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## THE ROLE OF MEDICAL-SCIENTIFIC RESEARCH ETHICAL COMMISSIONS IN THE PROTECTION OF HUMAN RIGHTS IN AZERBAIJAN

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**Abstract.** After gaining independence, the Republic of Azerbaijan has been carrying out a series of reforms to bring the Soviet socialist economic, political, legal and administrative system in line with advanced world standards, reconstruction and modern scientific bases, creating a legislative framework for all these processes.

The policy of transition from a totalitarian system to a democratic system, creating the foundations of a socially oriented market economy, ensuring social protection and protection of human rights, achieving serious national and spiritual unity had to go through difficult stages and be subjected to pressure from various political forces. In our opinion, the most difficult area in the implementation of social policy, which should provide everyone and everyone, is closely linked with the protection of public health, social protection and the creation of decent living conditions. Today, the world's best practices are being studied, the positive traditions formed over the years are being preserved, new technologies and management models are being tested, improved and applied to the new environment. At present, Azerbaijan is in the process of establishing ethical commissions for medical and scientific research to protect and ensure human rights, especially for patients rights. They need to be developed and a number of measures taken to ensure the sustainability of their work.

The main directions of the initial steps are to develop a strategic plan for the establishment and organization of ethical commissions in the country to ensure sustainable and systematic activities, to conduct a needs analysis with the participation of experts in the field of scientific research, researchers and members of the ethics commission. Providing trainings in accordance with the results of needs analysis, as well as training of trainers, preparation of scientific literature and materials, formation of methodological aids, increase of knowledge and skills of officials working in the field of ethics commissions, establishment of civil society institutions in the field of bioethics, public awareness there is a need to increase.

We hope that the activities and efforts of Azerbaijani health workers and lawyers in the field of bioethics, deontology, medical law and ethics will contribute to serious reforms in medicine and health in the country.

**Key words:** bioethics, law, human rights, research ethics committee, medical ethics committee, criminal legislation.

**Introduction.** Following the restoration of its independence, the Republic of Azerbaijan has undertaken consistent reforms aimed at aligning its economic, political, legal, and administrative systems with advanced global standards. These reforms have involved comprehensive restructuring and have been underpinned by modern scientific principles, with a corresponding legislative framework being developed to support these transformative processes.

The transition from a totalitarian regime to a democratic system, the establishment of a socially-oriented market economy, and the implementation of policies aimed at ensuring social protection and the safeguarding of human rights have proven to be complex and challenging. Among the most demanding aspects of social policy – whose overarching goal is to serve every individual and the population as a whole – is the protection of public health, the provision of social security, and the creation of dignified living conditions.

One of the most pressing and difficult issues in this context has been the replacement of the long-standing system of free healthcare services with alternative, high-quality medical services. The governance of the healthcare system, the establishment of private medical institutions, the adequate resourcing of public healthcare facilities, the appropriate remuneration and support for physicians

and medical personnel, and the proper regulation of patient-state relations continue to pose significant challenges in need of resolution.

Azerbaijan is actively studying best practices from leading countries, preserving long-established positive traditions, and experimenting with, refining, and implementing new technologies and management models. One of the emerging fields in this process is the establishment of ethical review committees for biomedical research, particularly aimed at protecting human rights, with a special emphasis on patient rights.

The commonly cited expression – “Today’s medical research is tomorrow’s quality healthcare” – aptly underscores the critical importance of biomedical research. The findings of such research contribute to the advancement of medicine and the provision of healthcare services better tailored to patients’ needs.

Medical research should be designed to benefit individual participants or particular population groups, or to expand existing knowledge in a given field. At the same time, it must ensure that participants or groups involved in research are not exposed to serious risks.

The dual imperative of facilitating the conduct of biomedical research while safeguarding the health and rights of research subjects makes adherence to international norms and standards indispensable. Key instruments in this regard include the Convention on Human Rights and Biomedicine (Oviedo Convention, 4 April 1997) adopted by the Council of Europe, the Declaration of Helsinki (1964) by the World Medical Association, and the International Ethical Guidelines for Health-related Research Involving Humans issued by the Council for International Organizations of Medical Sciences. (CIOM&WHO, 2016)

**Discussion.** An ethics committee is an institutional body that systematically and continuously monitors and applies the ethical dimensions of medical sciences, life sciences, and emerging health policies. Operating in accordance with both national and international standards, ethics committees ensure compliance with relevant regulatory frameworks, the needs of applicants, and the expectations of society.

