Ethics Soc. (2026) 20:4
https://doi.org/10.1007/s11569-025-00491-y

ORIGINAL RESEARCH PAPER

Ethical Challenges of New Technologies and Insights from Research Ethics Experts on Oversight of AI in Health, Extended Reality, Gene Editing and Biobanking

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Received: 28 May 2025 / Accepted: 15 December 2025

Abstract Research on emerging technologies such as AI-driven health interventions, extended reality (XR) systems, biobanks, and genome editing poses novel ethical challenges that traditional ethics governance models struggle to address. This article explores various models of research ethics governance within the European Union (EU) context, starting from traditional one-time research ethics committee (REC) reviews, REC review with post-approval monitoring, as well as alternative models such as ethics self-assessment, and ethics-by-design approaches. Based on literature analysis and a survey of European research ethics experts, the study identifies prevalent models of research ethics oversight, research ethics expert perceptions of their sufficiency, and challenges such as insufficient technical and ethics expertise, lack of specific guidelines, and unclear boundaries of REC responsibilities. Findings also indicate that traditional REC reviews remain dominant but have limitations in effectively managing rapidly evolving technologies. Research ethics experts highlighted the feasibility of continuous oversight mechanisms to better integrate ethical reflection throughout the research lifecycle. The article concludes by recommending a shift towards proportional, risk-based oversight, development of clearer, technology-specific guidelines, enhanced REC training, and improved harmonization across EU ethics governance systems to address current gaps.

Keywords Research ethics · Research ethics committee · Ethics by design · Research ethics oversight

Supplementary Information The online version contains supplementary material available at https://doi.org/10.1007/s11569-025-00491-y.

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Published online: 21 January 2026

Introduction

The rapid development of emerging technologies such as AI-driven health interventions, immersive extended reality (XR) systems, large-scale biobanks and CRISPR-enabled genome editing creates new opportunities for science and society. At the same time, their applications raise new and often complex ethical issues. AI applications often lack transparency, traceability and can exacerbate biases [1]. XR technologies can inversely affect users' physical and mental well-being in novel ways [2], genome editing poses profound safety and societal dilemmas [3–5]. Biobanks, though not a new technology, continue to present evolving challenges to traditional notions of informed consent and privacy [6]. Ensuring that research on these technologies adheres to established ethical standards is a growing concern for research ethics experts and the general public. Traditionally, research ethics committees (RECs) focus on protecting human research participants' rights and well-being in both biomedical and behavioral studies. They operate primarily via a one-time ethics approval of research plans (protocols) before the start of the relevant research project. However, it is increasingly recognized that the existing traditional research ethics governance framework is ill-equipped to address the new dimensions of risk and uncertainty introduced by many emerging technologies [7]. As Resseguier and Ufert argue, in the field of AI, "ethics review as carried out by RECs constitutes a powerful, but so far underdeveloped, framework" for ensuring ethical compliance in innovative research domains [8].

In practice, questions persist about how institutions can harmonize ethics standards for technologies that evolve faster than regulations, how RECs can be supported to evaluate research on different types of technologies, and what governance structures beyond the traditional one-time REC approval could proactively integrate ethical considerations throughout the research lifecycle [9]. Recent debates point to several gaps or tensions: for instance, should ethics oversight move beyond a one-time REC review toward a more continual engagement with research? [10]; are new kinds of ethics committees or advisory boards for digital technologies needed? [7]; how can consistency be achieved in ethics reviews across the European Union (EU) [11]?

This article addresses the above gaps by exploring different models of research ethics governance[1] in the context of four emerging technologies, including two digital technologies (AI related research in healthcare (AI in health) and XR) and two life sciences technologies (biobanks and genome editing). The article draws substantially on findings from the EU-funded project iRECs (Improving Research Ethics Expertise and Competences to Ensure Reliability and Trust in Science) that aims to provide support for RECs focusing on ethics review processes for four technology domains: AI in health, XR, biobanking, and genome editing.[2] These four technologies were selected to represent both digital and life sciences emerging technologies that pose numerous, diverse and urgent challenges for REC members and EU ethics appraisal scheme experts reviewing research projects. Therefore, they were chosen as technologies of particular current interest with a view for immediate remedial policy action. Including all four technologies also allows us to make a comparative analysis of both common (cross cutting) and specific ethics oversight challenges rather than provide an exhaustive analysis of each technology.

In analyzing research ethics governance models applicable across these technologies, we depart from the traditional one-time REC review model typically applied nowadays in many research fields. This review model was first introduced in the 1975 version of the World Medical Association (WMA) Declaration of Helsinki as a requirement of oversight in the biomedical field by an 'independent committee' prior to the initiation of research projects [12]. In the context of emerging technologies, we also examine the relevance of a one-time REC review followed by a post-approval follow-up (monitoring) model. The need to monitor ongoing research by RECs has been addressed internationally through numerous guidelines, including the recent World Health Organization (WHO) guidelines [13]. Such an approach may be particularly valuable in research contexts where ethical risks evolve over the course of a project. While this model is partially implemented in clinical drug trials (whereby trial protocols are often amended

[1] In this article we define research ethics governance as research ethics oversight of research with or on humans.

[2] https://www.irecs.eu/

during the project timeline), its application remains limited as post-approval activities are often restricted to reviewing protocol amendments, and only occasionally include continuing review procedures or the monitoring of adverse events and protocol violations. This is due to European RECs typically lacking the legislative mandate, organizational infrastructure, personnel, and resources required to conduct active post-approval follow-up or audits. These responsibilities often fall instead within the purview of regulatory authorities [14] and in cases of accidents or gross misconduct.

However, not all research on emerging technologies, sometimes even in the fields of health may fall under the scope of REC review depending on the national legislation. Where human participants are not directly involved, institutions can decide that a REC review is not needed. Moreover, current debates on research ethics oversight tend to focus on the development of models that systematically integrate ethical considerations into broader research and innovation ecosystems and mitigate the tendency to delegate nearly all practical aspects of ethical governance to RECs, which may not always possess the appropriate expertise to evaluate the full range of ethical issues posed by novel technologies [15]. Therefore, in this context, we also examine other approaches to embed ethical reflections directly into the research and innovation process, such as ethics self-assessment, or the "ethics by design" model.

By concentrating on the EU context, the analysis considers the unique regulatory and institutional landscape of Europe. The focus on the European Union (EU) is timely, given ongoing policy developments (e.g., implementation of the General Data Protection Regulation (GDPR) [16], the adoption of the European AI Act [17], and the European Health Data Space Regulation (EHDS Regulation) [18]) and collaborative efforts to strengthen research ethics oversight across EU countries.

Thus, the aim of this article is twofold: (1) to map the current common strengths and challenges of traditional one-time research ethics review governance models in the EU when dealing with AI in health, XR, biobanking, and genome editing research; and (2) to propose evidence-based recommendations to optimize research ethics governance in light of identified challenges and current regulatory developments at EU level.

Unlike prior work that often examines a single domain (such as AI ethics [19], big data [20] or genomic research ethics [21]) this article offers a broader perspective that highlights cross-cutting governance issues. Our recommendations seek to inform all relevant stakeholders ranging from research institutions, institutional RECs and national regulators to EU research funding bodies.

Methods

The study employs a qualitative, integrative approach combining theoretical analysis of academic literature, relevant regulatory and guidance documents, and findings of relevant scientific projects with empirical data. This approach was chosen over purely quantitative empirical or literature review methods to capture the complexity of multi-level ethics governance systems and enable the cross-technology comparison. The goal was to triangulate theoretical discussions with real-world practices and perceptions of REC members and other research ethics experts in Europe.

