

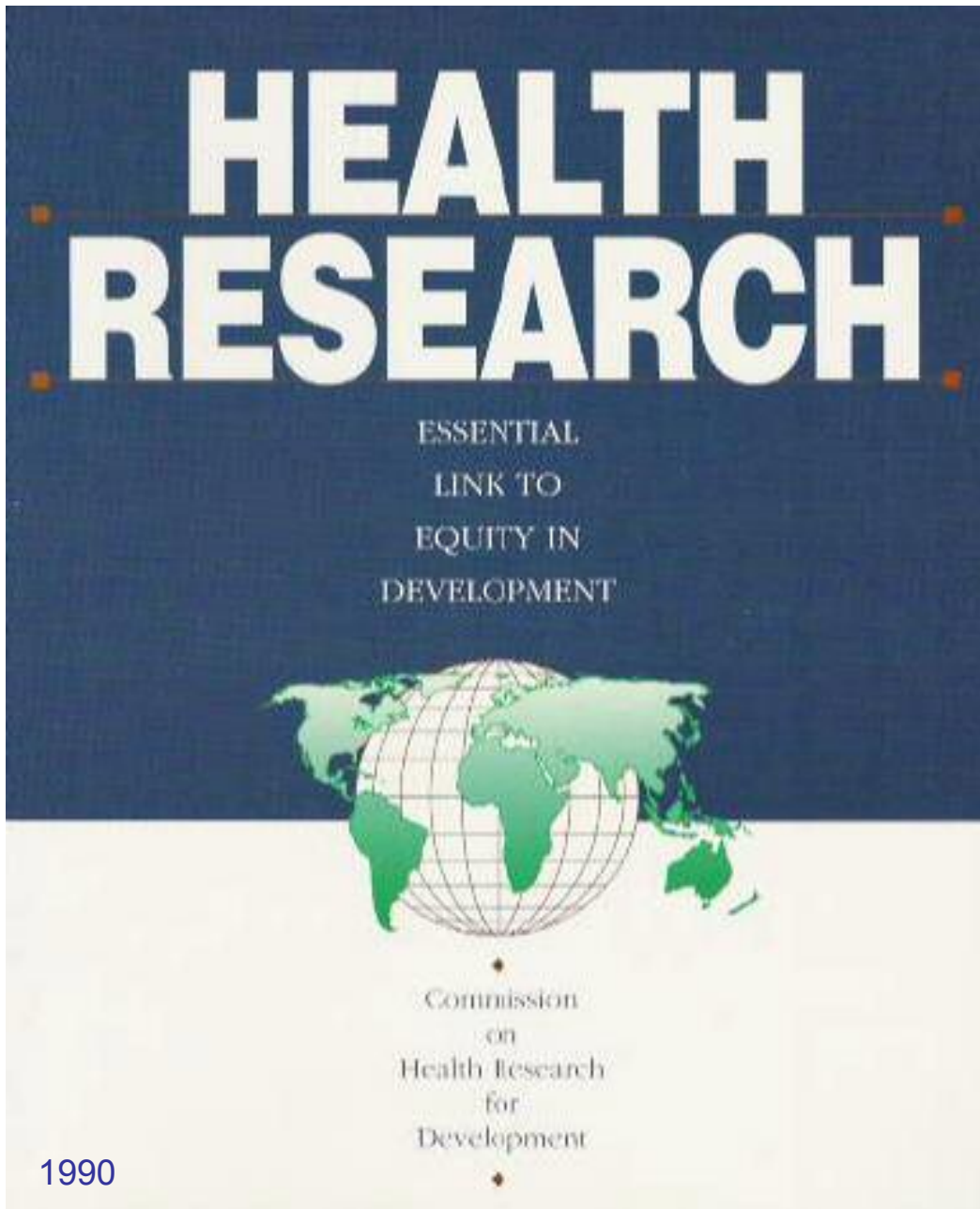
Ethics Review Capacity Building in International Health Research –

‘exactly whose capacity needs building?’

