Health Research Ethics Landscape in Africa over the last decade

... and future outlook

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Vice-Chair of CAMBIN (2009 --)

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Disclosure

Health Research Ethics Landscape in Africa over the last decade … and future outlook

Overview, my view
Not exhaustive, Based on my own knowledge & experience … and ideas

http://www.3dvf.com/forum/3dvf/Rendu-2/diffraction-decomposition-lumiere-sujet_63_1.htm

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Cameroon Bioethics Initiative (CAMBIN)
1. Global context over the last decade
2. Health Research Ethics in Africa over the last decade
3. Looking back in the mirror: lessons learnt
4. Perspectives for Africa
5. Conclusion
Plan of the presentation

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Health Research Ethics in a global context over the last decade

✧ **U.N. Institutions**

- WHO’s Ethics and Health Initiative (2002) → Department of Ethics and Social Determinants (Global Health Ethics)
- United Nations Inter-Agency Committee on Bioethics (UNIACB), under the UNESCO’s coordination (2003)

✧ **Global Conferences**

- World Congress of Bioethics (11th Rotterdam, The Netherlands, June 2012)
- Biennial Global Summit of National Bioethics Advisory Bodies (9th Carthage, Tunisia, Sept. 2012)
- Global Forum on Bioethics in Research, 1999 to 2008 (GFBR10 put on hold)
Health Research Ethics in a global context over the last decade

Series of texts & booklets
- CIOMS guidelines 2002, under revision
- UNESCO: Universal Declaration on Bioethics and Human Rights, adopted in 2005
- UNAIDS-AVAC: Good Participatory Practice guidelines for biomedical HIV prevention trials, 2007, 2011
- WHO: Guidance on ethics of tuberculosis prevention, care and control, 2010

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Health Research Ethics in a global context over the last decade

Series of texts & booklets (cont’ed)

- Nuffield Council Documents (not exhaustive):
  - The ethics of clinical research in developing countries: a discussion paper, 1999
  - The ethics of research related to healthcare in developing countries, 2002
  - The ethics of patenting DNA, 2002
  - The ethics of research related to healthcare in developing countries: a follow-up discussion paper, 2005
  - Critical care decisions in fetal and neonatal medicine: ethical issues, 2006
  - Medical profiling and online medicine: the ethics of 'personalised healthcare' in a consumer age, 2010
Series of texts and booklets (cont’d)

- WHO: Research ethics committees: basic concepts for capacity-building, 2009
Health Research Ethics in a global context over the last decade

Series of texts and booklets (cont’ed)

- ANRS chart of ethical research in developing countries, 2002, 2008
- IRD guidelines on good practice in research for development, 2005, 2012
- Pasteur Institute chart of ethics, 2009

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Health Research Ethics in a global context over the last decade

Between the past and the future (2014)

1. Burkina Faso
2. Cameroon
3. Democratic Rep of Congo
4. Egypt
5. Ethiopia
6. Malawi
7. South Africa

Handbook of Global Bioethics

Cameroon

Godfrey B. Tangwa

Introduction

Cameroon, a former German colony (1884–1914) and subsequently a United Nations mandated territory administered partly by France and partly to Great Britain, is a Central African country with a population of approximately 20 million inhabitants (EDS, 2006) of which about 50% are youths. Cameroon is a multilingual, multicultural, and multilingual country (Tangwa, 1999), having English and French as its official languages, with French clearly predominating. The sections of Cameroon that had come under French administration (about 1% of the total

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Any other business (from the US)

- Office for Human Research Protections (OHRP)
- Federalwide Assurance (FWA) for the protection of human subjects
- Educational online programs
  - Collaborative Institutional Training Initiative
    “Over 5.5 million CITI Program courses have been completed since 2000”
  - Family Health International Research ethics training curriculum

remember… not exhaustive…

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Health Research Ethics in Africa over the last decade

