

Ethical regulation of human research in educational institutions for health professions: A cross-national study

Research Ethics

1–17

© The Author(s) 2026

Article reuse guidelines:

sagepub.com/journals-permissions

DOI: 10.1177/17470161261495270

journals.sagepub.com/home/rea

Gerli Mõts¹ , Merle Varik¹, Mai Treial¹, Eliise Ott¹,
Evanthia Sakellari², Danguolė Šakalytė³ , Renzo Moreale⁴,
Alvisa Palese⁴, Hanna Hopia⁵, Kati Naamanka⁶, Mirka Toivonen⁶,
Stefania Chiappinotto⁴, Sebastian Rosendahl Huber⁷,
Zuzana Dvorakova⁸, Jolanta Pupure⁹, Signe Mežinska¹⁰ ,
Sanja Kalambura¹¹, Laura Žlibinaitė¹², Gioele Santucci¹³,
Gregor Omejec¹⁴, Diana Patricia Leal Tavares¹⁵, Jaan Looga¹,
Erik Landör¹ and Anna-Liisa Tamm¹

Abstract

Introduction: International research collaboration is increasingly valued. However, the diversity of ethical regulations for human research across health professions education institutions (HPEI) presents growing challenges. While international frameworks provide an ethical foundation for human research, their interpretation and implementation vary across global, national and

¹Tartu Applied Health Sciences University, Estonia

²University of West Attica, Greece

³Utenos Kolegija /Higher Education Institution, Lithuania

⁴University of Udine, Italy

⁵Jamk University of Applied Sciences, Finland

⁶Turku University of Applied Sciences, Finland

⁷University of Applied Sciences for Health Professions Upper Austria, Austria

⁸Czech Technical University in Prague, Czech Republic

⁹P. Stradins Medical College of the University of Latvia, Latvia

¹⁰University of Latvia, Latvia

¹¹University of Applied Science Velika Gorica, Croatia

¹²Kauno kolegija HEI, Lithuania

¹³University of Bologna, Italy

¹⁴Higher Educational Institution Fizioterapevtika, Ljubljana, Slovenia

¹⁵IR, ESS, Polytechnic of Porto, Portugal

Corresponding author:

Gerli Mõts, Tartu Applied Health Sciences University, Nooruse 5, Tartu 51004, Estonia.

Email: gerli.mots@tartuh.ee



Creative Commons Non Commercial CC BY-NC: This article is distributed under the terms of the Creative Commons Attribution-NonCommercial 4.0 License (<https://creativecommons.org/licenses/by-nc/4.0/>) which permits non-commercial use, reproduction and distribution of the work without further permission provided the original work is attributed as specified on the SAGE and Open Access pages (<https://us.sagepub.com/en-us/nam/open-access-at-sage>).

institutional levels, as well as during the ethical approval process, which poses obstacles to international collaboration. **Aim:** To explore the regulations and process for obtaining ethical approval governing human research in European HPEIs. **Methods:** A descriptive cross-sectional design was used, with a web-based survey administered to Erasmus+ Programme HPEIs ($n=15$) from different European countries ($n=11$). The survey was distributed to institutional representatives, including administrators, representatives responsible for Erasmus+ activities and research group leaders, who provided information on their institutions' research ethics regulations and practices. Descriptive statistics were used for data analysis. **Results:** Participating HPEIs follow international ethics frameworks and national legislation for human research, but their internal regulations vary. While following similar core ethical principles, differences emerged in national legislation, institutional procedures, the ethical review process and timelines. Additionally, as necessary background knowledge, the requirements and expectations for academic staff qualifications and tasks vary, which, in turn, influences international collaboration. **Conclusions:** Human research in participating HPEIs is framed by a combination of international, national and institutional regulations, ethical requirements and review procedures that may vary in how ethical requirements and review processes are organised across countries and institutions. Differences in the regulation of human research and the ethical review process may pose challenges for researchers, particularly in global partnerships, as they must navigate different legal standards, unclear expectations for ethical review and administrative burdens. Improving transparency, communication and coordination between institutions, while sharing good practices and supporting researchers and research ethics committees (RECs), may facilitate more predictable and ethically robust research collaboration.

Keywords

ethical regulations, human research, health professions education institutions, healthcare education, international collaboration, research ethics

Background

Health professions education institutions (HPEIs)¹ play an essential role in upholding ethical research practices in healthcare (Nott et al., 2024). Academic staff advance knowledge through research, and students participate in research as a part of their education, developing key research-related competencies such as critical thinking, analytical reasoning, ethical awareness and collaborative skills under the guidance of experienced supervisors. Alongside academic universities, applied research plays an increasingly important role in universities of applied sciences (UAS),² higher education institutions focused on professional education and applied research, in healthcare, addressing societal needs, advancing evidence-based practices and ensuring that healthcare interventions are effective and meet community needs (Coombs and Meijer, 2021; Santos, 2022). However, as research institutions, HPEIs often face challenges such as limited funding and resources, lack of labs, high workload, staff scarcity (Cavallaro, 2024), and pressure to publish (Golhasany and Harvey, 2022; Johann et al., 2022). Although HPEIs as teaching-focused institutions have limited research resources, these challenges may be even greater in fields that require substantial clinical education commitments (Lepori and Kyvik, 2010).

To overcome these obstacles, collaboration between HPEIs is crucial. International collaboration has become increasingly important during the last 15 years for HPEIs to strengthen their research capacity and address challenges in healthcare (Lepori and Kyvik, 2010). Internationally

standardised healthcare education provided by HPEIs provides a strong foundation for collaboration, thereby promoting student and staff mobility and collaboration in teaching, research and innovation (European Ministers of Education, 1999; Heiser, 2023; European Commission, 2017). Such collaboration enables institutions to apply for global research grants and gain credibility when seeking large-scale funding (Heiser, 2023).

