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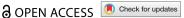
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RESEARCH ARTICLE



Knowledge needs of research ethics committees for the integration of ethics in research and technology development

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ABSTRACT

One well-established way of integrating ethics into the development of emerging technologies is the ethics review process which originated in biomedical research. This relies on an ex-ante review of research proposals through institutional bodies, usually known as research ethics committees (RECs). RECs are typically highly skilled in biomedical research questions and methodologies but are often less well equipped to deal with other types of research, notably research involving emerging technologies. Considering the dominance of RECs in the landscape of ethics and emerging technologies, it is, therefore, important to understand whether REC members perceive a need for the development of capacity and training regarding novel technologies. This article presents the findings of a large-scale pan-European survey of 261 REC members and ethics experts to explore their perceived training needs. It shows that such training needs are predominantly related to the relatively abstract level of technology families and broad applications.

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Ethics; emerging technologies; research ethics; training; REC

Introduction

author(s) or with their consent.

There are numerous ways of thinking about, approaching, or dealing with ethical and social issues arising from research and technology development. A key challenge is the balancing of expected and potential benefits and concerns, both of which are uncertain,

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but often to different degrees. One well-established mechanism of addressing the ethical challenges is through the institution of research ethics committees (RECs). RECs are widely spread in universities where they comprehensively cover medical research and increasingly have responsibilities in other disciplines, fields and domains.

The extension of research ethics review which originated in biomedical research and originally focused on protection of research subjects to other fields has raised challenges. There are fundamental questions about the appropriateness of the RECs approach to other fields, such as the social sciences, where subject protection may have a fundamentally different role to play. Similarly, research ethics applied to technology research and development brings new ethical concerns, at the interface between technology ethics – understood as ethical reflection applied to research, development, deployment, and use of technology – and research ethics, which is specifically dedicated to ensuring ethical conduct of research across all disciplines. This article takes its point of departure from research ethics but aims to be sensitive to the discussion of technology ethics.

In this article, we will focus on a practical challenge. Established RECs tend to draw mostly from the biomedical disciplines and normally have high level of expertise and competence in these fields. The application of the REC model of research review outside the biomedical area of origin can lead RECs to be faced with questions that are beyond their expertise and experience. In practice, one can observe the creation of discipline-specific RECs which may address the challenge linked to the expertise of REC members to some degree. However, in any event it is likely that the quickly developing nature of science and technology can easily lead to situations where existing RECs are faced with research ethics applications or proposals for ethics approval which cover topics that are outside of their expertise. One way of addressing such gaps in knowledge in RECs is to provide training to its members. The question that is unclear, however, is which knowledge gaps exist that can limit the effectiveness of RECs and which training activities could fill those gaps. This question arose from our work in an EU-funded project that aims to provide support for RECs and is based on the history of institutionalisation of research ethics processes in the European research framework programmes (European Commission 2014; European Commission 2021b). It thus fits into the discourse covering normative reflection and governance of research, science and technology development as reflected in the different streams of the responsible innovation (RI) discourse (Fisher et al. 2024).

In this article we therefore seek to answer the following research question: which training needs should be addressed to allow ethics review procedures to appropriately deal with the most pressing current developments, focusing on ethical aspects related specifically to emerging and in particular digitally enabled technologies? This question requires an understanding of who has such training needs, what subject areas the research ethics resources, and training are required in and the context and level of detail that is required for ethics processes to work. These questions are answered based on data collected via an online survey of REC members and other experts that received 261 responses and constitutes the first empirical study of REC training needs.

The survey results offer a number of important insights. It confirmed our starting hypothesis that there is a perceived need for training of REC members to improve their capacity to evaluate technology-driven research. It showed that REC members, many of whom have a background in the social science and humanities, are interested

mostly in broad technology areas and application. Training needs are located on this relatively abstract level and not on the level of specific techniques or specialist applications. The results can help the design of training provision for REC members. At the same time, they raise the question of the level of ethical novelty that new technologies bring to research projects and the balance between a detailed understanding of ethical issues, technical capabilities and underpinning values that REC members need to engage with during their evaluation activities.

The article makes a unique contribution to the question of how ethics can be integrated into the development process of emerging technologies to foster RI. More specifically, we contribute to responsible research and innovation (RRI) practices by finding out what RECs need to know regarding digital technologies in order to assess relevant research ethically, i.e. be able to actually fulfil their widened role outside biomedical research. We argue that knowledge about (digital) tech ethics is a prerequisite for the research ethics evaluation and that the research ethics approval process that is overseen by RECs is a key part of practically doing responsible research. Building on the established processes and structures of RECs the article not only addresses academic discussions but also offers empirical insights into training needs that provide much-needed context of the often predominantly theoretical discussion of the ethics of science and technology development. A better understanding of the knowledge needs is a precondition for practically dealing with ethics by providing the basis for practical training interventions that are required for ethics assessment procedures to work.

The article is structured as follows. It starts with a discussion of ethics of emerging and disruptive technologies, which leads to research ethics review structure as one way of dealing with such ethical questions and give rise to the need for novel training approaches. The subsequent section lays out the methodology of the paper that is based on an online survey covering both quantitative and qualitative input. The findings and their interpretation are then presented, leading to the conclusion which highlights in more detail the article's contribution to knowledge and further research.¹

Research ethics committees and the ethics of emerging and disruptive technologies

This article is predicated on the assumption that new and emerging technologies may have properties that can give rise to ethical concerns that are novel, not well understood or that may materialise in ways that existing RECs structures are not attuned to. We therefore briefly highlight the debate about the ethics of emerging technologies and then review the discussion of emerging and disruptive technologies, ethical concerns they can raise, and which role research ethics committees can play in this context.

Emerging and disruptive technologies

Emerging technologies drive global progress, impacting various industries and aspects of society (Rotolo, Hicks, and Martin 2015). However, they also pose numerous societal and ethical challenges, including concerns related to equity and access, bias, environmental sustainability, and even risk to human health (Swanton et al. 2021). Some technologies are more likely to raise technical-related concerns, such as security and privacy issues,

reliability, scalability, as well as data quality and integrity. For example, Internet of Things (IoT), blockchain technologies, quantum computing, cloud computing, and extended reality are technologies that are relying on large datasets, they collect personal and/or sensitive data, thus being subject to cyber-attacks and posing significant security and privacy risks (Alferidah and Jhanjhi 2020; Cavaliere, Mattsson, and Smeets 2020; Ma et al. 2020; Marques, Silva, and Santos 2023; Sun 2020).