First, the review of academic literature and reports from research institutions and EU projects (e.g., Ada Lovelace Institute's report on AI ethics committees [7], the SIENNA project on genomic technologies [22] and human enhancement ethics [23], TechEthos on ethics by design for new technologies [24], PANELFIT report on the governance of data protection ELI in ICT research and innovation [25], iRECs report [26]) that discuss challenges in REC processes or ethics oversight in the context of emerging technologies was conducted. To frame the governance landscape, the review also included EU regulatory and guidance documents, such as the European Commission's ethics appraisal procedure for Horizon Europe [27], GDPR, EHDS Regulation as it pertains to research, and relevant declarations and guidelines from the OECD and WMA for areas like biobanking and AI [28–30].

Based on the literature and policy review, an online survey was developed by the authors of this paper to investigate how research ethics experts approach ethical challenges in research involving these emerging technologies. Before dissemination, the survey instrument was piloted by the project partners, including experts in ethics, sociology, social psychology, to

ensure conceptual clarity, question relevance, and response validity. The survey was conducted from February to April 2024 and included research ethics experts such as institutional REC members, EU research ethics experts, external ethics reviewers (not REC members) and other independent research ethics experts in Europe not belonging to a particular group.

The survey addressed both procedural aspects (e.g., what research ethics governance models are used for a given technology and their evaluation) and content-related issues (e.g., competencies in expertise and evaluation of ethics guidelines) across the four technology domains. To maintain participant anonymity, no additional demographic data was collected except participants' country of work, years of experience in ethics assessment, main disciplinary background, and their role in the ethics assessment process. This information was used to contextualize the responses based on participants' background and expertise.

Invitation and Participation in the Survey

The survey's main target groups were the European Network of Research Ethics Committees (EUREC), the European Network for Research Ethics and Integrity (ENERI) e-community, the European University Association (EUA) Research & Innovation Strategy Group (Rectors or ViceRectors for Research) and the European Association of Research Managers and Administrators (EARMA). The survey was disseminated among members of ENERI, EUREC, EUA and EARMA, and in addition, iRECs project partners distributed the survey invitation to their networks via a link. The questionnaire was hosted online and managed by RAIT GROUP, an independent market research company, ensuring independence, confidentiality and professional processing of the data.

The survey was designed to allow experts to select one of the initial multiple-choice questions relevant to the technology they work with. Those who did not select a specific technology were not asked questions related to this technology. There were 187 respondents from European countries (non-European respondents are not included in this analysis). Most of the study participants are involved in the ethical assessment of research projects on AI in health (66%, N123) and human biobanking (56%, N104). The lowest number of participants are dealing with germline and somatic genome editing[3] (18%, N34 and 21%, N39, respectively). Half of the study participants have more than six years of experience in ethics assessment of research projects. Predominant disciplinary backgrounds among the respondents are biomedicine/health science (32%, N60), social sciences (22%, N41), and life sciences (17%, N32). The largest segment of study participants comprises members of RECs (58%, N108), followed by EU ethics experts (40%, N75), and a quarter were external ethics reviewers (not REC members) (27%, N50). In the presentation of the results, totals can exceed 100% because respondents were allowed to select multiple options.

Survey Data Analysis

Quantitative data were analyzed using descriptive statistics in Statistical Package for the Social Sciences (SPSS) to identify trends and patterns among participants. The initial data analysis was conducted by the independent market research company RAIT GROUP with guidance by the authors. Key quantitative results from this survey, such as the prevalence of certain research ethics governance models, perceived sufficiency of current governance, hindering factors for effective traditional REC review, and self-assessed competence in various ethics areas, were integrated into our analysis.

Results

Most Prevalent Models of Research Ethics Governance

The traditional model of ethics oversight (a one-time approval by a REC before the research begins) remains dominant in Europe. According to the expert survey, over 70% (N53) of participants indicated that REC review before starting a research project is the primary mechanism for AI in health, XR, and

[3] Although the survey addressed both human (somatic and germline genome editing) and non-human applications of genome editing technologies, this article analyzes only the human applications, encompassing both somatic and germline genome editing.

biobank research, and about 63% (N48) for genome editing research (Fig. 1).

However, alternatives and supplements to this model are also observed. One is the REC review and monitoring after approval model, where an initial REC approval is followed by some form of oversight during the project (such as progress reports, monitoring of compliance, or continuing review). The survey showed that this was the second most common model for AI in health, biobanking, and human genome editing projects in about 20% of cases (Fig. 1).

The survey found that ethics self-assessment is more often applied for XR research when compared to the other three technologies (Fig. 1). This might reflect that most XR studies involve healthy volunteers in non-medical experiments and thus, do not fall under the remit of the traditional RECs.

The survey also highlighted some variability in ethics review processes in biobanking. Specifically, 62% (N55) of respondents noted that an ethics review is required when establishing a new biobank, 65% (N58) when conducting a specific study, and slightly fewer (47%, N42) when amending an approved project. According to the opinion of experts, ethical review would be most necessary/preferable for research involving biobanks both during the establishment of the biobank and when a specific research study is planned to be conducted (74%, N58).

Sufficiency of One-Time REC Review

When asked whether the experts believe that the governance model applied in evaluating the particular technology research is sufficient, the answers show a difference of opinion comparing two life sciences technologies (biobanking and genome editing) and digital technologies (AI in health and XR). In genome editing, more than half of the experts (59%, N44) consider the existing governance sufficient, while in biobanking, the result rises to 69% (N52). Governance was deemed insufficient by only 13–15% (N10, N11) of experts in these life sciences technologies (Fig. 2).

The situation is somewhat different when it comes to digital technologies. Less than half of participants rate sufficiency at a high level (given 4 and 5 scores out of 5): only 41% (N31) of the respondents rate the existing governance model in both AI in health and XR

