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ETHICAL EXPERTISE OF BIOMEDICAL AND CLINICAL TRIALS: EXPERIENCE AND PERSPECTIVES

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In the current conditions of scientific and biomedical technological development, ethical and bioethical expertise of research in the fields of biology and medicine is becoming increasingly demanded and necessary. The requirement for independent monitoring of such research in specific areas is an integral component of science regulation. In his work «The Sociology of Science Theoretical and Empirical Investigations» Robert K. Merton highlighted the need for the application of certain guiding norms and prescriptions in science. These regulatory features were derived by Merton, as he understood science as a social institution. He introduced the widely used concept of the scientific ethos and outlined the fundamental requirements and imperatives for scientific research (Universalism, Communism, Disinterestedness, Organized Skepticism.) [1]

Conducting scientific research in higher education institutions should unquestionably be based on academic values and principles of academic integrity. The ethical expertise at our university has its history: in 2004, the Ethics Committee was established, and since 2014, the Ethics Commission for the examination and evaluation of ethical and legal aspects of research projects conducted in departments and clinical bases has been in place. In 2023, there was a rotation in the composition of the Commission, accompanied by the delineation of new goals and tasks.

Currently, the Commission's experts pay particular attention to adhering to the principles of academic integrity during scientific

research. Commission members provide guidance to applicants to prevent ethical violations in research, such as falsification of empirical data, plagiarism, manipulation of empirical data through the use of inadequate or knowingly manipulative algorithms for statistical analysis, and so on.

We annually conduct an anonymous survey of PhD students engaged in scientific research at our institution. In total, 240 surveys were processed, and average indicators were calculated for each question. The obtained data reveal the following: 220 respondents highlighted the importance of academic integrity issues.

The level of support for academic integrity within the institution was rated on a 10-point scale, with an average score of 8 points.

Respondents evaluated the level of informational support regarding adherence to ethical and bioethical principles in scientific research as sufficient.

However, more than 40% of respondents (96 individuals) emphasized the need for the introduction of a specialized discipline aimed at fostering academic scientific culture and developing written communication skills.

45% of PhD students (108 individuals) indicated that they made amendments to the protocol of biomedical research and informed consent for patient participants after undergoing the relevant expert assessment.

Additionally, 85% of respondents (204 individuals) underscored the importance of reviewing scientific research before its commencement, emphasizing that the key principle is ensuring the rights of patients.

In this context, Ethical Expertise of Biomedical and Clinical Trials appears as an integral component and prerequisite for academic integrity in the field of medicine.

References

1. Merton R. K. & Storer N. W. (1973). *The sociology of science: theoretical and empirical investigations*. University of Chicago Press.