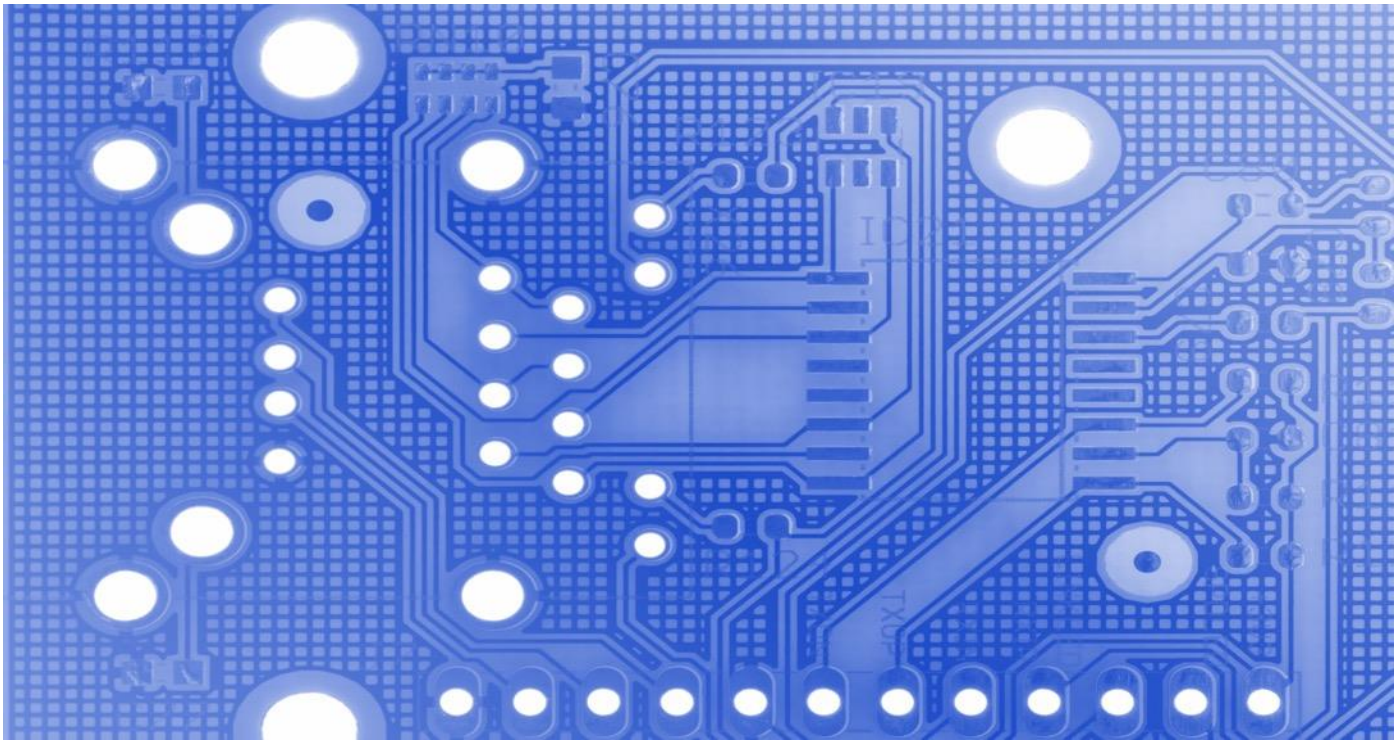
TECHETHOS

FUTURE ○ TECHNOLOGY ○ ETHICS

Criteria for ethical review by RECs in emerging technology research

D5.4



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D5.4 Criteria for ethical review by RECs in emerging technology research			
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The TechEthos Project

Short project summary

TechEthos is an EU-funded project that deals with the ethics of the new and emerging technologies anticipated to have a high socio-economic impact. The project involves ten scientific partners and six science engagement organisations and runs from January 2021 to the end of 2023.

TechEthos aims to facilitate “ethics by design,” namely, to bring ethical and societal values into the design and development of new and emerging technologies from the very beginning of the process. The project will produce operational ethics guidelines for three to four technologies for users such as researchers, research ethics committees, and policymakers. To reconcile the needs of research and innovation and the concerns of society, the project will explore the awareness, acceptance, and aspirations of academia, industry, and the public alike and reflect them in the guidelines.

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Abbreviations

Term	Explanation
ADIM	Advisory and Impact Board
AI	Artificial intelligence
CDR	Carbon dioxide removal
CE	Climate engineering
CIOMS	Council for International Organizations of Medical Sciences
DoA	Description of Action
DXR	Digital extended reality
EEA	European Economic Area
EARMA	European Association of Research Managers and Administrators
EC	European Commission
ENERI	European Network for Research Ethics and Integrity
ERC	Ethics review committee
ERCIM	European Research Consortium for Informatics and Mathematics
ESF	European Science Foundation
EU	European Union
EUREC	European Network of Research Ethics Committees
FERCAP	Forum for Ethical Review Committees in the Asian and Western Pacific Region
GCP	Good clinical practice
GDPR	General Data Protection Regulation
H2020	Horizon 2020
ICH	International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use
ICT	Information and communications technology
IEEE	Institute of Electrical and Electronics Engineers
IRB	Institutional review board
LMICs	Low- and middle-income countries
NLP	Natural language processing

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NT	Neurotechnology
OECD	Organisation for Economic Co-operation and Development
RE	Research ethics
REC	Research ethics committee
RI	Research integrity
RRI	Responsible Research and Innovation
SRM	Solar radiation management
UK	United Kingdom
UNESCO	United Nations Educational, Scientific and Cultural Organization
US	United States
WP	Work Package

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Executive Summary

New and emerging technologies, including neurotechnology (NT), digital extended reality (DXR), and climate engineering (CE), have the potential to profoundly impact society. However, research on these technologies raises a broad set of ethical concerns – ranging from questions on autonomy, misuse, and mental and physical health to privacy, equity, and ecosystems. These ethical concerns are often associated with the long-term societal and environmental impacts of these technologies, thus necessitating a reshaping of the research governance system supporting ethical research practices.

Ethics review bodies – referred to herein as research ethics committees (RECs) – play a vital role in furthering ethical research. However, the scope, structure, expertise, and principles of RECs, designed with a primary focus on reviewing biomedical research, are often ill-suited to conduct comprehensive ethics assessments of research related to NT, DXR, and CE as well as other new and emerging technologies.

To aid RECs in supporting ethical research related to NT, DXR, and CE, this deliverable addresses the following research questions:

- What challenges do RECs face when reviewing research involving new and emerging technologies, especially NT, DXR, and CE?[1]
- Do the scope and structure of RECs allow for adequate support for ethical research in new and emerging technologies?

A desktop review of relevant literature and guidelines, a survey of REC members, and an expert workshop yielded several key structural and topical challenges faced by RECs when reviewing research related to NT, DXR, and CE. Structural challenges were related to the processes and operations of RECs, whereas topical challenges encompassed thematic aspects of reviews of research in the NT, DXR, and CE technology families. Structural challenges included limitations to the scope of REC reviews, expertise within RECs, the resources available to RECs, and the applicability of REC guidelines and principles. Topical challenges included the assessment of data processing; the assessment of fairness, equity, autonomy, and social divisions; and the involvement of the private sector in NT, DXR, and CE research.

This report outlines recommendations to help RECs review research related to new and emerging technologies. In addition, it provides suggestions for other actors in the research governance system (policymakers, funders, research institutions, conference organisers, publishers, ethics organisations, and learned societies). These recommendations can be summarised as follows:

1) Encourage researchers to reflect on the potential societal and environmental implications of their research.
2) Determine which projects are high risk and conduct reviews proportionate to risk levels.
3) In high-risk projects, complement ex-ante review with further ethical reflection mechanisms.
4) Develop REC-specific guidance documents for ethics review in NT, DXR, and CE based on pertinent principles.
5) Assess ethics-by-design roadmaps, if applicable.
6) Ensure REC composition and the expertise of members are aligned with their purview.
7) Promote exchange amongst RECs and between RECs and researchers.
8) Require ethical reflection for researchers in publications and conferences.
9) Improve transparency in decision-making processes.
10) Ensure REC access to adequate resources.
11) Incentivise private-sector actors to engage in ethics review processes.

[1] These three technologies have been selected by the TechEthos project as technologies with high socio-economic impact. Click here to learn more about the technologies covered.

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1. Introduction

1.1. Background

In an era characterised by rapid technological advancement, research ethics contributes to the alignment of research and innovation with shifting societal needs, expectations, and values. Ethics review bodies – referred to herein as research ethics committees (RECs; also known as institutional review boards – IRBs – and ethics review committees – ERCs) – function as central nodes of the existing research ethics system. RECs represent the institutional bodies tasked with the ethical evaluation of research proposals.

RECs emerged and evolved primarily in the realm of biomedical research. As detailed in Section 2, they have since expanded to cover other types of research involving human participants, such as research in the social sciences. However, RECs often prove inadequate to govern research outside of the biomedical and social sciences.

The primary role of traditional RECs is to ensure that research participants involved in trials are protected. There is a lot of guidance on obtaining informed consent, selecting participants fairly and in an unbiased manner, and managing data to protect the privacy of research participants. However, it is also important for ethical reviews to consider how a research project might help or harm society and the environment. Defining the social value of a research project, as well as balancing the risks and benefits of the research, can be difficult for RECs, especially when considering projects that involve new technologies.

As explained in Section 2.2, the challenges RECs face in reviewing new and emerging technology research may be attributed to four broad characteristics:

- the question of the social value of technology research,
- shifting dynamics between researchers and those affected by research,
- the ex-ante nature of the review system,
- and the scale of potential social and environmental impacts resulting from technology research.

With these characteristics in mind, this report identifies challenges to REC reviews of new and emerging technologies, with a focus on neurotechnology (NT), digital extended reality (DXR), and climate engineering (CE).

NT, DXR, and CE demonstrate both high socio-economic potential and ethical relevance. As such, they represent the primary foci of the TechEthos project. In the context of this report, we define the three technology families as follows:

- NT consists of the "devices and procedures used to access, monitor, investigate, assess, manipulate, and/or emulate the structure and function of the neural systems of natural persons" (OECD, 2019).
- DXR represents technologies "with a common functionality to emulate and imitate human traits and social circumstances" (European Commission, 2022). This includes both extended reality and natural language processing (NLP) technologies.
- CE, also referred to as geoengineering, represents "the deliberate large-scale intervention in the Earth's climate system, in order to moderate global warming" (Shepherd et al., 2009). This report refers to both solar radiation management (SRM) and carbon dioxide removal (CDR) technologies when discussing CE.

After exploring empirically identified challenges to REC reviews of NT, DXR, and CE research, this report presents practical recommendations for RECs and other pivotal actors in the research governance system. Overall, these position RECs as central – rather than sole – actors in a responsible research and innovation system, suggesting an expansion of the conventional REC–researcher–participant paradigm traditionally constituting research ethics governance. Furthermore, the

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recommendations presented herein encourage RECs to act as ethical advisors beyond the ex-ante phase, participate in dialogue with key research governance stakeholders, and implement transparent and comprehensive reviews sensitive to the needs of society.

Relevance to existing work

This report follows TechEthos D2.2, "Identification and specification of potential ethical issues and impacts and analysis of ethical issues" (Adomaitis et al., 2022). D2.2 presents a detailed analysis, based on a literature review, expert consultations, and digital ethnographies, of ethical issues raised by NT, DXR, and CE. In addition, the report identifies cross-cutting issues in these three new and emerging technology families.

The empirical challenges cited in this report will build upon the ethical considerations outlined in D2.2 to explore the *challenges RECs experience in ethics review*. While many of the ethical considerations in D2.2 overlap with the topical challenges identified by ethics reviewers during the review process, the structure, institutional embedment, and scope of REC activities give rise to a distinct set of challenges specific to the REC assessment of NT, DXR, and CE research. However, this report will not engage with the thematic ethical debates already presented in D2.2.