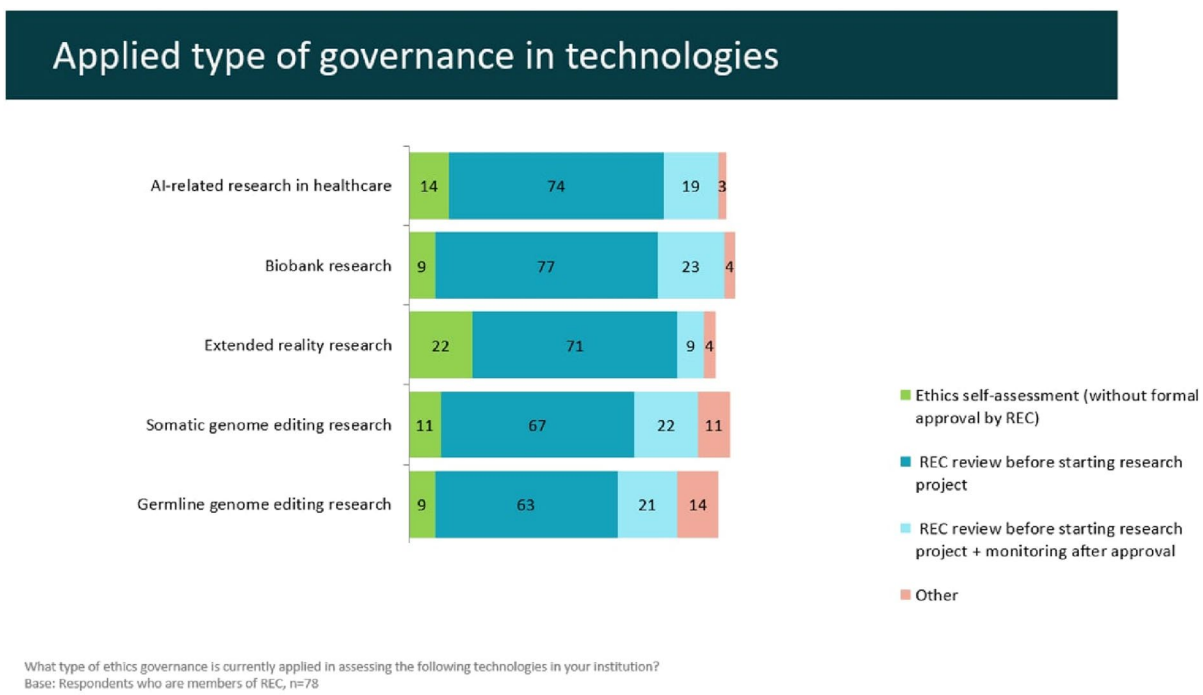

Fig. 1 Applied type of governance in technologies

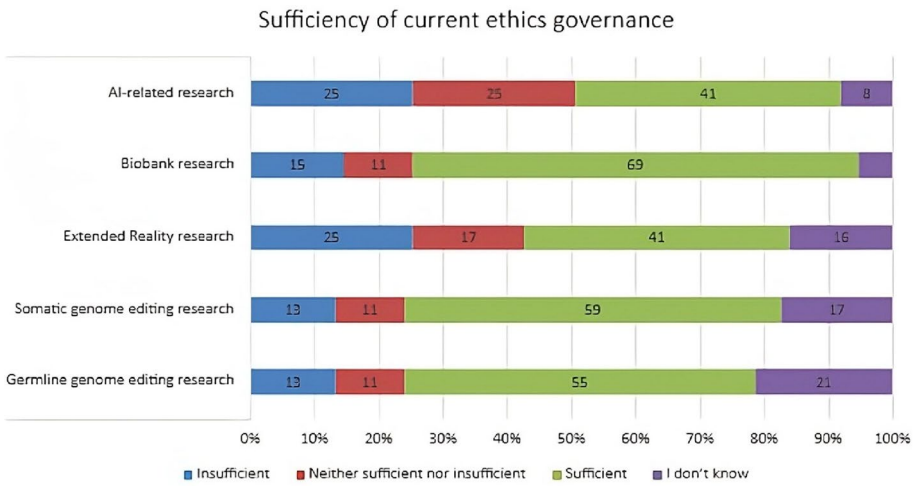

Fig. 2 Sufficiency of current ethics governance

technologies as sufficient and every fourth expert (25%, N19) considers the current model insufficient (Fig. 2). This result could be attributed to the novelty factor surrounding these technologies, whereby the pace of innovation and change is very rapid for the existing review process.

Continuous Ethics Oversight as Alternative Research Ethics Governance Approach

Another governance model, continuous ethics oversight, which corresponds to the concept of ethics by design, implies shifting some parts of the ethics assessment into earlier phases (design/development) and perhaps already having REC involvement at these phases of research.

The feasibility of applying continuous ethics oversight starting from the design phase of research and including ethics review and monitoring throughout its lifecycle (ethics by design) was assessed (Fig. 3).

The survey affirmed that many experts think that continuous oversight is most feasible in the fields of biobank research (79% N96) and AI-related research in health (73%, N89), while XR and genome editing

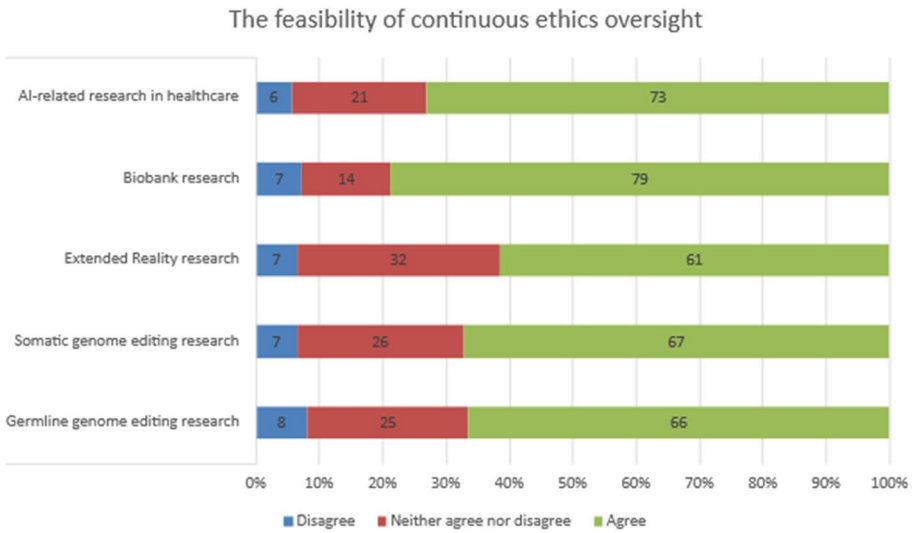

Fig. 3 The feasibility of continuous ethics oversight

were viewed slightly more cautiously (61–67%, N74-82), with a larger number of respondents neither agreeing nor disagreeing (26–32%, N32-39). The percentage of those who disagreed with the options was low across all technologies (6–8%, N7-10) (Fig. 3). This indicates recognition that an ethics governance model should possibly extend beyond one-time REC review before starting a research project. Although desirable, this review system poses a significant shift from how RECs operate currently, and it remains unclear what role the REC experts might have in addition to reviewing (e.g., advisory or enforcement).

Factors Hindering Research Ethics Oversight

The primary factors that hinder the ethics oversight of technologies vary across different technologies (Fig. 4).

Lack of Scientific/Technical Understanding and Ethics Expertise

A lack of scientific/technical understanding is the main factor for challenges in ethics reviews related to AI in health (59% N73), somatic (38% N 47), and germline (33% N40) genome editing (Fig. 4). Even if this factor is not the most problematic for other technologies, its status remains very high. Lack of scientific/technical understanding is significantly more important in digital technologies than in life science technologies. This is somewhat to be expected since both AI and XR are very new and rapidly developing technologies.

Lack of ethics expertise was also selected as an important aspect of all technologies, but was not the most important aspect in any of them (Fig. 4). The distribution was quite similar between technologies. As with the previous question, lack of expertise is higher in digital technologies (44%, N54 in AI and 38%, N47 in XR) than in life sciences technologies (22%, N27 in biobanking, 30(N37)−31%(N38) in different types of genome editing).

RECs in the EU tend to have substantial collective expertise in fundamental ethics domains such as informed consent, privacy and confidentiality issues or risk–benefit assessment. This existing expertise is highly relevant to emerging technologies like AI in health, XR, biobanking, and genome editing. For example, AI in health must address informed consent (do patients know that AI is involved?), data protection (since AI often relies on big data), and risk–benefit (accuracy vs. potential harm of AI decisions). Genome editing trials must rigorously consider risk–benefit and informed consent (especially given long-term and heritable implications).

The expert survey data confirmed that consent is an area of high confidence, for instance, when reviewing issues related to establishing a new biobank, respondents assert their highest level of competency in the areas of consent (80%, N40 of respondents have given highest scores of 4 and 5 out of 5), such as selecting the appropriate consent model and reviewing consent documents, and 72% (N76) felt competent on consent in AI-related health research.

The survey showed reasonably high confidence among experts in areas like data protection and privacy (with ~ 60% feeling competent in these areas for AI (N64), XR (N26), and biobanking (N31)),[4] likely reflecting how legal standards like GDPR have been internalized as part of ethics review. However, a few respondents did not feel competent in assessing data protection, possibly due to uncertainty about RECs' role in enforcing it.

When assessing biobank research projects, the least competency among survey participants is noted in commercialization of research results and/or data, with 39% (N19) feeling competent and 24% (N12) indicating they were not competent. This reflects the standard constitution of RECs that involve academics and researchers with little business and commercialization experience. More confident results were reported when asking about competencies regarding the return of individual health-related findings to biobank participants. In this context, nearly two-thirds (62% N32) of respondents feel confident in their abilities. About one-third (37% N19) have a neutral assessment of their competencies, while only one (2% N1) respondent considers themselves incompetent.