Carel IJsselmuiden

COHRED
(Council on Health Research for Development)

Brussels, May 14-15, 2007



Findings:

“10/90 Gap”

Recommendations:

1. ENHR

2. Global Funding

3. Partnerships

4. Global Platform

First Decade:

ENHR

- *advocacy*
- *priority setting*

Now:

NHRS

- health research **system support**
- country level
 - *enabling*
 - *long-term engagements*
 - *Equity and development as outcomes*

Structure:

- iNGO
- **southern owned**
(less than 5% of GHPs)
- with **key northern partners**

Funding:

- core & designated
- bilateral, foundation
 - competitive
EU FP6 SSA

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- [Call for Applications 21st Global Forum for Bioethics in Research](#)
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Strengthening national health research systems

Approaches and processes

Making health research work ... for everyone

Resources and Services

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[COHRED Briefing – synthesis and comment on research for health](#)

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National Health Research Systems:

•functional definition:

1. Governance
2. Financing
3. Capacity Building
4. Knowledge generation & translation
5. Knowledge utilisation

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National health research systems:

- Political commitment to *research for health*
- 1) Have credibly set & regularly updated **health research** (system) **priorities**
 - 2) Have a **research policy framework**, *including for oversight and ethical review process; and*
 - 3) Have a **national research management structure**, *including operationalisation of ethical review*

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National health research systems (NHRS):

4) Need to address Human Resources for Health Research (HR-HR)

** Including for ethical review of research*

5) Has to have financing strategy in place

- *Invest 2% of health program budget in research*

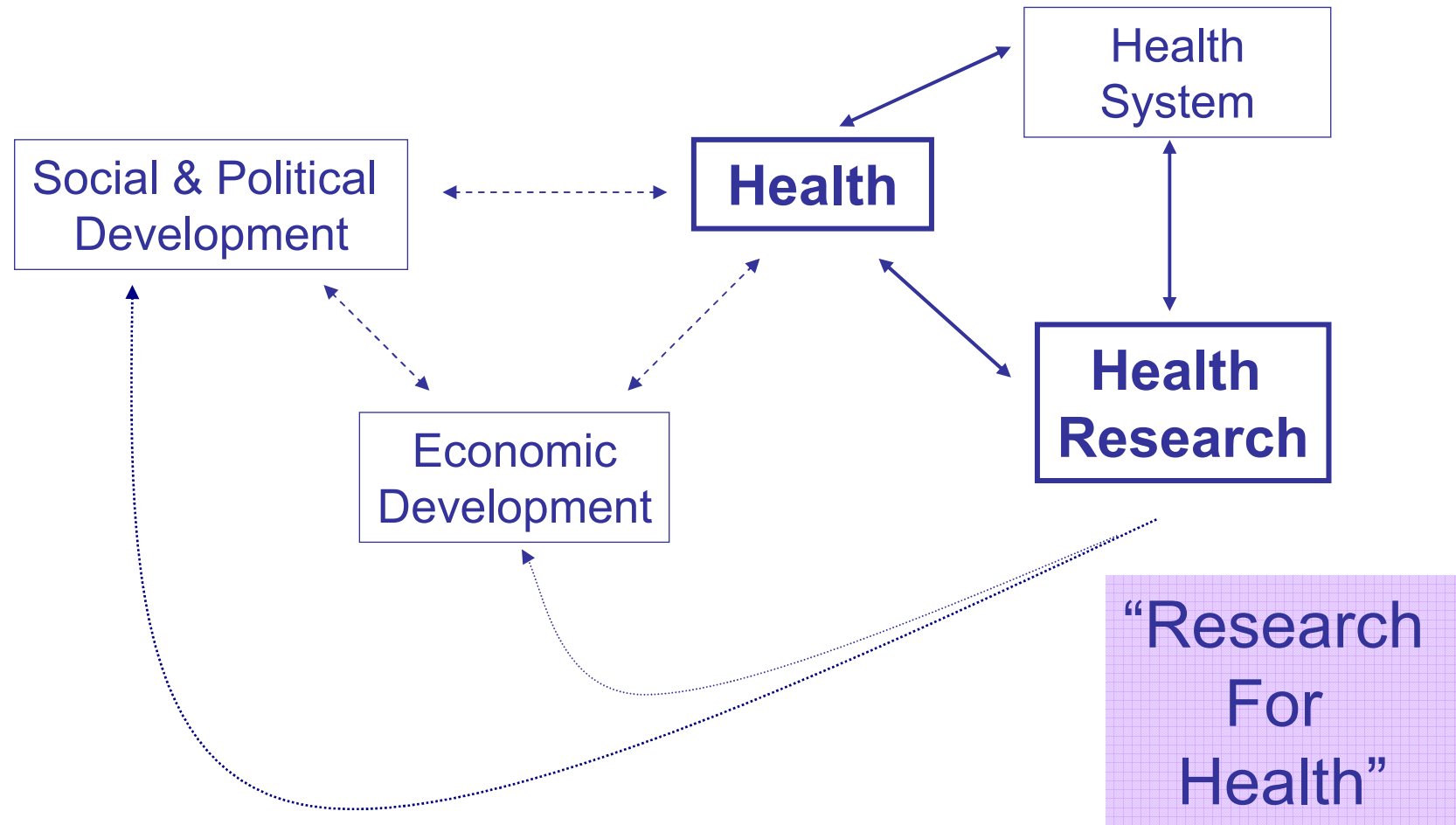
- *Partners to match with 5% of program support funding*

