# MEDICAL ETHICS FOR DOCTORS IN ETHIOPIA

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# PREFACE

This edition of "Medical Ethics for Doctors in Ethiopia" consists of an up to-date information and guideline for all practicing doctors in Ethiopia in line with the dynamic field of ethics in general and the medical ethics in particular. Since its first publication in 1988 entitled “Medical Ethics for Physicians practicing in Ethiopia”, no major revision or changes were made, neither the standing Ethics committee of the Ethiopian Medical Association had come up with opinions and position statements.

Nevertheless, EMA’s annual conferences have always put great emphasis on the issue of medical ethics. Accordingly, the first medical ethics draft document, which is the major resource to this edition, was produced in the year 2008. Besides, the continued discussions and recommendations have brought about significant improvement to the ethical principles and values that have been put together in the Ethiopian context of medical practice.

In addition, the standing ethics committee of EMA has shouldered responsibility to come up with timely opinions and positions that will gradually be reflected in the course of exercising the ethical code in both medical practice and medical research and to present it to the executive committee and the general assembly for endorsement. Moreover, EMA believes the inputs that could be obtained from theologians, sociologists, psychologists, philosophers, ethicists, lawyers, medical practitioners, etc. will have great importance to further adopt the document in the Ethiopian context.

As a final point, EMA will make an effort to carry on reviewing the document for the years to come in order to keep it up-to-date and functional.

Executive Committee
Ethiopian Medical Association
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*Dr Fuad Temam*
*EMA's President*

**CONTENTS**

# INTRODUCTION

## Historical Background

Ethics is a philosophical discipline which attempts to determine what is morally right and what is morally wrong with regard to human action. It was described by some of the Greek philosophers such as Socrates who said “The truly wise man will know what is right, do what is good and therefore be happy”. Aristotle also used to say “Rational development was considered the most important, as essential to philosophical self-awareness and as uniquely human” (Biomedical Ethics, 4th edition, 1996).

The word ethics is derived from the Greek ethos, which means custom or culture, a manner of acting or constant mode of behavior. Thus, ethics is defined as a systematic or scientific study of morality (of human acts through the medium of natural reason). It teaches us how to judge accurately the moral goodness or badness of any human action. While general ethics is the basic course of the science of ethics, medical ethics is a form of applied ethics concerned with the application of general principles to the moral problems of the medical profession. In short, medical ethics is the study of moral values and judgments applied to medical practice (WMA Medical Ethics Manual 2005).

Ethical principles started with the Code of Laws of Hammurabl (1790 B. C.) under which the Babylonian surgeons were rewarded or punished for the results of their efforts. Over the years, starting with Hippocrates, the most renowned Greek physician who is regarded as the Father of Medicine, important professional oaths have been publicly and solemnly pledged by physicians as they are admitted to the medical profession. The first of these professional codes was the Oath of Hippocrates 4th century, B.C. (See Appendix I)

There were few Jewish, Christian and Islamic teachings on conduct of doctors and medical ethics. Of these, a Jewish philosopher and physician named Moses Maimonides (born in Spain) in the Middle Ages (1135-1204) was known for introducing the Oath of Maimonides. In this oath Maimonides acknowledges that the eternal providence has appointed him to watch over the life, health and death of God’s creatures. He also admits to accept the vocation and takes it as his ultimate calling. This oath was also practiced in some medical schools upon graduation since the middle Ages (Bulletin of the Johns Hopkins Hospital 28:260-61, 1917).

The most significant contribution to Western medical ethical history was made by Thomas Percival, an English physician, philosopher, and writer. In those days Percival’s personality, his interest in sociological matters and his close association with infirmary, hospitals and charities were later reflected in his new preparation of professional conduct. Thomas Percival was able to draft Code of Medical Ethics that bears his name in 1803. In 1847 the American Medical Association’s first adopted Code of Ethics was based on Percival’s code. Although the original code adopted by the association remained the same throughout the years, there were major revisions that took place and since 1957 the format known as the AMA Principles of Medical Ethics was accepted. In order to lay down reasonable balance between professional

standards and contemporary legal standards in the changing society further revisions were mandated by the House of Delegates (AMA) to the Council on Ethical and Judicial Affairs to prepare current periodic opinions based on the Code of Medical Ethics of the Association (Code of Medical Ethics, Current Opinions, 2002-2003 edition).

The World Medical Association (WMA) since its establishment in1964 was sworn to put patients' interest first and to strive for the best possible health care for all regardless of race, creed, political allegiance and social standing. Its major activity was focused on medical ethics, medical education and socio-medical affairs. In 2003 WMA established an Ethics Unit with main goal to establish and promote highest possible standards of ethical behaviour and care by doctors. The Unit was instrumental in adopting policy statements on a large number of ethical issues related to medical professionalism, patient care, research on human participants and public policies. The major contribution of Ethics Unit of WMA in 2005 was the preparation of "Medical Ethics Manual" which was distributed to medical journals and medical schools throughout the world.

## Ethics in Medicine

The ethical concerns of medical care and prevention have been an integral part of western medicine since its inception that well known in history. However, it was the explosion of new medical technologies and procedures, growing social concern and human rights, major interest on moral obligation of the physician to the patient and to the society, complex medical decisions, and similar issues that had made medical ethics to emerge as an area of great concern beginning the late 1960s and the early 1970s until today. The existence of disparity in the distribution of health care both curative and preventive in both developed and developing nations has also raised serious concern about ethical issues. The major contributions of pharmaceuticals in conducting clinical trials that may make breakthroughs globally in curing and preventing some prevalent diseases cause to develop ethical issues when it comes to principles of beneficence and distributive justice to mankind.

According to the World Health Organization, (WHO), constitution signed July, 1986, "Health is a state of complete physical, mental, and social well-being and not merely the absence of disease or infirmity". Moreover, the health status of a population is often judged on the basis of life expectancy. Better nutrition, safe water supplies, improved sanitation and immunization or control of infection account for about 90% of the prolonged life expectancy in Western Europe and North America. Behavior, lifestyle and the environment definitely influence the health of man. Morbidity and mortality within these countries are significantly higher among low income groups as compared to high income groups. The health status of millions of people is unacceptable at this time, when medical knowledge is well advanced. It is estimated that more than half of the population of the world does not have adequate health care. As a result, the gap between the developed and the developing countries is very wide both in the existing health status and the means of improving health care.

Aware at the above facts, member nations of the WHO strongly affirmed that "health is fundamental human right and that the attainment of highest possible level of health

is the most important worldwide social goal whose realization requires the action of many other social and economic sectors, in addition to the health sector" Therefore, it is fair that people participate individually and collectively in the planning and implementation of their health care (WHO International Health Conference, New York, 19-22 June, 1946; signed on 22 July 1946).

On September 12.1978, the International conference 'On primary Health Care held in Alma Ata. jointly sponsored by WHO and UNICEF declared that primary health care is the key to attaining the target of health for all by the year 2000, as part of over-all development and the spirit of social justice. This declaration called on all governments to formulate national policies, strategies and action plans to launch and sustain primary health care as part of a comprehensive national health system and in coordination with other sectors. The declaration also called for urgent and effective international action to develop and implement primary health care throughout the world particularly in developing countries. The major ethical driving force was about "distributive justice" and how best access to health services is available to all people in line with the prevailing condition of inequality and human right (Declaration of Alma Ata).

