

HEALTH RESEARCH ETHICS AND LAW IN ETHIOPIA BY

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I. INTRODUCTION

Health research that uses human being as a subject has benefits and risks to the society. It is beneficial to the society in that it will enable the development of new technology that will address health problems and ensures good health. One writer explains " good health is the cornerstone of progress, a multiplier of society's human resources, and indeed, the primary objective of development"¹. It also evolves a risk in that the human participant of research may be exposed to undesirable consequences that may violate societal values such as respect of human rights.

In order to strike a balance between these two conflicting societal interests, countries have developed laws and ethics to promote health research while minimizing undesirable consequences.

The aim of this paper is not to discuss legal and ethical issues involved in health research as well as the law and ethical code of conduct developed to govern the relationship between the researcher and the human participant of the research but to give an overview of the preliminary finding of the law and ethics in Ethiopia that deals with the subject on question.

II. Definition

Health or medical research is defined by law there by making it a legal concept. An example of laws that defines health or medical is that of the Medical research act issued in Helsinki on 9 April 1999. This Act defines "Medical research as research involving intervention in the integrity of a person, human embryo or human fetus for the purpose of increasing knowledge of the causes, symptoms, diagnosis, treatment and prevention of diseases or the nature of disease in general".²

There is no law that defines the concept of health research in Ethiopia. The draft national health research ethics review guideline has no clear definition of the concept. However, the Preamble of the draft guideline states that "health research involving human participants be it biomedical, clinical or epidemiological (survey, surveillance etc..) should obtain ethics approval prior to their commencement". Based on this, health research that will be subjected to ethical review may be defined as a research involving

¹ Chen LC & Berlinguer G. Health equity in a globalizing world. in : Evans T , Whitehead M, Diderichsen F, Bhuiya A, Wirth M, editors. *Challenging inequities in health: from ethics to action*, Newyork: Oxford University press, 2001.p.35-44, quoted by Bhutta Za, ethics in international health research: a perspective from the developing world, p.114

² Statute No. 488/1999 Section 2

human participants. This definition is narrower than the meaning given to medical research by the Helsinki Medical research Act above. It is not clear whether it:

- a) includes research that use human embryo or fetus, and
- b) extends to research using personal information

III. Health research ethics

Health research is governed by ethical codes of conduct. Such a code has been used in Ethiopia since 1995. The more elaborated code of conduct, however, is drafted in 2004. In this section attempt will be made to high light the objectives and major provisions of the draft code of conduct in comparison with the code of conduct of New Zealand to see how comprehensive the draft is.

3.1 Objectives of the ethics review guideline

The general objectives of the guideline are to:

- a) safeguard the study participants from any harm related research , and
- b) assure that individual benefit and civil rights are being respected. These objectives are complemented by Specific objectives which include the following:
 - i. to safe guard research participants from any risk,
 - ii. to evaluate ongoing and post research implications on the participants and the community at large, and
 - iii. to make sure that research participants are participating in the study with written informed consent.

These objectives are similar to those that have been provided in similar instruments elsewhere. However, its scope is narrower than the objectives of similar guidelines. This may be illustrated by looking at the ethical guideline of New Zealand. The objectives of the guideline, amongst others, include:

- a) safeguarding the rights and interests of participants in research and innovative practice, and consumers of health,
- b) fostering awareness of ethical principles and practice with in service providers, researchers and the wider community,
- c) promoting excellence in research for the well being of society,
- d) giving due consideration to both local and national community views and perspectives in ethical review³.

3.2. Basis for the guideline

³ see New Zealand operational standards for ethics committee, section 8.

Ethical guidelines are developed based on relevant laws. They elaborate principles and rules enshrined in the laws⁴. The draft guideline indicates that it is based on the following instruments:

- a) The Ethiopian Science and Technology Commission mandate,
- b) The 1994 health S&T policy, and
- c) Internationally recognized principles of human rights including:
 - i. the 1942 Nuremberg code of human rights,
 - ii. the 2000 world medical associations declaration of Helsinki
Council for international organization of Medical Sciences (CIOMS)
2001
international guidelines for Biomedical Research involving human
subject
 - iii. 1995 the WHO and ICH (International Conference on Harmonization)
guidelines for good clinical practice, and
 - iv. The 1979 Belmont Report.