The recommendations herein elaborate on those developed for RECs in the ethics review of research related to AI and big data. Most notably, "Looking before we leap: Expanding ethical review processes for AI and data science research" (Ada Lovelace Institute, 2022) identified six core challenges faced by RECs in reviewing AI and data science research and suggested several mitigation measures for RECs as well as other actors in the research ecosystem.[2] Given the frequency of AI and big data applications in NT (e.g., machine learning, deep learning, and neural nets), DXR (e.g., virtual patient environments, robots, advanced visualisation, gaming, and armed forces training), and CE (e.g., collecting and processing satellite and sensor data), resulting in overlapping REC challenges, the recommendations in the Ada Lovelace Institute's report are of high relevance to our findings.

1.2. Methodology

This report is based on a comprehensive data collection approach consisting of three components: a review of relevant literature; a survey collecting both quantitative and qualitative data on ethics review challenges and best practices; and a discussion-based workshop to validate, contextualise, and deepen the findings from the literature review and survey.

The literature review explored scholarly discussions on the role of RECs in reviewing new and emerging technology research. It guided the survey development and suggested possible recommendations for the adaptation of RECs and research governance systems. Subsequently, the survey collected data on the breadth of attitudes and experiences of REC members in ethics reviews of research related to new and emerging technologies, especially NT, DXR, and CE. Finally, the workshop provided in-depth qualitative data to illuminate REC member perspectives. In addition, the workshop refined and validated initial findings from the literature review and survey and elaborated on best practices to generate a path forward for REC reviews of NT, DXR, and CE research.

[2] These challenges noted in the report were as follows: 1) RECs often lack the resources, expertise, and training to address challenges related to AI and data science research; 2) traditional principles relied upon by RECs are rooted in biomedical principles and human participant designs; 3) ethical principles are inconsistent across RECs; 4) multi-site and public–private partnerships complicate decision-making; 5) RECs are often unable to identify the potential risks of AI research; and 6) private-sector RECs are untransparent in their ethical decision-making. Relevant recommendations included 1) incorporating broader societal impact statements from researchers, 2) adopting multi-stage ethics review processes of some high-risk AI and data science research, 3) including interdisciplinary REC members, 4) developing standardised principles for AI and data science research, 5) cultivating a responsible research culture, and 6) increasing funding for ethical review of AI and data science research.

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Figure 1: Methodology

Literature review

The research team first carried out a review of published papers as well as grey literature. This included literature speaking to the traditional role and function of RECs, the position of RECs in reviewing research involving new and emerging technologies, and perspectives on REC reviews of non-biomedical research, including research in the social sciences and humanities.[3]

As part of the subsequently conducted survey, the research team asked respondents to list the guidelines they reference when reviewing research related to new and emerging technologies, including NT, DXR, and CE. The research team then carried out a second literature review on these guidelines. The referenced guidelines are listed in Annex 7.2.

Survey

The research team designed a survey to better understand how RECs and other ethics review bodies approach ethics reviews for new and emerging technology research with high socio-economic impact and ethical relevance.

The target sample of the survey consisted of ethics reviewers (i.e., REC members) with experience reviewing projects related to new and emerging technology. The research team especially sought respondents with experience in NT, DXR, and CE. Invitations to take part in the survey were distributed via email to members of the European Network of Research Ethics Committees (EUREC); the TechEthos cluster and Advisory and Impact (ADIM) Board; the European Network for Research Ethics and Integrity (ENERI) e-community; and the European Association of Managers and Administrators (EARMA), irecs project, European Research Consortium for Informatics and Mathematics (ERCIM), and European Science Foundation (ESF) networks. The research team also invited individual experts in the ethics review of NT, DXR, and CE research (e.g., those involved in relevant publications or projects) to participate.

The survey consisted of general questions, including background information on respondents as well as attitudes toward reviews of research related to new and emerging technology, and three optional sections seeking perspectives on the assessment of research in the fields of NT, DXR, and CE, respectively. The survey included open-ended short-answer questions, questions that asked respondents to rate their agreement or disagreement with statements using a Likert scale, and closed-ended tick-box questions. The survey questionnaire can be found in Annex 7.3.

Following the close of the survey, the research team used manual qualitative coding and descriptive statistics to analyse the survey results. Qualitative and quantitative data were extracted and placed into three general categories: REC operations, gaps and challenges, and recommendations. Due to the

[3] Animal research was not included in the scope of this deliverable.

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small sample (39 respondents) of the survey, the research team did not perform inferential statistical analysis.

Workshop

The workshop yielded in-depth qualitative data, building on the findings of the survey and literature review. Workshop participants were recruited through a registration link found within the survey as well as by personal invitation. As such, workshop participants consisted mostly of interested survey participants. To achieve balance amongst workshop participants with review experiences of the three technologies, additional invitations were sent to ethics review experts in DXR and CE.

The first part of the workshop consisted of a discussion on 1) the roles, scope, and function of RECs concerning reviews of new and emerging technology research and the extent to which RECs should consider the societal and environmental effects of research related to new and emerging technologies, 2) the extent to which traditional principles and norms for RECs are useful in reviewing new and emerging technology research, and 3) whether and how RECs should advise researchers beyond the design phase of research.

Following this general discussion, three breakout sessions for each technology family (NT, DXR, and CE) sought to 1) identify additional technology-specific challenges faced by RECs, 2) determine which recommendations from the Ada Lovelace Institute's report could be useful for reviews on research covering each technology, and 3) generate additional recommendations for ethics review.

Workshop notes were analysed to extract pertinent information regarding empirical challenges faced by RECs and corresponding solutions. An advanced draft of the report was sent to workshop participants for validation. Workshop participants' feedback was incorporated into the final version of the report.

1.3. Scope and limitations

Survey recruitment yielded only 39 survey respondents from RECs and other ethics review bodies.[4] As such, this sample may not be large enough to be representative of the target population. Inferential analysis is thus limited in this report. The research team supplemented descriptive statistics with qualitative survey findings elicited from the smaller, albeit non-representative, sample.

Though RECs are highly heterogeneous, operating within several institutional settings, survey respondents and workshop participants primarily represented academic RECs. While the recommendations produced from this research are relevant to corporate RECs (i.e., RECs located within companies or corporations), they are drafted with a view to academic RECs and RECs reviewing EU-funded projects and may not be operationalised in corporate contexts.

In addition, though the research team sought representation from experts in the three technology families, experts in CE were underrepresented in both the survey and the workshop. Only 9.7% of survey participants had experience reviewing projects in CE. Additionally, the breakout session of the workshop was attended by only two CE review experts. This may be ascribed to the comparably lower level of advancement in research on the main CE technologies considered, SRM and CDR, in contrast to the NT and DXR technology families.

[4] The survey invitation reached an estimated 500 contacts from the abovementioned networks. However, not all of these contacts fit the sample criteria.

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2. Evolution of ethics review

Scientific research is key to fostering innovation, explaining phenomena, and devising solutions to societal challenges. However, research does not exist in isolation from society and the environment. The possible detrimental effects of research on individuals, society, and, increasingly, the environment create a demand for robust research ethics governance systems.

Ethics review emerged from the field of biomedical research, and developments in this field have continuously shaped its evolution, with important conceptual and structural consequences for ethics review schemes in various areas of technology research. Even though several initiatives have proposed models of ethics review for other areas of research, and some institutions have created RECs for non-biomedical research or broadened the purview of existing RECs, efforts to adapt ethics review to new and emerging technology research remain fragmented. As the contours of the current ethics review system result from developments in biomedical ethics, the following section outlines the milestones with the greatest impact on the existing system.

2.1. A historical overview

The events of the 20th century laid the profound ethical implications of research on human participants bare, demonstrating the need for the systematic protection of those involved in the research process. As a result of heinous human experimentation on concentration camp prisoners undertaken during World War Two, the Nuremberg Code – a ten-point code outlining principles for human experimentation – functioned as one of the first ethical frameworks for research ethics.

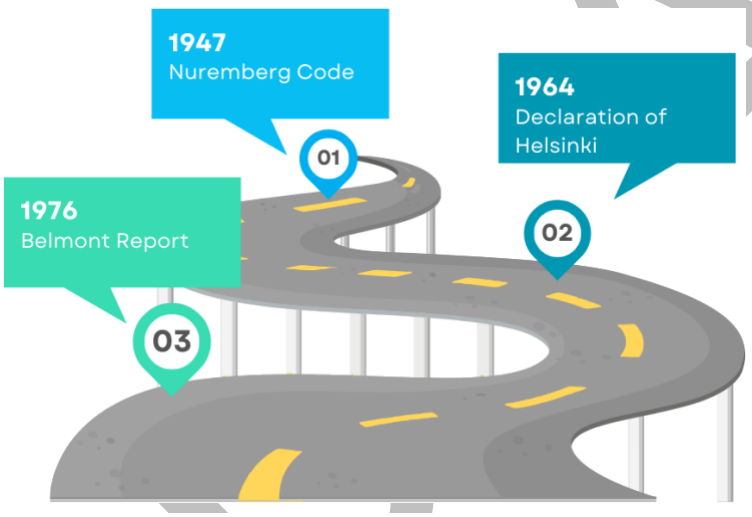

Figure 2: Road towards an ethics framework

The Nuremberg Code, decreed in 1947, sets standards on voluntary consent, the reduction of harm to research participants, and the allowance of research only with clear potential benefits to society (UNC Chapel Hill Office of Human Research Ethics, n.d.). The Nuremberg Code highlights the human rights of research participants, expanding Hippocratic ethics beyond the doctor–patient relationship to medical research between researchers and research participants (Shuster, 1997).

Subsequently, the Declaration of Helsinki, first adopted by the World Medical Association in 1964, emphasised the obligations of researchers to participants (Goodyear et al., 2007). In addition to its promotion of informed consent and the minimisation of risks to participants, the Declaration of Helsinki called for greater attention to the vulnerabilities evident in many subgroups of research participants, maintained that participants' well-being should take precedence over the needs of society, and demanded the need for ethical reflection in addition to regulations. Crucially, its operational principles – expanded upon during its second iteration adopted in Tokyo in 1975 – established the need for independent ethics review.

The Belmont Report, a US federal document that resulted from discussions at the Belmont Conference in 1976 surrounding the National Research Act, further expanded these frameworks. The report was published in the wake of the Tuskegee Syphilis Study in Alabama, a study that enticed black American men with syphilis to partake in research while denying them lifesaving medical care (Langford & Cummins, 2022). The Belmont Report set three core principles for researchers: respect for persons, beneficence, and justice. Even though its influence in Europe remained mostly indirect, it nonetheless shaped research ethics discourse and enriched its conceptual vocabulary (Holm, 2020).

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Closely following the Belmont Report were the principles proposed by Beauchamp and Childress (1979), i.e., autonomy, beneficence, nonmaleficence, and justice, which largely draw on those of the Belmont Report. These principles were intended to provide a comprehensive ethical decision-making framework for researchers. Autonomy recognises an individual's right to self-determination and informed decisions; beneficence highlights the importance of research with positive benefits on individuals and society, promoting the well-being of research participants; non-maleficence underscores the need to minimise harm to research participants; and justice calls for the fair distribution of the risks and benefits of research.

The formulation of these ethical principles coincided with the institutionalisation of research ethics review bodies. RECs largely resulted from the second iteration of the Declaration of Helsinki, adopted in Tokyo in 1975, which mandated that independent ethics review bodies be consulted for research with human participants (Krischel, 2021). The following decades saw the emergence of RECs in Europe, Asia, and the Americas. In the US, the rise of RECs followed the National Research Act of 1974 (Sabati, 2018), while in Europe, the varying legislative landscape of ethics approval of clinical research was harmonised by the European Clinical Trials Directive in 2004 (Druml et al., 2009). Subsequently, the Clinical Trials Regulation, introduced in 2014 and fully operational in 2022, as well as the Medical Device Regulation in 2017 strengthened this precedent.

Due to these legal and regulatory developments, RECs have a clearly defined mandate regarding biomedical research. Nonetheless, even in the biomedical field, RECs are heterogeneous in their scope and composition. However, this degree of variation is lower than in other areas of research. For example, though ethics review of social science research has expanded in recent years (e.g., Iphofen & Tolich, 2018), legal regulation does not define REC mandates in this field, and widely recognised good practice models have yet to emerge.

Recently, efforts to broaden the scope of RECs to other areas of research by expanding the mandate of existing RECs or creating new ones have accelerated. The impetus for these developments is based on at least three factors.