The primary objectives of ethics committees include enhancing the credibility of healthcare, increasing public trust in medical institutions and physicians, preventing conflicts of interest in medical practice, ensuring adherence to ethical codes of conduct by healthcare professionals, and expanding public influence in evaluating the activities of medical practitioners. These goals are pursued through regular, interactive discussions. Ethics committees function as forums for dialogue rather than judicial bodies. It must be recognized that the presence of conflict within such committees is not inherently negative; on the contrary, in reaching decisions, these bodies must navigate and reconcile various conflicting principles and perspectives. (CDBI, 2011)

The protection of public health is a fundamental responsibility of both the state and society. In fulfilling this social mission, the physician’s professional role and moral stance are of paramount importance.

Ethics committees may issue opinions on whether research is conducted, monitored, or terminated in accordance with ethical principles and rules. These committees represent organizational structures where value-based dilemmas arising in practice are identified, discussed, and addressed. Their core task is to detect ethical dilemmas that lead to conflict and to propose viable resolutions. Consequently, their function is not simply to prevent or control, but rather to offer constructive critique and practical recommendations.

Ethics committees define their general functions based on their specific responsibilities. They are typically categorized into various types, such as hospital ethics committees, research ethics committees, and animal research ethics committees. (Demir, 2011)

There are four principal types of bioethics committees, each devoted to the systematic and ongoing evaluation of the ethical dimensions of medical sciences, life sciences, and new health policies:

1. Policy-making and/or advisory councils: These bodies aim to formulate science and health policy in accordance with the needs of a country's citizens.

2. Ethics committees within professional healthcare associations: These are established to determine appropriate practices for professions that provide care to patients.

3. Ethics committees for healthcare services / Hospital ethics committees: Their goal is to improve the delivery of patient-centered care.

4. Research ethics committees: These aim to protect individuals participating in research that produces generalizable biological, biomedical, or epidemiological knowledge. (UNESCO, 2005)

Depending on the governmental structure, bioethics committees may operate at national, regional, or local levels.

A bioethics committee is fundamentally concerned with the systematic and continuous analysis of the ethical dimensions of (a) health sciences, (b) life sciences, and (c) new health policies. The committee's core function extends beyond the empirical realities it seeks to interpret. This leads us from traditional branches of philosophy – namely, ethics – into the realm of public policy, raising the question: “How should government act?” As such, bioethics committees formulate their inquiries in normative terms.

In other words, these committees serve as forums for the detailed generation and discussion of individual and collective values. This mode of operation requires individuals to critically examine not only their own behavior but also that of others.

Research Ethics Committees are independent decision-making bodies composed of members from various professional backgrounds, established to oversee and ensure the protection of the dignity, fundamental rights, safety, and interests of participants involved in biomedical research on humans.

Although there are some differences in the mandates and operational forms of research ethics committees across countries at the international level, these committees function in accordance with widely accepted ethical principles, rules, and methodologies. (Görkey, 2009).

Research ethics committees are responsible for evaluating the scientific quality of research projects and their compliance with national legislation.

Prestigious academic journals require ethical approval from a recognized ethics committee as a prerequisite for the acceptance of scientific articles submitted for publication.

In addition to protecting participants, these committees ensure that research projects are well-designed and methodologically sound, and that any proposed medical interventions or treatments are properly evaluated. In doing so, they contribute to the improvement of healthcare service quality. Increasingly, they serve as a bridge between public opinion and researchers on the ethical dimensions of biomedical research. (Karimova, 2021)

The Additional Protocol concerning Biomedical Research to the Convention on Human Rights and Biomedicine of the Council of Europe – adopted in Strasbourg on 1 September 2007 – addresses “Ethics Committees” in Chapter III as follows:

Article 9 – Independent review by an ethics committee

1. Every research project must undergo an independent review by an ethics committee in order to be considered ethically acceptable. Such research shall be subject to oversight by the designated bodies responsible for independent review in each State.

2. The primary objective of such review is to assess the ethical acceptability of the research and to ensure the protection of the dignity, rights, and safety of the research participants. This ethical evaluation must be grounded in professional judgment and experience.

3. The ethics committee must provide a reasoned justification for its decisions.

Article 10 – Independence of the ethics committee

1. Parties to this Protocol shall take measures to ensure the independence of ethics committees. These bodies must be protected from undue external influence.

2. Members of the ethics committee must declare any potential conflicts of interest. Those involved in a conflict of interest shall not participate in the review process.

