BMC Medical Ethics

RESEARCH Open Access

Survey on the current practice of research ethics committees in the Czech academic environment: a mixed-methods study

Renata Veselska[1,3*], Jan Sirucek[2] and Josef Kure[3]

Abstract

Background The primary objective of this study was to conduct a comprehensive questionnaire survey on the practices of research ethics committees reviewing academic research projects in Czechia. The study aims to provide an unbiased and objective assessment of the current practices of research ethics committees, namely to obtain the missing data on their functioning in the context of academic research, to identify difficulties and shortages that threaten the responsible functioning of research ethics committees in the country and to investigate the implementation of Additional Protocol on Biomedical Research CETS No. 195 in their practice. Such research has never been conducted in Czechia.

Methods This was a mixed-methods study, in which the online survey with closed and open-ended questions was chosen to explore the situation regarding ethics assessment of research involving human participants. We developed a questionnaire containing 18 questions concerning several aspects of the functioning of research ethics committees. The questionnaire was in Czech language and was administered through the Qualtrics platform anonymously. The target group of 61 research ethics committees at research institutions was approached by emails and we received 43 completely filled questionnaires, i.e., response rate of 67%.

Results We obtained valuable data on the functioning of research ethics committees in Czechia in three main domains: the mandate and composition of the committee; the scope of its agenda; the process of evaluation including the voting procedure. In addition, the final set of open-ended questions provided an in-depth look at the problems faced by research ethics committees in Czechia. From the results is evident that the responsible assessment of the ethics of research involving human subjects is still not satisfactorily addressed and established for routine practice in the country.

Conclusions The outcomes of our study revealed that the main problem of research ethics in Czechia is the lack of national legislation on research ethics governance. To address this problem, the country requires a legislative framework accompanied by supportive measures aimed at educating, guiding and advising research ethics committees, especially in the Czech academic environment.

Trial registration number Not applicable.

*Correspondence:
Renata Veselska
veselska@mail.muni.cz

Full list of author information is available at the end of the article

Keywords research ethics, human subject research, research ethics committees, international ethics standards, research ethics governance, academic research institutions

Introduction

Institutional Research Ethics Committees (RECs) were spontaneously established in Czechia in the early 1990s after the Velvet Revolution, with the task of ensuring the proper conduct of research involving human subjects. However, almost 35 years after their establishment, it is notable that these committees – except in the area of clinical trials – are still completely outside the legal framework, and their activities and evaluation practices are not standardized or regulated in any way.

Nevertheless, on September 1, 2001, Czechia entered into force the Additional Protocol to the Convention on Human Rights and Biomedical Sciences, relating to Biomedical Research, as Communication of the Ministry of Foreign Affairs No. 30/2020 Coll. (hereinafter referred to as Additional Protocol CETS No. 195) [1]. The main objective of this protocol is to protect the dignity and autonomy of human beings in any biomedical research that requires physical or other intervention (if such other intervention poses a risk to the mental health of the person concerned). Therefore, this protocol defines the general ethical requirements for biomedical research (primacy of the interests of human beings, scientific quality of the research, balance of benefits and risks, absence of alternatives) and, in particular, defines in detail the role and competencies of RECs in assessing research projects.

It should be noted that Czechia already ratified the Convention on Human Rights and Biomedicine (Oviedo Convention ETS No. 164) [2] itself in 2001.

In Czechia, the functioning of RECs in health care institutions is regulated by Act No. 378/2007 Coll. on Medicinal Products [3] and by Act No. 375/2022 Coll. on Medical Devices [4], but only in relation to the required ethical assessment of these two types of clinical trials. Nevertheless, these two legal norms limit the mandatory assessment of a clinical trial by the REC only to trials testing medicinal products or medical devices. However, there are also other types of clinical trials – for example, clinical trials of new surgical procedures – that are not covered by these national legal norms. In addition to this, many biomedical research projects that are governed by the Additional Protocol CETS No. 195 [1] or the Convention ETS No. 164 [2] itself are not clinical trials. Furthermore, these projects may be performed outside of healthcare settings, such as in universities or research institutes (hereafter referred to as "academic research").

In contrast to academic research in the field of biomedicine, where the functioning of RECs should be settled at least by the implementation of the Additional Protocol CETS No. 195 [1], the ethical aspects of research involving human subjects in the social sciences and humanities (hereinafter SSH) remain completely unaddressed in Czechia. However, this research also often has significant ethical relevance, and the assessment of research projects in the field of SSH is recommended by international standards of professional associations, especially but not only in the field of psychology and sociology.

Unfortunately, in all disciplines – except for the medical professions – training in research ethics is not a mandatory part of undergraduate or postgraduate studies. Thus, even the young generation of researchers is dependent either on elective courses that include more or less brief information on discipline-specific aspects of research ethics as part of the curriculum, or on rigorous training at the home institution. However, both require researchers or academics who have a certain non-trivial awareness of research ethics and who do not practice so-called "ethics washing" [5] – in other words, who are concerned about actually adhering to ethical standards in their own work.

Last but not least, it should be kept in mind that many interdisciplinary academic research projects also have ethical relevance: typical examples are projects using biomedical technologies and techniques to test hypotheses in other disciplines. Furthermore, any academic research involving vulnerable populations – typically children, the elderly, the subordinates, the socially excluded, etc. – also has clear ethical relevance.

As a necessary starting point for the possible regulation of RECs in Czechia, we decided to conduct a thorough questionnaire survey on the current practice of RECs that review academic research projects. To our best knowledge, a similar in-depth nationwide survey on the practice of RECs reviewing academic research projects involving human subjects has never been conducted in Czechia or in any other European country.

According to the published literature, the process of ethical review of research projects was analyzed for RECs in UK [6–8], Germany [9], in Australia particularly for research with participation of social workers [10] or for commercial research on human subjects in Unilever as a large multinational company [11]. Nevertheless, these studies were not based on direct surveys among REC members and provided only the external analyses of the REC functioning in the countries or companies, respectively.