- First, research funders and publishers increasingly require researchers to obtain a favourable ethics review before granting funds or publishing results if the research involves human participants or animals.
- Second, researchers and research institutions recognised that non-biomedical research often also has significant ethical implications that RECs could help manage, especially if it involves human participants or personal data.
- Third, several projects (at the EU level, e.g., SATORI, SIENNA, SHERPA, PANELFIT, and PRO-RES) that bridge responsible research and innovation, technology assessment, research ethics, and research integrity have proposed normative principles as well as procedures to address REC reviews of non-biomedical research.

A recent survey distributed amongst EUREC members suggests that the tendency of RECs to expand, at least in Europe, is especially evident in social science and technology research.[5] However, so far, these efforts are highly fragmented across and often even within countries. Moreover, many have endorsed the application of research ethics governance models, such as the ethics-by-design and ethics-of-use approaches,[6] which take a broader perspective on the ethics of research and innovation that goes far beyond governance via ethics review. The role RECs could and should play in these arrangements, the principles they should follow, and how they should interact with other key actors in the research ethics ecosystem, however, remain a matter of debate.

Despite these push factors to expand ethics review, several countervailing pull factors have hindered the expansion of RECs and contributed to the fragmentation of efforts. The structures, principles, and

[5] EUREC conducted a survey in May–June 2023 to provide an overview of how REC systems in non-biomedical research operate in different European countries. The purpose of the survey was to guide the structuring of future work of EUREC's Working Group on non-biomedical research. Survey results are not publicly available.

[6] Both ethics by design and ethics of use are ethics governance approaches, with the former referring to the incorporation of ethical principles into the development of a technology and the latter to the features that enable the use of a technology (Dainow & Brey, 2021, p. 3).

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scope of RECs are traditionally associated with clinical human subjects research and have displayed high degrees of inertia. Many believe RECs are ill-fitted to review research outside of the biomedical context because many of the risks other types of research pose may not be governable within a review-based structure. Finally, many believe RECs could hinder research and innovation if they are tasked with reviewing other research, especially if they lack domain expertise. Our empirical findings highlight these considerations in greater detail and are summarised in Section 3.

2.2. Concepts, assumptions, and their consequences

Due to their historical evolution, RECs are, by and large, structured to address ethical challenges common in biomedical research, especially those frequently identified in drug trials and trials of medical devices. Before taking a closer look at the survey results and turning to our recommendations for adapting ethics review, it is important to outline the central conceptual underpinnings of biomedical research ethics, as their limited applicability to other areas of research may hinder the adaptation of RECs to new and emerging technology research.

A first important premise of biomedical research ethics is the assumption that research is generally socially desirable, i.e., that there is no fundamental tension between the ends of research and the common good (even though there are debates about whether research is a moral imperative or morally optional; see London, 2022, pp. 41–45, for a critical summary of the debate). This assumption may hold in the development of drugs and medical devices because both aim to reduce suffering, alleviate pain, and uphold quality of life (i.e., research results that restore human agency). However, this premise may not extend to other areas of research, especially those that may affect social and environmental systems more broadly (for example, for research results that could reshape human agency, society, or ecosystems). Unlike in most biomedical research, the social value of a research project cannot be assumed for all research projects involving new and emerging technologies.

Due to the assumption that research as such is beneficial, research ethics traditionally focuses on safeguarding individual research participants from harmful treatment and exploitation in the name of the greater societal good. In practice, research ethics thus often operates within a triangle composed of RECs, researchers, and research participants (London, 2022, p.7). Not least because this triangle eschews societal considerations from the purview of research ethics, RECs tend to face challenges when reviewing research that may create societal or environmental risks rather than risks for research participants. Research that poses few risks to individual participants may, for example, contribute to the introduction of technology with the potential to perpetuate biases, compromise anonymity, or exacerbate inequality, placing increasing demand on RECs to expand the focus of their reviews. The role of RECs in ethics-by-design and ethics-of-use approaches is hard to define, since doing so systematically may presuppose breaking up the established triangle and adopting an ecosystemic view (see Stahl, 2021), a task that would involve consistent engagement with policymakers and the public.

Figure 3: The research ethics review triangle

What is more, the biomedical view of research ethics conceptualises the role of researchers in a way that does not apply to other areas of research. The researcher–participant relationship in biomedical research is often (but not always) simultaneously a physician–patient relationship. This creates potentially conflicting duties and role expectations for the researcher–physician that lead to ethical

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tensions. A further, albeit less categorical, distinction is that biomedical research teams usually interact directly with research participants; in many other fields of research, especially technology research, research participants often represent data subjects, constituting an indirect relationship between the participant and researcher.

The traditional and still highly relevant purpose of REC review is to ensure the dignity, well-being, and fundamental rights of research participants. To meet this goal, RECs are primarily tasked with reviewing research protocols in the ex-ante or design phase, thereby flagging potential ethical issues and compelling researchers to design ethically sound projects before commencing their research. REC reviews, in other words, are usually anticipatory. They involve a holistic measurement of the potential social value of a research proposal as well as risks of harm – whether physical, social, psychological, or legal – to participants and research teams. Importantly, RECs typically assess risks that might materialise during the implementation of the research methodology yet largely overlook risks that might occur after the end of the research. Hence, REC reviews, despite their anticipatory and forward-looking nature, are focused on the impact of individual research projects rather than the resulting applications of that research.

Three factors may reduce the robustness of an ex-ante review approach in the context of research with new and emerging technologies.

- First, the pace of innovation of new and emerging technologies, the broad scope of their application, and their embeddedness in multiple ecosystems may lead to a ripple effect of research invisible to RECs at the time of review yet detrimental to individuals, society, or the environment.
- Second, the structural opacity and complexity of some technologies, e.g., those with complicated algorithms like AI and machine learning, may be unknown to even researchers themselves, leading to a lack of explainability at the REC review level.
- Third, new and emerging technology research is sometimes conducted inductively, i.e., with flexible research designs or without specific hypotheses. Some believe this may better allow for envisioning possible future scenarios.

The emergence and evolution of research ethics in the biomedical field have thus had structural and conceptual consequences on research governance systems. While many research governance actors agree that ethics review needs to be adapted for other areas of research, they continuously debate the adaptations necessary to support ethical research involving new and emerging technology. In what follows, we aim to provide suggestions for possible adaptations to the research governance system and steps toward their implementation.

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3. Challenges in ethics review of new and emerging technology research

Results from the literature review, survey, and workshop indicated that RECs are currently limited in their ability to address ethical issues in NT, DXR, and CE research. The following sections elaborate on four key structural as well as three topical challenges faced by RECs when reviewing NT, DXR, and CE research. Some challenges represent structural concerns, i.e., those pertaining to the processes and operations of RECs, that are exacerbated by the exigencies of new and emerging technology reviews.[7] Others are related to thematic aspects of reviews of research in the NT, DXR, and CE technology families.

On a structural level, the role of RECs in reviewing NT, DXR, and CE research is widely undefined. RECs lack both the expertise and resources to adequately review research in these areas. In addition, guidelines and principles referenced by RECs are ill-suited for reviews of NT, DXR, and CE research. Topical challenges commonly encountered by RECs in reviewing NT, DXR, and CE research are concerns with data processing; fairness, equity, social divisions, and autonomy; and the involvement of the private sector.

The topical challenges faced by RECs largely overlap with the general ethical considerations for each technology family identified in TechEthos deliverable D2.2. Thus, this section will not include an in-depth analysis of the ethical discussions presented in D2.2. It will, instead, expand on empirical observations by REC members of challenges encountered during the review process. The topical challenges presented below were selected by relevance, according to the perceptions of the survey respondents and workshop participants.

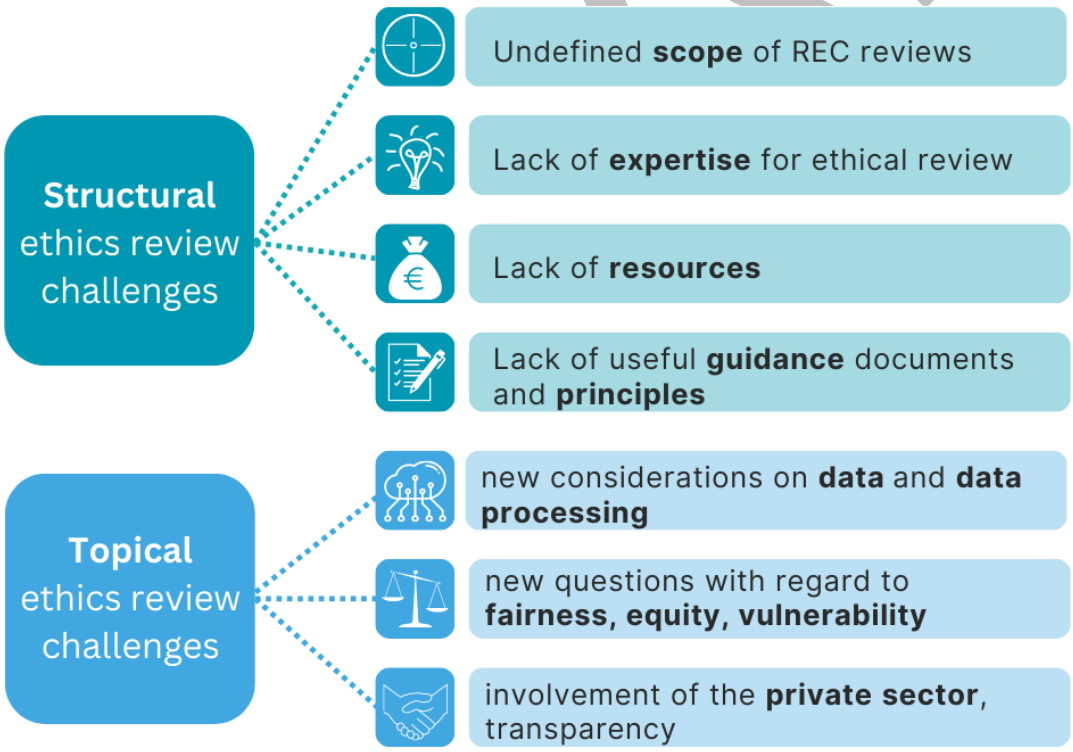

Figure 4: Ethics review challenges

[7] This is consistent with the definition of "purview weaknesses" provided by Ferretti et al., 2021.

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3.1. Structural challenges

Scope of REC reviews

NT, DXR, and CE research can entail wide-reaching societal and environmental impacts appearing at later stages of – or after – the research lifecycle. For this reason, REC members found ex-ante reviews to be insufficient in addressing the full spectrum of ethical concerns associated with research on and with new and emerging technologies. When asked about the timing and frequency of REC reviews of new and emerging technology research, 66.6% of survey respondents agreed with the statement that comprehensive REC reviews should take place beyond the ex-ante stage. Workshop discussions echoed this sentiment, noting that ethical issues surrounding NT, DXR, and CE research likely arise not because of a research project but as a result of the *applications* of the technologies developed within a research project.

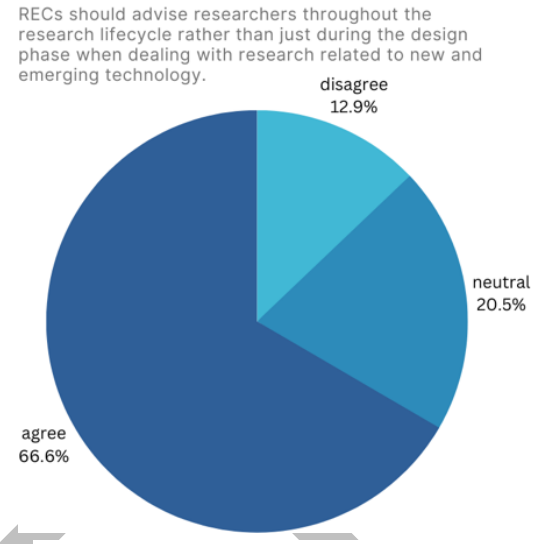

Figure 5: Survey results on ex-ante REC review

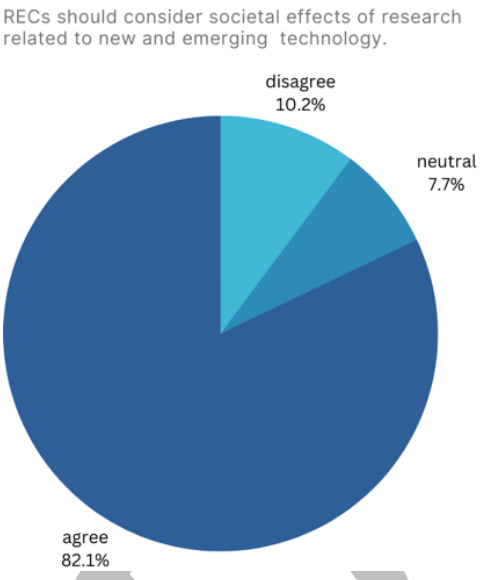

Figure 6: Survey results on societal effects of research

Most survey respondents found that RECs should consider the societal effects of new and emerging technologies (82.1% of survey respondents agreed with this statement). However, though they acknowledged the significance of societal impacts, REC members do not unanimously support the extension of REC activities beyond the ex-ante review phase, believing that other research governance actors are better suited to identify and respond to ethical concerns appearing after the research lifecycle.