Now after thirty years of the declaration of Alma Ata, there are improvements in many sectors, including health services in developing countries. There are also tremendous technological advances attained in medical sciences. Some of the advancements in health and medicine are found to be beneficial to both the developed and the developing world, although the gap between the rich and the poor countries are so wide that basic health services in developing countries were in a very serious condition.

Modern health care and public health practices are now faced with extremely complex and multifaceted ethical dilemmas. In addition to technological advancements including stem cell researches….cloning, etc. the emerging of pandemics like HIV infection since the late 80s have griped the whole world with major ethical issues. As ethics is a fundamental issue of the whole world, discussions, dialogues, position statements, declarations are needed with the help of experts in the field in order to guide the individual and corporate practitioners in health.

## Hippocratic Oath

The Hippocratic Oath was first revised and brought up-to-date by the World Medical Association as the Declaration of Geneva which was adopted by the Third General Assembly of the World Medical Association at Geneva, Switzerland, September 1948 and, later, by the International Code of Medical Ethics adopted by the General Assembly of the World Branch Association held In London, England, October, 1949. The Declaration of Geneva was amended by the 22nd World Medical Assembly, Sydney, Australia, In August 1968 and the 35th. World Medical Assembly, Venice, Italy, In October 1983, (See Appendix I).

### Modern Version

The modern version was written in 1964 by Louis Lasagna, Academic Dean of the School of Medicine at Tufts University, and used in many medical schools today. It reads as follows:

*I swear to fulfill, to the best of my ability and judgment, this covenant:*

*I will respect the hard-won scientific gains of those physicians in whose steps I walk, and gladly share such knowledge as is mine with those who are to follow.*

*I will apply, for the benefit of the sick, all measures [that] are required, avoiding those twin traps of over treatment and therapeutic nihilism.*

*I will remember that there is art to medicine as well as science, and that warmth, sympathy, and understanding may outweigh the surgeon's knife or the chemist's drug.*

*I will not be ashamed to say "I know not," nor will I fail to call in my colleagues when the skills of another are needed for a patient's recovery.*

*I will respect the privacy of my patients, for their problems are not disclosed to me that the world may know. Most especially must I tread with care in matters of life and death? If it is given me to save a life, all thanks. But it may also be within my power to take a life; this awesome responsibility must be faced with great humbleness and awareness of my own frailty. Above all, I must not play at God.*

*I will remember that I do not treat a fever chart, a cancerous growth, but a sick human being, whose illness may affect the person's family and economic stability. My responsibility includes these related problems, if I am to care adequately for the sick.*

*I will prevent disease whenever I can, for prevention is preferable to cure.*

*I will remember that I remain a member of society, with special obligations to all my fellow human beings, those sounds of mind and body as well as the infirm.*

*If I do not violate this oath, may I enjoy life and art, respected while I live and remembered with affection thereafter. May I always act so as to preserve the finest traditions of my calling and may I long experience the joy of healing those who seek my help.*

## Medical Ethics in Ethiopia

Until 1980 many doctors practicing in Ethiopia were trained abroad i.e. in different parts of the world and some of them had taken courses that train medical ethics in undergraduate classes. However, almost all graduates of the Faculty of Medicine, Addis Ababa University did not take courses of medical ethics during their training. The general curricula of the existing medical schools in Ethiopia do not include medical ethics course until recently. Nevertheless, a 1-credit hour medical ethics course was introduced at the Faculty of Medicine, Addis Ababa University in 2004 upon recommendations made by the Ethiopian Medical

Association and curriculum review committees of the Faculty of Medicine, Addis Ababa University.

The Ethiopian Medical Association had also conducted panel discussions and workshops during its annual conferences to gradually address issues of medical ethics in question. Meanwhile, the executive committee of EMA has set up ethics committee that organizes panel discussions and workshops whenever need arises. The committee also advises EMA on various issues of medical ethics and also attempts to provide information to doctors and to the media. In 1988, the Ministry of Health organized a drafting committee that consists of representatives of different institutions, organizations and associations to prepare an ethical code booklet entitled "Medical ethics for physicians practicing in Ethiopia". Members of the medical schools and EMA have actively participated and EMA in particular has played the major role in awareness-raising mainly by means of distribution of the booklet to all doctors in Ethiopia. EMA has also taken a major initiative in the second publication of the booklet in 1992. This booklet is still the binding ethical document that assists practicing doctors not to be involved in malpractice and thereby protects the public at large.

The care of human life is constantly in the hands of the doctor. Some may usher life into the world amidst many dangers. Others preserve life threatened by innumerable dangers. All see life depart from the world in spite of all efforts to prevent it happen. Thus, the doctor who is so intimately involved with the most noble and sacred realities of life must depend on ethical principles and ideals. A realization and clear understanding of such principles and their practical application will result in efficient service to man and normal satisfaction to on self.

Although medical ethics principles are universally accepted by all different countries, each country is endowed to adopt certain modifications and devise specific interpretations consistent with the prevailing culture, religious beliefs, social and anthropological norms, laws of the land, and standards of medical practice in the existing health system. It is understandable that as these conditions are sometimes in the state of fast or slow changes and transformations, issues in medical ethics are also bound to dynamism and frequent changes in implementations of the principles in the context of the health service environment within the respective country and the availability the standard of care required.

These and similar issues described above bring forward medical ethics as part and parcel of daily activities in all aspects of health services (preventive, curative etc…) in Ethiopia and the situation obliges all doctors to abide consistently with the principles. It is also mandatory that doctors practicing in Ethiopia themselves, and through their association (EMA) and Ethics standing committee need to discuss and come up with a universally agreed positions and statements that bind all of them in their respective practice. The ethical guidelines and code of medical ethics should be revised in 5-10 years interval with deletions, modifications and new additions. It is the duty of each and every doctor to know it and practice it accordingly. It is also high time to set up ethics committees that play a role in the respective health services and to use these committees to learn from each other, to exchange of views and norms with each other, to strengthen decision making capacity, and to undertake timely action to preventing mal practice.

We hope EMA and its standing Ethics committee will work towards the implementation of medical ethical principles that best serves the Ethiopian people.

# Code of Medical Ethics

The Code of Medical Ethics reflects the application of the principles of Medical Ethics in some of the ethical issues in medical practice including doctor's relationship to patients, to colleagues and to the community in general. A doctor as a professional is responsible to keeping medical secrecy, abiding by informed consent and disclosing conflict of interest at all times. It also indicates the position a doctor need to take when encountering torture and punishment situations, in issues related to advertisement. He/she is fully responsible to certificates, prescriptions and signatures of practical importance in delivering medical diagnosis and management.

This code does give an appropriate guideline and illustrates the acceptable behaviour of a doctor with a sound mind and self-control. It directs the doctor in his/her practice to discharge his/her responsibility in issues related to abortion, family planning, artificial insemination, severely handicapped children. The code of medical ethics fully authorizes the doctor's responsibility to confirm and issue death certificate. However, no doctor in this code is permitted to advocate or practice euthanasia.

In short, the following code of medical ethics is focused on the duties and obligations of the doctor towards his patients on the conduct and application of his or her professional arts and science as well as his or her association with professional colleagues.

# A.GENERAL CODE OF MEDICAL ETHICS

## I. Doctor-patient and Doctor-community Relationships

Article 1: The principal objective of the medical profession is to render service to the individual and the community with full respect for life and the dignity of man.