Key players

Institutions/Associations

Initiatives-projects

Continental
Regional
Local
Training
Institutional development
Networking
Health Research Ethics in Africa over the last decade

Education – training & capacity building
Health Research Ethics in Africa over the last decade

Online courses
• Basic HRE,
• French version of the Basic HRE,
• Advanced HRE
• Good Clinical Practice (GCP)

Workshops
• Advanced Health Research Ethics (HRE) for investigators
• Harmonization of standard operating procedures for Ethics Review Committees (ERCs)
Health Research Ethics in Africa over the last decade

E-learning modules
(a web-based learning program and certification)
Module 1: Introduction to research
Module 2.1: Research Ethics evaluation
Module 3.1: Informed consent
Module 3.2: Good Clinical Practice
Module 3.3: HIV Vaccine Trial

National supplements
(local experts explain requirements in their country)
Africa: Burkina Faso, Cameroon, Cote d’Ivoire, Mali, Mozambique, Nigeria, Senegal, Tanzanie
Europe: Switzerland, Germany

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Education & Training in Research Ethics

• South African Research Ethics Initiative (SARETI)
  • Short courses/modular courses
  • Full master programs
  • SARETI African Health Research Ethics Symposium, Durban 2010
Health Research Ethics in Africa over the last decade

Education & Training in Research Ethics

Stellenbosch University Tygerberg Campus

• Advancing Research Ethics Training in Southern Africa (ARESA, which replaced IRENSA)
  • postgraduate Diploma/Masters level educational program
  • national network for Research Ethics Committee (REC) members

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Education & Training in Research Ethics

University of Maryland School of Medicine Middle East Research Ethics training Initiative (MERETI)

- Masters degree programs with specialization in Research Ethics
- Online certificate Program
- MERETI program in Research Ethics
- Workshops in the Middle East

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Health Research Ethics in Africa over the last decade

Training in Clinical Research and Ethics

• Kenya
• Lambarene, Gabon (+++)
• Malawi
• South Africa
• Tanzania,
Health Research Ethics in Africa over the last decade

Training in Bioethics
• MSc. in Bioethics
• Online training (CITI program)
• WAB Newsletters
• Discussion forum for members
Health Research Ethics in Africa over the last decade

Selected Publications about training and capacity building-1

**Composition, training needs and independence of ethics review committees across Africa: are the gate-keepers rising to the emerging challenges?**

African Malaria Network Trust, Dar es Salaam, Tanzania. anyika@amanet-trust.org


**Capacity building of ethics review committees across Africa based on the results of a comprehensive needs assessment survey.**

Ndika A, Kilama W, Tangwa GB, Chilengi R, Tindana P.
African Malaria Network Trust, Dar es Salaam 33207, Tanzania.

Health Research Ethics in Africa over the last decade

Selected Publications about training and capacity building-2

**Capacity building in health research ethics in Central Africa: key players, current situation and recommendations**

Odile Ouwe-Missi-Oukem-Boyer, Nchangwi Syntia Munung, Francine Ntoumi, Aceme Nyika, and Godfrey B. Tangue

1. Centre International de Référence Chantal Bly (CIRCB), Yaoundé, Cameroon
2. University of Ilesa, Ilesa, Cameroon
3. Fondation Congolaise pour la Recherche Médicale (FCRM), Faculty of Health Sciences, Maron, Angoua University, Brazzaville, Republic of Congo
4. Institute of Tropical Medicine/University of Tübingen, Germany
5. African Malana Network Trust (AMANET), Dar Es Salaam, Tanzania
6. Department of Philosophy, University of Yaoundé I, Cameroon
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Health Research Ethics in Africa over the last decade

Selected Publications about training and capacity building-3

Role of e-learning in teaching health research ethics and good clinical practice in Africa and beyond.
Chilengi R, Nyika A, Tangwa GB, Noor RA, Ramadhani SW, Bosomprah S, Kilama WL.
University of Oxford, UK.
PMID: 23206363 [PubMed - indexed for MEDLINE]
Health Research Ethics in Africa over the last decade