National health research systems (NHRS):

6) Need to address many other issues, e.g. :

- health **equity**
- **negotiation ability** to deal with sponsors
- finding **external research expertise and partnerships** needed to address health priorities
- stimulate **alignment & harmonization** (Paris, 2005)
- promote research as a core asset for socio-economic development : **‘research for health’**

In a picture ...



Health research in LMICs - *from the minister's perspective*

At institutional level, for example:

- *Tanzania had 71 concurrent large health research contracts in 2004;*
- *ICDDR,Bangladesh has 132 concurrent health research collaborations in 2005;*

Health research in LMICs - *from the minister's perspective*

At national level, for example:

- Dr. Supachai Rerks-Ngarm,
Department of Disease Control,
Ministry of Public Health, Thailand
- Ethical issues of Medical Research in the Developing World: 18-20 Feb. 2006,
Annecy, France.

Types & number of projects reviewed:

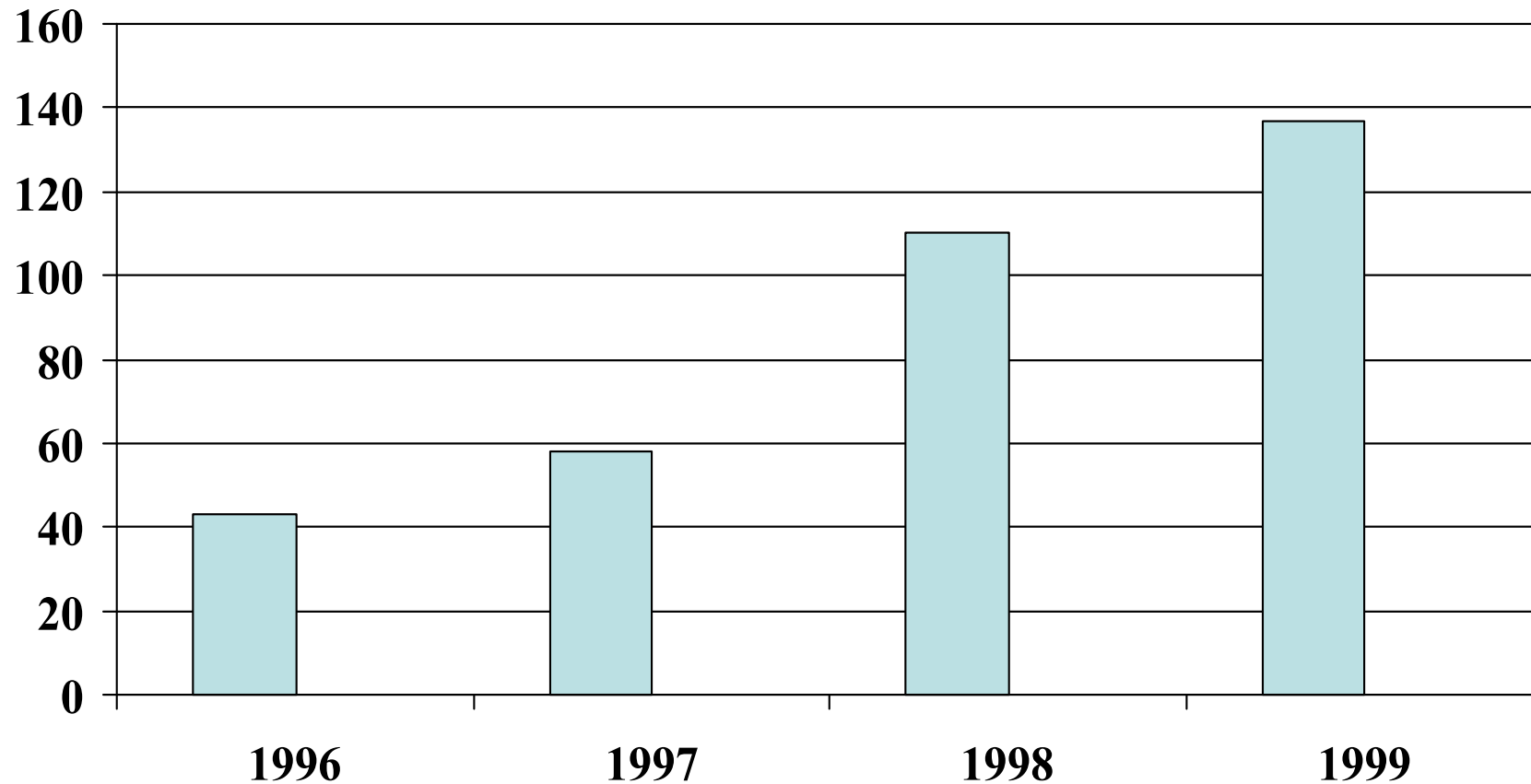
	2003	2004	2005
No. of projects reviewed	124	152	111
No. of multicenter study	75	96	98
multinational	41	52	70
in-country	34	44	28

