

REVIEW OF 'ETHICAL EXAMINATION IN BIOMEDICAL RESEARCH: PRACTICAL CONSIDERATIONS' FOR ETHICS COMMITTEES (THIRD EDITION, REVISED AND ENLARGED) UNDER THE GENERAL EDITORSHIP OF KHOKHLOV AL

Firsov DE, Miroshnikov AE ✉, Pozdnyakov NO

Yaroslavl State Medical University, Yaroslavl, Russia

The article reviews the edition known as 'Ethical Examination in Biomedical Research: Practical Considerations' (third edition, revised and enlarged) under the general editorship of Professor Khokhlov AL, a corresponding member of the Russian Academy of Sciences. Due to a constantly growing number of clinical trials of medicinal products and improved level and quality of medical technologies, the role of an ethical examination aimed at compliance with ethical rights of trial participants and consumers, and safety aspects is increased. The article sums up what was described in the published edition.

Keywords: clinical trials, ethical examination, personal data, ethics committees, biobanking, international standards

✉ **Correspondence should be addressed:** Alexey E. Miroshnikov
ul. Revolutsionnaya, 5, Yaroslavl, 115000, Russia; miraleff@mail.ru

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ОБЗОР РУКОВОДСТВА ДЛЯ КОМИТЕТОВ ПО ЭТИКЕ «ЭТИЧЕСКАЯ ЭКСПЕРТИЗА БИОМЕДИЦИНСКИХ ИССЛЕДОВАНИЙ: ПРАКТИЧЕСКИЕ РЕКОМЕНДАЦИИ» (ТРЕТЬЕ ИЗДАНИЕ, ИСПРАВЛЕННОЕ И ДОПОЛНЕННОЕ) ПОД ОБЩЕЙ РЕДАКЦИЕЙ А.Л. ХОХЛОВА

Д. Е. Фирсов, А. Е. Мирошников ✉, Н. О. Поздняков

Ярославский государственный медицинский университет, Ярославль, Россия

Статья посвящена обзору вышедшего в свет издания «Этическая экспертиза биомедицинских исследований: практические рекомендации» (3-е издание (испр. и допол.), под общей редакцией члена-корреспондента РАН, профессора Хохлова А. Л. В связи с постоянно растущим количеством клинических исследований медицинских продуктов, а также повышением уровня и качества медицинских технологий возрастает роль этической экспертизы, направленной на соблюдение этических прав участников исследований и потребителей, а также аспектов, касающихся их безопасности. Статья описывает краткое содержание опубликованного издания.

Ключевые слова: клинические исследования, этическая экспертиза, персональные данные, этические комитеты, биобанкинг, международные стандарты

✉ **Для корреспонденции:** Алексей Евгеньевич Мирошников
ул. Революционная, д. 5, г. Ярославль, 115000, Россия; miraleff@mail.ru

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Ethical aspects of human and animal trials are a source of concern for the society. Pharmaceutical companies that conduct the trials are subject to criticism because of poor transparency. Moreover, it is asserted that the trials of approved and commercialized medicinal agents are conducted mainly for marketing purposes or abroad to cut expenses or bend strict rules [1, 2, 3].

Ethical aspects of clinical trials are set in the Declaration of Helsinki. It's an ethical standard developed in 1964 that regulates human trials. Additional standards, regulations and ethical codes that guarantee the primary importance of safety and human well-being during the trial have been developed and implemented since then [4].

New challenges of modern healthcare promote constant improvement of approaches to diagnostics and treatment of various diseases [5, 6, 7]. Such issues as duration and quality of life, possibilities of medical and social support, rehabilitation and habilitation of physically disabled society members are top priority for scientists, public men and politicians globally. To estimate safety and effectiveness of new methods, it's obligatory to conduct clinical trials, the results of which allow to implement new technologies in clinical practice [8].

It means that a number of projects with participation of laboratory animals in experimental methods, healthy volunteers,

patients with various diseases and a total number of trials will not be reduced. Novel medicinal agents, medical devices, diagnostic procedures appear, genetic trials, trials of regenerative medicine, biomedical cellular products, information, reproduction and other technologies are carried out actively [9].

Clinical trials of brand-new medical technologies that haven't been used before are associated with some ethical issues. Scientific value of the results obtained during clinical trials must be in compliance with ethical standards [10, 11].

Modern interest to ethical and legal issues of biomedical human research is due to a number of reasons. Today their scope, range of tasks and practice undergo violent changes. Biomedical trials have lately become extremely important, necessary and essential from the economic point of view. It should be taken into consideration that many laws, orders, instructions and provisions acting in the Russian Federation and members of the EAEU require renewal and bringing to conformity with modern international requirements.

