



# ETHICAL ISSUES OF MEDICAL RESEARCH IN THE DEVELOPING WORLD

Anancy, Les Pensières April 18-20, 2006

## Background

More and more research is conducted in developing countries where populations suffer from a high burden of disease. Various factors affect the conditions under which this research is conducted, such as differences in cultures, in sanitation, in standards of care (that vary by sponsors and participants in studies), and differences manifested in political, legal and social contexts specific to these countries. Under these circumstances, it is not surprising that ethical issues emerge. They are generally viewed from two perspectives: by the universality or the relativity of the standards used, and through the perspective of the local ethics committees in the countries where the research is being conducted. One can only be delighted by the increasing number of initiatives aimed at dealing with these major issues. However, in so far as the ethical regulation of research in developing countries is concerned, a larger variety of actors and institutions needs to become involved.

Those actors should include sponsors of research, the investigators who conduct it, the national or international institutions that draw up codes of good practices, ethical review committees, legal practitioners and public authorities who draft the laws, academics or researchers who thoroughly analyse the issues, journal editors and scientific reviewers who require compliance with ethical rules as a condition of publication, the mainstream media who may denounce certain practices, or non-governmental organisations who may represent and translate the expectations of study subjects.

These different actors, who are subject to multiple and contradictory rationales, have the responsibility of supporting innovation in therapy or prevention, and ensuring the best possible protection of study subjects against abuses.

What are the challenges faced by each actor in this process? What are practical solutions? What dialogue occurs between those actors? To what degree, and how is greater interaction between these various actors possible? Is ethics really interdisciplinary, inter-institutional and international?

Basing our examples on authentic situations, the colloquium will try to provide answers to these different questions. The experiences relate to trials with vaccines, drugs and diagnostic tests, as well as to epidemiologic research. They also relate to the fundamental questions of the ethics of research such as: consent, comparative treatment and post-tests, as well as the role of ethics committees. Speakers from different countries, disciplines and professions will participate.

## Objectives

- 1. To share information and debate questions relevant to ethics of research in developing countries**
- 2. To foster dialogue on ethical issues among actors in the scientific and decision-making communities involved in medical research, with regard to ethical considerations.**
- 3. The discussions will relate to research ethics in the development of vaccines, drugs, and medical diagnostics, as well as research in epidemiology.**

## Tuesday April 18

17:30 - 18:30	Registration	
18:30 - 18:45	Welcome address	Darshna Tanna Director Fondation Merieux
18:45 - 19:15	Keynote lectures : Research for health in developing countries: promises, challenges and responsibilities	Marie Charlotte Bouësseau WHO/ETH
19:15 - 19:35	Considerations in fielding global clinical trials	Jean Louis Excler IAVI
19:35	Welcome dinner	

## Wednesday April 19

### Session I: Ethics and field research in developing countries

Irrespective of the type of research (therapeutic or vaccine trials, epidemiologic surveys or field trials of diagnostic tests), both sponsors and investigators are confronted with a number of ethical issues in field research which include: appropriate provision of information, consent of the study subjects, benefits for participants, appropriateness of the study based on country needs, safeguarding of the confidentiality and anonymity of the participants, and ensuring that the benefits from the research accrue to the community. How should these issues be dealt with in developing countries? Other issues such as the involvement of patient associations in study design, the role of anthropology in cultural mediation, and the role of philosophers in ethics of clinical research will be examined in this session.

Chairperson: Douglas WASSENAAR

<b>08:30 - 10:10</b>	<b>Experience from the actors on biomedical research in developing countries: example of HIV</b>	
08:30 - 08:50	Access to care and treatment in HIV vaccine research and clinical trials	Saladin Osmanov
08:50 - 09:10	Ethical issues related to diagnostic research and sample collection	Carine Malcus Vocanson
09:10 - 09:30	Ethical issues of medical research: experiences from Thailand	Supachai Rerks- Ngarm
09:30 - 10:10	Patients advocacy groups : <ul style="list-style-type: none"> <li>• The point of view from the North</li> <li>• The role of REDS (Network on Ethics, Law and AIDS) in the protection of participants in biomedical research in Cameroon</li> </ul>	Emmanuel Trenado Jean Marie Talom
<b>10:10 - 10:40</b>	<b>Panel discussion</b>	
<b>10:40 - 11:00</b>	<b>Coffee break</b>	
<b>11:00 - 11:20</b>	<b>Experience from a consortium coordinator: example of pneumococcal vaccine evaluation</b>	<b>Hanna Nohynek</b>
<b>11:20 - 11:40</b>	<b>Vaccination and vaccine acceptability by the population involved in a trial: example of enteric vaccine</b>	<b>Bonita Stanton</b>
<b>11:40 - 12:00</b>	<b>Role of the philosopher in biomedical research</b>	<b>Godfrey Tangwa</b>
<b>12:00 - 12:20</b>	<b>Clinical trials in developing countries: the contribution of anthropology</b>	<b>Christophe Perrey</b>
12:20 - 13:00	Discussion	
13:00 - 14:00	Lunch	

## Session II: Ethical committees in developing countries: their composition, their role

This session focuses on the opportunities and challenges in creating ethics committees in developing countries. Issues examined include: How are ethics committees structured? What profile do their members have? How do national or international texts factor in the ethical evaluation of research protocols? What relationships do these committees have with public institutions (Ministry of Health, Ministry of Research)? Can they resist political, economic, or institutional pressures? How are they financed? What are their real powers? Are they systematically consulted before any research on human beings is undertaken? Do they advise the local legislator?