When reviewing somatic gene editing research, study participants consider themselves to have a high level of competence across all areas assessed in the

[4] In the case of biobanks, 62–67% of respondents felt competent in data protection, data privacy, and data sharing, while for AI, the percentages were 58–64%, and for XR, they were 58–70%.

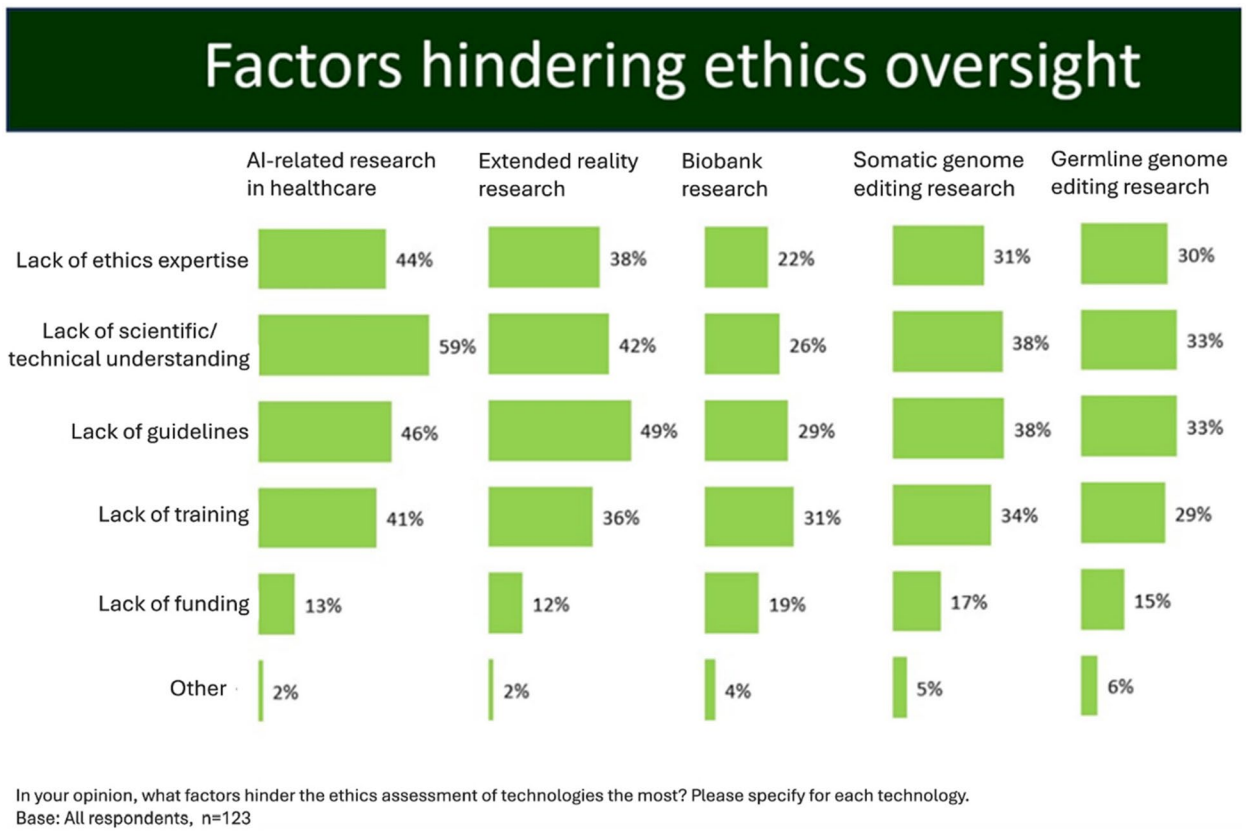

Fig. 4 Factors hindering ethics oversight

survey. For example, the competency to assess consent, safety, accessibility, enhancement, and misuse of this type of research was evaluated quite favorably; between 71%(N20) and 79%(N22) of responders considered themselves competent, and around 10% (N3) felt incompetent.

When evaluating AI-related research in health, the lowest number of respondents expressed a lack of confidence in assessing responsibility for consequences (12%, N13), rather more in the assessment of justice and fairness (16%, N17), and transparency/explainability (18%, N19), and even more in bias assessment, where more than one in five (21%, N22) considered themselves incompetent. This, again, is presumably the result of the novelty of the technology and its particularity in that AI models have not yet been researched in terms of quality and societal impact.

When it comes to XR-specific issues, such as violence/abuse, mental health concerns, AI usage in XR, the involvement of children, and cybercrime, experts demonstrate significantly less familiarity. A few respondents (23–40%, N10-17) consider themselves competent in these categories, with the lowest competence reported in violence/abuse (23%, N10). Additionally, many experts (33–42%, N14-18) felt incompetent in these areas. With limited knowledge about AI usage in XR (40%, N17 of experts felt competent and 33%, N14 felt incompetent) and even less knowledge about cybercrime (only 35%, N15 felt competent and 42%, N18 felt incompetent), experts have little ability to properly assess the differences between human and AI-generated actors, as well as the responsibilities that apply to their actions.

XR is therefore seen as both a new technology with little research experience in terms of ethics issues and also highly technical when it is combined with AI. As with the case of AI previously, XR is far too new to allow for widespread expertise to be included in standard RECs. It is rarely developed in public institutions, while there is little knowledge of its impact on users or even the regulatory regime applying to it [31].

Lack of Specific Guidelines

Another notable challenge that poses a significant problem for ethics reviews is the lack of specific guidelines for new areas of research. While general ethics principles exist, many emerging technology domains lack clear and specific ethical guidelines or policies. Lack of guidelines was noted as the most important hindering factor by survey respondents in XR (49%, N60). Similar to scientific/technical understanding, the lack of guidelines also occupies a very high position of uncertainty in other technologies. For example, in AI in health, 46% (N57) of respondents chose this answer as an important factor. Up to 1/3 of experts believe that the most significant hindering factor in the genome editing part is the lack of guidelines (38%, N47 in somatic genome editing and 33%, N41 in germline genome editing) (Fig. 4).

As many ethics guidelines are oriented around immediate interaction with participants, they often do not cover all the complexities of large data-centric research, such as AI and XR research (big datasets, sensor data, etc.) beyond standard regulatory obligations. Experts also believe that current guidelines focus on data ethics in a narrow sense and fail to address broader technological and societal contexts [20]. The challenge is how to develop standardized yet adaptive guidelines for these technologies. Similarly, for AI and data science, there have been calls to develop standardized ethics checklists or protocol templates that go beyond the usual biomedical checklist, covering issues like algorithmic bias, data provenance, and transparency [32]. Without them, RECs end up improvising, leading to inconsistencies and lower quality of ethics reviews that take ad hoc decisions when confronted with proposals on emerging technologies. This is particularly problematic at the EU level, where multi-site, multinational research proposals are common.

Lack of Training

In addition to the lack of expertise and guidelines, many experts emphasized that a better ethical evaluation requires additional training. The survey results show the greatest overall desire for training among digital technologies (AI 41%, N50 and XR 36%, N44). The need for training in biobanking and genome editing is a bit lower and similar between different technologies (29–34%) (Fig. 4).

While a lack of ethics expertise has been identified as less important hindering factor of ethics oversight compared to the lack of scientific/technical understanding and the lack of guidelines (Fig. 4), when

it comes to the training content, ethics experts have surprisingly rated the ethics assessment of technology research and development—closely related to ethics expertise—as the most useful training content (85%, N102), followed by complex case studies involving research and development of the technology (60%, N 72), cross-cutting ethics issues (e.g. international collaborative research) (58%, N 70), and scientific aspects of technology (57%, N68) (Fig. 5).

