Funded by the European Union

D2.3: Recommendations to address ethical challenges from technology research outside the EU

[WP2 – Ethical challenges of new technologies and ethics review processes]

Lead contributor	Miltos Ladikas, Claudia Brändle, Maria Maia, KIT
	miltos.ladikas@kit.edu
Other contributors	Wei Zhu, Yalin Wang, FDU
	Vygintas Aliukonis, VU
	Francis Kombe, ETHIXPERT NPC
	David Shaw, UM

Due date	30 September 2024
Delivery date	25 August 2024
Type	R — Document, report
Dissemination level	PU - Public
Keywords	Ethics reviews, non-EU, ethics guidelines, biobanking, artificial intelligence, extended reality, genome editing

Funded by the European Union

Funded by the European Union. UK participants in Horizon Europe Project irecs are supported by UK Research and Innovation grant numbers 10055935 (University of Central Lancashire) and 10037820 (De Montfort University). Views and opinions expressed are however those of the author(s) only and do not necessarily reflect those of the European Union or the Research Executive Agency or UKRI. Neither the European Union nor the granting authority nor UKRI can be held responsible for them.

Funded by the European Union

Funded by the European Union

Abstract

irecs is a Horizon Europe project tackling the ethical challenges of research in new technologies. It aims to reinforce the reliability of science by advancing research ethics expertise and competencies. Its goal is to improve the understanding of research ethics in Europe (and beyond) and provide interactive and sustainable training programmes for research ethics committees.

The project focuses on 4 emerging technologies (AI in health and healthcare; Extended reality; Genome editing; Biobanking) and develops, implements and disseminates training material for research ethics reviewers and early career researchers.

This report deals with ethics review processes that take place outside of Europe. Taking into consideration that new and emerging technologies are basically stateless, have a global impact, and create strong interdependencies amongst nation states around the world, it is imperative to provide a view on ethics beyond the limited bounds of Europe.

As part of WP2 that looks at ethical challenges of new technologies and ethics review processes in Europe, the report builds upon this work and expands the discussion to include perspectives from outside the European continent via quantitative (survey) and qualitative (interviews) methodologies. Based on previous research that identifies the main values and norms that influence the incorporation of ethics in official Science & Technology decision making around the world, we hereby offer a thorough analysis of ethical challenges that non-European ethics review processes are faced with. Particular attention is paid on non-European cultures represented in the project, namely those of Africa and China. Finally, recommendations on how to approach international collaborations on ethics is provided.

Funded by the European Union

Document history

Version	Date	Description	Reason for change	Distribution
V0.1	06 August 2024	First Draft	Outline and first draft by Miltos Ladikas	16 August 2004
V0.2	23 September 2024	Final Version	Feedback and Comments	24 September 2024

Information in this report that may influence other tasks within the project

Linked task	Points of relevance
Task 2.4	Analysis of ethics review processes and proposals for their adaptation
Task 3.2	Implementation of stakeholder engagement strategy
Task 4.3	Ongoing improvements and adaptation of training materials and translations
Task 5.4	Build a sustainable dissemination and exploitation alliance
Task 7.3	Building an irecs community

Table of contents

Funded by the European Union

Funded by the European Union

Executive summary

irec's mission is to enhance the reliability of science by advancing expertise and competencies in research ethics. It aims to improve the understanding of research ethics across Europe and beyond, focusing on four emerging technologies: artificial intelligence in health and healthcare, extended reality, genome editing, and biobanking. This report examines the ethics review process as conceived and conducted outside of Europe. It complements other project activities that address the ethical challenges of new technologies and ethics review processes within Europe, by extending the discussion to include perspectives from outside the European context. This broadening perspective to consider ethics beyond Europe's borders is crucial given that new and emerging technologies are inherently global, impacting and creating interdependencies among nations worldwide.

The report starts with reviewing relevant work that identifies dominant values in different cultures that inform the creation of an ethics decision making system. The example of Europe, India and China is used to showcase commonalities in value systems that can potentially create a common global ethics perspective in new and emerging technologies. This can be achieved by generating a continuum of values that, although seemingly different, refer to the same understanding of ethics.

Furthermore, we have undertaken a public survey on expert perceptions of the ethics review process, that provides us with comparisons between European and non-European perspectives. An interesting divergence is that traditional ethics review is much more highly prevalent in Europe, with higher incidence of post-approval monitoring in non-EU regions. In terms of factors hindering assessment of technologies, a significant majority of non-EU respondents mentioned lack of training, guidelines and technical/scientific knowledge in the biotechnology group of technologies. Lack of funding, particularly in Africa, is a crucial challenge for the smooth functioning of research ethics committees.

Following this analysis, we performed a series of personal interviews with non-EU experts for an in-depth analysis, aiming to understand possible gaps in ethics review processes with questions revolving around the availability of guidance documents for ethics reviews, cultural differences in ethics perspectives, and capacity building needs for ethics review bodies. We have found an overall satisfaction with how ethics reviews have developed throughout the years as a significant aspect of the research process. The main challenges are lack of funding for ethics committees that can create serious issues with effectiveness and fairness of the process, lack of national capacities in some new technologies (e.g. genome editing or Artificial Intelligence) that create gaps in ethics committees' knowledge and possibilities to expand their expertise, and the "westernisation" of ethics whereby there are few attempts to understand local variations of ethics concepts.

Moreover, we undertook a case-study analysis of Africa and China, in order to achieve a more detailed analysis of the historical perspective and the state-of-the-art in ethics reviews as a compliment to the previous research. Africa's particularities of traditions and norms that result in different ethics perspectives, are encompassed in the concept of Ubuntu that does not translate in European ethics, but has a direct influence in how ethics is viewed and applied. It describes a strong communitarian approach to ethics with ramifications in terms of consent procedures that many times come in direct conflict with European ethics guidelines. On the other hand, China's rapid development in research

ethics capabilities hides a number of pitfalls such as, the lack of knowledge of ethics standards and ethics knowledge by researchers themselves. In addition, as existing national ethics guidelines are usually a translation of the original European ones creates difficulties in incorporating national values such as the value of Harmony that is a widespread concept of moral decision making in the country.

Finally, we provide a list of recommendations for action, based on the analysis done so far. The recommendations are to enhance interdisciplinarity and intercultural capacities in Research Ethics Committees, provide capacity building for resource-poor RECs, develop research capabilities on global values and norms, establish regular global research ethics workshops, promote ethics by design systems, and stimulate research on big data and social sciences.

List of figures

List of tables

List of acronyms/abbreviations

Abbreviation	Explanation
AI	Artificial Intelligence
WP	Work Package
Del	Deliverable
GDPR	General Data Protection Regulation
IP	Interview Partner
LIA	legitimate interest assessment form
EC	European Commission
IRBs	Institutional Review Boards
HCRs	Early Career Researchers
HEIs	Higher Education Institutes
RPOs	Research Performing Organizations
RFOs	Research funding organizations
EU	European Union
DEC	Dissemination, Exploitation and Communication
SAB	Stakeholder Advisory Board
REC	Research Ethics Committee
R&D	Research and Development
S&T	Science and Technology
XR	Extended Reality, Immersive Technologies
BB	Biobanking
GE	Genome Editing

Table 1: List of acronyms/ abbreviations

Funded by the European Union

1. Introduction

1.1 Background

A key objective of national and European Union (EU) research policy is to ensure compliance with the highest standards of research ethics. Given the impact of research on society, in terms of potential to generate innovative solutions to problems, and yet with the associated risk of harm, rigorous ethical research conduct is essential to ensure public trust in the scientific endeavour.

Assuming the premises that: research ethics process is facing increasing challenges at a global level due to, for instance, the challenges presented by new and emerging technologies to ethics reviewers, who may be unskilled in the relevant fields; the increased internationalisation of research that has led to fears of ethics dumping; and the lack of standardisation across Europe and the world, the irecs (improving Research Ethics Expertise and Competencies to Ensure Reliability and Trust in Science) project addresses these problems by:

- scanning and mapping existing needs raised by new and emerging technologies in European and global research ethics communities
- producing and implementing training materials for European and global audiences in research ethics communities
- conducting and permanently establishing training programmes
- proposing adaptations to the research ethics process in Europe.

With its unique blend of expertise, its global partners and the involvement of European research ethics networks as partners or members of the Stakeholder Advisory Board, irecs includes 7 work packages that develop in three phases of the project (analysis, development, implementation) and a sustainability and impact strategy. Each phase is targeted towards developing and implementing irecs' key outputs of training materials, an ethics issues dataset, proposals for the adaptation of ethics review processes, an implementation guide for Higher Education Institutes (HEIs) and Research Performing Organizations (RPOs), and guidance on stakeholder involvement in ethics review processes.

The analysis phase considers challenges to ethics review processes arising from new technologies and relating to international issues (e.g. ethics dumping, bilateral technology research). The main part of this phase is conducted under Work Package WP2 "Ethical challenges of new technologies and ethics review processes". WP2 lays the analytical foundation and develops proposals for adapting ethics review processes. There are three main objectives in this WP:

- Identify main ethical and legal challenges and perform systematic mapping of new technologies with high socioeconomic impact.
- Analyse specific challenges arising from research activities involving new technologies in collaboration with partners, including stakeholders outside the EU to identify risks related to the globalisation of research.
- Identify needs to be addressed in training and the ethics review process and propose adaptations of the ethics review process.

To achieve these objectives, four tasks were defined. In the first task the selection of technologies of focus in irecs was conducted. Details of the process can be found in Deliverable 2.1 "Report on case studies"[1]. The irecs consortium has selected four technologies: Artificial Intelligence (AI) in health and healthcare, Biobanking, Genome-Editing and Extended Reality. These technologies pose numerous challenges in terms of ethical assessment for Research Ethics Committees (RECs) members and EU ethics appraisal scheme experts.

In Task 2.2., recommendations for addressing ethical challenges from research in new and emerging technologies were developed and compiled in Deliverable 2.2[2].

Task 2.3 "Development of recommendations for addressing ethical challenges in technology research outside the EU" and Task 2.4 "Analysis of ethics review processes and proposals for their adaptation" complement each other. While Task 2.3 focuses on identifying ethics challenges in global technology research, and differences in value systems and decision-making processes with the aim of avoiding ethics dumping, drawing on findings from relevant projects, insights from global technology assessment and non-EU partners, Task 2.4 focuses on collecting data on experiences, needs and gaps in the ethics review process and preferred methods of training.

1.2 The deliverable 2.3

As a result of Task 2.3, the present deliverable 2.3 titled "Recommendations to address ethical challenges from technology research outside the EU" addresses ethical challenges of technology research outside the EU that trainings and possible adaptations of review procedures need to consider. This deliverable is the outcome of qualitative and quantitative research into the training needs for RECs members and EU ethics appraisal scheme experts.

Because many of the ethical challenges in technology research are related to the increase of multi-centre projects spanning different regions of the world, the irecs consortium includes international consortium partners, namely Fundan University (FDU) from China and EthiXPERT from Africa. While communities in low- and middle-income countries, such as in many African countries, often face the risk of becoming the victims of ethics dumping, vibrant rising economies like China and technologically advanced countries like South Korea are less at risk of being treated as unequal partners in global research and innovation collaborations. However, their societies are based on value systems that to varying degrees diverge from fundamental European values so that ethics reviews of multi-centre research projects with partners from different regions of the world require a high degree of sensitivity and inter-cultural awareness. To ensure irecs addresses ethical challenges related to the increasing

[1] Resseguier, A., Naserianhanzaei, E., Mijatovic, A., Chatfield, K., Spyrakou, E., Proske, D., Aucouturier, E., Grinbaum, A. (October 2023) *Report on the case studies, irecs project D2.1.*
[2] Aucouturier, E., Grinbaum, A., et al. (November 2023) irecs D2.2 "Recommendations to address ethical challenges from research in new technologies".

globalisation of research in an appropriate manner, all international partners were integrated in the development of Task 2.3 and have contributed to the present deliverable.

1.3 Approach and Structure of the document

Desk research was firstly conducted to identify the state-of-the-art in international discussions on ethics, values and ethics review processes. Relevant project outputs (e.g. GEST, TRUST) were reviewed to detect primary data analysis that has direct applicability to our aims. In addition to desk research and considering research methods on strategies of inquiry, two strategies were chosen to collect data: an online questionnaire and semi-structured interviews.

The adopted strategies lead to two different research methods: quantitative and qualitative. For this reason, the **mixed method approach** was considered, since it incorporates elements of both qualitative and quantitative approaches[3]. In addition, justification for a mixed-method approach[4] is also based on combining qualitative and quantitative data to triangulate findings in order to uncover mutual corroborations and develop a more comprehensive account of the area of enquiry.

Quantitative data

To understand how Research Ethics Committees (RECs) and other ethics experts approach ethical reviews of research AI in health, extended reality, biobanking, and genome editing, an online survey was conducted from 02.02.24 to 02.04.24 The survey was developed under Task 2.4: Analysis of ethics review processes and proposals for their adaptation, led by the Vilnius University and the University Medical Center Amsterdam[5].

The target groups were the European Network of Research Ethics Committees (EUREC) network, the European Network for Research Ethics and Integrity (ENERI) e-community, the European University Association (EUA) Research & Innovation Strategy Group (Rectors or Vice-Rectors for Research) and the European Association of Research Managers and Administrators (EARMA). The questionnaire was set online and managed by the company RAIT GROUP, an independent market research company. The

[3] Creswell, John W. 2015. *A Concise Introduction to Mixed Methods Research*. Sage Publications, Inc.

[4] Bryman, Alan. 2006. "Integrating Quantitative and Qualitative Research: How Is It Done?" *Qualitative Research* 6 (1): 97–113. https://doi.org/10.1177/1468794106058877; Fielding, Jane, and Nigel Fielding. 2008. "Synergy and Synthesis: Integrating Qualitative and Quantitative Data." In *The Sage Handbook of Social Research Methods*, edited by Pertti Alasuutari, Leonard Bickman, and Julia Brannen, 555–71. Trowbridge: Sage Publications.; Brannen, Julia. 2005. "Mixing Methods: The Entry of Qualitative and Quantitative Approaches into the Research Process." *International Journal of Social Research Methodology* 8 (3): 173–84. https://doi.org/10.1080/13645570500154642.

[5] For more detailed information on the methodology and full results of the questionnaire please consult Del. 2.4: Proposals for adaptation of ethics review Processes (forthcoming).

questionnaire encompassed both closed and open questions. In total, 242 responses were collected, of which 149 were completed. In terms of geographic distribution, 187 responses were from Europe, 29 from China, 17 from Africa and 9 from other regions. Results of the questionnaire were analysed by the external company, who provided a full comprehensive report with the outcomes. The database was used in addition to make a comparison between EU and non-EU participants.

Qualitative data

Semi-structured interviews were conducted with the purpose of collecting experts' personal views. The focus of the interviews was centred on international experience with RECs, in order to provide complimentary knowledge to the EU-focused approach of the irecs project, with the aim to identify the commonalities and especially the differences between EU and non-EU REC experiences and challenges.

The strategy used was a convenience sampling, meaning that a a relatively purposed number of experts were selected[6], in order to provide particularly valuable information related to the above-mentioned aims. Participants were selected taking into consideration their role and involvement in ethics reviews. Inclusion criteria concerned: (i) extensive experience with international RECs and/or (ii) current or former members of RECs. Having knowledge about the core technologies relevant in the irecs project was desirable but not mandatory.

As this is a non-probability sample, it is not reasonable to extrapolate the results to the entire study population[7]. It was not the aim of the research to have statistical representativeness of the subjects. The aim of the sample in this research is to select participants who can best provide information in order to aid a better understanding of the central phenomena at stake. In total 10 interviews with experts were conducted between January and February 2024. 9 interviews were conducted virtually and 1 interview was conducted in written form as the interview partner felt more comfortable with this solution due to the language barrier. Virtual interviews were held via Microsoft teams or Zoom with a duration between 30 and 60 minutes. Informed consent was collected, and anonymity, privacy and confidentiality were assured to the interviewees.

[6] Tashakkori, Abbas, and Charles Teddie. 2009. "Integrating Qualitative and Quantitative Approaches to Research." In *The SAGE Handbook of Applied Social Research Methods*, edited by Leonard Bickman and Debra J. Rog, 2nd editio, 283–317. Los Angeles: Sage.

[7] Henry, Gary T. 2009. "Practical Sampling." In *The SAGE Handbook of Applied Social Research Methods*, edited by Leonard Bickman and Debra J. Rog, 2nd Ed., 77–105. Los Angeles: Sage.

A guideline for the interview was established, based on the survey "RECs and emerging technology research" developed by the EU-funded project TechEthos on its Deliverable 5.4 Criteria for ethical review by RECs in emerging technology research [8].

Although the interview was held in a more informal setting, the guideline helped to assure that the interview topics were focused, but providing the interviewer some liberty to explore a topic or further develop another issue raised by the interviewee[9]. The complete list of interview questions can be found in Annex 2.

The interview questions can be divided into two parts: 1) Part one focuses on general questions about RECs and addresses topics like guidance documents (existing guiding documents, gaps in these documents and guidance documents for emerging technologies), necessary resources for RECs, appropriate topics for RECs and the responsibility for their selection and value differences between EU and non-EU countries, and 2) part two focuses on international experience of RECs with the four core technologies featured within irecs: AI in healthcare, extended reality, genome editing and biobanking. Here, the questions revolve mainly around the existence of guidance documents and common challenges faced by RECs where these specific technologies are reviewed. The reasoning for the questions is described in Table 3.

The interviews were audio recorded and transcribed by the researchers, using Microsoft Word. The analysis of the interviews was made using a content analysis approach, a strategy that serves to identify a set of characteristics essential to the meaning or definition of a concept[10], an empirically grounded method, exploratory in process, and predictive or inferential in intent[11]. All interviews were coded in order to maintain the anonymity of the interviewees (e.g. IP1, IP2, IP3…).

A deep and careful first reading of the interviews was carried out, where the pre-established thematic areas were identified, and since these were semi-directed interviews, the sub-thematic areas that emerged during the interviews were also identified, aiming at a better organization of the text. Synopses of the interviews were organized in tables using Microsoft Excel. Synopses are syntheses of

[8] The project TechEthos – Ethics for Technologies with High Socio-Economic Impact, aimed at reviewing emerging technologies and the ethical issues these raise. The project developed an ethics framework and identified how to best support the research community in integrating the ethics dimension into their research. For more information on the project, please visit: https://www.techethos.eu/ (accessed in Setptember 2024). For more information on Deliverable 5.4, please visit: https://www.techethos.eu/wp-content/uploads/2023/11/TechEthos_D5.4.pdf (accessed in September 2024).

[9] Marconi, M.D., and E.M. Lakatos. 2002. *Técnicas de Pesquisa: Planejamento e Execução de Pesquisa. Amonstragens e Técnicas de Pesquisa - Elaboração, Análise e Interpretação de Dados*. 5a ed. São Paulo: Atlas.

[10] Fortin, Marie-Fabienne. 1999. *O Processo de Investigação - Da Concepção à Realização*. Loures: Lusociência - Edições Técnicas e Cientificas, Lda.

[11] Krippendorff, Klaus. 2013. *Content Analysis: An Introduction to Its Methodology*. 3rd ed. Sage Publications, Inc.

the speeches given by the interviewer, containing the essential message of the interview[12]. For all interviews informed consent was obtained. For the online interviews the informed consent was recorded before the meeting took place. For the written interview, the consent was obtained in a written form, via email.

[12] Guerra, Isabel Carvalho. 2006. *Pesquisa Qualitativa e Análise de Conteúdo*. Estoril: Princípia Editora.

Funded by the European Union

2. Ethics and values around the world

2.1 International perspectives on ethics

When dealing with ethics at an international level, there are certain parameters that one needs to take into consideration. Notwithstanding the fact that debates around ethics are very active in every country that the irecs project represents (and of course beyond these countries), there is still a need to define commonalities in our perceptions of what ethics is. The first step is to recognise that ethics is the cornerstone of responsibility. This is true when actions relate to everyday activities or promote a particular technological development. The next step is to acknowledge that ethics is a guiding policy principle. This is akin to the first step with the difference that it relates specifically to its use by policy makers and policy shapers. This is particularly relevant to the project objectives as it involves a key stage of applications of ethical principles. Policies on new technologies are guided by ethics and so are processes of ethics reviews. Also, there is and always will be a certain vagueness about the discussions on ethics. Definitions are not strict and concepts are not well defined in this realm. But there is nevertheless a strong appeal that makes it a powerful decision tool. Finally, when looking beyond the constraints of our immediate context, we see that ethics is the result of significant influences of the main culture, the dominant norms and even the current affairs that are to be found in every geographical and socio-political context.

One further aspect that is to be clarified is the need to have an international perspective on ethics. Considering the multitude of perceptions, values, norms, policy systems, it is a daunting undertaking that should not be taken lightly. But there is no real alternative to it. Globalisation has made it impossible to overlook differences in such matters. In the area of Science & Technology (S&T) there has been an exponential growth of international collaborations in the last decades. Every discipline and Research & Development (R&D) sector is affected directly and significantly by increasing international collaborations and this is more evident in the top 15 R&D active global players[13]. This trend has in turn created interdependencies between countries, particularly in sectors with rapid technological development trajectories (i.e. artificial intelligence, biotechnology, etc.). And although sometimes such dependencies have created political conflicts (e.g. see conflicts on microprocessors development and trade), there is a general acceptance that international collaborations enhance the effectiveness of S&T and the overall rate of innovation. However, when it comes to ethics and how this is applied in different contexts, international collaborations can lead to unwanted consequences. The most significant side-effect of this is “ethics dumping”, meaning the purposeful decision to defer ethics decisions to the least strict and most permissive member of the collaborative activity. This is a real

[13] https://direct.mit.edu/qss/article/4/4/938/117918/A-half-century-of-global-collaboration-in-science (accessed in September 2024)

problem that has been acknowledged as a major contributor to the dilution of ethics principles in S&T[14].

2.1.1 Definition of global ethics

There is already a number of attempts to look at comparisons between countries in terms of the implementation of ethics principles in S&T decision making[15]. Paramount amongst them was the project GEST (Global Ethics in Science and Technology Policy) that analysed in detail the constituents of ethics principles in Europe, China and India[16]. This included the analysis of social determinants that influence the general perception of ethics, analysis of the most dominant values systems in each region, and identification of best practices in the incorporation of ethics in new technologies.

When one attempts to look at ethics at an international level, there is a need to define it anew, as it is clear that perspectives on what is ethics differ between countries. Without seeking to discuss this matter further, one can adopt a definition that has been developed by a number of experts in S&T ethics, after long deliberations[17]:

"S&T ethics refers to a common public platform for deliberation and discussion of S&T issues that is an expression of the dominant values in society, is based on lay perceptions of right and wrong, and informs policy making"

This definition includes all the parameters that one needs to take into consideration when lifting ethics from a strictly delineated cultural background to a higher level of multi-cultural perspective. It is in this sense that ethics becomes the focus of public deliberations and it expresses the values system of each society. The question whether there are enough commonalities to allow us to form a common process of ethics deliberation is crucial and at the heart of this report.

[14] https://projects.research-and-innovation.ec.europa.eu/en/projects/success-stories/all/global-code-conduct-counter-ethics-dumping (accessed in September 2024)

[15] See Decker M, Ladikas M (eds) (2004) Bridges between science, society and policy: Technology assessment – methods and impacts. Springer Verlag, Berlin; Paula LE (2008) Ethics committees, public debate and regulation: an evaluation of policy instruments in bioethics governance. Ph.D. thesis. Free University, Amsterdam; Jesani A (2009) Ethics in ethics committees: time to share experiences, discuss challenges and do a better job. Indian Journal of Medical Ethics 6(2):62-63, Apr-Jun

[16] https://cordis.europa.eu/project/id/266592/es (accessed in September 2024)

[17] Ladikas, M., Chaturvedi, S., Zhao, Y. & Stemerding, D. (2015) Embedding Ethics in Science and Technology Policy; A Global Perspective. In M. Ladikas, S. Chaturvedi, Y. Zhao, & D. Stemerding (Eds) Science and Technology Governance and Ethics; A Global Perspective from Europe, India and China. Springer, Heidelberg. https://doi.org/10.1007/978-3-319-14693-5_5

2.1.2 The role of values in S&T ethics decision-making

It is clear that ethics cannot be perceived in isolation of the context in which it is expressed. A good way to depict how ethics decisions are made is to look at the role and location of values in the system[18]:

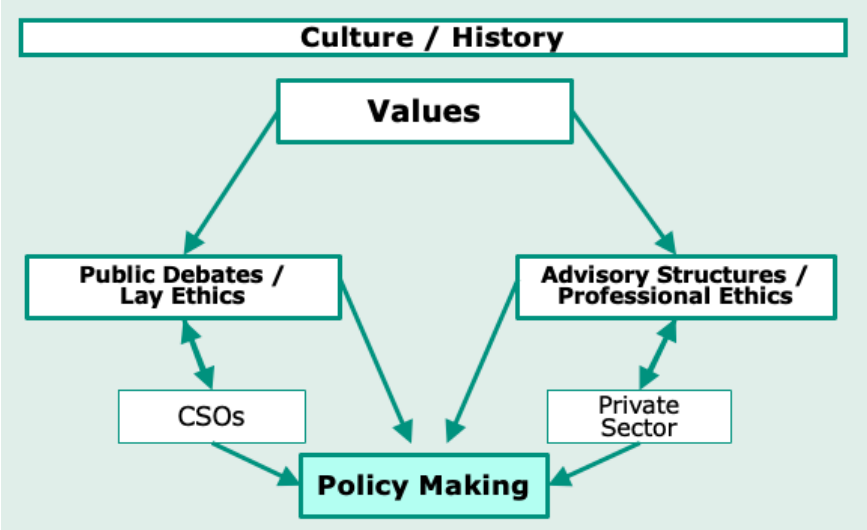

Figure 1: Incorporation of ethics in science and technology policy

If ethics is the result of dominant values in society, then these in turn derive from a deeper level of the historical and cultural context that creates the current perceptions of right and wrong. This level of analysis can go back hundreds or even thousands of years, evident in literature, art and in significant events that shape society's perceptions of world views and create a distinctly regional perspective on ethics. Although not an easy undertaking, the depth of such analyses can clarify issues and mitigate conflicts by better explaining arguments and decisions and therefore enhancing mutual understanding.

The dominant current values themselves are easily recognised as they are described in official documentation, including guidelines, strategy papers, policy white papers and more prominently, national constitutions and international treaties. But even when the values are described, they are not evident as a direct cause-and-effect in decisions. The reason is that there is a natural split in values perceptions between the academic and the lay world, in other words between formal and informal expressions of ethics.

[18] Ladikas, M., Chaturvedi, S., Zhao, Y. & Stemerding, D. (2015) Embedding Ethics in Science and Technology Policy; A Global Perspective. In M. Ladikas, S. Chaturvedi, Y. Zhao, & D. Stemerding (Eds) Science and Technology Governance and Ethics; A Global Perspective from Europe, India and China. Springer, Heidelberg. https://doi.org/10.1007/978-3-319-14693-5_5

Formal expressions of ethics take place via established advisory structures that range from ethics committees to think tanks. Ethics committees (that can be local, national or even supranational) will look at specific projects and specific issues but they might also be required to express a formal opinion about a wider ethics application. Think tanks that include high expertise in ethics will also advise governments on how to regulate ethics issues. In either case, the opinions are based on clear argumentation deriving from disciplinary knowledge and empirical evidence.

Informal expressions of ethics take place in the open, via media, social media, conversations, demonstrations, etc. For most people that lack relevant education that would allow them to substantiate an ethics opinion, the only way to take a stance is to simply express their disapproval directly, with the main argument being "I believe this is wrong". Such argumentation does not diminish the power of the stance or its effect in decision making. Many technological developments were not stopped by ethics experts but by lay people using informal ethics (e.g. see the debate on genetic manipulation of food). Since informal ethics do not have an identifiable structure, the main means to uncover and analyse them is via public perception surveys and qualitative research (i.e. focus groups, media analysis, etc.).

Finally, one should not underestimate the role that lobbying activities play in the final decision making. Ethics decisions have a direct and significant impact on the market. Businesses will lose or gain because of such decisions and are entitled to a representation in the discussions. This takes place via lobbying activities. The same is true for Non-Governmental Organizations and Civil Society Organizations that are considered representatives of interested citizens or even society at large. Their means to have a say in the discussions is also through lobbying activities. Both sides are active seekers of attention via argumentation that entails perspectives on dominant values.