Types & number of clinical trial projects reviewed:

	2003	2004	2005
Clinical studies	80	96	81
drugs	56	61	67
vaccines	6	12	6
diagnostic	18	23	8
Non-clinical	44	56	30

The case for investment in a permanent Research Ethics Review infrastructure

No Projects reviewed by Ethics Committee of MOPH, Thailand (Bhutta, 2000)



Challenges from multinational study protocols:

- PI doesn't have “authority” to modify the protocol as recommended by EC
- ICF prepared in other language, modification into the Thai context is not allowed ...'standard document'
- Too few sample size to yield any benefit to the study population and society at large
- Study samples were transferred out of the country 'standard lab.'

Challenges from multinational study protocols:(2)

- Excess blood draw for future study.....**too much sample**
- Thai researchers are, almost always, not able to get the study result...**societal benefit !!**
- Different rate of volunteer compensation
- Study project for PhD. thesis abroad, always claim that it has been approved by the university

Health research in LMICs - *from the minister's perspective*

*At the level of Global Health Partnership level,
for example:*

- **Jean-Louis Excler, MD**

Senior Medical Director, India, IAVI (International AIDS Vaccine Initiative)

- **AIDS Vaccine Trials: Ethical Considerations**

- Ethical issues of Medical Research in the Developing World: 18-20 Feb. 2006, Annecy, France.

