ETHICS IN MEDICAL RESEARCH AND PUBLICATIONS

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The purpose of this study is to examine the existing ethical standards and guidelines to provide a comprehensive overview of ethical issues and processes related to research and publications in domestic and international medical practice. The importance of informed consent, data integrity, plagiarism, authorship disputes, and conflicts of interest are just some of the key topics briefly covered in the article. It is obvious that ethical standards and regulations in medical (clinical) research are crucial for determining how research is conducted and how scientific articles are published.

Keywords: medical ethics, research, publications, medical law, academic dishonesty

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ЭТИКА В МЕДИЦИНСКИХ ИССЛЕДОВАНИЯХ И ПУБЛИКАЦИЯХ

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Целью данного исследования является изучение существующих этических норм и руководящих принципов для предоставления всестороннего обзора этических вопросов и процессов, связанных с исследованиями и публикациями в отечественной и международной медицинской практике. Важность информированного согласия, целостности данных, наличие плагиата, споров об авторстве и конфликтов интересов — вот лишь некоторые из ключевых тем, кратко затронутых в статье. Очевидно, что этические нормы и правила в медицинских (клинических) исследованиях, имеют решающее значение для определения того, как проводятся исследования и как публикуются научные статьи.

Ключевые слова: врачебная этика, исследования, публикации, медицинское право, академическая недобросовестность

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Dictionary of the Russian language by Ozhegov SI and Shvedov NYu (1997) states that ethics is the philosophical study of moral phenomena, its development, principles, norms, and role in the society [1, 2]. In turn, the Oxford Dictionary (1989) provides a similar definition of ethics as moral principles that govern human behavior, or a whole system of moral principles and rules of conduct [3]. As the definitions state, ethics includes people and their actions. In biomedical fields, the people involved in research are researchers, whereas the subjects they research and the actions involved are associated with how the researchers design, execute, analyze, report, and distribute research results to colleagues and general public for benefit [4].

Researchers execute various roles as team leaders, team members, authors, contributors, reviewers, and editors, and interact with publishers at different points of their research activity. Other people, fabrics, materials, machines and devices, and/or software (including artificial intelligence, robots, and ChatGPT) can be subjects of research [5].

Thus, ethics in research means a complex interaction of researchers, subjects, devices, authors, editors, reviewers, and publishers. All of them have their own role in obtaining the research result. Ethics in research is an essential element of the scientific process and is crucial for integrity and reliability of the research results.

FORMATION OF ETHICS IN MEDICAL RESEARCH

Ethics in research originates from the Second World War. The Nuremberg Code was developed in August 1947 as a result of the horrors that Nazi doctors committed in the name of scientific research. The Code provided a list of moral principles or ethical principles for conducting medical experiments on humans. These included the need for a preliminary animal experiment as the basis for research, voluntary informed consent of people to participate in the research, and avoidance of unnecessary suffering of test subjects.

At the 18th General Assembly in 1964, the World Medical Association (WMA) developed the Helsinki Declaration, which sets out guidelines for medical research involving human participants as subjects. It was amended nine times, most recently at the

64th General Assembly in Brazil in October 2013 [6]. In the United States, the Belmont Report (1979) identified three basic principles that guide research involving people as subjects, which include respect for the individual, charity, and justice. Respect for the individual requires that researchers treat research participants as people who have a right to make decisions about their own lives [7]. It includes voluntary participation, informed consent, confidentiality, and well-being of participants.

Codes of research ethics are a set of principles, guidelines, and standards that provide guidance for research ethical and responsible conduct. Various guiding principles for ethical research have been developed at the international and national levels, including the ones from the World Health Organization (WHO), the International Council for Harmonization (ICH, 1990), and the Ministry of Health of the Russian Federation. They were as follows: the Code of Professional Medical Ethics of the Russian Federation (2012), the Procedure for Organizing and Conducting Ethical Expertise (2024), guidelines of the Ministry of Health and the United States Department of Human Services (HHS) and the Indian Medical Research Council (ICMR), etc. The essence of these guidelines is to protect the interests of research subjects, especially vulnerable groups, minimize harm and risk, and regulate research in order to conduct legitimate and high-quality research [4].

ETHICAL RESEARCH IN RUSSIA

In Russia, the Ethics Committee of the Ministry of Health of the Russian Federation, a permanent body, has been established to protect the life, health and rights of patients who receive medical care as part of clinical testing of prevention, diagnosis, treatment and rehabilitation methods, as well as to review clinical testing protocols [8]. The Committee is guided by the Constitution of the Russian Federation, federal constitutional laws, and orders of the President and Government of the Russian Federation.

