AMENDMENTS AND ADDITIONS TO THE WORLD MEDICAL ASSOCIATION DECLARATION OF HELSINKI "ETHICAL PRINCIPLES FOR MEDICAL RESEARCH INVOLVING HUMAN PARTICIPANTS" [1]

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The current version of the Declaration of Helsinki, adopted at the 75th General Assembly of the World Medical Association in October 2024, represents a significant step forward in the updating one of the basic international documents defining fundamental approaches to regulating medical research involving humans. The amendments and additions to the Declaration reflect the task of ensuring compliance of ethical principles of medical research with real research practice. For 60 years, the Declaration of Helsinki has maintained its importance as an ethical guide upholding the humanistic principles of medical research, motivating the professional medical community to cooperate and consolidate in the prevention of risks to humans, following the interests of science and society.

Key words: the Declaration of Helsinki, World Medical Association, medical research involving humans, ethical principles, bioethics

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ИЗМЕНЕНИЯ И ДОПОЛНЕНИЯ К ХЕЛЬСИНКСКОЙ ДЕКЛАРАЦИИ ВСЕМИРНОЙ МЕДИЦИНСКОЙ АССОЦИАЦИИ «ЭТИЧЕСКИЕ ПРИНЦИПЫ МЕДИЦИНСКИХ ИССЛЕДОВАНИЙ С УЧАСТИЕМ ЛЮДЕЙ» [1]

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Принятая на 75-й Генеральной ассамблее Всемирной медицинской ассоциации, проходившей в октябре 2024 г., действующая редакция Хельсинкской декларации стала новым этапом процесса актуализации одного из базовых международных документов, определяющих принципиальные подходы к регламентации медицинских исследований с участием человека. Внесенные в текст Декларации изменения и дополнения отражают задачу обеспечения соответствия этических принципов проведения медицинских исследований реальной исследовательской практике. Хельсинкская декларация в течение 60 лет сохраняет свое значение этического руководства, отстаивающего гуманистические принципы медицинских исследований, оставаясь примером стремления профессионального медицинского сообщества к взаимодействию и консолидации в вопросах предупреждения рисков для человека, следования интересам науки и общества.

Ключевые слова: Хельсинкская декларация, Всемирная медицинская ассоциация, медицинские исследования с участием человека, этические принципы, биоэтика

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In October 2024, the 75th General Assembly of the World Medical Association (WMA General Assembly, Helsinki, Finland) unanimously adopted a new version of the Declaration of Helsinki. The history of this document dates back 60 years ago since adoption of its first version in June 1964 (18th WMA General Assembly, Helsinki, Finland) [1].

The 11th edition of the Declaration of Helsinki was the result of a long-term open discussion, analysis of expert assessments and public opinion, including the position of experts in bioethics.

Previously, revised versions of the document were adopted by the General Assembly of the World Medical Association in 1975 (29th WMA General Assembly, Tokyo, Japan), 1983 (35th WMA General Assembly, Venice, Italy), 1989 (41st WMA General Assembly, Hong Kong), 1996 (48th WMA General Assembly, Somerset West, Republic of South Africa), 2000 (52nd WMA General Assembly, Edinburgh, Scotland), 2022 (53rd WMA General Assembly, Washington DC, USA), 2024 (55th WMA General Assembly, Tokyo, Japan), 2008 (59th WMA General Assembly, Seoul, Republic of Korea) and 2013 (64th WMA General Assembly, Fortaleza, Brazil, October 2013) in addition to the first edition of 1964.

The changes to the Declaration consistently made by the international medical community have served and continue to serve the task of ensuring that the ethical principles of conducting medical research with human participation comply with current research practice.

Taking into account the overall increase in the volume of the Declaration of Helsinki in the 2024 edition compared to previous versions, several changes in its provisions can be noted, which are the most significant from the point of view of the evolution of approaches to the regulation of medical research.

1. The list of specialists (participants) to whom the Declaration is addressed and the regulatory nature of the document have been clarified and expanded (paragraph 2). In the 2013 edition, it was stated that "The Declaration is addressed primarily to doctors. The BMA encourages others involved in medical research with humans as

subjects to follow these principles." In the current version, this paragraph is as follows: "Despite the fact that the Declaration was adopted by doctors, the BMA believes that the principles set out herein should be followed by all individuals and organizations involved in medical research, since they are fundamental to respecting the interests of all research participants, including patients and healthy volunteers."

