Biomedical Research in Developing Countries:

The Promotion of Ethics, Human Rights and Justice

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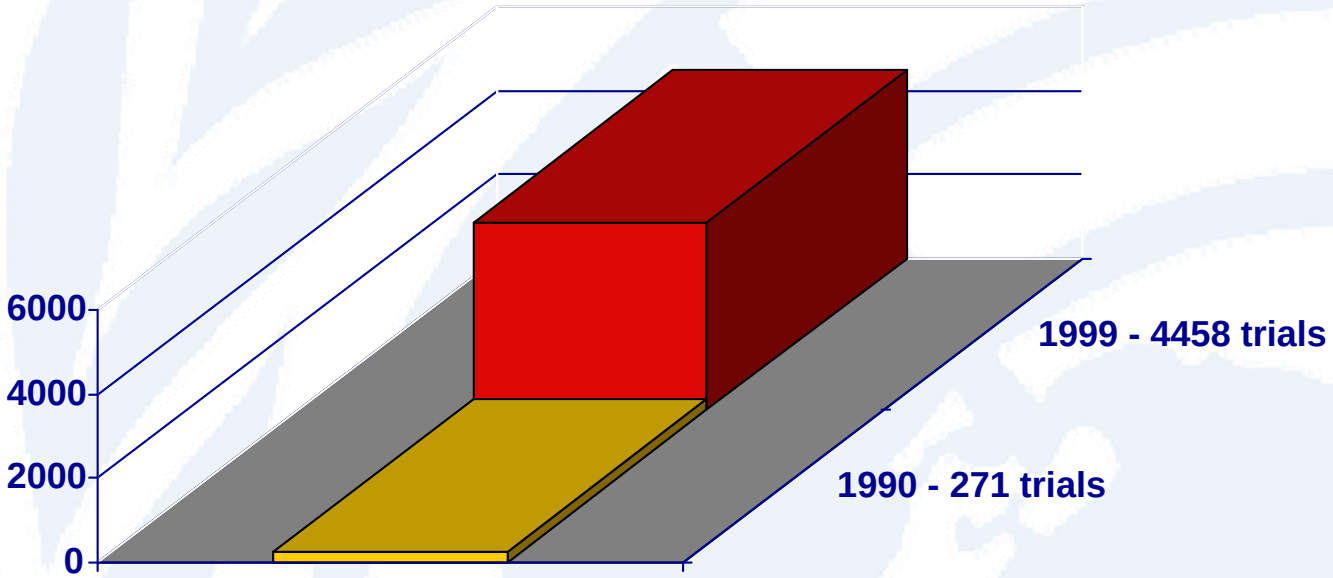
The state of legislation regarding ethics in biomedicine and the ethical review capacity in Africa

Number of US sponsored drug research abroad increased 16 times from 1990 to 1999



Most important documents in the field of protection of clinical research participants

- The Nuremberg Code 1947
- The Declaration of Helsinki 1975
- Belmont Report 1974
- CIOMS Guidelines 1982 Rev. 2002
- ICH Guidelines for Good Clinical Practice 1990
- UNESCO Universal Declaration on Bioethics and Human Rights 2005
- WHO, UNAIDS, TDR Standard Operating Procedures

Even if international ethical standards lay down the general ethical principles, they are considered limited in scope, limited by their voluntary compliance and by individual interpretation of three basic principles of:

- Beneficence
- Non-maleficence
- Justice

The importance of RECs is fundamental in ensuring the protection of the dignity, the rights, the safety and well-being of participants in clinical research

- Kilama W.L., “Equipping Africa’s researchers for global collaboration”,, Science and Development Network, 2003
- Hyder A.A., Wali S.A., Khan A.N. et al., “Ethical review of health research: a perspective from developing countries researchers”, J.Med. Ethics, 30:68-72, 2004
- Elsayed D.E.M., “Assessment of the ethical review process in Sudan”, Developing World Bioethics, 4 (2):154-159, 2004
- Kirigia J.M., Wambebe C., Baba-Moussa A., “Status of national research bioethics committees in the WHO African Region”, BMC Medical Ethics, 6-10, 2005
- “Final Report: networking for ethics on biomedical research in Africa (NEBRA)”, NEBRA, 2006
- Kass N., Hyder A.A., Ajuwon A., Appiah-Poku J., Barsdorf N. et al. “The structure and function of research ethics committees in Africa: a case study”, PLOS Med 4(1):e3, 2007
- Moodley K., Myer L. “Health research ethics committees in South Africa: 12 years into democracy”, BMC Medical Ethics 8 (1), 2007

Main challenges in the protection of the health research participants:

- Lack of specific laws and legislation, guidelines and good governance
- Lack of the independence of RECs
- Imbalanced REC composition - importance of lay members, gender balance
- Lack of the ethical training of RECs members
- Inadequate funding

Three questions for the Country Information Sheet

1) Existence of national specific legislation on ethics in biomedical research

2) Existence of national specific guidelines or standard operating procedures (SOPs) concerning ethics in clinical research

3) Presence of national or institutional research ethics committees reviewing biomedical research with human participants

Three options for responses to the three questions

- YES, if enough evidence was to be found, to justify a positive response.
- NO, if enough evidence was to be found, to justify a negative response.
- NOT AVAILABLE, if the information collected was not sufficient to formulate a positive or a negative response.