2.2 Commonalities and differences in values

Empirical research has shown that there are different apparent perceptions of values in cultures around the world. The unique undertaking of the GEST project in this field that compared the dominant values in Europe, China and India, showed the complexity of the issue[19]. After analysing official S&T documentation (e.g. strategy plans, white papers, policy debates, etc.) in the three regions, the dominant values that guide the decision making in ethics were identified (Figure 2).

[19] Ladikas, M., Chaturvedi, S., Zhao, Y. & Stemerding, D. (2015, Eds) *Science and Technology Governance and Ethics; A Global Perspective from Europe, India and China*. Springer, Heidelberg. https://link.springer.com/book/10.1007/978-3-319-14693-5

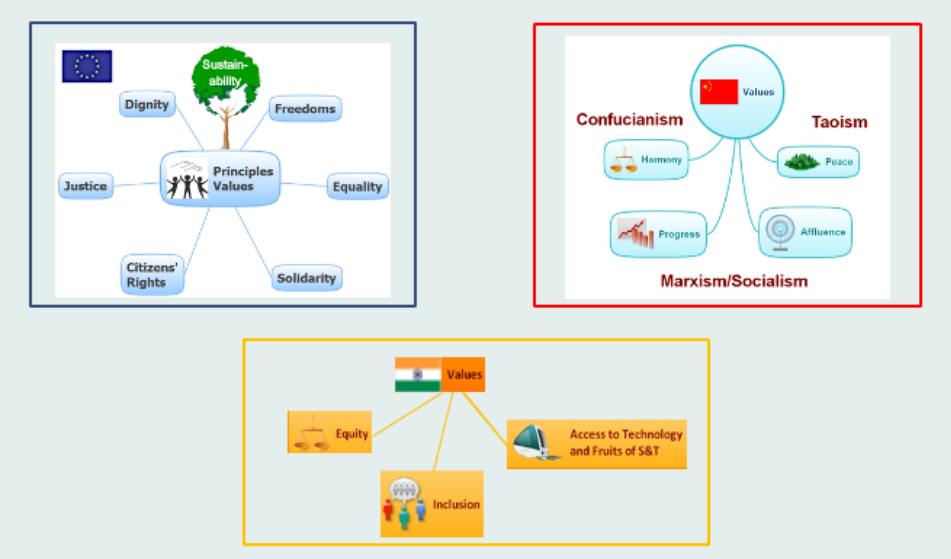

Figure 2: Values systems in Europe, India, China

In Europe, the main values of dignity, justice, equality, solidarity, citizens' rights and freedoms are identified[20]. In addition, the overarching value of sustainability seems to permeate all discussions about significant guiding values and deserves a special place in the current S&T debates. These values are enshrined in the official documentation overseeing the application of S&T in society and guiding perspectives of right and wrong in the process. In most cases it is easy to see how ethics decisions are influenced by these values. For instance, dignity, rights and freedoms of choice are all part of the standard consent procedures in research with human participants. Similarly, justice, equality and solidarity provide the guiding principles in cases that vulnerable people are involved in research. Finally, sustainability is an overall aim that any research should adhere to.

On the other hand, if one looks at the Chinese values, the values that are identified are not as easy to comprehend from the European perspective[21]. With a different ideological and cultural background (Confucianism, Taoism and Marxism) influencing the promotion of the dominant values and different linguistic roots, the main Chinese values are harmony, peace, progress and affluence. Although none of them are new concepts, it appears uncertain how they lead to ethics decisions. For instance, affluence is a value that is an aspiration for any fast-moving society that has only recently started

[20] Schroeder, D., Rerimassie, V. (2015). Science and Technology Governance and European Values. In: Ladikas, M., Chaturvedi, S., Zhao, Y., Stemerding, D. (eds) Science and Technology Governance and Ethics. Springer, Cham. https://doi.org/10.1007/978-3-319-14693-5_5

[21] Ma, Y., Zhao, Y., Liao, M. (2015). The Values Demonstrated in the Constitution of the People's Republic of China. In: Ladikas, M., Chaturvedi, S., Zhao, Y., Stemerding, D. (eds) Science and Technology Governance and Ethics. Springer, Cham. https://doi.org/10.1007/978-3-319-14693-5_6

accumulating material wealth. But it remains uncertain how an ethics decision can promote affluence per se, except if one sees it as equivalent to utilitarianism that attempts to enhance benefit for the greatest number of people possible under the given circumstances. Similarly, the value of harmony can be seen as equivalent to communitarian ethics whereby the benefit of the group supersedes that of the individual. In any case, Chinese values provide an intriguing perspective that needs further analysis.

Finally, in India the main values are equity, inclusion and access (to technology and the fruits of S&T)[22]. In this case, the values do not appear to be very different to the European ones, with one important difference. All dominant values point to the fact that the whole society should benefit and be included in the decision making. This is not an unknown inspiration to values such as equality, justice and solidarity. But in the case of India, they are the only values that matter. Individual rights and dignity are not to supersede the common good and societal development. One can argue that this is a common perspective in developing countries that uphold economic development, along with access to its benefits, as a key precursor for widespread wellbeing.

The differences that we see in values are clear and well-evidenced. This brings the question whether there are any commonalities that can be exploited in order to reach the desired aim of common ethics decision making processes. If we are to develop common collaborative research projects for the common good, how can we reach a common perspective on right and wrong in our undertakings, and where are we going to base this perspective upon? A possible solution could be to see the differences in values as a continuum and not as a black/white decision. This has been proposed as a basis for further international discussions on ethics[23].

As can be seen in Figure 3, all values analysed in the research on ethics in the three regions fit in continuum scales according to their common denominators. For instance, if the value of harmony can be interpreted as akin to community/group rights, the European value of citizens' rights falls in the same category, albeit on the other side of the continuum. Similarly, justice/equality can be depicted on one side of a continuum, where the other side contains access/equity. In this thinking, sustainability has a special role as it is universally acknowledged as an aspiration. As such, it can also form a

[22] Chaturvedi, S., Srinivas, K.R. (2015). Science and Technology for Socio-economic Development and Quest for Inclusive Growth: Emerging Evidence from India. In: Ladikas, M., Chaturvedi, S., Zhao, Y., Stemerding, D. (eds) Science and Technology Governance and Ethics. Springer, Cham. https://doi.org/10.1007/978-3-319-14693-5_7

[23] Ladikas, M., Hahn, J., Hennen, L & Scherz, C. (2019). Constructing a Global Technology Assessment- Its Constitution and Challenges. In: Hahn, J. & Ladikas, M. (eds). Constructing a Global Technology Assessment; Insights from Australia, China, Europe, Germany, India and Russia. KIT Scientific Publishing, Karlsruhe.

continuum with different perceptions of sustainability, one not relating to any other value (as an end in itself) and the other relating to the value of affluence as a related societal aspiration.

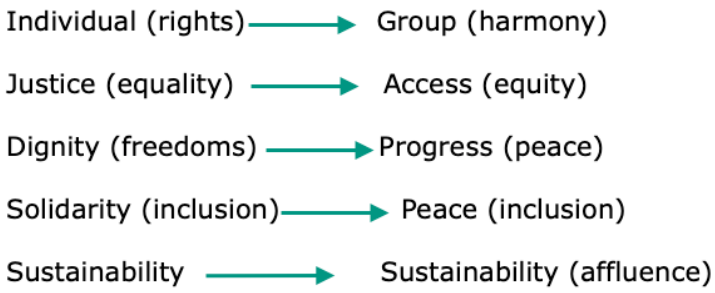

Figure 3: Values continuum in Europe, China, India

Relating values in this manner allow us to identify commonalities that can be put to good use in ethics decisions. There might be different ways of relating these values and there is certainly a different weight that experts can assign to one value and not the other. The main point though is to accept the relative dominance of values that does not exclude other interpretations that are based on national needs and are in accordance with deep-seated cultural prerogatives.

3. Public perceptions of S&T ethics and ethics reviews

The most direct way to uncover differences in perceptions of ethics is to ask people directly. The literature offers little in terms of public perceptions of ethics, values or norms, but it is evident that there are great cultural differences in public perceptions[24]. In irecs we had the unique possibility to run a survey on ethics and although this did not by any means involve national representative samples, it offers the possibility to compare perceptions from a variety of national and disciplinary backgrounds.

In order to get an overview of the current state-of-the-art in how ethics reviews are performed outside Europe and what challenges ethics reviewers are faced with, we have expanded the survey that was run as part of Task 2.4 "Analysis of ethics review processes and proposals for their adaptation" to include non-European respondents. In this manner we ensure a direct comparison between European and non-European perspectives. The online survey was conducted from February to April 2024 with the participation of 242 respondents in total, of which 149 completed the entire survey, while the rest have provided responses in parts of the survey. The survey aimed at understanding how Research Ethics Committees (RECs) and other ethics experts approach ethical reviews of emerging technologies, how they evaluate the ethics governance in their areas of work and what the challenges they are faced with when dealing with research in the fields of artificial intelligence (AI) in health and healthcare, extended reality (XR), biobanking (BB), and genome editing (GE) are. The full survey can be found in Annex 1.

3.1 Profile of survey participants

Based on the analysis of respondents' demographics, a significant majority of participants in this study work within Europe (77%). Comparatively, a much smaller portion originates from China, comprising 12% of the sample, followed by Africa with 7%. The remaining 4% come from various other global regions (Figure 4).

[24] Rerimassie, V., Ying, M., Srinivas, K.R. & Ladikas, M. (2015) Public Perceptions of Science and Technology in Europe, India and China. In M. Ladikas, S. Chaturvedi, Y. Zhao, & D. Stemerding (Eds) *Science and Technology Governance and Ethics; A Global Perspective from Europe, India and China*. Springer, Heidelberg. https://doi.org/10.1007/978-3-319-14693-5_5

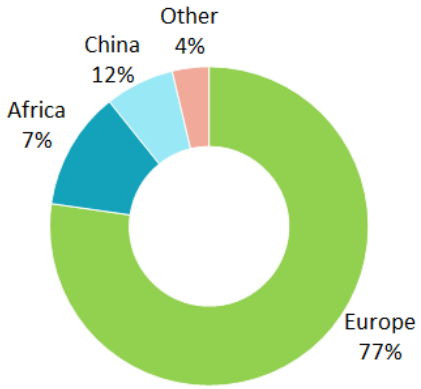

Figure 4: Respondents' demographics

Half of the participants have more than 6 years of experience in ethics assessment of research projects (Figure 5) and predominant disciplinary backgrounds among the respondents are biomedicine/health science (36%), social sciences (22%), as well as life sciences (15%) (Figure 6).

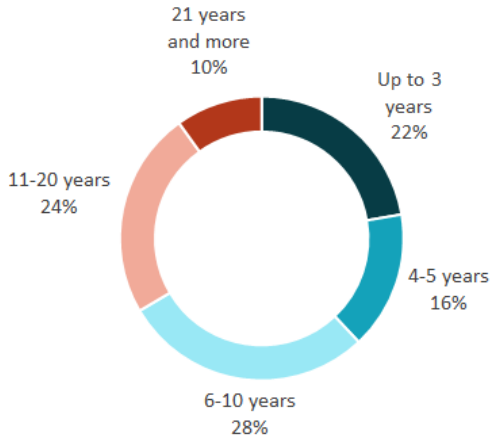

Figure 5: Respondents' experience in ethics assessment

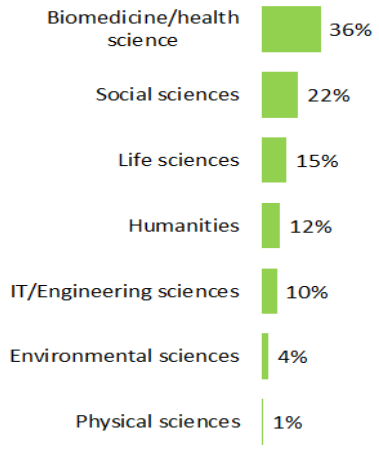

Figure 6: Respondents' disciplinary background

The largest segment of study participants comprises members of research ethics committees (RECs) (60%) (Figure 7). Nearly a third are EU ethics experts (33%), and a quarter are external ethics reviewers (not REC members) (26%).

Figure 7: Respondents' role in ethics assessment

Most of the study participants are involved in the ethical assessment of research projects centred on artificial intelligence in healthcare (60%) and human biobanking (63%). The lowest number of participants dealt with germline and somatic genome editing (17% and 20%, respectively) (Figure 8). This is not surprising, considering that germline and somatic genome editing require very advanced laboratory capabilities to train researchers that most developing countries do not possess.

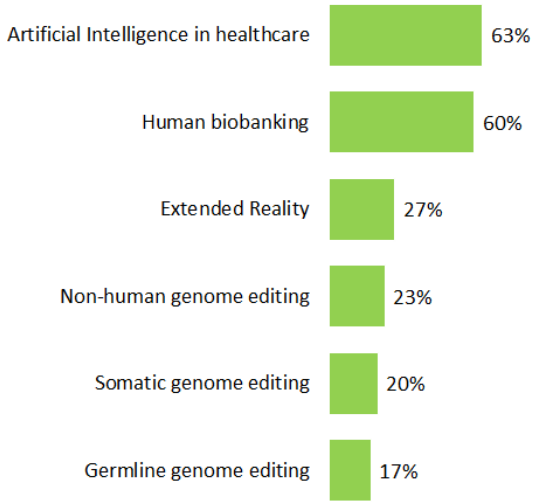

Figure 8: Respondents' fields of knowledge in ethical assessment

3.2 Evaluation of sufficiency of current ethics governance

Study results indicate that usual practice for applying ethics governance across different technologies is REC review before starting the research project followed by REC review and monitoring after approval (Figure 9).

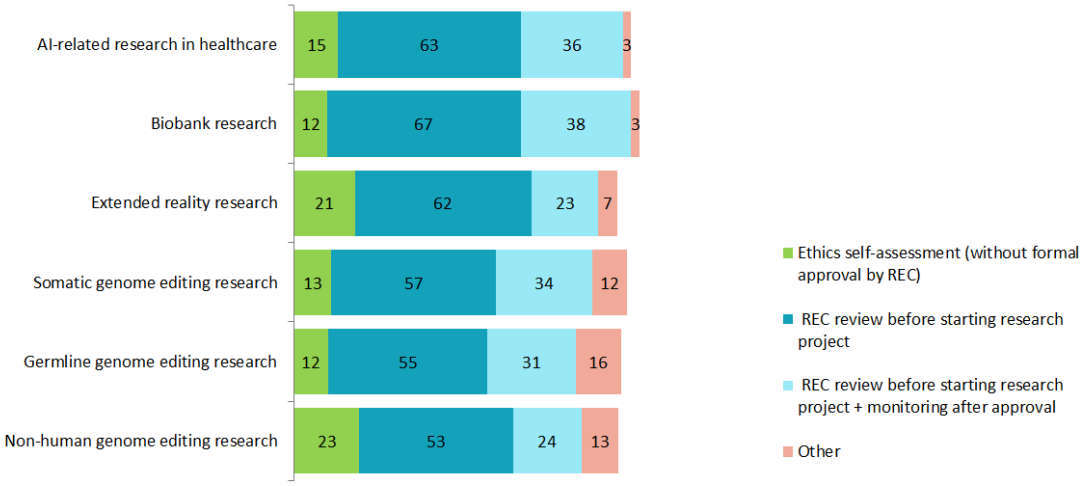

Figure 9: Practice of review activities across different technologies

However, there are considerable differences when the data is analysed separately for EU and non-EU respondents (Figure 10 – Figure 15). Traditional ethics review is more prevalent in Europe, while REC review and monitoring are more common in non-European countries. The overall distribution of the technology assessment might be skewed due to the large number of European respondents.

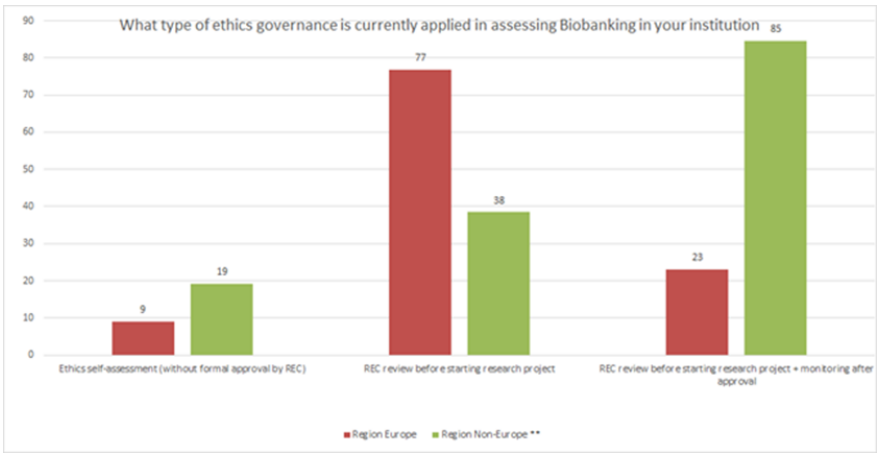

Figure 10: Type of governance currently applied in assessing Biobanking

Figure 11: Type of governance currently applied in assessing AI

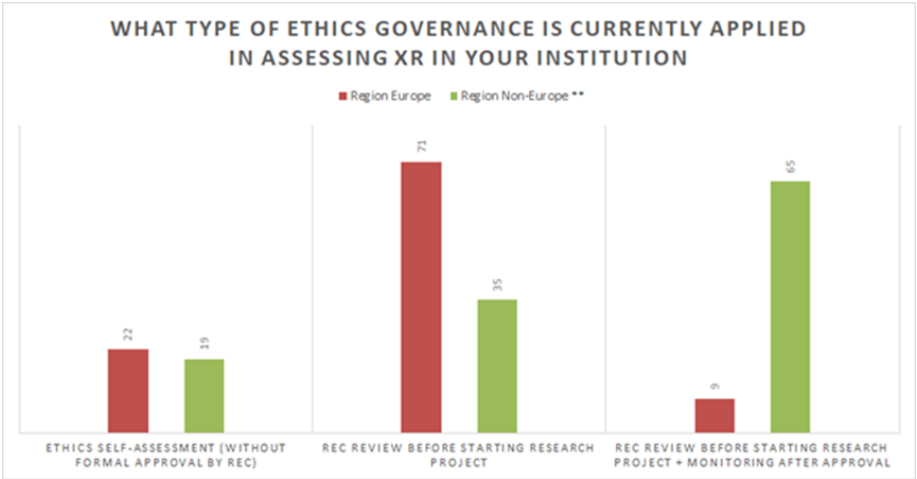

Figure 12: Type of governance currently applied in assessing XR

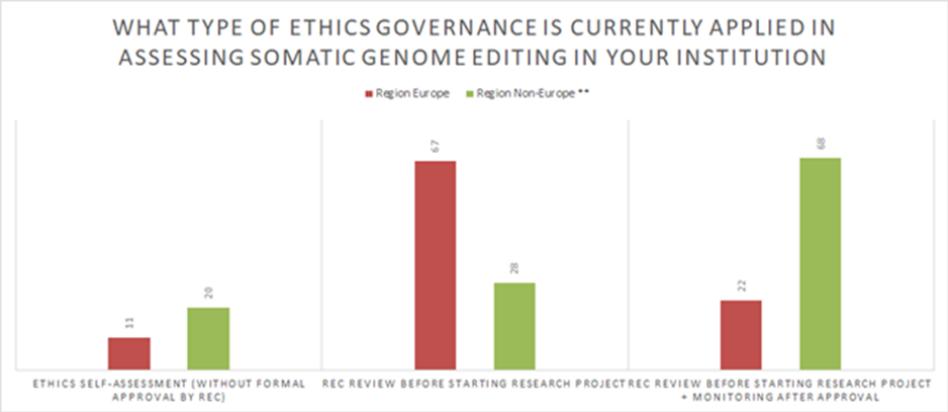

Figure 13: Type of governance currently applied in assessing somatic genome editing

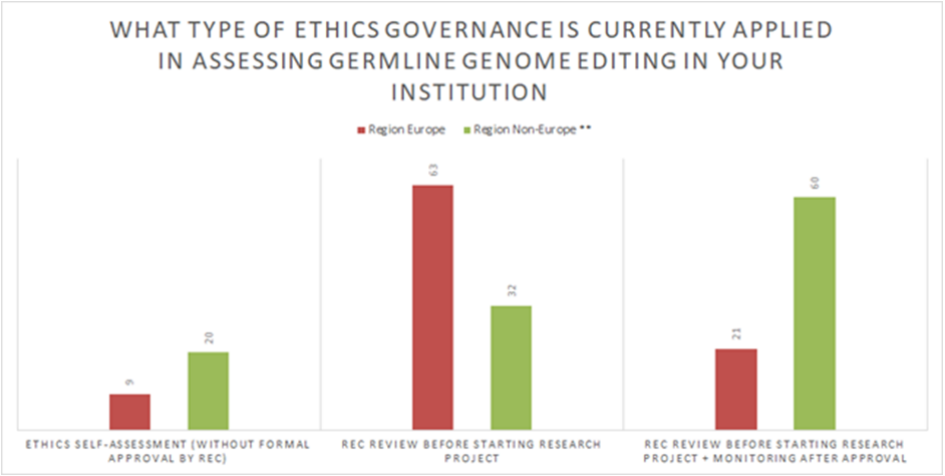

Figure 14: Type of governance currently applied in assessing germline genome editing

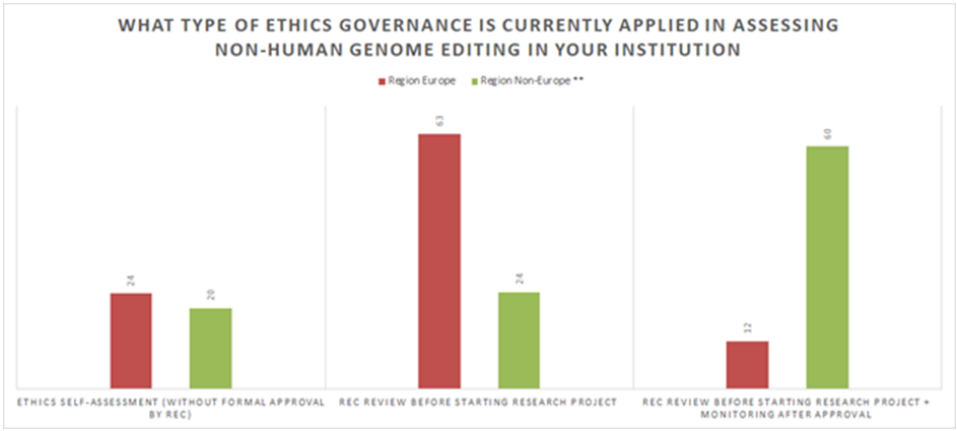

Figure 15: Type of governance currently applied in assessing non-human genome editing

3.3 Current ethics governance

The survey also reveals how experts assess the sufficiency of current ethics governance (Figure 16).

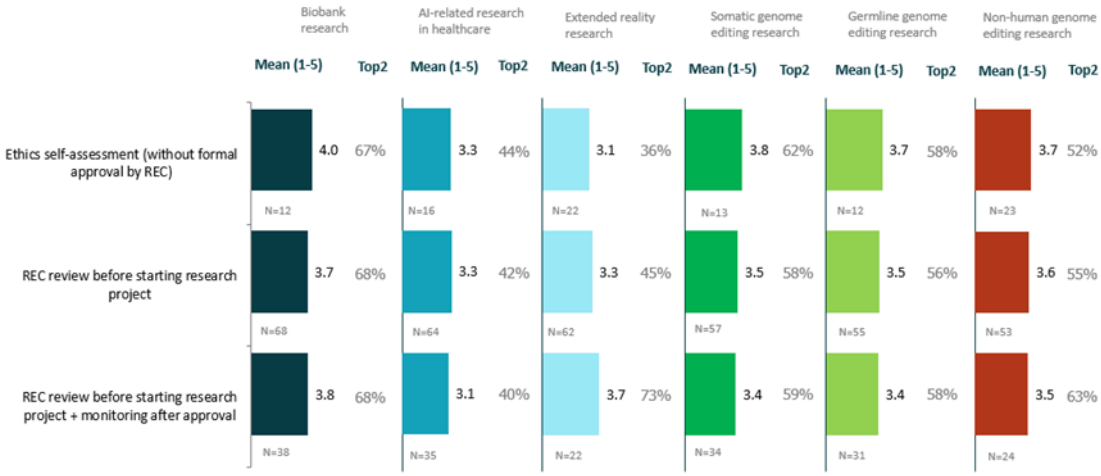

Figure 16: Sufficiency of current ethics governance. Comparison by technologies

When it comes to biobanking research (Figure 17), six out of ten survey participants, despite the ethics governance applied in the institution, view the current ethics governance as sufficient or highly sufficient. A similar situation is observed in the field of genome editing research (Figure 18-20), where sufficiency is reported at a relatively high level, ranging from 55% to 62% across different types such as somatic, germline, and non-human, as well as across various types of ethics governance.

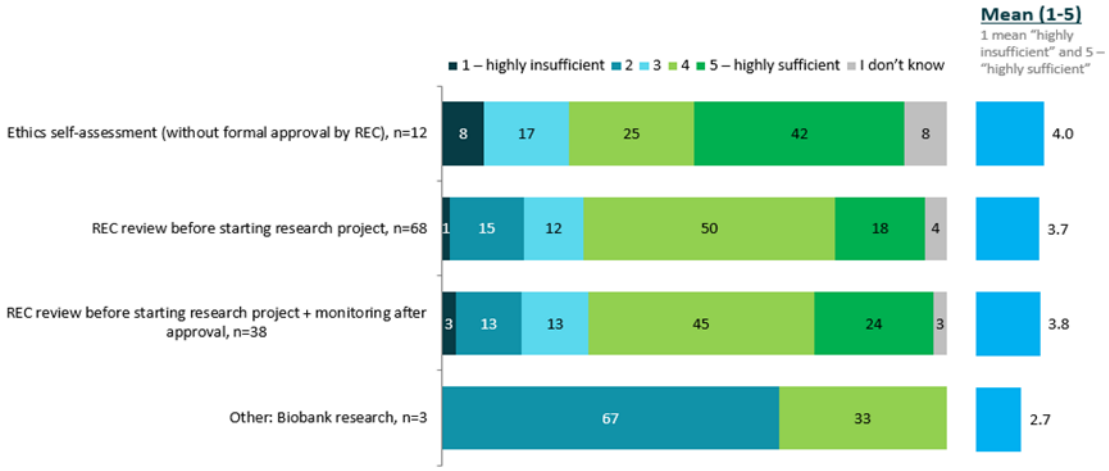

Figure 17: Sufficiency of current ethics governance. Biobank research

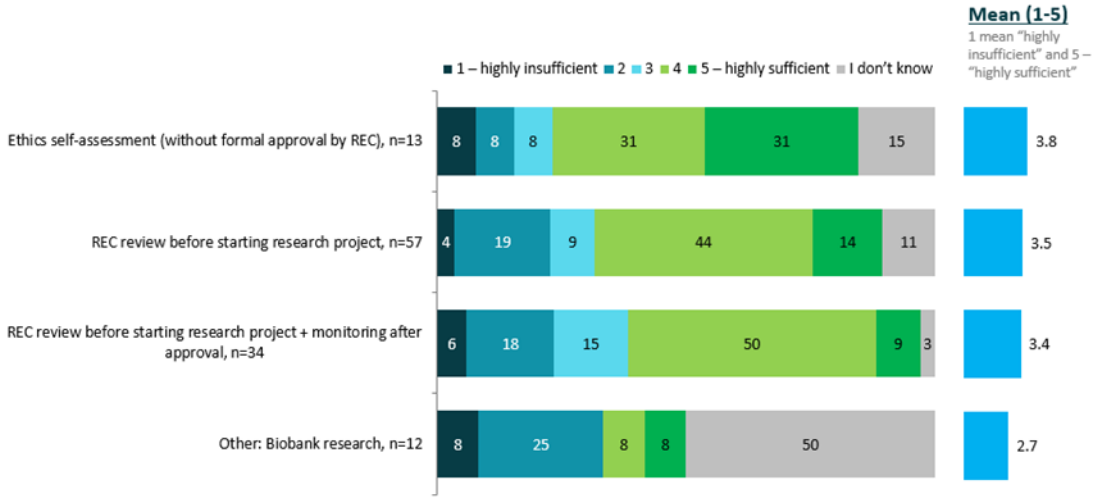

Figure 18: Sufficiency of current ethics governance. Somatic genome editing research

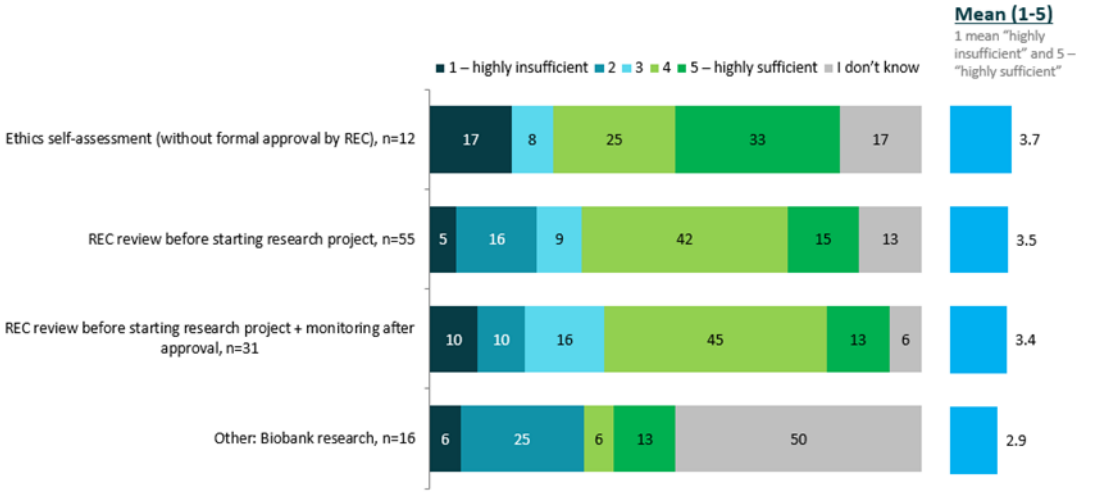

Figure 19: Sufficiency of current ethics governance. Germline genome editing research

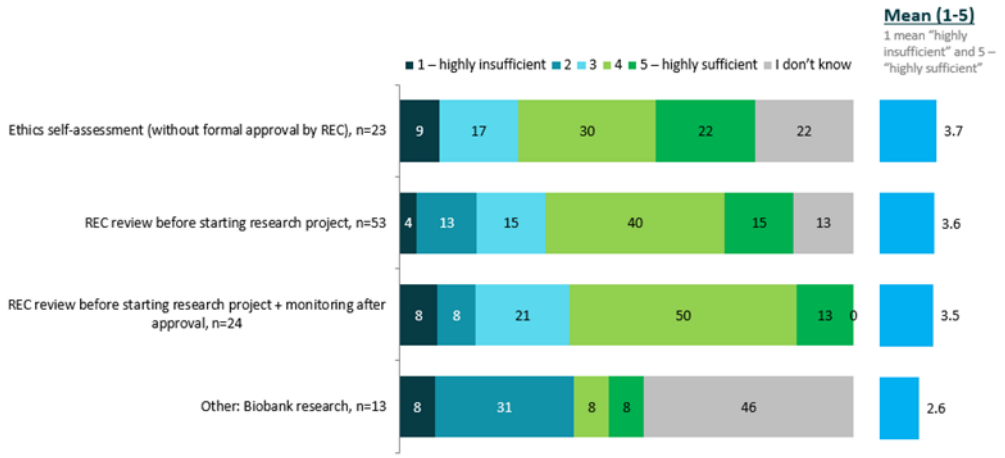

Figure 20: Sufficiency of current ethics governance. Non-human genome editing research

The situation is somewhat different when it comes to AI-related research in healthcare as well as extended reality. Less than half of participants rate sufficiency at a high level (given 4 and 5 scores out of 5), indicating the need for more attention in these areas. Interestingly, in XR, experts consider review plus monitoring as effective enough (Figure 21)., while in AI, all proposed models are evaluated more unfavorably (Figure 22).

