



ETHICS REVIEW GUIDELINES IN KENYA

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OUTLINE

- **What are ethical guidelines**
- **The origin of guidelines**
- **International guidelines**
- **Local guidelines**
- **Local issues**
- **conclusion**

A SIMPLE DEFINITION OF ETHICS

- **Ethics:- Some explanations:**

- **Oxford Dictionary- set of norms governing behavior**
- **Ethos- from Greek, meaning dwelling or habitat. This emphasizes a dynamic relation with others in the context of power, desire, knowledge (Spatial and temporal relations)**

UNDERSTANDING GUIDELINES

- **Guideline:- Principle or criterion guiding or directing an action. (Oxford Dictionary)**
- **Cf:- code ie, a set of rules on a particular subject**

ROLE OF GUIDELINES

- **Contribute to quality and consistency in ethical review and policy**
- **Express core commitments to common values which must be maintained**
- **Set minimum standards for the conduct of research**

WHY HAVE GUIDELINES?

- **Guidelines or codes are critical for professions;**
 - **To enforce shared values**
 - **Express common commitments of the members or practitioners**

ORIGIN OF GUIDELINES

- **Codes of conduct eg; Hammurabi (circa 1750 BC)**
- **Professional Codes eg Hippocratic oath.- arose when practitioners in medicine adopted conduct based on common values**
- **Historical Customs eg Justinian or what later became Roman Law**

EVOLUTION OF MODERN ETHICS GUIDELINES

- **Current guidelines are highly sophisticated, developed from**
 - **Nuremberg code, 1945; post ww2 trials of Nazi physicians**
 - **Received widespread acclaim**
 - **Determined the basis of modern bioethics**
 - **Rescued medical experimentation from the moral abyss of Nazi leadership**

NATURE OF GUIDELINES

- Non legal documents never the less respected and observed by practitioners and agencies.
- Have a purpose of improving on prevailing practice

INTERNATIONAL GUIDELINES

- **WMA's Declaration of Helsinki (1964)**
- **CIOMS' Int'l Ethical Guidelines for Biom. Research (1982)**
- **WHO's Operational Guidelines for EC's that review Biom. research (2000)**

OTHER GUIDELINES

- **Code of Federal regulations (CFR)
Public Health service Act, USA**
- **ICH (EU,USA, Japan) 1997**
- **Universal Declaration on Bioethics and
Human Rights UNESCO-2005**
- **Other UN conventions**

THE DECLARATION OF HELSINKI

● The Declaration of Helsinki

- Developed to fill gaps of the 1947 code
- Required that research protocols be scrutinized before start by independent committees
- Periodically reviewed,-'75,83,89,96,00,08

CIOMS

- **Council for International organizations of Medical Sciences (CIOMS)-1982**
 - Reviewed '91, '93, '02 (public health, epidemiology studies)
 - Addresses mostly govt. & commercial agency sponsored research

WHO GUIDELINES

- **WHO Standards and Operational Guidelines for Ethics Review of Health-Related Research with Human Participants (2011)**
 - **To contribute to the development of quality and consistency in ethical review of Biom. research**

USA 45 CFR46

- **Code of Federal regulations (CFR)
Public Health service Act, USA**
 - **Used in the US and abroad where sponsored research takes place**
 - **Specific composition and functioning of Ecs**
 - **Has the force of law in the US**

ICH GUIDELINES

- **International Conference on Harmonization (EU,USA, Japan with Australia, Canada, Nordic states and WHO as observers) 1997**
 - **Issued guidelines on GCP**
 - **Incorporates requirements for review in drug trials and**
 - **Adopted by drug licensing agencies**

AN OBSERVATION

- **Guidelines have moved from statements of principles in 1947 to partly legally enforceable recent documents like the ICH**
 - **Because guidelines alone do not ensure ethical conduct**

GLOBAL STREAMLINING EFFORT

- **Universal Declaration on Bioethics and human rights, UNESCO-2005**
 - **Biggest attempt to develop world guidelines applicable everywhere**
 - **Still in the process of adoption in many countries**
 - **Domestication processes ongoing in Kenya**