However, various challenges have been addressed in the context of international collaboration (Varshney *et al.*, 2016), including differences in regulatory approaches, governance structures and ethical review processes across institutions, which may affect how researchers interpret and fulfil ethical requirements (Dovey *et al.*, 2011; Hemminki, 2016; Rikkert *et al.*, 2005; Timmers *et al.*, 2020). The understanding of which research involving human subjects requires ethical approval varies by country and institutional level owing to differences in the classification of interventional studies (Rikkert *et al.*, 2005; Timmers *et al.*, 2020), the assessment of participant vulnerability, and what additional ethical safeguards are required (Council for International Organizations of Medical Sciences (CIOMS) and World Health Organization (WHO), 2016).

In European countries, research ethics regulations and ethical review processes, for human research particularly, are broadly guided by common principles set by the European Union (EU) and international regulations such as the European Code of Conduct for Research Integrity (All European Academies (ALLEA), 2023), General Data Protection Regulation (GDPR; European Parliament and Council of the European Union, 2016), Clinical Trials Regulation (EU) No 536/2014 (European Parliament and Council of the European Union, 2014), the Oviedo Convention (Council of Europe, 1997) and the Declaration of Helsinki (World Medical Association, 2025). While international guidelines provide a universal ethical foundation for the governance of human research, each country interprets and implements these principles in ways that reflect its own laws, culture and social norms. Some institutions follow strict national regulations or inter-institutional agreements (INGENIUM, 2025), and others incorporate additional institutional practices that may impact research workflow (European Network of Research Ethics Committees, n.d.). Consequently, variation may occur not necessarily in the fundamental ethical principles themselves, but in how these principles are interpreted, implemented and operationalised through national and institutional governance systems. Even institutions in the same country following the same global and national standards may apply research ethics requirements and organise ethical review processes differently in practice (Veerus *et al.*, 2014).

Variation is also evident in the organisation and implementation of the ethical review process. While some HPEIs have institutional Research Ethics Committees (RECs) to review research proposals, others utilise national or regional RECs and some combine different level RECs (European Network of Research Ethics Committees, n.d.; Timmers *et al.*, 2020). Combining institutional and national/regional REC structures may involve shared responsibilities, where institutional RECs conduct internal assessments and external RECs provide additional review or oversight for specific categories of research. Alternatively, institutions may rely on external REC review while maintaining internal procedures for research ethics assessment, monitoring and researcher guidance. These different governance arrangements influence how researchers navigate ethical review requirements. Variation in ethical regulation can therefore occur in the organisation and implementation of ethical review processes, including application procedures, decision-making structures, transparency of criteria, communication with researchers and available support mechanisms (Hemminki, 2016; Vadeboncoeur *et al.*, 2016). Approval timelines may vary from 1 to 2 months to up to 1 year (Timmers *et al.*, 2020; Veerus *et al.*, 2014). Such variation may create uncertainty regarding applicable ethical review pathways, increase administrative demands, affect project timelines and influence the feasibility of international research collaboration (Potthoff *et al.*, 2023). As a result, research deemed ethically sound in one country may require different ethical considerations in another.

In many European HPEIs, undergraduate and postgraduate students are involved in conducting research as a part of their education, for example through thesis projects or supervised research activities. However, the extent to which students are expected or required to undertake research varies across countries and educational systems. Differences in ethical review requirements and processes may therefore delay students' research activities or even completion of their studies. Variations in ethical regulation and the ethical review process pose challenges for researchers and supervisors involved in international research collaborations, particularly in obtaining ethical approval and securing funding, as our illustrative cases (Appendix 1) show. These cases illustrate how differences in national ethical requirements can complicate international research collaboration, even when involved parties follow the same fundamental ethical principles. Furthermore, they impact research efficiency, quality, compliance and ethical rigour (Veerus et al., 2014). To address these challenges, it has been suggested that greater transparency in ethical review requirements, sharing good practices, supporting researchers and RECs and simplifying ethical review processes by strengthening the capacity of research ethics committees may enhance international research collaboration (Glasziou et al., 2021).

The field of research ethics and human research has received significant attention over the years. While obstacles and issues regarding international research collaboration have been identified (Varshney et al., 2016), including some country-based (Vadeboncoeur et al., 2016) and international comparisons (Dovey et al., 2011; Hemminki, 2016; Rikkert et al., 2005; Timmers et al., 2020), there remains a scarcity of knowledge about how HPEIs across and within countries implement and manage research ethics governance, including ethical review procedures and institutional practices. This study provides a perspective across multiple European HPEIs involved in Erasmus+ Programme collaborations, a European Union initiative that supports international cooperation, mobility and collaborative projects in education, training, youth and sport among participating institutions. The ultimate aim is to support HPEI researchers in international collaboration and in navigating cross-country ethical requirements and review processes.

Aim and research questions

The study aims to explore practices in European HPEIs for obtaining ethical approval governing human research. The main research questions were:

- What regulations do HPEIs follow in human research?
- How do HPEIs in different countries organise ethical approval for human research?

Method

Study design

This study employs a descriptive cross-sectional study design (Zangirolami-Raimundo et al., 2018) to describe and compare the ethical review processes and regulations governing human research across European HPEIs.

Participants

The study's target population consisted of Erasmus+ partner higher education institutions within the Tartu Applied Health Sciences University (TARTUH) as the coordinating institution's network. The Erasmus+ Programme is an EU initiative that supports education, international collaboration and student and teacher mobility. Erasmus+ is not a directly research-focused programme, but it

enhances international collaboration and networking between academics and researchers, which is often a foundation for further research collaboration between HPEIs. The programme supports collaborative, interdisciplinary research aimed at driving educational innovation, developing skills and managing societal challenges. It prioritises research projects between partner institutions, international knowledge exchange and the production of practical outcomes that align with educational goals. While emphasising applied research, the Erasmus+ Programme has a strong focus on innovative, transformative educational approaches (European Commission, 2025).

