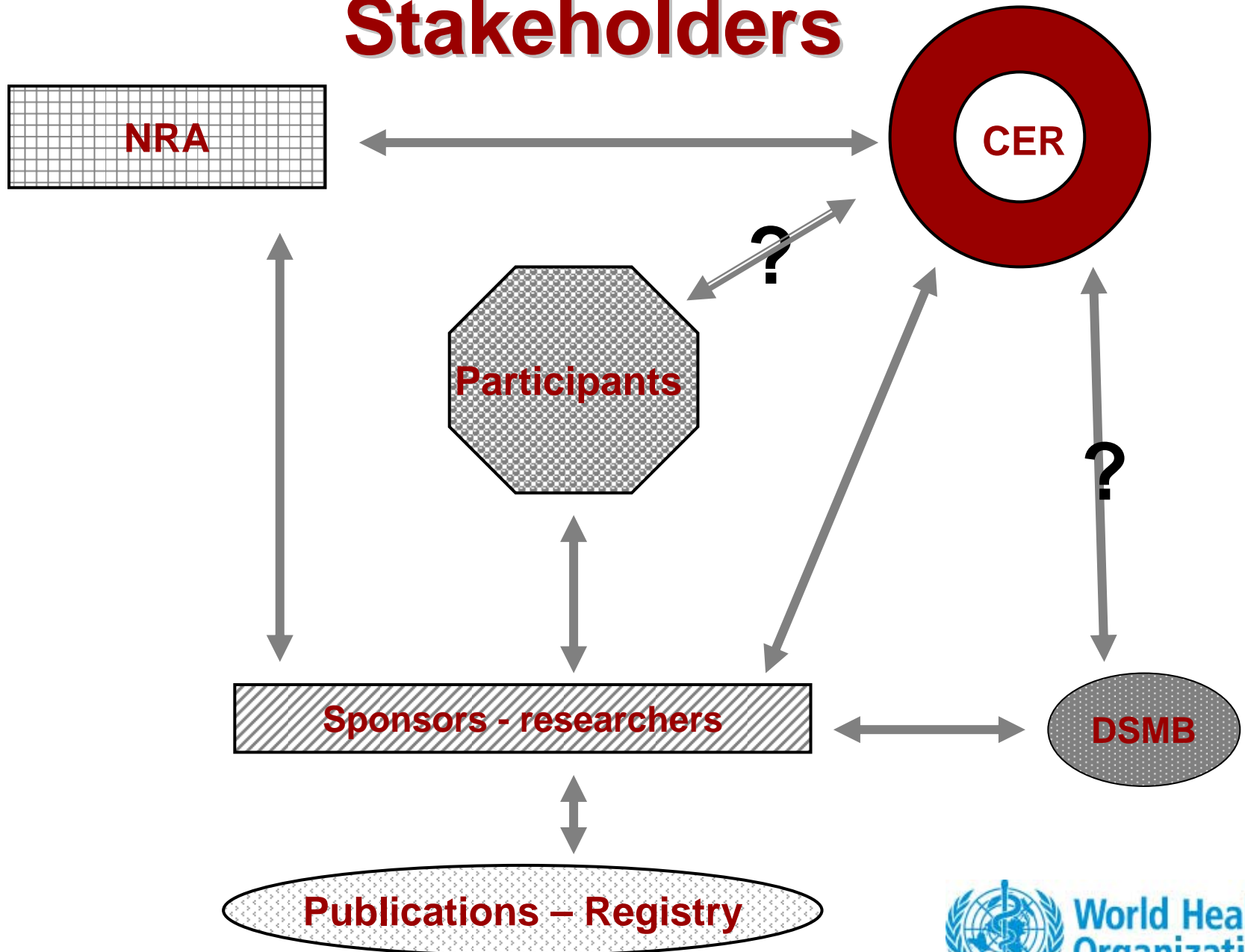
Major Achievements

- **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.)

What should be avoided

- **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**

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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

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Stakeholders

NRA

CER

?

Participants

Sponsors - researchers

DSMB

?

