

## Research Ethics

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Historically medical ethics may be traced to guidelines for the physicians such as the Hippocrates oath. In the early modern era to the Muslim physician such as Ishaq bin Al Rahawj who is the author of Conduct of a Physician which is the first book dedicated to medical ethics. Jewish thinkers such as Maimonides Roman Catholic scholastic thinkers such as Thomas Aquinas all have contributed towards medical ethics. These intellectual traditions continue in Catholic, Islamic and Jewish medical ethics. Later in 18th and 19th century medical ethics emerges as more self-conscious discourse. A British doctor Thomas Percival wrote about medical jurisprudence and also coined the phrase medical ethics. [1,2] In 1847 the American Medical Association developed the first code of ethics which was largely based on the work of the Percival [2]. The secular field borrowed largely from the Catholic medical ethics. It was in the 20th century that a much more liberal approach was taken by the liberal protestants. By 1960 and 1970 much of medical ethics went through dramatic shift and reconfigured itself into bioethics [3].

The need for this arose when it was observed that some medical practitioners withheld treatment from their patients so that their research study could be completed. Although penicillin was readily available some physicians withheld this to see the third and fourth stage of syphilis. This was an unethical practice and their licenses were later cancelled. After they underwent the famous Doctors Trial of Tuskegee Syphilis Study [4]. The defense given was that if treated their research work was effected. Thus the declaration of Helsinki came into being. Which states that at no stage will the patient or research subject be put in any undue harm for the benefit of research. The 18th World Medical Assembly in Helsinki in 1964 developed the famous declaration of Helsinki which thus came into being and has been amended regularly. Amendments were made in 1975, 1983, and 1989. It has also been updated in 1996 [5]. A fresh

clause has been added by The World Medical Association at its General Assembly in 2002 [6]. In the 55th World Medical Association 2004, modifications on Paragraph 30 were made and further modifications have been made in Seoul in October 2008 [7].

### The basic values of Medical Ethics are;

- Beneficence
- Non Malficence
- Autonomy i.e. the patient has the right to refuse or choose the treatment
- Justice due to scarcity of health resources: the decisions as to who gets what treatment.
- Dignity the patient and the person treating have the right to dignity
- Truth fullness and honesty. The importance of giving the correct information to the patients and subjects while carrying out research work.

These six basic values do not give answers of how to handle a particular situation but provide a framework for further understanding the conflicts that may arise.

In the United Kingdom General Medical Council provides clear overall modern guidance in the form of its Good Medical Practice [8].

The basic aim of the declaration are to highlight the responsibilities of the researchers about the patients or the human subjects they are dealing with.

The declaration binds the physician that health of the patient is top priority and the international code of ethics declares that the physician will act only on the interest of the patient in providing medical care. At no time should the interest of the medical researcher supersede that of the patient. In the third world countries more responsibility lies with the medical researchers. Here the public is uneducated and less aware of their rights.

Institutional ethical committees may not be present. Subjects may not be in position to comprehend the doctors view point. Fair subject selection may not be present. In consent the patient

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may be unwilling to give his signature as he may think that signature is being taken for some other purpose. It is not the responsibility of the subject to safeguard himself from harm. As stated in the declaration of Helsinki paragraph 16 the responsibility of the protection of the research subject must always rest with the physician or health care professionals and never the research subjects. Even though consent has been given.[9]

In Pakistan however the research ethics are in its infancy. Hence strict adherence to the paragraphs stated in the declaration of Helsinki can be the mainstay. In most research proposals and dissertations this ethical part of the research work regarding taking consent from the patients is incomplete. Hence clearance from the ethical review board cannot be obtained. The significant points of informed consent are highlighted here.

#### **Guidelines for drafting an informed consent form:**

All studies involving human subjects should have a properly drafted consent form. No study should be done on humans without obtaining informed consent from them.

Consent may be written or verbal. In verbal other person must also be made a witness.

In children the consent has to be taken from the parents or guardians. However the child should also be informed and his consent tried to be taken.

In case of handicapped or mental subjects consent must be taken from their guardians or relatives. In communities the leader should be informed and consent taken from him. In institutions it may also be the head of the institute in which research work has to be conducted.

The consent form should be in English with translation in Urdu or any other local language so that the subject is capable of comprehending it. The language used should be easy without any technical jargon.

#### **The elements of informed consent Are**

- Essential Information for Consent
- Comprehension of Consent Information
- Competency to give consent
- Voluntary Consent.

#### **INFORMED CONSENT MUST CONTAIN THIS ESSENTIAL INFORMATION**

(according to the declaration of Helsinki 2008 para 24)

- Introduction of the study
- Objectives of the study
- The methodology that will be used
- Sources of funding
- Any possible conflict of interest
- Institutional affiliation of the researcher
- The risks and benefits of the study
- Assure anonymity and confidentiality offer to answer question Option to withdraw must be mentioned. Informed consent in the form of signature to be obtained. This is according to paragraph 24 of the declaration of Helsinki presented in the World Medical Association General Assembly October 2008.

Hence a routine consent form used for qualitative research study will be like the one given below. An Urdu translation or any other local language of this form is also necessary. The language used should be kept as simple as possible so that the subject is able to comprehend it.

#### **CONFIDENTIAL**

#### **CONSENT FORM**

#### **TITLE OF STUDY:**

#### **PRINCIPAL INVESTIGATOR:**

#### **INSTITUTION:**

#### **INTRODUCTION:**

#### **OBJECTIVES OF THE STUDY**

#### **PROCEDURE/METHODOLOGY**

#### **POSSIBLE RESULTS AND BENEFITS: RIGHT OF REUSAL TO PARTICIPATE AND WITHDRAWAL**

You are free to choose to participate in the study. You may refuse to participate without any loss of benefit which you are entitled to. You will receive the best of care available irrespective of your participation in the study. You may withdrawal anytime from the study. If you have any further questions or any adverse effects please Contact Doctor.

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## SOURCE OF FUNDING

### ANY CONFLICT OF INTEREST

### AUTHORIZATION

I have read and understand this consent form, and I volunteer to participate in this research study. I understand that I will receive a copy of this form. I voluntarily choose to participate, but I understand that my consent does not take away any legal rights in the case of negligence or other legal fault of anyone who is involved in this study. I further understand that nothing in this consent form is intended to replace any applicable Federal, state, or local laws.

**Participant's Name.**

**Date:**

**Participant's Signature or thumb impression.**

**Date:**

**Principal Investigator's Signature:**

**Date:**

**Signature of Person Obtaining Consent:**

**Date:**

## REFERENCES

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