Article 2: The doctor shall attend her/his patient with maximum possible care, devotion and conscientiousness. She/he shall respect the dignity of her/his patient and her/his attitudes shall be sympathetic, friendly and helpful.

Article 3: In case of a female patient (client) presenting in a clinic, the doctor shall perform her/his examinations in the presence a female nurse or a chaperone.

Article 4: The doctor shall practice her/his profession without discrimination.

Article 5: The doctor shall provide her/his patient, the family and the whole Community with the prevention of disease or injury, maintenance of good health and rehabilitative services.

Article 6: The doctor shall cooperate with the public authorities in the prevention of disease or injury and in the maintenance of good health.

Article 7: The doctor shall make use of every opportunity to teach the patient and her/his family regarding the prevention of disease and the promotion of health.

Article 8: In case of emergency the doctor shall extend all possible assistance to the patient without fail.

Article 9: In the event of public danger, the doctor shall not abandon patients in her/his immediate care until all appropriate measures have been taken to secure the safety of the patients.

Article 10: The doctor shall do nothing wasteful or shall not do anything without justification for the health of· the Individual or the community.

Article 11: The doctor shall be the defender of the child when she/he judges the health of the child is not well protected.

Article 12: The doctor is obliged to consult colleagues when it is necessary to do so, and shall inform the patient and/or the patient's relatives about the consultations.

Article 13: The doctor is free to choose whom she/he will serve. The doctor should, however, respond to the best of her/his ability in case of emergency where first aid treatment is essential. While the doctor has the option of withdrawing from a case, she/he shall ascertain that:

a. the patient or the relatives or responsible person are notified ahead of time.
b. the patient will have adequate care
c. a colleague will replace her/him
d. all necessary information will be conveyed to the replacement.

Article 14: The doctor-patient relationship shall not be used as a means of developing intimacy.

## II. The Doctor as a Professional

Article 15: The doctor shall at all times conduct herself/himself in such a way that she/he may gain the respect and the confidence of her/his fellow man and maintain the dignity of her/his profession, and those conditions are essential for the best practice of her/his profession.

Article 16: The responsibility of the doctor shall be strictly personal.

Article 17: The doctor shall at no time divest herself/himself of her/his professional freedom.

Article 18: The doctor shall endeavor to improve continuously her/his knowledge and skill and should make them available to her/his patients and colleagues.

Article 19: The doctor shall use recognized scientific methods during her/his practice.

Article 20: The doctor shall not administer unjustified treatment.

## III. Medical Secrecy

Article 21: The doctor shall maintain her/his professional secrecy in respect for all matters which have come to her/his knowledge in the course of her/his duties to the patients except in those situations clearly stipulated by the law or when the patient gives written consent for the release of information.

Article 22: The use of any medium such as: film, videotapes, or otherwise record patient interactions with their health care providers requires the utmost respect for the privacy and confidentiality of the patient.

Article 23: In case of minors and unconscious patients or patients of unsound mind, the doctor may reveal his professional secret to the patient's relatives when such a revelation would serve any useful purpose for the cure of the patient or when her/his condition otherwise so requires.

Article 24: The doctor shall see to it that persons working with him respect medical secrecy.

Article 25: The doctor shall not disclose the identification of her/his patient in her/his scientific publications or lectures unless there is a written consent of the patient.

## IV. Patients' Consent

Article 26: It is the duty of the doctor to inform the patient about the treatment (Including surgical procedures), she/he intends to carry out. The doctor is always obliged to obtain a written consent of the patient before carrying out procedures. In the case of minors or persons who are unconscious or of unsound mind, the necessary consent should be obtained from parents or legal guardians, if there is no other legal provision.

Article 27: On legitimate grounds, left to the discretion of the doctor, information about serious diagnoses and/or prognosis may be withheld unless the patient demands it. However, it is, desirable to inform the nearest relative when the outcome is likely to be unfavorable.

Article 28: The doctor has an ethical obligation to help the patient make choices from among the therapeutic alternatives consistent with good medical practice.

## V. Torture and Punishment

Article 29: The doctor shall not participate in the practice of torture or other cruel, inhuman or degrading procedures. The doctor shall not provide premises, instruments, substances or knowledge to facilitate the practice of torture.

Article 30: Doctors may treat prisoners or detainees if doing so is in their best interest. But doctors should not treat individuals to verify their health so that torture can begin or continue. Doctors who treat torture victims should not be persecuted. Doctors should help provide support for victims of torture and, whenever possible, strive to change situations in which torture is practiced or the potential for torture is great.

## VI. Certificates, Prescriptions and Signatures

Article 31: Any documents of certificate issued by the doctor should bear his legible name and signature.

Article 32: The issuance of a tendentious report or a false certificate is unethical.

Article 33: Upon request of the patient or legal authorities the doctor shall issue certificate based solely on his medical observations. Documents or testimonies should be issued when authorized by courts of law.

Article 34: The doctor shall formulate his prescriptions with the necessary clarity. The doctor and/or the pharmacist make sure that the patient or his family has well understood the ordered prescription. The doctor will try her/his best to see that the treatment is carried out.

## VII. Undisclosed Gains

Article 35: It is unethical to accept any indirect gain based on a principle of dichotomy or undisclosed division of professional fees for a medical act such as for prescriptions of drugs, laboratory investigations, appliance, etc. with a medical partnership publicly known to exist.

Article 36: Complicity intended to get directly or indirectly any material benefit is forbidden among doctors themselves, and between doctors and other health workers, and between doctors and any other person.

Article 37: The doctor shall not allow a patient to obtain illegal or unjustified gains.

## VIII. Advertisement and Publicity

Article 38: The doctor in his practice shall avoid direct or indirect self advertisement.

Article 39: The doctor shall not use his mandate or administrative position in order to promote his practice.

## IX. The Doctor and his Professional Colleagues

Article 40: The doctor shall conduct himself in a loyal, fraternal and courteous way towards other members of his profession.

Article 41: The doctor shall never in any way discredit the acts or words of a colleague except where immoral words or acts directly harmful to the health of the patient or, to the community are involved, in which case she/he shall reveal her/his observation only to proper authorities. The doctor shall not tolerate that third parties disparage a colleague.

Article 42: Disputes between members of the medical profession must be resolved quickly and amicably within the profession itself. If this fails, the dispute shall be brought before the body administering this code of medical ethics.

Article 43: A consulted doctor shall not take over the management of the patient without the knowledge of the regularly attending physician.

Article 44: It shall be the duty and privileges of every doctor to attend free of charge any sick colleague or her/his dependents.

## X. Supervisory Role of the Doctor

Article 45: The doctor shall not allow any medical student and trainee paramedic to take direct responsibility of patient's care.

Article 46: The doctor shall closely supervise the intern in carrying out her/his duties and responsibilities

## XI. Mind and behavior control

Article 47:

a. The patient must be given the necessary information even if complex in order she/he reaches a decision about whether to accept or refuse the recommended psychotropic drug.

b. In the case of the patient who is capable of comprehending the information given to her/him about psychotropic drugs the patient's right to refuse treatment must be respected.

c. When the patient is regarded as too disordered to arrive at informed judgments, the physician/psychiatrists can .assume the duty to prescribe the medication she/he considers necessary for clinical needs, but it should be properly documented.

