Helsinki Declaration

**World Medical Association Declaration of Helsinki**

It was adopted at the 18th DTB General Assembly held in Helsinki in June 1964 and later on Changes have been made in the following General Assemblies:

29th DTB General Assembly, Tokyo, Japan, October 1975

35th General Assembly of the State Congress, Venice, Italy, October 1983

41st DTB General Assembly, Hong Kong, September 1989

48th DTB General Assembly, Somerset West, Republic of South Africa, October 1996

52nd DTB General Assembly, Edinburgh, Scotland, October 2000

53rd DTB General Assembly, Washington DC, USA, October 2002 (Explanatory note attached)

55th DTB General Board, Tokyo, Japan, October 2004 (with disclosure note)

59th DTB General Assembly, Seoul, Korea Republic, October 2008

64th TFB General Assembly, Fortaleza, Brazil, October 2013

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1. The World Medical Association (DTB) Declaration of Helsinki, identifiable human material and data A set of ethical principles relating to medical research on humans, including prepared as an explanation. The Declaration should be read and understood as a whole, each paragraph it contains should be interpreted with all other It should be applied together.
2. The 2nd Declaration is directed primarily towards physicians, consistent with the mandate of the WMA. However, DTB Encourage others involved in medical research to adopt these principles. is

General Principles

3. The WMA Geneva Declaration physician said, "My patient's health will be my first priority", The International Rules of Medical Ethics, on the other hand, “A physician should consider the best health service will present ”.

4.Observation of the health, well-being and rights of patients, including those involved in medical research. and its safeguarding is the physician's duty. The physician's knowledge and conscience instead of this duty should be dedicated to the introduction.

5. Medical progress depends ultimately on research, including studies on humans.

6. The main purpose of medical research on people is the causes of diseases, understanding its development and effects; Prevention, diagnosis and treatment interventions (methods, processes and applications). Even the most valid attempts in terms of safety, effectiveness, efficiency, accessibility and quality. need to be evaluated

7.Medical research promotes respect for all people under investigation, their health and It is subject to ethical standards that protect their rights.

8.While the primary purpose of medical research is to produce new knowledge, this aim has never been It cannot be excluded from the individual rights and benefits of the people involved.

9.The life, health, dignity, personality integrity of the persons investigated on UZ to protect the right to make a decision, his private life and the confidentiality of his personal information, medical It is the duty of the physicians involved in research. Protection of persons investigated on UZ The responsibility should always belong to the physician and other healthcare professionals, and they consent to this. This burden should never be left to those on whom research has been conducted, even if they have given them.

10. Physicians, in their own country, apply ethical, legal and legal principles to research using people. In addition to regulatory norms and standards, relevant international norms and standards are also taken into account. should receive. Any national or international ethical, legal or administrative requirement, should not undermine the protective measures provided by this Declaration to people used in research or eliminate it.

11. Medical research should be conducted in a way that minimizes potential harm to the environment.

12. Medical research involving people should only have adequate education in terms of ethics and science, It should be done by people who are educated and qualified. On patients or healthy people The researches to be conducted shall be made by a competent and qualified physician or health worker. should be carried out under the control.

13. Required for participation in researches for groups underrepresented in medical access should be provided.

14. Physicians conducting medical research and health services together can only In cases where it may be of safe or therapeutic value, and It is reasonable that the health of the patients taken will not be adversely affected by this situation. They should include their patients in their research if they have justifications.

15. Appropriate compensation and treatment for people who have been harmed by taking part in a trial. provision should be secured.

Risks, Burdens and Benefits;

16. In medical practice and medical research, most interventions carry risk and burden.

Medical research on people, however, is important to the significance of the purpose should be done when people outweigh the risks to be exposed and the loads they will be taken

17. Prior to all medical research conducted on people, the persons involved in the research and the predictable risks and burdens for the groups should be carefully evaluated; these risks and and other factors affected by the disease or agent under investigation. the decision by comparing the benefits individuals or groups can gain from the research should be given.

Precautions should be taken to keep the risks to a minimum. Risks are constantly monitored by the investigator. should be monitored, evaluated and recorded.

18. Physicians should note that the risks have been adequately assessed and that they are They are involved in researches on people unless they believe they can be managed. they should not take. Where the risks seem to outweigh the potential benefits, or to conclusions. When sufficient evidence is obtained, physicians may continue to work, change or change the study. should immediately consider stopping options.

Vulnerable Groups and People;

19. Some groups and individuals are particularly vulnerable and these groups and individuals They may be more likely to be abused or additional harm by researchers. Special protection should be given to all vulnerable groups and individuals.

20. Medical research with a vulnerable group may only be health needs or priorities, and research in this position. In cases where it is not possible to do it with another group, it can be justified. Additional As a matter of fact, the subject group is based on information obtained from research, practices or should be able to benefit from initiatives.

Scientific Requirements and Research Protocols;

21. Medical research on human beings must comply with generally accepted scientific principles. must be; a complete knowledge of scientific literature, other relevant information sources, adequate laboratory It should be based on its possibilities and, where relevant, animal testing. Animals used in research care should be taken to ensure well-being.

22. The design and implementation of every study, including people, is included in the research protocol. it should be clearly stated and justified. A statement about the ethical aspects of the research should be included in the prepared protocol and this It should be stated how the principles in the Declaration are observed. In the protocol; the financing provided, research will be conducted on sponsors, institutional connections, potential conflicts of interest the benefits provided to individuals and those who have suffered damage due to their participation in the research Information on treatment and / or compensation should be included. When it comes to clinical trials, the protocol is also should also define relevant appropriate regulations

Research Ethics Committees;

23. The trial protocol should be evaluated, commented, It should be submitted to the relevant research ethics committee for review and approval. In the functioning of this board it should be transparent; independent of researcher, promoters or any other external influence must remain and meet the qualifications required for evaluation. The Board, the relevant international norms and as well as the laws and regulations of the country or countries where the research will be conducted. but not to those on whom research has been conducted by this Declaration. It should not be allowed to undermine or eliminate the protections provided.

