ETHICAL AND LEGAL ASPECTS OF BIOMEDICAL RESEARCH

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Annotation. *The review article examines the main ethical and legal aspects of biomedical research. It covers historical background and international regulations, principles of research ethics involving humans and animals, requirements for informed consent, protection of vulnerable groups, regulation of clinical trials and biobanking, as well as issues of confidentiality, conflict of interest, and researchers' responsibility. The article provides recommendations for compliance with ethical standards and legal regulation.*

Keywords: *bioethics, biomedical research, informed consent, clinical trials, human subjects, vulnerable populations, data protection, research ethics committees, legal regulation, animal research.*

Introduction:

The rapid progress of biomedical research requires strict adherence to ethical standards and legal mechanisms to protect the rights and well-being of research participants. Historical abuses have led to the development of international documents and national legislation that serve as guidelines for researchers, sponsors, and regulators.

Historical and normative background:

• The Nuremberg Code, the Helsinki Declaration, the Belmont Report have formed the basic principles: voluntariness, informed consent, beneficence and justice.

• International norms are integrated into national legal systems and regulatory requirements for clinical trials and laboratory research.

Ethical principles for biomedical research:

• Respect for autonomy – mandatory obtaining of informed consent.

• Beneficence and non-maleficence – assessment of the benefit-risk ratio.

• Fairness — equal access to the benefits of research and equal distribution of risks.

• Transparency and accountability — disclosure of funding, conflicts of interest, and results.

Informed consent requirements:

• Accessible information about the goals, methods, risks, benefits, and alternatives.

• Voluntary participation without pressure or coercion.

• Specific rules for vulnerable groups (children, incapacitated individuals, and prisoners).

• Documentation procedures and the possibility of withdrawing consent at any time.

Protection of vulnerable populations:

• Special assessment of risks and limitation of interventions without direct benefits.

• Requirement for additional protection and oversight by ethics committees.

• Ethical rules for research on pregnant women, newborns, and economically vulnerable groups.

Research ethics committees and oversight:

• Availability of independent ethics committees (IRB/REC) for evaluating protocols, monitoring safety, and complying with legislation.

• Regular monitoring, auditing, and reporting requirements, as well as a mechanism for terminating trials in case of adverse events.

Legal regulation of clinical trials:

• Registration of trials in public registries.

• Requirements for the safety regulations, reporting of side effects, pharmacovigilance.

• Norms of data integrity, GCP (Good Clinical Practice) standards.

• Legal liability of sponsors and researchers for harm to participants.

Biobanking and data protection:

• Legal and ethical issues of storage of biosamples and genetic data.

• Requirement of informed consent for storage and secondary use of biomaterials.

• Compliance with privacy and personal data protection regulations (such as the GDPR in the EU).

• Issues of data access, commercialization, and donor rights.

Animal research ethics and regulation:

• The 3R principles: replacement, reduction, and refinement.

• Requirements for justifying the use of animals, minimizing pain, and overseeing animal care and use committees.

• Legal regulations on animal welfare, staff training, and reporting.

Conflicts of interest and transparency:

• Robust mechanisms for researchers and sponsors to disclose conflicts of interest.

• Limiting the direct influence of commercial interests on the design, interpretation, and publication of results.

• Open data and publication policies to increase trust.

Emerging issues and challenges:

Genome research, genome editing (CRISPR), and artificial intelligence in medicine pose new risks and legal gaps.

• International cooperation and regulatory heterogeneity.

• The commercialization of biotechnology and the protection of intellectual property conflict with the right to participation and donor information.

Recommendations for practice and policy:

• Strengthen the independence and competence of ethics committees and regulators.

• Ensure transparency in funding and conflicts of interest.

• Strict adherence to the requirements of informed consent, taking into account the local context.

• Develop flexible but reliable legal mechanisms for new technologies.

• Improve the educational level of researchers in bioethics and law.

• Protect the rights of participants through effective mechanisms for compensation for harm.

Conclusion:

Ethical and legal aspects of biomedical research are integral to ensuring the safety, trust, and effectiveness of scientific progress. By combining strict ethical principles, independent oversight, and an adequate legal framework, we can minimize risks and ensure a fair distribution of the benefits of research.

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