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Об особенностях этической экспертизы в исследованиях с применением технологий и систем искусственного интеллекта на базе Государственного бюджетного учреждения здравоохранения города Москвы «Научно-практический клинический центр диагностики и телемедицинских технологий Департамента здравоохранения города Москвы» (ГБУЗ НПКЦ ДиТ ДЗМ)

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АННОТАЦИЯ

Вопросы этики медицинских испытаний поднимались многократно. Этическое сопровождение исследований с участием человека в качестве субъекта исследований законодательно закреплено и требует особого внимания.

Особое место этические вопросы занимают при проведении клинических исследований лекарственных средств, где невозможно заранее и точно спрогнозировать эффективность и безопасность нового препарата на живой организм. В настоящее время при проведении экспертизы клинических исследований внимание уделяется качеству жизни пациентов, вопросам соблюдения прав пациентов, а также соблюдению правил надлежащей клинической практики и действующего законодательства. Благодаря техническому развитию увеличивается количество исследований не только лекарственных средств, но и медицинских изделий, использующих в том числе специализированные медицинские технологии и программное обеспечение.

Автоматизация, развитие, совершенствование, структуризация задействованных процессов обусловливают применение всё более техничных устройств, использующих в своей работе не только программы, но и системы. Особое место в развитии медицинской науки занимает программное обеспечение с использованием систем искусственного интеллекта.

Искусственный интеллект, который ещё лет 50–80 назад был областью научной фантастики, сейчас прочно вошёл в нашу обычную жизнь. Внедряя возможности искусственного интеллекта в медицинское программное обеспечение, применяя его в составе медицинского оборудования, разрабатывая медицинские изделия с системами искусственного интеллекта, получаем продукт, требующий тщательного изучения и дальнейшего развития, которое включает в себя комплекс работ по проведению научных исследований, регистрации и поддержанию подобных систем и комплексов. Все работы регулируются законодательством в сфере обращения медицинских изделий и требуют глубокого системного и научного подхода, в том числе с привлечением этики для контроля соблюдения прав и безопасности не только участников исследования, но и их медицинских данных.

Этический комитет является независимым органом, контролирующим соблюдение прав и требований законодательства, проводящим этическую и научную экспертизу документации исследований. Этические вопросы при планировании любых исследований с участием человека или его данных должны подробно обсуждаться и рассматриваться. Следует обращаться в этические комитеты не только на этапе одобрения материалов исследования, но и при планировании дизайна, разработке документации исследования и материалов для пациентов, а также регулярно на всех этапах проведения исследования.

Ключевые слова: искусственный интеллект; клинические исследования; этика; надлежащая исследовательская практика.

Как цитировать

Пчелинцева О.И., Омелянская О.В. Об особенностях этической экспертизы в исследованиях с применением технологий и систем искусственного интеллекта на базе Государственного бюджетного учреждения здравоохранения города Москвы «Научно-практический клинический центр диагностики и телемедицинских технологий Департамента здравоохранения города Москвы» (ГБУЗ НПКЦ ДиТ ДЗМ) // *Digital Diagnostics*. 2022. Т. 3, № 2. С. 156–161. DOI: https://doi.org/10.17816/DD107983

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Features of conducting ethical review of research on artificial intelligence systems on the basis of the research and practical clinical center for diagnostics and telemedicine technologies of the Moscow Health Care Department, Moscow, Russian Federation

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ABSTRACT

The ethics of medical tests have been raised many times. Ethical support of research involving a human subject is legally fixed and requires special attention.

Ethical issues occupy a special place when conducting clinical trials of medicines, where it is impossible to predict in advance and accurately the effectiveness and safety of a new drug on the human body. Currently, during clinical trial examination, attention is paid to patients' quality of life, and issues of compliance with patients' rights, as well as compliance with the rules of good clinical practice and current legislation. Thanks to technological development, the number medical studies and devices using, among other things, specialized medical technologies and software is increasing.

Automation, development, improvement, and structuring of the processes involved cause an increase in the use of technical devices that use not only programs but also systems in their work. Artificial intelligence system software have a special place in medical science development.