Article 11 – Information for the ethics committee

1. All information necessary for the ethical assessment of a research proposal must be provided in writing to the ethics committee.

2. In particular, the Additional Protocol must contain information relevant to the specific research project and must be consistent with its objectives. This annex may be amended by a two-thirds majority vote of the Committee, in accordance with Article 32 of the Convention.

Article 12 – Protection from undue influence

Ethics committees must be safeguarded not only from undue external interference but also from financial influence in order to protect the interests of research participants. Special attention must be paid to vulnerable groups and dependent individuals involved in research (Oviedo, 1997).

There are numerous international instruments, conventions, and declarations that establish the theoretical and legal foundations of ethics committees and regulate their activities. Among the most prominent of these are the Universal Declaration of Human Rights (United Nations, 1948); the International Code of Medical Ethics (World Medical Association [WMA], 1949); the Declaration of Helsinki – Ethical Principles for Medical Research Involving Human Subjects (WMA, 1964); the Principles of Medical Ethics Relevant to the Protection of Prisoners and Detainees Against Torture and Other Cruel, Inhuman or Degrading Treatment or Punishment (United Nations, 1982); the Declaration on Organ Transplantation (WMA, 1987); the Programme on Bioethics (UNESCO, 1993); the Convention on Human Rights and Biomedicine (Oviedo Convention) (Council of Europe, 1997); the Universal Declaration on the Human Genome and Human Rights (UNESCO, 1997); the ECOSOC Resolution on Human Rights and Bioethics (United Nations, 2003); the International Declaration on Human Genetic Data (UNESCO, 2003); the ECOSOC Resolution on Genetic Confidentiality and Non-Discrimination (United Nations, 2004); the United Nations Declaration on Human Cloning (2005); the Universal Declaration on Bioethics and Human Rights (UNESCO, 2005); and the Good Clinical Practice (GCP) Guidelines.

In accordance with these international standards, various issues have been incorporated into national legislation and medical practice in Azerbaijan. Notable examples include the Law on the Protection of Public Health, the Law on Medicinal Products, the Law on the Donation and Transplantation of Human Organs and Tissues, the Rules on the Conduct of Scientific Research, Preclinical Studies, and Clinical Trials of Medicinal Products as approved by the Cabinet of Ministers of the Republic of Azerbaijan (2018), and the Decision of the Collegium of the Ministry of Health on the Approval of the Guidelines on Good Clinical Practice (dated August 18, 2020), among others. These legal documents reflect the role and importance of ethics committees in medical research and practice.

Nevertheless, there remains a need for the further development of national legislation. In particular, the Republic of Azerbaijan should ratify the Convention on Human Rights and Biomedicine (commonly known as the Oviedo Convention), adopted by the Council of Europe in 1997, which is the only legally binding international instrument in the field of biomedicine. Furthermore, the revised 1975 version of the Declaration of Helsinki (originally adopted in 1964) emphasizes the principle that a research protocol must be submitted for review, evaluation, and interpretation by an independent body prior to the commencement of any study. This requirement has marked a significant step in the development of research ethics committees.

1. In line with international practice, it is considered necessary for the Criminal Code of the Republic of Azerbaijan to define the absence of ethics committee approval in the conduct of scientific research as a criminal offense, similar to Article 90(2)(a) of the Turkish Penal Code, which addresses “experimentation on humans.” (Turkish Penal Code. 2004.)

Examples of ethics committees in other countries include:

- United Kingdom – Research Ethics Committee (REC)
- Netherlands – Medical Research Ethics Committee (MREC)
- France – Committee for the Protection of Persons (Comités de Protection des Personnes, CPP)
- United States – Institutional Review Board (IRB)
- Canada – Research Ethics Board (REB)
- Australia – Human Research Ethics Committee (HREC)
- Israel – Institutional Review Boards based on the U.S. IRB system
- Turkey – University Ethics Committees (Üniversite Etik Kurulu)
- Kazakhstan – Local Commission on Bioethics at the Medical Center Hospital of the Presidential Administration

- Uzbekistan – Bioethics Committee of the Uzbekistan Medical Association

In Azerbaijan, the first national ethics committee was established in 1999 as the National Committee for Bioethics, Ethics of Science and Technology by the National Commission of the Republic of Azerbaijan for UNESCO and the Presidium of the National Academy of Sciences. The committee was registered with the Ministry of Foreign Affairs of the Republic of Azerbaijan. In 2010, a UNESCO Chair in Bioethics was established in Azerbaijan.