Artificial intelligence (AI) is another example of a rapidly evolving technology raising ethical concerns and requiring guidance framed in terms of human flourishing (Stahl 2021). The European Union (EU) has established a legislative – AI Act, addressing AI and its applications to ensure AI is used safely and ethically (European Commission 2021a). The Act assigns AI applications into three categories based on the risk in terms of health, safety and fundamental rights they pose: unacceptable, high-risk, and limited or low-risk applications. Consequently, the inclusion of AI and AI health-related systems holds significant importance in our list of technologies for the survey. According to the Act, software 'intended to provide information used to make decisions for diagnostic or therapeutic purposes', or 'intended to monitor physiological processes' qualifies as high-risk software (AI Act). This may imply that any medical device that incorporates an AI system belongs to the high-risk category under the AI Act.

Nevertheless, health-related technologies may not be AI-powered, but still pose highrisks (Galaz et al. 2021). For example, biobased technologies, bioinformatics, bioelectronics, neurotechnologies, and nanotechnologies provide innovative solutions to medical challenges, but also raise various threats to privacy, security, access, and informed consent, among other issues (Asveld, Osseweijer, and Posada 2020; Hussain 2020; McIntosh and DuBois 2020).

As the discussion in this section demonstrates, our interest in emerging and disruptive technologies focuses on digital technologies. These have some characteristics, such as the possibility of very quick diffusion, the problem of 'many hands', i.e. difficulties of ascribing responsibilities, and their wide-spread use across all areas of research that render them key targets for ethical reflection (Jirotka et al. 2017). However, most of the questions discussed in this article are not exclusively confined to digital technologies or application of new technologies to biomedicine. Other types of technologies can carry significant risks, for example climate-related technologies (e.g. Carbon Capturing and storage), or technologies energy production technologies (e.g. nuclear technologies). Especially for high-risk technologies important questions arise concerning the distribution of risks and benefits, thus of fairness and justice which brings us to questions of ethics.

The ethics of emerging technologies

The previous section has given an indication of the types of emerging technologies that are raising concerns about possible ethical issues. Such worries about ethics of emerging technologies are not new. One main reason is that their applications and social consequences are largely uncertain. This raises epistemological and methodological questions about how to approach them (Brey 2012). One reason for scholarly interest in emerging technology is the so-called dilemma of control, often also referred to as the Collingridge dilemma. Collingridge (1981) pointed out that the social and ethical consequences of

emerging technologies are difficult to predict at an early development stage, when it is still easy to change the technologies' structure and functioning. At a later stage, when the technology is better understood, consequences of use are easier to predict but the nature of the technology is more difficult to change.

The Collingridge dilemma supports the contention that there is no straightforward way of predicting the actual social and ethical implications of emerging technologies. At the same time, technical progress appears to continue to accelerate which leads to a similar acceleration of social changes (Habermas 2019). This acceleration of socio-technical change exacerbates the inherent complexity and uncertainty of technological innovations, rendering ethical reflection and even intervention highly challenging (Sollie 2009). The combination of uncertainty and high expected impact has given rise to frequent uses of the metaphor of a revolution. Popularised more recently by Schwab (2017), there is a history of seeing technology development as a revolution (Ellul 1973; Wiener 2013), typically in the context of industrial revolutions with the version of the industrial revolution that we are currently witnessing (Schwab suggests that it is the fourth one) being triggered by recent technical development, notably progress in information technology (Floridi 2010; Shapiro 1999).

The concept of industrial revolution points to two aspects of ethics to be considered: Ethics as a means of risk assessment and management to avoid harm, but also ethics as a set of guiding principles that can help achieve a desirable future. Proponents of the development of new technologies tend to focus on the former. Emerging technologies are typically portrayed as 'better' in a functional but also often in a moral sense as facilitating a better future (Karafyllis 2009). This perception of emerging technologies as being better than existing ones is arguably part of the social legitimation of scientific research and technology development (Reeves, Goulden, and Dingwall 2016).

The discourse on the ethics of emerging technologies has provided numerous suggestions on how best to address such questions. These include the discussion of responsible (research and) innovation (Shanley 2021). Without being able to provide a detailed justification of this position here, we understand the idea of responsibility in research and innovation as representing the principle that consequences of research and innovation activities need to be considered before and while undertaking these activities. It thus covers a broad set of potential ethical questions and raises fundamental questions of whether, how and to what degree this can be achieved. In practice, one established mechanism for dealing with ethics that increasingly covers work on emerging technologies is that of ethics review through specialised committees, which will be described in more detail in the next section. RECs thus form an integral part of what could be deemed RRI as well as similar concepts such as that of ethical, legal, and social aspects of research (Rip 2009). A key question motivating this article, however, is whether RECs are equipped to play this role and look beyond the immediate protection of research subjects, which is their traditional narrowly defined remit.

The role of research ethics committees in the integration of ethics in research and technology development

The necessity of ethics review is widely recognised in biomedical research and codified in international and national standards and standard operating procedures.

In some instances, such as clinical drug trials and interventional health research studies, ethics review may even be legally mandated (MDR 2017; World Medical Association 2013). Nevertheless, when it comes to research outside biomedical fields, approaches and procedures to ensure that research projects fulfil ethical criteria vary greatly across countries and institutions. Even in the member states of European Union ethics assessment practices for non-biomedical research vary significantly and range from ethical self-assessments conducted by researchers themselves prior to initiating a specific research project to different forms of mandatory ethics reviews carried out by research ethics committees (RECs)² (Koepsell, Brinkman, and Pont 2014; Lanzerath 2023; Spicker 2022). The following examples illustrate that approaches vary even across countries with robust research and innovation systems.

In Norway, for example, national ethics committees outside biomedical research were established as early as 1990, when the National Council for Science and Technology and the National Committee for Research Ethics in the Social Sciences and the Humanities were created. Unlike RECs in the biomedical field, these committees do not provide formal approval for research projects, but instead serve as advisory bodies. According to Norwegian policy, researchers are responsible for conducting their own ethical assessments of their research projects and, if they deem it necessary, seek guidance from the relevant national ethics committee (Norwegian National Research Ethics Committee 2018).

The Netherlands, by contrast, have adopted an institutionally oriented rather than a national approach. For example, Maastricht University has established three RECs specifically tasked with reviewing non-medical research conducted within its various faculties (Maastricht University 2024). Similarly, the University of Twente has established four domain-specific RECs (computer & information sciences, geo-information sciences, humanities & social sciences, and natural sciences and engineering sciences) based on the rationale that different domains of research typically face different ethical issues. The domain-specific RECs are complemented by a central REC composed of the chairs and vice chairs of the domain-specific RECs. The central REC's role is to review research proposals that are complex and/or controversial and involve multiple domains. Additionally, it serves as an appeal body in instances where objections are raised against the recommendations provided by a domain-specific committee (Universiteit Twente 2019).