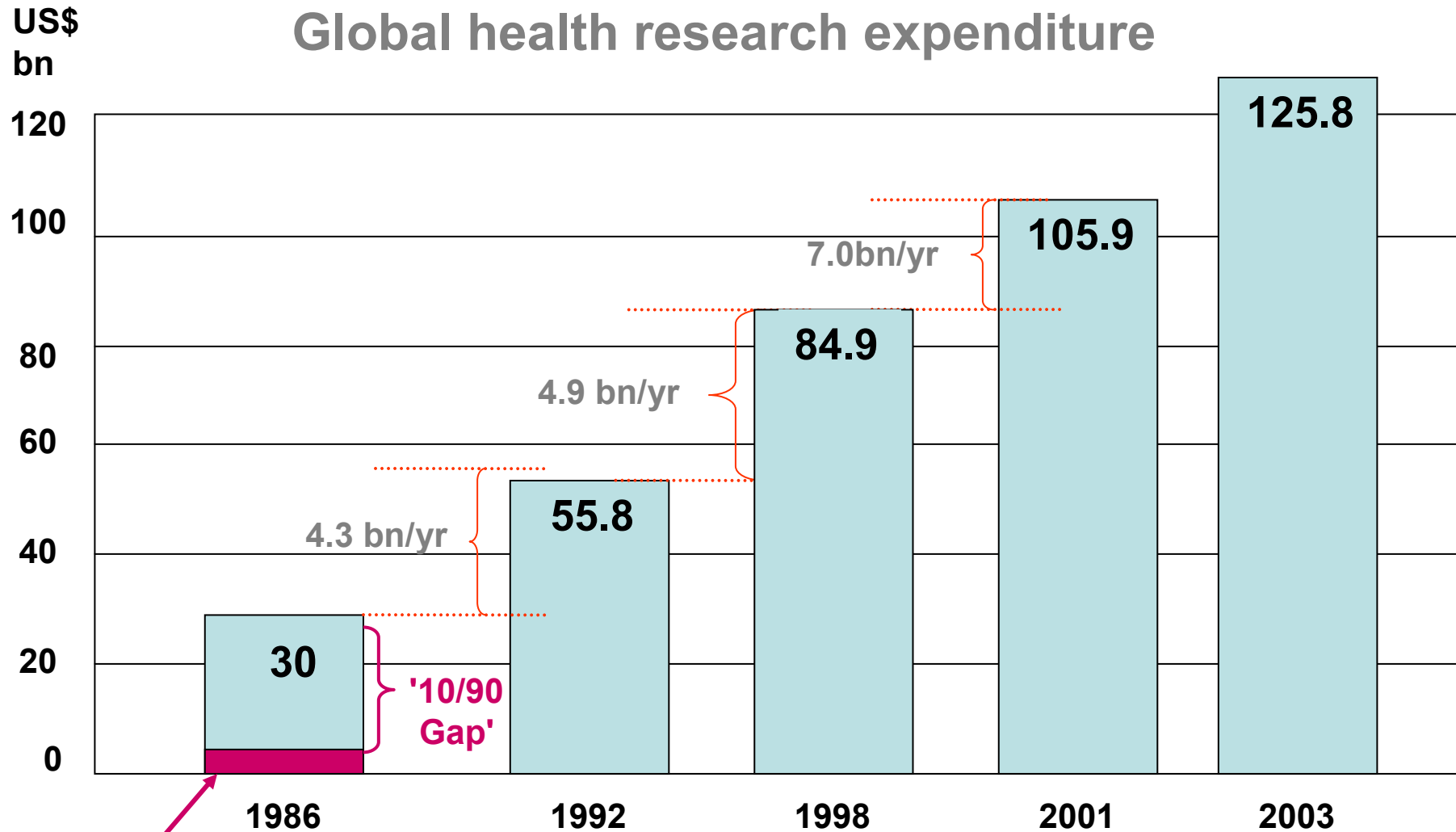
Ethics Committees *[in LMICs]*

- Overwhelmed by science and sensitivity
- Insufficient capacity
- Sometimes, more emotional than rational and often deploying the maximum umbrella to protect equally their reputation and volunteers
- Need to improve their GCP compliance
- Need to be trained, audited, and accredited

Health research in LMICs - *from the minister's perspective*

At the level of Global level, for example:

- massive increases in funding for research
- massive increases in developing countries



US\$ 1.6 bn - 5% for LMIC health needs

FDA / DHHS



European and Developing Countries Clinical Trials Partnership

Contact us | Site

EDCTP Vision

By **2012**, European research within the 3 poverty related diseases may operate as **joint programmes** with pooling of resources and thus maximizing the benefit of their research.

EDCTP & ethics review

- RTD/F.3 - 27.8.03 - final
- **4. Ethical issues**
- The EDCTP shall assess clinical trials for their relevance regarding health priorities of the partners, the risk/benefit balance for individuals and communities, and the potential impact on healthcare of the host country.
- Because EDCTP supported clinical trials shall take place as a partnership between European and developing countries, we must define the relationship between the researchers to avoid exploitation and increasing injustice.
- Many developed countries have their own legislative and ethical background regarding clinical trials. Lack of similar efforts in some developing countries may put at risk participants in clinical trials. **Therefore, strengthen the ethical review system in developing countries is an EDCTP priority.**
- The EDCTP shall strictly follow the rules and regulations currently in force at the DC, the European Community and the international level.

Health research in LMICs - *from the minister's perspective*

1.

- Low income countries need research ...
- but research needs low income countries
- ...

2.