Country information sheet

African Country

National specific legislation on ethics in biomedical research	
Guidelines and/or SOPs concerning ethics in research	
National/Institutional Bioethics Committees that review ethics of biomedical research with human participants	
Sources:	

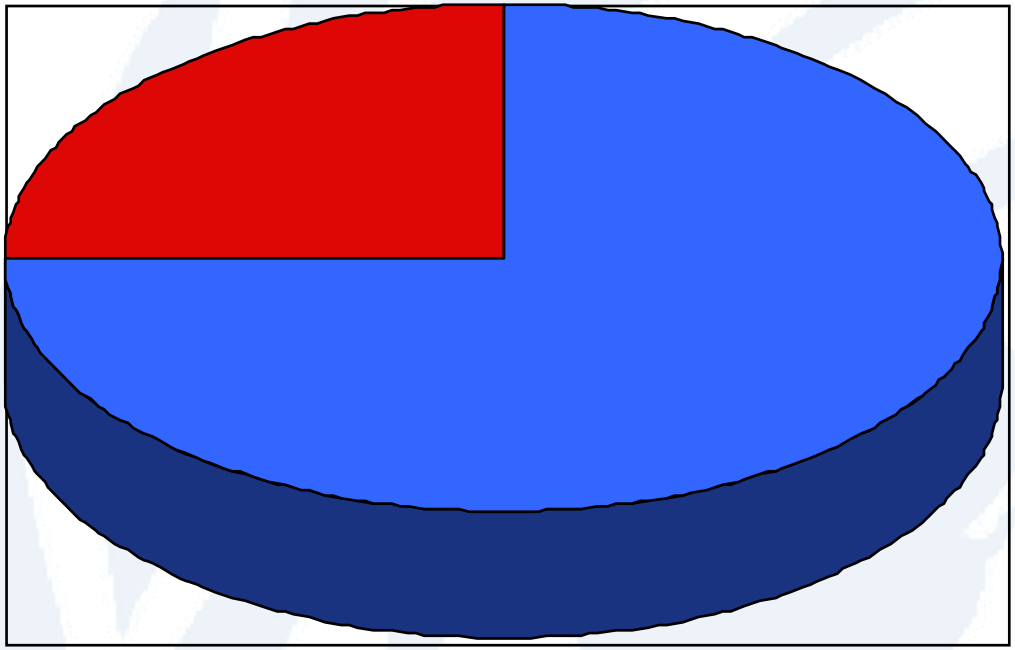
Situation analysis in Africa:

- Primary sources of information:
  - Emails sent to individual experts
  - Experts meetings
  - International and regional conferences
- Secondary information obtained from:
  - Database queries
  - Documents

Information was received directly from 10 countries: Egypt, Malawi, Mauritius, Morocco, Nigeria, Senegal, South Africa, Tanzania, Togo, Tunisia.

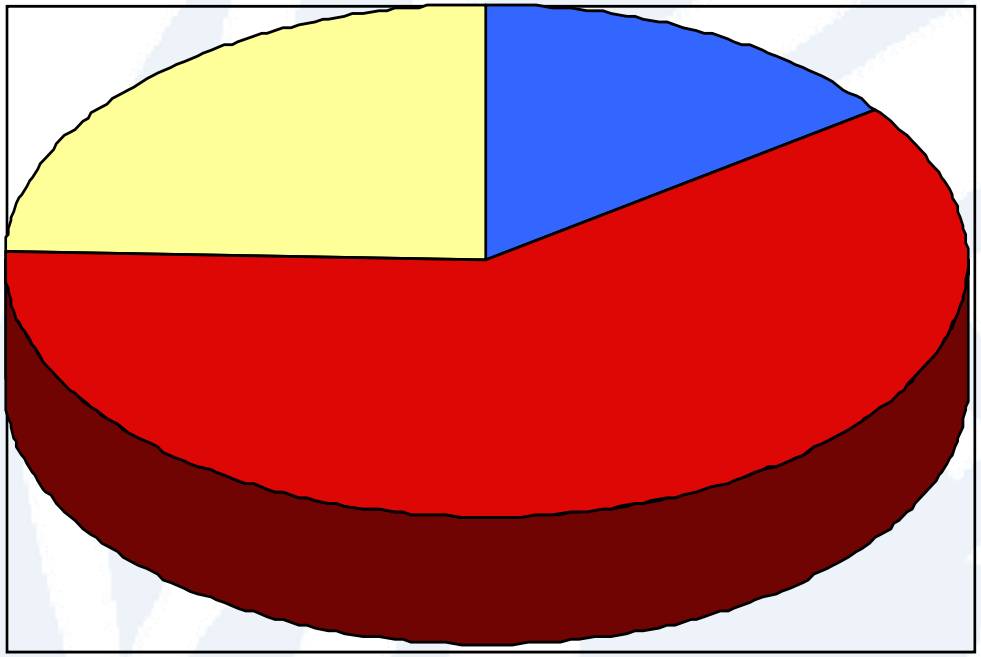
All other country information sheets were completed through the analysis of the documents collected during the research study.