The study used a convenience sampling approach (Etikan, 2016), and recruitment began with the leading partner TARTUH sending a research invitation to all its Erasmus+ Programme partner HPEIs ($n=60$) belonging to 22 European countries. The target population of the study consisted of HPEIs offering nursing, midwifery, radiography, biomedical laboratory science or physiotherapy programmes, which are primary programmes in which students are involved in conducting research projects, including human research, as an integral part of their curricula. In these disciplines, academic staff also actively supervise student research involving human participants. By focusing on programmes that train students to design and conduct research, the study captures ethics review and coordination processes in contexts where they are directly relevant.

The invitation letter was initially sent to administrators or representatives responsible for managing Erasmus+ activities within their institutions, or to research group leaders who collaborated in seeking funding for the Erasmus+ research ethics project. In the invitation, it was requested that primary recipients forward it to the most appropriate person within their institution who could provide detailed information on the ethical review process for human research. This could include lead persons, faculty members or other positions involved in research.

Data collection

The data were collected with a web-based questionnaire available in TARTUH's LimeSurvey (LimeSurvey GmbH) 11.11-10.12.2024. The questionnaire was created for a larger study by the members of the research group of TARTUH. The questionnaire consisted of 21 questions: seven covering the ethical review process and the applicable regulatory documents that underpin human research, and eight regarding theoretical and practical preparedness in research ethics that health-care programmes include in the participating HPEIs. Of these 15 questions, 14 were multiple-choice questions, and one was an open-ended question. Multiple-choice questions included open-ended commentary options to enrich the collected data. The remaining six questions were concerned with general information about the participating HPEIs.

Data analysis

The collected data were transferred from LimeSurvey to Microsoft Excel for Microsoft 365 (Version 2511), where they were reviewed by the research team. In cases where responses were incomplete or unclear, participating HPEI representatives were contacted for clarification to support the accuracy of the data. Data were entered and analysed using Microsoft Excel.

To address the aim of this paper, data from five questions were analysed. The questions focused on institutional procedures for the ethical review of health research involving human participants. Specifically, the survey examined (i) which health research generally requires approval from REC in accordance with institutional regulations, (ii) which international, national, and institutional documents are used to guide research involving human participants, and (iii) the average time required for the REC approval process. In addition, information was collected on (iv) whether the participating institution has its own REC and, where applicable, (v) on the specific role and responsibilities

of the institutional REC. The responses were analysed to provide an overview of institutional practices and approaches to the ethical review and governance of health research involving human participants. As an addition, background information was collected on the educational and research context of the participating institutions, including healthcare curricula and study levels offered, and the nature of theses, as well as academic positions for which research and thesis supervision are required by the job description, including the corresponding required academic degrees.

The results are presented using descriptive statistics and counts (n) to summarise participants' responses. Due to the small sample size ($n=15$), no inferential statistical analysis was conducted.

Ethical considerations

The study adheres to the principles of good research practice (All European Academies (ALLEA), 2023). According to the research governance procedures of the coordinating institution, formal approval from a research ethics committee was not required for this study. The individuals completing the questionnaire acted as institutional informants in their official roles and provided information about organisational practices and procedures. The study procedures were reviewed and endorsed by the Research and Development Council of TARTUH (protocol nr 1.1–2/26/95), the leading institution for the study, which confirmed that the study procedures complied with applicable ethical and research governance requirements. All participating institutions provided written and signed official confirmation of their participation in the study, ensuring that the data submission complied with institutional procedures. The study did not involve intervention, access to private information or collection of sensitive personal data as defined by applicable data protection requirements, including the GDPR. Personal contact details (names, positions and email addresses) of institutional informants were collected solely for communication and study coordination purposes and were not used as research data or included in the analysis. Before commencement of the survey, institutional informants were provided with information about the study's aim and the data protection measures. At the end of the questionnaire, they confirmed their agreement to participate in the survey. The results are presented only in aggregated form and are not attributed to individual HPEIs. The data were collected and stored securely on the TARTUH secure server and accessed only by authorised researchers involved in the study.

Results

Participants

A total of 15 HPEIs (Appendix 2) from 11 countries (Austria, Croatia, Czechia, Estonia, Finland ($n=2$), Greece, Italy ($n=2$), Latvia ($n=2$), Lithuania ($n=2$), Portugal and Slovenia) (Figure 1) participated. The most frequent healthcare programmes offered at Bachelor's (BA) levels included physiotherapy ($n=11$), nursing ($n=9$), radiography and biomedical laboratory assistance (both $n=8$). At the Master's (MA) level, the most frequently offered programmes were nursing and physiotherapy (both $n=6$) (Appendix 2). The included HPEIs offer Bachelor's ($n=15$) and Master's ($n=9$) programmes, in which students must write a thesis as part of the curriculum. These could comprise a literature review (Bachelor's level $n=14$, Master's level $n=9$), case study ($n=11$ and $n=9$), empirical study ($n=13$ and $n=9$), development project³ (both $n=8$) or treatment manual ($n=2$ and $n=1$). In nearly half ($n=7$) of the participating HPEIs, all academic positions or researchers have that requirement in their job description. Some HPEIs require at least a Master's ($n=3$) or PhD ($n=3$) degree for research management positions, although in a few HPEIs ($n=2$) there are not any degree requirements for research positions.