A specialized nationwide study mapping the activities of RECs reviewing the clinical trial protocols was performed in France [12]; however, its scope and methods

were markedly different from our survey. The only available data are from two large non-European countries and were collected one or two decades ago. The first study was based on a survey among members of 89 institutional review boards (IRBs) of the 892 registered IRBs in the USA at that time [13], the second on the interviews with 34 REC members in Australia [14]. Unfortunately, the total number of RECs in Australia is not provided in this study. Interesting data on this topic brought also the more recent study aimed at the certification of REC in Japan [15].

In this context, our study was aimed to provide an unbiased and objective assessment of the current practices of research ethics committees in Czechia, namely to obtain the missing data on their functioning in the academic research environment, to identify difficulties and shortages that threaten the responsible functioning of research ethics committees in the country and to investigate the implementation of CETS 195 in their practice.

Methodology

Questionnaire

To survey the situation, we developed an original online questionnaire in Czech language (translation of the questionnaire into English is provided as a Supplementary information – Additional File 1) covering three main domains related to the activities of the RECs: (i) the mandate and composition of the committee (5 questions, Q1-Q5), (ii) the scope of its agenda (3 questions, Q6-Q8), (iii) the way in which submitted projects are evaluated including the voting procedure (6 questions, Q9-Q14). The questions in these three domains were formulated as multiple choice with the possibility to add one's own answer. The other three open-ended questions (Q15-Q17) focused on the problematic experiences of the particular REC. These questions gave the chairs the opportunity to comment on what they would consider important to improve the functioning of their own commission and the functioning of RECs in the Czech Republic in general. The pilot version of the questionnaire was pretested with representatives from three RECs: The REC of the Institute of Psychology of the Czech Academy of Sciences, which evaluates only SSH research projects, the REC of the Faculty of Medicine of the Masaryk University, which evaluates only biomedical research projects, and the REC of the Masaryk University, which evaluates both biomedical and SSH research projects. This design of the pre-test corresponds to the size and composition of the target group in the country. The questionnaire was then optimized according to the feedback from this pretest. The final version of the questionnaire was administered through the Qualtrics platform anonymously, i.e. without collecting the IP addresses. However, the option to reveal the identity of the REC was provided in the last question (Q18). As a result of these measures to ensure anonymity, it was possible to fill out the questionnaire repeatedly, but only completed, unique responses were analyzed.

Target group

As the number of RECs in the Czech Republic is very small, we did not use any sampling technique and all respondents belonging to the target group were invited to participate in our study. The target group consisted of RECs at research institutions where research involving human subjects is conducted (universities, institutes of the Academy of Sciences of the Czech Republic, resort research institutes, teaching hospitals or other medical institutions cooperating with universities). The list of addressed institutions including contact addresses was compiled on the basis of an initial survey of the websites of the institutions concerned. In the case of the institutes of the Academy of Sciences of the Czech Republic, most of them have no information on their websites about the non/existence of RECs. Therefore, the directors of these research institutes were contacted directly, and they either confirmed the absence of RECs or forwarded the unpublished contact to the chairperson of their institutional REC.

Questionnaire distribution and achieved response rate

Data collection was conducted online over a 6-week period between December 2021 and January 2022. Based on the procedure described above, a total of 61 institutional REC chairpersons were contacted directly and asked to complete the online questionnaire. The first contact was in the form of a personal email addressed directly to the chair of the relevant institutional REC. Due to the anonymous collection of responses, a further repeated request was made by mass email to all selected recipients in week 5 of the above interval. A total of 43 respondents completed the questionnaire, for a response rate of 67%. For the remaining 18 incomplete questionnaires, the vast majority of respondents simply looked at the form and did not respond. Therefore, the sample base for the results presented below is the 43 respondents who provided valid responses to all parts of the questionnaire.

Ethical considerations

This study was conducted in full compliance with international research guidelines and Czech law (see the Ethical Declarations section for more details). No personal data of human subjects were collected during the research. Respondents participated in the survey as representatives of institutional research ethics committees and not as identifiable individuals. In addition, the survey was administered online only and was completely anonymous. Under these conditions, no informed consent

was obtained from the respondents (this is in complete accordance with the ethical standards for anonymous online surveys) and this study was not subject to the REC approval according to the Czech law. As described above, REC representatives were invited to participate in the study through personalized emails containing detailed information about the design and purpose of the study, the link to the online survey, and contact information for the principal investigator of this study (RV). In addition, the respondents were informed about the questionnaire format, length, and anonymity measures on the introductory screen of the survey. Taken together, this study fully met the requirements of confidentiality and voluntary participation.

Results

Mandate and composition of the RECs (questions Q1-Q5)

Regarding the mandate of the REC (Q1), 39 respondents (91%) identified the evaluation of the ethical dimensions of research involving human subjects as the primary scope of the committee's activities. 19 respondents (44%) also mentioned providing consulting services to researchers or academics. In addition, 15 respondents (34%) indicated that their activities include investigating cases of scientific misconduct.

Regarding the REC's size (Q2), 10 committees (23%) have a size of up to 5 members, 19 respondents (44%) have a size of 6 to 10 members, and 14 committees (33%) have a size of more than 10 members.

In terms of tenure (Q3), in most cases, membership of the REC is not limited to a specific mandate and is therefore not limited in time (33 responses, 77% of responses to the question). In 7 cases (17% of the responses to the question), membership is limited to a specific mandate and can be renewed. In 2 cases, term-limited membership cannot be renewed (5% of responses to the question).

Regarding the REC's composition (Q4), 88% (38 respondents) reported that the members should have the required expertise related to their field of work, and 83% (36 respondents) reported that the members should have a Ph.D. degree or higher. 20 participants (46%) confirmed that at least one member of their REC does not have a scientific degree in the field of the REC's activity but is a qualified expert in another field. 22 RECs (51%) have lay members and 28 RECs (65%) have extramural members, i.e., members who are not employed by the institution founding the respective committee.

