

*COHRED Submission to the latest revision of the
Declaration of Helsinki Consultative meeting
Helsinki 10-11 March 2008*

Societal Impact of Health Research

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INTERNATIONAL ROUNDTABLE

*Biomedical Research in Developing Countries:
The Promotion of Ethics, Human Rights and Justice*

16 December 2008, Rome

**Council on Health Research
for Development (COHRED)**
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COHRED Expertise

- Strengthening + managing national health research systems
- Priority setting for health research
- Improving health research communication

New resources on this website

- Yaoundé Process: Supporting countries to build a favourable environment for health innovation
- Framework - health research system development
- System mapping - Eastern Mediterranean

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Dialogues and expert consultations

- country needs for health research.

- ▶ [AHA-Alignment and harmonization in health research.](#)
- ▶ [Responsible programming of vertical health research initiatives.](#)

Reference Materials

- [Health Research: Essential Link to Equity in Development](#)
1990 Report of Commission on Health Research for Development (COHRED)

News

- [COHRED Annual Report](#) - achievements, year in review, new essays
- [Mapping Health Research Systems](#) in the Eastern Mediterranean - 10 country study
- [COHRED Statement](#) - Report on responsible programming of global health research initiatives

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[Presentations](#) - conferences and global health meetings

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COHRED Specials

[Yaoundé Process:](#) Supporting countries to

Perspectives on research for health



Dr. Aissatou Toure - Member of the Board of COHRED; Research Manager, Institut Pasteur, Senegal

Bamako 2008 Global Ministerial Forum on Research for Health

Key factors for promoting better 'research for health'

Creating new foundations to make research more relevant - for people, national policy makers, researchers, sponsors and donors.



GFBR-Secretariat

- Managed by:
 - COHRED on behalf of partners with twice yearly meeting of Steering Committee of Partners
- Staffed by:
 - Half-time ethics officer
 - Full-time fellow from a developing country p.a.
- Communicates through the:
 - GFBR Newsletter
 - GFBR Website
 - Webmaster is Aga Khan Univ, Pakistan

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GLOBAL FORUM
On Bioethics in Research

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GLOBAL FORUM
On Bioethics in Research

GFBR : Annual Meetings

GFBR1 Bethesda 1999
Partnerships between research sponsors and investigators involved in clinical trials in developing countries

GFBR2 Bangkok 2000
Capacity building for ethics review in developing countries

GFBR3 Cape Town 2002
Bioethics and public health research, including ethical guidelines related to post-trial access to drugs

GFBR4 Brasilia 2002
Ethics of Genomic Research

GFBR5 Paris 2004
Sharing the benefits from research in developing countries: equity and intellectual property

GFBR6 Blantyre 2005
What happens when the research is over? Post-trial obligations of researchers and sponsors

GFBR7 Karachi 2006
Ethical issues in research involving public health, health systems, and health services

GFBR8 Vilnius 2007
Fostering research ethics infrastructure in the developing world and transition societies

GFBR9 Auckland December 2008
Ethics of research involving indigenous peoples and vulnerable populations

GFBR10 Santiago September 2009
Conflicts of interest in health research

Global Funding for Health Research has Grown

Global funding for health research grew more than four times over the past two decades

Large and increasing proportion of drug registration applications submitted to the US FDA included trials conducted in low and middle income countries

In 2000 in LMICs, almost \$3.5 billions spent on clinical trials alone – up from virtually zero expenditure in 1990

Such large increases in health research spending can have major unintended effects in the health sectors of low and middle income countries.

Unintended Effects

Most of the funding for health research in low and middle income countries is spent on only three conditions: HIV/ AIDS, TB and Malaria

But ...

- Research into ageing and chronic diseases?
- Research into childhood disability?
- Research into mental health?
- ... implementation research ?
- Neglected diseases?

Unintended Effects

The magnitude of funding even in single trials can introduce serious imbalances in health systems of resource poor countries

- A drug trial conducted in Malawi (2006) recruited 40 nurses into the trial as observers; with salaries that were much higher than those paid in the public sector. This number was equivalent then to the total annual output of the Malawi nursing college.

Context of Health Research

- Health research is important to achieve health, equity and development
- Thus research priorities are set in many countries
- (Internationally funded) health research often does not take national research priorities into consideration

Context of Health Research

SOCIAL JUSTICE

- Responsiveness of research to national research priorities: Is it unethical not to consider research priorities?

BENEFICENCE/NON-MALEFICENCE

- Serious system disturbance

COHRED's Response

- Propose that RECs/IRBs include unintended “health system effects” of health research in resource poor settings in the ethical analysis of research protocols
- Try to get it included in recent round of revisions of the DoH.

COHRED Proposal: New Paragraph in the DoH

5A. Large research programmes should take appropriate measures to eliminate or minimize negative consequences on health system functionality, especially when conducted in low resource environments.

Questions for Discussion

- Should IRBs/RECs consider health research priorities and the context in which health research happens in their review of research proposals?
- Should this be formalised in existing guidelines and declarations?
- Is the COHRED proposal worded properly?

THANK YOU

For further information
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www.cohred.org