WHAT DO MEMBERS OF RESEARCH ETHICS COMMITTEES KNOW ABOUT THEIR ORGANIZATIONAL AND OPERATIONAL ASPECTS?

Chudova NV, Tsyzman LG ✉

Research Center of Neurology, Moscow, Russia

The article analyzes how well members of research ethics committees (RECs) know the operational and organizational procedures of REC and provides the assessment of standard operational procedures for professional training of REC members.

Keywords: ethics committee, training of specialists, ethical review

✉ **Correspondence should be addressed:** Lyubov G. Tsyzman
Petrovsky Boulevar 8, b. 2, Moscow, 127051; Cyzman@expmed.ru

Received: 20.03.2021 **Accepted:** 26.03.2021 **Published online:** 31.03.2021

DOI: 10.24075/medet.2021.008

ОСВЕДОМЛЕННОСТЬ СПЕЦИАЛИСТОВ ПО ВОПРОСАМ ОРГАНИЗАЦИИ И ДЕЯТЕЛЬНОСТИ ЛОКАЛЬНЫХ ЭТИЧЕСКИХ КОМИТЕТОВ

Н. В. Чудова, Л. Г. Цызман ✉

Научный центр экспертизы средств медицинского применения, Москва, Росия

В статье приведен анализ данных об осведомленности специалистов по вопросам организации и деятельности локальных этических комитетов (ЛЭК). Представлена оценка стандартных операционных процедур ЛЭК, определяющих обучение специалистов.

Ключевые слова: этический комитет, обучение специалистов, этическая экспертиза

✉ **Для корреспонденции:** Цызман Любовь Геннадьевна,
Петровский бульвар, д. 8 строение 2, Москва, 127051; Cyzman@expmed.ru

Статья получена: 20.03.2021 **Статья принята к печати:** 26.03.2021 **Опубликована онлайн:** 31.03.2021

DOI: 10.24075/medet.2021.008

Introduction

A research ethics committee (REC) is an autonomous independent voluntary body of specialists, scientists and clinicians with expertise in clinical trials of drugs (CTD).

From the outset of the COVID-19 pandemic, the operational principles of RECs have been subjected to a lot of scrutiny from all levels, including WHO [1,2,3].

In Russia, RECs operate according to the Constitution, other laws and regulations, the Declaration of Helsinki (World Medical Association), the guidelines of the Council for International Organizations of Medical Sciences (CIOMS), and the European Convention on Human Rights and Biomedicine.

Guidance for REC is provided by WHO, ICH GCP (International Conference on Harmonization — Good Clinical Practice), the Russian OST 42-511-99 Guidelines for Good Clinical Practice, the approved statute on the Committee, and the system of standard operational procedures (SOP). Oversight is performed by the Federal Service for Surveillance in Healthcare and Social Development (Roszdravnadzor). An inspection carried out by Roszdravnadzor in 2018 uncovered a number of violations in the activities of RECs, which were reported at the Conference on Ethical Challenges of the 21st century held on November 1, 2019 in Moscow as part of the 29th National Congress on Respiratory Diseases: non-compliance with SOP (38% of the violations), record-keeping and protocol violations (24%), violations pertaining to the evaluation of qualifications of the researcher (14%). A review of law implementation practices by Roszdravnadzor revealed that in some cases RECs did not control adherence to ethical norms during the trial, failed to make sure that the rights of study participants were observed, violated the procedures of informing the researcher or CT organizers about the decisions made and reasons for such decisions; in some cases there were not enough qualified experts in REC to carry out the ethical evaluation of the planned trial, or there was no confirmation that scientific consultants involved in decision making had not participated in the debate and voting [4].

Aim of study

The aim of the study was to evaluate the expertise of REC members in organizational and operational practices of REC and to analyze the system of SOP for REC in the context of decision making about external and in-house training of REC members.

METHODS

A survey was conducted among 97 members of 22 RECs across Russia (Moscow, Saint-Petersburg, Kazan, Nizhny Novgorod, Barnaul, Novosibirsk, Vladivostok, Belgorod, Omsk, Tomsk, Smolensk, Yaroslavl). The questionnaire contained 16 questions for REC members with expertise in ethics who are responsible for monitoring ethical conduct of CT and ensuring that the rights of CT participants are observed. The obtained data were processed, analyzed and summarized. Procedures related to the training of REC members were analyzed using a sample of 10 RECs.

RESULTS AND DISCUSSION

RECs from our sample comprised up to 15 people each. Each of the studied RECs, except those from Moscow and Kazan, reviewed an average of < 10 projects (initial applications) and 1 to 50 re-submissions, including amendments to the protocol, updated protocols or information leaflets, per month. For Moscow and Kazan RECs, the number of initial submissions

was higher: 50 to 85. Generally, submission assessment can be expedited or performed within an established period of time. The following response times were reported: 2 weeks (40% of the respondents), one month (20%) and 10 days (7%). Of all the respondents, 69% said their REC had a special peer review template and an established procedure for pre-review of applications; rejection of applications for clinical drug trials was reported by 51% of the respondents. However, the respondents did not specify whether regulatory agencies (Scientific Centre for Expert Evaluation of Medicinal Products and Council on Ethics of the Ministry of Healthcare) had reviewed the rejected applications prior to REC decision. Twenty-seven percent of the respondents said they knew about cases when REC members had decided to terminate a clinical trial.