Institutional Development
Health Research Ethics in Africa over the last decade


Goal: Situation of legislation and organization of RECs
Projects funded (n=75 in 3 categories)

- Training (TRREE, ERECCA)
- Institutional development (NEC, CAMBIN, OCEAC) +++
- Networking (MARC)

Anglophone > Francophone > Lusophone
Health Research Ethics in Africa over the last decade

Support to the federal Ministry of health

• Adoption of the National Code of Health Research Ethics
Health Research Ethics in Africa over the last decade

Selected Publications related to institutional development - 1

**Policy Forum**

The Structure and Function of Research Ethics Committees in Africa: A Case Study

Nancy E. Kass*, Adnan All Hyder, Ademola Ajuwon, John Appiah-Poku, Nicola Barsdorf, Dya Eldin Elsayed, Mantoo Mokhachane, Bavon Mupenda, Paul Ndebele, Godwin Ndossi, Bornwell Sikateyo, Godfrey Tangwa, Paulina Tindana

**RESEARCH ARTICLE**

Identifying structures, processes, resources and needs of research ethics committees in Egypt

Hany Sleem1, Samer S El-Kamary2 and Henry J Silverman2

**Development of an Accessible Self-Assessment Tool for Research Ethics Committees in Developing Countries**

Hany Sleem
National Malaria and Tropical Medicine Research Institute, Egypt

Essam Askar
Abed Aboulhai
Cairo University, Egypt

Imad Al-Abrahymi
Jordan University, Jordan

Mohammed Al-Naief
King Saud University, Jeddah, Saudi Arabia

Hala Mansour Gheb

pragmatic aspects of human subjects protection, is based on international standards, is straightforward in its completion, and its items are relevant to the administrative processes that exist in many RECs in the developing world.

KEY WORDS: research ethics committees, developing countries, human subjects protection, self-assessment, accreditation, Institutional Review Board

Received: May 20, 2010; revised: July 5, 2010
Health Research Ethics in Africa over the last decade

Selected Publications related to institutional development -2

Special Section: Bioethics beyond Borders 2011
Sprinting Research and Spot Jogging Regulation: The State of Bioethics in Cameroon

GODFREY B. TANGWA and NCHANGWI SYNTIA MUNUNG

© Cambridge University Press 2011.
doi:10.1017/S0963171311000541

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FOCUS: DEVELOPING WORLD BIOETHICS

Ethique dans les pays en développement, éthique en développement

Dominique Sprumont*, Jérome Ateudjieu*

a Professeur en droit et directeur-adjoint de l’Institut de droit de la santé, Université de Neuchâtel
b MD, MPhil, enseignant au département des sciences biomédicales, Université de Dschang, Cameroun

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Health Research Ethics in Africa over the last decade

Networking
Health Research Ethics in Africa over the last decade

Continental – Institutions – Pan African Bioethics Initiative

Ambitious Strategic Plan

• Developing & maintaining a registry of existing ERCs
• Developing ethical review capacity
• Developing guidelines for ethics review
• Developing educational programs in ethics and GCP and integrating them into University curricula
• Contributing a concerted African voice to the international discussions on both ethics and science in health research
• Being an exchange platform for African researchers and ethicists

Pan African Bioethics Initiative

Various Conferences

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National chapters of PABIN

- ETBIN
- CAMBIN
- NIBIN ? TABIN ? SUBIN ? GABIN ?
Health Research Ethics in Africa over the last decade

Project
• Mapping African Research Ethics Review Capacity (MARC)

Symposium/Conference/Forum
• First African Conference for Administrators of Research Ethics Committees, Kasane, 2011
• Global Forum on Health Research, 2012

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Health Research Ethics in Africa over the last decade

Working groups
• Ethics, Law and Human Rights (ELH) working group of AAVP
• HIV AIDS Vaccines Ethics Group (HAVEG)
Health Research Ethics in Africa over the last decade

Forum

• 1st Rome, 2004
• 2nd Durban, 2005
• 3rd, Stockholm, 2006
• 4th, Ouagadougou, 2007
• 5th, Arusha, 2009
• 6th, Addis Ababa, 2011
• 7th...