When the process of establishing the REC chairperson was surveyed (Q5), we found that in most cases, i.e., in 30 RECs (70% of the responses to the question), the REC chairperson is appointed by the founder. Only in 9 RECs (21% of the responses to the question) is the chairperson elected by the REC members. 4 respondents (9% of responses to the question) mentioned another way of establishing the REC chairperson, but without providing further details.

Table 1 Overview of results regarding the project types that are required to be reviewed by the relevant REC

Type of research:	No of RECs	%
Classification according to research field (Q6)		
Clinical trials	31	72
Other biomedical research with human subjects – not clinical trials	31	72
Research with human biological samples (not commercially available)	25	58
Other (non-biomedical) research with human subjects and with the use of biomedical methods or technologies	18	42
Behavioral research	18	42
SSH research	10	23
Research with sensitive personal data	21	49
Research involving deception	7	16
Other research not classified above	7	16
Classification of research with specific groups of participants (Q7)		
Research with patients	35	81
Research with minors	24	56
Research with persons in clinical need	15	35
Research with persons not able to consent to research	21	49
Research with vulnerable persons (elderly, pregnant, etc.)	22	51
Research with subordinate persons (students, soldiers, prisoners, etc.)	11	26
Other research not classified above	6	14
Classification of research according to the reason for approval by REC (Q8)		
Approval is required by international obligations	27	62
Approval is required by sponsor / granting agency	38	88
Approval is required by publisher of the results	32	74
Other research not classified above	4	9

The RECs agenda (questions Q6-Q8)

In this domain, we investigated which types of projects are required to be evaluated by the relevant REC – in other words, which types of projects the founder insists on being evaluated for ethical relevance. Obtained results for Q6, Q7 and Q8 are summarized in Table 1.

These results show that more than two thirds of the committees (31 RECs, 72%) are established according to Act No. 378/2007 Coll. on Medicinal Products [3] or by Act No. 375/2022 Coll. on Medical Devices [4] and, apart from academic research, primarily review these types of clinical trials for which evaluation according to these legal norms is mandatory.

The next question (Q6) focused on the mandatory evaluation of research based on Additional Protocol CETS No. 195 [1]. The results showed that the same number of committees (31 RECs, 72%) reported mandatory review of other types of biomedical research involving human subjects, and 25 RECs (58%) reported mandatory review

of projects involving human biological samples that are not commercially available.

Just under half (18 RECs, 42%) of the RECs assess other (non-biomedical) research involving human subjects and research using biomedical methods or technologies, which is also in line with the requirements of Additional Protocol CETS No. 195 [1]. The same number of committees (18 RECs, 42%) state that they require review of behavioral research.

However, the mandatory review of research projects involving deception is mentioned by less than a quarter (7 RECs, 16%) of the RECs that mention mandatory review of behavioral research in general. SSH research (other than behavioral research) is also evaluated only by a minority (10 RECs, 23%). Regarding the protection of research participants' personal data, only half of the total number of committees (21 RECs, 49%) require mandatory review of projects involving sensitive personal data.

Another area examined in the study involved the mandatory assessment of research involving specific groups of participants, which are generally considered to be highly ethically sensitive (Q7). Since the survey focused on RECs in academic environments, including teaching hospitals, the mandatory review is most commonly required for projects involving patients in healthcare settings (35 RECs, 81%). With approximately the same frequency, mandatory review was reported for research projects involving minors (24 RECs, 56%), projects involving vulnerable populations (22 RECs, 51%), and projects with persons not able to consent to research (21 RECs, 49%). Projects with persons in clinical need were listed as mandatory reviewed in only 15 RECs (35%) and projects with subordinate persons in only 11 RECs (26%).

The obligation to review a project according to the type of research and the type of participants with the obligation to review that is externally required (Q8) was also compared. It was found that 38 RECs (88%) are obliged to review projects where approval by REC is required by the funder (typically a grant agency). Similar results were found when the approval by REC is required by the publisher (32 RECs, or 74%, are obliged to review the project for this reason). Remarkably, only 27 RECs, i.e., 62% declared mandatory review in accordance with international obligations of Czechia, namely Oviedo Convention ETS No. 164 [2] and its Additional Protocol CETS No. 195 [1].

REC review practice (questions Q9-Q14)

The last domain focused in more detail on the actual review practice of the individual RECs, i.e., how the submitted documents are reviewed (Q9-Q12) and how the project is decided (Q13-Q14).

Although an informed consent and/or information for research participants is a key element in evaluating the ethical relevance of a research project, and its review is also required by the Additional Protocol CETS No. 195 [1], 37 RECs (86% of the total) listed this item as a mandatory part of their submission. Only one respondent clarified in an open-ended response that their REC requires this document as part of the preliminary project design.

29 RECs (67%) require a preliminary project design for review, 24 RECs (56%) require full project documentation. Only 18 RECs (41%) reported that they use a specific form or checklist to identify ethically relevant aspects of a given project. Approximately the same number of committees (19 RECs, 44%) require submission of documents proving collaboration with a healthcare provider.

Furthermore, 8 RECs (19%) stated that they require other documents in addition to the above; however, in most cases (7 RECs) without further specification. In the remaining case, the clarification was the requirement for the text of the informed consent and information for participants as described above.

Next question (Q11) was focused on what the REC actually evaluates when reviewing a project. Interestingly, only 16 RECs (37%) evaluate the compliance of the submitted project with international ethical standards for research. In only one response did the respondent add which international standards were in question – namely Oviedo Convention ETS No. 164 [2], UN Universal Declaration of Human Rights [16], WMA Helsinki Declaration as amended [17], and CIOMS/WHO 2016 Guidelines [18]. The remaining answers did not provide any further details.

Among the other response options presented regarding what RECs evaluate when reviewing research projects, the following responses were about twice as frequent as the previous one: the project's compliance with internal institutional standards (31 RECs, 72%), the project's compliance with legal requirements for the research area (33 RECs, 77%), and the processing of personal data (35 RECs, 81%). Furthermore, 4 respondents (9%) mentioned another evaluation parameter in general without any further specification.

