

Inter-phase between health research ethics, law and human rights

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outline

- Inter- phase between health research ethics, law and human rights
- Health research Ethics
- Human rights
- Recommendations to Researchers

Inter-phase between

health research ethics, law and human rights

(The big three) what is in common:

- International codes developed to guide and to provide an international points of reference in all three fields, adopted, ratified by countries for application
- All in operation following international accepted principles, at country level
- All focus on protecting the human research participant safety, safeguard human dignity, and fundamental rights and welfare

Inter-phase, Codes

Guidance documents

Nuremberg Code

was formulated by a Military Tribunal made up of US judges at the termination of an unprecedented trial – the so-called “Doctors’ Trial” (also known as the “Medical Case”) of Nazi physicians who had performed wholly reprehensible medical experiments on concentration camp prisoners during World War II. No consent was sought or obtained and thus it is not surprising that the Code places such emphasis on the voluntary consent of subjects of medical experimentation

Violations of ethical principles, human rights, and against the law that guided medical practice. Hippocratic oath

Declaration of Helsinki, 1964,...

- the “historic Nuremberg Code of 1947, which the 1964 Declaration of Helsinki was developed to amplify and explicate outside the Code’s conditioning environment of outrageous crimes against humanity, states as its first principle that: The voluntary consent of the human subject is absolutely essential...
- October 2000, the sixth version of the WMA’s Declaration of Helsinki (originally adopted in 1964),
- “the most widely accepted guidance worldwide on medical research involving human subjects.” It has also been described as “the cornerstone of biomedical research for the last 30 years

WMA: Declaration of Helsinki,

www.wma.net

World Medical Association Declaration of Helsinki

Serves as a statement of ethical principles to provide guidance to physicians and others involved in medical research

- with human beings and
- Identifiable human material or
- Identifiable data

CIOMS, Geneva, Switzerland, 2002

www.cioms.ch



- The Council for International Organizations of Medical Sciences (CIOMS) (International Ethical guidelines for biomedical research involving human subjects) , and WHO
- Designed to be of use to countries in defining national policies on the ethics of biomedical research involving human participants , applying ethical standards in local circumstances, and establishing or improving ethical review mechanisms
 - A particular aim of CIOMS is to reflect the conditions and needs of low-resource countries and implications for transnational or multinational research which they may be partners

CIOMS, 2009

- The Council for International Organizations of Medical Sciences (CIOMS): International Ethical guidelines for Epidemiological studies)
- Provides ethical guidance for epidemiologists, as well as those who sponsor, review, or participate in epidemiological studies.
- On identifying and responding to ethical issues that are raised by the process of producing this knowledge.
- Developed in collaboration with WHO

Other codes by UNESCO

UNESCO is actively engaged in bioethics in a range of capacities including the development of Universal declarations on bioethics and human rights such as:

- UNESCO Universal declaration on human genome and human rights. Paris, France , 1997
- UNESCO Universal declaration on bioethics and human rights. Paris, France , 2005
- International Declaration on Human Genetic Data, United Nations educational scientific and cultural organization, 2003
- UNESCO Global ethics observatory
 - Provides a number of ethical related databases

International Declaration on Human Genetic Data, United Nations educational scientific and cultural organization, 2003

- In the rapidly developing field of genetic research, many people fear that human genetic data will be used for purposes contrary to human rights and freedom
- Together with Universal declaration on human genome and human rights. Paris, France , 1997
- Universal declaration on bioethics and human rights. Paris, France , 2005
- The guidelines provide important point of reference in bioethics, bearing in mind the protection of human rights and fundamental freedoms and stressing that all medical data should be treated with same high standards of confidentiality

UNESCO Universal declaration on human genome and human rights. Paris, France , 1997

- First universal instrument in the field of bioethics
- It aims to establish a balance between safeguarding respect for human rights and fundamental freedoms and ensuring freedoms of research.
- It serves as a document committing states to take appropriate measures to promote these principles
- Awareness of the need of ethics in science and technology

Health research Ethics

- Research ethics is the interaction between the researchers and research participants
- Research ethics is defined to be the ethics of
 - ❖ Planning
 - ❖ Conduct
 - ❖ and reporting of research

Health research ethics

- It is clear that research ethics should include:

Protection of humans and animals

However:

not all researchers use humans or animals

Not all ethical dimensions of research is
confined solely to protections of research
participants including animals

There are other ethical challenges rooted in
research

Health research ethics

There are other ethical challenges rooted in research:

- Collection, use, and interpretation of research data
- Methods of reporting and reviewing research plans or findings
- Relationships among researchers with one another
- Relationships between researchers and those that will be affected by their research
- Means of responding to misunderstandings, disputes, or misconduct
- Options for promoting ethical conduct in research

Human rights

- Are the basic rights and freedoms to which all humans are entitled
 - Examples:
 - Civil and Political rights: the right to life and liberty, freedom of expression, and equality before the law
 - Social, cultural and economic rights:
right to participate in culture, right to food, right to work, and right to education
- On December 1948, the General assembly of UN adopted and proclaimed the Universal Declaration of Human rights

Universal Declaration of Human rights

UDHR

- A common standard of achievement for all peoples and all nations
- Every individual and every organ of the society should keep this declaration constantly in mind, shall strive by teaching and education to promote respect for these rights and freedoms and by progressive measures, national and international, to secure their universal and effective recognition and observance

Characteristics of hr

- Universal
- Guaranteed by international standards,
- legally protected,
- focus on the dignity of the human being and
- cannot be waived or taken away.

Research ethics and human rights

- They have issues in common
- Principles of research ethics puts issues of protection of humans, respecting the individual recognizing
 - their dues
 - rights
 - Respect as persons
 - Wishes

Violations in research

If one

- Will violate ethics of conducting research
- Violate laws regulating research (-fine, stopping)
- Human rights issues

e.g. Prisoners to be engaged in research

A researcher should ensure that there is social value for that study to be conducted among the prisoners, the principles of autonomy, justice, beneficence will be upheld

Types of research with all three implications

- Research on domestic violence
- Research on commercial sex workers, msm
- Sexual violence in emergencies
- Illicit drug users
- People living in poverty

Research on these populations is highly unlikely to alter their situation of vulnerability, *exploitation? (Loff B, 2011)*

Recommendations

To all researchers in Tanzania and outside
Research should observe the three

- Country law, to be guided and regulated, by specific institutions legislations
- Conduct research following ethics regulations and guidelines set forth
- Put emphasis on human rights

Way forward

- Research should be conducted by observing all three
- All three together forms research ethics
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References

- Several websites
- <http://www.ohchr.org/EN/UDHR>
- WHO casebook on ethical issues in international health research
- Loff B (2011) Improving human rights for better ethics in research