The underlying rationale for establishing a system of ethical review for human research outside the biomedical sciences is that research that poses similar or equal risks as health studies should undergo similar or equally stringent review procedures (E. Gefenas et al. 2010). In other words, if a technology research project involves significant privacy concerns (e.g. if developing new technologies necessitates collecting personal data from vulnerable individuals or if data can be easily misused), it should be ethically evaluated in a manner akin to biomedical research, regardless of the intended application. This is why the establishment of RECs in non-medical fields, such as technology, or the expansion of the mandates of existing RECs is becoming increasingly common.

Voices of concern: are RECs a good fit?

There are several complexities associated with ethics reviews in non-biomedical research, many of which are particularly acute in technology research. Challenges arise, for example, because a significant amount of technology research is conducted in the industry or business sector or in public-private partnerships. The different incentive systems that business and industry actors, on the one hand, and academic researcher, on the other hand, face, as well as the different governance schemes into which they are embedded, can create regulatory frictions between public and private research.

In their eagerness to swiftly bring technology products to the market, commercial actors may have strong incentives to bypass often time-consuming ethics review processes unless legally required to obtain a favourable ethics opinion. However, even in cases where researchers from the private sector would like their projects to undergo an ethics review, they may struggle to find a REC that is willing and authorised to review their research protocols. Such lack of access to a REC exists primarily because reviewing private sector research often falls outside the remit and scope of institutional RECs, while many companies, especially small- and medium-sized enterprises as well as companies outside the health-sector, do not maintain their own research ethics review infrastructures (Ada Lovelace Institute 2022). These differences between public and private sector research, as well as differences across private sector research, can create significant regulatory discrepancies that are grounded in governance arrangements rather than ethical considerations. This may lead to higher and more obligatory ethical standards and, thus, effectively tighter regulation for researchers in public research compared to their counterparts in business and industry, as well as intra-industry differences in ethics governance stringency, which are, however, not the result of differences in the magnitude of the ethical challenges related to their research, but consequences of divergent institutional arrangements.

However, due to the biomedical focus of most RECs, finding a suitable REC can be challenging even for academic non-biomedical research, as is shown by the fact that established biomedical RECs are sometimes asked to review non-biomedical research when institutional regulations or funder or publisher requirements oblige researchers to obtain ethics approval. Because expertise is critically important to conduct reviews competently, this can inadvertently compromise the quality of non-biomedical reviews. This, in turn, poses a significant issue as the legitimacy of RECs depends to a crucial extent on the quality of the review (Schrag 2010; Schrag 2011; Spicker 2022).

Additionally, even when RECs are mandated to review technology research, the question arises as to whether the REC expertise is well-suited for evaluating the ethical implications of technology research. REC expertise in biomedical research largely stems from their composition, which reflects the demands initially placed on them when they were created. Specifically, RECs have been predominantly composed of medical doctors (rather than technology researchers or social scientists), bioethicists (rather than technology ethicists), and individuals with expertise in quantitative biomedical methodology (rather than programming or machine learning) (Druml et al. 2009; Ludvigsson et al. 2015). This composition, as well as the guidance documents used by RECs, are reflective of the longtime primary focus of RECs, namely evaluating physical risks to research participants. However, research in other domains often poses different risks. Evolving research practices in technology, for example, increasingly involve processing large volumes of personal data and thus pose privacy risks rather than risks of direct physical harm. Thus, the different contours of ethical issues across research areas raise questions about the proper scope of the REC mandate, such as their role in data protection (Gefenas et al. 2022). In a similar vein, technology research typically impacts not only research participants, but also social and environmental systems more broadly. For example, research results could reshape human agency, society, or ecosystems (Ienca et al. 2018).

Therefore, it is plausible to argue that RECs should adapt their expertise and frameworks to these evolving research practices if they are expected to assess ethical risks on a more holistic basis that goes beyond mitigating direct physical risks to research participants. However, the discourse surrounding research ethics and the practices and structures developed to institutionalise it arose from biomedical research (Beauchamp and Childress 2009) and, as a result, most training programmes specifically designed for REC members are primarily focused on biomedical research ethics and the protection of research participants. This is not to suggest that research ethics is exclusively confined to biomedical research and has no relevance outside of such disciplines, but to explain why there may exist a gap in training on technology research ethics or research ethics applied to social sciences (Carniel et al. 2023). There are nevertheless long-standing concerns about the applicability of traditional research ethics approaches outside of the biomedical realm, for example the question whether and to what extent the principle of informed consent is applicable in non-medical research settings (Hansson 2006).

It is thus by no means certain that RECs are the optimal structure to deal with ethics of emerging technologies and integrating ethics with a view to fostering RI. However, RECs and their underlying rationales exist, and they dominate the way in which ethics is dealt with in research as well as technology development. Recognising this social reality implies that it would be desirable that the REC members have the expertise to meaningfully assess any ethics applications that involve the development of novel and emerging technologies, in particular if they have a great potential of unfolding disruptive consequences.

There are potentially many ways of ensuring RECs expertise, but the probably most straightforward one, that does not require a fundamental re-organisation of existing processes or rethinking of how ethical and social issues are to be dealt with, is to inject missing knowledge and expertise into the RECs via specific training interventions. In order to provide such training, it is imperative to know what training requirements are necessary to ensure that training is targeted and useful. The empirical research described in the next sections set out to understand these training needs and the knowledge profile of ethics reviewers who are likely recipients of such training.

Methodology

This methodology section describes our empirical data collection which was undertaken using an online survey. It starts by providing an account of how the survey instrument was constructed and proceeds to the description of the selection of recipients and the structure of data collection.

Development of the survey instrument – options and questions

We decided to use an online survey to collect data on the training needs of ethics experts (i.e. REC members and ethics reviewers) because we wanted to have maximum coverage and be able to draw on a broad range of responses. While we realise that ethics-related questions are often finely nuanced and call for individual engagement and reflection, the purpose of our data collection was to get a broad overview that could be used to structure training programmes for ethics experts across different fields and jurisdictions. We therefore designed all questions as closed questions to allow for a quantitative analysis, but in most cases allowed for an 'other' option that provided space to provide qualitative information as well. This structure of the survey is reflected in our description of findings below.

The survey included a series of eight questions (see the full survey in Annex 1). The two first questions aimed at identifying the profile of the respondents, i.e. the stakeholder group respondents belonged to (Question 1) and respondents' area of expertise/discipline (Question 2). The data was collected anonymously, and we therefore did not collect detailed demographic data. However, we felt that it was important to have an indication of the experience of respondents. It was particular important to be certain that our sample included significant numbers of our target audience, i.e. ethics experts, which was therefore an option included in the options. We also needed to understand whether and to which degree our assumption that ethics experts mostly have research backgrounds from biomedical fields was true for our sample.