The above instruments that are cited as a basis are legal and non-legal instruments. The later may serve very little for issues of legal nature dealt with the guideline. Furthermore, there is nothing that clearly specifies the relevant provision of the legal instrument referred to as a basis.

In addition to the above, the guideline has failed to refer to some of the laws that may provide a sound legal basis to some of the issues addressed in the draft document. In this regard, the following may be considered and used as legal basis to the draft guideline:

- a) The Constitution of the Federal Republic of Ethiopia,
- b) Relevant International conventions to which Ethiopia is a party, and
- c) Relevant laws

The constitution provides that “Every *person has the inviolable right to life, the security of person and liberty*”⁵. It also imposes an obligation on public officials to respect the inviolable right of correspondence.⁶ These provisions give a constitutional basis to some of the basic issues dealt with the ethics guideline such as respect to the life and body of the research participant and confidentiality.

⁴ See for example, the list of laws used as a basis

⁵ Article 14 Rights of life, the security of person and liability

⁶ Article 26 Right of privacy

Relevant international treaties such as those related to protection of human rights, the rights of the child and the like to which Ethiopia is a party may be referred to as a legal basis to the guideline. Furthermore, relevant laws such as the civil and criminal codes may serve as a basis for the guideline.

In spite of the above the legal basis, however, is not comprehensive and adequate. There is a legal lacuna in Ethiopia. There is no law that specifically and comprehensively deals with health research. As a result a number of the issues addressed by the guideline lack a legal basis. It will thus be difficult to enforce or seek the enforcement of the ethical requirements.

3.3. Principles and standards of ethical review

The ethical Principles enshrined in the draft guideline includes:

- i) informed consent
- ii) confidentiality, and
- iii) risks and benefits.

These principles are the same as those provided in similar foreign guidelines. However, the principles are not detailed. For example, the draft code of conduct does not define the basic elements to establish informed consent and deal with exceptional circumstances. This may give rise to disputes and cause difficulty in establishing whether there was informed consent or not.

To deal with such problems foreign guidelines elaborate what constitutes informed consent. The New Zealand ethical guideline, for example, states that:

“The elements of informed consent include but are not limited to the following basic criteria:

- a) the participants' legal competence and ability to understand,*
- b) information about the proposed research being comprehensively, properly and appropriately given, including any likely outcomes of participation in the research.*
- c) the participants' consent must be voluntary and not influenced by financial reward or by duress in any manner, nor must dependent or vulnerable groups be used.*
- d) participants must be able to withdraw from the investigation at any time without waiver of any rights and without giving reasons.*
- e) in the case of those who are unable to give their own consent, for example, the mentally incapacitated or the unconscious patient, proxy consent should be sought from a person with appropriate legal authority.*
- f) in the case of research participants who are children the signature of the parent or guardian should be obtained in addition to the child's consent.”⁷*

⁷ Health research council of New Zealand, guidelines on ethics and research, 2002

The draft guideline does not also include essential principles recognized elsewhere that include the following:

- a) Validity of research proposal,
- b) Minimization of harm,
- c) Justice,
- d) Cultural and social responsibility, and
- e) Compensation for research participant.⁸

In other countries, distinction is made between National and Operational standards⁹. Likewise, the draft guideline consists of standards that may be classified as such. Nevertheless, the standards are neither comprehensive nor detailed. One may argue that a separate instrument may address this. However, the major national and operational standards should form part of the guideline.

IV) Health research law in Ethiopia

4.1. General

The laws that deal with health research may be classified in to two as:

- A) Research law, and
- B) Laws governing Liability.

Like other countries, there are laws that fall in each of the categories in Ethiopia. Attempt will be made in the sections below to examine the relevant laws and see how adequate they are.