Some workshop participants, for example, felt that the strength of RECs is especially evident in their demonstrated ability to raise awareness on ethical issues during the design phase of research and that policymakers and relevant international committees,[8] with a wider mandate extending beyond the research lifecycle, should bear responsibility for societal impacts resulting from the application of research findings. Survey respondents expressed similar views, with many noting that the involvement of specialised ethics committees and external expert panels may be necessary when the long-term effects of NT, DXR, and CE appear after the conclusion of research. Overall, participants agreed that RECs are limited in their ability to assess the social impacts and that a multiplicity of actors, including policymakers, funders, learned societies,[9] and ethics organisations, should share the task of conducting risk–benefit analyses and identifying and responding to societal impacts.

In addition to the belief that RECs are ill-situated to conduct reviews beyond the ex-ante phase that identify and respond to societal impacts, others argue that resource constraints would hinder the implementation of alternative review models. Some have suggested multi-stage reviews, such as those at the data collection or publication stage, as a way of moving beyond ex-ante reviews (Ada Lovelace Institute, 2022, p. 9). However, some survey respondents as well as workshop participants found multi-stage review models to be infeasible, as RECs would require additional time and staff to revisit research projects at multiple phases.

[8] For example, the International Bioethics Committee of UNESCO.
[9] Organisations promoting research and innovation in a discipline or field.

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Furthermore, the literature review revealed that the expansion of RECs to consider wider societal effects at multiple stages may further the bureaucratisation of research ethics governance. Haggerty (2004), for example, argues that RECs are expanding unnecessarily, rendering ethics review processes sluggish (known as "ethics creep"). Some also argue that RECs are not authorised to speak to methodologies outside of the biomedical field (Sheehan et al., 2017). In the US, the desire to avoid "ethics creep" has led RECs to automate exemptions to some forms of research that do not attempt to generate generalisable results, including some anthropological and qualitative research.

In addition, RECs often root their assessments in risk–benefit analyses. REC conceptions of harm or risk are often loosely defined. Haggerty (2004) and Bell & Wynn (2020), for example, note that REC members sometimes conceive of harm too broadly and without ample evidence to support such risk assessments. This may suggest that, if RECs widen their scope to consider societal rather than just individual harms, especially where few precedents and standards exist regarding the former, research on NT, DXR, and CE may be unnecessarily inhibited.

Expertise in ethics review

The identification of the societal impacts related to new and emerging technology research demands RECs with interdisciplinary competence. When asked about REC competence, for example, 52.6% of survey respondents believed RECs lack the resources, expertise, and training to appropriately address the risks that new and emerging technologies pose, and 39.5% felt neutral about their ability to address these risks.

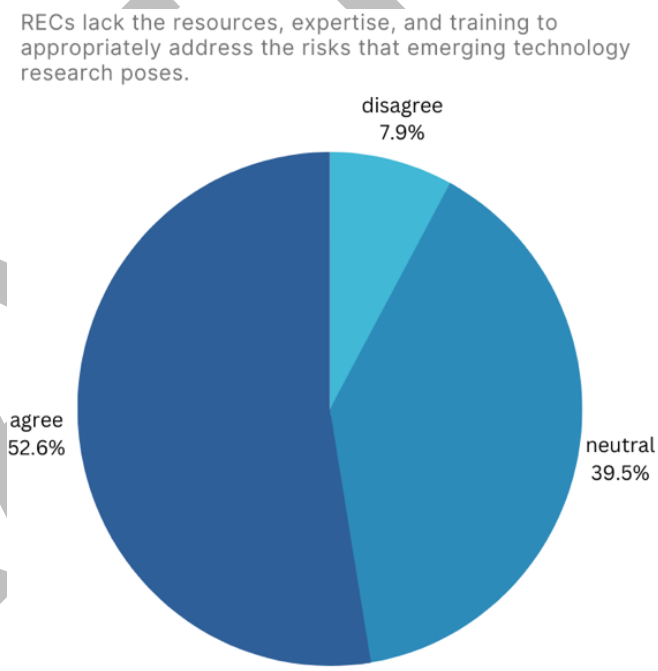

Figure 7: Survey results lack of resources

Despite their acknowledgement of gaps in REC expertise, survey respondents differed in their views on the skills and disciplinary backgrounds of REC members necessary to fill these gaps. Namely, while some stated that RECs lack the knowledge of *ethics* to conduct comprehensive ethics assessments, others found their lack of familiarity with the technological specifications of NT, DXR, and CE to be the greatest hindrance to REC reviews of this research. In addition, workshop participants noted that the lack of clear procedures for recruiting, assessing, and appointing REC members further widens these gaps.

Diversity amongst REC members is vital to the identification of ethical issues in research (see, e.g., Scherzinger & Bobbert, 2017). This is emphasised, for example, in the Council of Europe Guide for Research Ethics Committee Members, which recommends that RECs strive towards multi-disciplinarity, ideally reflecting "an appropriate range of professional and lay views" (Council of Europe Steering Committee on Bioethics, 2010, p. 19). Depending on the scope of a REC, its members can include philosophers, ethicists, social and behavioural scientists, statisticians, natural scientists, lawyers, and laypeople, amongst others (see, e.g., WHO, 2011). In REC assessments of AI and big data research, interdisciplinary expertise has been noted as increasingly important, as these projects entail physical, psychological, societal, political, legal, and environmental risks identifiable only through analysis by a range of experts who demonstrate competencies in the specific disciplines related to the object of research (see Ada Lovelace Institute, 2022, p. 83).

According to some survey respondents, REC members sometimes demonstrate little familiarity with the ethical principles necessary for the reflection on and discussion of research during the review

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process.[10] Many REC members believe that RECs should primarily act as the extension of the consciousness of a researcher, necessitating a keen understanding of and/or interest in philosophical perspectives. Some workshop participants stated that an increasing inclination amongst RECs towards experts with first-hand experience in technological research and innovation as well as regulatory compliance may obscure the fundamental focus of RECs on ethical reflection.

However, while ethical know-how is crucial to the functioning of RECs, so, too, is a nuanced understanding of the fields of NT, DXR, and CE. Many RECs are ill-equipped with knowledge of technological specificities, such as the design and intended use of NT, DXR, and CE systems. Survey respondents and workshop participants found that domain-specific knowledge is crucial in coping with the uncertainty and unpredictability associated with new and emerging technologies. RECs must, for example, understand how data are collected, processed, or stored in NT or DXR systems to map their potential impacts on both individual and societal levels.

RECs particularly struggle to recruit members with expertise in these technologies. Due to the rapid advancement and high socio-economic potential of these fields, experts in NT, DXR, and CE are in high demand, leaving RECs to compete with well-funded institutions and private-sector actors. In addition, RECs fear that the swift momentum of technological advancement will outpace their ability to recruit members that will fill gaps in technical knowledge.

Few RECs are equipped with members familiar with CE. CE refers to both the SRM and CDR technologies within the framework of the TechEthos project. However, such broad classifications of CE are rejected by many policymakers and researchers, as some view the term as synonymous with SRM. In addition, little research has been conducted on SRM as well as CDR when compared to new and emerging technologies like NT and DXR. SRM remains particularly under-researched; thus, ethical discussions revolve around the extent to which the field should be explored, considering both the real-world implications SRM research may entail as well as the need to slow climate change. The lack of well-defined parameters for CE points to inadequate preparation amongst RECs to review research projects in this field.

Lawyers are integral to the functioning of RECs due to their ability to navigate evolving regulatory landscapes. Some survey respondents found their skill sets to be highly important in the context of NT, DXR, and CE, as new and emerging technologies increase the complexity of regulatory challenges. For example, RECs are tasked with implementing the EU General Data Protection Regulation (GDPR), the provisions of which are not always clear in the context of new forms and applications of data (e.g., neural data in NT). In addition, RECs may grapple with understanding the Artificial Intelligence Act (AI Act), as its implications on research remain unclear. However, some workshop participants believed that RECs should not fulfil a strictly regulatory function and that a focus on regulation detracts from REC members' willingness and ability to engage in ethical reflection.

The lack of consensus on the actors responsible for appointing REC members and the ways in which these actors evaluate potential members' qualifications confounds the challenge of filling gaps in REC competencies. Aside from generally avoiding conflicts of interest amongst REC members, workshop participants remarked that there is little guidance on selection processes or application procedures for REC members. Members are usually nominated by the institutions hosting RECs, who may lack an understanding of the changing needs of RECs and may struggle to recruit candidates if they are unable to offer them adequate compensation.

Resource shortages

Resource shortages compound the limitations of RECs to review research related to new and emerging technologies like NT, DXR, and CE. Namely, they limit a REC's ability to implement multi-

[10] When asked about the resources (in terms of funding, human resources, expertise, institutional support, etc.) necessary to perform adequate reviews of projects in the field of emerging technology, several survey respondents noted the need for ethicists with an ability to extend the principles and guidelines for research with human subjects, e.g., the Belmont principles, to other research. This suggests that the effects of projects aiming to develop and disseminate such principles have thus far been limited.

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stage review models, recruit new members as well as external experts, and participate in training and networking activities.

Many REC members work on an honorary basis. Few RECs are specialised in reviewing research on NT, DXR, and CE. As a result, most RECs require additional training to keep pace with ethical debates and developments within these fields. Additionally, resource shortages limit REC members' ability to network and engage with other RECs and other stakeholders like policymakers; funders; NT, DXR, and CE researchers; and the communities likely to be affected by research with these technologies.

Furthermore, as noted by survey respondents, RECs often lack administrative support and are thereby increasingly burdened with bureaucratic, financial, and managerial duties. A recent survey amongst EUREC members shows that most RECs, including those that review non-biomedical research, have some form of secretariat or administrative support structure; however, REC members called for an expansion of these structures.[11] Such shortages aggravate REC competency gaps and create a vicious cycle in which REC members cannot acquire familiarity with the review of new and emerging technologies and thus increasingly seek support from paid external actors.

Survey respondents and workshop participants suggested the appointment of external reviewers – namely, experts in NT, DXR, and CE – as a solution to competence inadequacies within RECs. However, REC funds are often insufficient to provide financial incentives both to potential REC recruits as well as potential external reviewers.

These funding challenges are notable given the ample funds invested into the research of new and emerging technologies. The lack of resources earmarked for ethics review demonstrates a need for greater awareness amongst research stakeholders and the public on the importance of ethics.

Usefulness of written guidance & principles

REC members reviewing research related to new and emerging technology often refer to written guidance throughout the review process. Generally, written guidance outlines research governance processes; establishes review procedures; and contributes to monitoring, documentation, quality assurance, and coordination (e.g., WHO, 2011). Survey respondents believed written guidance to be crucial in reviewing research related to new and emerging technology. This is because the unprecedented nature and high potential impact of these technologies demand increased transparency in ethics review, and written guidance may thus help to maintain public trust in research governance.

The guidance documents used by RECs are highly heterogeneous. Those referenced by survey respondents include 1) EU-project-funded outputs, 2) EC guidance documents, 3) national and international organisation guidance, 4) professional society documents, and 5) acts and conventions. While some provide regulatory guidance, others present ethical principles, standards, and values helpful for assessment. The target audiences of the guidance documents also differ: while some directly address RECs, others are written for researchers, policymakers, or the public. A summary of all guidance documents provided by survey respondents is provided in Annex 7.2.