When designing training, it is important to understand the level of detail that is required by the trainee. It is clear that one cannot expect an ethics reviewer to be a subject specialist in all areas that may be subject to ethics review. Moreover, it is important to differentiate between procedural issues and substantive issues. On the one hand, procedural issues require less technology-specific knowledge, and they are often related to processes which are applicable in the context of different research projects and might, also, be more relevant to research integrity. For example, data management issues or issues related to informed consent processes. On the other hand, there are substantive issues particular to a specific technology that require more in-depth knowledge of the particularities of this technology, such as the feasibility of certain steps within a research project and the technical limits. At the same time, there are different levels of abstraction that can be used when designing training. Therefore, Question 3 asked about the level of granularity needed for the resources and training to be developed. Respondents were provided with the following potential responses:

- Broad technology family (e.g. artificial intelligence, synthetic biology);
- More specific member of a technology family (e.g. machine learning, CRISPR/Cas9);
- Application of a technology in a broad area (e.g. artificial intelligence in healthcare; nanotechnology in production);
- Specific application (e.g. machine learning for cancer diagnostic, facial recognition for law enforcement purposes).

In Question 4, respondents were asked the following question: 'how much need there is for research ethics resources and training for the following technologies?'. Respondents

were provided with a list of technologies that they had to rate from 1 to 5, where 1 means no need and 5 greatest need. The idea behind this question was to allow identify and rank technologies, in order to allow the development of a priority list of training needs.

Question 5 asked to indicate in a free text box if any technology in need for ethics resources or training were missing in the list provided as potential responses to the previous question. Questions 6 and 7 had a similar format to the two previous questions but with a focus on application areas, e.g. agriculture, health, etc. The list of technologies and application areas provided for Questions 4 and 6 were elaborated through an iterative process between this article's authors and research partners from current and past collaboration. The list aimed to be as comprehensive as possible and relied on past research activities related to the ethics of new and emerging technologies, including previous research projects such as SIENNA (https://www.sienna-project.eu/) and ETICA (https://www.etica-project.eu/). Question 8 gave the opportunity to respondents to provide free input to the project by asking whether there was anything else that respondents thought should be considered when developing case studies and training material.

This mixed approach in the survey helped to capture a diversity of insights into the subject of interest. The pre-populated answer choices allowed to make sure respondents clearly understood the type of responses that were expected and to be able to extract quantitative results from the survey. The open-ended questions enabled to capture anything that the researchers who drafted the survey might have missed when developing the questions and gave more flexibility and space to participants to share their view and perspective in a more nuanced manner. We acknowledge, however, that the survey was created by a group of researchers with particular knowledge needs and interests which, in conjunction with the selectin of researchers described below, may have inserted a bias in the findings.

Identification of respondents

The survey was sent to a diversity of stakeholders and stakeholder networks dealing with ethics challenges in research. These were chosen for their expertise on research ethics and the ethics of new technologies as we deemed these groups in the best position to identify gaps and needs on ethics resources and training. We aimed to cover a broad range of stakeholders in the field, including research ethics committee members, other ethics experts, researchers, research administrators and managers, as a well as diversity of domain applications, such as biomedical research or digital technologies to ensure a diversity of perspectives was reflected in the survey responses.

Emerging technologies are most likely to be developed in technical contexts and we therefore wanted to ensure that our respondents had significant strengths and experience in those. However, the distinction between emerging technologies and their application is not always obvious and some radical innovations may appear in non-technical disciplines, such as the biomedical sciences but also social science and humanities. We therefore aimed to have coverage across disciplines.

The survey was disseminated among the various networks of project partners. This included the members of the National Ethics Councils (NEC) Forum, the EUREC and EARMA networks, members of the ERCIM consortium (European Research Consortium for Informatics and Mathematics), members of the INRIA Digital Ethics Committee, EU



research ethics experts, the Ethics correspondent group, other funded projects linked to co-authors (including HYBRIDA, ROSiE, SOPs4RI, etc.), some of which shared in their social media account, etc. (the full list of stakeholders the survey was sent to is provided in Annex 2).

Data collection

The development of the survey was led by the lead author of the present article and reviewed and revised by project partners through a series of iterations in October 2022. The first version was shared with participants to the NEC Forum on 8-9 November 2022. Based on feedback received on this first version, the survey was updated for clarification and completeness. Ethics approval for the administration of the survey was provided by the Faculty of Computing, Engineering and Media of De Montfort University.

The survey was implemented and delivered using the Online surveys platform (https://www.onlinesurveys.ac.uk/). This platform was chosen because it offers a GDPR compliant survey tool that is open to UK-based academic users. It is owned by JISC, the joint information systems service provider for UK universities.

The survey was opened on 14 November 2022 and remained open until 31 December 2022. During this time, 261 usable responses were received. As it was distributed via various lists as well as social media, it is not known how many individuals it reached. We therefore cannot provide an exact response rate.

Findings

This section provides and overview of the findings, starting with a quantitative analysis based on descriptive statistics before exploring the qualitative insights in more detail.

Analysis of quantitative data

261 responses were eligible for analysis. The respondents can be characterised as follows: more than half belong to the research ethics committee member stakeholder group (n =147), followed by senior researcher group (n = 111). Policy makers (n = 6) and Industry (n = 8) are the less represented stakeholders groups. Since this was a multi option question, results reflect the percentage of respondents who selected each answer option. Thus 100% means that all respondents selected that option. The distribution of responses per stakeholder group is depicted in Figure 1.

Concerning the area of expertise³ (field of research and development), most respondents are from the Social Sciences and Humanities and Arts (n = 130) followed by Medical and Health Sciences (n = 122) fields, as Figure 2 shows. Also, this was a multioption question (ECD 2015). Thus, the results reflect the percentage of respondents who selected each answer option. 100% means that all respondents selected that option.

A closer look, focusing only on the three most identified answers by the respondents (Figure 3), shows that, for instance, 25 respondents have mentioned having expertise in Natural Science and Social Science and Humanities and the Arts. 19 have expertise in Social Science and Humanities and the Arts and in Medicine and Health Sciences.

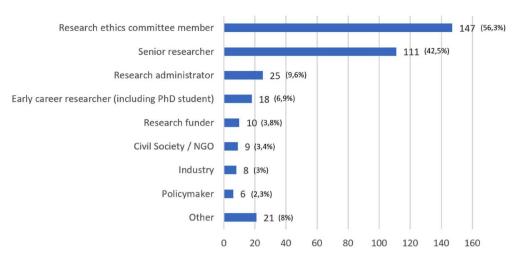


Figure 1. Characterisation of respondents by stakeholders' group.

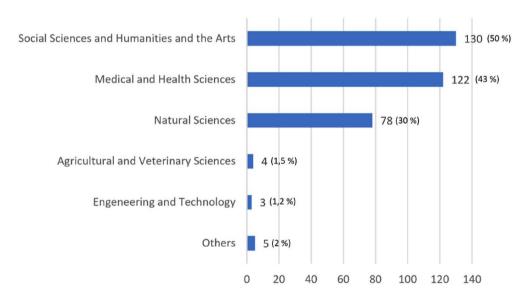


Figure 2. Characterisation of respondents by field of R&D.