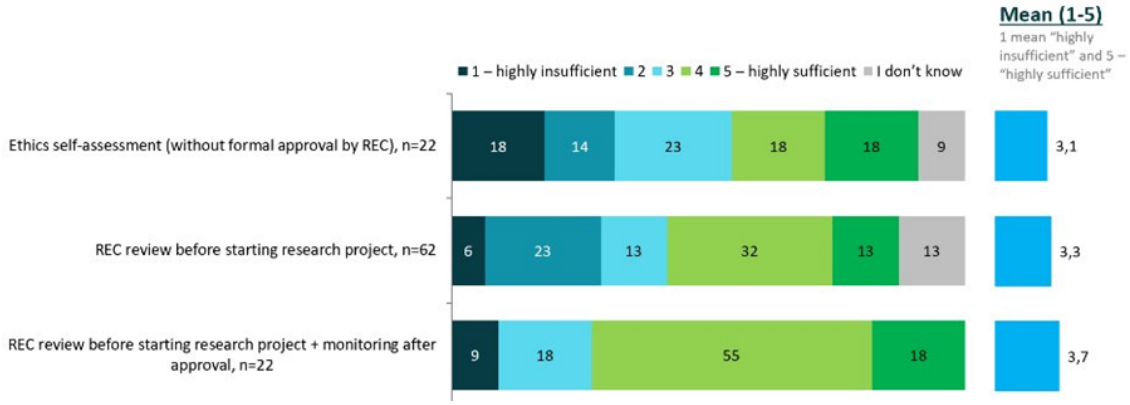

Figure 21: Sufficiency of current ethics governance. Extended reality research

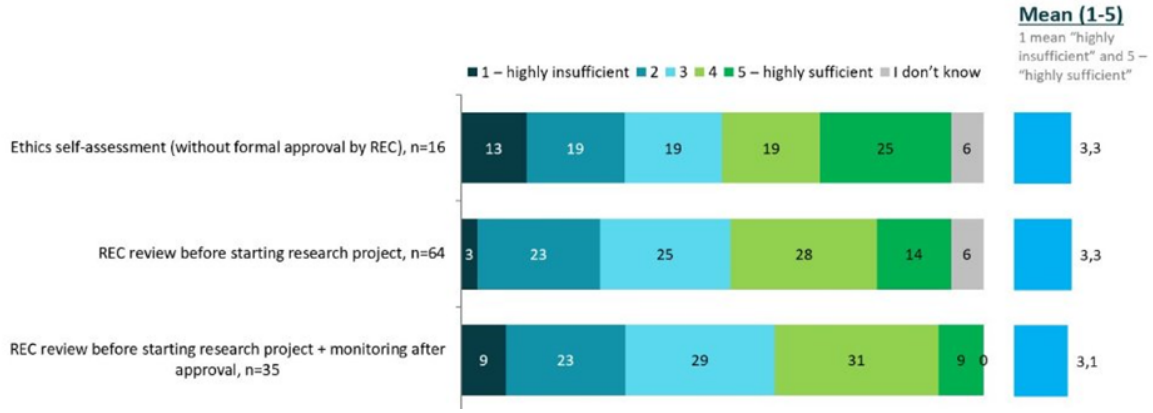

Figure 22: Sufficiency of current ethics governance. AI-related research

These findings are based on a sample of all respondents. However, the results are consistent for both European and non-European respondents. The only area where opinions differed between these groups was in somatic genome editing, which received much lower ratings in non-European countries (44 percent rated it as insufficient).

It is important to note that the non-EU countries included in the study are quite diverse. Further analysis found that representatives from African countries were most critical of the current models. African representatives rated all technologies, except biobanking, as insufficient in more than half of the cases. However, due to the small sample size, these results are statistically insignificant.

Despite the fact that the currently applied governance model is evaluated somewhat differently between technologies and regions, the majority of survey participants find that implementing continuous ethics oversight is feasible in every technology, with the most positive answers in the fields of biobank research and AI-related research in healthcare (Figure 23). The findings do not differ between European and non-European representatives.

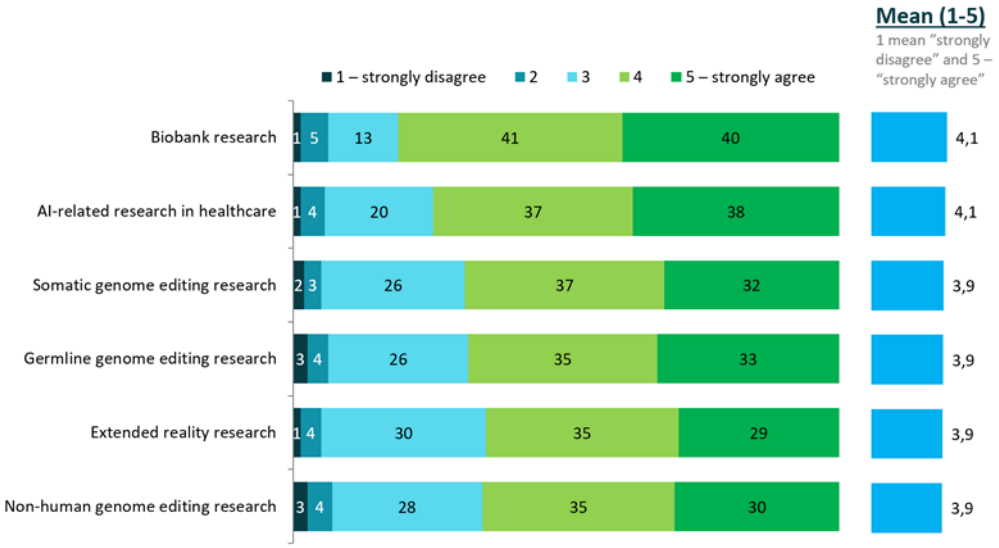

Figure 23: Feasibility of continuous ethics oversight

3.4 Factors Hindering the Ethics Assessment of Technologies

The primary factors that hinder the ethics assessment of technologies vary across different technologies (Figure 24). The main factor in AI-related research in healthcare as well as in genome editing is a lack of scientific/technical understanding, whereas for extended reality research, the key aspect is a lack of guidance followed by a lack of scientific/technical understanding. In biobank research, the most frequently mentioned aspect is the lack of training.

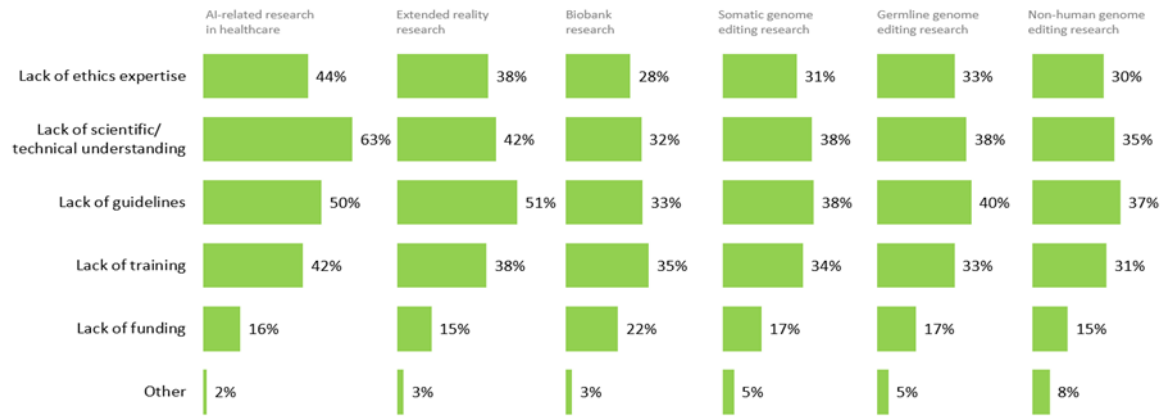

Figure 24: Main factors hindering ethics assessment of technologies

These results are from all responses. However, there is a noticeable difference between digital technologies (AI and XR) and biotechnologies (Biobanking and Genome editing). When separated into EU and non-EU countries, the EU results correspond well to the overall picture (Figure 25). In contrast, in non-EU countries, more than half of the respondents say there is a lack of training, guidelines, and technical/scientific knowledge in the Biotechnology group.

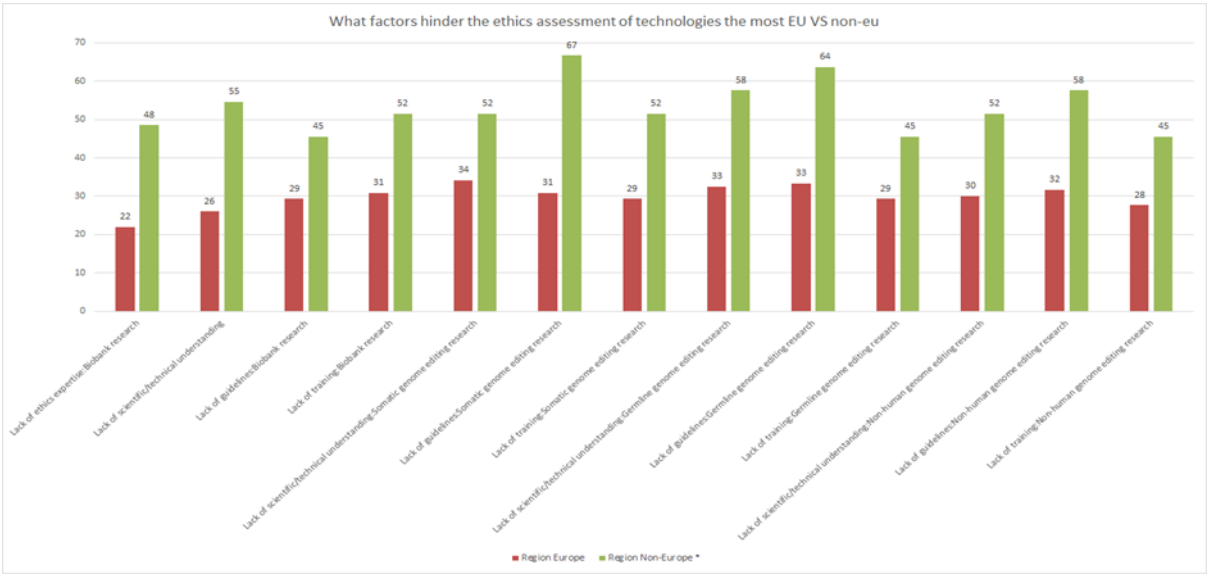

Figure 25: Main factors hindering ethics assessment of technologies EU vs non-EU

After further refining the groupings, differences emerge not only between EU and non-EU but also between Africa and China. In African countries, the need for more training and guidelines in the Biotechnology group is much more emphasized (Figure 26).

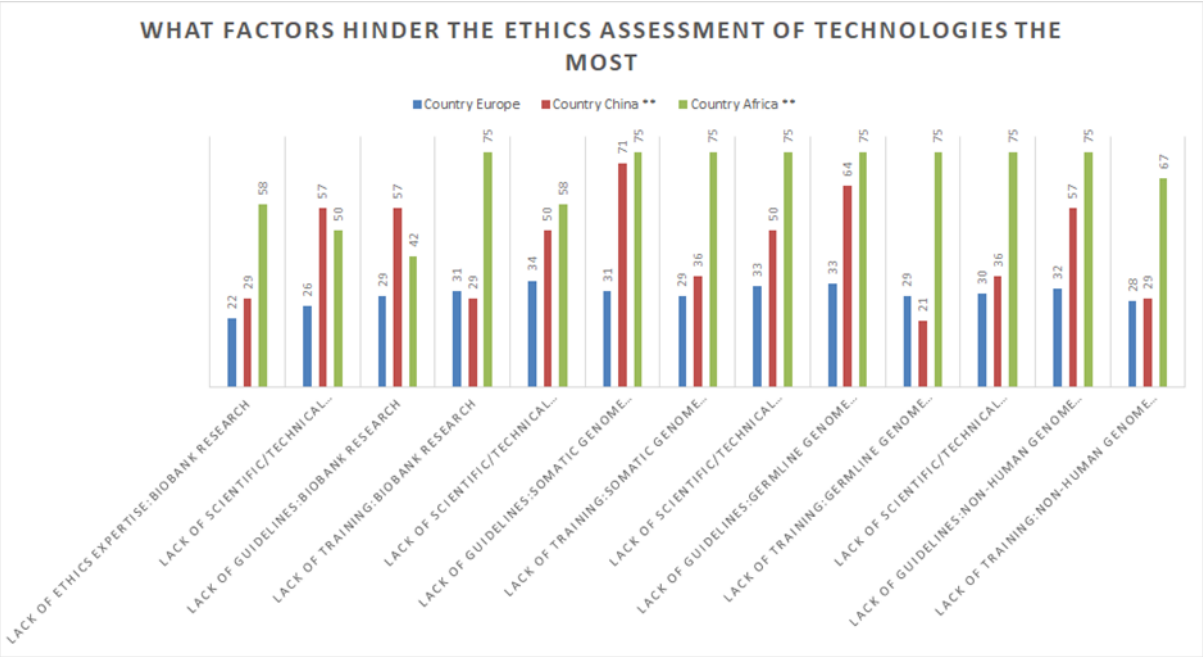

Figure 26: Main factors hindering ethics assessment of technologies Europe – China – Africa

After assessing the sufficiency of current ethics governance, the interviewees were asked an open-ended question: *How would you change it?* or *Do you have any suggestions on how to improve it?* Depending on whether the current governance is assessed as sufficient or insufficient.

A recurring theme in the responses is the need for guidance and training. The absence of guidelines poses a significant problem when assessing the overall survey data. However, it is important to mention that when examining the data across different regions, experts have identified challenges related to the lack of guidelines to be most pressing for digital technologies in Europe and China. However, in the African region, the most pressing issue appears to be the absence of guidelines for biotechnology group (Figure 27).

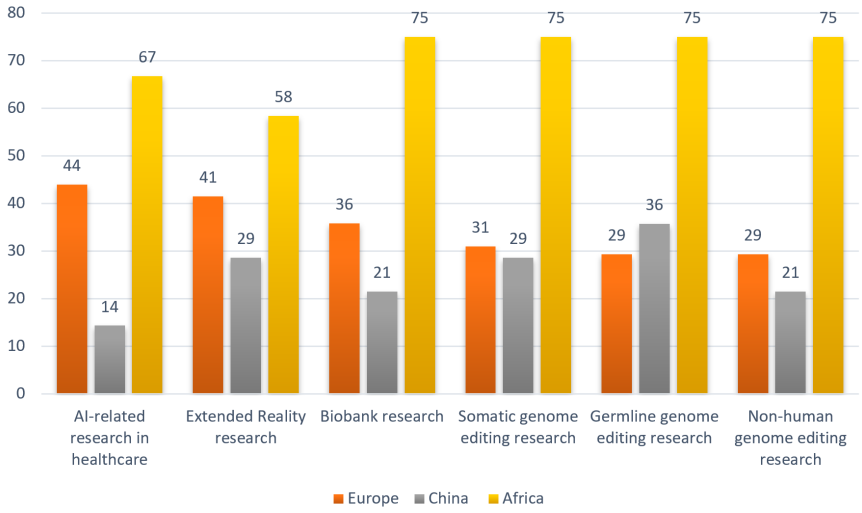

Figure 27: Lack of guidelines influence for ethics assessment Europe – China – Africa

The data indicates that different regions have varying guidance limitations. These findings reinforce the proposal for networking as a practical approach. In addition to the need for guidelines, many experts emphasized that a better ethical evaluation requires additional training. We see the greatest desire for training among digital technologies. The same results are observed both among European and non-European respondents.

Training is meant to enhance the expertise of professionals. Interestingly, when evaluating experts' competencies in various aspects of a particular technology, experts rated themselves lowest in areas such as explainability, justice, responsibility, bias (AI), mental health, violence, cybercrime, and involvement of children (XR). Despite the significant similarities between AI and XR technologies, as well as the overlap in the assessment of knowledge in areas required for evaluating social impact (Figure 30), respondents in the AI group expressed greater optimism about the potential for evaluating broader social impact compared to XR (Figure 28-29). When comparing the same answers between European and non-European experts, non-European experts show slightly higher confidence in their knowledge, but the differences are not statistically significant.

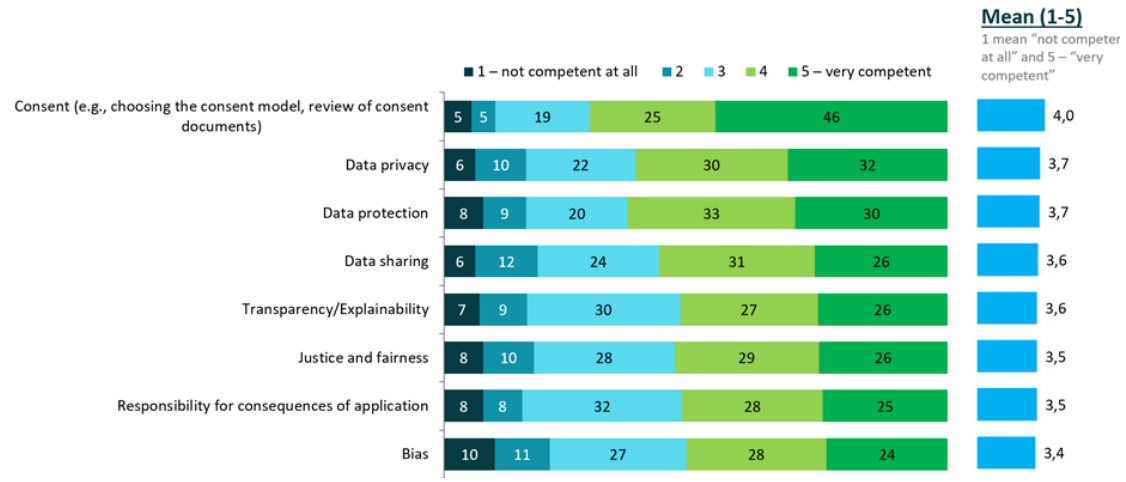

Figure 28: Ethical issues competence: AI

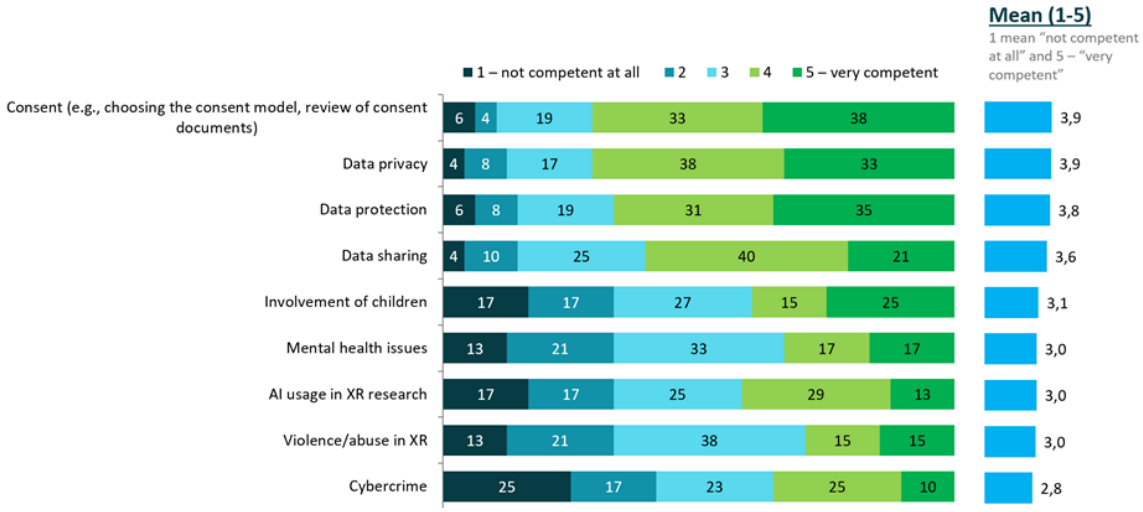

Figure 29: Ethical issues competence: XR

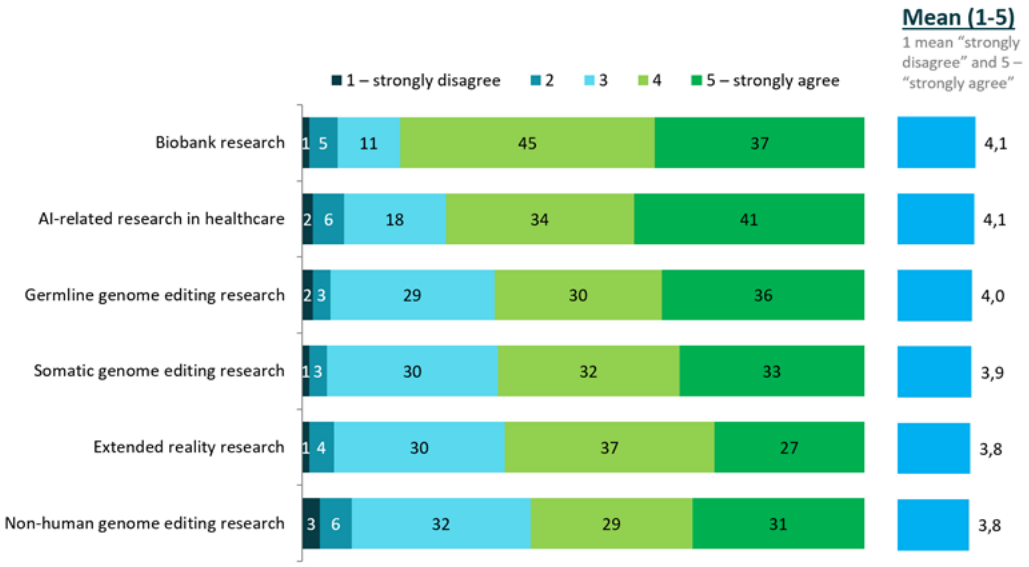

Figure 30: Feasibility of considering broader societal impacts

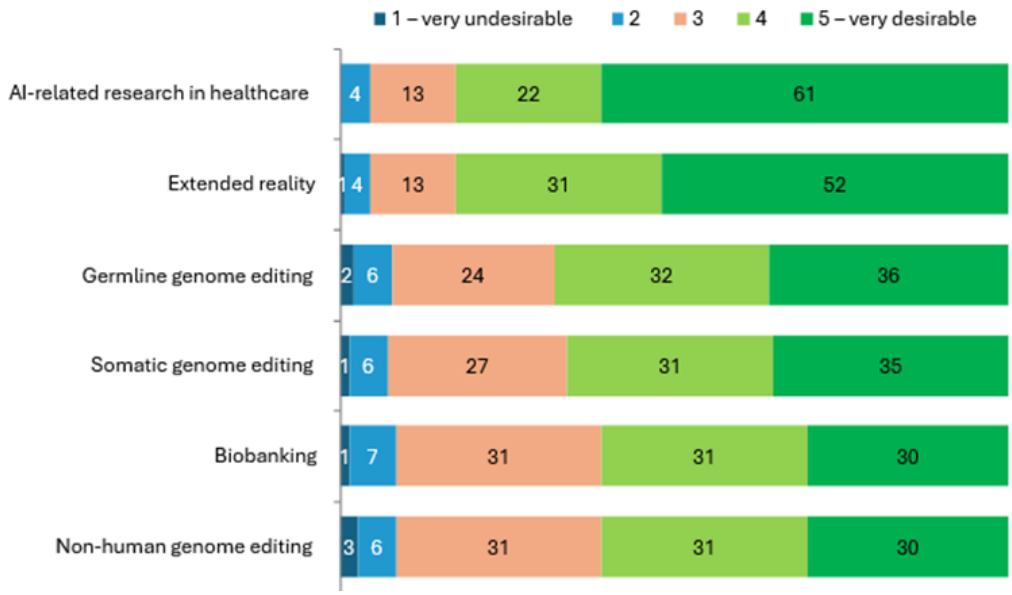

Figure 31: Lack of funding

The lack of funding was considered the least significant issue that hindered the ethics assessment (Figure 31). However, when the data was analysed by regions, between one-third and one-half of the African respondents identified lack of funding as a significant obstacle, probably due to the substantial financial disparity between European and African countries. Also, a low number for this answer could be misleading, as the questionnaire wording was about "funding" and the responses might not encompass issues like human resources.

3.5 Desire for Training

Ethics experts consider the ethics assessment of technology research and development to be the most useful training content (Figure 32).

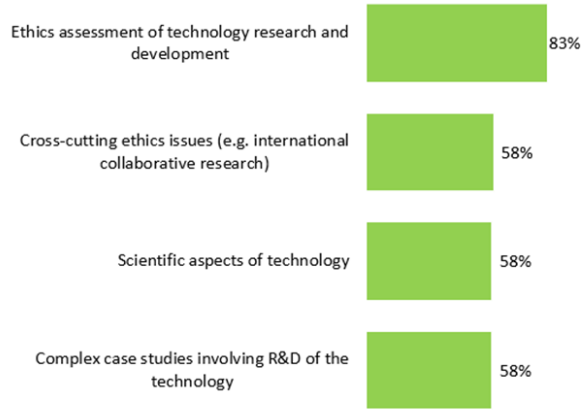

Figure 32: Most useful training

Regarding preferred training methods (Figure 33), participants rank them in the following order of preference: self-directed learning, online training, online group workshops, in-person group workshops, downloadable workbooks, and other methods.