Percentage of analyzed and not analyzed countries



- **Analyzed countries 75%**
- **Not analyzed countries 25%**

Country information sheets completion rate

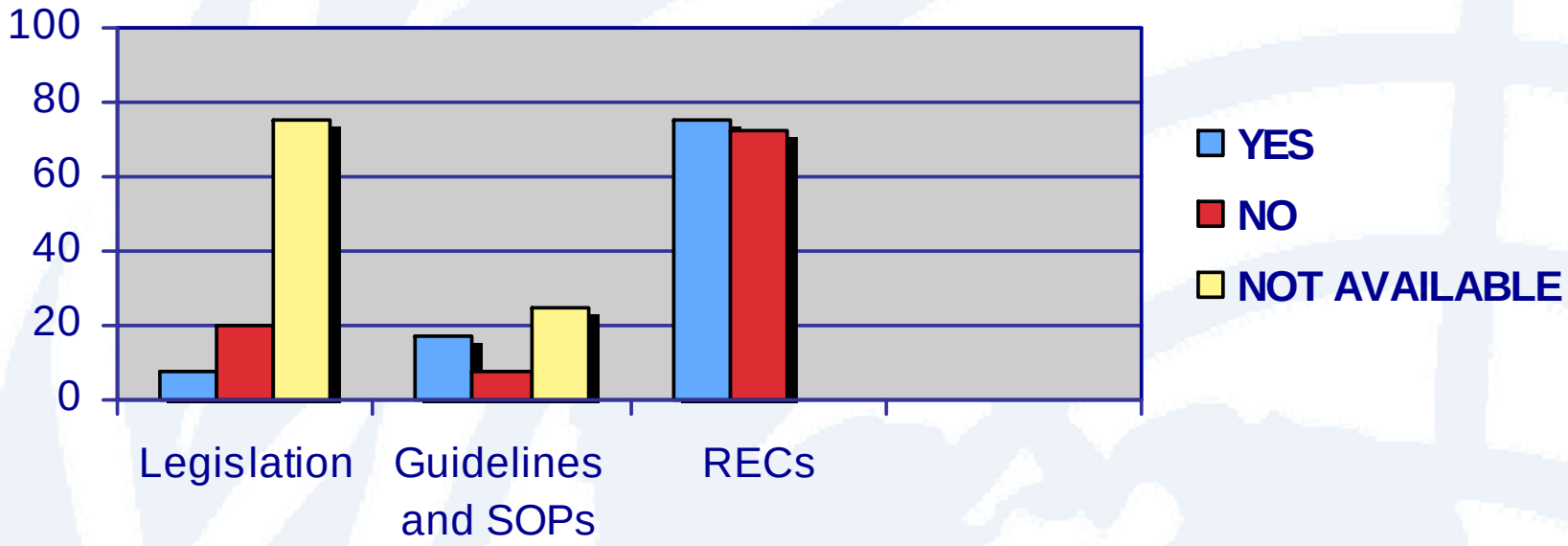


- **Fully completed sheets 15%**
- **Partially completed sheets 62%**
- **Totally empty sheets 23%**

Percentage of responses to the three questions of the study in the group of analyzed countries

	YES	NO	N/A
1) Existence of national specific legislation on ethics in biomedical research	7,5%	17,5%	75%
2) Existence of national specific guidelines and/or SOPs concerning ethics in clinical research	20%	7,5%	72,5%
3) Presence of national or institutional research ethics committees reviewing biomedical research with human participants	75%	25%	0%

Percentage of responses to the three questions of the study in the group of analyzed countries



- Training
- Organizational funding
- Independence

The United Nations and the international community at large must strengthen their role in promoting the importance of ethical review of biomedical research in a number of ways:

- By promoting GCP guidelines
- By promoting training activities for RECs
- By promoting ethical and human health sensitisation among policy makers, judges and governmental officers

Thank You for Your attention

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