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Networks of Excellence

- **WANETAM**
  - Senegal, Guinea, B-Faso
- **CANTAM**
  - Gabon, Cameroon, Rep of Congo
- **EACCR**
  - Kenya, Ethiopia, Tanzania
- **TESA**
  - South Africa, Botswana, Mozambique

*remember... not exhaustive...*
Health Research Ethics in Africa over the last decade

Selected Publications related to Networking

EDCTP regional networks of excellence: initial merits for planned clinical trials in Africa

George M Miro1*, Odile Ouwe Missi Oukem-Boyer2*, Ousmane Sarr3, Maerangis Rahmani4, Francine Ntoumi5*, Keeran Dheda1, Alexander Pym5, Souleymane Mboup4, Pontiano Kaleebu1 and On behalf of the NoEs’ programme

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Health Research Ethics debate
Health Research Ethics in Africa over the last decade

Selected Publications related to "HRE debate"

ETHICAL AND REGULATORY ISSUES SURROUNDING AFRICAN TRADITIONAL MEDICINE IN THE CONTEXT OF HIV/AIDS

ACEME NYIKA

View Point: Ethical dilemmas in malaria vector research in Africa: Making the difficult choice between mosquito, science and humans.

P. Ndebele¹, R. Musesengwa²
1. HJF-DAIDS, Bethesda, USA
2. Medical Research Council of Zimbabwe
Health Research Ethics in Africa over the last decade

Selected Publications related to « HRE debate »

Research article

Are students kidding with health research ethics? The case of HIV/AIDS research in Cameroon

Nchawgi Syntia Munung, Godfrey B Tangwa, Chi Primus Che, Laurent Vidal and Odile Ouwe-Missi-Oukem-Boyer

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Selected Publications related to « HRE debate »

ETHICS OF HUMAN GENETIC STUDIES IN SUB-SAHARAN AFRICA: THE CASE OF CAMEROON THROUGH A BIBLIOMETRIC ANALYSIS

AMBROISE WONKAM, MARCEL AZABJI KENFACK, WALINJOM F.T. MUNA AND ODILE OUWE-MISSI-OUKE-MOYER

COMMUNITY MEMBERS’ ENGAGEMENT WITH AND INVOLVEMENT IN GENOMIC RESEARCH: LESSONS TO LEARN FROM THE FIELD

MORENIKE O. FOLAYAN, KOLAWOLE S. OYEDEJI AND OLAJUNMI A. FATUSI
Plan of the presentation

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« Thinking ahead of course requires looking back, what have we learned in the past, which lessons have we not learned, what can contemporary bioethics show us for tomorrow ».

http://bioethicsrotterdam.com/
Looking back in the mirror: lessons learnt

EDCTP 4th Forum
in Ouagadougou,
2007
« Some achievements in term of awareness, capacity building, international debate, networking »

2013
« Significant/Strong achievements in term of awareness, capacity building, international debate, networking »
Looking back in the mirror: lessons learnt

EDCTP 4th Forum in Ouagadougou,

ISSUES RAISED

• Duplication of activities and lack of information
• Diversity of systems in the management and regulations of CT
• Scope of ERC versus NRA
• Inadequate and non sustainable funding of ERC activities
• Lack of sufficient expertises for evaluation and monitoring CT
• Inadequate legislation and regulation

Recommendations

• Improve coordination and information between stakeholders and joint activities
• Collect and dissemination of information on ongoing activities (training, networks, fundings, …)
• Harmonization needed but uniformisation to be avoided
• Continuation of support of networking
• Developing of harmonized SOP’s and regulations for ERC’s and NRA’s
• Clarification of functions and coordination needed between ERC’s and NRA’s
• Provide tools and guidelines in different languages
• Advocacy for sustainable fundings for ERC
• Strengthening capacities of NRA and ERC to be continued
Looking back in the mirror: lessons learnt