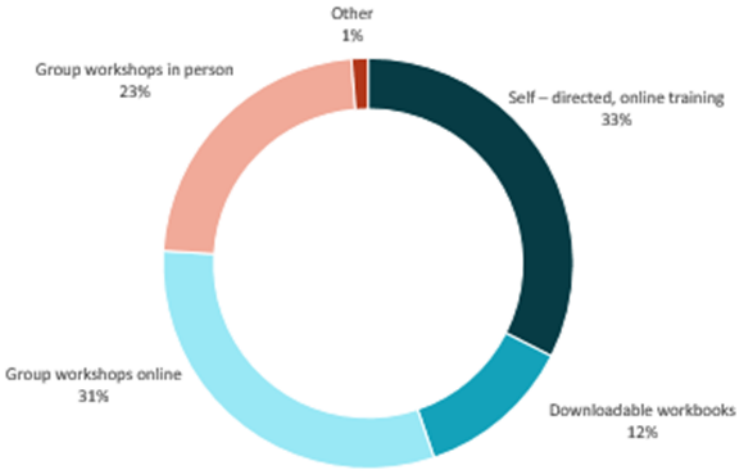

Figure 33: Preferred training methods

The two most preferred learning styles for online training are listening to presentations and watching videos (Figure 34).

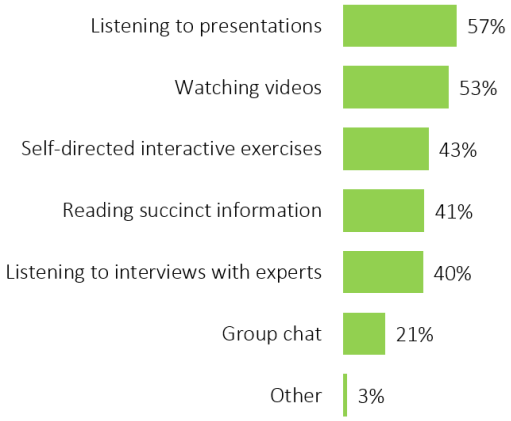

Figure 34: Preferred learning styles

All findings relevant to training preferences show no significant differences between EU and non-EU respondents.

3.6 Biobanking

During the survey, the question was asked: When is ethics review for biobanks required in your country? Possible answers were:

- When a new biobank is being established
- When a concrete research study on human biological material and health-related data taken from biobanks is planned to be conducted (biobank research). Please specify the criteria, if not all biobank research is reviewed.
- When you want to amend a project that has already been approved
- None of the above

In Europe, 62% of respondents noted that an ethics review is needed when a new biobank is being created, 65% when a specific study is being carried out, and slightly less (47%) for amending an approved project.

Next, the level of competence was assessed on various issues related to establishing a new biobank and on human biological material and health-related data taken from biobanks. Regarding establishing a new biobank, respondents asserted their highest level of competency in assessing the issue of consent: 82% felt competent, and only 2 % (1 answer) felt not competent.

In questions related to experts' level of confidence when assessing data related issues: data protection, data privacy, and data sharing, the interviewees also showed a reasonably high level of confidence – ranging from 62 to 67% felt competent. However, unlike consent, more respondents felt incompetent (12-14%). The rest (20-24%) marked the competence in data issues as neutral. Similar self-confidence data were obtained when assessing competence in the return of individual health-related findings to

biobank participants and involvement of children questions (61-65% competent). Still, the number of those who assessed themselves critically differed (10% were not competent with the involvement of children and only 4 % in return of findings).

The survey participants rated their competence as lowest in issues related to the commercialization of research results, where even 24% indicated their competence as not competent and only 39% as competent.

The same questions were asked to evaluate competence when reviewing a concrete study on human biological material and health-related data taken from biobanks. The results were similar, with the best confidence in issues of consent at 88% competence and lower confidence in understanding data related issues at 63-71% competence and 8-12% incompetence .

The answers to the questions *Return of individual health-related findings to biobank participants* and *involvement of children* are slightly different: more respondents (75% vs 61%) chose the competent option when evaluating knowledge related to the involvement of children, but at the same time, the number of not competent remained the same (10%). The Return of individual findings question is almost identical (62% competent and 2% not competent).

As in the previous question, competencies related to commercialization were evaluated as lowest; as 25% chose not competent, and only 42% felt competent. The obtained data show that regardless of the stage at which the biobank is being created or the evaluation of a specific study, the main problems in expert competence are very similar. The data agree between different regions in almost all criteria, except for commercialization, where representatives of African countries indicated a substantially lower level of competence.

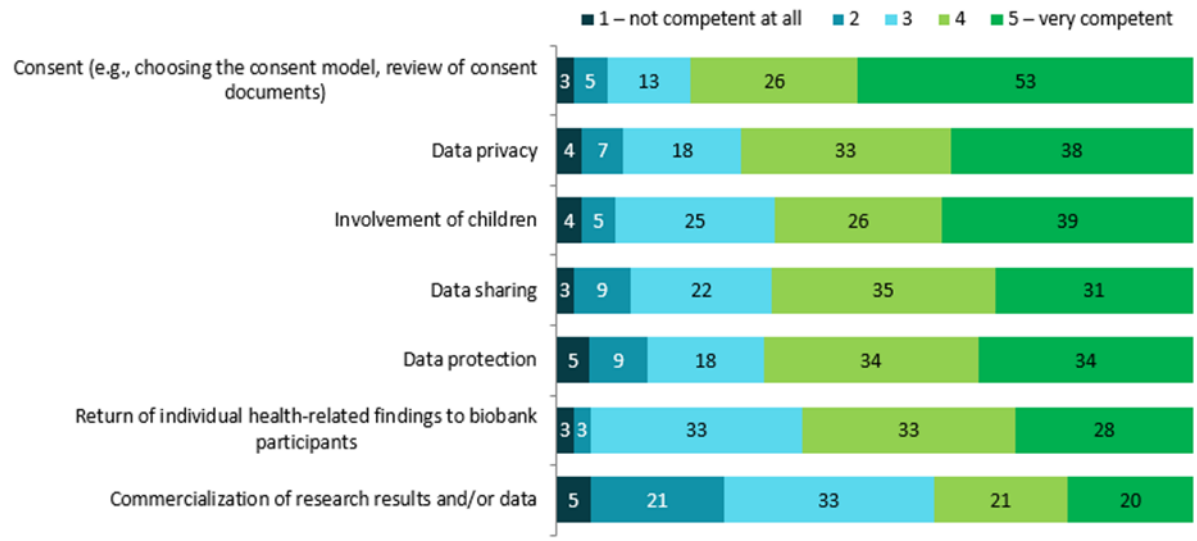

Figure 35: Perceived competency in assessing biobank research

Experts believe ethical review is necessary/preferable for research involving biobanks both during the establishment of the biobank and when a specific research study is planned to be conducted (Figure 36).

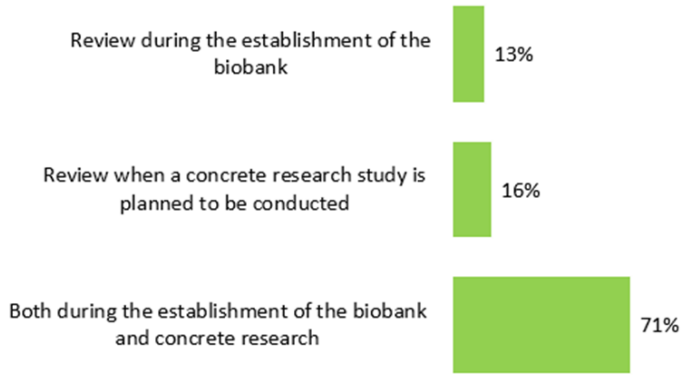

Figure 36: Appropriate time for review when establishing a biobank

It is worth noting that non-Europeans are statistically significantly more involved in the field of biobanking. However, at the same time, representatives of African countries note that training in the field of biobanking would be most desirable. Also, permission is required for the creation of a Biobank statistically significantly more often in non-EU countries, but the experts' opinions did not differ when they thought an ethical assessment was needed.

3.7 Extended Reality (XR)

Research participants are somewhat uncertain in understanding differences in XR technologies. Approximately one-third of the participants rate their competence at the highest level in all three research types: virtual reality, augmented reality, as well as extended reality using AI. The rest evaluate their competency at average level or below (Figure 37).

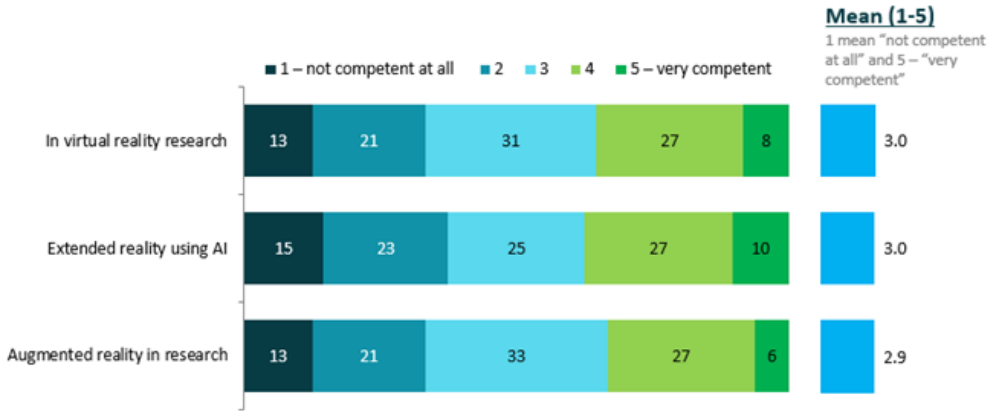

Figure 37: Inner workings and differences of XR technologies

The survey included an open-ended question to determine when AI and XR technologies research should be subject to ethics review. The most commonly cited reason for both technologies is research involving people or personal data. It is important to note that in AI technology, the responses often go beyond working with people; they also consider the potential impact on society, justice, and decision-making.

3.8 Genome Editing

Even in the absence of specific guidelines and with a considerable need for training, experts feel confident in assessing the field of GE.

When reviewing matters related to somatic gene editing (Figure 38), study participants consider themselves to have a high level of competence across all areas assessed in the survey, including consent, safety, accessibility, enhancement, and misuse. When it comes to germline (Figure 39) and non-human gene editing (Figure 40), respondents expressed a modest level of confidence in their competency.

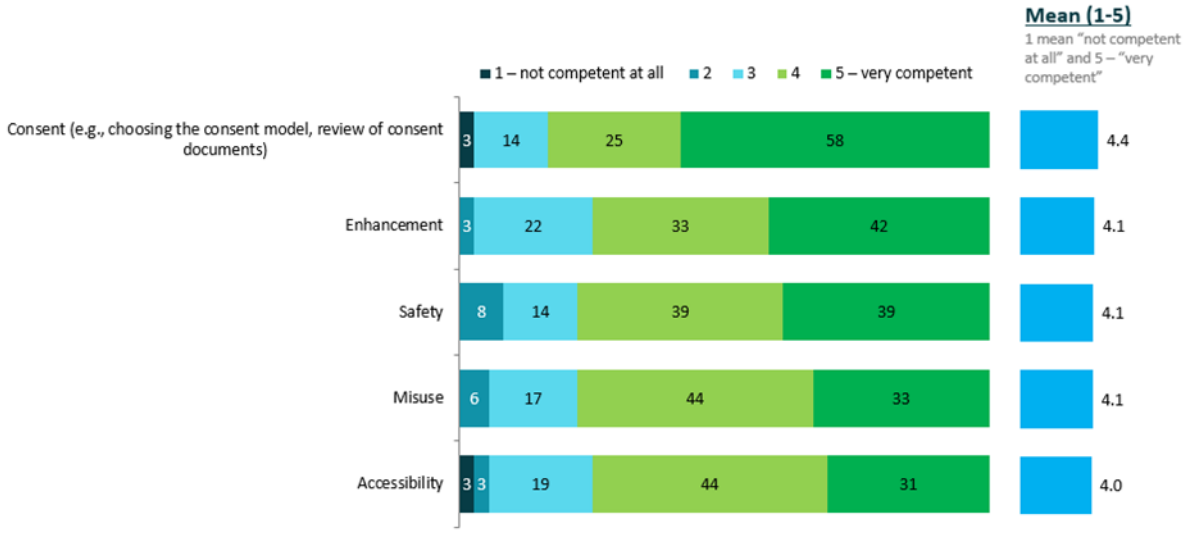

Figure 38: Ethical issues competence related to somatic gene editing

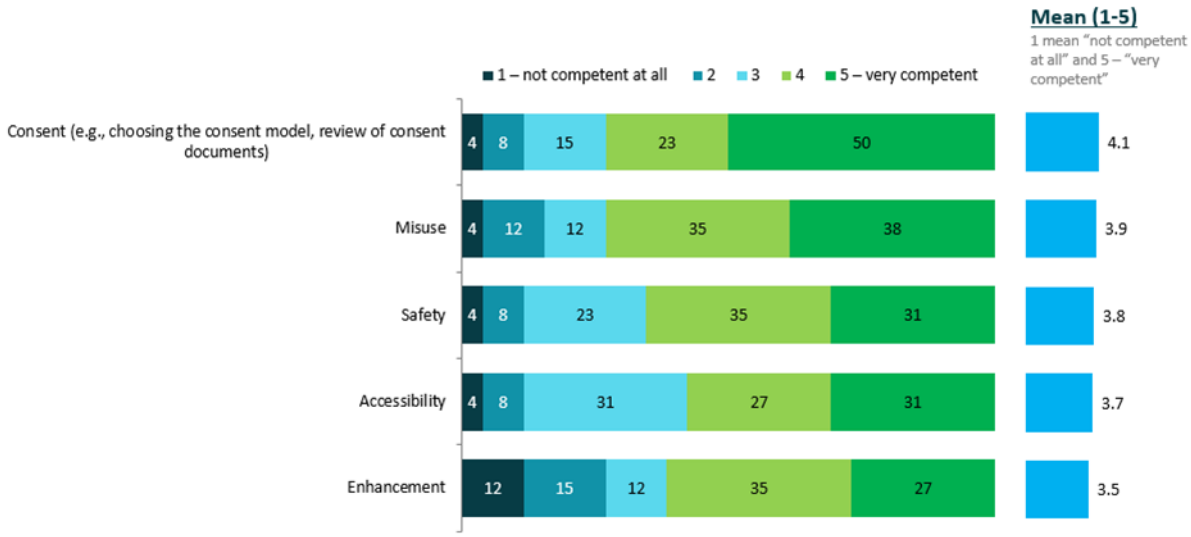

Figure 39: Ethical issues competence related to germline gene editing

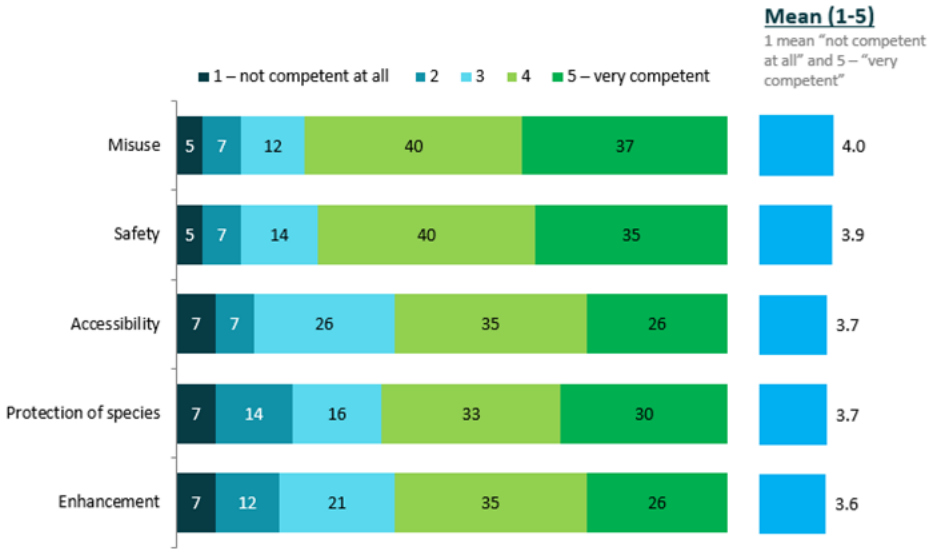

Figure 40: Ethical issues competence related to non-human gene editing

3.9 Conclusions on the comparison between EU and non-EU survey results

This section summarises the key differences between the survey results for EU and non-EU countries, and notes convergences and similarities. While there were some notable divergences, it should be noted that this may be in part due to the substantially smaller number of respondents from outside the EU. While 77% of responses came from the EU, only 12% came from China and 7% from Africa, with 4% from elsewhere. In terms of the number of respondents, this equates to 187 from Europe, 29 from China, 17 from Africa and 9 from other regions. Given the low sample size from China and Africa, it is important that caution is exercised in interpreting these results, and particularly in comparing individual non-EU regions. One striking divergence between the EU and non-EU responses was that traditional ethics review is much more highly prevalent in Europe, with higher incidence of post-approval monitoring in other world regions.

In terms of specific technologies, for biobanking there was relatively little monitoring after approval in the EU (77% traditional REC review and 38% monitoring). In contrast, 85% of respondents from outside the EU said REC monitoring normally takes place, with only 23% saying traditional REC review was practiced at their institution. This divergence was reflected in the other technologies with similar numbers. For XR, only 9% of EU institutions had monitoring after approval, compared with 65% of non-EU institutions; for AI, only 19% of EU respondents had monitoring after approval at their institution compared with 85% in non-EU countries. This discrepancy was also reflected in the numbers for the different types of gene editing; in all cases the percentage of respondents indicating that their institution had post-approval monitoring was around three times higher among non-EU countries. The finding that post-review monitoring was substantially more common than traditional review was found across all technologies among respondents from both China and Africa.

Results regarding sufficiency of current ethics governance were similar between EU and non-EU regions, with the exception of somatic gene editing, where 44% of non-EU respondents deemed current governance insufficient, much higher than EU respondents. Similarly, most respondents from all regions believed that continuous ethics oversight was feasible across all technologies, particularly in AI and biobank research. While respondents from the Africa region rated all review of all technologies except biobanking inadequate, these results were not statistically significant.

In terms of which factors hinder assessment of technologies, as opposite to the EU results, a majority of non-EU respondents mentioned a lack of training, guidelines and technical/scientific knowledge in the biotechnology group of technologies. This result was even more pronounced in African countries. To take the example of germline gene editing, the results for lack of scientific/technical knowledge were 33% for Europe, 50% for China and 75% for Africa; for lack of guidelines the results were the same except for 64% in China. For lack of training the results were 29% in Europe, only 21% in China, and 75% in Africa. Results for biobank training were broadly similar to the results for gene editing training across these regions at 31%, 29% and 75%, respectively.

Also, of note is that in Europe and China, the most important factor was identified as being lack of guidance for digital technologies, where guidance on biotechnologies was seen as more important in Africa. However, there was also a high perceived need for guidelines on AI-related and XR-related research in Africa, with 67% and 58% of participants, respectively, indicating this compared with only 14% in China and 44% in the EU. Across all the technologies, at least 50% of respondents from Africa indicated there was a lack of guidance.

There was general consensus that lack of funding was the least important issue in terms of hindering ethics assessment, but this issue was seen as more important in African countries where as many as 50% of participants selected this issue.

Results regarding training and training preferences was broadly similar between EU and non-EU regions. One technology-specific divergence was that permission was more often required for setting up a biobank in non-EU countries; respondents from African countries also felt less experienced in commercialization of biobanks and saw training in that area as most desirable.

Overall, the summary of similarities and divergences between EU and non-EU respondents shows that the most significant difference was the greater reliance on post-approval monitoring of research projects outside the EU. Additionally, respondents from Africa generally saw greater need for guidance across all technology areas.

4. Ethics reviews in non-European countries

4.1 Overview

As part of work package 2 and specifically task 2.3, a series of interviews was conducted with experts who either have extensive experience with international research ethics committees (RECs) or are current or former members of such RECs themselves. The focus of the interviews was centred around

the international experience with RECs specifically, in order to provide complimentary knowledge to the EU-focused approach of the irecs project with the aim to identify the commonalities and differences between EU and non-EU REC experiences.

Ten interviews were conducted to different interview partners (IP) in total: One interview, (IP 10, see table 3) was conducted as a written interview due to the language barrier. All other interviews were held via Microsoft teams or zoom with a duration between 30 and 60 minutes. The interviews were recorded and transcribed. The transcriptions formed the basis of the analysis of the interviews which will be the main subject of this section of the deliverable. The results of the analysis will be presented in a narrative style featuring some highlighting quotes from the interviews while following along the interview questions. Before we will discuss these results, however, we want to first give an overview of the interview questions and our interview partners.

The interview questions can be divided into two parts: Part one features general questions about RECs and addresses topics like guidance documents, necessary resources for RECs, appropriate topics for RECs and the responsibility for their selection and value differences between EU and non-EU countries. Part two of the interview focuses on the international experience of RECs with the four core technologies featured within irecs. Here, the questions revolve mainly around the existence of guidance documents and common challenges faced by RECs where these specific technologies are concerned. The complete list of interview questions can be found in Annex 2.

An overview and more detailed account of the IP, their background and their knowledge areas can be found in table 2. The IP come from a variety of different countries and disciplinary backgrounds with, in some cases, extensive knowledge about REC work in other countries as well: The IPs are e.g. currently working in India, Turkey, China, South Korea, the Philippines and Kenya. Six of the ten IPs had relevant experience with REC work outside of the country they were currently working in. This extended the range of knowledge about non-EU countries considerably to most parts of Asia (especially the Philippines, East Asia, Vietnam, Malaysia, Sri Lanka, Japan), Africa, specifically Western Africa, Latin America, Canada, the UK and the USA. Three of the ten IPs were working in European countries at the time of the interview (Norway, France), two of them had extensive knowledge about REC work in other parts of the world (e.g. many parts of Africa, Asia and Latin America, as well as Europe in general). IP 8 was the only interview partner with an exclusively European perspective (Norway, Sweden, Denmark) and was interviewed mainly because of their extensive knowledge about all four core technologies relevant in the irecs project.

Most of the IPs are members of a REC or similar body performing ethics reviews for research, only IP 1 and IP 9 are not, though they do have some insights into the work of a REC or similar body. Asking about the disciplinary and research background of the IPs revealed a wide range of knowledge areas from both natural sciences and the humanities (see table 2 for a detailed list). There are two areas of expertise uniting almost all IPs: the connection of their work to the medical and healthcare sector and their comprehensive knowledge about research ethics and integrity. Both aspects are unsurprising, given the focus of the interviews.

When it comes to the four core technologies of irecs, the answers were a lot more ambivalent: Four IPs cited having no experience in any of these technologies, the other IPs indicated having some experience in at least one or two of them, only one IP had experience in all four technologies. At least

in some cases of IPs indicating no experience about a specific technology, they did provide some interesting insights into the challenges of the technology later in the interviews (see table 2, this phenomenon is marked by the "~" symbol). Going by technology: AI in healthcare: four IPs affirmed to have some experience, two more IPs where somewhat knowledgeable. Extended reality: two IPs affirmed their experience. Genome editing: two IPs affirmed their experience, two were somewhat knowledgeable. Biobanking: five IPs affirmed their expertise, one IP was somewhat knowledgeable.

Code	Currently working in	REC experience in other countries	REC	Disciplinary and research background	AI	ER	GE	BB
IP 1	India	No answer	no	Law and social science: science, technology, innovation, diplomacy; technology regulation	no	no	no	~
IP 2	France	Europe, Asia (Vietnam, Malaysia), Latin America, Western Africa	yes	Biochemistry, immunology, ethics in medical research	yes	no	yes	yes
IP 3	Turkey	no	yes	Medical background, bioethics, qualitative studies in ethics, clinical ethics support, research ethics, health care policy, social science in healthcare	no	no	no	no
IP 4	Norway	the Netherlands, the Philippines, Asia and the Pacific, Africa	yes	(Medical) Research ethics, research integrity, ethical issues of immersive technologies, social science of health and well-being	~	yes	no	no
IP 5	China	no	yes	Clinical medicine, neuroscience, biobanking, basic medical research	no	no	~	yes
IP 6	South Korea	China, Japan, USA, East Asia in general	yes	(Western) Ethics theory/practice, social science, research ethics, research integrity and dealing with research misconduct	no	no	no	no
IP 7	the Philippines	India, South Africa, Sri Lanka	yes	Research ethics, applied political science, history, sociology and anthropology, Asian studies, (bio)medical research from social science, women's rights in research, activism	~	no	no	no
IP 8	Norway	Sweden, Denmark	yes	Natural sciences, bioengineering, medical technology, history of ideas in philosophy/ethics, research ethics, medicine and healthcare	yes	yes	yes	yes
IP 9	Kenya	Canada, USA, UK	no	Clinical medicine, epidemiology, HIV and covid research, hidden/marginalized populations	yes	no	~	yes

IP 10	China	no	yes	Automation, information security audit	yes	no	no	yes

Table 2: Overview of the interview Partners

4.2 Guidance Documents

The interviews started with some general questions about guidance documents, particularly about: country-specific guidance documents in health-related fields, guidance documents for research in emerging technologies and gaps in existing guidance documents to be able to review research projects that are not primarily focussing on the protection of research participants. The following section will provide a summary of the insight by the IPs to these questions. 4.2.1 Relevant country-specific guidance documents.

At the start of the interviews, we asked the participants about the guidance documents for health-related fields used in the review practice in their respective countries, offering some well-known examples like the Guide for Research Ethics Committee Members developed by the Council of Europe, The Good Clinical Practice (GCP) Guideline and the CIOMS guidelines. The IPs all answered the question similary: The national guidelines and guidance documents for health-related fields were adopted from the widely known existing guidelines mentioned as examples in our question and others, like the Belmont Report and the Declaration of Helsinki. For this reason, the varying national guidelines are extremely similar to each other, there seems to be very little differentiation. The IPs also agree that there is a certain quantity of guidelines available, e.g. IP 2 saying “we have a plethora of guidances that we can follow in our ethics review.” The relevant quotes about specific guidelines and the organisations releasing them are listed in table 3 below.

Code	Country	Relevant Quotes about specific guidelines and related organisations
IP 1	India	ICMR (Indian Council of Medical Research) […]. They have a lot of specific guidelines for human research. For departments like Department of Biotechnology have their own guideline. […] Most of them follow the ICMR ethical guidelines.
IP 2	France	National Ethics Committee / Comité Consultatif National D'éthique: They have provided us with a lot of documentation for guidance in regard to the health research field.
IP 3	Turkey	We use the Helsinki Declaration by World Medical Association very often. We refer to that declaration very often in clinical research ethics committees. Other than that, we have some national guidelines which were published by the Ministry of Health
IP 4	Norway	In Norway we have several guidance documents, one for each broad field (humanities, social sciences, natural sciences …) It's not uncommon for several European countries to have some kind of different types of guidance documents depending on broad academic fields.
IP 5	China	A new release called […] Personal Information Security Inspection specification, they have a personal information protection law
IP 6	South Korea	I think our guidelines […] are very similar to European countries, because our country adopted some basic guidelines like the Declaration of Helsinki, the Belmont Report, the Good Clinical Practice Guideline and the CIOMS guidelines – with small revisions because of the different cultural background.