Article 48: In cases of social deviance, it is unethical to use psychotropic drugs as 'chemical restraint', as a form of social control or as punitive measures in psychiatric hospitals, prison practices or elsewhere.

Article 49: In the treatment of addicts suffering from withdrawal symptoms, appropriate care and support must be provided without discrimination.

Article 50:

a. In the administration of Electro-Convulsive Therapy (ECT), unless the patient is unable to understand what is proposed, informed written consent is ethically required. However, the patient may withholds the consent at any time during the course of treatment.

b. When a patient is unable to understand what is proposed or when a patient refuses treatment and Electro-Convulsive therapy is considered essential, consent must be obtained from the relative.

c. With regard to the administration of ECT, it must be properly supervised by senior psychiatrists with a continuing interest in treatment. The hospital must also meet internationally accepted ethical and technical standards on ECT therapy.

Article 51: It is the duty of the doctor to explain the mode and the program of behavioral psychotherapy to the patient and the patient must give her/his consent.

Article 52: Aversion treatment may be used after full inter-disciplinary discussion and after obtaining written consent from the patient.

Article 53: Psychiatrists at times necessary, in order to protect the patient the community from imminent danger to reveal confidential information discussed by the patient.

## XII. Abortion

Article 54: The first moral principle imposed upon the doctor is respect for human life from its beginning.

Article 55: An abortion is justified only when it is performed for the purpose of saving the endangered life or health of a woman.

Article 56: Abortion is justifiable if performed by a doctor in health institutions where appropriate facilities are available.

Article 57: It is mandatory to treat a patient who is suffering from the effect of an abortion induced by another person.

Article 58: The doctor must never disclose the cause of her/his patient's condition to anyone else without the consent of the patient unless ordered to do so in court of law.

Article 59: An abortion leading to death should be reported to the concerned authorities by the treating doctor.

## XIII. Family Planning

Article 60: It is ethical for a doctor if she/he informs, educates and communicates knowledge of family planning to individuals, families or the general public.

Article 61: It is the duty of a doctor to prescribe scientifically acceptable means and methods of family planning to individuals or couples who have attained the age of 18 years and who freely and responsibly decide to postpone or prevent pregnancy.

## XIV. Artificial insemination

Article 62: It is ethical for a qualified and experienced doctor to perform artificial insemination.

Article 63: The doctor should obtain a signed document from the wife and her husband setting forth the desire of both parties.

Article 64: The name of the donor should not be disclosed to the husband or the wife and the names of the married couple should not be given to the donor.

Article 65: The doctor should provide information about screening (full range of infectious diseases including HIV and genetic diseases) costs, and procedures for confidentiality when applicable. .

## XV. Severely handicapped children

Article 66: It is unethical to withhold the means necessary for the survival of a severely handicapped child.

## XVI. Care of children

Article 67: It is the duty of the doctor to assist the parents to consent to treatment, procedures and general care for the wellbeing of a minor child.

Article 68: In emergency situation, however, and where parents can not be reached, the attendant, relatives, guardian (in case of orphans) can provide verbal consent and the doctor can go ahead for emergency intervention. Three doctors' agreement may be an alternative for emergency surgical intervention when parents are not reached.

Article 69: The age of consent acceptable by the family law of the land is 18 years. Therefore, for all minors less than 18 years the doctor upon the request of the parents can keep the interactive interviews, examination results, counseling outcomes conducted with the minor confidential. No information will be disclosed without the consent of the parents.

Article 70: In some situations for minors between ages 12-18 years, when the doctor believes that without parental or guardian involvement and guidance, the minor will face a serious health threat, and there is a reason to believe that the parents or guardians will be helpful and understanding, disclosing the problem to the parents or guardians is ethically justified.

## XVII. Death

Article 71: It is part of the duty of the doctor to issue a death certificate.

Article 72: The doctor should summarily reject any suggestion to modify accuracy or to alter truth when issuing a death certificate.

Article 73: The doctor should not sign a death certificate unless she/he has personally ascertained the facts pertaining to the death.

Article 74: The protection of the confidential nature of the medical information stated in the certificate must be ensured as much as possible.

Article 75: It is permissible to remove organs from the cadaver provided requirements for consent have been fulfilled.

Article 76: It is ethical to perform postmortem examination with the consent of the immediate relatives. In the absence of claimants this holds true when legitimate medical reasons exist.

## XVIII. Euthanasia

Article 77: No doctor can take life deliberately as an act of mercy even at the direct request of the patient or the patient's family.

## XIX. HIV Infection and Doctors

Article 78: Doctors should encourage patients to have HIV testing voluntarily to enhance early diagnosis and treatment of HIV infection or of medical conditions that may be affected by HIV.

Article 79: Doctors should ensure that HIV testing is conducted in a way that respects patient autonomy and assures patient confidentiality as much as possible.

Article 80: In a health facility level, when a health care provider is at risk of the infection due to puncture injury or mucosal contact with potentially infected bodily fluids, it is acceptable to test the patient for HIV infection even if the patient refuses consent.

Article 81: If a doctor knows that a sero-positive individual is endangering a third party, the doctor should, within the constraints of the law: a) attempt to persuade the infected patient to cease endangering the third party b) if persuasion fails, notify authorities; and c) if authorities take no action, notify the endangered third party.

Article 82: It is unethical to refuse to treat a patient whose condition is within the doctor’s current realm of competence solely because the patient has HIV/AIDS.

Article 83: A doctor who knows that she/he is sero-positive should not engage in any activity that creates a significant risk of transmission of the disease to others. She/he should consult colleagues as to which activities she/he can pursue without creating a risk to patients.

Article 84: Doctors should persuade all pregnant mothers to be screened and prevent mother to child transmission of HIV.

# B. RESEARCH ETHICS

Research Ethics involving human participants

## I. Research in Medicine

Medical practice and research are dynamic. The physician shall make maximum effort to continuously improve his/her knowledge and skill to provide patients with the highest medical care. In order to carry out this responsibility, physicians need to use the results of medical research and constantly upgrade their competence by keeping up with research findings in the area of their respective specialties. Even the best current interventions must be evaluated continually through research for their safety, effectiveness, efficiency, accessibility and quality (DoH, 2008). As mentioned in the ethics manual of the World Medical Association (WMA), the functions of medical research among other things is monitoring and evaluation of even the most widely accepted treatments, in addition to the development of new treatments, especially drugs and medical devices. Research is the only means of answering the many unanswered questions in Medicine. In order to carry out research or even interpret results of research done by others, a basic familiarity with research methods is essential for competent medical practice. The most common method of research for practicing physicians is the clinical trial.

Distinctions between practice and research should be done, even though these two often occur together. “Practice” involves interventions designed solely to enhance the well-being of the patient or client. These interventions are undertaken because there is a reasonable expectation of a successful outcome. On the other hand “Research” constitutes activities designed to contribute to generalizable knowledge. Typically in research a set of activities is consistently applied to groups of individuals in order to test a hypothesis and draw conclusions. These activities do not necessarily provide direct benefit.

## II. Research Ethics – Historical Background

The ethics of human subject research has evolved over the past decades, whereby guidelines, codes and regulations have been created, to guide the ethical conduct of research involving human participants. Some of these guidelines were created in response to an ethical lapse. The first one of the kind, the *Nuremberg Code,* a 10-

point statement outlining permissible medical experimentation on human participants, came into being as a result of the prosecution of Nazi war criminals at the end of World War II. The first provision of the code requires that “the voluntary informed consent of the human subject is absolutely essential.”