One purpose of the study was to come to a view of which training material would be useful to provide to REC members. Respondents were therefore asked about the level of granularity that would be most interesting for them, when it comes to the evaluation of ethical issues in research projects in the selected technology fields. Results show that the majorly of respondents (n = 111) are interested in the application of a technology in a broad area (e.g. artificial intelligence in healthcare; nanotechnology in production), as an opposite of a more specific member of a technology family (n = 23) (such as for example machine learning, CRISPR/Cas9), as can be seen from Figure 4.

Considering the level of granularity stated by the responses regarding the technology focus, participants were asked to indicate how much need there is for research ethics

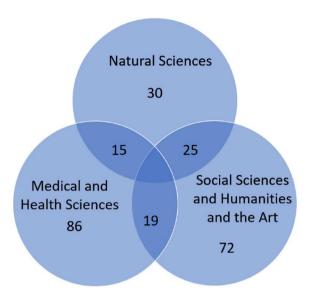


Figure 3. Expertise overlapping of respondents.

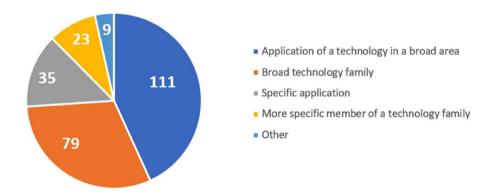


Figure 4. Respondents' preferred level of granularity of trainings for ethics experts.

resources and training according to the different technologies, using a Likert scale (5 =great need, 1 =no need).

Figure 5 represents the level of interest that respondents assigned to the different technologies that were listed on the survey. This radar diagram shows that there are relevant differences between these technologies. To assess and rank those, Figure 6 contains the same information but lists the technologies in rank order.

Respondents were also asked about the need for specific ethics resources and training for specific application areas, using a Likert scale (5 = great need, 1 = no need). Figures 7 and 8 depict the level of need according to the respondents.

Health and Health care and Research are the two areas where ethics resources are needed.

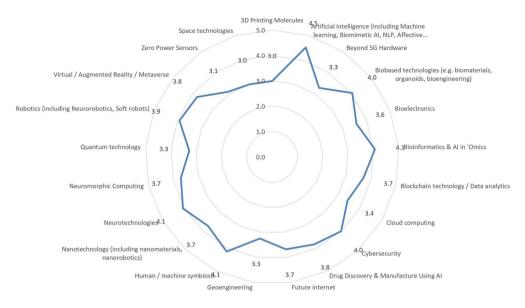


Figure 5. Radar diagram of perceived relevance of different technologies.

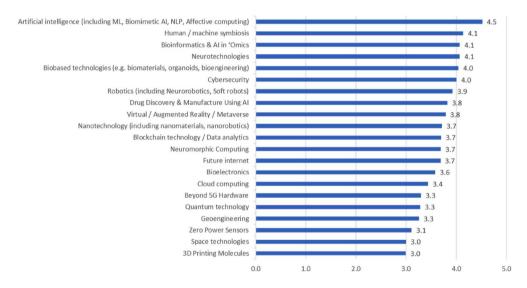


Figure 6. Need for research ethics resources and training.

Much of the data collected by the survey is of quantitative nature from closed questions as presented above. Before we discuss and interpret these data, however, it is important to also describe the findings from the qualitative data collected in the survey.

Analysis of qualitative data

To gain a comprehensive understanding of the knowledge requirements of RECs, our survey incorporated open-ended questions. These questions were strategically worded

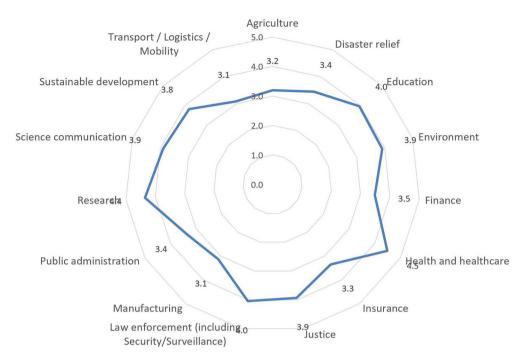


Figure 7. Radar diagram of needs for specific ethics resources and training.

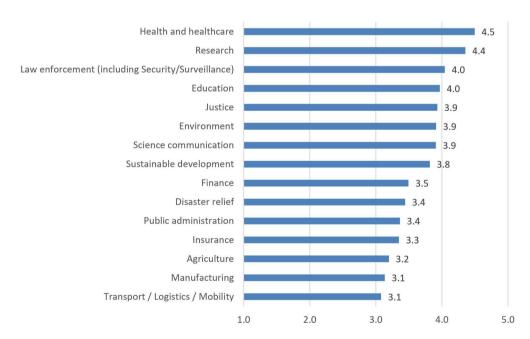


Figure 8. Need for specific ethics resources and training, for specific application areas.

to enable respondents to offer a diverse range of suggestions beyond those predefined in the survey, shedding light on the specific technologies and application areas deserving of focus in training initiatives. The flexibility of free-form text allowed participants to provide nuanced responses and offer richer insight into the rationale behind their suggestions. This section describes how we analysed these free-text answers.

The responses received covered a broad spectrum of suggestions related to both technologies and applications, necessitating a meticulous sorting process. Some ambiguity arose as respondents occasionally blurred the distinction between these terms or used them interchangeably. For example, when asked about other technologies (that have not been previously listed) for which ethics resources or training are needed, the responses received include 'social networks', 'human machine-interaction', 'biobank', 'internet of things' and several other technologies and application areas. As this was space for free-form text, we also received longer suggestions that highlighted several areas of interest. One respondent, for instance, wrote '... ensure you cover cognitive techs, all related to the interaction with the virtual world, nudging, dark patterns, online profiling etc...' As the responses mixed both technologies with application areas, there was a need for clearer distinctions to ensure appropriate categorisation. To address this issue, we adopted an instrumental definition of technology as the basis for categorising the items into distinct groups.

In essence, we used a simple definition of 'technology' as a complex system of artefacts designed to achieve practical goals (Huyke 2001). This definition underscores the idea that while there is an intrinsic relationship between the artefact and its application to achieve tangible outcomes, the use of an artefact by itself does not constitute technology but rather an application. The term 'application' was consequently framed in terms of the utility or the use of technology to address real-world problems across fields or industries (see examples of applications in Table 1 below).