When further asked more specifically to rank preferred training methods, participants ranked them in the following order of preference: self-directed online training (34%, N41), group workshops online (33%, N40), in-person group workshops (18%, N22), and downloadable workbooks (14%, N17). When asked the additional question what their preferred learning styles for online training are, the top two most preferred learning styles for online training are listening to presentations (54%, N63) and watching videos (50%, N59). Other learning styles, such as listening to interviews with experts (41%, N48), reading succinct information (44%, N51), and self-directed interactive exercises (45%, N53), are less preferred. The least preferred option is group chat (20%, N23). That shows a wish for interactive training, albeit in a standard official manner.

Lack of Funding

The lack of funding is considered the least significant issue hindering the ethics assessment of every technology (Fig. 4). However, the question revolved around funding and not human resources, which, although can be construed as a similar issue, are not the same. Many European RECs are composed of experts volunteering their time and operating with limited administrative support. The emerging technology research often involves complex protocols and specific interdisciplinary ethical considerations, increasing the time and expertise needed per proposal. This may add additional workload for RECs without necessarily increasing support and can lead to delays and lower quality reviews.

While REC members might not directly acknowledge funding of ethics review as a significant challenge, insufficient funding underlies other challenges, like a lack of training or inability to hire technical consultants. One of the often-mentioned challenges in the literature in the context of emerging technologies, confirmed by our survey results is that many research ethics experts lack specialized knowledge of the technologies under review. The consequence is twofold: RECs might become overly conservative, blocking or slowing research out of caution, or they might miss important ethical issues because they don't fully understand the technology [20, 33].

Discussion

Our findings confirm that the traditional REC review model, characterized by a one-time ethics review conducted prior to the start of research, remains the standard of research ethics oversight in EU countries. The expert survey indicates it is still the primary ethics governance mechanism for a large majority of projects in domains like AI in health, XR, genome editing and biobanking.

Most EU countries require a one-time REC review for any study involving human participants, human biological material or personal data, often as a legal requirement or as a prerequisite for funding or publications. However, the organizational models vary by country: some have a centralized or regional REC system (e.g., national ethics committees for clinical trials), while others rely on institutional RECs at universities or hospitals.

Despite these differences, core principles are shared that are rooted in international ethics guidelines (WMA Helsinki Declaration [34], CIOMS guidelines [35], etc.) and European regulations [36–38]. This framework provides REC members with guidance on issues related to new technological developments, such as informed consent, privacy, risk–benefit assessment, and protection of vulnerable groups. Additionally, global guidelines (like the WHO governance framework for human genome editing [39]) inform European practice.

On the other hand, RECs not only review protocols, but are also expected to advise researchers and monitor compliance, creating an ethics ecosystem that extends beyond a one-time review and approval [40]. The involvement of RECs at early research stages is a strength that ensures ethics is at least initially considered in emerging technologies projects.

The established legal and ethical framework underpinning REC reviews across Europe enables RECs to address ethics issues in every science technology and

Fig. 5 The most useful training according to the study participants

innovation (STI) field. The main question is whether this system is equally effective in every new field of technology development.

Rethinking the Traditional REC Review Model

Despite the strong basis of the existing review system, the traditional governance model of a one-time ethics review before a project starts shows its limitations for research in fast evolving emerging technologies [41]. A fundamental critique of the traditional ethics oversight is that RECs have historically focused on biomedical paradigms, which involve clearly identifiable human subjects and interventions, whereas emerging technologies research (e.g. digital technologies) may not fit into this framework. In fields like XR (e.g., when a study uses XR to simulate social interactions, without the involvement of human participants) or in certain types of genomic research (e.g., creating gene editing tools without an immediate human application), it is unclear whether systematic REC review is required. It is possible that some institutions might not require an ethics review for such studies, although there are potential risks to applications with human users. This has led to what some describe as "grey areas" in the ethics review process, whereby research with potentially high societal impact might not go through the REC review.

Even if research is reviewed by a REC, as the Ada Lovelace Institute observes, RECs are often poorly equipped to evaluate the wider societal impacts of AI and data science research beyond immediate human subjects protection [7]. This is because a one-time REC approval cannot possibly address all ethical issues that emerge at different stages of technologies like AI, XR, or genome editing. AI research, for example, might be exploratory and its risks (e.g., model bias or unexpected findings) only become apparent after its real-life applications. Similarly, XR interventions might have unforeseen psychological effects, and genome editing experiments might raise new ethical questions as scientific knowledge progresses. The main gap is that current processes usually lack formal mechanisms for ongoing oversight or continuous review once the initial approval is given (with the exception of certain regulated areas like clinical trials). In contrast to academic and publicly funded research, ethics oversight in the private sector often remains even more fragmented and self-regulated. Industry-driven technology development may rely on internal ethics boards or compliance officers with limited external accountability. Issues of regulatory accountability are beyond the scope of this paper but it is an area worth researching in detail.

Our analysis has also shown that the lack of specific ethical guidelines for novel research areas is identified as a major limitation that can undermine effective oversight. While general principles exist, many emerging fields have no detailed guidelines beyond general frameworks or prohibitions.

The technical complexity of emerging research further strains the traditional model. A substantial number of experts reported that a limited understanding of new technologies among REC members hinders rigorous review. These findings align with prior observations that traditional RECs, historically operating in the field of biomedicine, may lack the capacity to fully grasp novel methodologies in digital technologies [42] or genomic interventions [43]. Without domain-specific expertise, the traditional one-time review model risks providing only partial oversight for complex emerging technology projects.

Blurred Boundaries of REC Responsibilities

Another important challenge of the traditional REC review model is uncertainty about what falls under the REC's review versus other oversight mechanisms. A prominent example is data protection in research. With GDPR in effect, most research institutions are obliged to have a Data Protection Officer (DPO) while their legal offices focus heavily on privacy compliance (due to potential penalties). REC members, who traditionally dealt with data privacy, are left with uncertainty over whether certain issues fall under the RECs' remit or should be left to other oversight bodies (such as institutional DPOs) [44]. Such role ambiguity can lead to ineffective assessments: some RECs might assume that personal data issues are being handled elsewhere and not scrutinize them, whereas others might review them in depth despite a lack of expertise, resulting in inconsistent scrutiny. The survey results tie into this: while many felt competent in data protection, there was a notable number of respondents who did not, and the lack of REC role clarity in this area might explain this result.

Similar blurred lines may arise with emerging conceptual areas like research integrity, biosecurity or dual-use research that are ethically relevant but not always formally within REC mandates. While research integrity deals mainly with issues of reproducibility, transparency, research misconduct and responsibility, it also touches on research ethics [45, 46]. As such, it is not clear whether ethics reviews should remain outside the discussion of research integrity and who has an overview remit for which part of the research process [47, 48]. Similarly, security and dual-use concerns are not always clearly mandated for REC review, yet they are ethics issues [49, 50]. In genome editing, for example, issues like biosecurity or dual-use (using CRISPR) span across ethical, legal, and security domains. Similarly, AI applications can easily cross the line between civil and military-focused research. Nevertheless, bodies dealing with security research may be different than those dealing with other research (e.g. biosafety committees). Thus, both RECs and other governance bodies can be looking at the same research.

This leads to the need to clarify governance structures and remits between various oversight bodies (RECs, DPOs, Research Integrity Officers (RIOs), biosafety committees, etc.) while establishing open lines of communication amongst them for the increasing number of overlaps.