The committee should have the right to monitor ongoing work. The researcher is particularly It should submit monitoring information to the Board, especially any serious negative consequences. No changes should be made to the protocol without the review and approval of the Board. Of study At the end, the researchers submit a report containing the findings and results of the study to the Board. they must present.

Private Life and Privacy;

24. Protecting the private life and confidentiality of personal information of people used in research All kinds of precautions should be taken.

Informed consent;

25. Participation of people with the competence to give informed consent to the research, voluntariness should be on the basis. Consulting family members or community leaders Even if appropriate, anyone capable of giving informed consent, should not be included in the research.

26. In medical research to be carried out on persons who have the competence to give informed consent, each potential participant, research objectives, methods, sources of funding, potential interest institutional connections of the researcher, expected benefits and potential of the study. risks, inconveniences, actions to be taken after the research and other It should be properly illuminated about its directions. Participant candidate; any later refuse to take part in the study or consent at any time that he has the right to withdraw. These persons individually Particular attention should be paid to information requirements and lighting methods.

After making sure that the participant candidate has grasped the information provided, another qualified person, preferably in writing, of the participant candidate's own free will. must obtain the informed consent to give. If the consent is not possible in writing, Unwritten consent must be formally documented in the presence of witnesses.

To everyone who is used in medical research, about the overall output and results of the study the option to be informed should be offered.

27. While the physician obtains informed consent from the persons to be used in a study, the whether he has an addictive relationship with him or whether his consent was unintentionally given with a certain obligation. should pay particular attention to issues as not given. Informed consent in such cases, this Must be taken by someone who has the appropriate qualifications, wholly outside of such relationships

28. In the case of a candidate who is not qualified to give informed consent, the physician must obtain consent from the legal representative of this person. By the candidate of the research participant observing the health benefit of a represented group, the same research is It is not possible to conduct the research with people who are qualified to consent and Consent, except where only minimal risk and burden conditions are met Research should not be done on individuals who are not qualified to give

29.A candidate candidate who is evaluated to be unable to give informed consent If the physician is able to disclose his opinion, the physician may should also take into account. Respect for the prospective participant's view not to participate in the study should be seen.

30.The ability to give physically and mentally informed consent such as unconscious patients Research on nonexistent individuals can only If the mental state is an obligatory feature of the research group, it can be done. So In cases where the physician must obtain the informed consent of the legal representative. If the patient is legal if there is no representative and the investigation is postponed; competence to give informed consent Special reasons for research on non-existent individuals Provided that it is specified in the protocol and the research is approved by a research ethics committee, research can be done without obtaining informed consent. In such a case, the shortest possible In the course of time, the request from the patient or legal representative to stay in the trial informed consent should be obtained.

31.The physician informs the patient exactly what aspects of his treatment are should be well lit. If a patient does not want to participate in the study or Deciding to withdraw from the study does not negatively affect the patient-physician relationship in any way. should not affect.

32. Such as material or data held in bio-banks or similar medical research using identifiable human material or data physicians, their collection, storage and / or reuse must obtain informed consent. Consent for such studies is impossible or There may be some exceptional situations that are very difficult to realize. In such cases, research, It can only be done upon the review and approval of the research ethics committee.

Use of Placebo;

33.The benefits, risks, burdens and effectiveness of a new medical intervention, the following situations Besides, it should be tried against the best proven method: In the absence of proven intervention, use of placebo or no intervention absence is acceptable;

or

Using a less effective intervention than the best proven method or placebo the effectiveness or safety of an enterprise, using or not taking any action. convincing and scientifically sound procedural justifications that it is necessary to determine when found and less effective intervention than the best proven method or placebo given or no intervention depends on the best proven intervention if they cannot suffer additional serious or return damage. Care should be taken to ensure that this option is not used badly.

Post-Research Provisions;

34. Before a clinical trial; supporters, researchers and host country governments, After the research, all participants had interventions that were found to be useful during the trial. also make arrangements that will ensure their access. This information is given to the participants, informed consent. should be explained in the process of taking.

Registration of Research, Publication and Dissemination of Findings;

35. Any research to be conducted on people should be made public before the first participant is admitted to the study. must be saved in an open database.

36. All researchers, authors, sponsors, editors and publishers It has ethical obligations to publish and disseminate its results. Researchers' task is to make the results of their research on people public and the completeness and accuracy of its reports on this matter. your responsibility. General acceptance in observance of ethical rules in the research report. must adhere to the guidelines that see. Negative and inadequate results as well as negative consequences it should be published or made available to the public in some other way. On the air, funding sources, institutional connections and conflicts of interest should also be indicated. Specified in this Declaration Research reports that do not comply with the principles should not be accepted for publication.

Use of Unproven Interventions in Clinical Practice

37. An operation where no proven initiative has been found or other known attempts have been ineffective. In the treatment of the patient, the physician, after taking the expert opinion, the patient or his legal representative With his informed consent, he can save lives, restore health or suffer He may take an initiative that he thinks can mitigate that has not yet been proven. Such an initiative then, the research subject should be made in terms of its safety and effectiveness. In any case, new The information should be recorded and made available to the public when appropriate.