4.2. Research related laws

There are two pieces of proclamations that deal with health research. These are:

- a) Drug Administration and control proclamation No. 176/1999, and
- b) Ethiopian Health and Nutrition Research Institute establishment council of Ministers Regulation No.4/1996.

The drug administration and control proclamation provides that the authority has the power to issue license for conducting clinical trial; monitor the process; evaluate the results and authorize the use of the result in such a way that it benefits the country.¹⁰ It also defines the conditions under which clinical trial may be conducted.

Article 21 provides that:

⁸ See operational standard for Ethics committees, New Zealand.

⁹ see ibid

¹⁰ Article 6 (11)-

1. *A clinical trial shall be conducted only on a human being who has given his consent in writing and on domestic animals with the consent of the owner and on wild and sea animals when permission of the Government is obtained, and all of which are subject to the authorization of the Authority in accordance with the regulations issued for the implementation of this proclamation.*
2. *Notwithstanding sub article (1) of this article, a clinical trial shall not be conducted on nursing and pregnant women, on children under the age of 18, on prisoners, on insane persons, and on persons dependent on the investigator or on the institution.*
3. *No clinical trial result, which has not been evaluated and approved by the Authority, shall be published or disseminated in any way.*
4. *Any identifying data about the trial subjects shall be kept confidential .*

The consequence of failure to comply with the above requirement will result in a criminal liability. The offender will be punished with imprisonment of not exceeding two years and with a fine of not exceeding ten thousand Birr unless a stronger penalty is provided with the Ethiopian penal code.¹¹ Furthermore the property used to or derived from the commission of the offence will be confiscated.¹²

In view of the provisions of this proclamation, the mandate given to the national Ethics review committee under 4.2.1 (i) of the draft guideline needs to be reconsidered.

It appears that there is an apparent conflict between the draft guideline and the proclamation. The conflict may be easily resolved, as a non-legal instrument may not affect the power given by law. However, for purposes of clarity, the provision of the draft guideline should be rewritten in the course of the further refinement of the instrument.

The Ethiopian Health and Nutrition Research Institute establishment council of Ministers Regulation No.4/1996 defines the objectives, power and duties of the institute. The Institute has the following two major objectives:

- a) to conduct research on the causes and spread of diseases, nutrition, traditional medicines and medical practices and modern drugs and thereby support the activities for the improvement of health in the country.
- b) to contribute to the development of health science and technology.¹³

To realize these objectives, the Institute is vested with powers and duties that will enable it to undertake health research render professional consultancy and laboratory services.

There is no provision that deals with ethical issues. The regulation cannot thus be taken as a research law that may serve as a legal basis for ethical guideline.

4.2.2. Laws governing liability

Health research may result in harm, which may entail civil and criminal liability.

The civil liability may be contractual or extra contractual depending on the relationship of the parties concerned.

¹¹ Article 33.

¹² Article 35

¹³ See article 4 of the regulations

Contractual liability may be based on the relevant provisions of the 1960 civil code of Ethiopia. These include:

- a) Book IV, Title XII general provisions of contract, and
- b) Chapter Article 2639-2652 medical or hospital contracts.

The non-contractual liability may be based on fault or provisions of vicarious liability. Fault may be established using provisions such as article 2031. There will be vicarious liability when an employee researcher of an institute causes harm. In such a case, the institute may be held vicariously liable within the meaning of the relevant provisions of the civil code.

The person who inflicts harm may be held criminally liable under the 1957 penal code of Ethiopia. In such a situation, the researcher may have the following defenses:

- a) Where the harm is inflicted in the exercise of a professional duty, he may invoke article 65 of the penal code,¹⁴ and
- b) In case of damage caused from breaches of professional secrecy, one may invoke that disclosure of information is authorized.¹⁵

V. Recommendations and conclusion

5.1 Conclusion

The draft guideline is a pioneer work not only in Ethiopia but also in Africa. The achievement made thus far is commendable. However, the draft guideline:

- 1) is narrower in scope in that it does not include research that may be made using personal health information, fetus, part of the body etc.,
- 2) does not consist of relevant principles recognized elsewhere and the recognition of which is deemed relevant to Ethiopia,

¹⁴ Article 65 provides that Acts done in the exercise of a professional duty is not liable to punishment when it is in accordance with the accepted practice of the profession and the doer does not commit any grave professional fault. Nothing in this article shall affect civil liability.