IP 7	the Philippines	My NGO was able to formulate the first and I think it's the only one up to the moment easy to read, easy to carry guidelines for ethical social research [...] with vulnerable communities. Philippine Health Research Ethics Board actually produced a set of guidelines against ethics dumping […] I think these have been adopted by the European Union There are other institutions and organizations which have their own guidelines, for example, associations of Filipino psychologists, anthropologists who have their own guidelines, the Philippine Social Science Council, the Philippine Medical Association, they have their own guidelines.
IP 8	Norway	We are very much in line with the general guidelines provided internationally. The Ethics Committee also provide some specific guidelines for the various fields, like social sciences, but also in medicine and health research. Of course, these guidelines are very much based on international guidelines.
IP 9	Kenya	[The Declaration of] Helsinki is a widely used one. They have also adopted the code of conduct.
IP 10	China	China's medical ethics-related regulations, mainly: Biosafety Law, Measures for Ethical Review of Life Science and Medical Research Involving Human Beings, Measures for Ethical Review of Science and Technology (for Trial Implementation), Ethical Norms for the New Generation of Artificial Intelligence, Data Security Law, Law on the Protection of Personal Privacy

Table 3: Quotes about Guidance Documents

4.2.2 Guidance documents for emerging technologies

The next question focused on other guidance documents that are particularly useful for REC members or ethical reviewers when reviewing research projects in emerging technologies. Here, the situation seems to be the exact opposite, with no real guidelines available to properly assess and review research projects in emerging technologies. As IP 1 says: “They are very limited. [...]Ethical guidelines are primarily applicable when you do human [...] or when you do large scale field work involving children, women etc. But those guidelines are more applicable for data collection and more related to data ethics than ethical guidelines per se.”. IP 8 bluntly states: “No, there are no specific [guidance documents] for emergent technologies”. IP 2 answers a bit less direct: “When it comes to emerging technologies, I really don't know.” The situation in the Philippines is similar, according to IP 7: “Maybe in some specific institutions like computer science or the professional associations of engineers, but I am not aware. […] In terms of the current guidelines in the Philippines, I don't think there is really anything that is really very useful in terms of the official guidelines.” IP 4, in turn, has a more measured answer stating that it depends on the emerging technology in question: “When we talk of emerging technologies, of course, then it will be very varied. If we want to talk about biobanking, then there's regulation and there are guidelines on it, but we cannot say the same, for example, for extended reality technologies.” Some IPs issue somewhat of a call to action, which of course aligns well with the project goals of the irecs project, like IP 8: “I think everybody is very eager to have some help and some guidance with regards to how to regulate these technologies. […] There is a clear need for further guidance, mainly because the existing guidance and guidelines are not covering all the aspects of these new and emergent types of technologies.” IP 9 gives a similar answer: “The legal framework is silent because things are new. So, we need to go quickly and we need to be sensitized about them. So at least we know what to do in terms of the legal framework.”

4.2.3 Gaps in guidance documents beyond the protection of research participants

The last part of the questions about guidance documents focuses on what is missing in the existing guidelines to be able to review research projects that are not primarily focussing on the protection of research participants. One of the results when looking at all answers is that only very few of the IPs

actually address specific gaps in the guidelines or guidance documents themselves and are instead more focused on the circumstances in which research and ethics review happen. Another interesting fact is that the answers are usually very idiosyncratic – there is very little overlap between the different answers, each IP usually brought forth an individual issue, with the exception for the need for adequate training. We will start the section with a short description of the gaps directly related to guidance documents, before saying more on the accompanying circumstances of ethics reviews. The first aspect sometimes missing in guidance documents for emerging technologies is identified by IP 8, who states that "some of these technologies at least are information driven and these are not well protected. […] Some of the existing key principles and concepts like autonomy and privacy may not be as well suited and as protective as they are for other types of research." A second aspect attests a lack of consideration for research in the social sciences dealing with emerging technologies. To this end, IP 3 says: "When it comes to national guidelines, there are still some gaps […] about the social sciences. […] [For] medical studies we can find relevant documents […] but when it comes to social sciences – since social science is also in the process of transforming [with] new data collection methodologies – […] you don't know how to deal with them."

Another aspect that has been neglected in the development of guidance documents consists in the lack of focus on and regard for vulnerable communities and a bias in terms of adopting specifically Western concepts. This is an important result of the interviews as it shows the problematic aspects of research ethics that do not sufficiently account for the problem of the North-South divide. We will address this important issue again in section 4.5. For now, we would like to describe how this issue affects the guidelines for ethics reviews in general. Here, it is especially IP 7 addressing these issues in the context of gaps and missing aspects in the available guidelines: "I would say the fundamental issues, problems that we are facing in social research or non-modern technology-based research are practically the same. […] like exploitation of vulnerable populations, […] theft of intellectual property, [...]issues of ownership, issues of access to the product or the benefits of the research. […] There is definitely a need to make guidelines specific." To this end, IP 7 states that it is important "to formulate guidelines that are useful not only for researchers but for communities. That's one of my major criticisms about guidelines. Guidelines, even if you translate them to the local language, cannot be understood by farmers in my country. I think one of the things that an ethics review board should do is to ensure that in every informed consent form, there is a copy of the guidelines [that is] easy to understand, so that they know the rights in research. […] There are practically no guidelines specific to this, even the fundamental guidelines are not enough. They're not even updated. So, you have now an increasing number of populations who are displaced by war, by conflicts, by pandemics […] These are highly, highly vulnerable [populations] and there are practically no guidelines for them. Guidelines that [are] sensitive to realities, cultures, needs, vulnerabilities, especially of people in the South." What needs to be done, according to IP 7 is the following: "We need people who are being exploited by research to speak. The guidelines that should be formulated must be genuinely sensitive to the experiences, the histories, the values of people who are traditionally abused in research. […] My dream is that a time will come when the people who are being researched will be the ones to make the guidelines. […] I hope that a time will come when the people who are most affected, who have the most at stake, will be the ones to make the guidelines or will be the ones to approve the guidelines."

The following aspect figures somewhat in the middle of specific gaps in guidelines and problems arising from the circumstances and was addressed by IP 3. They state that “we only have some general legislative documents [that] we try to interpret: What could we decide in a specific or unique situation? […] [We have no] specific legislation about it. There are some things, but they are not enough, they are not adequate in guiding us through the complicated, procedural steps. Apart from helping reviewers to find their way through the midst of all these social sciences researchers, the government sometimes does the opposite, for example, you're a researcher and try to come up with a social research, let's say, on the perceptions of health care professionals regarding their working, worsening working conditions, it's very likely that you cannot get permission from the Ministry of Health. It's an intervention to the freedom of research. We can write down perfect legislative sentences, but […]in the real life there are other challenges researchers face in Turkey.” While this can be interpreted as a problem of guidelines, the context makes it clear that in this case it is also the political sphere that can impact the work of reviewers, but also of research on ethically impactful topics negatively.

The next aspect relates firmly to the outside circumstances in which research and its accompanying ethics review happen instead of the guidelines themselves. One of the IP brought up the lack of appreciation for the work that reviewers do stating quite bluntly: “To be frank, these are mere formalities because all the institutional review boards, they do not go deep: You need to fill up some forms. You need to get it vetted. This is what we are doing. When you go to the field, you get some prior informed consent, you get it signed or you get it ticked, that's all. So that aspect of ethics in data collection is not taken very seriously. [The] Guidelines are perfect. No, what I'm saying is, the practice varies. The practice will vary because institutions are not very keen or they are not very much bothered about adhering to the guidelines in letter and spirit. They [are] just a formality to be completed.” (IP 1) This issue has been raised by other IPs as well, though in the context of other questions and will be discussed later on in this report.

The last important issue raised in regard to what is missing in the guidelines is shared by a few IPs and also centres around the issues outside of guidance documents themselves: It consists in the lack of sufficient knowledge and lack of training about how to adequately review research projects dealing with emerging technologies. We will only provide a short quote illustrating this point here, since it will also be a topic in the next section about necessary resources for RECs as well as in the sections on the specific technologies at the end of this report. In short, IP 2 describes the situation in France and potentially other countries this way: “In France, like in other countries, in our ethics committee we have members from the civil society, for instance, for patient representation, and we have ethicists, physicians, pharmacists and sometimes nurses as well. It's impossible for us to really appreciate the [new/emergent] technology itself. So, we have to rely on what is provided to us when the company says it's robust, when the company says it's fair. […] What can we say? [...]In other countries it should be the same unless you have an engineer […] in the ethics committee. […] In terms of IT based tools, I'm not sure that have the in-house expertise so far.”

4.3 Necessary Resources for REC

The next question of the interview revolved around the necessary resources, e.g. in terms of funding, human resources, expertise, institutional support, or others, to adequately perform reviews of projects about emerging technologies. Unsurprisingly, most answers concentrate on the three overarching issues of funding and human resources, expertise as well as institutional support. A minor aspect

brought up by two interview partners concerns the necessity of adequate monitoring or supervision of the review process for it to happen and to enable accountability. Here, one interview partner noted, regulation plays a crucial role in a type of “carrot and sticks” approach (IP 4).

4.3.1 Lack of Funding and Human Ressources

One of the more prominent answers to this question mentions the lack of both monetary resources as well as a lack of personnel to perform adequate reviews in general and in the case for new and emerging technologies as well. As IP 2 put it: “There is a lack of human resources even in France. We have 39 registered ethics committees, and each of them […] [is] working on a voluntary basis. We're not paid for that.” This situation, is the same in other countries and will get more urgent with an additional need for reviews for research involving emerging technologies. This sentiment is reiterated by IP 3: “One of the problems is that ethics committee members do a great job, but they are not paid for it. […] the whole burden seems to be put on their shoulders.” IP 3 goes so far to consider using AI technology “for the purposes of supporting ethics reviewers and researchers in the evaluation process.” In general, there is a need for significantly more funding especially for the review of research of emerging technologies at least in the case of Turkey when compared to the EU. Another aspect concerning human resources includes also “problems about researcher wellness” (IP 3) characterized by a lack of support not only in terms of payment and funding, but also in terms of working conditions and necessary infrastructure. This is connected to the second overarching topic – institutional culture and support.

4.3.2 Institutional Culture and Support

A couple of interview partners mention institutional support as a necessary resource for REC work and research in general. This includes, as mentioned in the section above, establishing necessary infrastructure and a “peaceful working environment” (IP 3). The same IP describes the situation as follows: “[The] amount of time and human resources not just researchers but ethics committees is very limited. So, they are going too slowly. [...] They might get into burnout [...]. That's why it diminishes the quality of the reviews in general, because they tend to be quick and rapidly, you know, wrap up all the research evaluations in many ethics committees and it makes everything more mechanical than reflective. [...] Instead they use a kind of mechanical approach, [...] for example, they use a checkbox”. Here, we can already see that the issue is not only about the very material, physical support needed from the institution, say in terms of funding, personnel, infrastructure, but also the necessity of establishing a certain institutional culture that values and appreciates the work of RECs instead of seeing “this procedure as an obstacle in their way.” (IP 3). Other IPs answered this question in a similar manner. IP 1, for example, puts it like this: “Too many people think that it [ethics or ethics review] is just a formality. [...] people need to be sensitized, made aware that this is an essential part of the research programme.” A third IP put it equally succinct: “I give trainings to different ethics review committees in this country. [...] The participants are usually like 95% ethics review committee members. And I always ask at the beginning of the training, where are your deans, your chancellors, your directors? They should be here, you know, because after the training, you need support from them. They need to establish an institutional support." (IP 7) The lack of appreciation for REC work and the need for a specific intuitional or research culture is an overarching theme that infuses the whole interview process and is raised by many IPs at one point or another.

4.3.3 Expertise and Training

The most common answer to the question about necessary resources for RECs in terms of evaluating research featuring emerging technologies is the need for more expertise, either by bringing them in from the outside or by training REC members themselves. In the words of IP 4: “An ethics committee member does not become an ethics committee member without any kind of training. So, they also need some kind of training when it comes to emerging technologies, including immersive technologies. If an ethics committee is evaluating a proposal of a special type of health technology, they bring in a person who somehow knows what this technology is about, and the same thing should go for such emerging technologies. There has to be a real specialization and acknowledgement that there needs to be that specialization and of course, some kind of training. They need to know that they're dealing with something else here.”

IP 7, who has more knowledge in the other core technologies of the irecs project, goes in the same direction, stating that “you need committee members who have expertise about artificial intelligence, research about human genome, etc.[...]” Concerning the situation now, IP 7 states that “at the moment committees that receive proposals in this area would usually ask an independent external expert who cannot vote, of course.” Overall, though, it seems that training is the more common answer, over outside expertise: “You need training. They need to have the expertise, at least some of them in every ethics committee. […] Not only for the technical review, but for the ethics review and for experts who can see the significance of the relationship between the technical and the ethical. Because many people think that there is this dichotomy between the technical and the ethical, but I don't believe that. [..] You cannot divide technical issues with ethical issues.” (IP 7) Especially in this latter part of the statement, the connection between the need for training and the institutional culture that was the topic of the section directly above, is implicit in the sense that having both the technical and the ethical expertise are both incredibly important. Here, it is the need for technical expertise for the REC members that must be provided in some way, preferably through training. In the section above, it is the need for researchers and the institutional governing bodies to have ethical knowledge and appreciation in addition to their technical expertise. Fostering and enabling such a deep mutual understanding and appreciation would go a long way to facilitate the review process of emerging technologies.

In one of the interviews, another aspect in relation to the need for training was raised that specifically calls out the relationship between countries of the Global North and of the Global South. They write: “Ethics boards have to be trained. There is a big need for Europe or the high-income countries to actually train and sensitize individuals in the Global South in terms of this technology because the advancement in Europe is happening in our settings immediately. [...] We are able to access anything, any technology that is available. But the question is, how do we interact [with] that technology and where are the guidelines." (IP 9). The thesis from IP 9is that the Global South lacks a certain experience in how to deal with new and emerging technologies since they went from relatively low-tech societies to having access to the full range of technologies available in the span of a couple of decades. This is different for countries in the Global North who had more time to adapt to new and emerging technologies through being part of their development, and thus where able to develop strategies on how to deal with the effects such technologies could have, e.g. through developing guidelines for their use and developing the concept of an ethics review for certain technological applications. This leads

to a certain type of responsibility to offer training, sensitization and knowledge transfer from North to South. The topic of the differences in needs and approaches to technology between the Global South and the Global North was raised by other IPs and in other parts of the interviews as well and will be revisited in other sections of this report.

4.4 Approval and Responsibility

The next topic introduced in the interviews aimed to go beyond the established ethics reviews or ethics approval by a REC which are mandatory for research involving people directly as research subjects. Instead, IPs were asked whether other types of research, not involving human subjects, would require an ethics approval by a REC. Additionally, a follow-up question was posed: Who should be responsible for deciding whether a review by a REC is necessary if no legal obligations for a review exist? This section, addressed both questions in turn, starting with other research areas needing ethics approval outside of human research subjects.

Looking at the answers to this question reveals how entrenched most of the interview partners are in the areas of medical research: The most common answer states that research involving animal studies are and should be subject to an ethics approval by a REC. This shows very clearly a straightforward adaptation of human research subject to animal research subject. It also reveals another peculiarity in the answers in the sense that the IPs rarely answered outside of the box, so to speak, but rather explained the status quo of what types of research currently needs an ethics approval by a REC in their respective country. The answers also span the whole spectrum of reactions from a resounding “No.” (IP 2), stating that an ethics approval for research without human (or animal) subjects is not necessary, especially considering the work overload experienced by REC members already together with it being unpaid work, as addressed in the section above. As IP 2 puts it: “Imagine that you need some extra ethics committees to review [this] type of research, I mean, nobody will come.”. On the other hand, IP 4 clearly sees that there is this bias towards health research: “When it comes to doing research with humans generally outside health, even using immersive technologies, all you need is some kind of ethics notification. [...] Just make sure you have your informed consent. But it's not like a full-blown research ethics committee deliberation. [...] You include humans, but if it's outside health, all you need is some kind of notification. You don't need ethics committee approval, and this tells you the bias towards health research.” Some of the few answers that could be considered more “outside the box” address environmental topics, e.g. IP 3 saying “research concerning environmental issues; risk of, for example, damaging the environment - such research should definitely need ethics approval. I mean, about the planet in general, directly or indirectly.” The same IP also brought up the very intriguing issue of industrial research with a decidedly political component: “Industrial research should also look for approval or it should be made mandatory. Frame it and explain it to the society so that we as ordinary citizens or citizen bodies [know] what they are doing with all [this] information. [...] I want to know, as a citizen, their purposes. […] There are powerful companies, and they can have impact on the society, on the planet, on the life we live, in general. So that's also something else that should be watched and needs ethics approval.” (IP 3).

Similar to the starting question about appropriate topics for an ethics approval, the answers to the question who should be responsible for deciding whether such an ethics approval should be

mandatory or not also contain a lot of answers primarily describing the status quo of the situation in the respective countries and extrapolate from there. In general, three main players were identified by the interview partners as candidates for taking responsibility for such a decision: Government, industry and research institutions.

4.4.1 Government

A substantial part of the IPs think that the national governments and their related regulatory bodies should be responsible for deciding which kind of research needs ethics approval by a REC. Most of the answers revolve around the status quo that can be summed up in the words of IP 4: “In all these countries [Europe] that have this model it is the task of the National Ethics Committee to make such decisions in terms of guidance, in terms of structure. From a very regulatory perspective, it is the task of this governmentally mandated organization called national Ethics committees to provide the structure and the guidance on how to go about the different types of research.” IP 2, IP 5 and IP 9 also argue in a similar direction: “[The National] Commission, would actually be the correct word because that's supposed to be now having all the research studies. [...] So, if it is in energy then they need to work with the Minister of Energy. If it is in health, the Ministry of Health [...]”. (IP 9). IP 1 also adds an interesting perspective when such a governmental oversight is inadequate: “So at the national level, there is no ethical review board or ethical review committee that oversees all these things. It is left to the institutions to comply with that. It is left between the funding agencies and the departments to ensure that they comply. So, there is no national mechanism, there is no independent evaluation and review mechanisms for ethics committees. These guidelines are often very voluntary in the sense that they differ from ministry to ministry. Suppose if one institution doesn't follow these guidelines set up by ICMr, ICMr cannot intervene and ask questions. Only the department that funds that institution can ask questions. So, there is no national level mechanisms to monitor as to whether they are being followed.” This is an interesting perspective in so far as it focuses on the need for a mechanism of evaluating and reviewing ethics in research independently of the institutions and their funding agencies. While the latter do certainly bare responsibility for deciding what type of research needs an ethics approval by a REC, that does not exclude the need for such independent evaluation preferably set up through the national government. IP 3 also offers a similar perspective, stating quite succinctly: “I think it should be a legal obligation. [...] Research projects should be reviewed by a body and this body should be independent from political or power relations and/or monetary or financial conflicts and so on. But it's very hard to do that. The government wants them [the research institutions] to establish such committees, but they don't care. I mean, there's no legislation about it.” (IP 3).

Another perspective well aligned with the topic of the next interview questions about value differences, was offered by IP 7: “Maybe they are not directly part of the research, but the Filipino people say, for example: They can decide. They should decide.” This is an interesting understanding what it could mean for a government to decide about the types of research in need of an ethical review: This could also mean explicitly including the voices of the people, not only directly involved e.g. as research subjects, but as citizens. This could be either interpreted as a need for involving citizens directly in the decision-making process or as seeing governmental decision-making and oversight over the actions of research institutions (and industry research) as responsibility in the name of the citizens of the respective countries.

4.4.2 Industry

A second likely candidate for responsibility regarding deciding to have ethics reviews for new and emerging research topics is industry, according to three of the IPs. Two of them talked more about the status quo, like IP 5, who shared insights in their work as an independent reviewer often working with industry: “So usually in the hospital we have our own [review process]. But a lot of industry [don’t], that's the reason I'm an IRC independent review consultant. I review most of the applications from industry. […] The industry itself mostly probably 90%, I guess they do not have their own IRC. So, they have to trust somebody. […] It’s a different way to review it. […] Whatever the ending kind of thing coming out, we first look at all the documents, you know, the guidance documents.” Following this, industry seems at least for the already established research ethics process to be treated similarly to academic research, by following the same guidelines. But there seems to be a lack of structure that compares to academic research which leads to the need to rely on independent reviewers.

IP 2, in contrast, states on the topic ethics reviews for new and emerging technologies quite succinctly: “[It] should be a responsibility of the designers of the private industries or [who] are developing these new technologies.” They further describe that some of the companies involved in research on new technologies see that need themselves: “In the United States there are now some companies that say, well we went too far, we have to draw back. We have to think about the ethical concerns [and] that there are responsibilities.” They also share an interesting example of the smartwatch that is usually seen as an accessory, but can also be treated as a medical device which then as further implications: “As soon as they're a medical device, the company has to comply with the new regulations for instance.” This example of a new technology and its different uses can be a problem depending on how it is used and defined when it comes to the need of an ethics review, where it probably wouldn’t be necessary for a simple accessory, but would be necessary as a medical device. This can be extrapolated to other new and emerging technologies that may not initially have a medical application but could be used in such a setting in the future.

IP 3 aligns with IP 2 as well, when they state that: “Industrial researchers should also look for approval or it should be made mandatory, companies analysing big data, for example. I mean, they collect [a] vast amount of data from the users, from customers and so on and we really don't know what they are doing with this data. This should be watched I think either by an ethics committee or by another body and they should be made accountable.” IP 3 then goes on to add another layer to this discussion that aligns well with the last point of IP 7 in the previous section, by introducing the notion of the citizen and their right, as well as underlining just how impactful industry research can be: “Frame it and explain it to the society so that we as ordinary citizens or citizen bodies [know] what they are doing with all this information, for which purposes they use it. I want to know, as a citizen, their purposes […]. They are powerful companies and they can have impact on the society, on the planet, on the life we live actually, in general. So that's also something else that should be watched and needs ethics approval.”

4.4.3 Research Culture / Institution

Apart from the government and even more than private industry, it was research institutions that many of the IPs feel should be responsible for deciding whether or not a review by a REC is necessary

if no legal obligations for a review exists. While IP 6 sees this as more of a shared responsibility between the government and the researchers, IP 8 is more direct here: “I think what we have done so far is to push more and more of the responsibility on the institution and the researchers. So that's in a way been the standard answer to that. Well it is the researcher and the research institution that will be responsible for the research that is performed. Whether that works in a legal setting, I'm not quite sure. […] For those where it has been difficult to find legal solutions or place the legal responsibility, the ethics has been placed more and more on the institution and the researcher. The question is, of course, whether the research institution or the researchers is aware of and willing to take this responsibility.” IP 8 also goes on to describe the case of a researcher in the field of gene editing who was convicted personally for ethics violations. According to IP 8 then, “at least for some emerging technologies, we see an attitude with regards to personal responsibility as well.”

The role of research institutes and by extension the (individual) researcher concerning the responsibility of the decisions for or against an ethics review by a REC was often discussed in tandem with a more general call for the need to establish a certain type of research culture best described in the words of IP 3: „Maybe we need some new kinds of mechanisms. Mostly the culture is important [...] ethics is transferred to the work of ethics committees, of professionals by the researchers. But maybe they should see that ethics is also intrinsic to their work. So, we need to develop such a culture.” This is an iteration of the point about the need for institutional support and a specific institutional culture described above in section 3 on the necessary resources for RECs. The status quo, so it seems from the interviews, is very much lacking in this regard. According to IP 6: „In our country setting the guideline and the policy is very, very good. […] Researchers, university and the institution don't have the higher awareness of guidelines’ importance or necessity. So, a part of researchers still doesn’t know why we comply with this guideline, why we submit the research plan. […] Our university and the institutions have provided very useful and [many] programs to promote researchers’ awareness. But researchers don't care.” This later point is also reiterated by IP 3, when they state quite bluntly: „I would say researchers, they just don't care.” IP 3 goes on to sketch how such a culture could look like in some more detail: “Ideally the researchers, universities, institutions should have this organisational culture: Research projects should be reviewed by a body and this body should be independent from political [power], power relations and/or monetary or financial conflicts and so on. But it's very hard to do that. The government wants them to establish such committees, but they don't care. I mean, there's no legislation about it, they only care about the technology or drug or clinical studies.” This lack of an institutional or research culture that recognizes and values the ethics considerations inherent in their research is not just a problem for RECs, but for the researchers themselves or put with a positive spin from IP 3: “The relationship between the ethics committee and the researchers might be good for both sides. You know, the researchers might have the opportunity to rethink or reflect on their research procedures from another perspective, from the perspective of ethics. On the other hand, ethics committee members maybe can see that there's that variety of research being done and they have this broad view of what's going on in the field.” This call for and need of establishing a mutually appreciative and thereby mutually beneficial relationship between researcher and reviewer is one of the more prominent takeaways from the interviews especially since it so well aligns with the goals of the irecs project.

4.5 Country-specific differences in values

The last general question we asked during the interview focused on the differences between countries when it comes to ethics discussions. The IPs were asked whether they felt that ethics discussions are different in their country vis-á-vis other countries and if so, in what way. We also asked whether the IPs attribute these differences to different values. The IPs offered a lot of input in this part of the interview ranging from descriptions of ethics discussions in their country to more overarching issues of research and research ethics when it comes to the North-South divide and research involving vulnerable communities. We will first describe some of the more general assessments from the IPs, and then turn to the North-South divide and its related problems in the second part of this section.

4.5.1 General Value Discussion

Some IPs offered a very descriptive answer that allowed for an interesting insight into the way ethics is discussed in their respective country. IP 1, for example, talks about their experience in India the following way: “Ethics discussions are there, but then again, they're very limited in the sense that, for example, if you look at ethics and science and technology, there is not much discussion. Ethics in medicine, yes, but that is again very limited because medical ethics and bioethics in India as a field has not developed much. Things are often reduced to filling forms, adhering to some procedures or doing some routine activities […] you won't find a dynamic and vibrant bioethical debates or ethics in science, technology debates commensurate with this countries’ population and the number of institutions. Discussion in Europe is different because […] you look at the number of publications, reports and the institutions themselves are telling us about how they [deal] with the research misconduct, ethical misconduct and all. [It] is very clear that those things are not given the importance they deserve in India. It has more to do with the institutional culture, the way emphasis is given to these things and the way the guidelines being thought about more as a formality than as an essential.” This is an interesting take in so far as it shows not so much a difference in values and instead showcases once more one of the major themes of the interview results: a lack of an institutional culture that takes ethics more seriously. This sentiment is echoed by IP 3 though they describe the ethical discussions and the values they revolve around as very similar: “I would say, not much different […] basic issues are the same. […] I always worked in bigger institutions in Turkey, and they [are] quite like the ones in Europe or in the USA. […] I don't see much difference in that sense, but the type of research projects [is] different. So usually small scale here, PhD thesis or something like that. And in the Netherlands the projects are usually a part of a major project. I just realized that the main problem is the […] lack of communication between research ethics committees and researchers. [...] Maybe we should get together often – ‘we’ means ethics committee members and researchers. […] The research community with all its branches should look for opportunities to share much more so that we can develop the culture that we were talking [about].”

In general, for most IPs the dominant sentiment is that the core values are very similar, the differences appear in the nuances, e.g. in the primacy of certain principles as well as differences due to cultural and historic background. IP 5, for example, is of the opinion that “in terms of ethics, it’s not really different” and that any differences arising in shared projects with European researchers can be “harmonized” when broadening the scope. IP 8 points out that even among the different European countries, who share the same general values, there are differences in how the ethical dimensions of new and emerging technologies are approached, e.g. a more liberal approach by the UK, compared to

a more restrictive approach in Germany due to historical reasons. IP 7 answers in a similar fashion that "the fundamental issues are the same, but maybe [there are] different nuances, maybe different specific issues", as does IP 9 by stating: "We all hold the same values, in terms of fairness, in terms of retaining integrity, like respect for participants. All those values are actually universal. [...] The difference is sensitization and exposure." IP 6 agrees that it is not so much different values, but that the implementation of "the principle or value depends on the cultural and historical background." In the same vein as other IPs before, IP 6 also calls out the importance of "all researchers to promote the higher-level awareness and good research practice abilities." They also point out another interesting aspect that will be taken up next in this section: "East Asian countries have [a] different cultural and historical background. [But] the guidelines of biomedical research is started [with] Western background. So [there] is difference."

4.5.2 The North-South Divide, benefit sharing and vulnerable communities

The aspect mentioned by IP 6 of guidelines being adopted world-wide from the Western countries can lead to the impression that there is overall agreement about how technology and research ethics is to be approached. The section above indicates that most IPs stated that they share many values across different countries, with differences appearing more in the details. However, many IPs question whether these similarities in values stem arise from genuine mutual agreement or if they exist because the guidelines and preceding ethical discussions are adopted from Western countries. They also call into question whether the differences in the details of cultural and historic backgrounds are as negligible as they might appear against this backdrop of overarching shared values. Indeed, it could be the case that important ethical considerations are missing from the ethical discourse in general and for new and emerging technologies specifically if the ethics discussion is centred on a Western approach and does not sufficiently include other perspectives. There is a quote among many during the interviews which encapsulates the general conflict: „We are moving into new fields of research, but we have not even touched, genuinely touched, substantially age-old issues of exploitation and injustice in research, the North-South divide, for example." (IP 7)

IP 7 goes on to further elaborate this point: "It speaks to [a] larger and much [more] ancient issue. People in the Philippines, India, Mexico and others would simply say, Hallelujah, researchers from Sweden are here. So, we welcome them because there is so much need for funding, for international linkages. They will not ask questions […]. That's why I said the old issues would still be there, whether it's human genome, whether it's AI". Here, IP 7 offers a key insight into the North-South divide, namely the lack of funding in the Global South and their reliance on researchers from the Global North that leads to a power imbalance to the disadvantage of countries in the Global South and their respective population. This problem is echoed by IP 9 when talking about Kenya: "Now machine learning is at the universities in the high-income countries, but you don't have machine learning here. Again, I feel this is unequal because even if I was to collaborate with the university, maybe in Germany, I don't have the structure to do the analysis unless they do [a] technology transfer. But in terms of the hardcore science, I'm not able to participate because I don't have the tools. […] Europe and America go ahead and then the Global South is left behind."