When asked about the way in which submitted projects are reviewed (Q9), a total of 15 RECs (35%) indicated that all members of the committee have access to the submitted materials, read them simultaneously and comment on them. 22 RECs (51%) then reported the usual practice of having one or more designated committee members (rapporteurs) reviewing the project in detail and then presenting the report to the others, while the others have access to all submitted materials. 1 REC reported a remarkable variation on the previous procedure, whereby one or more designated committee members (rapporteurs) are assigned to review the project in detail and report back to the others, but the others do not have

access to the submitted materials. Furthermore, 3 RECs (5%) indicated a different method of review, with one respondent stating that projects with minimal risk are evaluated by the REC secretary together with the REC chair, while other projects are evaluated by the entire committee.

Regarding the approval procedure itself (Q13), 18 RECs (42%) reported voting at the REC meeting, with either a vote in favor by a super-majority of those present (15 RECs, 35%) or a vote in favor by a super-majority of all committee members (3 RECs, 7%) required for project approval. 10 RECs (23%) reported that the approval process is by per-rollam voting, with approval of a project requiring the vote in favor of a super-majority of those voting (3 RECs, 7%) or the vote in favor of a super-majority of all committee members (7 RECs, 16%). Other 10 RECs (23%) then indicated another voting method as their chosen answer option, with only 2 RECs specifying in an open-ended response that it was to reach a consensus position.

The next question focused on quorum, management of conflicts of interest, and other conditions for committee voting (Q14). Two RECs consistently stated that the quorum for approval was 5 committee members, and one REC declared that there was no quorum for approval. This is supplementary information to the previous question on project approval parameters. Only 24 RECs (56%) indicated that a member can abstain from voting on a project.

Regarding the management of conflicts of interest, a total of 37 RECs (86%) indicated that the member who declared a conflict of interest for a particular project would not vote on that project. In such cases, 20 RECs (54% of the responses on managing conflicts of interest) do not change the quorum, while 17 RECs (46% of the responses on managing conflicts of interest) do not include such a member in the quorum required for project approval.

When asked about other voting conditions, 20 RECs (47%) stated that in the event of a tie, the chairperson's vote would prevail. Only 4 RECs (9%) confirmed the possibility of a presidential decision. Two additional respondents answered the open-ended question concerning the conditions for a presidential decision. For one REC, this option is used exceptionally before the publication is sent out for peer review – when the editors require REC research approval.

Reservations and comments on the functioning of RECs in Czechia

The last series of open-ended questions (Q15-Q17) encouraged respondents to share experiences and ideas that had not been the subject of previous questions in the domains described above. The full answers are shown in Table 2 (for question Q15), Table 3 (for question Q16), and Table 4 (for question Q17).

When asked what the RECs consider to be the biggest obstacles to their activities (Q15), the main problem that was repeatedly criticized was the complete lack of uniform and comprehensible rules for the functioning of RECs, not only in the academic environment (Table 2, answers Q15-A03-A, B, Q15-A08-A, Q15-A12; Table 3, answers Q16-A03, Q16-A05; Table 4, answers Q17-A01-B, Q17-A12, Q17-A13-A). More specifically, the lack of legal regulations for research involving human gametes (Table 4, answer Q17-A17) and the ambiguous interpretation of some legal terms and legal norms (Table 2, answer Q15-A01-C).

Another frequently cited barrier was the absence of an educational system and consulting service in research ethics, both for researchers and for REC members (Table 2, answers Q15-04-D, Q15-A07-B, Q15-A13; Table 4, answers Q17-A03, Q17-05, Q17-A06-A, Q17-A13-B) and lack of well-functioning cooperation among RECs (Table 4, answers Q17-09, Q17-A15-C). Several respondents mention the problems arising from insufficient training of investigators in research ethics (Table 2, answers Q15-A07-C, Q15-A14-A, B, Q15-A21). In contrast, two respondents appreciated the opportunities for education, consulting, and sharing of experiences in the area of clinical trials of medicinal products and medical devices (Table 3, answer Q16-A01, Table 4, answer Q17-A16-B).

Another criticism was focused on the current practice of funding agencies in Czechia, as these funders usually require the final approval of all ethically relevant projects before submitting them to the specific call (Table 2, answer Q15-A02-B; Table 4, answer Q17-A06-B); however, at the same time, it is unclear which projects will be awarded, so most of them are evaluated by REC in vain (Table 2, answer Q15-A03-C).

The issue of overloading RECs with many projects that for various reasons are not necessarily subject to ethical assessment, typically combined with insufficient time for such redundant assessment, was also raised several times (Table 2, answers Q15-A02-A, Q15-A04-A, Q15-A07-A, Q15-A17). Some respondents also emphasized the need to increase the number of institutional (local) RECs to reduce the overload of already existing RECs (Table 2, answer Q15-A02; Table 4, answers Q17-A01-A, Q17-A16-A).

The problematic experiences with the "internal" functioning of the RECs include namely the low prestige of the RECs within the scientific community, which results in low interest in becoming a REC member (Table 2, answers Q15-A06, Q15-A20-B), inadequate work capacity dedicated to REC membership (Table 2, answers Q15-A04-B, Q15-A05, Q15-A19) insufficient administrative,

Table 2 Overview of answers to open question Q15 "What do you consider to be the biggest problems in the functioning of your ethics committee?"