- Research is needed to control diseases
- But research is also 'income, jobs, careers, organisation, development'



GLOBAL FORUM
On Bioethics in Research

background

The GFBR is the only global platform specifically provided **to promote debate on emerging ethical issues in international collaborative health research between developing and developed countries**

The debate (*not declarations, resolutions*) takes place in an annual meeting with 100-150 participants over a two- or three-day period.



GLOBAL FORUM
On Bioethics in Research

mission

To promote ethical international health research by bringing together ethicists, researchers, and policy makers from developing and developed countries to debate emerging ethical, social, legal and public policy issues related to health and biomedical research in international settings.



GLOBAL FORUM
On Bioethics in Research

specific aims

To strengthen the protection of human participants in international health research;

To provide a forum for developing country perspectives on ethical issues in research;

To explore opportunities to enhance capacity for ethical review of research;

To create a context for research involving human subjects in which developing and developed country scientists, ethicists, community representatives, policy-makers, and other relevant stakeholders can **address ethical issues in ways that encourage expeditious long-term joint management of research protocols.**

Council for International Organizations of Medical Sciences
(CIOMS)



*International Ethical Guidelines for Biomedical
Research Involving Human Subjects*



The Council for International Organizations of Medical Sciences (CIOMS) announces the publication of its revised/updated *International Ethical Guidelines for Biomedical Research Involving Human Subjects*.

This 2002 text supersedes the 1993 Guidelines. It is the third in the series of biomedical-research ethical guidelines issued by CIOMS since 1982. Its core consists of 21 guidelines with

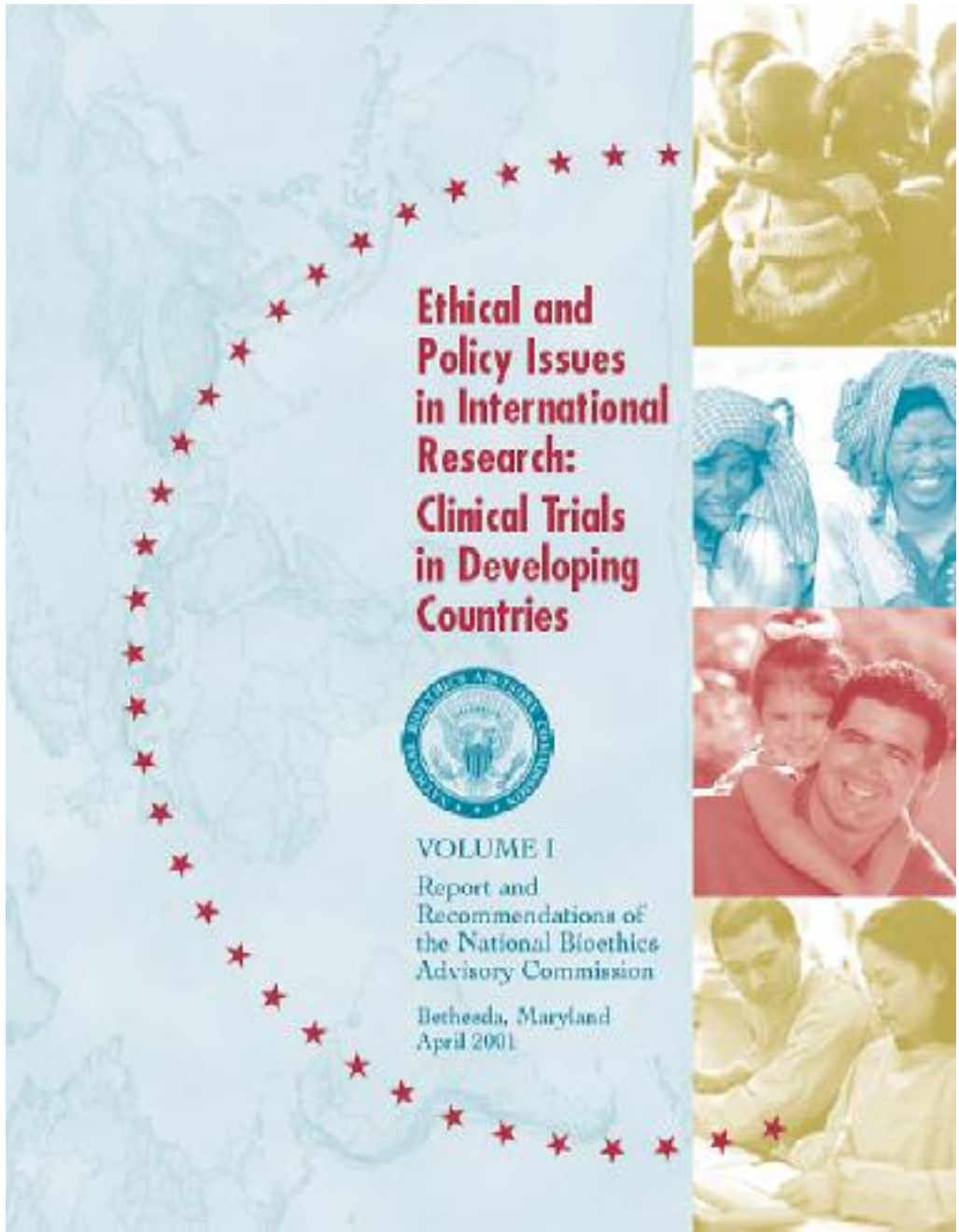
The Guidelines relate mainly to *ethical justification and scientific validity of research; ethical review; informed consent; vulnerability of individuals, groups, communities and populations; women as research subjects; equity regarding burdens and benefits; choice of control in clinical trials; confidentiality; compensation for injury; strengthening of national or local capacity for ethical review and obligations of sponsors to provide health-care services.*