The usefulness of the guidance cited by REC members to NT, DXR, and CE ethics reviews is compromised by the following dichotomy. On the one hand, guidelines drafted specifically for REC target audiences provide guidance applicable to "traditional" research undergoing REC review, i.e., they pertain mostly to the ex-ante review of biomedical research with human participants and hence lack operational recommendations for ethics review where human participants are not involved or where the risks of the research are likely to be felt on a societal level. For example, most existing guidance for RECs does not include specific provisions for data subject research, and guidance for human participant research often cannot be applied due to the lack of direct interaction between researchers and participants. On the other hand, guidelines specific to NT, DXR, and CE – which often

[11] EUREC conducted a survey in May–June 2023 to provide an overview of how REC systems in non-biomedical research operate in different European countries. The purpose of the survey was to guide the structuring of future work of EUREC's Working Group on non-biomedical research. Survey results are not publicly available.

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outline relevant ethical considerations and the potential societal impacts of these technologies – are oriented toward policymakers, researchers, or the broader public rather than RECs.

While the latter group of guidelines lack grounding in ethical principles, the former lack the technology-oriented contextualisation necessary for comprehensive risk–benefit analyses and the identification of the potential societal implications of research in NT, DXR, and CE. This results in the perception that guidelines are, on the one hand, ill-suited for the ethics review of NT, DXR, and CE research and, on the other hand, cannot be operationalised by RECs.

RECs often rely on biomedical research ethics principles to guide their decision-making. These principles – primarily referring to those of Beauchamp and Childress (1979; i.e., autonomy, beneficence, non-maleficence, and justice) – were designed within biomedical contexts. These refer to harms and risks associated with individuals rather than long-term impacts on society at large (Holm, 2020). REC members cited the need for principles adjusted to NT, DXR, and CE contexts, noting that these principles should be co-created with a multiplicity of stakeholders as well as the public and demonstrate cross-cultural applicability.

3.2. Topical challenges

Data processing

Data processing constitutes a key thematic challenge in the ethics review of NT and DXR research. New and emerging technologies in NT and DXR gather and replicate data in novel ways largely unfamiliar to many RECs. In particular, RECs struggle to apply the GDPR, guide the management of incidental findings, and assess research with neural and behavioural data.

While the EU General Data Protection Regulation (GDPR) sets regulations and principles for the governance of data processing, REC members note the inability of the GDPR to address emerging data processing aspects in NT and DXR. For example, the GDPR does not speak to the processing of incidental findings or brain data, which are key to much DXR and NT research.

The handling of data that generate incidental findings constitutes a key ethical concern in reviews of DXR and NT research. Incidental findings refer to researchers' observations that are unrelated to the purpose of a study. They occur, for example, in neuroimaging, such as in the identification of tumours or illnesses during brain imaging conducted for unrelated purposes (e.g., Graham et al., 2021). DXR technologies may generate large volumes of sensory data, e.g., data from the surrounding environment of participants, which may yield incidental findings that could either harm or benefit participants. RECs often require researchers to provide plans on how they will process collected incidental data; however, little institutional and REC-specific guidance addresses how RECs should evaluate this information.

NT often involves accessing and analysing sensitive neural information, raising ethical concerns on privacy, consent, and data protection. Data privacy in the context of NT should consider the intimate nature of brain data as well as the intrusion of NT on privacy (Goering et al., 2021). A report on the ethical issues of neurotechnology by the International Bioethics Committee of UNESCO (2021) suggests that neural data could be considered "the origin of the self," necessitating special protections beyond those awarded to other physiological data. However, workshop participants noted that definitions of neural data are contested due to the wide range of signals and measurements obtained from the brain.[12] A lack of consensus on the definition of neural data may hinder efforts to develop standards for REC reviews of NT research.

Fairness, equity, autonomy, and social divisions

REC members struggle to assess the ethical questions on fairness, equity, autonomy, and social divisions raised by new and emerging technologies. REC members cite four key areas of concern in

[12] E.g., electroencephalography – EEG, functional magnetic resonance imaging – fMRI, local field potentials – LFPs, multi-unit recordings, calcium imaging.

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reviewing NT, DXR, and CE research: the use of NT for enhancement purposes, the exclusion of low- and middle-income-country (LMIC) actors in CE research, harassment and discrimination in DXR research, and risks to minors participating in NT research. These areas of concern complicate risk–benefit assessments by RECs, and little guidance exists on how, and to what extent, RECs should take these effects into account.

NT interventions designed to enhance human capabilities raise complex ethical questions related to fairness, equity, autonomy, and potential social divisions. Workshop participants and survey respondents noted that RECs struggle to weigh the risks and benefits of NT research when boundaries between therapy and enhancement are blurred. In the case of enhancement, benefits can also entail the realisation of an aspiration rather than just recovery from a malady. Preventative neurology, for example, which focuses on strengthening neurological resilience, represents a grey area between therapy and enhancement. Interventions focused on enhancement challenge conventional ethics review frameworks, as RECs must also gauge the impact on fairness, equity, and potential social divisions arising from NT (in)accessibility (Giordano, 2015; Giordano, 2017).

SRM and CDR research raises ethical questions related to global equity. SRM and CDR projects may affect countries in the Global South, which are typically less resilient to climate change and thus more susceptible to the potential negative effects of SRM or the damages caused by global warming.[13] RECs are also tasked with evaluating whether SRM and CDR could exacerbate or alleviate existing socio-economic divisions on a global scale.

Harassment and discrimination in DXR research represent a key concern for RECs. Workshop participants noted the importance – and the challenge – of identifying these issues in the design phase of research. DXR, involving complex programming and intricate virtual environments, may give rise to harassment, sexism, and racism when introduced to the public. To pinpoint these impacts, RECs must acquaint themselves with the cultural, gender, and social dynamics associated with the design and use of DXR technology. Furthermore, ex-ante review processes must account for the possibility of such impacts.

Research involving minors may present further ethical challenges, as the application of NT on the growing brains of children and adolescents may inflict irreversible damage. RECs must ensure the adequacy of informed consent processes for research with minors, ensuring parental consent while balancing their autonomy and best interests. In addition, RECs must consider the wider societal implications of NT for minors, including the potential for NT to exacerbate inequality by being accessible to a select few who are able and willing to use these technologies.

Involvement of the private sector

NT, DXR, and CE research challenges the ways in which private actors can – and should – be engaged in the ethics review process. As noted by workshop participants, many CDR projects in CE receive funding from both public and private bodies. As such, RECs are tasked with identifying potential conflicts of interest and commercial objectives, an issue of high relevance in all research conducted within the framework of academia–industry collaboration or other forms of public–private partnerships.

The involvement of the private sector necessitates an evaluation by RECs of their motivations and intentions. This is because incentive structures in the private sector differ from those common in academia, though motivations in both sectors vary widely. Though the values of many private-sector actors may include sustainability and equity, commercial interests can skew research priorities, hinder the dissemination of research findings, and prevent those who would benefit most from accessing technologies and other results developed from research. As discussed within the workshop breakout group on CE, REC review processes rarely account for the engagement of the private sector.

[13] The ethics of stopping or slowing research into SRM and CDR may also be questioned, as RECs are tasked with evaluating whether the risks of SRM technologies are greater than the risks of a warmed world without SRM.

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4. Criteria & recommendations for ethics review by RECs

The following recommendations provide a path forward for RECs in reviewing NT, DXR, and CE research. They position RECs to work with other actors in the research governance system – including policymakers, funders, conference organisers, publishers, ethics organisations, and learned societies – to provide ethical support beyond the ex-ante phase, improving the transparency, inclusivity, and effectiveness of REC reviews. They suggest ethics by design, or the incorporation of ethical principles into the development process of technologies (Dainow & Brey, 2021), to this end. The target groups of these recommendations are defined as follows:

- RECs. Ethics review bodies.
- Funders. Public or private entities funding research.
- Publishers. Actors involved in the dissemination of research.
- Conference organisers. Actors involved in hosting events related to research.
- Research institutions. Institutions that conduct research and may host RECs.
- Researchers. Actors conducting research.
- Policymakers. Elected officials, EC bodies, and key decision-makers at research-performing organisations.
- Learned societies. Organisations promoting research and innovation in a discipline or field (e.g., in NT, DXR, and CE).
- Ethics organisations. Governmental or non-governmental organisations and ethics councils.

These recommendations act as a starting point for the adaptation of the research governance system. Further work should involve the co-creation of guidelines and principles with a variety of stakeholders. Such co-creation processes fall outside of the scope of this report.

Several workshop participants suggested that discussions and developments in research ethics should address public and societal concerns. Thus, discussions on the adaptation of the research governance system should transcend the REC–researcher–participant research ethics triangle keeping in mind that technology impact assessment cannot be done by RECs alone.[14]

1) **Encourage researchers to reflect on the potential societal and environmental implications of their research.** Instruct researchers to include a social and environmental impact statement on their research when submitting research protocols to RECs. This is aligned with the first recommendation from "Looking before we leap" (Ada Lovelace Institute, 2022, pp. 73–76). These statements should detail how their research may impact individuals, society, and the environment and how their research may contravene the main principles of NT, DXR, and CE research (see recommendation 4 below) both during and after the research lifecycle. This can follow, for example, the Ethical Impact Assessment framework proposed by the SATORI project.[15] Where applicable, such as in large-scale outdoor CE experiments, require researchers to specify the populations likely to be impacted by this research and to seek community input on their social impact statements.
   Target group: RECs and research institutions

[14] Work conducted by numerous previous and ongoing projects, such as SIENNA, SHERPA, PANELFIT, PRO-RES, SATORI and RESPECT, could offer many useful starting points for addressing public concerns.
[15] See the Ethical Impact Identification and Evaluation stages; Callies, I. et al. (2017) DELIVERABLE D4.2 Section 5: Ethical Impact Assessment. Available at: https://satoriproject.eu/framework/section-5-ethical-impact-assessment/.

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2) **Determine which projects are high risk and conduct reviews proportionate to risk levels.** The magnitude of risks associated with NT, DXR, and CE research projects varies greatly. Determine which projects may benefit from multi-stage reviews, as these reviews should be proportionate to risk levels. Work with research governance stakeholders, especially experts in NT, DXR, and CE, to determine criteria to be used to classify risk levels.[16] Draft exemptions or expedited review procedures for low-risk projects. Consider the EC's proposed regulatory framework on artificial intelligence as a model for assessing risk, though such a framework requires adjustment to account for NT, DXR, and CE specifications. Ensure risk levels align with the scope and mandate of each REC.
Target group: RECs and research institutions

3) **In high-risk projects, complement ex-ante review with further ethical reflection mechanisms.** Mandate the assignment of an ethics officer to act as a first contact point for researchers and maintain regular contact throughout the research lifecycle. These ethics officers should perform intermittent ethics checks for such projects and, where necessary, assist researchers in resolving conflicting ethical objectives. Maintain communication with these advisors throughout the project. This process could follow that of the EC, in which ethics officers are appointed to higher-risk projects flagged during an initial ethics review.[17]
Target group: RECs and funders

4) **Develop REC-specific guidance documents for ethics review in NT, DXR, and CE based on pertinent principles.** Create targeted guidance on NT, DXR, and CE reviews, including ethics review protocol templates,[18] for RECs to operationalise principles identified by the TechEthos project (see Appendix 7.1: TechEthos guiding principles and values) and, where appropriate, other relevant principles. Update this guidance regularly. Guidance should ideally be maintained by a permanent body such as a learned society or ethics organisation. Co-create guidance through multiple iterations of input from a variety of stakeholders, including RECs; researchers; policymakers; funders; NT, DXR, and CE experts; and those likely to be affected by NT, DXR, and CE research. Distribute guidance to REC networks – such as EUREC and the Forum for Ethical Review Committees in the Asian and Western Pacific Region (FERCAP) – to increase the visibility of developed guidance.
Target group: policymakers, learned societies, and ethics organisations

5) **Assess ethics-by-design roadmaps, if applicable.** If research aims to develop a technology or create an application for a technology, request researchers to develop an ethics-by-design roadmap. This roadmap should specify how researchers will maintain ethical compliance, following the six stages in the Generic Model for AI Development.[19] Instruct researchers to reflect on the points listed in the "Specification of Objectives against Ethical Requirements" in Dainow & Brey (2021, pp. 26–28). Where applicable, such as in large-scale, outdoor CE experiments, require researchers to specify the populations likely to be impacted by this research and to seek community input on ethics-by-design roadmaps.
Target group: RECs

[16] The AI Act, for example, categorises AI into four risk levels: unacceptable risk, high risk, AI with specific transparency obligations, and minimal or no risk. See https://artificialintelligenceact.eu/the-act/.
[17] For example, ethics officers within the EC ethics appraisal process. For more information on the EC ethics appraisal process, see European Commission (2023) Horizon Europe (HORIZON) Programme Guide. Available at: https://ec.europa.eu/info/funding-tenders/opportunities/docs/2021-2027/horizon/guidance/programme-guide_horizon_en.pdf. pp. 23–28.
[18] See, e.g., the EChOES for International Review Boards (Research Ethics Committee, Research Integrity Organizations) protocol; Chneiweiss, H. et al. (2022) D5.1: Operational guidelines for the field of organoids and organoid-related technologies. HYBRIDA. Available at: https://hybrida-project.eu/wp-content/uploads/2023/01/D5.1-Operational-guidelines.pdf, pg. 44.
[19] I.e., specifying the technology's objectives, specifying its requirements, verifying the overall architecture of the system, outlining how data will be collected and prepared, implementing an ethical development architecture, and setting up testing and evaluation mechanisms (Dainow & Brey, 2021, pp. 12–22).