Number	Answer(s)
Q15-A01	A. Unduly administration. B. Necessity to archive documentation and lack of storage space. C. Ambiguous, possibly changing interpretation of certain laws (e.g., definition of intervention).
Q15-A02	A. Absence of self-assessment using a "checklist" for simple projects with only minimal risk. B. Ambiguity in communication with the Czech Science Foundation (GAČR) or other funding agencies about the need for approval from the REC before submitting a project to a specific call. C. Overloading by applications in some time periods: we have to deal with the ethical aspects of almost all projects we work on with partner institutions within our own REC, which increases the number of assessments (as it is still not common for research institutions to have their own REC).
Q15-A03	A. Unclear rules for research ethics assessment in Czechia (except for clinical trials), especially for SSH projects. B. Lack of legal framework for research ethics review in Czechia (except for clinical trials). C. Inconsistent approach of funding agencies to research ethics assessment, in particular requiring final approval of the project at the time of submission to a specific call (scientific quality of the project cannot be taken into account, most projects for a specific call are assessed by REC vainly).
Q15-A04	A. Insufficient time for assessment of research project proposals, resulting in time-critical evaluation). B. Inadequate work capacity dedicated to the REC (in terms of individual members), resulting in the inability of the REC to act. C. Inadequate financial, administrative and personnel support of the REC (lack of adequate budget, lack of technological support which should be in line with 21st century capabilities, lack of fair remuneration of REC members for the work done, which is now only a symbolic reward). D. Systematic education and training of existing and new EC members – completely absent in our conditions; the work of the REC is largely amateurish.
Q15-A05	Time overload, the necessity to study project documentation outside of the working hours.
Q15-A06	The activities of the REC do not receive sufficient professional and social recognition, which results in low level of interest among experts to serve as REC members.
Q15-A07	A. Before submitting the project proposals to the funding agency, there is no time for a detailed discussion of them in the REC (researchers usually submit them for ethical assessment on the last day for their submission, or 2 or 3 days prior to the deadline). B. Researchers and investigators do not even know the Czech (let alone international) standards on research with human subjects. C. Researchers belonging to the medical profession (hospital employees) or non-professional contractors often submit their projects for ethical review in an extremely poor state, when their repeated revisions are necessary.
Q15-A08	A. Missing laws. B. Incompetent lawyers, e.g. on issues of informed consent. C. Dysfunctional ethics committees and dysfunctional codes of conducts.
Q15-A09	The legislation is very extensive in this regard.
Q15-A10	A. Increase in the amount of documentation, e.g. very long questionnaires filled out by the contractor, which the REC does not really need. B. Instead of a real information document for the research participants, informed consent becomes a "safety measure" for lawyers.
Q15-A11	In cases of suspected scientific misconduct, we considered the main problem to be the unwillingness of those involved to communicate and cooperate with the REC in a meaningful way.
Q15-A12	Unclear legal conditions for the evaluation of projects other than clinical trials of medicinal products (e.g. documentation requirements, archiving periods).
Q15-A13	Inconsistent instructions for evaluating project proposals (forms not available, etc.).
Q15-A14	A. Incomplete documentation and repeated errors in documentation submitted to REC. B. Repeated unnecessary questions from the contractors or monitors. C. Inconsistent requirements of multicentric RECs regarding the maximum length of the ICF document (maximum 10 pages). D. Further new EU regulations, too much bureaucracy.
Q15-A15	*Because this answer indirectly identified the respondent, it has been omitted from this overview for privacy reasons.*
Q15-A16	Excessive administration, especially in clinical trials of medicinal products. Nowadays, however, due to Regulation (EU) No. 536/2014 of the European Parliament and of the Council of April 16, 2014, the number of ethical assessments of these trials is expected to decrease significantly, as it will be possible to assess such clinical trials by the REC of the State Institute for Drug Control (SÚKL).
Q15-A17	The range and frequency of ethics assessments required.
Q15-A18	Currently*, only teleconferences and online meetings are possible. Outside of the pandemic period, REC works without problems. **) December 2021 – January 2022*
Q15-A19	Low attendance of REC members.
Q15-A20	A. Limited archive storage capacity. B. Unwillingness to serve as a REC member and especially as a chairperson.
Q15-A21	Closer collaboration with clinical departments and units to clarify research objectives and necessary ethical and legal measures.

Table 3 Overview of answers to open question Q16 "If you have additional information about the functioning of your ethics committee that you consider important and that we have not asked in the previous questions, please provide it here."

Number	Answer(s)
Q16-A01	Regarding clinical trials, we positively evaluate the helpful and fast communication with the regulatory authority (State Institute for Drug Control, SÚKL), including consulting activities and a large number of organized educational events.
Q16-A02	Administrative overload, especially in relation to contracts with pharmaceutical companies.
Q16-A03	The lack of a legal framework does not allow the REC to do more than improvise.
Q16-A04	*Because this answer was solely methodological, it has been omitted from this overview due to thematic inconsistency.*
Q16-A05	Unclear rules for clinical research related to clinical trials and involving a non-medical/research institution.
Q16-A06	*Because this answer indirectly identified the respondent, it has been omitted from this overview for privacy reasons.*

personnel and financial support (Table 2, answer Q15-A04-C; Table 4, answer Q17-A06-C, Q17-A11, Q17-A14). Furthermore, the high administrative burden of the committee was also emphasized repeatedly (Table 2, answers Q15-A01-A, B, Q15-A10-A, Q15-A14-D, Q15-A16, Q15-A20-A). In addition, the administrative overload was also mentioned for the other open question (Table 3, answer Q16-A02).

In terms of protecting research participants, the relatively frequent practice of drafting informed consent documents and/or instructions for research participants by lawyers was also identified as a problem (Table 2, answers Q15-A08-B, Q15-A10-B; Table 4, answer Q17-A01-C). In this context, the exceeding length (more than 10 pages) of this document was also criticized (Table 2, answer Q15-A14; Table 4, answer Q17-A15-B). One respondent also calls for a unified method of payment for compensation to clinical trial participants (Table 4, answer Q17-A15-A).

Finally, criticism with regard to scientific misconduct came from only two of the respondents. In one case, the unwillingness of the researchers concerned to cooperate with the institutional REC was described (Table 2, answer Q15-A11). In the second case, an established institutional practice was reported in which only the head of the institution can submit initiatives to the committee. However, the head of the institution is also not obliged to deal with the committee's findings, thus creating opportunities for the cover-up and concealment of individual cases (Table 4, answer Q17-A07; the full text / quote of this answer cannot be provided for privacy reasons).