All of the respondents (100 %) claimed that they strictly adhered to the established SOP, which is a mandatory requirement for an ethics committee at any medical facility; this requirement is specified in the Order 200n of the Ministry of Healthcare dated April 1, 2016. The procedure of granting the sponsor of CT, the researcher and regulatory agencies unlimited access to SOP and REC members data was familiar to 100 %, 93 % and 97 % of the respondents, respectively. Some of the respondents (36 %) believed that patients or their family members should be invited to participate in REC meetings in order to organize CT more effectively, because their opinion about the tested drug is based on personal experience. Fifty-nine percent of the respondents said that the applicant/sponsor/researcher could participate in the discussion of specific issues during a REC meeting only if they had permission of the chairman/deputy chairman; 32 % said that only clinicians/researchers themselves could participate in REC debate; 9 % said that the applicant/sponsor/researcher could not participate in a REC meeting. Over 7 % of REC members reported that independent consultants participated in the vote during a REC meeting.

As part of our study, we analyzed documentation provided by 10 RECs describing how training of REC members should be organized in order to improve the quality of ethics expertise.

In 2 cases (20%), Kazan State Medical University and Sechenov First Moscow State Medical University introduced the concept of internship to REC. A person who wants to become a REC member signs the confidentiality agreement and gets access to all REC documents. The intern is allowed to be present at all REC meetings but cannot participate in voting. At Kazan State Medical University, such internship lasts for 2 months; at Sechenov First Moscow State Medical University, it lasts at least 1 year. During this period, the intern learns about GCP and ethics expertise. Upon completing their internship, the intern receives a certificate and becomes a full-fledged REC member [5,6,7]. In our study, 30 % of RECs (3 cases) did not have a provision about the training program for REC members in SOP; in 3 cases (30 %) it was impossible to assess how training procedures were implemented due to the absence of publicly available information about SOP on the web-site of the institution. Only in 2 cases (20 %) SOP outlined the duties and responsibilities of those REC members who would be in charge of organizing educational programs on medical ethics and take a training course/internship program to improve their own qualifications.

CONCLUSION

The survey shows that most of our respondents knew how RECs operate. Only a few respondents (7%) did not have full knowledge of REC procedures (participation of independent consultants in the vote, participation of the applicant/researcher/sponsor in the discussion, considering the existing conflict of interests, granting the researcher and regulatory agencies unlimited access to SOP and REC members data, etc).

Continuous education of REC members and maintenance of corporate culture are essential tasks for any medical facility. The analysis of REC documentation revealed that 1/3 of SOP did not contain information about REC members training. Besides, in 30% of cases it was impossible to assess decisions on training procedures made by REC due to their unavailability to the public.

The role of REC is becoming more significant during the current coronavirus pandemic, when ethics committees are more focused on post-registration studies and positive/negative effects of trialed drugs need to be scrutinized.

Thus, additional training programs for members of ethics committees are needed to reduce the rate of errors in expert assessments, ensure high quality of clinical trials and guarantee safety of their participants.

References

1. World Health Organization (2020). Ethical standards for research during public health emergencies: Distilling existing guidance to support COVID-19 R&D. https://www.who.int/blueprint/priority-diseases/key-action/liverecovery-save-of-ethical-standards-for-research-during-public-health-emergencies.pdf/.
2. World Health Organization. 2020. 2019 novel Coronavirus: Global research and innovation forum: towards a research roadmap. https://www.who.int/blueprint/priority-diseases/key-action/Roadmap-version-FINAL-for-WEB.pdf?ua=1/.
3. World Health Organization. Guidance for research ethics committees for rapid review of research during public health emergencies. 28 May 2020: https://www.who.int/publications/i/item/9789240006218/.
4. Review of the law enforcement practice of control and supervision activities of Roszdravnadzor for the 2nd quarter of 2018. https://www.roszdravnadzor.ru/discussion/control/prevention/doc7/.
5. Regulation on the local ethics Committee, version 2.0. from 25.10.2017. https://www.sechenov.ru/upload/iblock/30a/polozhenie-lek-versiya-2.0.pdf/ Russian.
6. The Standard operating procedure of The Local ethics committee of Kazan State Medical University. https://kazangmu.ru/science-and-innovation/lokalnyj-eticheskij-komitet/main-doc/. Russian.
7. Resolution of the Government of the Russian Federation of April 3, 2020 № 441. https://www.garant.ru/products/ipo/prime/doc/73750814/

Литература

1. World Health Organization (2020). Ethical standards for research during public health emergencies: Distilling existing guidance to support COVID-19 R&D. https://www.who.int/blueprint/priority-diseases/key-action/liverecovery-save-of-ethical-standards-for-research-during-public-health-emergencies.pdf/.
2. World Health Organization. 2020. 2019 novel Coronavirus: Global

research and innovation forum: towards a research roadmap. https://www.who.int/blueprint/priority-diseases/key-action/Roadmap-version-FINAL-for-WEB.pdf?ua=1/.
3. World Health Organization. Guidance for research ethics committees for rapid review of research during public health emergencies. 28 May 2020: https://www.who.int/publications/i/item/9789240006218/.
4. Обзор правоприменительной практики контрольно-надзорной деятельности Росздравнадзора за 2 квартал 2018 года. https://www.roszdravnadzor.ru/discussion/control/prevention/doc7/.
5. Положение о локальном этическом Комитете, версия 2.0. от 25.10.2017. https://www.sechenov.ru/upload/iblock/30a/polozhenie-lek-versiya-2.0.pdf/.
6. СОП ЛЭК КГМУ, Редакция 8 от 10.12.2018 г. https://kazangmu.ru/science-and-innovation/lokalnyj-eticheskij-komitet/main-doc/.
7. Постановление правительства РФ от 3 апреля 2020 г. № 441. https://www.garant.ru/products/ipo/prime/doc/73750814/.