Their scope reflects the changes, the advances and the controversies that have characterized biomedical research ethics in the last two decades. Like those of 1982 and 1993, the 2002 CIOMS Guidelines are designed to be of use to countries in defining national policies on the ethics of biomedical research involving human subjects, applying ethical standards in local circumstances, and establishing or improving ethical review mechanisms. A particular aim is to reflect the conditions and the needs of low-resource countries, and the implications for multinational or transnational research in which they may be partners.

ISBN 92 9036 075 5

Price: Swiss francs 20.

Order from CIOMS,
c/o WHO, Avenue Appia 20,
CH1211 Geneva 27, Switzerland.

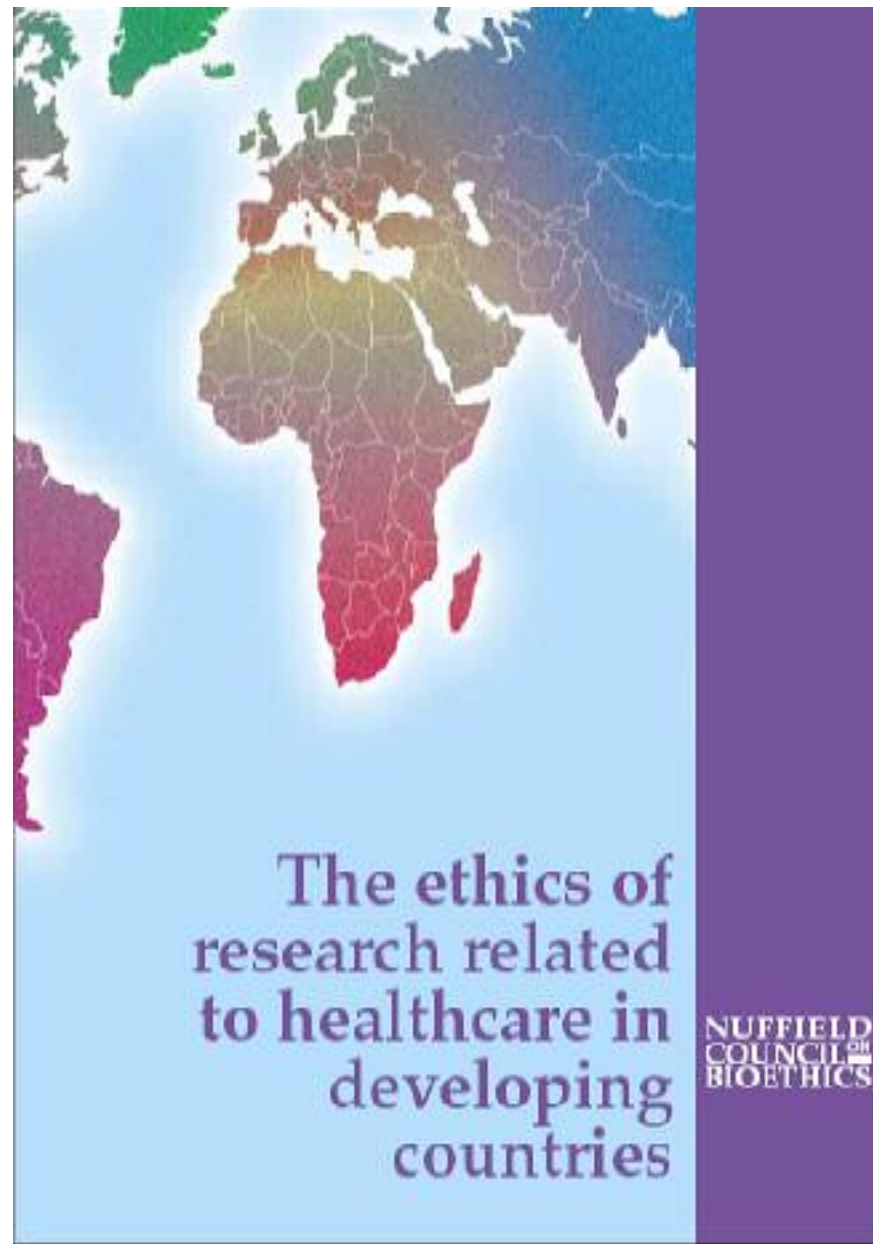


**Ethical and
Policy Issues
in International
Research:
Clinical Trials
in Developing
Countries**



VOLUME I
Report and
Recommendations of
the National Bioethics
Advisory Commission

Bethesda, Maryland
April 2001





GLOBAL FORUM
On Bioethics in Research

history & topics

1. Bethesda, USA, 1999: **partnerships between research sponsors and investigators, distributive justice**
2. Bangkok, Thailand, 2000: **fairness, benefit sharing, and community benefit agreements in the context of clinical trials**
3. Cape town, South Africa, 2002: **bioethics and public health research & post-trial access to drugs**



4. Brasilia, Brazil, 2002: **bioethical issues in genomics research, commercial use of genetic information, and the need for education about genomics for the public**

5. Paris, France, 2004: **sharing the benefits from research in developing countries, equity and intellectual property**

6. Blantyre, Malawi, 2005: **what happens when the research is over ?**



7. Karachi, Pakistan, 2006: **bioethics in public health research**
8. Vilnius, Lithuania, 27-29 June 2007: **fostering the research ethics infrastructure in the developing world / transition societies; and ethical aspects of mental health research**
9. Auckland, New Zealand, Feb 2008: **ethics of health research in vulnerable and indigenous populations; and ethical issues in mental health research**



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current partners