Artificial intelligence, which was the field of science fiction 50–80 years ago, is now firmly embedded in our everyday life. By introducing artificial intelligence's capabilities into medical software, using it as part of medical equipment, and developing medical devices with artificial intelligence systems, we get a product that requires careful study and further development, which includes a complex of works on conducting scientific research, and registration and maintenance of such systems and complexes. All work is regulated by legislation in the field of circulation of medical devices and requires a deep systematic and scientific approach, including involving ethics to monitor compliance with the rights and safety of study participants and their medical data.

The Ethics Committee is an independent body that monitors compliance with the rights and requirements of legislation and conducts ethical and scientific examination of research documentation. Ethical issues when planning any research involving a person or his/her data should be discussed and considered in detail. The ethics committees should be contacted not only at the stage of approving research materials, but also when planning the design and developing research documentation and materials for patients, as well as regularly at all stages of the study.

Keywords: artificial intelligence; clinical trials; ethics; good research practice.

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关于基于莫斯科市国家预算医疗保健机构“莫斯科市卫生管理局诊断和远程医疗技术科学与实践临床中心”应用人工智能技术和系统的研究中的伦理鉴定的特征

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简评

关于医学试验的伦理问题已被多次提出。对涉及人作为研究对象的研究的伦理支持是立法规定的，且需要特别注意。

伦理问题在药物的临床试验中特别重要，因为不可能事先准确地预测一种新药对活体的疗效和安全性。目前，临床试验鉴定的重点在于患者的生活质量、患者的权利问题，以及对适当临床实践规则和现行法律的遵守。技术的发展不仅导致了对药品研究的增加，也导致了对医疗设备研究的增加，包括使用专门的医疗技术和软件。

相关流程的自动化、开发、改进和结构化导致了越来越多的技术设备的应用，这些设备在工作中使用系统，而不仅仅是软件。在医学科学的发展中，应用人工智能系统的软件占据了一个特殊的位置。

人工智能在50–80年前还是科幻小说的范畴，现在已经牢牢地融入了我们的日常生活。通过将人工智能的能力引入医疗软件，将其作为医疗设备的一部分，开发带有人工智能系统的医疗产品，我们得到了一个需要仔细研究和进一步开发的产品，其中包括对此类系统和综合体的科学研究、注册和维护等一系列工作。所有这些工作都受医疗器械流通领域的立法监管，需要深入的系统和科学态度，其中包括伦理，以监测不仅是研究参与者的权利和安全，也包括其医疗数据。

伦理委员会是一个独立的机构，负责监督对法律权利和要求的遵守情况，对研究文件进行伦理和科学鉴定。在计划任何涉及个人或其数据的研究时，应详细讨论和考虑伦理问题。伦理委员会不仅应在研究材料的批准阶段联系，而且在研究设计的规划、研究文件和患者材料的制定以及研究的所有阶段都要定期与伦理委员会接触。

关键词：人工智能；临床研究；伦理；适当的研究实践。

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SCIENTIFIC STUDIES: GOALS, STAGES, AND MARKETING AUTHORIZATION

An ethical review is mandatory for all scientific studies involving human subjects or their health-related data. The objective of the ethical review is to protect rights and confidentiality of study subjects while ensuring compliance that all legal requirements are met.

Not only drug products are subject to in vitro and in vivo research. Studies with medical devices are also increasingly involving human subjects or their health information.

Toxicological tests, technical tests, and other stages of research are mandated by law before medical devices can be registered. But what about software?

The software shall undergo evaluation by certain types of studies that the regulator (Federal Service for Supervision in Healthcare of Russia) uses to decide whether to approve or refuse a marketing authorization. A regulatory dossier includes a Clinical Study Report. Clinical trials of medical devices are performed mainly in special healthcare institutions and involve patients as study subjects. As we all recall, human research participation is possible only if there are document for the planned study, which is considered by the Ethics Council with granting permission for conducting the study based on council's approval.

THE SIGNIFICANT ROLE OF ETHICS COMMITTEES AS IN THE CASE STUDY OF THE INDEPENDENT ETHICS COMMITTEE OF THE MOSCOW ORGANIZATION OF THE RUSSIAN SOCIETY OF ROENTGENOLOGISTS AND RADIOLOGISTS

A local (independent) ethical committee (IEC) of a study site reviews all materials when obtaining the study permission. Studies are typically prospective in design, and ethical committees play the significant role in conducting such studies. Based on the study results, the IEC may refuse to approve the study. For example, if there are patient safety risks, based on interim safety reports, the national ethics committee has the right to suspend the study in the site.