Publications – Registry

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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

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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

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3. Towards national strategies

Strategy

Quantitative and qualitative indicators

...hical review process

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

Processes
- **National regulation**
- **Capacity building**
- **Networking**

Input
- Human resour...
- Financial resources
- Infrastructures

N E B R A
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Collaboration within and outside WHO

- Capacity building
- Research Ethics
- Networking
- International debate
- Regional & country support

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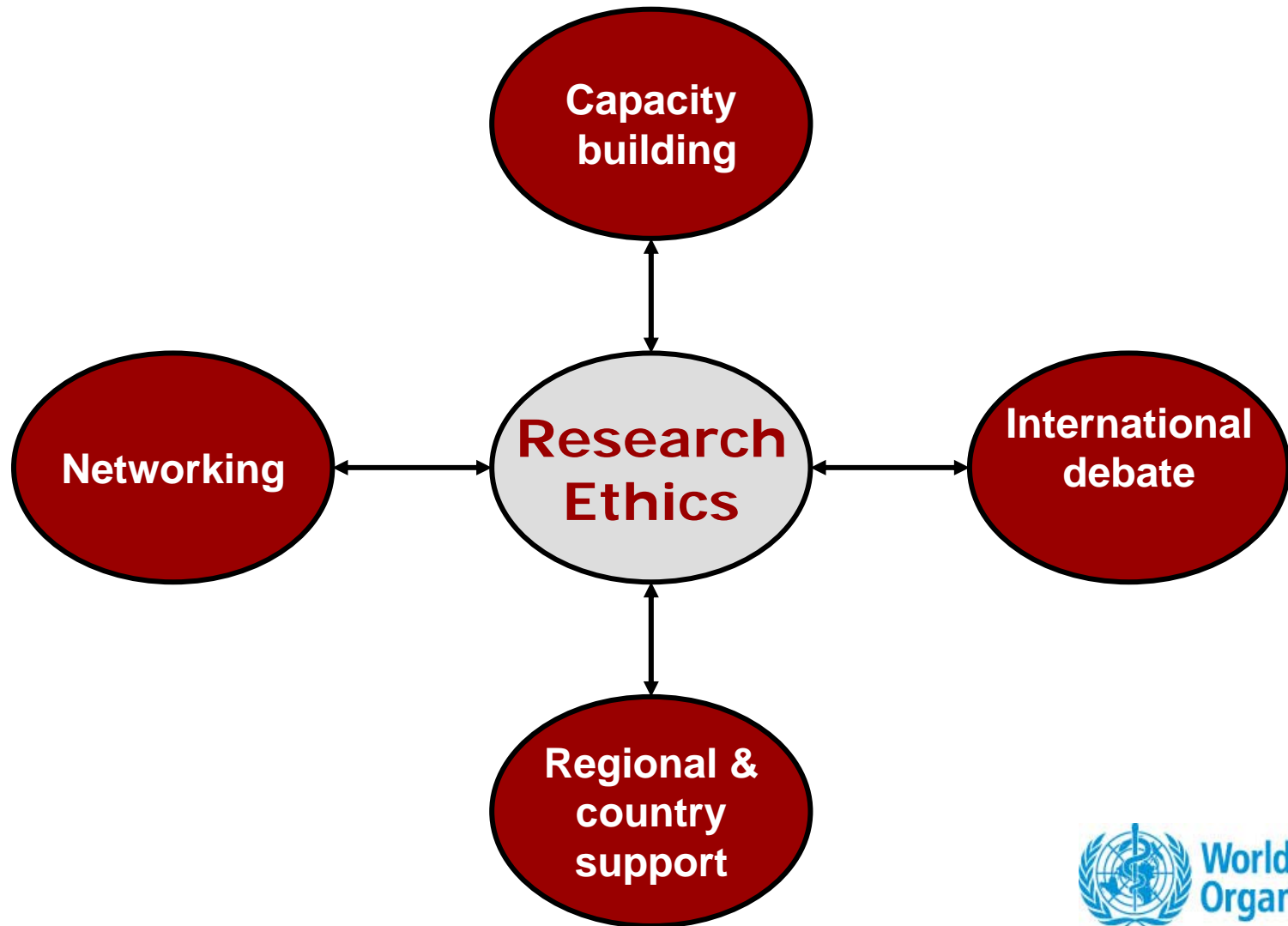
Capacity building

- 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

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"Science and ethics tell us what we must do"

Margaret Chan to the World Health Assembly

November 2006

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