On the other hand, several guidelines were developed in an attempt to address solutions to the changing world of research and provide means to address new challenges. But all of them reflect the principles of respect for persons, beneficence and justice. The World Medical Association was established in 1947, and in the year 1964, it came up with the *Declaration of Helsinki,* a concise summary of research ethics, which provides for extra protection for persons with diminished autonomy and urges caution on the part of the physician researcher who enrolls his own patients, and further gives emphasis to the principle that the well-being of the participant should take precedence over the interests of science and society. Since the first version, the *Declaration of Helsinki* (DoH) has been revised six times with the most recent revision in 2008. In 1978, *The Belmont Report: Ethical Principles and Guidelines for the Protection of Human Subjects of Research* appeared, which sets forth the three ethical principles—respect for persons, beneficence, and justice. Over the years several more detailed guidelines were produced. One of these guidelines is the International Ethical Guidelines for Biomedical Research Involving Human Subjects (CIOMS), with the purpose to indicate how the ethical principles can be applied effectively, particularly in developing countries. This is an important guideline, because many researches in Ethiopia are presently done in partnership with the developed countries, many ethical issues are raised through such collaborations. Meanwhile, researchers come for cheap access of participants to developing countries. Like those of the 1982, 1993, and the 2002 CIOMS Guidelines are designed to be of use to countries in defining national policies on the ethics of biomedical research involving human subjects, applying ethical standards in local circumstances, and establishing or improving ethical review mechanisms.

Eventually, these international regulations and recommendations need to be adapted or transformed into institution operational guidelines to be used at the local level to guide the planning, review, approval and conduct of human research, by applying the fundamental principles within the context of local laws and cultural circumstances. The ultimate responsibility for the acceptable conduct of research with human

subjects rests with the investigator. The Declaration of Geneva of the WMA binds the physician with such motto, “The health of my patient will be my first consideration,” and the International Code of Medical Ethics declares that, “A physician shall act in the patient's best interest when providing medical care.”

When Physicians conduct research with human participants they should consider the ethical, legal and regulatory norms and the standards for research involving human subjects in Ethiopia as well as applicable international norms and standards.

The first National Health Researches Ethics Guideline in Ethiopia was issued in 1995, which has subsequently been revised three times and the latest is the 2005 version. In Ethiopia, Health Research Ethics Review Committees are established at three levels: National, Regional and Institutional All health researches involving human participants must be subjected to independent ethics review and this should be conducted by the health research ethics review committee. As advocates for the safety of our patients and as potential participants in research, the role associations in formulation of National guidelines play should be given due attention.

## III. Principles of Research Ethics

There are three fundamental principles for the ethical conduct of research involving human participants, which are commonly embodied in national regulations and international recommendations and guidelines. The first one is *Respect for Persons* which deals with the principles of autonomy and the protection of persons with diminished autonomy. The application of this principle is the use of the individual informed consent which comprises the three elements: information, comprehension and voluntariness; it requires that subjects to a degree that they are capable, should be informed and should be freely given a chance to decide what shall and shall not happen to them. The second ethical principle involves *Beneficence,* which is synonymous with do no harm and maximize possible benefits and minimize possible harms. The assessment of risks and benefits requires a careful arrayal of relevant data, including, in some cases, alternative ways of obtaining the benefits sought in the research. The third principle is *Justice*; translated into who ought to receive the benefits of research and bear its burdens and issue of "fairness in distribution “, its application is manifested during the recruitment of study subjects.

# IV. General Code of Ethics in Medical Research

## A. The Role of Investigator and Ethical Norms

Article1. A physician shall continue to study, apply, and advance scientific knowledge, maintain a commitment to medical education, since research is potentially of significant value when ethically conducted

Article 2: Honesty and integrity must govern all stages of research, from the initial grant application, to publication of results. Fabrication, falsification, plagiarism should be avoided in proposing, conducting and reporting research.

Article 3: Medical research involving human subjects must conform to the generally accepted current scientific principles, be based on a thorough knowledge of the scientific literature, and supported with other relevant sources of information.

Article 4: When conducting a clinical trail, a state of clinical equipoise must exist at the inception of the trial, regarding the advantage of the regimens to be tested.

Article 5: Since the ultimate responsibility of the protection and the safety of the research participants rest upon the physician-investigator, individuals conducting the study must have the appropriate scientific training and qualification.

Article 6: Benefits and risks of research must be distributed fairly, and particular care must be taken to avoid exploitation of vulnerable populations. Careful assessment of any predictable risks in comparison with foreseeable benefits to individuals and the community at large should be done beforehand and the benefit-to-risk ratio must be high enough to justify the research effort.

Article 7: In externally funded research, the research must hold the promise of direct, tangible, and significant benefit to the host country's population, if not to the study subjects themselves.

Article 8: Physicians involved in research with human subjects must first write a clear research protocol with proper design and performance of each study. As stated in paragraph 14 of DoH, the protocol should contain a statement of

the ethical considerations involved and should indicate how the ethical principles have been addressed. Additionally, the protocol should include information regarding funding, sponsors, institutional affiliations, other potential conflicts of interest, incentives for subjects and provisions for treating and/or compensating subjects who are harmed as a consequence of participation in the research study. The protocol should describe arrangements for post-study access by study subjects to interventions identified as beneficial in the study or access to other appropriate care or benefits.

Article 9: Before initiation of any study, all proposed research, should be approved by the research ethics committee/ review board (National /Institutional/regional) in order to assure that the research plans are reasonable and that research participants are adequately protected. The protocol must take the national guidelines and International norms and standards into consideration.

Article 10: All changes, amendments of the research protocol must be approved by the ethics committee/board before implementation of the changes.

Article 11: The nature of the research must be explained in plain and understandable local language to research participants, and informed consent must be obtained from the research participant or from an authorized representative for those with diminished capacity to consent. The consent process should reflect all the elements of consent: information, comprehension and voluntariness: It should include basic elements such as a statement that the study involves research and expected duration, purpose of the study and procedures to be followed , any anticipated risks or discomforts, description of any benefits, alternative procedures or treatment, confidentiality, compensations to study related injury, statement that shows voluntariness, whom to contact for responses to study related queries and questions about participant's rights.

Article12: The consent should be documented, by use of a consent form that has been approved by the ethics committee, dated and signed by the study participant or legally authorized representative. For participants who cannot

read and write, a witness signature should be obtained in addition to index finger print of the participant.

Artcle13: As paragraph 25 of DoH stipulates, for medical research using identifiable human material or data, physicians must normally seek consent for the collection, analysis, storage and/or reuse. There may be situations where consent would be impossible or impractical to obtain for such research or would pose a threat to the validity of the research. In such situations, the research may be done only after consideration and approval of the research ethics committee/board.

Article14: When the effectiveness of a new intervention is being tested, the physician must adhere to the latest national and international norms and guidance.

## B. Medical Research Combined with Professional Care

Article15: The physician who participates in research must protect the life, health, dignity, integrity, right to self-determination, privacy, and confidentiality of personal information of research subjects.

Article16: The health and welfare of the patient must always be the physician's primary consideration. Medical research can be combined with medical care only to the extent that the research is justified by its potential preventive, diagnostic or therapeutic value. If the physician has good reason to believe that participation in the research study will not adversely affect the health of the patients who serve as research participants and that the patient is fully informed which part is care and which part is research.