Studies using artificial intelligence (AI) systems are included in separate dossier block. For most AI-based studies, it is acceptable to use a retrospective design with existing databases.

Ethical issues are not clearly regulated in AI-based studies, but ethical committees are usually aware of planned retrospective studies. Although this approach does not violate any applicable laws and regulations, it involves some risks that are better to be minimized. When dealing with a patient database, it is necessary to anticipate risks of data leak and personal patient identification, as well as to obtain sufficient high-quality data for further analysis.

In Russia, not all ethical committees review AI-based studies. However, in 2019, the Scientific and Practical Clinical Center for Diagnostics and Telemedicine Technologies of the Moscow Health Care Department (SPCCDTT) hosted an independent ethics committee of the Moscow Regional Branch of the Russian Society of Roentgenologists and Radiologists (RSRR MRB IEC) with the primary goal to implement good research practices for AI-based studies.

The RSRR MRB IEC has reviewed 45 studies; 60% of them were initially did not receive approval due to design errors. In just 3 yr, we managed to reduce the number of refusals to 10% using an individual approach to each application and standardizing documents and processes consistently and systematically.

Each IEC expert has more than 5 yr of research experience and has received training in good clinical practice. We evaluate study designs, including those that are retrospective, paying close attention to data security issues, data use, and possible risks, the process of obtaining data, and their storage and processing.

Due to the rapid scientific progress and wide opportunities for AI system application, the deeper approaches should be used when planning such studies for ethical analysis and assessment of potential risks. In SPCCDTT, all studies are initially (at the planning stage) considered by an IEC, regardless their design. Information on study progress is submitted at least once a year. The study is supervised by the Principal Investigator, who is also considered by the IEC.

In addition to reviewing studies, the ethics committee is responsible for peer review of scientific work of SPCCDTT members. For each paper, the IEC prepared a review and a list of recommendations, assisting authors in avoiding errors before submitting the manuscripts for publication. Therefore, the IEC is an additional scientific supervisory body, which helps authors to improve the quality of their publications for top-rated journals.

The world's leading scientific journal do not consider manuscripts without the approval of the ethical committee. The modern scientific world places high priority on protecting patient rights, data security, confidentiality, and legitimacy of materials submitted for publication. Not only researchers are responsible for data accuracy, but also ethical committees that approve studies and review manuscripts.

The RSRR MRB IEC experts thoroughly check all documents provided by applicants. Our researchers request that we review and approve their studies. We carefully analyze documents, including at least a study plan, informed consents of patients, and curriculum vitae of the principal investigator. To avoid possible errors when conducting the study and interpreting results, we check each document and, together with the applicant, adjust the work plan.

In most documents submitted, we note the lack of the randomization process description or the lack of

randomization step in controlled trials, as well as the small size of population and incorrect patient selection criteria. Special attention is paid to an informed consent because its content directly affects the rate of enrollment.

Our help is requested by graduate students and candidates for degrees. A potential thesis is comprehensively analyzed. We take into account the study's abstract, scientific content, originality, and practical relevance. We check if the research plan reflects study goals and methods. We analyze patient data, its storage and transfer, its confidentiality, and the protecting rights of study subjects.

When reviewing documents for AI-based studies, we carefully check reference data sources, processing algorithms, and ways of health information storage and transfer. We also consider potential risks for patients and study integrity in case of partial or complete loss of data.

CONCLUSION

In addition to the comprehensive analysis of documents submitted, the ethics committee give advice on improving manuscripts for their subsequent publication in top-rated journals.

The main principle of the IEC is to comply with good research practices at each stage of the study.

The IEC provides ethical support for scientific and clinical trials of drug products and medical devices.

We are open for collaboration with candidates, graduate students, researchers, and third-party applicants.

We are always ready to help in conducting high-quality clinical and scientific studies.

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O.I. Pchelintseva — literature review, analysis of literary sources, writing of the text of the article

O.V. Omelyanskaya — literature review, analysis of literary sources, correcting the article

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