Chairperson: Blaise BIKANDOU

14:00 - 14:20	<b>Different steps towards the establishment of a local research ethics committee: an experience from South Africa</b>	<b>Douglas Wassenaar</b>
14:20 - 15:00	<b>Fostering ethics committees</b>	
14:20 - 14:40	Experience of FLACEIS: Latin American Forum for Ethics Committees for Health Research	Dafna Feinholz
14:40 - 15:00	Experience of NEBRA: Networking for Ethics on Biomedical Research in Africa	Assétou Derme
15:00 - 15:30	Coffee break	
15:30 - 15:50	<b>Do ethics committees need a legal framework?</b>	<b>Christian Byk</b>
15:50 - 16:20	Panel Discussion	
16:20 - 18:30	<b>Meeting of working groups</b>	
	<b>I:</b> How can a local research ethics committee be established that is both strong and independent? Experience and recommendations	Coordinator Douglas Wassenaar
	<b>II:</b> Is an informed consent process generated in a developed country applicable in the developing world?	Coordinator Florencia Luna
	<b>III:</b> What happens to the enrolled population when the research is over?	Coordinator Banson J. Barugahare
	<b>IV:</b> Should new antigens being developed by industry be tested simultaneously in developed and developing countries or in sequence?	Coordinator Charles Weijer
19:00	Dinner	

## Thursday April 20

Working Groups presentations

Chairperson: Nouzha GESSOUS

08:30 - 08:45	<b>Presentation of the working group I</b>
08:45 - 09:00	<b>Discussion</b>
09:00 - 09:15	<b>Presentation of the working group II</b>
09:15 - 09:30	<b>Discussion</b>
09:30 - 09:45	<b>Presentation of the Working group III</b>
09:45 - 10:00	<b>Discussion</b>
10:00 - 10:30	Coffee break
10:30 - 10:45	<b>Presentation of the Working group IV</b>
10:45 - 11:00	<b>Discussion</b>

### Session III: Role of international institutions in fostering an ethical review process

The ethical regulation of research in developing countries is based on texts and statements produced by various international organizations. This session examines: How are these guidelines developed? How are they revised? What are the historical and philosophical sources of these texts? What is the influence of these standards on international biomedical research? Are they the basis of legislation in developing countries? What legitimacy do these international institutions have? How are developing countries represented in these institutions?

Chairperson: Adeyinka Falusi

11:00 - 11:15	COHRED/Global Forum for Bioethics and Research	Carel IJsselmuiden
11:15 - 11:30	CIOMS: Council for International Organizations of Medical Science	Idänpään-Heikkilä
11:30 - 11:45	World Medical Association	John Williams
11:45 - 12:00	EDCTP: European & Developing Countries Clinical Trials Partnership	Aissatou Toure Balde
12:00 - 12:15	Ethical standards in biomedical research: the work of the Council of Europe	Laurence Lwoff
12:15 - 12:45	Panel Discussion	
12:45 - 14:30	Lunch	

### Session IV: Role of the media in maintaining ethical standards

This session examines the roles of publishers and the media in the ethics of research. One of the objectives of research is to publish, and publication is linked to observance of ethical rules. How do the leading scientific reviewers exercise their role in this field? What are their references?

Recent experience shows that the media can be alarmist. The denunciation of studies, on ethical grounds, can seriously damage the reputation of researchers, sponsors or investigators. Because of the ease of worldwide dissemination of information, the media have become real actors in the international regulation of research. How, and on what principles, do they exercise this role? How do they contribute to the debate on the ethics of research? Do they raise awareness on these questions over the medium and long term? If so, how?

Chairperson: Didier SICARD

14:30 - 14:50	Ethics and the publication process: authors, editors and the media	Michael J.G. Farthing
14:50 - 15:50	How can a journalist participate in the debate on research ethics?	
15:10 - 15:30	Experiences from a decade of ethics in medical research in Cameroon	Mme Irène S. Ndjabum
15:30 - 15:50	Ethics and responsibilities of journals	Stuart Spencer
15:10 - 16:30	Panel Discussion	
16:30 - 17:00	Closing remarks	Anne-Marie Moulin
17:00	Coffee Break – End of the meeting	