Article 17: If the research participant is in a dependent relationship with the physician-investigator, consent should be obtained by another independent individual who is very familiar with the study to avoid coercion.

Article 18: Physician-investigators may find themselves in dual roles with respect to patients who are also research participants and they should avoid situations that facilitate for them a reward for particular outcomes.

Article19: Physicians who refer patients for participation in research protocols must be satisfied that the program follows established ethical guidelines, provides for realistic informed consent, gives reasonable assurances of

safety, and has an acceptable benefit-to-risk ratio. If the risks of the research become too great or if continued participation cannot be justified, the physician must be willing to immediately advise the patient to withdraw from the study.

Article 21: Giving finder's fees to individual physicians for referring patients to a research project generates conflict of interest

Article 22: The outcome of the consent process shall not interfere with the physician-patient relationship**.**

## C. Protection of Special Groups involved in Research

Article 23: The rational and details of the inclusion of vulnerable population in research (Children, pregnant women, prisoners, mentally disabled etc.) should be included in the research protocol**.**

Article 24: Special precautions must be taken when recruiting potential participants who are incompetent or do not have the legal capacity to give consent. They should not be included, if there is no likelihood of direct benefit from the study to the individuals or to the health of the population represented by the potential participant. In situations when they are included in a study, informed consent should be taken from parents/guardians or legally designated individual.

Article 25: Children should be included in research, only in cases where their participation is indispensable for researches of diseases of childhood and conditions to which children are particularly susceptible and when the risk is justified by the anticipated benefit from participation.

Article 26: If the potential subjects are children, the consent of a parent or legal guardian after a full explanation of the aims of the experiment and of possible hazards, discomfort or inconvenience, is always necessary. In addition to this, to the extent that it is possible, which will vary with age, the assent (willingness) of the child should be sought with due respect to the dissent of the potential participant.

Article 27: Special safeguards should be put in place when involving pregnant women in research. Pregnant women should not be included in non-therapeutic research that carries any possibility of risk to the fetus or neonate, unless

this is intended to elucidate problems of pregnancy or lactation. Scientifically appropriate preclinical studies and clinical studies on non pregnant women should be done so that to provide data to assess the potential risk in pregnant women and fetuses.

## D. Scientific Publication

Article 28: Being authors of scientific publications should mean that the individuals are sufficiently acquainted with the work being reported, that they can take public responsibility for the integrity of the study and the validity of the findings, and they must have substantially contributed to the research itself.

Article 29: All authors have a professional responsibility to make public their research findings and be honest in their publications, make clear that research has been carried out in accordance with the ethical principles.

Article 30: Plagiarism is unethical. Incorporating the words and ideas of others or one's own published words, either verbatim or by paraphrasing without appropriate attribution is unethical and may have serious consequences.

# Appendices

**Appendix 1-1**

## WORLD MEDICAL ASSOCIATION DECLARATION OF HELSINKI
**Ethical Principles for Medical Research Involving Human Subjects**

### A. Introduction

1. The World Medical Association (WMA) has developed the Declaration of Helsinki as a statement of ethical principles for medical research involving human subjects, including research on identifiable human material and data.

   The Declaration is intended to be read as a whole and each of its constituent paragraphs should not be applied without consideration of all other relevant paragraphs.

2. Although the Declaration is addressed primarily to physicians, the WMA encourages other participants in medical research involving human subjects to adopt these principles.
3. It is the duty of the physician to promote and safeguard the health of patients, including those who are involved in medical research. The physician's knowledge and conscience are dedicated to the fulfilment of this duty.
4. The Declaration of Geneva of the WMA binds the physician with the words, "The health of my patient will be my first consideration," and the International Code of Medical Ethics declares that, "A physician shall act in the patient's best interest when providing medical care."
5. Medical progress is based on research that ultimately must include studies involving human subjects. Populations that are underrepresented in medical research should be provided appropriate access to participation in research.
6. In medical research involving human subjects, the well-being of the individual research subject must take precedence over all other interests.
7. The primary purpose of medical research involving human subjects is to understand the causes, development and effects of diseases and improve preventive, diagnostic and therapeutic interventions (methods, procedures and treatments). Even the best current interventions must be evaluated continually through research for their safety, effectiveness, efficiency, accessibility and quality.
8. In medical practice and in medical research, most interventions involve risks and burdens.
9. Medical research is subject to ethical standards that promote respect for all human subjects and protect their health and rights. Some

research populations are particularly vulnerable and need special protection. These include those who cannot give or refuse consent for themselves and those who may be vulnerable to coercion or undue influence.

10. Physicians should consider the ethical, legal and regulatory norms and standards for research involving human subjects in their own countries as well as applicable international norms and standards. No national or international ethical, legal or regulatory requirement should reduce or eliminate any of the protections for research subjects set forth in this Declaration.

## B. Basic Principles for all Medical Research

11. It is the duty of physicians who participate in medical research to protect the life, health, dignity, integrity, right to self-determination, privacy, and confidentiality of personal information of research subjects.
12. Medical research involving human subjects must conform to generally accepted scientific principles, be based on a thorough knowledge of the scientific literature, other relevant sources of information, and adequate laboratory and, as appropriate, animal experimentation. The welfare of animals used for research must be respected.
13. Appropriate caution must be exercised in the conduct of medical research that may harm the environment.
14. The design and performance of each research study involving human subjects must be clearly described in a research protocol. The protocol should contain a statement of the ethical considerations involved and should indicate how the principles in this Declaration have been addressed. The protocol should include information regarding funding, sponsors, institutional affiliations, other potential conflicts of interest, incentives for subjects and provisions for treating and/or compensating subjects who are harmed as a consequence of participation in the research study. The protocol should describe arrangements for post-study access by study subjects to interventions identified as beneficial in the study or access to other appropriate care or benefits.
15. The research protocol must be submitted for consideration, comment, guidance and approval to a research ethics committee before the study begins. This committee must be independent of the researcher, the sponsor and any other undue influence. It must take into consideration the laws and regulations of the country or countries in which the research is to be performed as well as applicable international norms and standards but these must not be allowed to reduce or eliminate any of the protections for research subjects set forth in this Declaration. The committee must have the right to monitor ongoing studies. The researcher must provide monitoring information to the committee, especially information about any serious adverse events. No change to the protocol may be made without consideration and approval by the committee.
16. Medical research involving human subjects must be conducted only by individuals with the appropriate scientific training and qualifications.

Research on patients or healthy volunteers requires the supervision of a competent and appropriately qualified physician or other health care professional. The responsibility for the protection of research subjects must always rest with the physician or other health care professional and never the research subjects, even though they have given consent.