Self-Assessment as an Alternative to REC Review

As mentioned before, traditional REC review models do not universally fit all ethically sensitive research areas. Certain types of emerging research are not consistently subject to REC review, exposing gaps in the oversight system. For example, in many countries or institutions, studies using XR interventions that do not involve an intervention or invasive procedures are deemed outside the scope of health research regulations, and thus no REC review is required. The survey findings show that "ethics self-assessment" is commonly applied for XR research, ranking as the second-most used ethics oversight approach in that domain. Thus, ethics self-assessment may serve as an alternative approach to formal REC approval (as is the case in Norway for social science research) [51], or it can be a compulsory procedural step conducted by researchers prior to submission of the research proposal for EU funding[5] or, for national REC evaluation, and certain aspects of self-assessment may be integrated and operationalized within the ethics-by-design framework.

While a self-assessment model can expedite low-risk studies and empower researchers, it relies on subjective ethical judgments and individual honesty. Thus, this approach can introduce conflicts of interest, since without external review, there is less assurance of accountability or transparency.

Another challenge is creating a risk-based tiered review system, which, although some RECs already employ it (e.g., expedited review for minimal risk research), is required at a broader governance level. This can, of course, depend on the pace of technological development, e.g., an AI project could undergo either a self-assessment or a full REC review plus monitoring. Implementing such a differentiated oversight is challenging because it demands well-defined criteria for risk levels and additional resources to undertake follow-ups on approved projects.

These limitations point to the need for new models that extend ethical scrutiny throughout the research lifecycle and accommodate cross-cutting ethical dimensions beyond human subject protections.

Continuous and Embedded Ethics Oversight

To address the above challenges, our results point toward ethics governance models beyond the traditional one-time REC review.

Within EU research governance, the concept of integrating ethics throughout the research lifecycle (not just at the outset) is gaining traction. The ethics by design approach is already part of the Horizon Europe ethics review framework for AI. This reflects an increasing expectation that ethical considerations be built into the development process of new technologies. For example, AI grant proposals are prompted to describe how they address ethics by design, meaning that RECs and ethics reviewers can push researchers to think ahead about ethics issues (e.g., choosing

[5] The ethics self-assessment tool provided by the European Commission specifically flags technologies like biobanking and AI in its checklist, which raises awareness among researchers and RECs about particular concerns in these fields.

training data to minimize bias, planning user oversight features for an AI tool, etc.). While the practical implementation of this system varies by project and research area, the very presence of this concept at the funding level is a strength as it paves the way for a more dynamic ethics governance process as opposed to the current one-off gatekeeping. This approach embeds ethical reflection and compliance into the research and innovation process from the outset, promoting proactive risk identification and responsible design choices [41].

Our survey findings demonstrate strong support for this approach across multiple domains, not only for AI. Our data show comparable or even greater support for this model in life science fields: respondents acknowledged that ongoing ethical reflection is necessary when managing biobanks or conducting long-term genome editing research. This opens the possibility of extending ethics by design principles into life sciences technologies. For instance, ethics review mechanisms in biobank governance often operate in two phases: first, during the establishment of the biobank, and second, when issuing project-specific permissions for data or biological material access. These dual entry points offer a useful precedent for a layered or phased review model that ethics by design could further operationalize.

While continuous ethics oversight offers significant advantages in terms of responsiveness and accountability, it may also introduce new challenges. These include increased administrative burden for RECs and researchers, risks of procedural formalism that could suppress innovation, and the need for additional funding and training to sustain continuous review processes, which risk inadvertently constraining research freedom. Furthermore, sustaining this model requires additional funding and training.

In this context, supplementary, domain-specific governance structures should also be mentioned. Biobanking offers a pertinent example where ethics oversight has evolved beyond a single REC approval. Large biobanks, which collect, store, and share human biological samples and data, face ongoing ethical obligations (data privacy, equitable access policies) that persist long after initial collection. The OECD [28] and WMA [29] have recommended that biobanks have an independent ethics board or similar governance structure in addition to REC approvals to oversee ongoing operations. In response, many biobanks have established dedicated ethics advisory boards or governance committees to oversee their operations continuously. These bodies can provide specialized, long-term ethical guidance that a one-time REC review cannot, ensuring that biobanks uphold commitments to donors and adapt to new ethical challenges (such as novel data uses or return of results) over time. Although approaches vary, some RECs review each new research use of biobank samples, while others defer to the biobank's own ethics oversight. This underscores an important principle: for complex research infrastructures like biobanks, a multi-layered oversight model may be beneficial, blending initial REC scrutiny with ongoing monitoring by an internal ethics body.

The idea of specialized data ethics committees or advisory boards has been suggested to handle AI/big data projects that fall outside standard REC mandates [7]. Following this thinking, some corporate technology firms have established internal ethics boards, and many universities have created ethics review processes specializing in areas like computer science.

In the context of genome editing, we observed a similar pattern of specialized oversight emerging. Several European countries have national bioethics councils or gene technology commissions that weigh in on ethically sensitive research areas, such as human gene editing[6] or embryo research. While these bodies may not issue project approvals, they play a crucial role in guiding policy (e.g., formulating positions on allowable genome editing practices or reviewing contentious proposals). Empowering these complementary structures (biobank committees, data ethics panels, or national ethics councils) can strengthen the overall governance ecosystem.

Additionally, many EU-funded projects in emerging technologies are required to have independent ethics advisors and may even require expert review and oversight both before and during the research phase, especially for high-risk research projects. This helps to identify issues that a one-time institutional review might miss and fosters continuous ethical reflection.

Recommendations

Drawing on the above findings, several recommendations emerge to enhance research ethics oversight for emerging technologies.

[6] E.g., The Gene Therapy Advisory Committee (GTAC) in UK (https://www.hra.nhs.uk/planning-and-improving-research/policies-standards-legislation/gene-therapy/).

First, our findings support moving towards a risk-based, proportional oversight model. Rather than replacing the traditional model, continuous ethics oversight (ethics by design) and self-assessment should be seen as complementary elements within a broader governance framework. This reflects the expert community's endorsement of a lifecycle approach to ethics oversight and the need to tailor ethics governance depending on the level of risk and uncertainty of specific research. For instance, the EU's Horizon Europe ethics appraisal process already includes an initial ethics screening followed by a detailed assessment for higher-risk projects, mirroring a tiered model that allocates review intensity based on project risk level. Low-risk projects might be sufficiently managed through an ethics self-assessment or expedited review, freeing resources for more intensive scrutiny of high-risk projects, medium-risk projects receive traditional REC review and high-risk research (e.g. first in human genome editing trials, or AI studies processing sensitive identifiable personal data) might be approved only with conditions such as ongoing monitoring, mid-term ethics audits, or periodic progress reports to the REC. Implementing them will require developing specific criteria to classify the level of risk involved and establishing infrastructures for follow-up activities. Considering the radical changes that these might entail for many current RECs, pilot programs could be initiated to develop scalable models for implementation. Alongside this, institutionalizing ethics by design, not only in digital technologies but also in life sciences technologies and other domains, as a formal prerequisite for research funding, would embed ethics throughout the research lifecycle. We recommend that institutions and funders incentivize researchers to engage with ethics experts at the project design phase and to treat ethical considerations as integral aspects of the research plan. This cultural shift, already encouraged by EU funding requirements, is supported by our empirical data as an urgently needed evolution of the current ethics review paradigm.

Second, it is vital to develop and disseminate clear, technology-specific ethics guidelines. Our analysis shows a lack of adequate knowledge in ethics of novel developments that must be addressed by providing RECs with concise and clear guidelines for novel topics (such as e.g., AI research involving behavioral interventions or genomic studies using CRISPR). This is the only way that consistency and quality of REC reviews in these fields can be improved. Efforts at the EU and international level to create consensus guidelines or checklists would directly address this need.