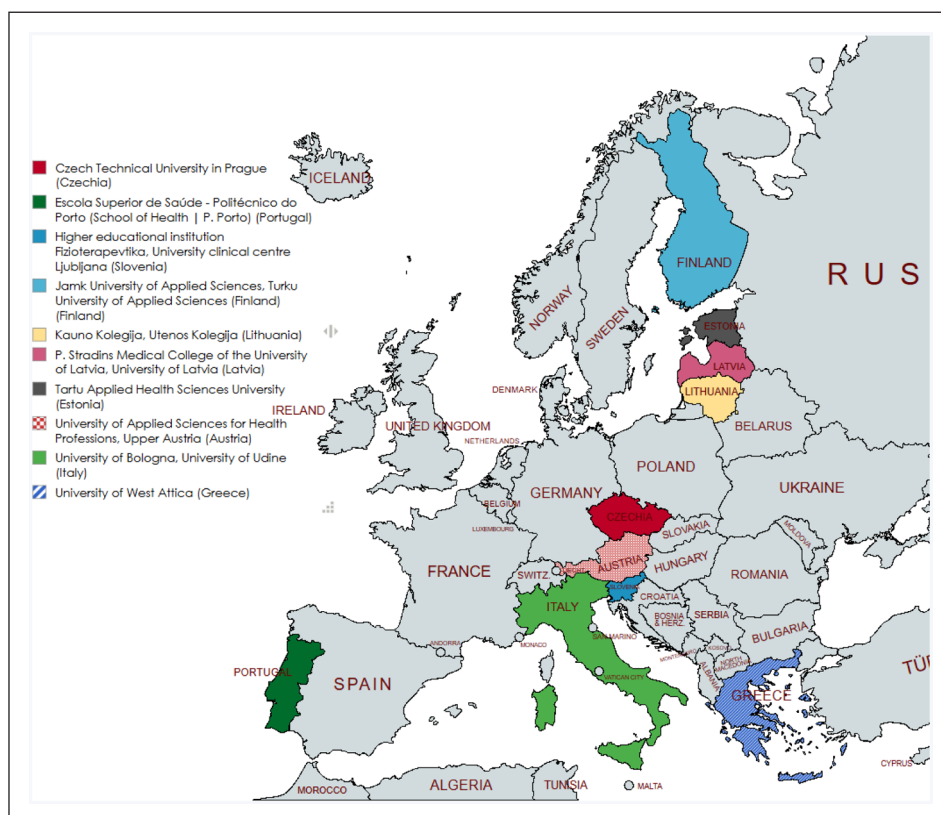


Figure 1. Geographical distribution of participating HPEIs.

Regulation of human research

The HPEIs reported following both international ($n=13$) and national legislation ($n=10$) to ensure the ethical conduct of human research (Table 1). International frameworks and agreements such as the GDPR (European Parliament and Council of the European Union, 2016), the Declaration of Helsinki (World Medical Association, 2025), the European Code of Conduct for Research Integrity (All European Academies (ALLEA), 2023), and the Oviedo Convention (Council of Europe, 1997) were followed to ensure that research involving human participants is conducted ethically, with respect for individuals' rights and privacy and in compliance with international human rights standards. The HPEIs follow various national regulations that frame good clinical and scientific practices, data processing, patients' rights and recommendations from RECs. In addition, over half of the HPEIs ($n=9$) reported to have institution-level research ethics documents, such as a research policy, guidelines for conducting research involving humans or recommendations for researchers. These HPEIs also required specific documents to be submitted for ethical review, including research applications, study protocols or plans, data management and protection plans, participant information sheets and consent forms, privacy statements and other study-related materials. One HPEI reported that it had no specific institutional regulation or formal guidance for this process.

Table 1. Research ethics governance approaches and ethical review processes for human research.

Research ethics governance approaches and ethical review requirements	HPEIs (n)	Intra-country differences (n) between HPEIs
Sources of guidance for human research ethics		
National regulations or requirements	10	3
International ethical frameworks and guidelines, including	13	3
Oviedo Convention	2	
General Data Protection Regulation	5	
Declaration of Helsinki	7	
European Code of Conduct for Research Integrity	4	
Institutional regulations or requirements	9	2
Ethical review requirements for research involving humans		
Mandatory ethical approval	13	
Not mandatory	1	1
Not specifically regulated	1	
Estimated duration of the ethical approval process		
Up to 1 month	6	
2–3 months	6	
4–5 months	3	

HPEIs: health professions education institutions.

Ethical review process

In most of the HPEIs ($n = 13$), ethical approval for research involving humans is mandatory, but in a few cases, this is not required ($n = 1$) or not explicitly regulated ($n = 1$). The approval timelines across participating HPEIs vary, ranging from 1 month ($n = 6$) to 2–3 months ($n = 6$) and 4–5 months ($n = 3$). However, the exact length of the process is influenced by both the complexity of the study design and the quality of the submitted application. Studies involving vulnerable populations, interventions, experimental designs or complex procedures typically require more extensive review. The clarity and completeness of the application, including the description of study procedures, may also influence the duration of the process, as unclear information may require further clarification or revisions. Most of the HPEIs ($n = 13$) reported having their own institutional REC, which primarily coordinates research applications ($n = 11$), addresses research ethics issues, including plagiarism ($n = 9$) and provides advisory services to researchers ($n = 10$). Other HPEIs ($n = 2$) submit the research proposals to regional or national RECs for approval. Some HPEIs have established internal advisory boards or working groups on research ethics ($n = 2$). While these bodies do not issue formal ethical approvals, they play an important role in promoting ethical research conduct within the institution. Their responsibilities include advising researchers on ethical issues, supporting the preparation of applications for formal ethics review and fostering a culture of ethical awareness in research practices.

Discussion

This study aimed to examine the research ethics governance approaches and regulatory frameworks reported by HPEIs to guide the planning and implementation of human research and the organisation of the ethical approval process. International collaboration is increasingly expected

from HPEIs to enhance research capacity and improve research quality. However, differences in ethical governance approaches and processes for obtaining ethical approval can challenge international collaboration. The findings highlight the universal yet diverse ethical landscape of human research governance in HPEIs. While all European countries are expected to follow the same basic international regulations as the foundation for human research, the present study indicates variation in the reported approaches of HPEIs to navigating national and institutional requirements for human research ethics.