U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES
National Institutes of Health



World Health Organization



Medical
Research
Council

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THE AGA KHAN UNIVERSITY

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VILNIUS UNIVERSITY



Health Research Council of New Zealand
Te Kaunihera Rangahau Hauora o Aotearoa



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secretariat



Inserm



wellcometrust



- 50% FTE Ethics Officer
- 2 Fellowships
- some operational costs

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secretariat



- enabling vs 'capacity building'
- 'capacity building' is more than training people
- fellowship based – having highly qualified persons around the world who understand EU & member countries' approach to ethics
- can become the global voice for global health research ethics debate – needs continuity and follow-up between meetings
- and needs to enable participation from south & north !



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- but EU needs to move beyond competitive funding
- need to increase funding commensurate with research investments
- needs to engage in long-term support for capacity building – for example, 5% of health programme funding (e.g. *EDCTP*)
- encourage partners in the south to spend 2% as well



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future



- Context in which health research happens is likely to change ethics review and debate is very necessary:
 - Ethical framework
 - ... *principles applied to individual projects*
 - Human rights framework
 - ... *extension to include 'right to health', 'right to self-determination', other 'rights'*
 - Negotiation
 - ... *sure, countries need vaccines, but researchers do need countries*
 - ... *countries need many other things as well*
 - Advocacy & Activism
 - *becoming more and more prominent, also in the south*



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future



- Linking ethics to ‘research for health’
- Mainstreaming ethics in research

**2008 Global Ministerial Forum on Research
for Health**

Bamako, Mali: 17-20 November 2008

Strengthening Research for Health, Development and Equity

Organized by