SIDCER: Strategic Initiative for Developing Capacity in Ethical Review

Credibility? Sustainability?
## Looking back in the mirror: lessons learnt

### What has positively increased

<table>
<thead>
<tr>
<th>Ethics’s awareness</th>
<th>Legislation governing HRE (very little legislation or it exists but not applicable or in progress or inconsistent)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Amount of training on (Basic and Advanced) Health Research Ethics (&amp; Good Clinical Practice)</td>
<td>Professionalization of training (integration of ethics programs into university curricula)</td>
</tr>
<tr>
<td>Number of African countries with formalized ethics committees (and with Research Ethics review capacity)</td>
<td>Professionalization of Research Ethics Committees / Administrators of RECs</td>
</tr>
<tr>
<td>Number of initiatives/projects dealing with Health Research Ethics</td>
<td>Landscape of Ethics Committees in Francophone Africa</td>
</tr>
<tr>
<td></td>
<td>Advocacy at the political level (combined with advocacy on clinical research and trials)</td>
</tr>
</tbody>
</table>
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Perspectives for Africa

- Research Ethics Committee “universal coverage”
  - Every country should have a REC because health research can be carried out everywhere
  - A country with no REC is put at risk of unethical research
  - No blank country should be tolerated
  - Let’s see how it works with the OCEAC example

- African Accreditation Body (FWA-like for Africa)

- Centralized registry of clinical trials and clinical research

- All Editors of Health medical journals: require to document Ethics approval AND Administrative authorization of research
H3Africa initiative: Human Heredity and Health in Africa

- Informed Consent: one or two steps?
- Community engagement
- Biobanking / Biorepository (Abuja, Stellenbosch)
- Cell lines: immortalization of cells of individuals for future use
- Education of Ethics Committees around these issues

Genetics, genomics, Molecular biology, phylogeny, population genetics bioinformatics etc...

2012-2016
Perspectives for Africa

Cameroon Bioethics Initiative (CAMBIN)

Policy makers
Investigators
RECs
NRAs
Community

Perspectives for Africa

High Level meeting

- Policy makers
- Investigators
- Community
- RECs
- NRAs

Training


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Perspectives for Africa

- Collaborative (and multidisciplinary) research/Externally sponsored research
  - Dual ethics approval
  - Fair negotiation (data sharing, material transfer agreement, authorship)
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What else EDCTP could do?

- Biennial Global Summit of National Bioethics Advisory Bodies
  - Fellowship for representatives of national ethics committees
- Advocacy for a greater participation of Africa in the revision of texts (DoH, CIOMS, UNESCO), including francophone (& lusophone) Africa
- EDCTP award for outstanding African ethicists (irrespective of age)?
Conclusion

TRREE:
- National supplement to be expended to all African Countries
- EDCTP/us to promote this training tool (requested for applicants)

SAREN:
- Book to be provided to African Ethics Committees
- To be translated in French and Portuguese
- EDCTP/us to promote this tool

MARC:
- To be expended to mapping of NRAs
- To be translated in French and Portuguese and Arabic
- Appropriation and update by RECs themselves

EDCTP/us to promote these tools

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THANK YOU SO MUCH!

Godfrey B. Tangwa
Nchangwi Syntia Munung
Francine Ntoumi
Dominique Sprumont
Mariana Kruger
Marie-Charlotte Bouesseau
Aceme Nyika
Tom Nyirenda
Pierre Blaise Matsiegui
Honoré Ntsiba
Carel IJsselmuiden
Doug Wassenaar
Boitumelo Moipolai
Mary Kasule
Azza Saleh Radwan
Evelyn Anane

remember… not exhaustive…

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