Third, there is a need to bolster expertise and training within RECs. Our data demonstrated insufficient technical and ethics expertise. Addressing this could involve targeted capacity-building programs for REC members, as well as mechanisms to incorporate external experts when reviewing high-tech protocols or establishing technology-specific subcommittees within RECs for areas like AI or XR. Clarifying REC roles vis-à-vis other oversight offices is also critical here, for example, formalizing collaboration between RECs and DPOs or biosafety boards can ensure that complex data privacy or biosecurity issues receive due expert attention.

Finally, to combat fragmentation and strengthen oversight consistency, stakeholders should pursue greater harmonization and networking in ethics governance. European networks such as the European Network of Research Ethics Committees (EUREC) already facilitate the exchange of best practices and training for REC members across countries.[7] These efforts should be supported by funding agencies and enlarged. For example, creating EU-wide repositories of case studies, ethics decision summaries, or guidance documents on emerging technologies would allow committees to learn from each other and to promote a more harmonized ethics review culture.

Conclusion

The last decades have seen a significant increase in the attention of academia, industry and policy on research ethics. Ethics reviews have turned from a casual inspection of research protocols to a highly focused, necessary prerequisite for research activities. At least in Europe (but basically in all STI-intensive economies), awareness of research ethics issues is widespread in the research community and discussions on ethics issues are evermore prominent and in many cases, polarized. New technology developments bring in new aspects and additional challenges that must be dealt with.

[7] https://eurecnet.eu/

It is in this context that our work is taking place. Questions on the governance and everyday functioning of research ethics oversight are at the core of our focus. There are different contexts at the institutional, national and international levels that are affecting the needs and the solutions. There are also multiple actors and disciplines that are in play. With this in mind, we have accumulated new and original data that provides a first concrete input in the ensuing debate. Our analysis points to new issues, knowledge gaps and structural weaknesses affecting the work of RECs in Europe. Our results point to concrete recommendations that can improve the functions of RECs and lead to improved ethics oversight. Further research in this area is definitely needed, but what we provide in this paper is an evidence based argument for a way ahead that we hope can promote a more coherent, successful and human-centered technology development.

Limitations

The survey was designed for input in four specific technologies, but the participants were allowed not to complete parts of the survey if they did not assess specific technology projects. This resulted in varying sample sizes for different technology areas. In addition, self-assessment of technology-specific competencies may not accurately reflect actual expertise.

Response bias, including self-selection and social desirability bias, is a common issue with any survey and might influence the results. Participants with a particular interest in emerging technologies may have been more likely to respond, leaving out of the analysis a number of experts who have less knowledge or interest in these fields. Although this possibility cannot be confirmed, it allows for further speculation that emerging technologies introduce even more significant challenges in ethics reviews.

Despite these limitations, the survey provided valuable and original insights into the current state of ethical reviews for emerging technology research and highlighted areas where further support and development are needed.

The inherent limitations of our research are balanced out by the use of multiple sources of evidence in order to mitigate bias. Nevertheless, results should be treated with caution and must be eventually reproduced in future research in this field. We see this paper as one step towards a confirmed need to restructure the current ethics review models.

Acknowledgements The article draws substantially on findings from the EU-funded IRECS *(Improving Research Ethics Committee Support)* project that aims to provide support for RECs focusing on ethics review processes for four technology domains: AI in health, extended reality, biobanking, and genome editing.

Authors' Contributions All authors contributed to the study conception and design. Material preparation, data collection and analysis were performed by Vygintas Aliukonis, Jūratė Lekstutienė, Eugenijus Gefenas and Vilma Lukaševičienė. The first draft of the manuscript was written by Vilma Lukaševičienė and all authors commented on previous versions of the manuscript. All authors read and approved the final manuscript.

Funding This study was funded by the IRECS project (HORIZON-WIDERA-2021-ERA-01-91) under grant agreement number 101058587.

Data Availability The anonymised data collected are available as open data via EU Open Research Repository Zenodo: https://zenodo.org/records/17426521.

Declarations

Ethics Approval and Consent to Participate The web-based anonymous survey of research ethics experts on research ethics governance did not fall within the scope of human research that requires REC approval by Lithuanian law. Therefore, approval from REC was not obtained. Only anonymized data were collected, and informed consent was obtained from all participants prior to their completion of the questionnaire.

Competing Interests The paper was written as part of the EU-funded project IRECS *(Improving Research Ethics Committee Support)*. The authors have no competing interests to declare beyond the academic funding of the study that are relevant to the content of this article.

References

1. Albahri AS et al (2023) A systematic review of trustworthy and explainable artificial intelligence in healthcare: Assessment of quality, bias risk, and data fusion. Inf Fusion 96:156–191. https://doi.org/10.1016/j.inffus.2023.03.008
2. Newbutt N, Bradley R (2025) Exploring ethical research issues related to extended reality technologies used with autistic populations. J Respons Technol Volume 21: 100102, ISSN 2666–6596, https://doi.org/10.1016/j.jrt.2024.100102
3. Gibelli F, Ricci G, Bailo P (2025) Genome editing in medicine: A scoping review of ethical, bioethical, and medico-legal implications. J Law Med Ethics Published online 2025:1-9. https://doi.org/10.1017/jme.2025.48
4. Lorenzo D, Esquerda M, Palau F et al (2022) Ethics and genomic editing using the Crispr-Cas9 technique: Challenges and conflicts. NanoEthics 16:313–321. https://doi.org/10.1007/s11569-022-00425-y
5. Baumann M (2016) CRISPR/Cas9 genome editing – new and old ethical issues arising from a revolutionary technology. NanoEthics 10:139–159. https://doi.org/10.1007/s11569-016-0259-0
6. Staunton C, Slokenberga S, Parziale A, Mascalzoni D (2022) Appropriate safeguards and article 89 of the GDPR: Considerations for biobank, databank and genetic research. Front Genet 13:719317. https://doi.org/10.3389/fgene.2022.719317
7. Ada Lovelace Institute (2021) Looking before we leap: AI and data science research ethics. Ada Lovelace Institute report – Project on supporting AI research ethics committees
8. Resseguier A, Ufert F (2024) AI research ethics is in its infancy: The EU's AI act can make it a grown-up. Res Ethics 20(2):143–155
9. Ladikas M, Chaturvedi S, Zhao Y, Stemerding, D (eds) (2015) Science and technology governance and ethics; A Global Perspective from Europe, India and China. Springer, Heidelberg. https://link.springer.com/book/10.1007/978-3-319-14693-5
10. TechEthos Project (2023) Ethics by design in cutting-edge tech development
11. Timmers M, van Dijck 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 Med Ethics 21:36. https://doi.org/10.1186/s12910-020-00480-8
12. Riis P (1977) Letter from...Denmark. Planning of scientific-ethical committees. BrMedJ 2:173 https://doi.org/10.1136/bmj.2.6080.173
13. World Health Organization (2023) WHO tool for benchmarking ethics oversight of health-related research involving human participants. Available at: https://www.who.int/publications/i/item/9789240076426
14. Cox S, Solbakk JH, Bernabe RDLC (2022) Research ethics committees and post-approval activities: A qualitative study on the perspectives of European research ethics committee representatives. Curr Med Res Opin 38(11):1897–1907. https://doi.org/10.1080/03007995.2022.2115773
15. Stahl, Bernd Carsten (2021) Artificial intelligence for a better future: An ecosystem perspective on the ethics of AI and emerging digital technologies. SpringerBriefs in Research and Innovation Governance. Cham: Springer International Publishing. https://doi.org/10.1007/978-3-030-69978-9.
16. 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, and repealing Directive 95/46/EC (General Data Protection Regulation), (OJ L 119, 4.5.2016, pp. 1–88)
17. European Commission (2024) AI Act, 6 March 2024. Available at: https://digital-strategy.ec.europa.eu/en/policies/regulatory-framework-ai
18. European Parliament, Council of the European Union. Regulation (EU) 2025/327 of the European Parliament and of the Council of 11 February 2025 on the European Health Data Space and amending Directive 2011/24/EU and Regulation (EU) 2024/284, OJ L, 2025/327
19. Grinbaum A (2023) Parole de machines. Humensciences
20. Ferretti A, Ienca M, Sheehan M, Blasimme A, Dove ES, Farsides B, Friesen P, Kahn J, Karlen W, Kleist P, Liao SM, Nebeker C, Samuel G, Shabani M, Rivas Velarde M, Vayena E (2021) Ethics review of big data research: What should stay and what should be reformed? BMC Med Ethics 22(1):51. https://doi.org/10.1186/s12910-021-00616-4
21. Pullman D, Etchegary H (2021) Ethical, legal, and social issues (ELSI) in clinical genetics research. In: Parfrey, P.S., Barrett, B.J. (eds) Clinical Epidemiology. Methods in Molecular Biology, vol 2249. Humana, New York, NY. https://doi.org/10.1007/978-1-0716-1138-8_5
22. Howard H, Niemiec E, Soulier A (2019) SIENNA D2.1: State of the art review of human genomic technologies (Version V0.4). Zenodo. https://zenodo.org/record/4067912#.YXfGwZ5ByUk; https://zenodo.org/record/4067912#.YXfGwZ5ByUk
23. Jensen SR, Nagel S, Brey P, Ditzel T, Rodrigues R, Broadhead S, Wright D (2018) SIENNA D3.1: State-of-the-art Review: Human Enhancement (Version V1.1). Zenodo. https://zenodo.org/record/4066557#.YXfG3p5ByUk; https://zenodo.org/record/4066557#.YXfG3p5ByUk
24. Seedall C, Lindemann T, Klar R, Tambornino L (2023) Criteria for ethical review by RECs in emerging technology research. TechEthos Project Deliverable. Available at: www.techethos.eu
25. Lekstutiene J, Mönig JM, et al (2021) PANELFIT D 5.3 Report on the governance of data protection ELI in ICT research and innovation. Available at: https://www.panelfit.eu/other-outcomes/
26. Aliukonis V, Gefenas E, et al (2024) irecs D2.4: Proposals for adaptation of ethics review processes.. Available at: https://irp.cdn-website.com/5f961f00/files/uploaded/Deliverable_2.4.pdf
27. European Commission (2021) How to complete your ethics self-assessment. Available at: https://ec.europa.eu/info/