The imbalance between Global South and Global North is also evident in the principles and values that inform the Euro-American-centric guidelines and how they prioritize certain values over others. To

quote IP 7 again: “In the usual traditional Euro-American ethics guidelines, principles [such as] respect for person[s] is basically translated, of course with some qualifications, to [respecting a] person’s autonomy. Autonomy equals [being] respectful [of a] person and informed consent is its most classical demonstration. The principles of justice, I think should be there and if informed consent is the most visible, demonstrated manifestation of justice, then it must be done.” The sentiment that Euro-American ethics guidelines are strongly focused on autonomy and privacy over considerations of justice, equity, fairness, solidarity and empathy is also illustrated by IP 4: “I do work a lot with Asia and Africa and I also have partners, for example, from Latin America. The ethical discussions are different not only in terms of topics, but in terms of primacy of certain principles. In Asia, Africa and a little bit of Latin America, we're talking about the stress on equity, the stress on justice. That's very big because there's really a lot of exploitation going on. That's in terms of differences in terms of topics, but that also dictates the differences in terms of principles. If in Asia and Africa we're talking about issues of justice, for example, when research happens in their countries, do the products of this research actually come back? Are they able to use the benefit from this [research]? This is what's happening in low- and middle-income countries and therefore the ethical principle that is most dominant will be fairness, justice, equity, etc. But here in Europe and in the United States, we're very much focused on autonomy. Do you have the right to use my data? How can I protect my data? Will I have access to my data? Will I be able to remove my data? This is what we're concerned with because we're not concerned about access to health […], because we do have that access. Of course, I'm not saying that the issue of autonomy and privacy and security is not an issue, of course it is, but there are more basic human needs that need to be addressed and that's why the issue really becomes [an issue] of justice, of equity.” This quote offers a further key insight and an explication what a dominant focus on justice and equity could mean in the context of a global understanding of research ethics: It could consist in the sharing of benefits generated by research in the Global South, as IP 4 further elaborates: “If I send my genetic material outside, will I benefit from it? Will my country benefit from it? You know, that becomes the real issue. Some countries in Asia have a very American perspective when it comes to ethics. For example, the Philippines, because we were once an American colony […] This whole issue of equity, injustice, some Asian countries are just starting to catch up and that means research ethics committees make decisions that can be against the real societal interest of the country. We're not thinking of the wider issue of justice that is benefit sharing and distribution.”

This difference between Global North and Global South in approaching questions of research ethics, e.g. by using an approach based on Western philosophy like Utilitarianism or Deontology over ethics of care and Communitarianism is explicitly addressed by IP 7 who states in regard to the guidelines available for ethics review: “There has been legitimate criticisms about the guidelines. They are still strongly Euro-American in terms of its values – utilitarian, individualistic, corporate capitalist. Many of the values, not only the Philippines, but I think all over the Global South are not there, like ethics of care, communitarianism. These are absent.” This problem becomes very apparent when dealing with vulnerable communities as research especially in the Global South often does. To this, IP 7 says the following: “In the Global South, including deprived communities in the North, I would consider them as part of that Global South. So not geographic, but in terms of vulnerability. [...]I would say there are very similar issues that have been spoken about and discussed and brought to the attention of people like us, but there are also very specific issues, for example […] the caste system, the untouchables, intersecting with gender. Vulnerabilities of specific groups like commercial sex workers, transgenders,

the LGBTQ+ community, so very specific groups of highly vulnerable people. I would inject the values in feminism, of ethics of care. [...] which is very different from utilitarianism, deontology […] Women, highly vulnerable populations can connect with ethics of care, with empathy and solidarity. […] Whatever research you do […] you have this commitment to carry empathy and a sense of solidarity." (IP 7) This last call is of special importance when dealing with new and emerging technologies, as IP 7 further elaborates: "No ethics guidelines are maybe necessary. Maybe you need to [have] some kind of the technical [guidelines]. It's very difficult even if you come up with the best excellent ethics guidelines if you don't have these fundamental values. Maybe we should put in the centre [ideas of] communitarianism or ubuntu. Maybe we need more caring, maybe we need more empathy, maybe we need more solidarity instead of more sophisticated technology."

4.6 Technology-specific questions

The following section examines the answers specific to the four exemplary technologies of irecs: AI in healthcare, Extended Reality, Genome Editing and Biobanking. For each technology the same questions were asked. First, the IPs were asked which guidance documents or guidelines they find particularly helpful for reviewing research projects in these fields. The second question addressed the most common challenges that RECs or other ethical review bodies face in the context of research in these four fields.

4.6.1 AI in Healthcare

Many of the IPs could contribute information to the current situation of AI in healthcare. Concerning important guidelines, the consensus is that they are emerging but at least on the national level they are sometimes only preliminary. There are some guidelines mentioned more often, some concrete examples being: "The EU's Artificial Intelligence Act, EU's White Paper on Artificial Intelligence in 2019, and the Artificial Intelligence Bill in April 2021" (IP 10). This is also mentioned by other IPs, e.g. IP 4: "I would say that the most relevant would be the EU AI act [...] followed up by GDPR. [...]I would think that [the EU AI Act] will be the most influential of them all." Other interesting guidelines come from the US: "US NIST: Artificial Intelligence Risk Management Framework and US FDA: Proposed Regulatory Framework for Modifications to Artificial Intelligence/Machine earning (AI/ML)-Based Software as a Medical Device (SaMD)-Discussion Paper and Request for Feedback" (IP 10). Other work on guidelines is mentioned in relation to the UNESCO: "I was in UNESCO last year, headquarters in Paris, and I was just so happy to see they developed several sets of guidelines in human genome and artificial intelligence […] and UNESCO guidelines generally speaking are very strong on the social sciences." (IP 7) The national regulations however, according to several interviews, are usually inspired by the EU Artificial Intelligence Act, but very preliminary: IP 10 says: "In China's ethical review practice, they have very important references [to the EU AI Act], but there are no such norms and best practices as a guide in China." Similarly, IP 7: "As of now, [for] the Philippine Health Research Ethics Board […] the official guidelines have just a few sentences on research using AI." IP 8 sums up that "in AI there are emerging guidelines now. […] To my knowledge [there are no] ready-made guidelines that are applied in countries."

The IPs identified some relating challenges of reviewing projects in the field of AI in healthcare, the most prominent being the lack of necessary tools and expertise to assess such research projects as discussed early on in section 4.2. IP 2 summarizes the problem as follows: “We are not engineers, so we can't have access to the algorithm, for instance. We rely on what is written on the project because we have not the tools to analyse it […] We don't have the tools for assessing the technology in the ethics committees.” IP 4 argues in a similar vein, though with a positive spin, saying that many people know about AI, but “only very few would have any kind of sufficient knowledge on what AI means. Why am I saying this? It's because the research ethics committee members are not very different. I think there is more consciousness of the risks of AI and I would even say that sometimes the risks are too inflated. […] It can be inflated because of the fear of the unknown or of the fear of the novel, but I think what's good about the fact that there's this fear, will be also the push for us to know a little bit more about it.” For IP 8, the most pressing issue concerns privacy and the question of risk vs. benefits in using AI in healthcare: “The types of applications in proposals will be very, very different in AI and healthcare. So, it's very hard to generalize, but of course one of the challenges is the information that goes into the algorithms and whether it violates privacy issues. [The] overarching issue is the privacy issue with regards to the data going into it and the validation of the output or the outcome, whether it's actually depicting anything of relevance to the person. […] The validation of the algorithms coming out of AI research is crucial and of course that goes to the principle of beneficence. How can you be certain that it actually will benefit people and not harm them?” IP 10, at last, offers a comprehensive discussion of potential challenges of AI in healthcare which includes the problem of medical practitioners or researchers not being aware of using medical devices that operate with AI applications: “Problems are becoming more and more prominent in areas such as medical devices, diagnostic imaging and assisted diagnosis and treatment. AI and big data models have been introduced in large quantities in the above fields to help doctors make decisions or to replace them, and in the development process of these information systems, the intervention of ethics committees is not required. Even many doctors do clinical trials without knowing that the basis of his decision-making has been screened by AI. […] More and more imaging assistance software is being used, a large amount of imaging data is used for oncology diagnosis, assisted diagnostic software uses a large amount of machine learning, graphical big model technology, the doctor reads the impact of the images that have been repaired by the AI, but many doctors are not aware of this, the doctor has no way of knowing what useful information has been thrown away, and whether the AI will give the wrong diagnosis in one of the training deviations conclusions.” IP 10 also presses the issue of privacy concerns and the necessary protection of sensitive personal data in the context of cybersecurity and risk: “Big data is used in a large number of aggregations, and the potential for group privacy breaches, e.g., hiding personally identifiable information alone protects the individual, but does not prevent the genetic vulnerability of an ethnic group (e.g., allergy to a certain drug) from being calculated through cluster analysis. Cybersecurity risks are increasing but are not recognised in the diagnostic process: this software can fail, causing loss of patient data and interruption of surgical procedures, e.g., there are backdoors in clinic software that, if exploited by hackers, can cause group harm. Purchasing committees in healthcare organisations need to be reminded: is the information coming from, or being passed on to patients something that needs to be processed through an information system? Is the process processed by AI? Will the data be aggregated for use? If so, then the REC may need to be invited to participate in the review.” Another challenge for IP 10 lies in the vagueness of definitions

regarding privacy: “The definition of privacy data is confusing between the legislative branches, e.g., the definition of anonymised data, desensitised data, de-identified data is vague, so there are conflicts between regulations. There is no specific legislation on how to protect private data when using AI, therefore, conflicts arise as to whether privacy protection is prioritised or efficiency is prioritised. The definition of stakeholders' right to know of private data is vague, e.g., whether spouses of AIDS patients have the right to know.” Overall, there is “1) insufficient knowledge of policy makers; 2) IT technology has penetrated into all areas of medical diagnosis and treatment and is developing very fast, and 3) REC's ability to publicise and promote it is insufficient.”

4.6.2 Extended Reality

The second core technology of irecs is extended reality, where only two of the IPs could offer some insight. Where guidelines for assessing and reviewing projects in this field are concerned, there seems to be a lack of guidelines. IP 8 states that „as far as I know, there are no specific guidelines used for this that are developed in Norway. So, we rely on international regulation.” IP 4 answers in a similar vein: “There are not many guidelines when it comes to extended reality technologies. One of the earliest countries that actually came out with a guideline on the metaverse is South Korea.“They go on to further describe the situation, saying that with immersive technologies “organizations come up with their own checklists or guideline of some sort, or at least some kind of reflective, ethically reflective materials. But when it comes to national or international guidance documents, we’re sorely lacking in that. […] ethics committees are just grappling with what they can.” Though IP 4 also mentions that there is work currently going on about developing a guidance document “on human centred and ethically reflective development of extended reality technologies.”

The two IPs identified three main challenges for extended reality and its review process: The first deals with the difficulty of assessing future benefits of this technology, with IP 8 stating: “Now we get a lot of knowledge with regards to the potential harms of extended reality. Those projects I know of are very aware of the potential harms to research participants. But assessing the potential future benefits is quite challenging.” Another challenge is the problem of data privacy, with IP 8 also stating that there are “issues of privacy and autonomy” with immersive technologies. IP 4 also underlines this challenge specifically about the amount of data generated via extended reality technology: “The type and amount of data it gathers on an individual per minute is, I would say is almost unprecedented. […] It's a kinematic fingerprint. It's not comparable for example to the data that you give if you go to a clinic […] and they put that in a data bank and a researcher investigates it. That's totally different compared to this kind of data, because this is continuous […] and it's very personal.”

A very big challenge for reviewing projects in the field of immersive technologies for IP 4 lies in the lack of understanding by REC members. In IP 4’s own words: “Many research ethics committee members – because of this bias towards health research – it's [extended reality] not something that they can grasp. Maybe many of them have never really used VR. I have never really surveyed them, but this is my impression: They think VR is a toy. Without this personal knowledge and without any kind of guidance documents on how to evaluate this, they will evaluate this de facto on what they're used to, and therefore they will be using their health research guidance documents [...] and they don't really fit the bill. It’s really that lack of knowledge and sometimes lack of appreciation of how different this technology is compared to, for example, x-ray machines or even MRI machines, which they're very

familiar with because they're coming from that background. [...] Because of the false impression that this is largely only used for entertainment, this bias can create a risk for research participants if not addressed." At least this last challenge is one that can be addressed with the work being done in the irecs project by training and educating REC members on the ethical implications of extended reality.

4.6.3 Genome Editing

For the case of genome editing, very few answers were given overall. Concerning important guidelines for reviewing projects in this field the answers were very restrained. IP 2, for example, said „I'm not aware of any." IP 8 also shares this perspective, saying: "with the guidance to for instance, gene editing, there are no broadly accepted guidelines for how to do that. So of course, that is one area where it's clearly wanted." (IP 8). IP 7, on the other hand, mentions some work in progress on guidelines for genome editing: "I was in Unesco last year, headquarters in Paris, and I was just so happy to see they developed several sets of guidelines in human genome, artificial intelligence."

Concerning the challenges, the IPs perceived with this technology, the few answers they gave nevertheless offered some interesting insight. For example, IP 2 doesn't see any specifically ethical challenges with the technology, stating that "in a scientific committee [it] could be different because genome editing could have some issues itself. But in an ethics committee, there won't be any discussion regarding the technology itself. We have no difficulty in our ethics committee to review the project and to give a clearance if the project is well written and the participants are well protected." IP 2's only concern relates to the accessibility: „My concern will be the access of this technology to all, […] how much it costs to treat someone with a genome editing based drug today. It's amazing. It's millions of dollars. So how can you afford it?" IP 8, on the other hand, perceives some challenges of genome editing when it comes to consequences in the future: „If you're going to assess the consequences of gene editing, the consequences may come in generations from now […]. So, of course, it's very hard to make good protocols to do them in a safe and controlled manner." Another challenge identified by IP 9 lies in the cross-border transfer of data: "These [samples] cannot be analysed locally. They have to be shipped out. We can do a few things here, but most of the basic science, the technological advance studies on this and especially on maybe genome editing, […] those ones have to actually be done outside the country. [...] I have to ship samples. That is when the problems begin. Things can go very, very south." The cross-border transfer of data is a challenge for some of the other technologies as well and IP 9 also mentions some potential challenges faced by genome editing if it is combined with AI technology as well, calling it "a new area" where it is necessary to understand where all these technologies like genome editing, biobanking and AI in healthcare fit in in this time of technological advancement.

4.6.4 Biobanking

In contrast to the previous technologies, biobanking seems to be, according to many of the IPs, to be very well regulated with solid guidelines for ethics reviewers to follow. IP 2, for example, says that "In France we do have some guidance issued by the medical agency and by the research ministry as well. [...] We have good practices in how to collect, to process, to maintain the samples in biobanks." IP 8 confirms this for the European perspective, saying that "in the health research law in Norway, for instance, specific points on biobank research have been included." These points, so IP 8, "come from

general guidance and regulations in [the] EU and outside the EU." which is more general, while "the Biotechnology Act in Norway has been quite restrictive."

Outside of the EU, the situation is similar. IP 1, for example, says that the ICMR, the Indian Council of medical research, offers guidelines for biobanking. IP 4 also mentions that there is regulation and guidelines for biobanking available. The situation in China seems similarly well regulated. IP 5, for example, went into great detail in the interviews describing the situation in China and some very new developments concerning biobanking guidelines, saying that there is a "new regulation […] officially released by the China government, which is called New Regulation on Human Genetic Resources" which "pretty clearly define" how to deal with this resource, how the samples are collected, the data generated and how sharing it internally, from institution to institution happens while protecting privacy and benefit sharing. There are other regulations for dealing with the biological material, but also this regulation is more focused on dealing with the data generated through these samples. In practice, this means that "every biobanking or clinical research or any research involving human samples, they use [this] as a very important government document, for example, when you [first] submit the application […], you have to get approved or get the permission from the government […] when you submit the application, you definitely involve six key points about ethics". While "the framework doesn't change", it is updated regularly, which includes a change of scope in the sense that the guidelines now extend to general life science beyond clinical medical research. They also include information on how to deal with international collaboration with regards to samples: "You also need ethical review. [...] you have to make sure the source material has to be legally approved." This is very interesting in so far as cross-border sharing of samples and data is one of the challenges of biobanking identified by some of the IPs, so it would be interesting to see how this issue is addressed in the guidelines specifically. IP 5 also mentions other regulations like the biosafety law and new laws coming out about data security. This last law is also mentioned by IP 10 in relation to Chinas regulation of biobanking, the Personal Privacy Protection Law. IP 10 also offers some other regulations and guidelines important for biobanking, namely the GDPR for the EU, HIPPA for the US and also for the US the Informed Consent Guidance for IRBs, Clinical Investigators, and Sponsors by the FDA. IP 9 is more ambivalent concerning the situation in Kenya, saying that "the only thing that I have is for me to ship any samples based on the Data Protection Act. I need ethics approval to ship those samples. […] Those are the guidelines that I have. But in terms of what can be done with the samples? […] Now we rely on the goodwill of our collaborators."

Despite the relatively good regulation and guidelines available, there are still quite a few challenges in the field of biobanking. One challenge consists in the lack of an established mechanism for monitoring adherence to existing guidelines, at least in some countries. For example, IP 1 mentions that especially for independent research projects "there is no national level mechanism that monitors or that coordinates all these things. […] There is no other mechanism to verify as to what they are doing with the ethical guidelines." IP 5 mentions a similar point when talking about industry research, where e.g. research goals are only formulated very vaguely contrary to the requirements by the guidelines and special care has to be taken to clarify why taking specific samples is needed in the first place. Another challenge that relates to IP 9's more ambivalent stance on guidelines and that also most of the IPs mention is problems arising in the cross-border transfer of data. IP 10 summarizes it as follows: "The cross-border transfer of data and the principle of long-arm jurisdiction make biosample banking a

multi-jurisdictional challenge." IP 5 and IP 2 both mention this challenge, IP2 elaborating that "in my ethics committee, for instance, we're very careful about sending samples outside of EU. […] We very often ask the promoter of the research to ensure that the data linked to the samples will comply with our EU regulation. Same when the promoter needs to import the samples from outside the EU, we also ensure that it has been done complying with proper guidance." These challenges are also mentioned by IP 9, who characterizes the situation as follows: "I have to send that data which is de-identified to my colleagues in Manitoba. But then I don't have any control over what they can actually do with the samples. […] We can agree with the ethics board here and in Canada that you're going to do A, B, C, D, but I cannot stop them from doing X, Y, and Z. I can also not stop them from sharing the samples with somebody else." IP 9 also demonstrates how this challenge leads to further difficult questions that are strongly interrelated with another challenge identified by many of the IPs, namely issues around privacy and collecting of sensitive data in the context of biobanking. Illustrating one side of this conundrum, IP 9 says: "Kenya has actually produced a document called the Data Protection Act [that is] actually in conflict with a lot of other things that we do in terms of biobanking, in terms of shipping of samples. […] The people I'm collaborating with can actually make a diagnosis, […] if they're able to look into the genetics and then tell me these individuals are at high risk of breast cancer, what do I do with that information? [...] They have that information, are they allowed to give it back to them? And because I work with the communities, if I know an individual X, Y, and Z is part of that group, do I have a right to go and tell them? […] How do I use that information? So, the high-income countries have a lot of benefits. But the problem is, then I have a flood of legal, ethical, and regulatory challenges because I wouldn't know what to do with that information. I'm the gatekeeper. I'm the one who got the permit to export the samples to my colleagues in Manitoba. […] Eventually they do those studies [and find important health information] and they don't tell me, are they violating any ethical frameworks? Yes. But do they have any right to actually give me that information? No. They are able to see who is likely to get cervical cancer because of HPV and they can't give me that information because that is not what we're looking for. […] Is it ethical for them to share that information? Yeah. And if I get that information, what do I do with it? Do I tell everybody who is at high risk of getting cervical cancer?" This challenge is according to IP 9 exacerbated by the fact that they work with vulnerable communities who might not have the necessary resources to even address the health issues potentially detected by the work on their samples.

This case described by IP 9 illustrates well the challenges arising between privacy concerns on the one hand and information garnered through biobanking samples on the other and it is an issue that resurfaces in various ways in project work. One way is the aforementioned difficulty to deal with information about the sample donors that exceeds the research goal and could be vital for the original sample donors to know. IP 1 also mentions a difficulty concerning access, data and benefit sharing – the existing guidelines don't cover this issue of re-contacting sample donors. A very similar issue that arises out of this conflict relates to the future use of the samples and the fact that biobanking requires a long-term strategy. As IP 8 puts it very similarly: "It's the future use of it, handling the information, the secondary outcomes, for instance, how to handle if you find something that can be very important to the patient with regards to re-contacting, for instance. You can use biobank material for other issues, which they haven't been collected for and of course, that falls under the principle of autonomy and informed consent. These issues have been known for quite a while. There have been some measures to try to handle [this]. I would definitely think that some of the outcome assessments and

safety assessments with regards to long time consequences would be really hard to assess." IP 9 also illustrates the difficulties about the long-term thinking required for biobanking: "We've been in existence for the last 30, 40 years. […] There are samples that were collected from the sex workers in Nairobi, maybe in the 1980ies. [...] Can you use those samples because they're very, very useful samples [...]But now the question is, how do I share those samples with the biotech companies? I didn't get ethics approval during that time, because ethics was actually not very well enforced. But then I can't find the individuals that actually donated the samples. [Who is] the right person to actually give consent for the samples to be used, do I need to talk to the community of sex workers who were not even existing? Some of them were born after that. [...] So, the question is can they give consent?" In this case it is not only that the future use of samples collected today has to be considered, e.g. when designing consent information sheets etc. today, but also how to deal with valuable data whose donors can't be re-contacted.

IP 10 also identifies a related challenge: "When the bio-sample bank is created, it does not know which personal privacy data are useful for future research, so it tries to collect as much personal privacy data as possible, which often violates the privacy collection principle of the least amount of data". Privacy concerns, even though they are in the forefront of many of the guidelines existing, still offer a variety of challenges, as IP 10 further elaborates: "Different data storage methods make it very difficult to fulfil the expiry of deletion of privacy data: Based on the automatic operation of computer programmes, manual deletion of data is very difficult: subjects have the right to withdraw from the test at any time, and when they do so, the sample bank should delete their personal identity data at the same time, which are very difficult to be deleted manually. When personal privacy data is used, it may reveal privacy information of different ethnicities and different biological types due to clustering."

To sum up: Despite the relatively solid regulations and guidelines in place, challenges arise especially in the conflict between privacy concerns and the future use of data, information garnered beyond the promised research goal and the ability to re-contact sample donors as well as the limited ability to gain informed consent after the original purpose of taking the sample has passed.

4.7 Concluding Remarks

The interviews proved to be a well of interesting and important insights into the practice of the work of RECs as well as some of the frequent challenges they face. There are a couple of overarching themes throughout all the interviews: The first would be the prominent role that research institutions play in the perception and appreciation for REC work as well as general necessity of institutional support and establishing a research culture that takes the ethical impacts of research, especially research centring around emerging technologies, more seriously. Another important theme was the need for training and appropriate guidance documents that are necessary for REC members to adequately review and assess research projects featuring new and emerging technologies, especially in the case of research featuring AI technology. In this context, the necessity of technology-specific expertise was emphasized by most of the IPs to ensure an adequate review process. Last, many IPs agree that there should be a stronger focus on vulnerable communities, especially when they are directly involved in research. This was discussed in the wider context of Guidance documents predominantly expressing Western value systems that may not be sufficient to address wider issues stemming from the North-South divide and

may cement existing inequality if not addressed appropriately, e.g. by including other, more community-oriented value systems. Overall, the interviews confirm that the irecs project is on the right track and addressing urgent needs for REC members with its research goal of providing adequate training to further the necessary knowledge of REC members new and emerging technologies.

5. In-depth case: Africa

The need for local ethics review is enshrined in most international ethical guidelines. In Africa, the need to conduct ethics reviews was, to some extent, promoted by international donors, who required local ethics approval prior to funding research projects[25]. Consequently, several African countries established independent research ethics committees (RECs) to review and approve proposals and promote the safety and welfare of research participants. Currently, nearly every African country has at least one national ethics review committee. In addition, some countries have up to fifty institutional research ethics committees, scientific review committees and medicine regulatory committees, mandated to conduct scientific and ethics review. In some countries, studies have to be submitted to more than one ethics and regulatory ethics committee and wait for their clearance and ethical approval before they (studies) commence[26]. Although the process differs from country to country, multiple approvals, especially for large clinical trials, remain common and have been blamed for impeding timely approval and commencement of sometimes highly promising research interventions in the continent.

5.1 Strengths, weakness and opportunities

African research ethics and regulatory systems have evolved and matured over time. Since the first REC was established in 1967 in South Africa[27], several developments have occurred, ranging from a situation where most RECs lacked basic ethics review instruments, such as standard opening procedures and templates, and were barely able to conduct any reliable review; to the current situation where most RECs have the basic requirements and can perform well articulated and robust ethics review. In addition, most African research ethics committees are currently well established with a reasonable number of diverse and multidisciplinary members. The need to conduct ethics reviews has also become an integral part of the research ethics and regulatory system. As such, there is more awareness and appreciation of the role of RECs in most African countries.

Despite the above developments it is worth noting that most RECs in Africa still have serious gaps related to training, budget, office space and technology, all of which affect their operations and

[25] https://cioms.ch/wp-content/uploads/2017/01/WEB-CIOMS-EthicalGuidelines.pdf
[26] Kruger, M., Ndebele, P., & Horn, L. (Eds.). (2014). Research ethics in Africa: A resource for research ethics committees. African Sun Media
[27] Silaigwana, B., & Wassenaar, D. (2015). Biomedical research ethics committees in sub-Saharan Africa: a collective review of their structure, functioning, and outcomes. *Journal of Empirical Research on Human Research Ethics*, *10*(2), 169-184

efficiency[28]. EthiXPERT's experience of working with most RECs in Africa shows that most RECs depend on their host institutions for budget allocation and lack any means of income. This does not only affect their independence but also their ability to carry out basic functions such as training and proactive assessment of approved studies. Consequently, most REC members lack relevant ethics training to help them perform their tasks optimally. Limited training of REC members has implications for the quality of review. It is also worth noting that most REC members offer voluntary services. Without any source of income, most RECs struggle to provide even modest allowances to their members, leading to demoralisation and long turn-around time for reviews. Lack of budget allocation and income may also lead to the inability of RECs to pay for their overheads such as office space, power and internet, which could have implications for their operations and quality of review. Lack of budget allocation and income also leads to overreliance on external funding. While some RECs have now started charging a small fee for reviewing protocols, this could make them develop the notion that their survival depends on the availability of funding through researchers who submit protocols and seek funding from external donors which their host institutions also rely on. Such circumstances might affect the independence of RECs through unconscious bias or conflict of interest which may affect the quality of the review, potentially exposing research participants to harm.

With the ever-changing and dynamic research environment, one would have expected RECs to be at the forefront in investing in technology such as online review systems and training in ethical issues raised by new biotechnological and emerging technology research such as genome editing, AI, and bioengineering, among others. Unfortunately, most African RECs continue to use manual review systems involving recovering and storing voluminous printed protocols without the benefit of training in the ethics of modern scientific methods[29]. Using such analogue/manual systems not only makes the review process cumbersome but is also prone to hazards, un-standardised review processes, poor tracking of applications, fragmented communication and long turn-around time.

5.2 Similarities and Differences between European and African RECs

The African research ethics and regulatory systems borrow heavily from the Global North because this is where the original research atrocities took place, leading to the development of the famous universal ethical principles followed by international guidelines[30]. In addition, as stated above, due to the over-

[28] Nyika, A., Kilama, W., Chilengi, R., Tangwa, G., Tindana, P., Ndebele, P., & Ikingura, J. (2009). Composition, training needs and independence of ethics review committees across Africa: are the gate-keepers rising to the emerging challenges?. Journal of medical ethics, 35(3), 189-193.

[29] Mokgatla, B., IJsselmuiden, C., Wassenaar, D., & Kasule, M. (2018). Mapping research ethics committees in Africa: evidence of the growth of ethics review of health research in Africa. Developing World Bioethics, 18(4), 341-348.