THE MAIN PART

As the topic is highly relevant, the guideline known as 'Ethical Expertise of Biomedical Trials' has been prepared. A large team

of writers including clinical pharmacologists, pharmacologists, specialists in bioethics, sociology and philosophy of medicine, clinicians, health professionals, those involved in medical education, regulatory authorities, and lawyers participated in creation of the guideline under the aegis of the Russian Academy of Sciences.

The guideline reviews pressing topics related to compliance with ethical principles. First and foremost, it deals with the history of ethics in medicine as a separate branch that comes through constant changes, and presents doctors' mistakes that were subsequently analyzed with their minimization methods being addressed.

Recommendations on establishment and activity of ethics committees, including international standards, basic ethical principles and fundamental documents, standard operating procedures are presented. The chronology of creating the legal base as the basis for ethical review has been described. Real examples of ethical reviews in the Eurasian Economic Union have been presented. Practical recommendations on establishment of the charter of the ethics committee are provided in detail; purposes, tasks, objectives and authorities of ethics committees are specified.

Standard operating procedures of ethics committee are described in a separate chapter. A standard operating procedure is a document that deals with the procedures used by the committee and where the committee's policy is reflected. The written guideline states as follows about the Ethics Committee's procedures: 'describe the operating procedures step by step and with enough details to make an outsider understand how the ethics committee functions and how it performs its principal functions'. Every ethics committee must create and subsequently follow an own set of instructions a point of application and sphere of influence of which reflect the activity of this committee and correspond to the national and international standards of ethics expertise of research and legislative regulations. The data presented in this chapter need to be used by ethics committees of all levels to develop and correctly select standard operational procedures. The procedure and inspection of ethics committees with controlling functions are also described to assess the quality of the conducted expertise.

The guidelines contain detailed requirements to preparation of documents to assess whether it is possible to conduct clinical trials. An informed consent form is given special attention. The document with key functions is of primary importance. On the one hand, it is intended for a participant of the clinical trial. It is written in accessible language and provides clear understanding of the situation. On the other hand, the document allows to conclude that the subject voluntarily consented to participation and that his/her rights are not restricted. The procedure of obtaining informed consent from vulnerable groups (disabled people, minors, incurable persons) is separately described. A separate chapter is devoted to obtaining an informed consent.

The principles of protecting personal data of trial subjects, insurance of trial participants, differentiation and interrelation between clinical trials and real clinical practice are also examined. Specific considerations of an ethical review including vulnerable groups of population, trials of healthy volunteers, ethical issues of medical technology assessment are described.

A separate chapter is devoted to ethnocultural and confessional peculiarities of biomedical trials. It is known

that sociocultural environment plays an important role while planning biomedical research. It is about selection of both the trial subjects, and members of the study personnel. Ignoring sociocultural peculiarities at all trial stages is a typical mistake. Taking into account ethnocultural and confessional components of biomedical research helps avoiding stress among subjects and violation of human rights during biomedical trials.

A specific nature of the projects associated with biobanks, use of gene therapy and biomedical cellular products, tissue engineering preparations, artificial intelligence software, robotic medical complexes, 3D-bioprinting, use of medical devices with the Internet of Bodies, and translational research has been shown. The types of biomedical trials are reviewed. Recommendations are provided concerning proper organization of an ethical examination amidst the pandemic and emergency situations.

Separate chapters are devoted to an ethical examination of medical devices, animal trials and translational trials.

CONCLUSION

There are many current concerns about an adequate, timely, scientifically grounded, independent review of high technologies due to the increasingly active development and implementation of biological and information technologies into a significant number of both new, and traditional, long-established groups of public relations, necessity in getting the balance of interests, including citizens, businesses, social groups, and the state.

That's why the issue about development and adoption of a set of standards that mediate relations associated with ethical and legal support, support of newly forming technological reality (arising and developing at the interface of general humanitarian, sociocultural, technological, biological, medical and other disciplines) has been discussed in increasing frequency.

The guideline is intended for daily use by ethics committee members during an expert assessment of biomedical trials; specialists engaged in the trials; those who are busy in clinics, pharmaceutical companies, contract research organizations, supervisors of scientific and clinical projects, representatives of regulating bodies, research and development establishments, and higher attestation commissions.

The presented information is useful for research associates and postgraduates who are planning to begin or have already begun conducting biomedical trials in accordance with international requirements. The guideline can also be used to develop basic training courses devoted to biomedical ethics in higher educational facilities; it is also suitable for teachers while planning and conducting training sessions. Experienced specialists such as ethics committee members and clinical investigators can use the presented information to broaden their horizons, improve the scientific part, supplement legal knowledge, understand the methodology of various biomedical trials in accordance with international standards and modern ethical principles.

Considering the importance, novelty and practical significance of the issues reviewed, it can be concluded that 'Ethical Examination in Biomedical Research: Practical Considerations for Ethics Committees under the general editorship of Khokhlov AL' will make a huge contribution into bioethics development in Russia and in functioning of ethics committees during improvement of an ethical examination, in particular.

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