The findings suggest that, despite shared ethical principles, participating HPEIs operate within diverse research ethics governance contexts. This is consistent with previous European comparisons demonstrating that ethical review systems differ in their structure, level of centralisation and procedural requirements (Hemminki, 2016; Veerus et al., 2014). In the present study, HPEIs reported consulting different combinations of national legislation, international ethical frameworks, data protection requirements and institutional policies when planning and conducting human research. Some HPEIs also reported having their own institutional regulations or guidelines governing research involving humans. Similar differences in national ethical review structures and approval requirements have been reported previously, suggesting that variation in governance approaches is a persistent feature of European research ethics systems (Hemminki, 2016; Veerus et al., 2014). These findings should not, however, be interpreted as demonstrating substantive differences between the regulations themselves or differences in institutional adherence to them, as the content of the relevant regulations was not analysed. Rather, the findings indicate variation at the level of reported governance arrangements and sources of guidance used by participating HPEIs. Previous studies have shown that differences in national ethical review structures and regulatory environments may create challenges for international research collaboration. Such variations have been identified as an obstacle to international research collaboration, particularly when research governance areas are not covered or are addressed differently in the legislation of collaborating countries (Veerus et al., 2014). The variation observed in the present study may therefore be particularly relevant when institutions from different governance contexts collaborate in international research.

Differences were observed in how HPEIs organise ethical review processes, including procedures, required documentation and estimated approval timelines. This aligns with previous studies, which have reported considerable variation among European countries and research centres in submission processes, approval requirements and the degree of centralisation in ethical review (Hemminki, 2016; Timmers et al., 2020). Nevertheless, institutional RECs might be more likely to face conflicts of interest, especially in small institutions. RECs must be independent, but it is hard to ensure independence and avoid conflicts of interest in a small institution. In contrast, reliance on external bodies may result in longer approval timelines due to broader administrative procedures, as noted in a multicentre study (Timmers et al., 2020). In our study, however, the variation in average reported review timelines among HPEIs was less pronounced than in some earlier reports (Timmers et al., 2020; Veerus et al., 2014). These differences are not only international but can also occur within countries, as our study shows. Similarly, a study in England documented striking variation among 101 universities in how they reviewed the same student-focused research project (Vadeboncoeur et al., 2016).

Our study suggested that researchers may need to navigate differing expectations regarding which types of studies require ethical approval. This observation is consistent with previous research showing that interpretations of which studies require ethical review may differ depending on national context, institutional policies and research characteristics (Rikkert et al., 2005; Timmers et al., 2020) and may create challenges for international research collaboration (Timmers et al., 2020). It can be particularly confusing when HPEIs lack clear institutional guidance on when

ethical approval is required and how the ethical review process should be conducted, as our study shows. Therefore, researchers may encounter different ethical review pathways for similar types of research depending on the institutional and national context. This can complicate collaborative efforts involving multiple partners, as researchers may need to undergo several parallel approval processes, each with its own documentation and procedural requirements, which adds administrative burden and can impact project timelines (Timmers et al., 2020). Additionally, differences in ethical review pathways and institutional requirements may complicate the coordination of participant protection and data management procedures across study sites. Addressing these challenges requires practical solutions that make international research collaboration easier and more predictable. For researchers, navigating the complex mix of national laws, institutional policies and international standards can be challenging, especially when requirements vary by study focus, location or data involved, or when no precise requirements are specified. Understanding the local legal context is essential, but it can further increase researchers' administrative workload. Therefore, as international collaboration becomes increasingly common among HPEIs, greater clarity and coordination of ethical review requirements across institutions and countries may facilitate collaborative research (Veerus et al., 2014).

Potential approaches to improving international collaboration include increasing transparency in ethical review requirements, sharing best practices and developing resources to support researchers and RECs in navigating diverse governance contexts while respecting local requirements. A notable example is BBMRI –ERIC's Ethical, Legal and Societal Issues (ELSI) support in the biobanking field, which facilitates the exchange of best practices, templates and resources among biobanks and provides an ELSI helpdesk (BBMRI-ERIC, n.d.) for researchers to submit inquiries. Joint training for both researchers and ethics committee members could also strengthen shared understanding of international standards and build stronger foundations for collaboration. Such approaches would not require identical ethical review systems across countries but could facilitate more predictable and efficient collaboration by helping researchers understand and manage different ethical governance requirements.

An additional observation emerging from the study was variation in how HPEIs define research-related responsibilities for academic staff and students. While students in all participating HPEIs conduct research and write theses as part of their studies, the role and scope of these research activities vary across institutions. Differences in thesis requirements and permitted research methods may influence the extent to which students encounter ethical review procedures and require guidance on research involving humans. Differences in the role of student research, in the education regarding ethical implications of their thesis and requirements for academic staff involvement may also influence how research ethics processes are implemented within HPEIs. This is also consistent with previous research showing variation in how students are prepared to address research ethics (Papastavrou et al., 2025). For example, when student research is an integral part of degree completion or when specific staff qualifications are required to supervise research, institutions may need to establish clear guidance on ethical review responsibilities and procedures. Moreover, with the expected expansion of advanced research pathways in postgraduate education, including opportunities to engage with patients internationally, manage complex clinical needs, and undertake advanced research activities, these challenges may become even more pronounced (Dimonte and Saiani, 2026). Although institutional differences in staff qualification requirements, student research requirements and procedures are unlikely to be fully eliminated across HPEIs, greater transparency regarding institutional expectations, clearer guidance on research ethics responsibilities and effective communication between collaborating partners may support researchers in navigating these differences.

Overall, the findings suggest that variation in research ethics governance among HPEIs does not necessarily represent a lack of ethical commitment or inconsistent standards. Rather, it may reflect different institutional and national approaches to organising ethical review and supporting responsible research practices. Recognising these differences while improving transparency and coordination may help facilitate more efficient and ethically robust international research collaboration.

Strengths and limitations of the study

Involving HPEIs from multiple countries provided a valuable comparative perspective on how Erasmus+ Programme partners with a healthcare focus reported research ethics governance practices and sources of guidance within their unique national and institutional contexts. This helps highlight common challenges and areas that deserve further attention to strengthen ethical human research and support international collaboration. At the same time, the relatively small number of participants limits the generalisability of the findings. It is also possible that the institutions that chose to take part were already more active or interested in research ethics, which could mean the study reflects more examples of good practice than might be typical (Althubaiti, 2016). Moreover, the participating HPEIs were not evenly distributed across Europe, with some regions more strongly represented than others. The uneven geographical distribution of participating HPEIs represents a limitation, as it may introduce regional bias and limits the generalisability of the findings across the European context. Furthermore, the sampling frame was restricted to Erasmus+ partner HPEIs within the network of coordinating institution. Consequently, the participating institutions may not represent the full diversity of HPEIs across Europe.