[30] Code, N. (1949). The Nuremberg code. Trials of war criminals before the Nuremberg military tribunals under control council law, 10(1949), 181-2., Sims, J. M. (2010). A brief review of the Belmont report. Dimensions of critical care nursing, 29(4), 173-174.

reliance on donor funding, it was easy for donors to influence the need for local ethics approval as a requirement for adhering to international guidelines. Because of this, Africa missed the opportunity to either develop Afrocentric ethical codes of conduct or participate in developing the universal codes of ethics and international ethical guidelines. Therefore, it suffices to say Africa follows the Global North's universal ethical principles and international policies and guidelines, whose revision has gradually involved the participation of a few bioethicists from the Global South. Therefore, the similarities in ethics and regulatory systems between Europe and Africa can be traced back to the historical development of ethics systems, especially the use of universal principles and guidelines.

Notwithstanding the above similarities, it is worth noting that the application of ethical principles has increasingly been shaped by new and emerging debates and views on their blanket application. For example, while there is consensus on the need for autonomy, the original/western conceptualisation of the principle of autonomy, which was very individualistic, did not seem to respect the African cultural norms, which looked at autonomy from a more communitarian perspective. As such, applying basic ethical principles associated with the principle of autonomy, including informed consent, has increasingly taken a more societal approach. According to Akpa-Inyang & Chima (2021), who studied the South African traditional values and beliefs regarding informed consent and limitations of the principle of respect for autonomy in African communities, Ubuntu focuses more on the interests of the collective community rather than the Westernised individualism[31].

Consequently, collective decision-making processes within the Ubuntu perspective precede individual autonomy and consent. This therefore conflicts with Westernised autonomy and has serious implications for informed consent practice in Africa. Arguably, this may hinder ethical principlism in African bioethics. Using the Ubuntu approach requires more flexible ways of consenting, including allowing for spousal consultation and permission in addition to the index individual consent. Furthermore, approaches such as community engagement and citizen science have been growing in popularity to accommodate community consultation and gatekeeper permissions as alternative approaches for strengthening the informed consent process. It is also to be noted that the emergency of African philosophy brought with it a paradigm shift in how people and society relate. For example, the concept of Ubuntu[32] underscores the notion that all people are interrelated (I am what I am

[31] Akpa-Inyang, F., & Chima, S. C. (2021). South African traditional values and beliefs regarding informed consent and limitations of the principle of respect for autonomy in African communities: a cross-cultural qualitative study. BMC medical ethics, 22, 1-17.

[32] Hailey, J. (2008). Ubuntu: A literature review. Document. London: Tutu Foundation, 1-26, Praeg, L. (2008). An Answer to the Question: What is [ubuntu]?. South African Journal of Philosophy= Suid-Afrikaanse Tydskrif vir Wysbegeerte, 27(4), 367-385, Seehawer, M. K. (2018). Decolonising research in a Sub-Saharan African context: Exploring Ubuntu as a foundation for research methodology, ethics and agenda. International Journal of Social Research Methodology, 21(4), 453-466, Ewuoso, C., & Hall, S. (2019). Core aspects of ubuntu: A systematic review. South African Journal of Bioethics and Law, 12(2), 93-103.

because of who we all are). As such, people and society are expected to be more concerned about what kind of research everyone gets involved in and what their participation means to society.

This is especially important when it comes to new research technologies such as genetic research, which may have implications for those involved in the research, their families, relatives, and society. This concept has increased the need for more community consultation and involvement in research. In this context, the reviews undertaken by African RECs increasingly focus on benefit sharing for the wider community, ancillary care, infrastructural development, capacity building, and empowerment for researchers and the community[33]. This could be argued as a departure from the traditional Westernised individualistic application of ethical principles to a wider communitarian approach of applying the same ethical principles of autonomy, beneficence and justice.

Indeed, debates on how universal ethical principles are applicable in Africa, amid its rich cultural diversity and multidimensional value system, have taken centre stage in the last few decades. Scholars argue that rather than take a strict principlism approach, there is a need to use a more flexible approach that could accommodate more communitarian dimensions through, for example, the frameworks such as the Emanuel et al. framework[34.] Through this framework and others, there is a realisation that although the ethical principles remain the same, the way they are applied, including how respect, informed consent, and beneficence are used, must consider the local contexts. This view is also supported by guidelines such as the TRUST code, a global code of conduct for equitable research partnerships[35], which underscores the need for promoting fairness, respect, care and honesty in conducting research to avoid ethics dumping and exploitation to support long-term equitable research relationships between partners in lower-income and high-income settings.

Despite the universal ethical principles and the evolving development of ethical guidelines, it is important to note that Africa is diverse. As such, guidelines such as the global code of conduct for equitable research partnerships emanating from one homogeneous San community in South Africa may not necessarily apply in all African communities and settings. However, such guidelines, like the universal ethical principles, provide an important blueprint that can be adopted and used in different contexts where the values described in the guidelines apply. Therefore, although there is consensus that fairness, respect, care and honesty are important values, as well as respect for persons, beneficence, and justice are critical in the conduct of ethical research, there is an emphasis on the need to continuously reflect on the application of these principles and values to ensure the target

[33] Emanuel, E. J., Wendler, D., & Grady, C. (2000). What makes clinical research ethical? Jama, 283(20), 2701-2711, Holzer, J. K., Ellis, L., & Merritt, M. W. (2014). Why we need community engagement in medical research. Journal of Investigative Medicine, 62(6), 851-855, Adhikari, B., Pell, C., & Cheah, P. Y. (2020). Community engagement and ethical global health research. Global Bioethics, 31(1), 1-12.
[34] Emanuel, E. J., Wendler, D., Killen, J., & Grady, C. (2004). What makes clinical research in developing countries ethical? The benchmarks of ethical research. Journal of infectious diseases, 189(5), 930-937
[35] TRUST. (2018). The TRUST code-A global code of conduct for equitable research partnerships.

communities are well engaged and their views and expectations included in the planning, implementation and dissemination of research. Although this approach may conflict with the principlism approach, it is increasingly becoming more acceptable in conducting research in Africa as it allows research to remain sensitive to contextual realities and expectations[36].

5.3 Conclusion

This chapter has presented the historical evolution of African ethics and regulatory systems. Although the ethical principles and guidelines used in Europe and Africa are largely the same, the way they are applied differs between the two contexts. Largely influenced by African philosophical concepts such as Ubuntu, the application of ethical principles and guidelines have moved from individualistic to communitarianism, hence increasing the need to focus more on the community and family units and consultations as opposed to the autonomous decision of the individual involved in research per se. Arguably, this paradigm shift has led to calls for decolonisation[37] and the indigenisation of research[38], supporting the view that insisting on using Westernised approaches is akin to neo-colonialism.

[36] Sambala, E. Z., Cooper, S., & Manderson, L. (2020). Ubuntu as a framework for ethical decision making in Africa: Responding to epidemics. Ethics & Behavior, 30(1), 1-13, Ekmekci, P. E., & Arda, B. (2017). Interculturalism and informed consent: Respecting cultural differences without breaching human rights. Cultura, 14(2), 159-172.

[37] Ngaruiya, C., Muhammad, M. I., & Sam-Agudu, N. A. (2024, June). A proposed guide to reducing bias and improving assessments of decolonization in global health research. In Frontiers in Education (Vol. 9, p. 1233343). Frontiers Media SA, Chandanabhumma, P. P., & Narasimhan, S. (2020). Towards health equity and social justice: An applied framework of decolonization in health promotion. Health Promotion International, 35(4), 831-840, McCoy, D., Kapilashrami, A., Kumar, R., Rhule, E., & Khosla, R. (2024). Developing an agenda for the decolonization of global health. Bulletin of the World Health Organization, 102(2), 130.

[38] Semenya, S. S., & Burman, C. J. (2019). Towards the indigenisation of mode 3 knowledge production: an engaged research schema. Journal for New Generation Sciences, 17(1), 15-34.

Funded by the European Union

6. In-depth case: China

Early in the late 1980s, the ethical review system started to make its way to China. Over the past 40 years, significant progress has been made in the building of a comprehensive ethical review framework. Many ethics committees have been established in institutions across the country. Regulations and guidelines have been drafted and released to standardize ethical review practice and internationally recognized ethical guidelines have been translated into the Chinese language.

This chapter provides an attempt to offer an overall picture of the development of ethical review in China by outlining the history of ethical review, the current development, and the challenges faced in the area of ethical review in the country.

6.1 The Development History of Ethical Review in China

Ethical review in China initially emerged and developed mainly in the field of medicine. With the rise of medical research involving human subjects and the increase of international cooperation at the time, the need to conduct research ethically and ensure the rights of research participants became highlighted. Corresponding to this trend, the ethical review system developed gradually, and expanded to cover other fields, such as biotechnology, social science research etc.

The emergence of ethics committees in China can be traced back to 1987 when Peng Ruicong, Professor from Peking Medical University (now Peking University Health Science Center) proposed the concept of the "ethics committee" at the Fourth National Symposium on Medical Dialectics.[39] In 1988, The Chinese Medical Association established its Medical Ethics Branch.[40]

At the beginning of 1990s, calls for ethics committees to be set up in medical institutions were growing. In 1991, Zhang Jun, a scholar from the Chinese Academy of Medical Sciences (now Peking Union Medical College) first proposed the idea of establishing ethics committees in hospitals.[41]In 1994, at the Fourth National Conference of the Chinese Medical Association in Guangzhou, an initiative to establish

[39] Peng Ruicong. *Some Opinions on the Research of Medical Philosophy* [J]. Medicine and Philosophy, 1988(04): 1-3.

[40] Sun Puquan. *The Establishment of the Medical Ethics Society of the Chinese Medical Association* [J]. Morality and Civilization, 1989(01): 45. DOI: 10.13904/j.cnki.1007-1539.1989.01.025.

[41] Zhang Ju. *Hospital Ethics Committee and Its Proposed Establishment in China [*J]. Chinese Medical Ethics, 1991(06): 32-35.

hospital ethics committees was passed.[42] Following that, ethics committees were set up one after another in hospitals such as Tianjin First Central Hospital[43] and Beijing Chaoyang Hospital[44].

Still later, voices for putting regulatory measures at the national level regarding ethical review into place started to catch attention. In 1998, the Ministry of Health (now the National Health Commission, NHC) released the report "Measures for the Ethical Review of Biomedical Research Involving Human (Trial)".[45] In 1999, the National Medical Products Administration (NMPA) released the first "Good Practice for Clinical Trials of Drugs (GCP)" in China, which stated explicitly in Article 9 that "ethics committees should be established in medical institutions conducting clinical trials to ensure the rights of human subjects in clinical trials and to provide them public assurance."[46] In 2003, NMPA released its revised edition of "Good Practice for Clinical Trials of Drugs (GCP)"[47], and in 2007 the Ministry of Health (now NHC) also released the revised edition of "Measures for the Ethical Review of Biomedical Research Involving Humans (Trial)."[48]

In the meantime, preparation for the construction of a national ethics review oversight system was under way. In 2000, a "Medical Ethics Expert Committee"[49] was set up as a high-level advisory body under the Ministry of Health (now NHC).

Entering into the 2010s, with the steady increase of the number of medical research, the SFDA (from March 2013 to February 2018, NMPA was renamed SFDA) released the "Guidelines for Ethical Review of Drug Clinical Trials" which stated clearly for the first time not only standard work procedures of the ethics committees, but also the scope of review for clinical trials and the standards to be followed.[50]

[42] *Review and Reflection on the Development of Hospital Ethics Committees in China* [J]. Chinese Medical Ethics, 2017, 30(11): 1321-1325.
[43] Liu Bing. *The Constitution of the Ethics Committee of Tianjin First Central Hospital* (draft) [J]. Chinese Medical Ethics, 1995 (01): 28.
[44] *Our Hospital's Medical Ethics Committee Officially Joined the Beijing Medical Research Ethics Review Mutual Recognition Alliance* [EB/OL]. https://www.bjcyh.com.cn/Html/News/Articles/51882.html?check=true, 2021-03-23.
[45] Chen Yuanfang, Qiu Renzong. *Biomedcial Research Ethics*. Peking Union Medical College Press, September 2003, p401-406.
[46] *Drug Clinical Trial Management Specification (GCP)* [J]. Chinese Journal of Medical Guide, 1999(01): 5-9.
[47] Xie Qin, Cao Cai. *Introduction to the Key Amendments of the New "Good Clinical Practice for Drugs*" [J]. The Chinese Journal of Clinical Pharmacology, 2003(05): 351. DOI: 10.13699/j.cnki.1001-6821.2003.05.008.
[48] *The Ministry of Health promulgated the Measures for Ethical Review of Biomedical Research Involving People (Trial)* [J]. Chinese Medical Ethics, 2007 (01): 34.
[49] Cao Yongfu, Wang Yunling, Yang Tongwei, et al. *Suggestions on the establishment background, function and construction of the "Medical Ethics Committee" in China* [J]. Medical Ethics of China, 2004 (05): 31-32 + 46.
[50] *SFDA recently issued the Guidelines for ethical Review of Drug Clinical Trials* [J]. Licensed pharmacist in China, 2010,7 (12): 52.

In 2016, the National Health and Family Planning Commission (now the NHC) released "Measures for the Ethical Review of Biomedical Research Involving Humans."[51]

In 2018, in the wake of the "He Jiankui gene-editing scandal", work concerning the construction of a national ethical review oversight system was further strengthened. In 2019, the 13th National People's Congress Standing Committee revised and passed the "Act on Drug Administration", making ethical review a legal requirement in the country for the first time.[52] Meanwhile, in "The Civil Code" which came into force in 2021 there was also clear stipulation regarding the scope and procedure for human clinical trials, highlighting the importance of ethics committees in the approval mechanism for human clinical trials.[53]

In 2022, the State Council of China released "Opinions on Strengthening the Governance of Science and Technology Ethics".[54] This indicates that effort to push forward the construction of research ethics governance is stressed at the central government level.

In the meantime, NHC started to revise "Measures for the Ethical Review of Biomedical Research Involving Humans" which was released in 2016, andnd by 2023, its latest version, "Measures for the Ethical Review of Life Sciences and Medical Research Involving Humans"[55] was jointly issued by the National Health Commission, the Ministry of Education, the Ministry of Science and Technology, and the State Administration of Traditional Chinese Medicine.

On the side, the Ministry of Science and Technology promoted the establishment of the "National Science and Technology Ethics Committee" in 2020.[56] In 2023, along with other 9 government departments, it released the "Measures for the Ethical Review of Science and Technology (Trial)".[57]

---

[51] *Measures for the Ethical Review of Biomedical Research Involving Human Subjects* [EB/OL]. https://www.gov.cn/gongbao/content/2017/content_5227817.htm, 2016-10-12.
[52] *Law of the People's Republic of China on Drug Administration* [EB/OL]. https://www.gov.cn/xinwen/2019-08/26/content_5424780.htm, 2019-08-26.
[53] *Civil Code of the People's Republic of Chin*a [EB/OL]. https://www.gov.cn/xinwen/2020-06/01/content_5516649.htm, 2020-05-28.
[54] *Opinions on Strengthening the Governance of Science and Technology Ethics* [EB/OL]. https://www.gov.cn/gongbao/content/2022/content_5683838.htm, 2022-03-20.
[55] National Health Commission, Ministry of Education, Ministry of Science and Technology, and National Administration of Traditional Chinese Medicine. *Notice on Issuing the Measures for Ethical Review of Research Involving Human Life Sciences and Medical Sciences*. [2023-02-18]. https://www.gov.cn/zhengce/zhengceku/2023-02/28/content_5743658.htm.
[56] China News Service. *China Has Established the National Committee on Science and Technology Ethics*. [2020-10-21]. https://www.chinanews.com/gn/2020/10-21/9319022.shtml.
[57] Ministry of Science and Technology, Ministry of Education, Ministry of Industry and Information Technology, Ministry of Agriculture and Rural Affairs, National Health Commission, Chinese Academy of Sciences, Chinese Academy of Social Sciences, Chinese Academy of Engineering, China Association for Science and Technology, Science and Technology Commission of the Central Military Commission. *Notice on Issuing the Measures for the*

6.2 The Current State of Ethical Review in China

6.2.1 Ethical Governance System

China's existing ethical governance system is basically composed of ethics committees at four levels: national ethics committees, provincial ethics committees, regional ethics committees, and institutional ethics committees. According to statistics from NHC, as of today there are a total of 9,771 ethics committees registered with NHC, of which 9,571 are located within medical and health institutions.

6.2.2 National Ethics Committee

Presently, China's national ethical governance and oversight system runs under the supervision of three government authorities. The first is the National Health Commission（NHC, formerly the Ministry of Health). In 2000, NHC promoted the establishment of the "Medical Ethics Expert Committee".[58] This committee, ever since its launch, has played a significant role in pushing forward the construction of ethical governance and oversight system in China. The experts of the committee are at the forefront of research on major ethical issues concerning biomedical research involving human subjects. They also offer consultation and recommendation over major ethical issues. In addition, they are responsible for guiding and supervising the work of the provincial medical ethics expert committees and that of ethics committees in the health system, as well as for providing regular training and consulting for ethics committees at the lower level.

The second is the State Administration of Traditional Chinese Medicine (SATCM). In 2011, SATCM promoted the establishment of a similar panel, "the Chinese Medicine Ethics Expert Committee"[59], whose major task, besides offering suggestions over major ethical issues in TCM and providing policy consultation, is to draft ethical guidelines and quality control standards and norms.

The third is the Ministry of Science and Technology (MOST). In 2019, MOST launched its "National Science and Technology Ethics Committee"[60], whose job is to provide guidance and coordination for the construction of the national research ethics governance system. Since its establishment, the

Review of Science and Technology Ethics (Trial). [2023-09-07]. https://www.gov.cn/gongbao/2023/issue_10826/202311/content_6915814.html. Measures for the Review of Science and Technology Ethics (Trial).

[58] Cao Yongfu, Wang Yunling, Yang Tongwei, et al. *The Background, Function and Construction Suggestions of "Medical Ethics Committee" in China* [J]. Chinese Medical Ethics, 2004(05): 31-32+46.

[59] National Administration of Traditional Chinese Medicine. *Notice on the Establishment of the Expert Committee on Chinese Medicine Ethics of the National Administration of Traditional Chinese Medicine*. [2011-07-23]. http://www.natcm.gov.cn/kejisi/zhengcewenjian/2018-03-24/3539.html.

[60] Ge Haitao, An Hongxuan. *Progress in building a Chinese science and technology ethics governance system* [J]. Science and Technology Herald, 2022,40 (18): 21-30.

committee has played an important part in integrating various resources, in strengthening work related to ethical review and supervision, and especially in quickening the pace for the construction of a comprehensive and coordinated science and technology ethics governance system.

6.2.3 Provincial Ethics Committees

The "Measures for the Ethical Review of Biomedical Research Involving Humans" , which was released in 2016 by SHC, stipulated that provincial medical ethics expert committees should assist in promoting the institutionalization and standardization of ethical review work in their administrative regions, should guide, inspect, and evaluate the work of ethics committees in medical and health institutions conducting biomedical research involving humans, and should conduct related training and consulting work. Since then, medical ethics expert committees at provincial level began to perform their duties of guiding and evaluating the work of institutional ethics committees for medical institutions within their jurisdictions.

Meanwhile, after the establishment of the National Science and Technology Ethics Committee by Ministry of Science and Technology (MOST), several science and technology ethics committees at provincial level have been established that aim to strengthen the national endeavour to construct the science and technology ethics system.

6.2.4 Regional Ethics Committees

Regional Ethics Committees (RECs) are generally ethics committees established outside of institutions in a particular region. Initiated and established by academic groups, professional associations and research institutions, though not affiliated to any government body, are under supervision and assessment of relevant government departments. In 2012, RECs started to appear in some regions in China. For example, Sichuan Traditional Chinese Medicine Ethics Review Committee[61], affiliated to Chengdu University of Traditional Chinese Medicine, was the first regional ethics committee established in the country. Following the example of Sichuan, more RECs were set upin places like Shenzhen, Shandong, Shanghai, Guangdong, Beijing, and Jiangxi. These RECs exercised their roles in conducting ethical reviews of major medical research projects or traditional Chinese medicine research projects, and providing training and consultation in their regions.

Based on the collective action of academic groups and industries, the position of RECs was confirmed by subsequent regulations. On October 23, 2017, the National Medical Products Administration (NMPA) released the "Drug Registration Management Measures (Revised Draft)".[62] The measures

[61] Ma Xitao, Wang Yanqiao, Luo Xiaoqiong, et al. *Construction practice and thinking of Sichuan TCM Regional Ethics Committee* [J]. Medicine and Philosophy (A), 2018,39 (12): 11-14 + 52.
[62] *The Office of the General Administration of the Food and Drug Administration publicly solicited opinions on the Drug Registration Administration Measures* (Revised Draft) [EB / OL].(2017-10-23) ［2019-10-04］ .http://samr.cfda.gov.cn/WS01/CL0778/178900.html.

require that before an applicant submits a drug clinical trial application, the trial protocol must be reviewed and approved by the ethics committee of the leading unit conducting the drug clinical trial or by a commissioned Regional Ethics Committee (REC). Other participating units should accept the review conclusions of the leading unit or REC without duplicating the review of the clinical trial protocol.

In the meantime, the 2023 “Measures for the Ethical Review of Life Sciences and Medical Research Involving Humans” by NHC and the “Measures for the Ethical Review of Science and Technology (trial)” by MOST both emphasize the importance of establishing Regional Ethics Committees (RECs). In the “Measures” by NHC, there is further clarification as to the functions and areas of responsibility of RECs. These are indicators that much importance has been attached to RECs from the perspective of administrators at the national level.

The usual function of a REC is to offer ethical review and approval for research related to humans, although it is generally believed that the scope of responsibilities of a typical REC also include matters such as providing policy consulting, training, supervision and evaluation for institutional ethics committees within the region[63]. According to the “Measures” by NHC, the status of a regional ethics committee is the same as that of an institutional ethics committee. However, taking the work of Shanghai Clinical Research Ethics Committee (SECCR, a REC in operation) as an example, in addition to reviewing close to 300 projects annually (which covers areas ranging from drug trials, medical devices, vaccine trials and biobanks, big data research, public health, psychology and social science research to cosmetic products and food research), SECCR also works with the Shanghai Municipal Health Commission to provide consultation and training to research institutions and ethics committees in Shanghai, to formulate some ethical guidelines, and actively participate in government decision-making.

6.2.5 Institutional Ethics Committees

Most research ethics committees in China are based within the institutions. According to the "Measures (trial)” released by MOST in 2023, universities, research institutions, medical and health institutions, and enterprises, are responsible for the conduct of ethical review for research projects within the institutions. Institutions where research activities involve life science, medicine, artificial intelligence, and other areas of science and technology should set up their own ethics review committees.

At the same time, in the spirit of the "Measures” released by NHC, medical institutions of the secondary class or above and municipal-level health institutions (including the disease prevention and control centres, maternal and child health centres and blood supply institutions), universities, research

[63] Huang Dongmei, Xiao Jiewen, Xie Renwei. *Construction status and Countermeasures of Regional Ethics Committee in China* [J]. Chinese Medical Ethics, 2020,33 (06): 731-736

institutions, etc., are the main bodies responsible for ethical review work and should set up ethics review committees of their own.

6.3 Values and Norms

6.3.1 Guiding values

Both reports prepared by NHC and MST stress that scientific and technological activities should adhere to the ethical principles. The "Measures" by NHC states clearly that life science research and medical research involving humans should be sure of producing scientific and social value, must not violate national laws and regulations, should adhere to internationally recognized ethical principles, and must not harm public interests. It lists some key principles, which include risk control, informed consent, fairness and justice, privacy protection, and special protection for the vulnerable group.[55]

In the "Measures (Trial)" prepared by MOST, there are similar articles which require that scientific and technological activities should adhere to certain principles. It states that "while complying with legal requirements and relevant ethical standards, scientific and technological activities should be carried out in accordance witt he principles of promoting human welfare, respecting the right to life, upholding fairness and justice, reasonably controlling risks, and keeping openness and transparency.[57]

6.3.2 Standards and guidelines

Since 2003, China has released eleven administrative laws and regulations related to medical ethics review.[64] The above-mentioned laws and regulations, such as the "measures" from NHC and MOST, constitute the core in China's effort to promote capability in ethics reviewing and to construct a regulatory framework of ethics governance.

In addition to the general principles at national guiding and regulatory level, some regions, institutions, associations and industries have formulated their own regional or industry-specific standards. For instance, Shanghai released the first local standard in the country for "Ethical Review of Human Biomedical Research" in 2015.[65] Shenzhen released its local standards for "Ethical Review of Biomedical Research Involving Humans" in 2019,[66] and in 2020 Fudan University, in collaboration with

[64] Feng Xia. *On the Administrative Regulations System of Medical Ethics Review in China* [D]. Qingdao University, 2024. DOI:10.27262/d.cnki.gqdau.2023.002196.
[65] Shanghai Municipal Bureau of Quality and Technical Supervision. *Practice for ethical review of biomedical research involving human* [S]. Shanghai: 2015.
[66] Ji Ping, Li Xiao, Xu Weiwei, et al. *Interpretation of the Ethical Review of Biomedical Research Involving human* in Shenzhen [J]. Chinese Medical Ethics, 2020,33 (11): 1363-1366.

Shanghai Xinchao Biotechnology Co., Ltd., developed the national standards for human biobank preservation--"Ethical Requirements for Human Biobank Preservation ".[67]

In 2019, NHC's "Medical Ethics Expert Committee", together with China Hospital Association, prepared and released the "Guidelines for the Construction of Clinical Research Ethics Committees in China". Beijing released four ethical review guidelines in 2020[68], covering areas ranging from Geriatrics, clinical research involving children and clinical research involving the mentally disordered to CAR-T cell immunotherapy. In 2020, Zhejiang Province established its Zhejiang Clinical Trial Ethics Collaborative Review Alliance and released "Consensus of the Zhejiang Clinical Trial Ethics Collaborative Review Alliance".[69] In 2020, Shanghai Ethics Committee for Clinical Research released "Ethical Review Template for Human Biobank".[70] In 2021, the National New Generation Artificial Intelligence Governance Professional Committee released "Ethical Norms for the New Generation of Artificial Intelligence"[71] and on July 8, 2024, the National Science and Technology Ethics Committee issued "Ethical Guidelines for Human Genome Editing Research".[72]

6.4 Challenges Facing the Ethical Review System in China

6.4.1. Knowledge and Awareness of Research Ethics among Researchers

Although real progress has been made in China in recent years in research ethics system and capacity building, a considerable number of researchers still have inadequate knowledge and awareness of research ethics. A big number of researchers still hold stereotypical misconceptions such as "No boundaries should be set for research" and "Stressing the role of ethics means slowing down scientific

[67] National Standard. Ethical Requirement of Human Biobanking. [2020-04-28]. https://std.samr.gov.cn/gb/search/gbDetailed?id=A47A713B765014ABE05397BE0A0ABB25. GB/T 38736-2020. Ethical Requirement of Human Biobanking.
[68] Beijing Municipal Health Commission. *Notice on Further Strengthening the Management of Medical Ethics and the Construction of Review Capacity*. [2020-11-27].https://wjw.beijing.gov.cn/zwgk_20040/zxgk/202011/t20201127_2152258.html.
[69] Zhang Shuang, Ye Hong, Cao Chen, et al. *Current status and construction of medical ethics laws and regulations system* [J]. Health Service Management in China, 2022,39 (11): 843-847.
[70] Shanghai Ethics Committee for Clinical Research. *Human biobank sample ethical review model* [J]. Medicine and Philosophy, 2020,41 (02): 74-80.
[71] National New Generation Artificial Intelligence Governance Professional Committee. *The Ethics Code of the New Generation of Artificial Intelligence*. https://www.most.gov.cn/kjbgz/202109/t20210926_177063.htmlr, September 26, 2021.
[72] Ministry of Science and Technology of the People's Republic of China. https://www.most.gov.cn/kjbgz/202407/t20240708_191311.html

progress". A proportionate number of them still treat ethical review as an unnecessary burden.[73] It is not uncommon for researchers to choose to compromise the ethical soundness and prepare their research proposals in a way more likely to win approval from the ethics committees. Even more, some researchers may be engaged in unethical research by allowing their foreign counterparts to conduct studies in China which will not be approved in their own home countries. This has been done in the guise of international cooperation.[74]

6.4.2 Capacity Building of Ethics Committees

As mentioned above, most ethics committees in China are located within hospitals, universities and research institutes. Although both "measures" released by the NHC and MOST emphasize the importance of setting up institutional ethics committees, a large proportion of the institutions and enterprises simply do not have the resources and capabilities needed for running ethics committees. While institutions themselves prefer to have their own ethics committees, many are actually known to suffer flaws in terms of expert qualifications and conflicts of interests. This has led to a situation where institutional ethics committees across the country increase in number, but capacity building still lags behind. Issues such as having the institutional head chairing the REC panel, or reviewing projects linked with institutional reputation, or ignore of conflicts of interest are not uncommon.[75]

6.4.3 Ethical Regulations and Governance

With the rapid development of science and technology and with the integration of life sciences, medicine, and emerging technologies, new ethical regulatory issues arise which are not being fully addressed by existing regulations.[76] The regulations and guidelines, which are in place so far, though sounding authoritative, usually cover only the aspect of work regarding ethical governance within their departments. For example, the "Measures" prepared by NHC was issued jointly by 4 departments, and the "Measures" by MOST was the result of work done by 10 departments. However, due to the differences in administrative jurisdiction and the differences in their professional scope, these departments have different work mechanisms, policies and requirements for ethical review and supervision. It is inevitable that difficulties may arise when it comes to the setting of standards and principles in real practice, particularly since interdisciplinary research is increasing, that necessitates

[73] Retraction Notice. *Retraction of: Draft Ethical Principles for Therapeutic Assisted Reproductive Technologies by He, J et al., CRISPR J 2018; fast track. DOI: 10.1089/crispr.2018.0051*. CRISPR J. 2019 Feb 1;2(1):65. doi: 10.1089/crispr.2018.0051.retract. Epub 2019 Feb 14. PMID: 30799870; PMCID: PMC6383508.
[74] Liao Bohua, Ma Yonghui & Lei Ruipengl. *Analysis of ethics dumping and proposed solutions in the field of biomedical research in China.* Front Pharmacol. 2023 Aug 28;14:1214590. doi: 10.3389/fphar.2023.1214590. PMID: 37701030; PMCID: PMC10494434.
[75] Chen, Yongchuan. *Review and Outlook: The development trend of ethical review of biomedical research in China* [J]. Medicine and Philosophy, 2020,41 (15): 1-7.
[76] Wang Z G. *Improve the governance system of scientific and technological ethics to ensure the healthy development of scientific and technological innovation*[J]. Qiushi, 2022(20):43-47.

cross-departmental reviews. Researchers, administrators as well as ethics committee members are therefore concerned with the establishment of a common set of principles and norms, applicable to multi-central and multi-disciplinary research, within a unified administrative system.