On the basis of these definitions, we organised the survey outcomes into separate groups. By consulting the definitions of the items, those identified as artefacts were grouped into the 'technology' category, while those defined by their use or field of application were placed in the 'application' category. Figure 9 illustrates two primary categories within the technology group: 'health/biomedical technologies' and 'ICT/ computing technologies'. Similarly, the application areas neatly align with these two

Table 1. Examples of technology applications.

Metabolomics	This has been defined in Britannica as the study of metabolites – chemical substances produced as a result of metabolism encompassing all chemical reactions taking place within cells to provide energy for vital processes. Patti, Yanes, and Siuzdak (2012) and Danzi et al. (2023) who agree with this description have suggested that metabolomics is a field that relies on analytic tools such as mass spectrometry, nuclear magnetic resonance (NMR), ultra-visible spectroscopy and flame ionisation.
Mobile Health	This is also referred to as mHealth and generally describes the use of mobile wireless technologies for public health (Director General WHO 2018). This term is sometimes used interchangeably with eHealth defined by the European Health Parliament (Otto et al. 2018) as the use of 'digital tools and services for health'. This indicates that mHealth is better suited to the category of applications as it is not a technology in its own right.
Biometry	This typically refers to the use of statistical analysis techniques for the measurement and analysis of biological data (Wilson 2002). By itself, Biometry is not a technology, but a scientific field and methodology used in various research such as biology, ecology, genetics and epidemiology.
Biobank	The OECD defines biobanks as structured resources that can be used for the purpose of genetic research, and which include (a) human biological materials and/or information generated from the analysis of the same and (b) extensive associated information (OECD 2009).
Genome Editing	This refers to a suite of methods for creating changes in DNA more accurately and flexibly and is hailed as a powerful tool for making precise additions, deletions and substitutions in the genome (Human Genome Editing: Science, Ethics, and Governance 2017; Directorate-General for Parliamentary Research Services (European Parliament), Nordberg, and Antunes 2022)

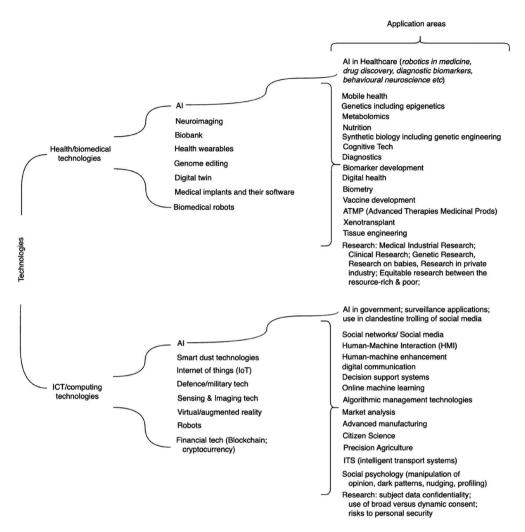


Figure 9. Primary technologies and applications.

technology categories, resulting in 'health/biomedical applications' and 'ICT/computing applications'.

Interestingly, not all items suggested by the respondents fit neatly into the broad categories of 'technology' and 'application' areas. To accommodate such outliers, we introduced an additional category termed 'technology impact areas'. This category primarily encompasses items describing the effect or impact of the application of technology. It includes three identified subcategories namely, sustainability, animal welfare, and social welfare. Relevant items within these categories were subsequently aggregated to provide a clear understanding of the diverse suggestions provided by the respondents (see Figure 10).

The qualitative analysis thus shows that the assumptions about the categorisation of technologies and applications that underly the structure of our online survey may not fully reflect the REC members' perceptions. This is one of the themes worth unpacking in the following discussion.

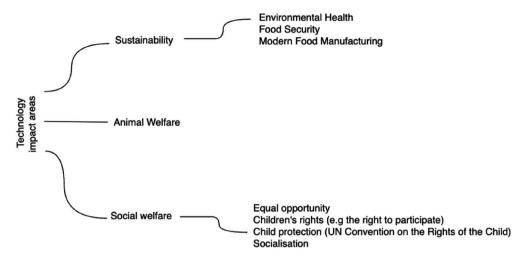


Figure 10. Technology impact areas.

Discussion

In this discussion section, we first show which topic areas are of most interest to our respondents. We then look at the background of our respondents and, by implications, of RECs as well as their level of interests.

Topics of interest

Some of the findings outlined in the preceding section were to be expected. In light of the current public debate of the ethics of AI, it is unsurprising that AI would figure highly on the list of technologies that respondents felt there was a training need. Another finding that was to be expected, given the historical roots of ethics review in the biomedical sciences, was that many of the highly ranking topics had a biomedical angle. And in particular the combination of information technologies (including AI) and biomedical topics seemed to rank consistently high. This can probably be explained by the difficulty of predicting consequences of use of an ICT which is typically built as a muti-purpose technology that has been described as being 'logically malleable' (Moor 2008). When such often unpredictable technologies are applied to biomedical work, it is easy to see immediate concern about health, wellbeing and life that raise the need for detailed ethical scrutiny. This same type of reasoning may explain why ICT technologies that are already established and familiar to people are ranked less highly, such as cloud computing or internet technologies. At the same time, the combination of information technology with technologies affecting the human body form a core aspect of so-called converging technologies, which have long been flagged as being of particular ethical relevance (Roco and Bainbridge 2007) and are increasingly understood as calling for appropriate governance structures (Helbing and Ienca 2024).

Composition of RECs and knowledge interests

While some of the findings thus have a high level of predictability to them, there are nevertheless numerous novel insights one can derive from the survey. This starts with

the composition of RECs and ethics experts. We cannot prove that our respondents are a representative sample of the population of ethics experts. This is caused by difficulties of defining such a population in the first instance and our method of contacting them does not allow us to statistically confirm their representativeness. However, we are confident that the size of the sample as well as the breadth of organisations involved in approaching respondents has allowed us to target a significant percentage of ethics experts on the European level. One surprising insight from the survey with regards to the profile of the respondents is the dominance of individuals who consider themselves to have roots in the social sciences and humanities (SSH). It could reasonably be expected that social science and humanities would be reflected in the sample, but it was a surprise that this was one of the largest groups of respondents. This may be because some SSH disciplines have a natural affinity to research ethics, notably philosophy that counts ethics as one of its components. In addition, there are other SSH disciplines such as science and technology studies or the sociology of science that have an interest in research and innovation and may therefore be drafted onto RECs. The overall percentage of individuals with an SSH background nevertheless remains surprising.

The responses we received to the question relating to the level of granularity that would be of interest is important because it can inform potential training providers. The answers show clearly that the perceived knowledge gaps and training needs are focused on broad technology areas, if possible, in a recognisable application field. This reflects the nature of RECs as having to deal with applications from across their area of remit. It is nevertheless surprising that only a small minority of respondents (23/ 220) were interested in a specific technology. In light of the current debate of the ethics of specific topics, one could have expected a stronger interest in specific technologies such as machine learning. However, this interest remained marginal. Even more marginal (not present at all) were specific applications, such as the examples we provided in the question of machine learning for cancer diagnostic, or facial recognition for law enforcement purposes. Both of these are controversially discussed but our respondents did not prefer this level of granularity.