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6) **Ensure REC composition and expertise of members are aligned with their purview**. Consistent with Recommendation 3 in "Looking before we leap" (Ada Lovelace Institute, 2022, pp. 82–85), include interdisciplinary and experiential expertise in REC membership. Seek a range of competencies within RECs, including, for example, philosophers and ethicists; social and behavioural scientists; statisticians; natural scientists; lawyers; laypeople; and experts in NT, DXR, and CE. Set parameters within RECs on the composition of RECs and devise procedures for the selection and appointment of candidates. Identify gaps and, if necessary, fill these gaps with external advisors. Specify transparent criteria for the involvement of external experts, including how experts will be recruited, chosen, engaged, and compensated during the review process.
Target group: RECs and research institutions

7) **Improve the expertise of REC members, including their knowledge of ethics and relevant fields of technology, by promoting greater exchange with researchers and other RECs.**

- **Participate in relevant training programmes,[20] conferences, workshops, fora,[21] and other events related to new and emerging technologies** – particularly those pertaining to the fields of NT, DXR, and CE. Discuss challenges encountered in the ethics review of NT, DXR, and CE research, especially the potential risks and benefits of this research, with experts and policymakers.
  Target group: RECs and policymakers
- **Network with other RECs**. Share best practices in reviewing NT, DXR, and CE projects on an ongoing basis. Networks like EUREC and FERCAP can serve as a starting point for such discussions. Interact with RECs both within and beyond the EU.
  Target group: RECs
- **Encourage mutual learning between RECs, researchers, and other research governance actors**. Invite REC members to attend workshops, conferences, and other events related to new and emerging technologies and their ethical and societal impacts.
  Target group: conference organisers
- **Develop training programmes for REC review of new and emerging technologies**. Contribute to training programmes supporting the adaptation of RECs to new and emerging technology research, especially regarding reviews of NT, DXR, and CE research.
  Target group: funders, research institutions, learned societies, and ethics organisations

8) **Require ethical reflection for researchers in publications and conferences**. Encourage researchers to submit social impact statements (see recommendation 1) before publishing or presenting their findings. This is consistent with Recommendation 7 of the Ada Lovelace report "Looking before we leap" (Ada Lovelace Institute, 2022, pp. 95–97).
Target group: publishers and conference organisers

9) **Improve transparency in decision-making processes.** Make REC procedures, principles, accountability measures, and guidelines publicly available, e.g., via an institutional website. Where feasible and per data privacy regulations, publish summaries of decision-making processes for new and emerging technology research. For example, the National Office for Research Ethics Committees (NREC) in Ireland publishes meeting minutes documenting its review procedures.[22]
Target group: RECs

[20] Such as those to be developed by the iRECS project. See https://www.irecs.eu/project-outline.
[21] For example, the National Ethics Councils (NEC) Forum.
[22] See, e.g., the National Office for Research Ethics Committees (2023) NREC-MD Meeting Minutes , National Research Ethics Committee. Available at: https://www.nrecoffice.ie/wp-content/uploads/NREC-MD-Meeting-Minutes-2023_05_18.pdf.

This project has received funding from the European Union's Horizon 2020 research and innovation programme under grant agreement No.101006249.

10) **Ensure REC access to adequate resources.** This includes funding to compensate REC members; provide administrative support for RECs; hire external experts, where necessary; train REC members; and allow REC members to participate in networking events, conferences, and workshops. This is consistent with Recommendation 8 of the Ada Lovelace Institute.
Target group: policymakers, funders, and research institutions

11) **Incentivise private-sector actors to engage in ethics review processes.** Where corporate or private entities are involved in funding or conducting research, develop ethics review certificates to encourage their commitment to ethical research.[23]
Target group: policymakers

[23] These could follow the example of the British Standard Institute's PAS 440/2020, a voluntary standard on responsible innovation in the private sector, which allows companies to demonstrate responsible innovation. See https://pages.bsigroup.com/l/35972/2020-03-17/2cgcnc1?utm_source=pardot&utm_medium=email&utm_campaign=SM-STAN-LAU-PAS-PAS440-2003.

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5. Conclusions and future outlook

New and emerging technologies, including neurotechnology (NT), digital extended reality (DXR), and climate engineering (CE), have the potential to profoundly impact society. Research governance systems – including RECs – are crucial in identifying and mitigating the risks associated with NT, DXR, and CE research. However, traditional REC reviews are insufficient for this purpose.

Data from the literature review, survey, and workshop pinpointed both structural and topical challenges of RECs. The scope and composition of RECs, their access to resources, and their commonly used guidelines and principles should be adjusted to account for new and emerging technology research. Furthermore, RECs struggle to assess data processing; fairness, equity, social divisions, and autonomy; and private-sector involvement in NT, DXR, and CE research.

RECs as well as funders, research institutions, policymakers, publishers, conference organisers, learned societies, and ethics organisations play a role in addressing ethical challenges related to NT, DXR, and CE. Ethics review of NT, DXR, and CE research should be transparent, interdisciplinary, balanced, and inclusive, demanding greater attention to REC structures and procedures. RECs should encourage researchers to reflect on the potential societal impacts of their research. When risks of negative social impacts are high, RECs and other actors should support the assessment of ethical issues at multiple stages.

Several recommendations point to the need for further work with other stakeholders. In particular, the principles identified by the TechEthos project associated with NT, DXR, and CE should be expanded with input from funders, research institutions, policymakers, publishers, conference organisers, learned societies, ethics organisations, and the wider public. The activities of the iRECS project as well as the objectives of HORIZON-WIDERA-2023-ERA-01-12 and HORIZON-WIDERA-2024-ERA-01-12 provide room for the further development of adaptation for RECs in the assessment of new and emerging technology research.

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7. Annexes

7.1. TechEthos guiding principles and values

Adequate guidance in the ethics assessment of research projects in NT, DXR, and CE must present relevant ethical principles and values. In addition, to support comprehensive reviews of research with these technologies, they must guide RECs in the operationalisation of those principles and values during the review process (see recommendation 4 above).

The operationalisation of ethical principles and values varies according to the specific contexts in which research is conducted, depending on the field of research and designs employed, those conducting the research, and those likely to be affected by the research. Thus, the application of principles may be highly contested and require input from a variety of actors, including RECs; researchers; policymakers; funders; NT, DXR, and CE experts; and communities likely to be affected by NT, DXR, and CE research.

As this input is vital for operationalisation, and different operational guidelines are needed for specific applications, the development of general guidance for NT, DXR, and CE (SRM and CDR) lies beyond the scope of this report. However, the principles and values elicited in TechEthos D2.2 (Adomaitis et al., 2022) are presented below to provide a viable starting point for policymakers, learned societies, and ethics organisations. These are supplemented with points raised by TechEthos ADIM board members and participants and respondents of the D5.4 workshop and survey, respectively.

DXR

As TechEthos identified the two most important technologies of DXR as extended reality and NLP, principles and values are presented for each.

Values and principles in XR

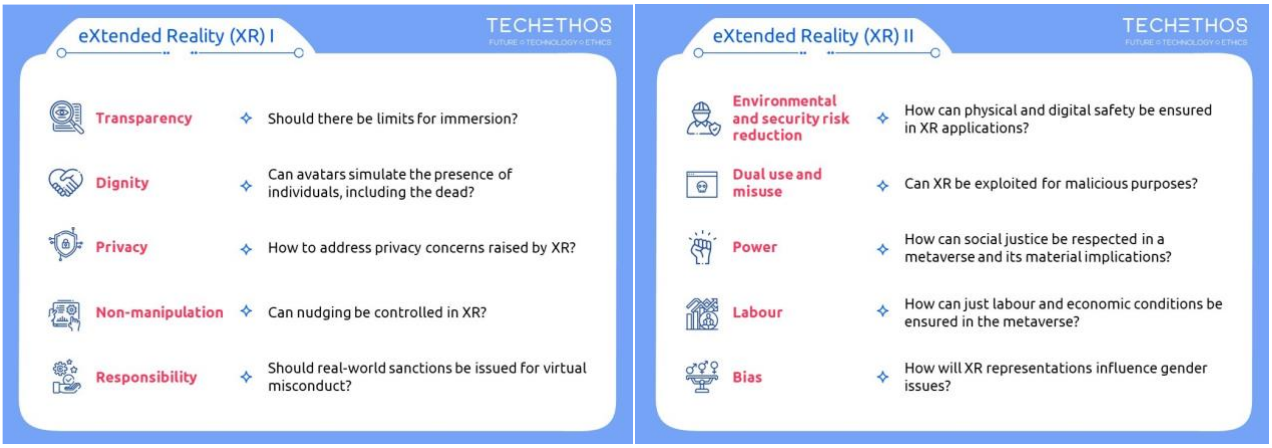

Figure 8 – These figures are taken from TechEthos D2.2. The questions on the righthand side aim to operationalise the values and principles.

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Values and principles in NLP

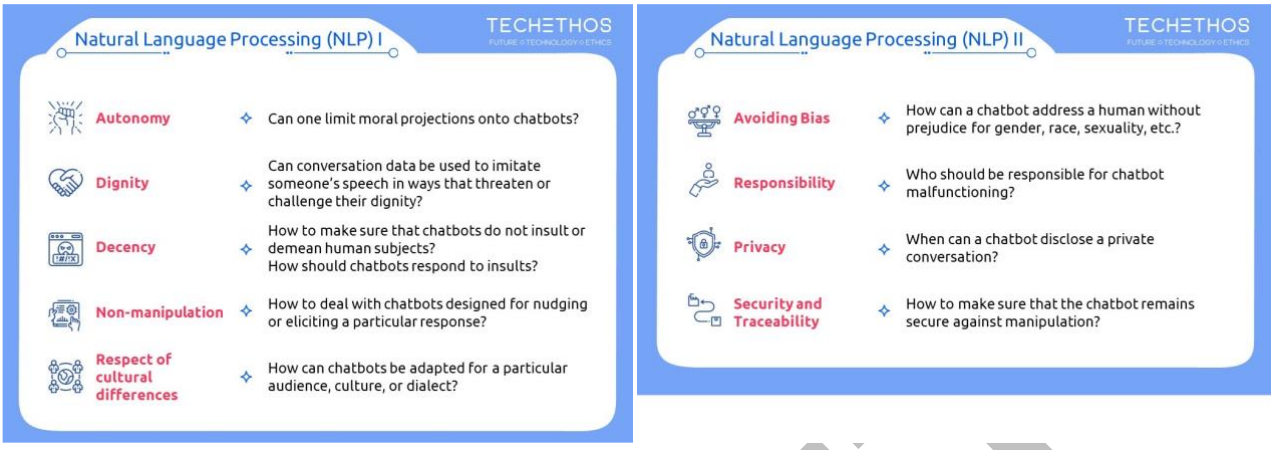

Figure 9 – These figures are taken from TechEthos D2.2. The questions on the righthand side aim to operationalise the values and principles.