By the decision of the Scientific Council of the Azerbaijan State Advanced Training Institute for Doctors named after A. Aliyev, dated June 24, 2016, an Ethics Committee was established within the Institute. In addition, ethics committees have also been formed in certain professional associations such as the Azerbaijan Society of Cardiology and in several state scientific-research hospitals, including the Thalassemia Center (National Center for Hematology and Transfusiology). Currently, ethics committees also operate in some private medical institutions.

In 2021, ethics committees were established in scientific-research institutes under the auspices of the Administration of the Regional Medical Divisions (TABIB) to ensure that biomedical research is conducted, monitored, and evaluated in accordance with international standards and ethical principles. The establishment of ethics committees was officially ordered in the following institutions: the Scientific Research Institute of Medical Rehabilitation (28.09.2021), the Scientific Research Institute of Medical Prophylaxis (01.10.2021), the Scientific Research Institute of Pediatrics (05.10.2021), the Scientific Research Institute of Obstetrics and Gynecology (25.10.2021), the Scientific Surgical Institute (01.11.2021), the Scientific Research Institute of Lung Diseases (21.12.2021), and the Scientific Research Institute of Traumatology and Orthopedics (28.12.2021). For each institution, the chair, secretary, and members of the committee were appointed, and the committees began their activities. Although these medical institutions have since been transferred under the jurisdiction of the Ministry of Health of the Republic of Azerbaijan, the ethics committees within them continue to function, at least partially (TABIB, 2021).

Since 2011, the Institute of Law and Human Rights under the Azerbaijan National Academy of Sciences (now functioning under the Center for Legal Expertise and Legislative Initiatives) has conducted research in the field of bioethics, established doctoral programs, and published numerous academic materials. Since 2018, the Faculty of Law at Baku State University (BSU) has been admitting students into a master's degree program in medical law. Courses on bioethics and medical law are taught at both undergraduate and graduate levels within the Faculty of Law at BSU. At the Azerbaijan Medical University, there is a pressing need for the wide inclusion of bioethics and medical law courses alongside the existing instruction in the history of medicine and medical ethics (deontology).

Based on the results of the “Survey on the Perception of the Importance of Ethics Committees among Members of Scientific Research Ethics Committees and Other Professionals in Azerbaijan,” developed by the author, the following findings were obtained:

Out of a total of 65 participants, 53 had served as members of ethics committees. Of these, 45 were women and 20 were men. The age distribution of respondents was as follows: 4 participants were aged 18–30, 18 were aged 31–40, 19 were aged 41–50, 13 were aged 51–60, and 11 were over the age of 61. The professional background of participants included: physicians – 46, lawyers – 2, pharmacists – 6, and other professions – 11.

Regarding educational qualifications: 6 held a bachelor's degree, 16 held a specialty degree or master's degree, 36 held a PhD, and 7 reported other forms of education. In terms of work experience: 1 participant had 0–5 years, 8 had 6–10 years, 12 had 11–15 years, 4 had 16–20 years, and 40 had more than 21 years of professional experience. The fields in which the participants were employed included: administrative – 3, scientific research – 40, medical services – 11, and other sectors – 11.

Twenty-five respondents reported having received some form of training in research ethics, while 40 had not received any training in the field. Among those trained, 1 had received training during undergraduate studies, 6 during postgraduate/specialty education, 3 during doctoral studies, and 15 during other stages of their careers.

All 65 respondents unanimously stated that ethics committees are necessary in Azerbaijan.

In response to the question “How do you assess the importance of ethics committees?” participants answered as follows: Very important – 49, Somewhat important – 14, No opinion – 1, Slightly important – 1, Not important – 0.

To the question “Which professionals should be represented in ethics committees?” the responses were as follows: physician – 63, nurse – 6, pharmacist – 53, lawyer – 58, social worker – 28, psychologist/psychiatrist – 40, biomedical engineer/biophysicist – 28, biostatistician – 37, theologian (clergy) – 27, public representative – 28. Other responses included: senior state official, experts depending on the subject area of the committee, family physician, ethics specialist, pediatrician.

When asked “What is the main function of an ethics committee?” the participants responded as follows: distribution of responsibility – 14, protection of human rights (protection of patient/healthy volunteer) – 61, ability to publish in high-impact journals – 18, fulfillment of administrative requirements – 1, development of a research culture in the country – 47, integration of the country into the international research community – 49.