17. Medical research involving a disadvantaged or vulnerable population or community is only justified if the research is responsive to the health needs and priorities of this population or community and if there is a reasonable likelihood that this population or community stands to benefit from the results of the research.
18. Every medical research study involving human subjects must be preceded by careful assessment of predictable risks and burdens to the individuals and communities involved in the research in comparison with foreseeable benefits to them and to other individuals or communities affected by the condition under investigation.
19. Every clinical trial must be registered in a publicly accessible database before recruitment of the first subject.
20. Physicians may not participate in a research study involving human subjects unless they are confident that the risks involved have been adequately assessed and can be satisfactorily managed. Physicians must immediately stop a study when the risks are found to outweigh the potential benefits or when there is conclusive proof of positive and beneficial results.
21. Medical research involving human subjects may only be conducted if the importance of the objective outweighs the inherent risks and burdens to the research subjects.
22. Participation by competent individuals as subjects in medical research must be voluntary. Although it may be appropriate to consult family members or community leaders, no competent individual may be enrolled in a research study unless he or she freely agrees.
23. Every precaution must be taken to protect the privacy of research subjects and the confidentiality of their personal information and to minimize the impact of the study on their physical, mental and social integrity.
24. In medical research involving competent human subjects, each potential subject must be adequately informed of the aims, methods, sources of funding, any possible conflicts of interest, institutional affiliations of the researcher, the anticipated benefits and potential risks of the study and the discomfort it may entail, and any other relevant aspects of the study. The potential subject must be informed of the right to refuse to participate in the study or to withdraw consent to participate at any time without reprisal. Special attention should be given to the specific information needs of individual potential subjects as well as to the methods used to deliver the information. After ensuring that the potential subject has understood the information, the physician or another appropriately qualified individual must then seek the potential subject's freely-given informed consent, preferably in writing. If the consent cannot be expressed in writing, the non-written consent must be formally documented and witnessed.

25. For medical research using identifiable human material or data, physicians must normally seek consent for the collection, analysis, storage and/or reuse. There may be situations where consent would be impossible or impractical to obtain for such research or would pose a threat to the validity of the research. In such situations the research may be done only after consideration and approval of a research ethics committee.
26. When seeking informed consent for participation in a research study the physician should be particularly cautious if the potential subject is in a dependent relationship with the physician or may consent under duress. In such situations the informed consent should be sought by an appropriately qualified individual who is completely independent of this relationship.
27. For a potential research subject who is incompetent, the physician must seek informed consent from the legally authorized representative. These individuals must not be included in a research study that has no likelihood of benefit for them unless it is intended to promote the health of the population represented by the potential subject, the research cannot instead be performed with competent persons, and the research entails only minimal risk and minimal burden.
28. When a potential research subject who is deemed incompetent is able to give assent to decisions about participation in research, the physician must seek that assent in addition to the consent of the legally authorized representative. The potential subject's dissent should be respected.
29. Research involving subjects who are physically or mentally incapable of giving consent, for example, unconscious patients, may be done only if the physical or mental condition that prevents giving informed consent is a necessary characteristic of the research population. In such circumstances the physician should seek informed consent from the legally authorized representative. If no such representative is available and if the research cannot be delayed, the study may proceed without informed consent provided that the specific reasons for involving subjects with a condition that renders them unable to give informed consent have been stated in the research protocol and the study has been approved by a research ethics committee. Consent to remain in the research should be obtained as soon as possible from the subject or a legally authorized representative.
30. Authors, editors and publishers all have ethical obligations with regard to the publication of the results of research. Authors have a duty to make publicly available the results of their research on human subjects and are accountable for the completeness and accuracy of their reports. They should adhere to accepted guidelines for ethical reporting. Negative and inconclusive as well as positive results should be published or otherwise made publicly available. Sources of funding, institutional affiliations and conflicts of interest should be declared in the publication. Reports of research not in accordance with the principles of this Declaration should not be accepted for publication.

## C. Additional Principles for Medical Research Combined with Medical Care

31. The physician may combine medical research with medical care only to the extent that the research is justified by its potential preventive, diagnostic or therapeutic value and if the physician has good reason to believe that participation in the research study will not adversely affect the health of the patients who serve as research subjects.
32. The benefits, risks, burdens and effectiveness of a new intervention must be tested against those of the best current proven intervention, except in the following circumstances:

- The use of placebo, or no treatment, is acceptable in studies where no current proven intervention exists; or
- Where for compelling and scientifically sound methodological reasons the use of placebo is necessary to determine the efficacy or safety of an intervention and the patients who receive placebo or no treatment will not be subject to any risk of serious or irreversible harm. Extreme care must be taken to avoid abuse of this option.

33. At the conclusion of the study, patients entered into the study are entitled to be informed about the outcome of the study and to share any benefits that result from it, for example, access to interventions identified as beneficial in the study or to other appropriate care or benefits.
34. The physician must fully inform the patient which aspects of the care are related to the research. The refusal of a patient to participate in a study or the patient's decision to withdraw from the study must never interfere with the patient-physician relationship.
35. In the treatment of a patient, where proven interventions do not exist or have been ineffective, the physician, after seeking expert advice, with informed consent from the patient or a legally authorized representative, may use an unproven intervention if in the physician's judgement it offers hope of saving life, re-establishing health or alleviating suffering. Where possible, this intervention should be made the object of research, designed to evaluate its safety and efficacy. In all cases, new information should be recorded and, where appropriate, made publicly available.

22.10.2008

**Appendix 1- 2**

# The Nuremberg Code

1. The voluntary consent of the human subject is absolutely essential. This means that the person involved should have legal capacity to give consent; should be so situated as to be able to exercise free power of choice, without the intervention of any element of force, fraud, deceit, duress, over-reaching, or other ulterior form of constraint or coercion; and should have sufficient knowledge and comprehension of the elements of the subject matter involved as to enable him to make an understanding and enlightened decision. This latter element requires that before the acceptance of an affirmative decision by the experimental subject there should be made known to him the nature, duration, and purpose of the experiment; the method and means by which it is to be conducted; all inconveniences and hazards reasonable to be expected; and the effects upon his health or person which may possibly come from his participation in the experiment.

   The duty and responsibility for ascertaining the quality of the consent rests upon each individual who initiates, directs, or engages in the experiment. It is a personal duty and responsibility which may not be delegated to another with impunity.

2. The experiment should be such as to yield fruitful results for the good of society, unprocurable by other methods or means of study, and not random and unnecessary in nature.

3. The experiment should be so designed and based on the results of animal experimentation; and knowledge of the natural history of the disease or other problem under study that the anticipated results will justify the performance of the experiment.

4. The experiment should be so conducted as to avoid all unnecessary physical and mental suffering and injury.

5. No experiment should be conducted where there is an a priori reason to believe that death or disabling injury will occur; except, perhaps, in those experiments where the experimental physicians also serve as subjects.

6. The degree of risk to be taken should never exceed that determined by the humanitarian importance of the problem to be solved by the experiment.

7. Proper preparations should be made and adequate facilities provided to protect the experimental subject against even remote possibilities of injury, disability, or death.

8. The experiment should be conducted only by scientifically qualified persons. The highest degree of skill and care should be required through all stages of the experiment of those who conduct or engage in the experiment.

9. During the course of the experiment the human subject should be at liberty to bring the experiment to an end if he has reached the physical or mental state where continuation of the experiment seems to him to be impossible.

10. During the course of the experiment the scientist in charge must be prepared to terminate the experiment at any stage, if he has probably cause to believe, in the exercise of the good faith, superior skill and careful judgment required of him that a continuation of the experiment is likely to result in injury, disability, or death to the experimental subject.

