

# REVIEW

## MEDICAL ETHICS 1 Guidelines for Research

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Ethics is a system of morals, rules of behaviours, treatise on morals. Ethical is relating to morals, the science of Ethics, professional standard of conduct, relating to or in accord with approved moral behaviour <sup>1</sup>.

Research guidelines for humans have been established many years ago. This presentation is a review of the most important development in the field of human research.

Post World War II the Western Governments and the United States have invested heavily in the field of Bio-medical research. Thinking, and rightly so, that this kind of research will yield and will give results.

### 1950

Because of the heavy investment of the United States and the Western Governments in research, there were results, but along with that some abuses and the first one to point it out is Dr. Joseph Fletcher from United States, when he wrote a book titled "Medicine and Morals" <sup>2</sup>, but the book fell on deaf ears. Joseph Fletcher was not alone in his trial, after 30 years (1981) I have written a booklet on proposed code of ethics of the Medical Profession <sup>3</sup> and that one too, fell on deaf ears.

### 1960

1960's prenatal diagnoses and genetic screening were developed <sup>4</sup>. With it research had developed. Is

it Ethical to advise termination of pregnancy based on prenatal diagnosis? Is it advisable? Is it ethical to advise against marriage because of mismatch during genetics screening?

1960's was the birth of organ transplants and vast amount of abuses as well. In mid 1960 the first heart transplant was done by Christian Bernard. Most of the old civilization considered the heart as the centre of the soul. It even took some nations about 25 or 30 years to legalise the heart transplant.

1960's we were surprised by being asked the definition of death. Therefore it was necessary to include ECG, EEG and clinical data in order to certify death. Care of dying came under bombardment from the public because many researches have been done on terminally ill patients. Dr. Beacher of United States and Dr. Papworth of Great Britain exposed some of the bio-medical research abuses <sup>2</sup> and because of that, the Medical Research Council drew up fundamental guidelines in research involving the human subjects <sup>5</sup>. It is important to read and review these documents because some of us are going to be indulged in research involving human subjects.

1964 we witnessed the declaration of Helsinki by the World Medical Association<sup>6</sup>. That declaration amounts to the declaration of the independence of the United States in 1776 and the declaration of the rights of man and citizens in 1789 of the French Revolution. The World Medical Association had two declarations, one in Geneva which deals with

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the modifications of the hippocrate oath, and the other in Helsinki which deals with human experimentation and the latter is divided into three, basic principles of research, clinical research combined with the professional care and non-therapeutic clinical research.

1960's the Peer Review Committee by the Surgeon General of United States was established <sup>5</sup>. The committee is in response to the abuse in research. This committee approves grant, withdraws it, or stops it, if it feels that there are some abuses.

### 1970

Non-therapeutic research was highlighted in the lay and professional media. Is it ethical to subject a healthy human being to non-therapeutic research and most of these people were prisoners and medical students. It is agreed now that more than minimal risk in non-therapeutic research is unethical.

In the 70's, most of the Western and American Medical Schools started to teach ethics. Unfortunately, no information is available about teaching Medical Ethics in the Middle East Medical Colleges.

In the 70's we witnessed the patient's rights and autonomy, doctor-patient relationship <sup>2</sup>. In response to that, doctors adopted a defensive medicine, either it is positive making use of unnecessary diagnostic or therapeutic measures, primarily to protect themselves, in case things go wrong, or negative avoiding potentially effective measures because an adverse outcome might place them in a vulnerable position. Here in Bahrain some of us are already practising defensive medicine, because of the lay media which strive on attacking medical establishments and individuals, for example, a patient who have soft tissue injury of the nose, usually have an X-ray of the nasal bones. This X-ray will serve nothing, except to protect the doctor when he is dragged to court.

1974 we witnessed the National Commission for the protection of human subjects in United States <sup>2</sup>. Due to the vast development between 1964 and mid 70's, the World Medical Association reviewed the Helsinki declaration in Tokyo <sup>5</sup> in 1975.

1979 the Royal College of Physicians pioneered a Research Ethics Committee now attached to hospitals, universities and all Medical Research

Centres in U.K. No research will be allowed in any hospital without being approved by this committee.

1979 the President's Commission (USA) for the study of Ethical problems in Medicine, Bio-medical and Behavioural Research <sup>2</sup>.

In the 70's more than 20 centres of bio-medical ethics have been established in Western Europe and the same number in United States. <sup>2</sup>. Unfortunately there is no information about the availability of any centre in the Middle East which deals with Medical or Bio-medical Ethics. The Index Medicus <sup>2</sup> which is an essential source of information on medical writings and books, began to index ethics in 1970, which represented a significant change.

In the 70's lot of research has been done on a terminally ill patient or virtually dead patient due to severe accidents. These patients were kept on life support systems for many years, due to this the problem of the cost to the health service and the suffering of the families was highlighted and therefore the ethical question, who is going to switch these machines off? Once you put them on.

### 1980

In the 80's we were not satisfied with the word consent. We invented the word informed-consent. According to Chambers Dictionary inform means to impart knowledge, to tell, to direct, to give information to. It does not mean make them understand. Consent means, to agree, to get assent, to yield, to comply, to allow, accordance with actions or opinion of another. What is wanted really, by joining the two words of informed-consent? They actually want to understand, then agree, but informed-consent does not mean that. The problem of informed-consent appeared because of many abuses, for example, Mrs. Margaret Wigley <sup>7</sup> in United Kingdom. A lady, 83 yers old, who had surgery for cancer of the bowel. She was entered into randomized controlled trial. Given fluouracil without her knowledge or consent, after one month she died due to bone marrow depression caused by the fluouracil. This case has created a public uproar to the extent that Carolyn Faulder<sup>7</sup> has written a book entitled "Whose Body Is It?" Therefore, we can see why in United States they had established uniform requirements for informed consent in early 1980.