FOCUS OF LOCAL GUIDELINES

- **Achievement of a balance in values between the public and the research system**
- **Guide the development of appropriate legal instruments for ethics and regulation of scientific activities and**
- **Establishment a suitable regulatory environment for research activities**

FOCUS OF LOCAL GUIDELINES CONT'D

- **Spearhead the development of good practices through standardized authorization procedures**
- **Promote ethics education at all levels of the education system**
- **Raise awareness about ethics**

FOCUS OF LOCAL GUIDELINES CONT'D

- **Develop relevant ethics disciplines through research and public discourse i.e. ethics of the entire STI;- bioethics, environmental ethics, information society ethics, energy ethics and others.**
- **Establish organs for:**
 - **ethics review and surveillance**
 - **Information and documentation observatory for analysis and promotion**

3 TYPES OF ETHICS GUIDELINES

- General
- Specific
- Regulatory

GENERAL GUIDELINES

- **Guidelines for Ethical Conduct of Biomedical Research Involving human Participants in Kenya, (2004) *revised 2012***
 - Defines what is ethical research
 - Guides institutions in preparing Standard Operating Procedures
 - Guides on specific local and cultural issues

SPECIFIC GUIDELINES

- **Guidelines for the development of HIV vaccines,**
- **Guidelines for Clinical Trials,**
- **Guidelines for Reproductive Health research, etc**

HIV Vaccine guidelines as an example

- Facilitate development of HIV vaccines in Kenya
- Explain all about research regulation to those interested in vaccine research
- Provide an outline of national policy on HIV vaccines
- Explain the indicators used for monitoring vaccine studies
- List institutions involved in regulation of various aspects of vaccine research

REGULATORY GUIDELINES

- **Accreditation Guidelines-2011**
 - **Outlines the roles of the different IERCs**
 - **Defines the formal review system**
 - **Guides institutions in establishing IERCs and SOPs**

SOME LOCAL BIOETHICS ISSUES

- **Conflict of social values and research requirements**
 - **New ideas and ways of conceptualizing the environment**
 - **Exploitation of natural resources**
 - **Expansion of technical possibilities**
 - **Pollution of natural purity**
 - **Unintended effects and their mitigation**

MORE LOCAL BIOETHICS ISSUES

- **How to Resolve local issues**
 - **Cultural values (customs, ideas etc of a particular group)**
 - **Conflict in prioritization and implementation in S&T**

DILEMMAS IN LOCAL BIOETHICAL ISSUES

- **Conflict of social values and research requirements**
 - **New ideas and ways of conceptualizing the environment**
 - **Exploitation of natural resources**
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DILEMMAS CONT'D

- **How to Resolve local issues**
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 - **Conflict in prioritization and implementation in S&T**

EMERGING ISSUES

- **Emerging technologies in the life sciences (mapping of the human genome, xenotransplantation, etc)**
- **Genetically modified Organisms; release into the environment, commercial use and acquisition of source material from nature**

EMERGING ISSUES

- **Social utility of research; sharing of knowledge & other outcomes of collaborative studies, use of indigenous knowledge and Collaboration with foreign countries**
- **Application of traditional knowledge in the modern health care industry**
- **Environmental problems; dumping of toxic waste, pollution etc**

Biomedical Research in Kenya

- **Started in East Africa in the 1940s**
- **Focused on opening up the country for immigrant settlers**
- **At independence, refocused towards local infectious diseases**
- **Currently a mixture of emerging lifestyle diseases alongside infections; waterborne, airborne, insect borne**

Research Authorization

- **Levels of authority**
 - **Cabinet**
 - **MHEST**
 - **NCST**

Function of the NCST in Research Authorization

- **Review and grant of authority**
- **Development of policy**
- **Development of guidelines**
- **Accreditation of review committees**

Regulatory Challenges

- **Legal shortfalls**
 - **Inadequacy of the S&T Act and other supporting statutes**
- **inadequate monitoring**
- **Lack of local studies in bioethics**

CONCLUSION

- **Reinforce the legal environment**
 - Review of the S&T Act
- **Strengthen the NBC**
 - Enact new legislation
- **Promote the teaching of bioethics at all levels of the education system; tertiary, secondary, primary and general public awareness.**

THANK YOU

- Always do right; this will gratify some people and astonish the rest
 - *Mark Twain, 1835-1910*