Discussion

In this study, we plan to address the following important issues: (i) to obtain the missing data on the functioning of RECs outside the framework of clinical trials, especially in the context of academic research; (ii) to identify difficulties and shortages that threaten the responsible functioning of RECs in the country; (iii) to investigate the implementation of CETS 195 [1] in the practice of RECs in the country. All this information and data are still missing in the national context. As this type of study has never been conducted in Czechia in the past, the results obtained, in combination with the high response rate, provide truly representative and unique data on these issues.

A fundamental limitation of this study is the selective returnability. A 67% response rate is considered a solid result, but it is certainly not a random selection. However, we have no indication of the reasons why particular respondents chose not to participate. The results must therefore be read as the statements of those REC representatives who were willing to share their experiences – and this limits the external validity of the results.

Another limitation is based on the principle of the online survey as such. By using a qualitative approach, i.e. in-depth interviews, it would be possible to gain a deeper insight and understanding of the functioning of RECs. However, this approach would necessarily violate the condition of complete anonymity of statements in a very small group of REC chairs in Czechia, who very often know each other personally. Therefore, we consider an online survey to be more considerate of the respondents.

Another specific limitation is the application of the authors' own ideas about the optimal functioning of RECs. We have taken this into account by basing the questionnaires on internationally accepted standards, in particular the CETS 195 Additional Protocol, and by pretesting the questionnaire before the actual data collection.

Although the sociodemographic data (population size, number of universities and other research institutions) and completely different historical perspective of both countries mentioned above does not allow us to compare our data with the results of similar studies from the USA and Australia, our target group encompassing all relevant RECs in the country and high response rate indicates the representative nationwide overview for Czechia, as mentioned above. Furthermore, it is necessary to highlight that Czechia as the country in which both the Oviedo Convention ETS No. 164 [2] and its Additional Protocol CETS No. 195 [1] were ratified, is obliged to complain about a very different research ethics governance framework. For this reason, our aim was not to compare the findings from Czechia with those from other countries, but rather to perform an in-depth analysis of the

Table 4 Overview of answers to open question Q17 "What do you consider important for improving the functioning of ethics committees in Czechia?"

Number	Answer(s)
Q17-A01	A. RECs should be established routinely in larger numbers. B. Ethical standards and rules for assessment should be established in a way that is as understandable as possible to researchers, REC members, and research participants. C. Framing by international conventions and general legal norms is necessary, but the submission and assessment of research projects and the writing informed consents should not become a formal and legal issue (e.g. the text of the informed consent would – in an extreme caricature – resemble an energy purchase contract).
Q17-A02	If possible, a quick and smooth transition to the new assessment system for clinical trials within the EU.
Q17-A03	Common knowledge about RECs – many people do research and have no idea that they need to get approval from RECs, they have no idea that their institution has a REC.
Q17-A04	Biomedical research precedes REC's possibilities and knowledge. It is therefore important to understand the potential risks associated with the application of new biomedical technologies and their impact.
Q17-A05	A centralized consulting service in the field of research ethics.
Q17-A06	A. A well-functioning training system for prospective and current REC members (not just formal training, but real quality training/education). B. Streamlining the RECs' activity: assessment only of funded projects (not all proposals submitted to a specific call), as it works within the European Research Area. C. Ensuring administrative, personnel, and financial support to the REC.
Q17-A07	*Because this answer indirectly identified the respondent, it has been omitted from this overview for privacy reasons.*
Q17-A08	In the field of clinical trials, a total change is coming, with centralization, a different setting within the entire EU. Now we have a transition period, in which there will be important clear and timely information on the requirements for the functioning of existing RECs and the procedure for transition to a new practice.
Q17-A09	Coordination of cooperation among RECs.
Q17-A10	REC independence from the employer (founding institution).
Q17-A11	For the founding institutions of multicenter RECs, the not inconsiderable income from the clinical trials will now decrease. At present, we have been happy to be able to give members of the REC a quarterly reward. Its amount depends on the presence and activity of individual REC members. For the University Hospital as the REC founding institution, part of this income was thus "dissolved". However, this situation will disappear with the entry into force of Regulation (EU) No 536/2014 of the European Parliament and of the Council of 16 April 2014.
Q17-A12	Uniform rules for research other than clinical trials of medicinal products.
Q17-A13	A. Setting of rules or introduction of minimum standards for assessment of research ethics in projects in Czechia (except clinical trials). B. Preparing educational materials for researchers and RECs.
Q17-A14	Establishing rules for the financial remuneration of the work of REC members, as the founding institution has no generally defined obligations in this area.
Q17-A15	We will appreciate: A. Unification in the method of payment for compensation to clinical trial participants. B. Unification in the maximum length of the ICF (10 pages maximum). C. Better cooperation on controversial issues.
Q17-A16	A. We all believe it is necessary to maintain the local RECs, including their decision-making powers, because only local RECs are able to assess the level of local workplaces and investigators. B. We have very good long-term cooperation with the multicentric REC in cases of dispute. The meetings of the Forum of Ethics Committees with the participation of experts from the State Institute for Drug Control, (SÚKL) are also very important.
Q17-A17	Improving legislation and defining legal standards for research on human gametes, especially eggs, which are not included in current legislation.

situation in this country with regards to its international obligations in this field. Such analysis may be of interest and use not only to the RECs themselves and their founding institutions, but also to the policymakers responsible for implementing the Additional Protocol CETS No. 195 [1].

The first domain of our survey, covered by questions Q1-Q5, focused on the mandate and composition of RECs. The results (Q1) showed that ensuring the protection of research participants is anticipated to be the key responsibility of RECs not only in clinical trials, but also in the academic environment. From the results obtained, it is also clear that some of the formal aspects of the functioning of RECs in Czechia are quite heterogeneous. This outcome is undoubtedly due to the long-term absence of both a research ethics culture and a legal framework for biomedical research in the academic environment, which leads to improvisations in the establishing of institutional RECs, including their statutes and rules of procedure. There are substantial differences in the RECs size (Q2), but these findings are not very surprising, as the target institutions also vary considerably in size, and the number of research projects to be reviewed should therefore vary proportionately. Nevertheless, approximately

one-third of the RECs have no extramural members and these RECs are therefore not independent of the founder. This aspect of the RECs composition should be seen as potentially problematic.