2. In the 2024 edition, the term "human subjects" was replaced by "human participants". The definitions of "a person as a subject" are excluded from paragraphs 1 and 5.
3. Along with the concept of "individual health", the categories of "public health" (paragraph 7) and "public healthcare" (paragraph 8) are fixed.
4. Paragraph 8 includes the requirements for compliance with ethical principles "in case of emergency situations in the field of public health."
5. Paragraph 11, which previously defined that "medical research should be conducted in such a way as to minimize possible harm to the environment," is worded as follows: "Medical research should be designed and conducted in such a way as to avoid or minimize harm to the environment and ensure environmental sustainability."
6. Paragraph 12 has been supplemented with the following provision: "Scientific integrity is important when conducting medical research involving humans. They include individuals, teams, and organizations should never allow misconduct against them."
7. Paragraphs 19 and 20 have been expanded to define the concepts of "individual, group and social vulnerability".
8. In paragraph 21, the requirement "to show humanity towards animals used in research" has been replaced by the following provision: "It is necessary to ensure the safety of animals used for research."
9. The term "Ethics Committees" has been clarified as "Research Ethics Committees". Their functionality has also been clarified (paragraph 23):
   [The Committee] "should take into account the laws and regulations of the country or countries in which the research is planned, as well as relevant international norms and standards, which, however, should not detract from or cancel the measures for the protection of research subjects established by this Declaration" (2013);
   "The Committee should be sufficiently familiar with the local conditions and environment, and it should include at least one representative of the general public. At the same time, it is necessary to take into account the ethical, legal and regulatory norms and standards of the country or countries in which the study is planned to be conducted, as well as international norms and standards, but they should not be allowed to contradict any measures for the protection of research participants set out in this Declaration" (2024).
10. The concept of "Informed consent" (paragraphs 25–27) has been expanded to "Voluntary and informed consent".
11. Paragraph 27 has been expanded as follows: "Upon obtaining informed consent to participate in a study, a doctor or another researcher …" (see also paragraph 12: "Such a study requires supervision of a competent and appropriately qualified doctor or another specialist").
12. Paragraph 32 is supplemented by the provision on the need to follow the rules of WMA Declaration of Taipei (2016) while collecting and storing data or biological samples, 'including the rights of individuals and principles of management' which corresponds to the present principles of personalized medicine. The terms 'data bases and biobanks' have been introduced. Their creation and control of regular use are regulated by Research ethics committees.
13. Paragraph 34 sets the need for preliminarily organized control of results after completion of a clinical trial.
14. Paragraph 37 ("Unproven interventions in clinical practice") has been supplemented with the following requirement: "Doctors involved in such interventions should seek the advice of a specialist, weigh the possible risks, difficulties and benefits and obtain informed consent. They should also log and share data when appropriate, and avoid compromising clinical trials. In no case should these interventions be undertaken to circumvent the protection measures for research participants set out in this Declaration".

The changes in the provisions of the Declaration of Helsinki reflect a consistent confirmation of the basic ethical principles of research involving humans, fixing current requirements for improving safety and risk prevention of all research participants. Undoubtedly, the process of updating the provisions of the Declaration will continue in the context of the emergence and actualization of new ethical issues of technological development [2].

CONCLUSIONS

The development of modern clinical research, especially research involving humans, taking into account the growing technological possibilities of introducing research results into practice requires constant updating of regulatory norms and requirements concerning all participants in the process [3]. For 60 years, the Declaration of Helsinki has maintained its status as a fundamental document developed and updated by the World Medical Association in order to consolidate and clarify ethical regulations for conducting research with human participation. The 11th edition of the Declaration, adopted in October 2024, was the result of a long-term analysis of expert and public opinion, reflecting the willingness of all stakeholders to engage in a constructive and productive dialogue.

In modern bioethical discourse, the Declaration of Helsinki remains not only the most important international document aimed at regulating medical research, but also one of the most significant examples of the professional community's desire to improve interaction and consolidation for the benefit of man in the interests of science and society.

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