The questionnaire used in this study was developed specifically for this study, which may limit its validity, comparability with other studies and the generalisability of the findings (Rattray and Jones, 2007). In addition, the descriptive design and structured data collection may not have captured contextual and experiential factors that influence research ethics practices in HPEIs, such as institutional culture, stakeholder perspectives and informal decision-making processes. Another limitation is that the study relied on responses from designated representatives of participating HPEIs, and the researchers did not control which individuals completed the questionnaire. Therefore, responses may have reflected the respondents' individual knowledge and interpretation of institutional practices rather than providing a complete representation of all perspectives within the institution (Althubaiti, 2016). The content of the national and institutional regulations, policies and guidance documents reported by participating HPEIs was not independently analysed. Therefore, the study cannot determine the substantive similarities or differences between these documents or assess institutional compliance with them.

Conclusions

The HPEIs in this study are guided by international, national, and institutional frameworks for human research. Although these are grounded in shared ethical principles, the findings suggest that research ethics governance varies across participating institutions, particularly in sources of guidance, ethical review and institutional procedures. Such variation may contribute to additional administrative work and challenges in international research. Early exchange of institutional requirements between collaborating partners could help identify differences, align expectations and make research ethics processes more consistent and easier to navigate.

Ethical approval procedures also appear to vary across participating HPEIs, with some relying on institutional RECs and others on national or regional bodies. These differences may increase

administrative complexity, particularly in international collaborations. Greater dialogue between institutions, shared templates and guidance and appropriate mutual recognition approaches could support more transparent, coordinated, and predictable ethical review processes

ORCID iDs

Gerli Mõts  <https://orcid.org/0000-0002-8308-3109>

Danguolė Šakalytė  <https://orcid.org/0009-0007-8638-0540>

Signe Mežinska  <https://orcid.org/0000-0002-3190-100X>

Ethical considerations

According to the research governance procedures of the coordinating institution, formal approval from a research ethics committee was not required for this study. The individuals completing the questionnaire acted as institutional informants in their official roles and provided information about organisational practices and procedures.

Consent to participate

All participating institutions provided written and signed official confirmation of their participation in the study, ensuring that the data submission was in compliance with institutional procedures.

Author contributions

Study design: Mõts, G., Tamm, A-L., Varik, M., Looga, J., Landõr, E., Treial, M., Ott, E. Literature review: Mõts, G., Tamm, A-L., Varik, M. Methodology: Mõts, G., Tamm, A-L., Varik, M. Data collection: Mõts, G., Tamm, A-L., Varik, M., Looga, J., Landõr, E., Treial, M., Ott, E., Sakellari, E., Šakalytė, D., Moreale, R., Palese, A., Hopia, H., Naamanka, K., Chiappinotto, S., Rosendahl Huber, S., Dvorakova, Z., Pupure, J., Mežinska, S., Kalambura, S., Žlibinaitė, L., Santucci, G., Toivonen, M., Omejec, G., Cervellieri, F., Tavares, D.P.L. Data analyses: Mõts, G., Landõr, E. Original draft preparation: Mõts, G., Tamm, A-L., Varik, M., Looga, J., Landõr, E., Treial, M., Ott, E. Review and editing: Sakellari, E., Šakalytė, D., Moreale, R., Palese, A., Hopia, H., Naamanka, K., Chiappinotto, S., Rosendahl Huber, S., Dvorakova, Z., Pupure, J., Mežinska, S., Kalambura, S., Žlibinaitė, L., Santucci, G., Toivonen, M., Omejec, G., Cervellieri, F., Tavares, D.P.L. All authors have read and agreed to the published version of the manuscript.

Funding

The authors received no financial support for the research, authorship, and/or publication of this article.

Declaration of conflicting interests

The authors declared no potential conflicts of interest with respect to the research, authorship, and/or publication of this article.

Data availability statement

Data available upon reasonable request.*

Notes

1. Any institution, whether an academic university, applied sciences university, university college or another type of educational institution as named according to local traditions, that offers at least one bachelor-level curriculum in a healthcare-related field.
2. Universities of applied sciences (also known in some countries as professionally oriented higher education institutions) emphasise professional education, close collaboration with employers and applied research, in contrast to the traditionally research-intensive mission of academic universities.

3. In this study, a development project refers to a student-led project conducted as part of the completion of a study programme, where students identify a practice-based problem, apply evidence-based knowledge to plan a solution or improvement and develop a project proposal to address the identified need. In health professions education, such projects support the integration of theoretical knowledge with practice development and strengthen students' research and evidence-based practice competencies.