Local ethics committees (LECs) have been established in Russian universities and research institutes to monitor the quality of research and protect patients' rights. All research proposals in biomedical, behavioral sciences, or social research involving humans as subjects, including their biological materials and related data, must be reviewed and approved by LECs prior to starting the project. These committees should follow the guiding principles of the Helsinki Declaration, other relevant ethical codes and orders of local and international law.

In all higher medical institutions of Russia, “bioethics” is a mandatory discipline, where the search for options and solutions to controversial topics of Russian society in the field of medicine, law, ethics and science are discussed [9]. Some universities, such as MGIMO, offer educational programs in Publication Culture and Research Ethics. The Institute of Psychology, Sociology and Bioethics has been established at YSMU (Yaroslavl State Medical University), which is a modern scientific and educational platform for these programs. At Pirogov Russian National Research Medical University, Bioethics and Legislation in Biomedicine is a mandatory part of Biomedicine.

Training in Bioethics is currently carried out in 44 universities of Russia.

ETHICS OF SCIENTIFIC PUBLICATIONS

To prepare a high-quality publication, researchers must follow reporting criteria for each research type. Guidelines published for each type of research are available. The roles involved in the publishing process include authors, reviewers, editors, and publishers, and each role has important contributions and responsibilities in the publishing process. Moreover, there are organizations that develop guidelines for maintaining ethics in publications and journals. The most notable ones include the International Committee of Medical Journal Editors (ICMJE), the Committee on Publication Ethics (COPE) and the World Association of Medical Editors (WAME). These organizations regularly develop guidelines on various issues related to each aspect of the publishing process, including developing ethics for authors, reviewers, editors, and publishers [7].

Ethical issues related to authors include authorship, plagiarism, fabrication and falsification of data, conflicts of interest, and data transparency [10]. The author comes into play when the research is completed and the manuscript starts being prepared. The research material is published when a suitable journal for publication is found and the manuscript is prepared according to the journal recommendations. Then the manuscript is sent to the editorial office of the journal, and we are patiently waiting the review results. It is necessary to be polite while communicating with the journal. When the manuscript is sent back for revision, the corresponding author must answer all the questions of the reviewers and editors, politely addressing them during the discussion. If the authors disagree with the reviewers, they should explain their position in a polite and reasonable way. It should be remembered that reviewers are experts in the field who have found time in their busy schedules to review and improve the manuscript. The corrected manuscript is being sent, and the decision of the editorial board of the journal is being awaited. After accepting the article, the author responsible for correspondence must promptly respond to the issuing (technical) editor of the journal to approve the proofreading before it is sent for publication. Since copyrights are transferred to the journal, the rights to distribute the article must be executed in accordance with the journal terms. The author must be aware of his rights regarding distribution of the published content [11].

In turn, the reviewer has a number of serious obligations during the review of a scientific research article. In each publication, checklists should be published for reviewers to evaluate the manuscripts including:

1) Compliance with the approved deadlines specified by the journal;
2) Providing an unbiased assessment of the manuscript;
3) Suggesting useful criticism to improve the article;
4) Compliance with ethical standards to ensure that the research was done in accordance with ethical standards, and the results are presented truthfully and accurately;
5) Confidentiality (the manuscript and its contents should not be disclosed to anyone who is not involved in the review process).

The scientific editor of the journal should not only communicate with the authors and control the review process, but also resolve any issues arising from misconduct of the authors or reviewers, as well as making appropriate decisions regarding a specific issue based on ethical principles.

CONSEQUENCES OF ETHICAL VIOLATIONS

Research misconduct is a serious problem. It can lead to misleading results that may affect scientific research and further research on the topic in the future. Misconduct is fabrication and falsification of data (deceptive use of statistics), or plagiarism during the proposal, execution, review, or reporting of a study [12, 13].

Fabrication and falsification of data directly threaten the goals of science, as such behavior leads to publication of erroneous results, which undermines the search for knowledge and truth. Although plagiarism does not imply publication of erroneous results, it indirectly threatens the goals of science, as it is a form of intellectual theft that negatively affects the social structure of science, undermining trust among researchers, creating hostility and resentment, and hindering career growth [7, 13].

Misconduct is any highly unethical behavior that threatens the integrity of science and can be clearly identified.

Conclusions. Ethics in medical research and publications plays a crucial role in establishing the authority and standard of scientific work. This study focuses on the key concepts of ethics that guide the publication process and various types of research. It also highlights the need for frameworks and guidelines for specific medical fields of clinical research.

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