Ensuring the reliability of the country in the field of scientific research was emphasized by 39 participants, facilitating access to international research grants was highlighted by 25 participants, and the effective utilization of the country's material resources allocated to scientific research was noted by 31 participants.

Responses to the section on suggestions for improving the functioning of ethics committees were as follows:

- Development of relevant legislation (i.e., drafting national legislation and ratifying existing international instruments) – 48 responses
  - Inclusion of ethics in higher education curricula – 30 responses
  - Provision of training for professionals working in the field – 31 responses
  - Recognition of ethics committee membership as part of academic activity and its evaluation accordingly – 33 responses
  - Support from non-governmental organizations (NGOs) in the field of ethics/bioethics – 22 responses
  - Organization of academic exchange programs with foreign countries – 35 responses
  - Translation of international regulatory documents in the field of ethics/bioethics into the Azerbaijani language – 41 responses
  - Preparation of a glossary of terms in ethics/bioethics in the Azerbaijani language – 38 responses
- Additionally, in the “Other Suggestions” section, participants made the following recommendations:
- Establishment of a state-registered ethics committee with an active and functioning structure

- Allocation of remuneration for ethics committee members
- Implementation of public and academic awareness-raising campaigns (e.g., through the use of short informational videos)
- Strengthening cooperation between the government and NGOs
- Regular briefings and informational updates for committee members
- Clarification of the functions and powers of ethics committees in relation to Problem Commissions and Scientific Councils.

**Recommendations:**

- A separate normative legal instrument regulating the activities of ethics committees should be adopted within national legislation, and existing international instruments should be ratified accordingly.
- A comprehensive needs assessment should be conducted with the participation of professionals working in the field of scientific research, including researchers and members of ethics committees. Based on the results of this assessment, certification training programs should be organized for both researchers and ethics committee members. Additionally, organizing “training of trainers” programs may prove beneficial, facilitating the country’s future capacity to independently deliver training in this field.
- To support ethics committee members, researchers, and the scientific community, relevant international normative documents and academic literature should be translated into Azerbaijani. Furthermore, Azerbaijani-language methodological manuals and educational materials should be developed. Support should be provided for the preparation of such scientific and methodological resources.
- The establishment of civil society institutions operating in the field of bioethics and medical ethics should be encouraged. Specifically, it has been proposed that a Bioethics Association be established in Azerbaijan and that relevant non-governmental organizations (NGOs) be formed in this area. It is essential to involve respected public figures in these civil society organizations in order to promote ethically sound research practices and to protect fundamental medical rights, particularly the rights to life and health. Overall, various public awareness initiatives should be implemented to foster a culture of bioethics in the country.
- Courses on bioethics and medical ethics should be incorporated into relevant higher education curricula and syllabi.
- The Criminal Code of the Republic of Azerbaijan should recognize the conduct of scientific research without obtaining the opinion of an ethics committee as a criminal offense. (Azerbaijan Criminal Code. 1999)

**Conclusion.** The establishment and current functioning of ethics committees represent an important step in Azerbaijan for the analysis, oversight, and application of the ethical aspects of research involving human subjects, despite all justified criticisms. Significant progress and achievements have been made by both ethics committee members and researchers in this process.

It is a fact that with the adoption of new legal regulations addressing the impact of scientific and technological advancements on human life, the country has entered – and continues to enter – a new phase. However, with the exception of a few limited measures, it cannot be claimed that ethics committees have been fully implemented nationwide. Moreover, there remains no national ethics committee in Azerbaijan that actively addresses fundamental issues of ethics, bioethics, and medical ethics or proposes solutions to these challenges. For reference, it is noteworthy that among European Union member states, there is no country without a national ethics committee.

As key directions following these initial steps, there is a pressing need to develop a strategic plan for the establishment and systematic operation of ethics committees to ensure continuous and organized activities in the country. This should include conducting a needs assessment with the par-

ticipation of specialists working in scientific research, researchers, and ethics committee members; delivering training based on the outcomes of this needs analysis to researchers and ethics committee members; organizing “training of trainers” programs; preparing scientific literature and methodological materials; enhancing the knowledge and skills of authorized personnel responsible for the organization of ethics committee work; supporting the establishment of civil society institutions active in the field of bioethics; and increasing public awareness on these issues.

We are hopeful that the collaborative efforts of medical professionals and legal experts in Azerbaijan in the fields of bioethics, deontology, medical law, and ethics committee work will make a significant contribution to the ongoing comprehensive reforms in the country’s medical and healthcare sectors.

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