OPINION

INTERNATIONAL ETHICAL GUIDELINES FOR BIOMEDICAL RESEARCH INVOLVING HUMAN SUBJECTS

Medical scientific writing is most often the logical sequence of Biomedical research involving human subjects. Biomedical research should be conducted in an ethical way. The term "research" refers to a class of activity designed to develop or contribute to generalized knowledge. Ethical principles about biomedical sciences was first introduced by the World Medical Association and was set forth in the *Declaration of Helsinki in 1964*.

The *Declaration of Helsinki* is the *fundamental document* in the field of ethics in biomedical research. Revisions and updating gradually were necessary, related to human rights as research subjects, as well as of health professionals as researchers. Adopted in 1964 in Helsinki Finland, it was first amended in 1975 in Tokyo, later revisions were made in Italy 1983 and in Hongkong 1989. The Declaration of Helsinki has influenced the formulation of many international codes of conduct.

CIOMS (Council for International Organizations of Medical Sciences) in 1993 published *CIOMS - Guidelines*. The *WHO* in *1995* made *Guidelines for Good Clinical Practice*. In *2002* in Geneva the *CIOMS in collaboration with the WHO* prepared the "*International Ethical Guidelines for Biomedical Research involving, Human Subjects*." The latter has far-reaching consequences as the guidelines should be adopted by all countries, as the name already said International Ethical Guidelines. Hence, Biomedical Research involving human subjects when performed **not** in accord with these guidelines is considered not ethical, resulting in an unethical medical scientific report and writing. Ethical justifications and scientific validity goes hand-in-hand.

Cases of Biomedical Research involving human subjects should follow the International ethical guidelines. There are 21 guidelines to follow:

The Guidelines

Guideline	1	:	Ethical justification and scientific validity of biomedical research involving human beings
Guideline	2	:	Ethical review committees
Guideline	3	:	Ethical review of externally sponsored research
Guideline	4	:	Individual informed consent
Guideline	5	:	Obtaining informed consent : Essential information for Prospective research subjects
Guideline	6	:	Obtaining informed consent : Obligation of sponsors and Investigators
Guideline	7	:	Inducement to participate
Guideline	8	:	Benefits and risks of study participation
Guideline	9	:	Special limitations on risk when research involves individuals who are not capable of giving informed consent
Guideline	10	:	Research in populations and communities with limited resources
Guideline	11	:	Choice of control in clinical trials
Guideline	12	:	Equitable distribution of burdens and benefits in the selection of groups of subjects in research
Guideline	13	:	Research involving vulnerable persons
Guideline	14	:	Research involving children
Guideline	15	:	Research involving individuals who by reason of mental or behavioral disorders are not capable of giving adequately informed consent
Guideline	16	:	Woman as research subjects
Guideline	17	:	Pregnant women as research participants
Guideline	18	:	Safeguarding confidentiality
Guideline	19	:	Right of injured subjects to treatment and compensation
Guideline	20	:	Strengthening capacity for ethical and scientific review and biomedical research
Guideline	21	:	Ethical obligation of external sponsors to provide healthcare services

Nanizar Zaman-Joenoes
Department of Medical Pharmacy
Airlangga University School of Medicine