Furthermore, the field of research ethics is still perceived as unrelated to the field of scientific integrity, and research institutions mostly use mechanisms other than RECs to deal with scientific misconduct. In this context, it is important to note that in Czechia, the bodies responsible for investigating cases of scientific misconduct are referred to as "ethics committees/commissions", which leads to a number of problems and confusions in the scientific community, as it is not clear to researchers which body to address with which ethical problem.

The details of the REC agenda were the subject of the second domain of our survey, covered by questions Q6-Q8. In terms of mandatory ethics assessment settings, it is noteworthy that regardless of the type of research or the involvement of groups with greater ethical sensitivity, research projects are more often mandatorily assessed in situations where the approval is requested by the sponsor or publisher (i.e., a formal request) than in situations where the ethical assessment resulting in approval by REC is inherently necessary to protect research participants (i.e., a factual request).

As an example can be demonstrated the results for Q7, showing that only one-third of RECs mandatorily review projects with persons in clinical need and only one-quarter of RECs mandatorily review projects with subordinate persons. These findings indicate that RECs are still viewed as primarily a formal component in research regulation and participant protection. Moreover, these results also indicate a possible failure to fulfill the main role of RECs, i.e. the protection of research participants, because in both of these two types of projects the main problem – or at least one of the main problems – is the respect of the principle of autonomy of the participant in the decision whether or not to participate in research.

Another systemic problem arises from the answers to Q8, i.e. whether the REC in question is required to assess projects on the basis of the international obligations of Czechia, namely Oviedo Convention ETS No. 164 [2] and its Additional Protocol CETS No. 195 [1]: only 62% RECs declared mandatory assessment in such cases. This indicates that approximately one-third of the RECs surveyed are either unaware of the obligation to review biomedical research under Additional Protocol CETS No. 195 [1] or are aware of the obligation but are deliberately not complying with it.

As a curiosity can be mentioned one response to the question of what types of projects, besides those listed above, are mandatory reviewed by REC at the founding institution (Q8) – the respondent states that at the home institution, there are no projects that are mandatorily submitted to the REC for ethical assessment and that everything is done on the basis of voluntary submission of the project by the researcher. However, such a response indicates a complete lack of knowledge of international standards of research ethics, regardless of the field of research.

In summary, the results collected in the second domain focusing on RECs agenda indicate in some aspects a persistent understanding of RECs as only a formal element in the regulation of research, where projects are reviewed mostly on the basis of the general requirements of funding agencies or publishers of scientific literature. Given that the primary role of the RECs is to ensure the protection of research participants, it is clearly desirable to take greater account of the real risks to which research participants may be exposed. However, this problem is clearly linked to the obvious lack of a national legal framework, especially for academic research, as will be discussed in more detail below.

The third domain of the survey was focused on the REC review practice, covered by questions Q9-Q14. Given the complete absence of regulation of RECs in the Czech academic environment, we assumed a certain degree of heterogeneity, but the results again point to a somewhat formal functioning of RECs without adequate review practice. This is especially evident in the responses to the question of whether RECs require informed consent and/or information for research participants as part of the submission (Q10). The results implies that 14% of the RECs either did not require the text of the informed consent and/or information for research participants at all for their review, or respondents did not consider it necessary to indicate this response in their questionnaires. Although this is not a majority problem, in the 14% of RECs mentioned above, it may be considered as another indicator of predominantly formal evaluation of research projects.

From the results of this domain it is also evident that RECs prefer the possibility of direct discussion of the project, including a subsequent voting by the committee, as opposed to discussion and/or a per-rollam voting. Nevertheless, the clear disadvantage of this procedure is that it limits the vote to the committee members present, including the determination of a quorum. However, in order to ensure objectivity, plurality of views and consistency of judgments, it would probably be preferable for the RECs to consider optimizing the deliberation procedure, for example, in the form of a per-rollam vote after the physical meeting of the committee. In this manner, those members of the RECs who for various reasons are unable to attend the physical meeting would also be able to express their positions. In this case, the resulting dis/approval will indeed be the statement of the entire committee, not just the members currently present.

There were also significant differences in the review process itself among the RECs participating in the survey. It is apparent from the results that formalism still prevails in the functioning of RECs in Czechia: the results obtained clearly indicate that RECs mostly evaluate only compliance with the law and not adherence to the research ethics standards. However, legal compliance should be only a necessary prerequisite for the assessment of ethical aspects of research, not the subject of the review itself. The results also showed that only one-third of the RECs surveyed adhere to international ethical standards for research, which is completely inadequate – especially considering that the committees call themselves RECs and as such approve the project to be conducted.

The answers collected from the last series of open-ended questions (Q15-Q17) provided a very important complement to the previously described findings. These questions were intentionally designed as a possibility to identify the main difficulties and bottlenecks affecting the practice of RECs, as well as to express ideas on how to improve the responsible functioning of RECs in Czechia.

As mentioned above, although Czechia has special laws on clinical trials of medicinal products [3] and of medical devices [4], which also cover ethics review of these types of clinical trials, other areas of research are completely unregulated, which makes it very difficult for RECs as well as for the researchers themselves.

Not surprisingly, this absence of a national legal framework for ethics review of research other than above-mentioned clinical trials, was repeatedly reported as the most important problem, especially in the academic environment. Furthermore, the lack of a national legal framework for research ethics is apparently related to the missing educational and consultation support for RECs in the country, which was reported by respondents as a second serious obstacle to the functioning of the RECs. The third problem, which is obviously also related to the lack of a national legal framework for research ethics, is the problematic approach of the funding agencies in the country: respondents repeatedly criticized the necessity to assess all projects proposals submitted to a given call, regardless of the low success rate and the absence of evaluation of the scientific quality of individual proposals prior to their ethics review. In this context, the respondents called for a system of ethics review similar to that established in the European Research Area, i.e., an assessment of funded projects only during the negotiation period.