*from: Trials of War Criminals before the Nuremberg Military Tribunals …1949*

## INTERNATIONAL ETHICAL CODES

### *The Original Hippocratic Oath* (about 460-377 B.C.)*

I swear by Apollo Physician, by Ascleplus, by Health, by Heal-all and by all the gods and goddesses, making them witnesses, that. I will carry out, according to my ability and judgment, this oath and this indenture:

To regard my teacher in the art as equal to my parents; to make him partner in my livelihood, and when he is in need of money to share mine with him; to consider his offspring equal to my brothers; to teach them this art, if they require to learn it, without fee or indenture; and to impart precept, oral instruction, and all the other learning, to my sons, to the sons of my teacher, and to pupils who have signed the indenture and sworn obedience to the physicians' Law, but to none other.

I will use treatment to help the sick according to my ability and judgment, but I will never use it to injure or wrong them. I will not give poison to anyone though asked to do so; nor will I suggest such a plan. Similarly I will not give a pessary to a woman to cause abortion. But in purity and in holiness I will guard my life and my art. I will not use the knife on sufferers from stone, but I will give place to such as craftsmen therein.

Into whatsoever houses I enter, I will do so to help the sick, keeping myself free from all Intentional wrong-doing and harm, especially from fornication with woman or man, bond or free.

Whatsoever in the course of practice I see or hear (or even outside my practice in social intercourse) that ought never to be published abroad. I will not divulge, but will consider such things to be holy secrets.

Now if I keep this oath and break it not, may I enjoy honor, in my life and art, among all men for all time; but if I transgress and forswear myself, May the opposite befall me.

*The Oath of Hippocratic has been the most enduring of all medical oaths and today is still an inspiration to those who have dedicated themselves to the medical profession. An illustration of Hippocrates and his Oath, taken from a 14$^{th}$ century Greek Manuscript, is found in the Bibliotheque National Paris

***The Chinese Code of Sun Ssu – mais*- (7th Century, A.D.)***

"Aristocrat or commoner, poor or rich, aged or young, beautiful or ugly, friend or enemy, native or foreigner, educated or uneducated, all are to be treated equally"

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*Spicker, Sf and Engelhardt, HT (ed.) 1977. Philosophical Medical Ethic: Its Nature and Significance. In Proceeding of the Third Trans – disciplinary Symposium, pp. 30, D. Reidal Publishing Company, Dordrecht – Holland/Boston, USA.

## *The Declaration of Geneva* (1971)*

I solemnly pledge myself to consecrate my life to the service of humanity;

I will give to my teachers the respect and gratitude which is their due;

I will practice my profession with conscience and dignity;
The health of my patient will be my first consideration;

I will respect the secrets which are confided in me, even after the patient has died;

I will maintain by all the means in power, the honor and the noble traditions of the medical profession;

My colleagues will be my brothers;

I will not permit considerations of religion, nationality, race, party politics or social standing to Intervene between my duty and my patient;

I will maintain the utmost respect for human life from its beginning even under threat and I will not use my medical knowledge contrary to the laws of humanity;

I make these promises solemnly, freely and upon my honor.

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*This is the first International Code of Medical Ethics drawn by the World Medical Association as a modern version of Hippocratic Oath. It was amended by the 22nd World Assembly, Sydney Australia in August 1968 and the 35th World Medical Assembly, Venice, Italy in October 1983.

## *The Declaration of Lisbon on the Rights of Patients* (1981)*

The patient has the right to choose his physician freely.

The patient has the right to be cared for by a physician who is free to make clinical and ethical judgments without any outside interference.

The patient has the right to accept or to refuse treatment after receiving adequate information.

The patient has the right to expect that his physician will respect the confidential nature of all his medical and personal details.

The patient has the right to die in dignity.

The patient has the right to receive or to decline spiritual and moral comfort including the help of a minister of an appropriate religion.

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*This Declaration was adopted by the World Medical Association in 1981, in Lisbon, Portugal.

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***The Declaration of Tokyo on Torture and other Cruel, Inhuman or Degrading Treatment or Punishment* (1975)***

The doctor shall not countenance~ condone or participate in the practice of torture of other forms of cruel, inhuman or degrading procedures, whatever the offence of which the victim of such procedures is suspected, accused or guilty, and whatever the victim's beliefs or motives, and in all situations, Including armed conflict and civil strife.

The doctor shall not provide any premises, instruments, substances or knowledge to facilitate the practice of torture or other forms of cruel, Inhuman or degrading treatment or to diminish the ability of the victim to resist such treatment.

The doctor shall not be present during any procedure during which torture or other forms of cruel, inhuman or degrading treatment is used or threatened.

A doctor must have complete clinical Independence in deciding upon the care of a person for whom he or she is medically responsible. The doctor's fundamental role is to alleviate the distress of his or her fellow men, and no motive, whether personal, collective or political, shall prevail against this higher purpose.

Where a prisoner refuses nourishment and is considered by the doctor as capable of forming an unimpaired and rational judgment concerning the consequences of such a voluntary refusal of nourishment, he or she shall not be fed artificially. The decision as to the capacity of the prisoner to form such a judgment should be confirmed by at least one other independent doctor. The consequences of the refusal of nourishment shall be explained by the doctor to the prisoner.

The World Medical Association will support and should encourage the international community, the national medical associations and fellow doctors. To support the doctor and his or her family in the face of threats or reprisals resulting from a refusal to condone the use of torture or other forms of cruel" inhuman or degrading treatment.-

*In 1975 the World Medical Association, at its meeting in Tokyo, Japan, adopted the above Declaration in relation to torture, cruel and inhuman or degrading treatment or punishment

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# GLOSSARY

The definitions provided within this glossary apply to terms as they are used in this document. The terms may have different meanings in other contexts

**Assent** - affirmative agreement of a subject/participant

**Beneficence –** literally, “doing good”. Doctors are expected to act in the best interest of their patients.

**Bioethics/Biomedical ethics –** the study of moral issues that occur in medicine, health care and biological sciences.

**Confidentiality**- prevention of an authorized disclosure of private information that has been collected from being shared with others.

**Clinical trial/study** –any investigation in human subjects intended to discover or verify the clinical, pharmacological and/or other pharmacodynamic effects of an investigational product(s) and/or to identify any adverse reactions to an investigational product (s). and/or to study absorption , distribution, metabolism, and excretion of an investigational product(s) with the object o ascertaining its safety and efficacy. The terms clinical trial and study are synonymous.

**Informed consent** – a process by which a potential participant voluntarily confirms his or her willingness to participate in a particular research after having been informed of all aspects of the study that are relevant to the participants decision to participate. Informed consent is documented by means of a written, signed and dated informed consent form.

**Justice –** fair treatment of individuals and groups

**Legally authorized representative –** an individual or juridical or other body authorized under applicable law to consent on behalf of a prospective participant, to the subjects’ participation in a study.

**Minor –** children, legally have not attained the age where they can grant consent for research or treatment.

**Non-maleficence –** literally, “not doing wrong”. Doctors and researchers are to avoid inflicting harm on patients and research participants.

**Participant** - An individual who participates in a research project, either as the direct recipient of an intervention, as a control, or through observation. The individual may be a healthy person who volunteers to participate in the research, or a person with a condition unrelated to the research carried out who volunteers

to participate, or a person (usually a patient) whose condition is relevant to the use of the study product or questions being investigated.

**Protocol** - A document that provides the background, rationale, and objective(s) of a research project and describes its design, methodology, and organization, including ethical and statistical considerations.

**Vulnerable group** - those groups that may contain some individuals who have limited autonomy, i.e. they cannot give informed consent. Such groups include children, some mentally incapacitated, individuals with dementia and other cognitive disorders, prisoners etc.