The discussion so far refers predominantly to the quantitative data. We provided the opportunity to give qualitative responses as well, in order to ensure that we were open to positions that diverged from our assumptions about possible knowledge gaps when we designed the survey. While this section allowed for free-form text, most respondents simply identified a single technology or application area for consideration. Only a few provided longer, detailed responses that helped to clarify their reasoning or identified several other areas for consideration. Such input was valuable as it offered context and nuance that quantitative data alone could not capture. However, the brevity of most of the responses received in this section did not allow for a deeper interpretive analysis. This limitation means that while the qualitative data added some richness to our understanding, it fell short of providing the depth of insight needed for a more thorough interpretive analysis.

To some degree, the analysis of the qualitative data confirms the insight gained from the quantitative data. Where respondents provided free text descriptions of technologies or applications, we could cluster those responses in ways that correspond to our earlier clusters, focusing on ICT and computing technologies on the one hand and health related and biomedical technologies on the other hand (see Figure 5). In many cases, these two

clusters overlap and merge into one another. Maybe the most interesting aspect of this analysis was that it did not contain anything fundamentally novel or unexpected. Many of the additional technologies or applications were very specific such as digital twins or blockchain technology or extended to applications we had not included, such as precision agriculture or tissue engineering. This highlights the challenge of delineating the area of responsibility of RECs. But at the same time, it suggests that staying on the relatively abstract level of focusing on application areas for broad technology families should be able to capture most topics of interest. It is worth underlining that we administered the survey prior to the launch of ChatGPT and including this specific technology or its underlying technology of large language models or foundation models might lead to different results, if the survey were administered today.

Novelty of concerns

This observation leads us back to the underlying motivation of undertaking the research in the first instance, namely the assumption that emerging and disruptive technologies raise novel ethical concerns that RECs need to be able to identify. To some extent, this assumption is doubtlessly true and confirmed by our survey, as many of the ethical concerns we encounter in our daily lives are based on or facilitated by technical developments. Early attention to such issues in the form of appropriate ethics review may have the potential to proactively address or maybe even avoid them. However, it is less obvious that the ethical concerns change fundamentally when new technologies are introduced. A recent discussion of the ethical issues of ChatGPT (Stahl and Eke 2024), for example, uses established methods of ethical impact assessment to assess possible ethical issues arising from this prominent example of generative AI. The analysis of that piece of research suggests that despite the novelty of this particular technology and the huge expected impact it has, the ethical issues that have been discussed so far were all predictable looking at past experience of ethics of ICT. This raises the question whether novel technologies do indeed call for more training of REC members and ethics experts and the degree to which this needs to be geared towards specific technologies. One can interpret the focus on broad technology areas and applications as an acknowledgement of the somewhat generic nature of ethical issues, which do not require detailed expertise in all emerging technologies to be held within RECs.

This exploration of the novelty of issues leads to a further aspect that arose from our analysis of the qualitative data which we discussed under the concept of impact areas (see Figure 10). The three areas we derived from this were social welfare, animal welfare and sustainability. These are not technologies, nor are they applications but fall under different categories which might be called ethical issues, values, or principles. In the survey we did not explicitly ask about these, working on the assumption that emerging technologies when applied in various application areas would raise such issues or require recourse to such values. The analysis of our responses suggests, however, that there may be training interests regarding such topics. This insight corresponds to the one developed in the preceding paragraph. The knowledge gaps and training needs may cover specific issues, topics, or values in the context of novel technologies or application areas.

This line of thinking corresponds with findings from other research. In a systematic review of the ethics of ICT, for example, Stahl, Timmermans, and Mittelstadt (2016) demonstrated that the ethical issues that arise from information technologies had remained fairly constant for a decade. While we have no recent evidence to determine whether this has changed since 2016, one can certainly observe that many of the top issues of that paper remain relevant. Issues such as privacy, professionalism, autonomy, agency or trust still dominate the headlines. It is also fairly easy to explain this continuity at least to some degree. The nature of ICTs as collecting, processing and distributing information means that privacy becomes an issue where personal data are involved. The steadily growing ability of ICTs to take decisions and act without immediate user involvement explains the interest in autonomy and agency, a topic that would likely be rated even higher, if a similar review were undertaken now, in the age of generative AI. The conclusion to be drawn from this is that meeting the training needs of REC members and ethics experts is likely to require attention to prevalent issues, the reason why they are considered to be issues and the normative underpinnings on which such judgments rest. These questions are often not explicitly considered in REC training, given its relatively stable normative foundation on mid-level ethical principles such as beneficence, non-maleficence, autonomy and justice (Beauchamp and Childress 2009). There are, however, questions whether these principles are sufficient when looking at emerging technologies (Floridi and Cowls 2019).

Limitations of RECs

Notwithstanding the key role RECs can play in promoting and safeguarding ethical research, it is worth noting that even if their members are trained adequately and once they possess expertise in technology research, with guidelines adapted to address all relevant ethical issues, it is important to recognise that RECs cannot comprehensively address every aspect related to responsible research. Ferretti et al. (2021) suggest that RECs are unable to fully ensure/control/oversee how research will be handled in subsequent stages without becoming overburdened, as they are just one actor within a larger system. While we argue that RECs should play a role in shaping the research ethics governance system, it is crucial to avoid portraying them as a panacea (Spicker 2022). The key lies in clearly delineating responsibilities, acknowledging potential design and expertise flaws, and avoid thinking that RECs can single-handedly solve all ethical and social issues.

Conclusion

This paper describes the first large-scale survey of REC members and related ethics experts to understand the knowledge gaps and potential training needs that these experts perceive. It thus makes an important contribution to the research on research ethics and the various processes employed for purposes of research ethics assessment. As RECs are internationally well-established and institutionalised, they have a very prominent role in integrating ethical considerations into scientific research and technology development. Anybody interested in questions of integrating ethics will thus need to understand how RECs work, what their current roles are and, by implications which limitations the REC process as a whole has which includes matters of expertise and ability to adequately judge ethics approval processes.

Our survey managed to mobilise 261 responses and can thus be seen as providing a reasonably reliable insight into the perception of ethics experts and REC members. It demonstrates that there are perceived gaps in knowledge and training needs that would help inform the work of RECs. In addition, it provides pointers to what these gaps are and which knowledge needs are present. This is of practical interest for RECs and for individuals, groups and institutions who work on supporting and developing research ethics structures. It is core knowledge for the development of actual training, one of the intentions that the authors of this article pursue.