References

- All European Academies (ALLEA) (2023) The European Code of Conduct for Research Integrity. Revised edition 2023. Available at: <https://allea.org/code-of-conduct/>
- Althubaiti A (2016) Information bias in health research: Definition, pitfalls, and adjustment methods. *Journal of Multidisciplinary Healthcare* 9: 211–217. <https://doi.org/10.2147/JMDH.S104807>
- BBMRI-ERIC (n.d) *ELSI Helpdesk*. BBMRI-ERIC.
- Cavallaro M (2024) Universities of applied sciences' EU research project participation through the lens of differentiation. *Science and Public Policy* 51(1): 1–14. <https://doi.org/10.1093/scipol/scad048>
- Coombs SK and Meijer I (2021) Towards evaluating the research impact made by Universities of Applied Sciences. *Science and Public Policy* 48(2): 226–234. <https://doi.org/10.1093/scipol/scab009>
- Council for International Organizations of Medical Sciences (CIOMS) and World Health Organization (WHO) (2016) *International ethical guidelines for health-related research involving humans*, 4th edn. CIOMS. <https://doi.org/10.56759/rgxl7405>
- Council of Europe (1997) *Convention for the Protection of Human Rights and Dignity of the Human Being With Regard to the Application of Biology and Medicine: Convention on Human Rights and Biomedicine*. Council of Europe.
- Dimonte V and Saiani L (2026) [The new clinical master's degrees: what does this really mean for the Italian nursing profession?]. *Assistenza Infermieristica e Ricerca* 45(2): 59–62. <https://doi.org/10.1702/4723.47393>
- Dovey S, Hall K, Makeham M, et al. (2011) Seeking ethical approval for an international study in primary care patient safety. *British Journal of General Practice* 61(585): e197–e204. <https://doi.org/10.3399/bjgp11x567144>
- Etikan I (2016) Comparison of convenience sampling and purposive sampling. *American Journal of Theoretical and Applied Statistics* 5(1): 1. <https://doi.org/10.11648/j.ajtas.20160501.11>
- European Commission (2025) *Erasmus+ Programme Guide 2026*. <https://erasmus-plus.ec.europa.eu/erasmus-programme-guide>
- European Ministers of Education (1999) *The Bologna Declaration: Joint Declaration of the European Ministers of Education*. European Ministers of Education.
- European Network of Research Ethics Committees (n.d) *RECs in Europe*. European Ministers of Education.
- European Parliament and Council of the European Union (2014) Regulation (EU) No 536/2014 of the European Parliament and of the Council of 16 April 2014 on clinical trials on medicinal products for human use, and repealing Directive 2001/20/EC. *Official Journal of the European Union (OJ L 158)*, 1–76.
- European Parliament and Council of the European Union (2016) Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data (General Data Protection Regulation). *Official Journal of the European Union (OJ L 119)*, 1–88.
- Glasziou P, Scott AM, Chalmers I, et al. (2021) Improving research ethics review and governance can improve human health. *Journal of the Royal Society of Medicine* 114(12): 556–562. <https://doi.org/10.1177/01410768211051711>
- Golhasany H and Harvey B (2022) Academic freedom, the impact agenda, and pressures to publish: understanding the driving forces in higher education. *SN Social Sciences* 2(8): 163. <https://doi.org/10.1007/s43545-022-00468-8>
- Heiser RE (2023) The emergence of the open research university through international research collaboration. *International Review of Research in Open and Distributed Learning* 24(3): 99–124. <https://doi.org/10.19173/irrodl.v24i3.7328>

- Hemminki E (2016) Research ethics committees in the regulation of clinical research: Comparison of Finland to England, Canada, and the United States. *Health Research Policy and Systems* 14(1). <https://doi.org/10.1186/s12961-016-0078-3>
- INGENIUM (2025) The Munster statement on the principles of research ethics and research integrity. <https://doi.org/10.34719/YEHB3860>
- Johann D, Raabe IJ and Rauhut H (2022) Under pressure: The extent and distribution of perceived pressure among scientists in Germany, Austria, and Switzerland. *Research Evaluation* 31(3): 385–409. <https://doi.org/10.1093/reseval/rvac014>
- Lepori B and Kyvik S (2010) The research mission of universities of applied sciences and the future configuration of higher education systems in Europe. *Higher Education Policy* 23(3): 295–316. <https://doi.org/10.1057/hep.2010.11>
- Nott M, Schmidt D, Thomas M, et al. (2024) Collaborations between health services and educational institutions to develop research capacity in health services and health service staff: A systematic scoping review. *BMC Health Services Research* 24(1): 1–13. <https://doi.org/10.1186/s12913-024-11836-w>
- Papastavrou E, Chiappinotto S, Gastmans C, et al. (2025) Ethics in undergraduate nursing degrees: An international comparative education study. *Nursing Ethics* 32(2): 472–485. <https://doi.org/10.1177/09697330241247322>
- Pothoff S, Hempeler C, Gather J, et al. (2023) Research ethics in practice: An analysis of ethical issues encountered in qualitative health research with mental health service users and relatives. *Medicine Health Care and Philosophy* 26(4): 517–527. <https://doi.org/10.1007/s11019-023-10169-5>
- Rattray J and Jones MC (2007) Essential elements of questionnaire design and development. *Journal of Clinical Nursing* 16(2): 234–243. <https://doi.org/10.1111/j.1365-2702.2006.01573.x>
- Rikkert MGMO, Lauque S, Frölich L, et al. (2005) The practice of obtaining approval from medical research ethics committees: A comparison within 12 European countries for a descriptive study on acetylcholinesterase inhibitors in Alzheimer's dementia. *European Journal of Neurology* 12(3): 212–217. <https://doi.org/10.1111/j.1468-1331.2004.00980.x>
- Santos JMRC (2022) On the role and assessment of research at European Universities of Applied Sciences. *Journal of Higher Education Theory and Practice* 22(14): 81–94. <https://doi.org/10.33423/jhetp.v22i14.5537>
- European Commission (2018) The European Qualifications Framework: Supporting learning, work and cross-border mobility. Luxembourg: Publications Office of the European Union.
- Timmers M, Van Dijk JTJM, Van Wijk RPJ, et al. (2020) How do 66 European institutional review boards approve one protocol for an international prospective observational study on traumatic brain injury? Experiences from the CENTER-TBI study. *BMC Medical Ethics* 21(1): 36. <https://doi.org/10.1186/s12910-020-00480-8>
- Vadeboncoeur C, Townsend N, Foster C, et al. (2016) Variation in university research ethics review: Reflections following an inter-university study in England. *Research Ethics* 12(4): 217–233. <https://doi.org/10.1177/1747016116652650>
- Varshney D, Atkins S, Das A, et al. (2016) Understanding collaboration in a multi-national research capacity-building partnership: A qualitative study. *Health Research Policy and Systems* 14(1): 64. <https://doi.org/10.1186/s12961-016-0132-1>
- Veerus P, Lexchin J and Hemminki E (2014) Legislative regulation and ethical governance of medical research in different European Union countries. *Journal of Medical Ethics* 40(6): 409–413. <https://doi.org/10.1136/medethics-2012-101282>
- World Medical Association (2025) World Medical Association declaration of Helsinki: Ethical principles for medical research involving human subjects. *JAMA—Journal of the American Medical Association* 333(1): 71–74.
- Zangirolami-Raimundo J, Echeimberg JDO and Leone C (2018) Research methodology topics: Cross-sectional studies. *Journal of Human Growth and Development* 28(3): 356–360. <https://doi.org/10.7322/jhgd.152198>

Appendix I

Illustrative cases about difficulties in international research collaboration due to inconsistencies in the approach to research ethics

Illustrative case 1. Two HPEIs in different countries plan a joint qualitative study to interview nurses about workplace experiences, recruiting participants via social media. Both research teams fully adhere to research ethics principles, including informed consent, confidentiality and secure data handling.