Points that came up in the discussion with workshop and survey participants as well as ADIM board members were the importance of avoidance of harassment, sexism, and racism in DXR research. Board members, workshop participants, and survey respondents stressed the importance of identifying these issues in the design phase of the research. This necessitates a nuanced understanding of the cultural, gender, and social dynamics associated with the design and use of DXR technology. ADIM board members pointed out that the fundamental do-no-harm principle should feature centrally in reviews of DXR research.

NT

Points that came up in the discussion with workshop and survey participants as well as ADIM board members were boundaries between treatment and enhancement and the principles and values of fairness and equity.

Regarding the principle of privacy, workshop participants noted that brain data, due to their intimate nature, are vital to personhood, dignity, and mental integrity.

In addition, the ADIM board highlighted the importance of user safety, i.e., how can it be guaranteed that no harm is done to the users in applying NT? Risk reduction is complicated by a lack of knowledge about the physical, mental, and social consequences of NT, which are largely unknown and would factor into risk–benefit analyses. The avoidance of stigma, non-manipulation, and nudging should be considered in risk–benefit analyses.

Values and principles in NT

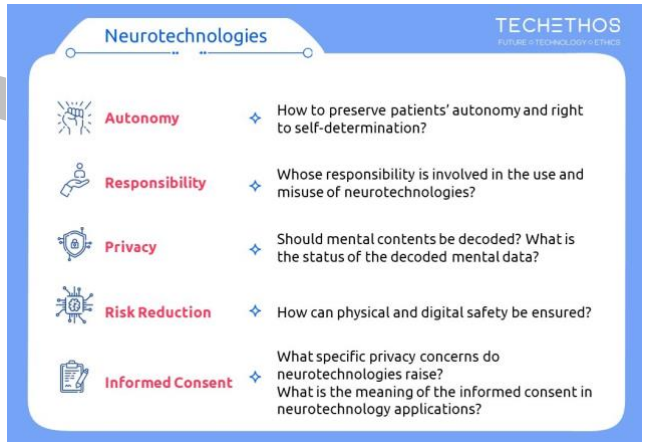

Figure 10– This figure is taken from TechEthos D2.2. The questions on the righthand side aim to operationalise the values and principles.

Another aspect highlighted by workshop participants and survey respondents is the interests of minors in research. Minors must be protected, as the application of NT on their growing brains may inflict irreversible damage. The application of informed consent is also made more difficult here, as informed consent should consider autonomy as well as the best interests of minors.

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CE

As TechEthos identified the two most important technologies of CE as CDR and SRM, principles are presented for each.

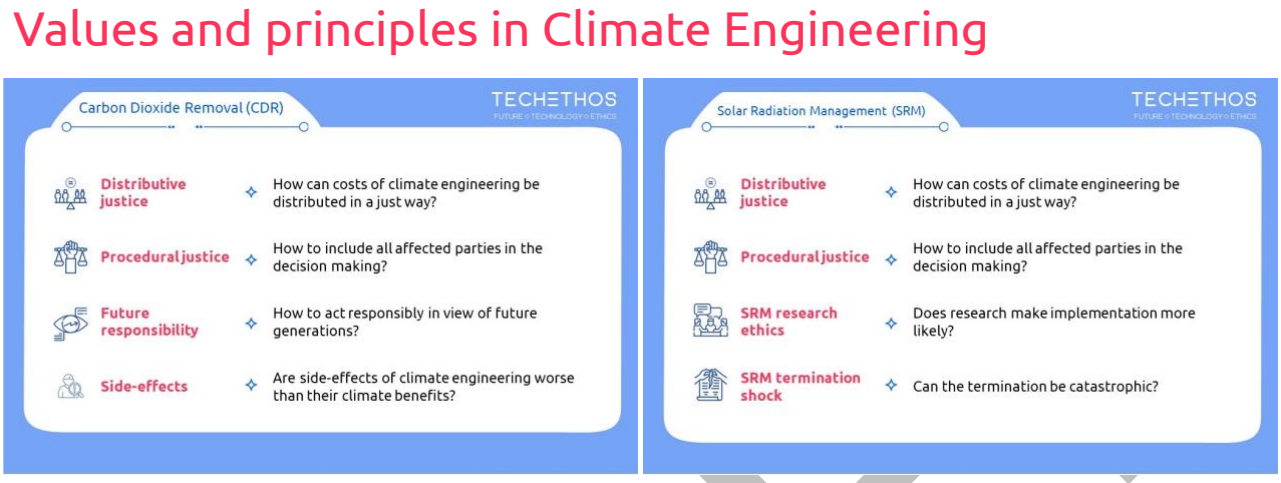

Figure 11– These figures are taken from TechEthos D2.2. The questions on the righthand side aim to operationalise the values and principles.

ADIM board members pointed out that there is not only a risk in researching, developing, and implementing SRM technologies. There might also be a risk in not doing this (constituting a risk–risk paradigm). This might lead to a different weighting of principles. Workshop participants emphasised the inclusion of LMICs in the context of justice (both in terms of procedural and distributive justice). CDR and SRM could either reduce or exacerbate existing socio-economic divisions between countries. Additionally, ADIM board members found the principles of accountability, transparency, beneficence, and sustainability (i.e., including the interests of further generations) to be pertinent to both using or rejecting CDR and SRM.

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7.2. Summary of guidance provided by survey respondents

The following guidance is labelled with its relevance to the three TechEthos technologies: blue is indicative of guidance relevant to NT, green of CE, and red of XR.

EU project outputs

🔵 ? 🔴	**PRO-RES Toolbox**
The Toolbox, developed by the PRO-RES project, guides ethics reviewers through the process of ethical and integrity evaluation of research using stakeholder-tested tools. Particularly relevant is the guidance on Ethical Issues in Covert Research, Security and Surveillance, which touches on the manipulation, dual use, and rapid development of technology.	
Themes addressed: • Potential for manipulation • Dual-use technology	
Link: https://prores-project.eu/toolbox-2/	

🔵 ? 🔴	**Responsible Research and Innovation (RRI) Toolkit**
The RRI toolkit aims to support responsible research and innovation by promoting framework principles. It takes issues like ethics, gender equality, governance, open access, public engagement, and science education into account.	
Themes addressed: • Public awareness and engagement • Equity in access to technology	
Link: https://rri-tools.eu/search-engine	

🔵 🔴	**SIENNA Ethical Guidance for Research With a Potential for Human Enhancement**
These guidelines, developed by the SIENNA project for researchers and developers, outline ethical considerations for human-enhancement-related technologies in different fields, including biomedicine, biomedical engineering, and human–machine interaction.	
Themes addressed: • Dual-use technologies • Data processing	

This project has received funding from the European Union's Horizon 2020 research and innovation programme under grant agreement No.101006249.

• Behavioural impacts of technologies • Human enhancement
Link: https://ec.europa.eu/info/funding-tenders/opportunities/docs/2021-2027/horizon/guidance/ethical-guidance-for-research-with-a-potential-for-human-enhancement-sienna_he_en.pdf

	PANELFIT Guidelines
These guidelines aim to support stakeholders within the research community in understanding the ethical and regulatory landscape surrounding information and communications technology (ICT). Relevant guidelines to RECs in new and emerging technology include guidelines on biometric data and GDPR.	
Themes addressed: • Data processing • Biometric data	
Link: https://guidelines.panelfit.eu/	

	SHERPA Guidelines for the Ethical Development of AI and Big Data Systems: An Ethics by Design Approach
These guidelines, developed by the SHERPA project, advise on the ethical development and use of AI and big data systems via an ethics-by-design approach.	
Themes addressed: • Dual-use technologies • Data processing • Behavioural impacts of technologies • Public awareness and engagement • Equity in access to technologies • Impacts on local and global climates and ecosystems	
Link: https://www.project-sherpa.eu/guidelines/	

EC Guidance

	Ethics Guidelines for Trustworthy Artificial Intelligence
These guidelines, produced by the EC High-Level Expert Group on AI presented Ethics Guidelines for Trustworthy Artificial Intelligence, present requirements and criteria for AI.	

This project has received funding from the European Union's Horizon 2020 research and innovation programme under grant agreement No.101006249.

Themes addressed: • Data processing • Human enhancement • Behavioural impacts of technologies
Link: https://digital-strategy.ec.europa.eu/en/library/ethics-guidelines-trustworthy-ai

	Council of Europe Guide for Research Ethics Committee Members Steering Committee on Bioethics
This guide is a tool for RECs reviewing biomedical research. It presents both common ethical and legal aspects found in biomedical research and describes the roles and makeup of RECs.	
Themes addressed: • Data processing • Human enhancement • Research with minors	
Link: https://www.coe.int/en/web/bioethics/guide-for-research-ethics-committees-members	

	Ethics By Design and Ethics of Use Approaches for Artificial Intelligence
These guidelines were developed by the European Commission to promote the ethical development of AI systems. They outline the characteristics an AI system needs to promote core principles (respect for human agency; privacy, personal data protection, and data governance; fairness; individual, social, and environmental well-being; transparency; and accountability and oversight) and provide concrete tasks to produce ethical AI according to these principles.	
Themes addressed: • Data processing • Behavioural impacts • Dual-use technologies • Equity in access to technologies • Impacts on local and global climates and ecosystems	
Link: https://ec.europa.eu/info/funding-tenders/opportunities/docs/2021-2027/horizon/guidance/ethics-by-design-and-ethics-of-use-approaches-for-artificial-intelligence_he_en.pdf	

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	EU Statement on artificial intelligence, robotics and 'autonomous' systems
This statement proposes ethical principles to guide ethical reflection and dialogue on AI, robotics, and 'autonomous' technologies.	
Themes addressed: • Data processing • Dual-use technologies • Behavioural impacts • Equity in access to technologies • Impacts on local and global climates and ecosystems	
Link: https://op.europa.eu/en/publication-detail/-/publication/dfebe62e-4ce9-11e8-be1d-01aa75ed71a1#:~:text=This%20statement%20calls%20for%20the,%2C%20and%20'autonomous'%20systems.	

National and international organisation documents

	Agenda 2030
The Agenda 2030, also known as the Sustainable Development Goals, outlines goals for all stakeholders and countries to achieve resilience and sustainability at a global scale, with a focus on people, the planet, prosperity, peace, and partnership (manifested in 17 objectives). They were developed in 2015 by the United Nations General Assembly.	
Themes addressed: • Public awareness and engagement • Impacts on local and global climates and ecosystems • Equity in access to technologies	
Link: https://sdgs.un.org/2030agenda	

	Comité Consultatif National d'Ethique (National Ethics Advisory Committee) Guidance
The Comité Consultatif National d'Ethique, a French governmental advisory council focused on bioethics, published statements on several topics related to new and emerging technology. Of relevance to the TechEthos technologies are "Ethical issues raised by collections of biological material and associated information data," "Big data and health: State of play, prospective and new ethical questions," "Ethical issues of functional neuroimaging," and "Biodiversity and health: new relationships between humanity and the living."	
Themes addressed: • Data processing	

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• Neuroimaging • Research with minors • Impacts on local and global climates and ecosystems
Link: https://www.ccne-ethique.fr/fr

	**IEEE ETHICALLY ALIGNED DESIGN - A Vision for Prioritizing Human Well-being with Autonomous and Intelligent Systems**.
This document, created by the IEEE Global Initiative on Ethics of Autonomous and Intelligent Systems, puts forth guidelines that empower stakeholders to value ethical considerations when designing autonomous and intelligent systems.	
Themes addressed: • Data processing • Dual-use technologies • Behavioural impacts • Impacts on local and global climates and ecosystems • Research with minors • Public awareness and engagement • Equity in access to technologies	
Link: https://standards.ieee.org/wp-content/uploads/import/documents/other/ead_v2.pdf	

	**Council for International Organizations of Medical Sciences (CIOMS) International ethical guidelines for health-related research involving humans**
These guidelines put forth an ethical framework for conducting research with human subjects which protects human rights and dignity. They target stakeholders involved in the research design process and include recommendations related to research in resource-poor settings.	
Themes addressed: • Data processing • Research with minors • Equity in access to technologies • Public awareness and engagement	
Link: https://cioms.ch/publications/product/international-ethical-guidelines-for-health-related-research-involving-humans/	

	**Arbeitsgemeinschaft Medizinischer Ezhik-Kommissionen – Recommendations for the review of clinical trials by ethics committees**

This project has received funding from the European Union's Horizon 2020 research and innovation programme under grant agreement No.101006249.