6.5 Scientific Integrity in Ethical Review

In recent years, with the rapid increase in the number of scientific papers published in China, more cases involving research misconduct, such as plagiarism, data falsification, ghost-writing, and peer review manipulation, have been brought to light.[77] To strengthen the construction of research integrity, particularly in system building, in supervision, and in the education of researchers, the Chinese government has released a series of policy papers in recent years. In May 2018 and June 2019, the General Office of the CPC Central Committee and the State Council released successively the "Opinions on Further Strengthening the Construction of Research Integrity"[78] and the "Opinions on Further Promoting the Spirit of Scientists and Strengthening Work Style and Academic Style Construction"[79], setting the tone for recognizing research integrity as the lifeline of scientists and researchers and "zero tolerance" for research misconduct.

In addition, at both national and provincial levels, much effort has been made to strengthen the construction and supervision of research integrity. In 2018, MOST approved the establishment of a new department -- the Department of Science and Technology Supervision and Integrity Construction, which is responsible for the development of research integrity.[80] Correspondingly, sections for intensifying the work regarding research integrity have also been set up within provincial science and technology committees.

6.6 Conclusions

Whether in terms of regulatory efforts or mechanism construction, China has been continuously striving for a healthier environment for ethical review and a sounder ethics governance system. Admittedly, more effort has yet to be made for a robust and comprehensive supervision mechanism.

---

[77] Tang L, Wang L, Hu G. *Research Misconduct Investigations in China's Science Funding System*. Sci Eng Ethics. 2023 Nov 22;29(6):39. doi: 10.1007/s11948-023-00459-9. PMID: 37991609.
[78] General Office of the CPC Central Committee, General Office of the State Council. *Several Opinions on Further Strengthening the Construction of Scientific Research Integrity*. [2018-05-30]. https://www.gov.cn/zhengce/202203/content_3635308.htm.
[79] General Office of the CPC Central Committee, General Office of the State Council. *Opinions on Further Promoting the Spirit of Scientists and Strengthening the Construction of Style and Style of Study*. [2019-06-11]. https://www.gov.cn/zhengce/2019-06/11/content_5399239.htm.
[80] Ministry of Science and Technology. *Provisions on the Functions, Internal Institutions, and Staffing of the Ministry of Science and Technology* [EB/OL]. (2019-07-09) [2023-07-19]. https://www.most.gov.cn/zzjg/kjbzn/201907/t20190709_147572.html.

For instance, with the development of interdisciplinary and cross-sector emerging technologies, still more is to be achieved in coordination and cooperation among various government departments in ethical governance and supervision work. For the future development of research ethics governance in the country, the focal aspect in the construction of ethical governance for science and technology lies in the development of a coordinated and uniform national ethics supervision framework.

7. Recommendations for Action

We have seen that there is considerable complexity when it comes to perceptions of ethics and ethics review processes outside Europe. Although the project focuses on European ethics reviews (and in a manner, wider western approaches in the field), we have decided to offer another perspective outside our own comfort zone, both because the project consortium includes representatives from non-European and even developing countries, and also because it makes sense to understand better ethics reviews processes in countries that are part of our wider research collaborations. As it is a requirement to perform ethics reviews for research in any country that is part of the European funding schemes, we are constantly faced with a variety of cultures, norms and decision-making processes that we have little knowledge of. This report is one step in providing more information towards a better understanding of the issues that such collaborations are dealing with.

As the analysis above has shown, there are certain disparities in ethics values that are well embedded in the cultures and behavioural norms of different countries. The research that has taken place in Europe, China and India shows that ethics perceptions are directly influenced by cultural values and lead to diverse decisions in the ethics review processes. Although it is possible to place this variety of values in easily identified continua, we are still faced with the fact that local values must be understood if we want to promote international research collaborations. A revealing analysis is given in the case of Africa, whereby the local value of “ubuntu” provides a new perspective that is not immediately recognisable in European or otherwise western ethics. This aspect of community perspective can also be identified in Chinese dominant values. The key aspect here is to acknowledge that ethics review processes are affected by these values and lead to non-standard decisions, such as the need to acquire community consent, elder consent or even spousal consent, in addition to the individual consent that is the standard in European ethics reviews.

In terms of perceptions, we have seen that there is considerable difference in how Europeans and non-Europeans view ethics reviews. Although our sample can in no case be considered representative of the national perceptions of the countries represented in it, we can nevertheless draw some conclusions from the analysis. The first one is that ethics reviews have a different approach in non-European countries as they are also concerned with post-approval monitoring. This happens rarely, if at all, in Europe and it is a significant difference as it allows for a longer process with the possibility of redress at any point in time. The second major difference is the need for training, particular in emerging digital technologies and genome editing, that non-Europeans acknowledge. This is not to say that Europeans do not feel a need to train, but it is less prominent than in the other group. Otherwise, the perceptions as they were captured in the survey do not differ greatly. Both groups find the overall ethics review processes satisfactory, but also facing challenges in terms of expertise, knowledge and pace of technology.

In order to understand the situation in non-European ethics reviews in depth, the interviews we undertook were very instructive. Here we also witness an overall satisfaction with how ethics reviews have developed throughout the years from a niche undertaking without any real decision-making power to a standard and significant aspect of the research process. No country of the ones represented in the sample had no overseeing of ethics in research, particularly in medical research. The real

challenges appear to be in the governance of the ethics reviews. Here, we see that lack of funding for ethics committees can create serious issues with effectiveness and fairness of the process. For instance, conflict of interest cannot easily be accounted for, while post-review monitoring cannot be done effectively. In addition, lack of national capacities in some new technologies (e.g. genome editing or AI) creates gaps in ethics committees' knowledge and possibilities to expand their expertise. Further training and capacity building needs were widespread concerns for the majority of the interviewees.

Another interesting aspect that was raised in the interviews was the concept of "westernisation" of ethics and ethics reviews. In many cases, non-European experts stated that, although there are plenty of good ethics guidelines, there are few attempts to understand local variations of ethics concepts. This is a major challenge as it relates to differences in values and social norms that are not fully reflected in international guidelines. Moreover, there is a general view that external people do not always appreciate the complexities that local cultures add to the standard ethics review processes. Sometimes, what is fully acceptable (and expected) in the local context, is considered of dubious ethics balance (or outright unethical) in the European context.

The cases of Africa and China

The in-depth view of the functions and challenges that RECs are faced with in Africa and China has been very revealing. Taking advantage of the fact that these two regions are represented in the project, we opted for a more detailed analysis of the historical perspective and the state-of-the-art in ethics reviews as a compliment to the extensive research that has been conducted so far.

We see that African RECs have historically been dealing with biomedical research only, following closely the guidelines produced in Europe and the processes that European RECs are following. This has proven to be a superficially successful approach to ethics reviews that nevertheless hides a number of challenges unique to the region. One is the lack of funding for the establishment of permanent interdisciplinary RECs that can ensure neutrality and include the possibility for knowledge and expertise development. This is a thorny issue as it is evident that RECs are sometimes established ad hoc to deal with international collaborations that require local approvals. The need for regular capacity building activities is evident and must be addressed.

Another significant issue that has been identified in this case is the particularities of traditions and norms in many African societies that result in different ethics perspectives. The traditional concept of Ubuntu is described as a par excellence value that does not translate in European ethics, but has a direct influence in how ethics is viewed and applied. This aspect of a strong communitarian approach to ethics has ramifications in terms of consent procedures that many times come in direct conflict with European ethics guidelines. The inability to account for such differences in ethics perspectives has created arguments on the need to relieve dependence on European (or western) processes of ethics reviews.

The situation in China is very different to that in Africa but with nevertheless noteworthy nuances. To start with, China is a late-comer to the establishment of ethics reviews and RECs, but it has created an impressive organization of RECs at a national, regional and institutional level. Nowadays there is no research process in the country that does not need ethics approval. In terms of guidelines, both funders

and policy making institutions have been very active in developing detailed instructions, rules and standards that must be followed by RECs. Overall, the country shows a remarkable effort in embedding ethics in its Science & Technology system.

However, the façade of development hides a number of pitfalls that must be addressed. One is the lack of knowledge of ethics standards by researchers themselves. As is the case in many western countries, the view that ethics is another bureaucratic "checklist" seems to be widespread in the research community. Closely related is the lack of expert knowledge within RECs. The rapid establishment of RECs in the country has not been followed by the requisite capacity building activities. This allows for knowledge gaps that translate to wrong decisions and lack of ethics oversight. Finally, there seems to be a real issue with research integrity in the country that has direct ramifications in ethics. The somewhat lax attitude to research standards and an increasing number of uncovered cases of research fraud is evidence of the lack of discussions on research ethics and research integrity.

China, like Africa, appears to suffer from a similar difficulty in the incorporation of western ethics concepts and ethics review processes in their context. The fact that European/western ethics is dominant at the global level and the existing national ethics guidelines are usually a translation of the original European ones creates difficulties in balancing local and imported norms. For instance, as in the case of Africa's Ubuntu value, China's value of Harmony that is a widespread concept of moral decision making, does not translate well in western values systems. As this is a perspective on communitarian ethics, it finds no equivalence in European ethics guidelines and it is not evident in the current RECs decision making processes.

Recommendations and next steps

It has been our aim in providing such an extensive analysis of non-European ethics to also attempt to offer some evidence-based thinking in terms of specific future steps. If we are to create a more comprehensive international ethics review processes, we ought to design them better based on the current results of our analytical efforts. Our recommendations for action are therefore the following:

- Interdisciplinary and intercultural Research Ethics Committees

There is currently no doubt that RECs must be constituted with a wide spectrum of disciplines represented. This has not always been the case, since the origins of RECs had a very narrow disciplinary approach that proved soon to be inadequate, since, for instance, no research in the biomedical fields is void of social issues and biomedical professions are not equipped to deal with such issues. Our own analysis in non-European ethics shows a similar problem. Our current interdisciplinary RECs are not equipped to deal with non-European ethics approaches as they lack understanding of local values, norms and customs. The addition of anthropology in RECs would be a desirable step forward and an even better one would be the inclusion of experts from countries that participate in the international collaboration under review. We must stress the point that this is not equivalent to requiring an additional REC review from a local REC, since we have seen that local RECs face considerable challenges

that have a direct impact in their abilities to review international research efforts. The ideal case is to incorporate non-European expertise in European interdisciplinary RECs.

- Capacity building for resource-poor RECs

The need for training is widespread in every REC that we have analysed in this project, whether European or not. There is no doubt that continuous training in new and emerging technologies should be the norm for a good functioning REC. But the review of non-European RECs shows a particular and urgent need to undertake capacity building on even the most basic functions of a REC. The fact that non-European RECs base their work on European or international guidelines that were made with different research contexts in mind creates significant challenges in their adaptation to the local context. We see that happening in Africa and China whereby participants have expressed their wish for wider capacity building efforts that can establish a culture of understanding of ethics. In this case, the need can be covered with the promotion of capacity building programmes on ethics, perhaps along with other existing capacity building programmes in Science & Technology areas. A biomedical capacity building programme or even engineering programme could easily have an ethics part as add on.

- Research on global values and norms

We have witnessed that our understanding of non-European ethics and REC processes is at its infancy. There is much more to know, understand and incorporate in the current state-of-the-art. For this reason, we need more research in this field. As with any other field of international (or even global) research outreach, it is not easy to create funding and decision-making platforms. This will need a new type of thinking and even the involvement of international organisations in the process. But any step in this direction is welcome, whether stemming from a specific EU programme (like the projects we drew knowledge from in this report) or a global effort undersigned by an international organisation (that is yet to happen). Any effort will add necessary knowledge and will instruct more efficient REC processes.

- Regular global research ethics workshops

In addition to research and knowledge generation via international collaborations, it is advisable to develop further exchange possibilities. This can take the form of international workshops with thematic focus on research ethics challenges. This will give the chance to hear voices that would otherwise not be heard at the international stage (e.g. local stakeholders) and also disseminate knowledge gathered at a national level, independently from international collaborations. Such workshops are not different from the well-established disciplinary international conferences, but so far, there is no disciplinary association dedicated to ethics with regular annual conferences. Interestingly, the relevant area of research integrity can boast such an association with thousands of members and biannual conferences, whereby ethics is also discussed, but the need for ethics-only focus meetings is still valid.

- Ethics by design

It has been clear in this analysis that ethics reviews need a fresh perspective in relation to new and emerging technologies. Not only knowledge of the state-of-the-art in many technologies is missing in RECs, but even more significantly, there is widespread lack of interest in ethics from research scientists working in these areas. A possible solution to this conundrum could be the "ethics by design" approach. This means the embedment of ethics in early stages of technological development in tandem with researchers and developers. In this manner, ethics becomes a design principle for the technology product, avoiding future mishaps when people are faced with its implications. Ethics by design can be incorporated at a local level with guidance by local principles. There is no reason to believe that this approach is not amenable to the different values systems that have been explored so far.

- Big data and social science research

Big data is a new phenomenon that has changed the perception of technology. AI is the par excellence technological development based on big data and it has been clear in this analysis that it has created a qualitatively different problem in RECs. The existing knowledge gaps in relation to AI in RECs is not only significant, but it is also very difficult to fill in. Social scientific research in big data lags behind and the result is evident in ethics review processes.The impact of big data research can hardly be assessed and as such the risks and the steps that must be taken to avoid them can't be easily assessed. There is a need for much more social scientific research in big data to help RECs provide a clearer and more effective guidance in research collaborations.

Funded by the European Union

Annex 1: Survey Questions

Dear ethics experts,

As a part of a Horizon Europe project called irecs, we are conducting an anonymous survey to understand how Research Ethics Committees (RECs) and other ethics experts approach ethical reviews of emerging technology research. Specifically, we seek to gather information about experts' experiences, needs, and any gaps they see in the ethics review process. We are particularly interested in the ethics assessment of Artificial Intelligence: Artificial Intelligence (AI) in healthcare refers primarily to the application of machine learning to improve various aspects of healthcare and medical practices, e.g., diagnostics or remote consultation. AI has the potential to enhance accuracy, speed, and efficiency of medical treatment by automating standard or repetitive tasks, as well as to help maintain a better organized and efficient doctor-patient relationship. Research Ethics Committees (RECs), traditionally focusing on protecting participants' well-being, face a number of challenges when reviewing research involving AI. , Biobanking: In this questionnaire, biobanking refers to collecting and storing human biological materials and their associated data. As biobanking practices continue to evolve, it is essential to address the changing nature of ethical considerations associated with the collection, use, and sharing of these valuable resources., Genome editing: Genome editing (GE) modifies an organism's DNA by adding, removing, or replacing specific sequences using programmed proteins or protein/RNA complexes. CRISPR/Cas-based systems are widely used for this purpose, enabling efficient and targeted changes across various organisms. This technique offers applications in research, medicine, agriculture, and industry, with potential for heritable alterations and species-wide changes through technologies like gene drives., and Extended Reality: Extended reality (XR) is a broad term for technologies that create virtual and simulated experiences merging physical and virtual environments. It includes natural language processing models, like ChatGPT. Other examples of the technology are virtual and augmented reality (used in games like Pokémon GO and Minecraft) and mixed reality (popularized by Instagram and Snapchat filters). Virtual Reality (VR) immerses users in a fully artificial digital environment, where they can interact with surroundings using specialized hardware like VR headsets and controllers. Augmented Reality (AR), on the other hand, overlays digital objects or information on the user's real-world view, usually through a smartphone camera or specialized glasses. While VR creates a completely simulated experience, AR enhances the real world with additional layers of digital information. Additionally, we want to know people's preferred training methods to improve competencies with regard to ethics review of research related to these technologies. Your participation in this survey is greatly appreciated for a better understanding of current ethical review practices in the face of technological advancement. The survey is estimated to require approximately 15-20 minutes of your time. Privacy policy Your responses in this survey will be completely anonymous. No personal information or any information that could lead to the identification of you or your institution will be collected. We will use your anonymized responses in a report we are writing for the irecs project. Please confirm that you understand and agree by clicking below. Thank you for your time and valuable contribution.

Survey

1. What country do you work in?
2. How many years of experience do you have in ethics assessment of research projects?
3. What is your main disciplinary background?
    a. Life sciences
    b. Biomedicine/health science
    c. Social sciences
    d. Humanities
    e. IT/Engineering sciences
    f. Environmental sciences
    g. Physical sciences
    h. Other (text box)
4. What is your role in ethics assessment process? *(multiple choice)*
    a. Research Ethics Committee (REC) member (including chairs)
    b. EU ethics expert
    c. External ethics reviewer (not a REC member)
    d. Other, please specify
5. What are the main fields covered by your review body? (*multiple choice*)
    a. Life sciences
    b. Biomedicine/health science
    c. Social sciences
    d. Humanities
    e. IT/Engineering sciences
    f. Environmental sciences
    g. Physical sciences
    h. Other, please specify
6. Which area of ethics assessment of research projects are you involved in? (*multiple choice*)
    a. Human biobanking
    b. Artificial Intelligence in healthcare
    c. Extended Reality
    d. Germline genome editing
    e. Somatic genome editing
    f. Non-human genome editing

BIOBANK

7. When is ethics review for biobanks required in your country?

a. When a new biobank is being established
b. When a concrete research study on human biological material and health-related data taken from biobanks is planned to be conducted (biobank research) (please specify the criteria, if not all biobank research is reviewed) (text box)
c. When you want to amend a project that has already been approved.
d. None of above

8. Which of the following ethical issues do you consider yourself competent in addressing when reviewing issues related to establishing a new biobank? (*SCALE 1-5*)

a. Consent (e.g., choosing the consent model, review of consent documents)
b. Data protection
c. Data privacy
d. Data sharing
e. Return of individual health-related findings to biobank participants
f. Involvement of children
g. Commercialization of research results and/or data
h. Other

9. Which of the following ethical issues do you consider yourself competent in addressing when reviewing a concrete study on human biological material and health-related data taken from biobanks? (*SCALE 1-5*)

a. Consent (e.g., choosing the consent model, review of consent documents)
b. Data protection
c. Data privacy
d. Data sharing
e. Return of individual health-related findings to biobank participants
f. Involvement of children
g. Commercialization of research results and/or data
h. Other

10. In your opinion, when would ethical review be most necessary/preferable for research involving biobanks?

a. Review during the establishment of the biobank
b. Review when a concrete research study is planned to be conducted
c. Both during the establishment of the biobank and concrete research
d. Other (please specify)

AI in healthcare

11. Which of the following ethical issues do you consider yourself competent in addressing when reviewing AI-related research in healthcare? (*SCALE 1-5*)

a. Consent (e.g., choosing the consent model, review of consent documents)

b. Data protection
c. Data privacy
d. Data sharing
e. Bias
f. Justice and fairness
g. Transparency/Explainability
h. Responsibility for consequences of application
i. Other

12. If not all AI-related research in healthcare is subject to the traditional ethical review conducted by RECs, which criteria determine when a study falls within REC scope?

EXTENDED REALITY (XR)

13. Which of the following ethical issues do you consider yourself competent in addressing when reviewing issues related to Extended Reality (XR) research? (*SCALE 1-5*)

a. Consent (e.g., choosing the consent model, review of consent documents)
b. Data protection
c. Data privacy
d. Data sharing
e. Violence/abuse in XR
f. Mental health issues
g. AI usage in XR research
h. Involvement of children
i. Cybercrime
j. Other

14. How well do you understand the inner workings and differences of XR technologies?

a. In virtual reality research (Scale 1-5)
b. Augmented reality in research (Scale 1-5)
c. Extended reality using AI (Scale 1-5)

15. If not all XR-related research is subject to the traditional ethical review conducted by RECs, which criteria determine when a study falls within REC scope?

GENOME EDITING

15. Which of the following ethical issues do you consider yourself competent in addressing when reviewing research related to somatic gene editing? (*SCALE 1-5*)

a. Consent (e.g., choosing the consent model, review of consent documents)
b. Safety
c. Accessibility
d. Enhancement
e. Misuse
f. Other

16. Which of the following ethical issues do you feel comfortable in addressing when reviewing research related to germline gene editing? (*SCALE 1-5*)

    a. Consent (e.g., choosing the consent model, review of consent documents)
    b. Safety
    c. Accessibility
    d. Enhancement
    e. Misuse
    f. Other

17. Which of the following ethical issues do you consider yourself competent in addressing when reviewing research related to non-human gene editing? (*SCALE 1-5*)

    a. Safety
    b. Accessibility
    c. Enhancement
    d. Misuse
    e. Protection of species
    f. Other

*QUESTIONS FOR ALL TECHNOLOGIES***

18. What type of ethics governance is currently applied in assessing the following technologies in your institution?

*** Multiple choice grid**

	Ethics self-assessment (without formal approval by REC)	REC review before starting research project	REC review before starting research project + monitoring after approval	Other (please specify)
AI-related research in healthcare				
Biobank research				
Extended reality research				
Somatic genome editing research				
Germline genome editing research				
Non-human genome editing research				

19. Do you think current ethics governance as indicated in previous question is sufficient for:

	Highly sufficient	Sufficient	Neither sufficient nor insufficient	Insufficient	Highly insufficient	I don't know
Biobank research						
AI-related research in healthcare						
Extended reality research						
Somatic genome editing research						
Germline genome editing research						
Non-human genome editing research						

(TECHNICAL NOTE: IF INSUFFICIENT OR HIGHLY INSUFFICIENT CHECKED THEN NEXT QUESTION APPREARS)

20. How would you change it? (*For every technology)*

(TECHNICAL NOTE IF highly sufficient, sufficient on neither sufficient NOR INSUFFICIENT CHECKED THEN NEXT QUESTION APPREARS):

Do you have any suggestions on how to improve it? (*For every technology)*

21. In your opinion, what factors hinder the ethics assessment of technologies the most? Please specify for each technology (Multiple choice grid)

	Lack of ethics expertise	Lack of scientific/technical understanding	Lack of guidelines	Lack of training	Lack of funding	Other (please specify).
AI-related research in healthcare						
Extended reality research						
Biobank research						
Somatic genome editing research						
Germline genome editing research						
Non-human genome editing research						

22. It is feasible to consider the broader societal impacts (e.g., on different communities, risks of discrimination and stereotyping) of research in the following areas:

	Strongly agree	Agree	Neither agree nor disagree	Disagree	Strongly disagree
Biobank research					
AI-related research in healthcare					
Extended reality research					
Somatic genome editing research					
Germline genome editing research					
Non-human genome editing research					

23. Continuous ethics oversight starting from the design stage of research and including ethics review and monitoring throughout its lifecycle (ethics by design) is feasible in the following areas:

	Strongly agree	Agree	Neither agree nor disagree	Disagree	Strongly disagree
Biobank research					
AI-related research in healthcare					
Extended reality research					
Somatic genome editing research					
Germline genome editing research					
Non-human genome editing research					

TRAINING

24. In which areas do you desire more training in your work?

	Very desirable	Somewhat desirable	Neutral	Somewhat undesirable	Very undesirable
Biobanking					
AI-related research in healthcare					
Extended reality					
Somatic genome editing					

Germline genome editing					
Non-human genome editing					

25. What content of training do you think would be most useful? (Multiple choice)

    a. Scientific aspects of technology
    b. Ethics assessment of technology research and development
    c. Complex case studies involving R&D of the technology
    d. Cross-cutting ethics issues (e.g. international collaborative research)

26. What mode of training would you prefer?

    a. Self – directed, online training
    b. Downloadable workbooks
    c. Group workshops online
    d. Group workshops in person
    e. Other – please specify

27. What are your preferred learning styles for online training? (pick up to 3)

    a. Listening to presentations;
    b. listening to interviews with experts;
    c. watching videos;
    d. reading succinct information;
    e. self-directed interactive exercises;
    f. group chat;
    g. other - please specify

Annex 2: Interview Template

Introduction and consent (to be recorded)

New and emerging technologies present challenges to ethics reviewers who may be unskilled in the relevant fields while increased internationalization of research has led to fears of ethics dumping and finally, there is a lack of standardisation across Europe and the world.

The project irecs scans and maps existing needs raised by new and emerging technologies in European and global research ethics communities. It produces and implements ethics training materials, and proposes adaptations to the research ethics process.

The purpose of this interview is to draw upon your knowledge and appreciation of ethics at international level, in order to understand possible gaps in ethics review processes. Questions revolve around the availability of guidance documents for ethics reviews, cultural differences in ethics perspectives, and capacity building needs for ethics review bodies.

No personal data will be collected in this interview and the results will feed the relevant report to the European Commission anonymously and in an aggregate manner (e.g. non-EU or EU experts are of the opinion that xxx). The interview will be recorded in order to ascertain proper representation of the views and suggestions that you hold. Interview recording will be held at the secure ITAS internal server where only members of the irecs ITAS team have access. You will receive an update and a link to download the report, once approved by the European Commission. Do you agree to continue with the interview and record it?

General questions

1. What is your primary disciplinary background and the country you're working in?

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. Do you have experience or knowledge of RECs in other countries? Which countries?

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

- AI in healthcare
- Extended reality
- Biobanking
- Genome editing (including both human and non-human applications).

4. 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. Are there other relevant documents in your country that you use as guidance?

5. Are there other guidance documents that are particularly useful for REC members or ethical reviewers when reviewing research projects in emerging technologies? In your opinion, what is missing in the existing guidelines to be able to review research projects that are not primary focussing on the protection of research participants?

6. 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 technologies?

7. In many countries, ethics approval by a REC is mandatory for research involving human subjects. In your opinion, are there other types of research, not involving human being, that would require ethics approval by a REC? Who should be responsible for deciding whether or not a review by a REC is necessary if no legal obligations for review exist?

8. Do you feel that ethics discussions are different in your country than other countries you know of? If yes, in what way? Do you think that these differences are due to different values? Can you explain?

AI in Health Care

Please answer the following questions only if you have experience with or expertise in research projects in the field AI in Health Care.

- What are the most common challenges RECs or other ethical review bodies are dealing with in the context of research in the field AI in Health Care?
- Which guidance documents or guidelines are particularly helpful for reviewing research projects with a focus on AI in Health Care?

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.

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

Biobanking

Please answer the following questions only if you have experience with or expertise in research projects in the field of Biobanking.

- What are the most common challenges RECs or other ethical review bodies are dealing with in the context of research in the field Biobanking?
- Which guidance documents or guidelines are particularly helpful for reviewing research projects with a focus on Biobanking?
-

Genome Editing

Please answer the following questions only if you have experience with or expertise in research projects in the field of Genome Editing.

- What are the most common challenges RECs or other ethical review bodies are dealing with in the context of research in the field Genome Editing?
- Which guidance documents or guidelines are particularly helpful for reviewing research projects with a focus on Genome Editing?