funding-tenders/opportunities/docs/2021-2027/common/guidance/how-to-complete-your-ethics-self-assessment_en.pdf
28. OECD Organization for Economic Cooperation and Development (2010) OECD guidelines on human biobanks and genetic research databases. Eur J Health Law 17(2):191–204. PMID: 20443450
29. The World Medical Association (2002) The Declaration of Taipei on ethical considerations regarding Health Databases and Biobanks (last revised 2016). Available at: https://www.wma.net/policies-post/wma-declaration-of-taipei-on-ethical-considerations-regarding-health-databases-and-biobanks/
30. OECD (2019). Recommendation of the council on artificial intelligence, OECD/LEGAL/0449. Available at: https://legalinstruments.oecd.org/en/instruments/oecd-legal-0449
31. Ladikas et al (2024) Regulatory gap analysis of Extended Reality related regulations. Report prepared for the European Commission. Available at: https://xr4human.eu/deliverables/
32. Aucouturier E, Grinbaum A (2025) Training bioethics professionals in AI ethics: A framework. J Law Med Ethics. Published online 2025:1-8. https://doi.org/10.1017/jme.2025.57
33. Kerasidou, Angeliki, et Ruth Horn. Trustworthy ethics review of medical AI research protocols: Developing a research ethics practical guide for ethics review committees, 17 juillet 2023. https://www.ndph.ox.ac.uk/study-with-us/dphil-population-health/dphil-researchprojects/2023-dphil-projects/trustworthy-ethics-review-of-medical-ai-research-protocolsdeveloping-a-research-ethics-practical-guide-for-ethics-review-committees
34. World Medical Association (2024) Declaration of Helsinki—ethical principles for medical research involving human participants. Available at: https://www.wma.net/policies-post/wma-declaration-of-helsinki
35. Council for International Organizations of Medical Sciences (CIOMS) (2016) International ethical guidelines for health-related research involving humans. Geneva, Switzerland: CIOMS
36. Regulation (EU) 536/2014 on 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, (OJ L 158 27.5.2014, p. 1)
37. Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC, (OJ L 117, 5.5.2017, pp. 1–175)
38. Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017 on in vitro diagnostic medical devices and repealing Directive 98/79/EC and Commission Decision 2010/227/EU, (OJ L 117, 5.5.2017, pp. 176–332)
39. WHO Expert Advisory Committee on Developing Global Standards for Governance and Oversight of Human Genome Editing (2021). Human genome editing: Recommendations. Available at: https://iris.who.int/bitstream/handle/10665/342486/9789240030381-eng.pdf?sequence=1
40. Lanzerath D (2023) Research ethics and research ethics committees in Europe. In: Zima, T., Weisstub, D.N. (eds) Medical Research Ethics: Challenges in the 21st Century. Philosophy and Medicine, vol 132. Springer, Cham. https://doi.org/10.1007/978-3-031-12692-5_22
41. Brey P, Dainow B (2024) Ethics by design for artificial intelligence. AI Ethics 4:1265–1277. https://doi.org/10.1007/s43681-023-00330-4
42. Stahl BC, Aucouturier E, Lekstutiene J, Lindemann T, Maia M, Marušić A, … Spyrakou E (2025) Knowledge needs of research ethics committees for the integration of ethics in research and technology development. J Responsible Innov 12(1). https://doi.org/10.1080/23299460.2025.2466904
43. McGahan E, Berkman J, Milne D, et al (2015) Empowering human research ethics committees to review genomics applications: Evaluating the utility of a custom online education resource. Eur J Hum Genet https://doi.org/10.1038/s41431-025-01846-5
44. Gefenas E, Lekstutiene J, Lukaseviciene V et al (2022) Controversies between regulations of research ethics and protection of personal data: Informed consent at a crossroad. Med Health Care Philos 25:23–30. https://doi.org/10.1007/s11019-021-10060-1
45. Kolstoe SE, Pugh J (2023) The trinity of good research: Distinguishing between research integrity, ethics, and governance. Account Res 31(8):1222–1241. https://doi.org/10.1080/08989621.2023.2239712
46. Muthanna A, Chaaban Y, Qadhi S (2023) A model of the interrelationship between research ethics and research integrity. Int J Qual Stud Health Well-Being 19(1). https://doi.org/10.1080/17482631.2023.2295151
47. Redman BK, Caplan A (2021) Should the regulation of research misconduct be integrated with the ethics framework promulgated in the Belmont Report? Ethic Hum Res 43(1):37–41. https://doi.org/10.1002/eahr.500078
48. Vie KJ (2022) Empowering the research community to investigate misconduct and promote research integrity and ethics: New regulation in Scandinavia. Sci Eng Ethics 28:59. https://doi.org/10.1007/s11948-022-00400-6
49. Magdalena Guraiib M, Ross AL, Frewer A, Sprumont D, Shamsi Gooshki E, Dzenowagis J, Alois RA (2024) Oversight of dual-use research: What role for ethics committees? Health Secur 22(4):281–293. https://doi.org/10.1089/hs.2023.0095
50. Salloch S (2018) The dual use of research ethics committees: Why professional self-governance falls short in preserving biosecurity. BMC Med Ethics 19(1):53. https://doi.org/10.1186/s12910-018-0295-0
51. Camilla Bø Iversen. RECs reviewing non-health-related research. Available at:https://eurecnet.eu/recs-in-europe/norway/