¹⁵ Article 408 provides that
Any disclosure made especially in court or on the occasion of a dispute relating to insurance or compensation, shall not be punishable:
(a) where it is made with the express consent of the person interested in keeping the secret;
(b) where, at the suggestion or request of the possessor of the secret, the competent higher professional or supervisory body has given its written permission for disclosure;
(c) where it is made following an express and reasoned decision of court of justice in a specific case;
(d) where special provisions of the law, by a court of justice or by the competent authority, the possessor of the secret can not invoke his professional obligation to maintain secrecy.

- 3) does not provide a possibility of review of decision of the ethical committee unlike the experience of other countries¹⁶.
- 4) fails to elaborate some of its principles such as informed consent as made in similar instruments elsewhere.¹⁷
- 5) deal with issues that should be left for the law or that are not in line with existing laws , which include the following:
 - a) it consists of issues that should be dealt with legislation. These include the establishment and definition of the powers and duties of ethical review committees and the national Health research Council,. fixing of Fees etc
 - b) it deals with issues that conflict with existing laws. An example is the issue of ethical clearance of health research that involves clinical trial. The Drug Administration and Control Authority is entrusted with the power to issue a license for clinical trial.

Unlike other countries, there is no specific law that exclusively governs health research in Ethiopia. Indeed, there are provisions that deal with substantive issues that relate to a research involving human beings¹⁸. However, these provisions deal with only one aspect or form of health research, which is clinical trial.

The laws that deal with liabilities arising from damage caused as a result of health research are relatively comprehensive. This may, however, have an adverse effect in the absence of a health research law. It may discourage or negatively affect health research. Researchers may refrain from undertaking health research for fear of liability even in situations where the act or harm is justified. There is thus a need to enact a health research law to encourage research and to strike a balance between the two sets of laws- research and liability to cater for the need and address the concerns of the society.

5.2. Recommendations

Based on the aforementioned discussion the writer of this paper would like to make the following proposals:

- 1) There is a need to further elaborate the guideline based on experiences elsewhere and in line with the specific needs and conditions of the country,
- 2) There is a need to provide a sound and comprehensive legal basis for the ethical review system by enacting a comprehensive health research law.
- 3) There is a need to review the provisions governing the remedies for civil and criminal liability in the existing legislation with a view to determine that they are not lopsided in favor of the victim and to ensure that the interest of society to promote health research is taken on board.
- 4) The enactment of a law and the issuance of a well-developed code of conduct is not an end on its own. What is important is the effective implementation of the instruments and meeting the intended objectives. To this end, complementary

¹⁶ see for instance , the New Zealand Guidelines on Ethics in Health Research, section 2.4.

¹⁷ In this regard the New Zealand guideline , may be cited as example. it defines the basic criteria that should be met as well as the situation where written informed consent may not be required.

¹⁸ se the Drug Administration and Control proclamation.

measures such as introduction of a course on health research ethics and law in to the curriculum of medical faculties should be taken.

VI. Reference materials

1. National Research Institute of Health Establishment Proclamation No. 26/1986
2. Ethiopian Health and Nutrition Research Institute Establishment Council of Ministers Regulations No.4/1996.
3. Drug Administration and Control Proclamation No.176/1999.
4. Ethiopian Science and Technology Commission Establishment Proclamation, Proclamation No.7/1995.
5. The Constitution of the Federal Democratic Republic of Ethiopia, Proclamation No./1994
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10. ESTC Health department, Draft National Health Research Ethics Review Guidelines, 2004.
11. Health research Council of New Zealand, Guidelines on Ethics in Health Research, October 2002
Ministry of Health, New Zealand, Operational Standard for Ethics Committees, march 2002