The findings furthermore are of theoretical interest to various audiences. This starts with ethics experts who can use this article to reflect on the underlying knowledge requirements and training structure of REC processes in general. As indicated earlier, REC structures differ in different areas and jurisdiction, but they all rely on the ability of ethics experts to understand research that is proposed and make appropriate judgments on ethical questions and proposed mitigation measures. Our findings call for a reflection on the relationship between emerging technology, application, issues these may raise, and the values that underpin the ethics review.

Our findings should moreover be of interest to the community of scholars and practitioners interested in RI. The institutional embedding of research ethics predates RI and the relationship between them is not always clear. Research ethics forms a core aspect of ethics in the traditional approach of ELSA (ethical, legal, social aspects) and related work (Rip 2009). The link between RI, ELSA and research ethics has long been discussed and remains contested (Ryan and Blok 2023). However one interprets this relationship, it is important to appreciate the social fact of the existence of REC structures that play a fundamental role in the integration of ethical questions concerning research and development of novel technologies. Understanding the current state including knowledge gaps in REC processes can thus inform RI practices.

While we believe that our study has made relevant contributions to knowledge, it displays limitations that point to further research. One of these is our strong focus on digital technologies. We believe that these are currently set to significantly affect research across most disciplines, but we concede that there are other types of technologies that may warrant closer attention. In addition, we chose an online survey to be able to reach out to a large number of individuals and get an encompassing understanding of the current perception of knowledge gaps and training needs. The downside is that our insights remain somewhat superficial. We furthermore pre-structured the questions thus limiting possible answers. This is normal research practice and we tried to mitigate this limitation by offering the opportunity to add open-ended responses. However, we concede that more detailed qualitative and observational research on the social practices within RECs would provide more detailed insights into the exact nature of knowledge gaps and how they influence ethics reviews.

Our research, despite its limitations, nevertheless provides relevant insights that can help structure training for RECs and thereby hopefully ensure that RECs can operate to the best of their abilities. In addition, we believe that the article can contribute to the discussion of RECs in the broader field of ethical reflection and RI and thereby ensure that ethical question are duly considered in the process of technology research and development.



Note

- 1. This paper and the survey upon which it is based were conducted as part of the irecs project, a Horizon Europe project dedicated to training on research ethics for new technologies. It focuses on the ethics of four technologies: genome editing, biobanking, extended reality, and artificial intelligence. It is funded by the European Union. UK participants in Horizon Europe Project irecs are supported by UK Research and Innovation grant numbers 10055935 (University of Central Lancashire) and 10129349 (University of Nottingham).
- 2. Also known, more widely in the US, as Institutional Review Boards (IRBs).
- 3. Areas of expertise included in the questionnaire were re-classified according to the Frascati fields of R&D classification.

Disclosure statement

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Appendix

Appendix 1: Survey questions

1. Please let us know which stakeholder group(s) you belong to. This will help us tailor our training to relevant groups.

- · Research ethics committee member
- · Senior researcher
- Early career researcher (including PhD student)
- · Research administrator
- Research funder
- Policymaker
- Industry
- · Civil Society / NGO
- Other

1.a. If you selected Other, please specify:

2. What is your area of expertise / discipline?

- Biomedical
- Information technology
- Climate and environmental sciences
- · Social Sciences and Humanities
- Other

2.a. If you selected Other, please specify:

3. [...] Can you please tell us which level of granularity would be most interesting to you?

- Broad technology family (e.g. artificial intelligence, synthetic biology)
- More specific member of a technology family (e.g. machine learning, CRISPR/Cas9)
- Application of a technology in a broad area (e.g. artificial intelligence in healthcare; nanotechnology in production)
- Specific application (e.g. machine learning for cancer diagnostic, facial recognition for law enforcement purposes)
- Other
- 3.a. If you selected Other, please specify:
- 4. Keeping in mind the level of granularity you stated a preference for in the previous question, can you indicate how much need there is for research ethics resources and training for the following technologies? (5 = great need, 1 = no need) 4.1. 3D Printing Molecules 4.2. Artificial intelligence (including Machine learning, Biomimetic AI, NLP, Affective computing) 4.3. Beyond 5G Hardware 4.4. Biobased technologies (e.g. biomaterials, organoids, bioengineering) 4.5.



Bioelectronics 4.6. Bioinformatics & AI in 'Omics 4.7. Blockchain technology / Data analytics 4.8. Cloud computing 4.9. Cybersecurity 4.10. Drug Discovery & Manufacture Using AI 4.11. Future internet 4.12. Geoengineering 4.13. Human / machine symbiosis 4.14. Nanotechnology (including nanomaterials, nanorobotics) 4.15. Neurotechnologies 4.16. Neuromorphic Computing 4.17. Quantum technology 4.18. Robotics (including Neurorobotics, Soft robots) 4.19. Virtual / Augmented Reality / Metaverse 4.20. Zero Power Sensors 4.21. Space technologies

- 5. Are there other technologies for which ethics resources or training are needed that we have not listed in the previous question? Please name them here.
- 6. How much need is there for specific ethics resources and training for the following application areas? (5 = great need, 1 = no need) 6.1. Agriculture 6.2. Disaster relief 6.3. Education 6.4. Environment 6.5. Finance 6.6. Health and healthcare 6.7. Insurance 6.8. Justice 6.9. Law enforcement (including Security/Surveillance) 6.10. Manufacturing 6.11. Public administration 6.12. Research 6.13. Science communication 6.14. Sustainable development 6.15. Transport / Logistics / Mobility
- 7. Are there other application areas for which ethics resources or training are needed that we have not listed in the previous question? Please name them here.
- 8. Is there anything else you think the iRECS consortium should consider when developing its case studies and training material?

Appendix 2: stakeholders the survey was shared with

Note: the number of recipients in each group is provided when we have this data.

- National Ethics Councils (NEC) Forum
- EUREC members
- EARMA network
- ERCIM consortium (European Research Consortium for Informatics and Mathematics)
- INRIA Digital Ethics Committee
- EU research ethics experts (473 individuals reached through SYNAPSE plus 200 per email)
- Ethics correspondent group
- Cluster projects: HYBRIDA, ROSiE, HBP, STARLIGHT, TechEthos, SOPs4RI, including the social media accounts of these projects
- Cross SwafS Stakeholders Forum for responsible OS
- French national ethics committee and French network of research ethics committee (about 300 individuals)
- ALLEA Science and Ethics Group (14 individuals)
- Responsible Innovation IISCmail list (130 individuals)
- European University Association network
- Trilateral Research employees (120 individuals)
- ENERI e-community (179 individuals)
- Steering Committee on Bioethics (47 individuals)
- PRIDE network: Association for Professionals in Doctoral Education (363 individuals)
- Social medial account of irecs: Twitter and LinkedIn
- Irecs' Stakeholder Advisory Board members (and their own networks)