A key challenge arises from differing national regulations regarding ethical approval:

- **Country A:** Any study involving human participants and qualitative interviews requires approval from the national ethics committee. The process typically takes at least 2 months.
- **Country B:** No national ethics approval is required for interviews with competent adult professionals, such as nurses; local institutional guidelines and informed consent are sufficient.

As a result, the team in Country B can begin recruitment immediately, while the team in Country A must wait for committee approval. This regulatory mismatch creates practical difficulties, including potential delays, imbalanced data collection and additional coordination to ensure the study design, instruments and consent procedures remain harmonised across countries.

Illustrative case 2. A research team at university A developed and validated a survey to assess nursing students' clinical decision-making skills. The university's research ethics committee (REC) approved the tool and the study.

When the researchers attempted to collect data at university B, located in the same country, its REC declined approval, arguing that some survey items could cause unnecessary stress for first-year students. As a result, the researchers were permitted to collect responses only from university A.

Because the final sample size was much smaller than initially planned, the study may have missed essential differences between the two institutions, potentially affecting the reliability and generalisability of the results.

Illustrative case 3. As part of a European Erasmus+ project, a pilot study was carried out involving students and healthcare professionals from several partner countries. The study was non-interventional and non-experimental, with voluntary participation and data collection via questionnaires. In accordance with the project protocol, ethical procedures were coordinated by the lead country researchers, who submitted the relevant documentation to an institutional REC. This committee, responsible for the assessment of non-experimental studies, provided a favourable opinion within a defined timeframe.

However, due to different interpretations of national ethical regulations, the following situations occurred:

- **Researchers from the lead country** requested ethical approval on behalf of all partners and obtained it through its institutional REC.
- **Researchers in the second country** had to submit the study for independent review by their own REC. This was necessary because local regulations required approval from a national REC, rendering the lead country's approval invalid.

- **In the third country**, ethical approval for non-interventional observational studies was not required and the researchers in that country were able to start data collection immediately.
- **Researchers in the fourth country**, although legally required to obtain REC approval, considered the process too burdensome. To avoid it, the researchers proposed modifying the questionnaire by removing certain sensitive demographic questions and requested that all other partners adopt the same reduced version to avoid triggering ethical review requirements in their own countries.

These differences in ethical requirements and national interpretations resulted in: (a) Extensive and complex discussions on the most appropriate ethical approach; (b) Deviations from the original research protocol, which clearly stated the need for ethical approval; (c) Reduced the quality and scope of collected data, particularly regarding demographic information, due to the adoption of a shortened questionnaire.

Illustrative case 4. Two HPEIs from different countries collaborated to conduct a comparative study examining healthcare students' perceptions of mentoring during clinical placements. Both institutions adhered to national and institutional research ethics principles, ensuring informed consent, voluntary participation and anonymity.

The key challenge arises from different requirements for data protection and assessment of the ethical status of research participants:

- **Country A:** The institutional Bioethics Commission classified these participants as potentially vulnerable groups and required additional approval from the regional Bioethics Committee, enhanced management oversight and stricter data anonymisation. Also, in accordance with national data protection law, signed written consent forms and individual data retention declarations for each participant were required.
- **Country B:** Ethics permission was granted based on common consent forms and a uniform description of data processing, without additional requirements or classification of vulnerabilities.

Due to these differences, the research team in Country A had to postpone data collection until approval from the regional Bioethics Committee for all consent and data protection forms had been obtained. In contrast, the team in Country B was able to start the study earlier. This discrepancy required additional coordination to harmonise documentation and ensure that the final data met the ethical and legal requirements of both countries.

Appendix 2. Participating HPEIs with studied curricula.

HPEI (Country)	Curricula											
	Nursing			Midwifery			Physiotherapy			Radiography		
	BA	MA		BA	MA		BA	MA		BA	MA	
1. Czech Technical University in Prague (Czechia)				X	X		X	X		X	X	
2. Escola Superior de Saúde - Politécnico do Porto (School of Health P. Porto) (Portugal)				X	X		X	X		X	X	
3. Higher Educational Institution Fizioterapevtrika, University Clinical Centre Ljubljana (Slovenia)				X	X		X	X				
4. JAMK University of Applied Sciences (Finland)	X	X		X	X		X	X				X
5. Kauno Kolegija (Lithuania)	X			X			X			X		X
6. P. Stradins Medical College of the University of Latvia (Latvia)												X
7. Tartu Applied Health Sciences University (Estonia)	X	X		X	X		X	X		X	X	X
8. Turku University of Applied Sciences (Finland)	X	X		X	X		X	X		X	X	X
9. University of Applied Sciences for Health Professions Upper Austria (Austria)	X			X			X			X		X
10. University of Applied Science Vellika Gorica (Croatia)												X
11. University of Bologna (Italy)	X	X		X	X		X	X		X	X	X
12. University of Latvia (Latvia)	X	X					X					X
13. University of Udine (Italy)	X	X		X	X		X	X		X		X
14. University of West Attica (Greece)												X
15. Utenos Kolegija (Lithuania)	X			X			X					X
Total	9	6	7	3	6	8	3	8	3	2	12	

BA: Bachelor's level; MA: Master's level.