In addition to these "external" issues, respondents also reported serious "internal" obstacles that complicate and hinder the proper functioning of RECs. In particular, the low recognition of RECs within the scientific community, typically combined with no or inadequate remuneration, poor administrative support, and time and work overload, leads to an unwillingness of qualified professionals to serve as REC members.

Taken together, it is evident from the obtained results that even more than twenty years after the ratification of the Oviedo Convention ETS No. 164 [2] and three years after the ratification of its Additional Protocol on Biomedical Research CETS No. 195 [1], the responsible assessment of the ethics of research involving human subjects is still not satisfactorily addressed and established for routine practice in Czechia. From an international perspective on ethical standards for human research, the legislation currently pertains solely to two types of clinical trial research [3, 4]. Nonetheless, human research, including biomedical research, occurs both in clinical and non-clinical settings, particularly in academic environments. As also our findings clearly show, there is an urgent need to establish a unified framework for assessing the ethical implications of research involving human subjects in Czechia.

Although the established system of research ethics governance was questioned and criticized repeatedly [19, 20], the arguments against mandatory ethics review were found weak and mostly problematic [21, 22]. Furthermore, new cases on breaches of basic standards not only of scientific integrity but also of research ethics have been reported again and again: typical and the most famous examples from the last decade are the Paolo Macchiarini case [23] or the Jiankui He case [24, 25]. It is necessary to keep in mind that the primary role of RECs in any country is not to increase the bureaucracy associated with research activities involving human subjects or to hamper the already hard work of researchers but primarily to protect the interests of research participants. The Oviedo Convention ETS No. 164 [2] and especially its Additional Protocol CETS No. 195 [1] are very valuable tools on how to accomplish this task on the national level.

Additional Protocol on Biomedical Research CETS No. 195 [1] was ratified by 12 Council of Europe member states at the time of this text's revision in December 2024 – namely, Bosnia and Herzegovina, Bulgaria, Czechia, Georgia, Hungary, Moldova, Montenegro, Norway, Portugal, Slovakia, Slovenia, and Turkey – while an additional 11 states signed the document without subsequent ratification. In most of the aforementioned countries, it is difficult to find valid information about national regulatory mechanisms and legal frameworks related to research ethics, particularly the status and role of RECs in this process.

In general, three models of legislation regarding RECs can be found at the international level. (1) A given country has a specific legislation (law) regarding all human research, with no difference between biomedical research and SSH research. This legal regime usually also defines

the method of protecting research participants and evaluating the ethical aspects of research projects. (2) The country in question has specific laws regulating biomedical research on humans, or the law is particularly related to bioethics. (3) Ethical considerations of research, mainly biomedical, are addressed within a broader legal framework that typically governs the conditions for the health services in a given country.

Given the ever-increasing interdisciplinary character of research involving human subjects, we consider the first model to be the optimal solution, i.e., to define the conditions for research involving human subjects in general, including the method and parameters of its ethical assessment, in a separate legal regulation. Nonetheless, selecting any of the constructive solutions listed above, and not continuing to ignore the problem, will be a significant improvement over the current situation.

Conclusion

In conclusion, the data obtained in this study clearly show that the lacking regulation of research with human participants does not only cause an inadequate level of their protection, especially in the academic environment in the field of social sciences and humanities: the other issue is the still missing legal framework for RECs in academic institutions, which leads to extreme heterogeneity in their practice. This heterogeneity needs to be harmonized in order to better comply with international research ethics standards. Nevertheless, the main problem is the lack of national legislation on research ethics governance in the country and, as mentioned above, this legislation is urgently needed. Such legislation should not only serve as a tool to put pressure on research institutions but should be accompanied by supporting measures to provide qualified guidance and support to the institutional RECs. This will be particularly important for those that operate from the outset on an essentially voluntary or enthusiastic basis. We wish our policymakers a lot of courage, endurance and strength on the path of RRI or Responsible Research and Innovation, where the word "responsible" with regard to the research ethics will no longer be an empty concept.

Supplementary Information

The online version contains supplementary material available at https://doi.org/10.1186/s12910-024-01157-2.

Supplementary Material 1

Acknowledgements
The authors would like to thank Jana Klimentova, Veronika Smitkova, Blanka Jancekova and Miroslav Filip for their critical review of the questionnaire during the pre-test phase. The authors also thank Anna Rabelova for her critical review of the questionnaire translation into English and Jana Vozenilkova for consultation on the Czech national legislation on clinical trials.

Author contributions
RV and JK conceptualized this study; RV, JS and JK created the questionnaire; RV and JS identified the target group and collect the contact information; RV performed the communication with the target group; JS administered the questionnaire and collect raw data; RV and JS analyze and interpret the data; RV wrote the manuscript; JS and JK critically revise the manuscript.

Funding
This work was supported by the Technology Agency of the Czech Republic under the Eta Program (project No. TL03000215). The funding agency had no role in the design of the study and in the collection, analysis, and interpretation of the data, and in the preparation of the manuscript.

Data availability
All data and materials related to this study are available upon request from the corresponding author, Renata Veselska, at *veselska@mail.muni.cz*.

Declarations

Ethics approval and consent to participate
This study was conducted in accordance with international research guidelines and Czech law. No personal data of human subjects were collected during the research and respondents participated in the survey as anonymous representatives of institutional research ethics committees and not as identifiable individuals. Therefore, informed consent to participate in the study is not relevant for this type of research according to the Communication No. 30/2020 Collection of International Treaties. The Research Ethics Committee of Masaryk University stated in document No. EKV-LS-2023-017 that the study does not require formal ethical review and that this situation is in compliance with Czech law.

Consent for publication
Not applicable.

Competing interests
The authors declare no competing interests.

Author details
[1]Department of Experimental Biology, Faculty of Science, Masaryk University, Brno, Czechia, Czechia
[2]Department of Psychology, Faculty of Social Sciences, Masaryk University, Brno, Czechia, Czechia
[3]Bioethics Consulting, Brno, Czechia, Czechia

Received: 28 October 2023 / Accepted: 10 December 2024
Published online: 23 December 2024

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