These recommendations, developed by the German Association of Medical Ethics Committees, aim to help RECs evaluate human subject clinical trial research robustly.
Themes addressed: • Data processing • Research with minors • Public awareness and engagement
Link: https://www.akek.de/pruefkriterien/

	OECD Recommendations on Responsible Innovation in Neurotechnology
These recommendations help actors in the research ecosystem support the ethical development and use of neurotechnology, promoting transparency, accountability, and engagement with stakeholders.	
Themes addressed: • Data processing • Dual-use technologies • Neural data • Public awareness and engagement	
Link: https://www.oecd.org/science/recommendation-on-responsible-innovation-in-neurotechnology.htm	

	The National Academies of Sciences, Engineering, and Medicine report on Neuroscience Data in the Cloud
This report, resulting from a 2019 workshop of the National Academies Forum on Neuroscience and Nervous System Disorders, addresses ethical considerations regarding cloud-based neuroscience initiatives.	
Themes addressed: • Data processing	
Link: https://nap.nationalacademies.org/catalog/25653/neuroscience-data-in-the-cloud-opportunities-and-challenges-proceedings-of	

	Recommendations for Responsible Development and Application of Neurotechnologies (Goering et al., 2021)
This paper outlines four key ethical areas (identity and agency, privacy, bias, and enhancement) of neurotechnology and suggests possible mitigation measures.	

This project has received funding from the European Union's Horizon 2020 research and innovation programme under grant agreement No.101006249.

Themes addressed: • Data processing • Neural data • Human enhancement • Dual-use technologies • Equity in access to technologies
Link: https://doi.org/10.1007/s12152-021-09468-6

	International Conference on Harmonisation of technical requirements for registration of pharmaceuticals for human use (ICH) Good clinical practice (GCP) guidelines
These guidelines speak to the development of ethical standards for ICH regions in designing and conducting clinical research involving human participants.	
Themes addressed: • Data processing • Research with minors	
Link: https://www.ema.europa.eu/en/documents/scientific-guideline/ich-guideline-good-clinical-practice-e6r2-step-5_en.pdf	

	Oxford Principles
The Oxford Principles, endorsed by the UK House of Commons Science and Technology Select Committee on "The Regulation of Geoengineering" in 2009, consist of four key principles to support the sound governance of geoengineering.	
Themes addressed: • Equity in access to technologies • Public awareness and engagement • Impacts on local and global climates and ecosystems	
Link: http://www.geoengineering.ox.ac.uk/www.geoengineering.ox.ac.uk/oxford-principles/principles/	

Acts, conventions, and regulations

	General Data Protection Regulation (GDPR)
The GDPR, put into effect in 2018 in the European Union and the European Economic Area (EEA), regulates data privacy and security. It mandates the processing of the personal data	

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of individuals located within the EU/EEA, regardless of the location of the data processor (for purposes of commercial and professional activities). It applies to research ethics in that it limits how researchers can collect and process identifiable data.
Themes addressed: • Data processing • Research with minors
Link: https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32016R0679

	EU AI Act
This proposed act by the European Commission establishes regulations for anyone offering or using AI as a product or service. It categorises AI tools according to their risk level, presenting four risk categories. High-risk AI tools to be introduced to the EU market must comply with regulations to ensure human rights and freedoms are protected.	
Themes addressed: • Dual-use technologies • Data processing • Research with minors • Behavioural impacts • Public awareness and engagement • Impacts on local and global climates and ecosystems	
Link: https://artificialintelligenceact.eu/the-act/	

	Oviedo Convention
Also known as the Convention for the Protection of Human Rights and Dignity of the Human Being concerning the Application of Biology and Medicine, the Oviedo Convention was ratified in Europe in 1997 and aims to protect human rights and dignity regarding medicine and research involving human subjects.	
Themes addressed: • Research with minors • Equity in access to technologies • Public awareness and engagement • Data processing	
Link: https://www.coe.int/en/web/conventions/full-list?module=treaty-detail&treatynum=164	

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	Declaration of Helsinki
This declaration was introduced in 1964 by the World Medical Association and set a precedent in research ethics by protecting the rights of human participants in health-related research.	
Themes addressed: • Data processing • Research with minors • Behavioural impacts • Equity in access to technologies • Impacts on local and global climates and ecosystems	
Link: https://www.wma.net/policies-post/wma-declaration-of-helsinki-ethical-principles-for-medical-research-involving-human-	

Professional society documents

	NSPE Code of Ethics for Engineers
This code outlines obligations and rules of practice for engineering professionals.	
Themes addressed: • Impacts on local and global climates and ecosystems • Public awareness and engagement	
Link: https://www.nspe.org/resources/ethics/code-ethics	

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7.3. Survey questionnaire

Survey: RECs and emerging technology research

EUREC Office is contacting you on behalf of the EU-funded project TechEthos.

We would like to understand how Research Ethics Committees (RECs) and other ethics review bodies approach ethical reviews for emerging technology research with high socio-economic impact and ethical relevance. If you have already reviewed projects in these fields as a REC member or if you have other experience in performing ethical reviews of emerging technology research, it would be great if you could share your experiences with us in this short survey - it should take 15-20 minutes of your time.

In the main section, we ask general questions about ethical reviews for emerging technology research. The other sections are dedicated to three technology families; the TechEthos project focuses on Neurotechnologies, Digital Extended Reality and Climate Engineering. You can leave these sections open if they are not relevant to you.

Please complete the survey by April 30, 2023. Thanks very much for your support!

We will use your anonymized responses in a report we are writing for the TechEthos project. The findings of the report will also feed into work EUREC conducts in other projects, especially PREPARED and iRECS. Please confirm that you understand and agree by clicking below.

◯ I agree.

General questions

1. What is your primary disciplinary background?
2. Are you or have you been a member of a Research Ethics Committee (REC) or another body performing ethical reviews of research (e.g., Institutional Review Board – IRB)? If so, please specify the type of body you belong to. If you belong to more than one REC, please list all.
3. What are the main fields covered by your REC or other ethical review body? (If you belong to more than one REC, please tick all the relevant boxes.)

   Check all that apply.

   ☐ Medical ethics, clinical trials Health-related research
   ☐ Biotechnology
   ☐ Social sciences and humanities
   ☐ Technology
   ☐ Data science
   ☐ AI and robotics
   ☐ Natural sciences
   ☐ Engineering
   ☐ Other:_____

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4. TechEthos is focusing on three research fields with high socio-economic impact. **In which of these fields, if any, do you have experience as an ethics reviewer?**

Check all that apply.

- ☐ Neurotechnologies (e.g. deep brain stimulation, optogenetics, fMRI with machine learning, brain–computer interfaces)
- ☐ Digital extended reality (e.g. virtual reality, augmented reality, avatars and the metaverse, digital twins, chatbots, natural language processing)
- ☐ Climate engineering (e.g. bioenergy with carbon capture and storage, enhanced weathering, ocean fertilisation)

5. Which other emerging technology research fields with high socio-economic impact do you have experience in as an ethics reviewer?

6. Which of the following ethical issues do you feel comfortable addressing when reviewing research related to new and emerging technology?

Check all that apply.

- ☐ Informed consent: Ensuring that participants are fully informed of the potential risks and benefits.
- ☐ Risks and benefits for research participants: Assessing the risks and benefits for individual participants.
- ☐ Social and ethical impact: Assessing the broader social and ethical implications of the research project.
- ☐ Data protection, privacy and confidentiality of research participants: Ensuring that appropriate measures are in place to protect the privacy and confidentiality of research participants.
- ☐ Data protection, privacy and confidentiality of potential users of the technology: Ensuring that appropriate measures are in place to protect the privacy and confidentiality of the potential users of the technology to be developed.
- ☐ Bias and fairness: Ensuring that the planned research is conducted in a fair and unbiased manner.
- ☐ Dual use: Ensuring that researchers consider the potential dual use of the technology under development and take steps to prevent their misuse.
- ☐ Other: _

7. What do you think about potential **challenges RECs might face** with regard to new and emerging technology research? (Please indicate whether you agree or disagree for each statement below.)

8. RECs should consider the societal effects of research related to new and emerging technology.

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Mark only one oval.

strongly disagree

1

2

3

4

5

strongly agree

9. RECs should help to ensure ethics by design when dealing with research related to new and emerging technology.

Mark only one oval.

strongly disagree

1

2

3

4

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5

strongly agree

10. RECs should advise researchers throughout the research lifecycle rather than just during the design phase when dealing with research related to new and emerging technology.

Mark only one oval.

strongly disagree

1

2

3

4

5

strongly agree

11. RECs lack the resources, expertise, and training to appropriately address the risks that emerging technology research poses.

Mark only one oval.

strongly disagree

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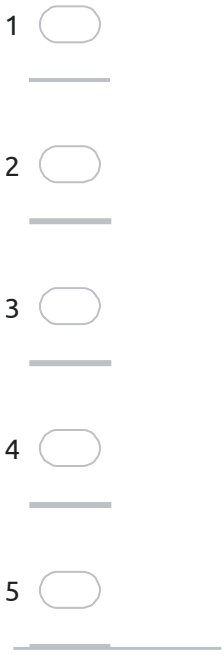

12. If a REC is lacking the competence to review a research project related to new and emerging technology, e.g. because societal and long-term effects cannot be assessed appropriately, what should the REC do?

13. RECs in health-related fields often use **guidance documents** as a basis for their review, e.g., the Guide for Research Ethics Committee Members developed by the Council of Europe, The Good Clinical Practice (GCP) Guideline and the CIOMS guidelines.

    These documents provide guidance on various aspects of research ethics, including **informed consent, risk-benefit assessments, confidentiality, privacy, and data protection**.

    In your opinion, what is missing in these guidelines to be able to review research projects that are not primarily focussing on the protection of research participants?

14. Which **guidance documents** are particularly useful for REC members or ethical reviewers when reviewing research projects in emerging technology?

15. What **resources** (in terms of funding, human resources, expertise, institutional support, etc.) are necessary to perform adequate reviews of projects in the field of emerging technology?

16. In many countries, ethics approval by a REC is mandatory for research involving human subjects. Which types of emerging technology projects should be reviewed by a REC?

    Check all that apply.

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- ☐ All projects that involve research with human participants must get ethics approval by a REC.
- ☐ If research projects do not involve human participants, ethics approval by a REC is not necessary
- ☐ All projects that are likely to have high societal impact must get ethics approval.

17. Who should be responsible for deciding whether or not a review by a REC is necessary if no legal obligations for review exist?

Check all that apply.

- ☐ Research funding organisations
- ☐ Publishers
- ☐ Research institutions where the researcher leading the research is based
- ☐ Researchers and innovators
- ☐ Conference organisers
- ☐ Other:_____

Neurotechnologies

Please answer the following questions only if you have experience with or expertise in research projects in the field **neurotechnologies**. If not, please click "Next" at the bottom of this page.

18. What are the most common challenges RECs or other ethical review bodies are dealing with in the context of research in the field **neurotechnologies**?
19. Which **guidance documents or guidelines** are particularly helpful for reviewing research projects with a focus on **neurotechnologies**?
20. Are you aware of RECs or other ethical review bodies that regularly review research proposals in the field of neurotechnologies? If so, please note their names.

Digital extended reality

Please answer the following questions only if you have experience with or expertise in research projects in the field of **digital extended reality**. If not, please click "Next" at the bottom of this page.

21. What are the most common challenges RECs or other ethical review bodies are dealing with in the context of research in the field **digital extended reality**?
22. Which **guidance documents or guidelines** are particularly helpful for reviewing research projects with a focus on **digital extended reality**?

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23. Are you aware of RECs or other ethical review bodies that regularly review research proposals in the field of digital **extended reality**? If so, please note their names.

Climate engineering

Please answer the following questions only if you have experience with or expertise in research projects in the field of **climate engineering**. If not, please click "Next" at the bottom of this page.

24. What are the most common challenges RECs or other ethical review bodies are dealing with in the context of research in the field **climate engineering**?
25. Which **guidance documents or guidelines** are particularly helpful for reviewing research projects with a focus on **climate engineering**?
26. Are you aware of RECs or other ethical review bodies that regularly review research proposals in the field of climate **engineering**? If so, please note their names

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