



## D2.2: Report on case study findings (Focus groups and interviews)

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## Executive Summary

D2.2. summarizes the findings and insights from the CHANGER project Tasks T2.3 and T2.4, respectively based on expert interviews and focus groups. These tasks were to provide qualitative data on perceptions and experiences from ethics experts who are connected to Research Ethics Committees (RECs) or otherwise engaged in research ethics. The data and findings are to inform the other Work Packages (WPs) of CHANGER, particularly WP3, as a basis for their work. The data were multi-national and cross disciplinary. These are the main insights:

### Systemic and Structural Barriers

- Ethics review systems are fragmented and inconsistent across institutions and countries.
- Medical-style 'checkbox' approaches are ill-suited for broader research domains.
- Lack of domain expertise and opaque appointment procedures weaken REC effectiveness.

### Insufficient Resources

- Most RECs operate with unpaid, part-time staff and little infrastructure.

### Lack of Recognition and Trust

- Ethics perceived as bureaucratic or adversarial by many researchers.
- Low trust between researchers and ethics reviewers due to disciplinary siloes.

### Western Bias and Value Conflicts

- Current ethical frameworks often reflect Anglo-Saxon / Eurocentric norms.
- Challenges in global or intercultural collaborations due to differing ethical priorities.

### Technological Innovation Challenges

- Ethical guidance lags behind technological development (e.g., AI, Big Data).

### Ambiguity Around AI

- AI raises complex ethical concerns but often seen as scaled-up versions of older issues.
- Need for specific tools like decision trees to guide ethics assessments.

### Social Sciences and Humanities Ethics

- Current ethics models often incompatible with qualitative or covert research methods.
- RECs in some regions do not assess non-GDPR social science projects.

### Need for Support Structures

- Call for helpdesks, ombuds offices, and mentoring to support ethics work.
- More proactive institutional support needed to integrate ethics into research.

#### Regulation vs. Advisory Role

- Preference for advisory roles over gatekeeping functions in RECs.
- Ethical reflection is an ongoing process, not a one-time approval.

#### Proposed Improvements

- Interdisciplinary REC membership and stakeholder diversity.
- Post-award ethics monitoring and innovative tools like ethics matrices.

### List of Terms & Abbreviations

| Abbreviation | Definition                         |
|--------------|------------------------------------|
| AI           | Artificial Intelligence            |
| D            | Deliverable                        |
| FG           | Focus Group                        |
| GDPR         | General Data Protection Regulation |
| M            | Month                              |
| P            | Participant or Interviewee         |
| REC          | Research Ethics Committee          |
| T            | Task                               |
| WP           | Work Package                       |

## 1. Introduction

### 1.1. Project Summary

CHANGER aims to foster changes in (external) research ethics reviews and (internal) ethical assessments, and to build up capacities within the scientific community to address ethical issues in research in general. The European Union (EU) which funds the CHANGER project has voiced the overall aim of “ethics-by-design” in clear recognition of shortcomings of current practices.

### 1.2 Brief description of Tasks 2.3 and 2.4

This report (D2.2) aims to present the basic and most salient insights from two work tasks within WP2 of the CHANGER project: T2.3 (Expert interviews) and T2.4 (Focus groups). These work tasks addressed the views of practitioners / members of RECs and other ethics experts (hereafter simply referred to as stakeholders) in a cross-national and cross-disciplinary study. The participants varied in age, gender, professional training and work experience. T2.3 was based on individual interviews and T2.4 was based on focus groups results. The qualitative data obtained from these studies were supplied and administered by several CHANGER project partners. Data from these studies will also be used for informing the work in other WPs of CHANGER, foremost WP3.

## 2. Purpose and scope

Given the general objectives of CHANGER, namely to “*promote changes in research ethics reviews that strengthen the capacity of researchers to incorporate ethical judgements in the project design and implementation, and to support ethics committees in addressing new challenges posed by new technologies and new research*”, the main purpose of the two stakeholder studies was to identify the current perceived challenges in the ethics review system, to identify legal, institutional and governance related barriers in the system, to gain insights in new research topics / formats and their particular ethical challenges, and to look for ideas and solutions how to implement ethics by design in a more coherent manner.

Due to the non-probability sampling of participants and informants in both tasks, the resulting data were qualitative. Given the nature of the qualitative studies reported here, it

was clear from the outset that no truly representative study could be performed, not for all RECs in Europe nor for all ethics experts across Europe. The weight of such qualitative studies comes from the context and experience the participants report on, and helps to understand the research context and structure. Furthermore, such data reveal underlying meaning assumptions and check them against incoherence. From this basis one can then often generate hypotheses about the whole system and put forward tentative recommendations how to change the system in a certain direction. This is done in D2.3 Report on current ethics review recommendations (submitted at M18).

### 3. Methodological background

#### **Participants-recruitment**

In order to better explore the issue at hand, a qualitative approach was considered to be most suitable. The sampling of participants was largely done by local partners of CHANGER, using their own institution, network and colleagues. Including respondents who are or were active in one of the RECs, and have marked themselves as people with reflected views on ethics in research was of particular interest. Furthermore, social scientists and humanities, and experts related to technological fields were sought out specifically (though not exclusively) since the initial working hypothesis was that these fields may be characterized by larger ethical challenges than others. A cross-country mix and a good gender balance were important criteria in both tasks.

The project aimed at 10 focus groups and 20 interviews as targets. In the end, 13 focus groups with 57 participating individuals and 21 interviews were conducted. Nearly all were conducted in English and analysed with codes. Members of CHANGER acted as moderators / interviewers.

The detailed results are described in two task reports, one for the interviews and one for the focus groups. The first task (interviews) is here attached as Appendix 1 and the second task is attached as Appendix 2 (focus groups).

## **Interviews and Focus Groups Guide**

The questions for the focus group included few abstract discussion points and specific prompts to provide deeper insight into the topics. The questions addressed the challenges and solutions to ethics review and were flexibly adapted to the group dynamic, discussion and composition of each focus group according to the methodological principles of qualitative research approaches. A protocol for a semi-structured interview guide was developed by NORSUS and discussed with several project partners. The final version was communicated to the partners who indicated willingness to conduct interviews. However, not all partners followed the protocol strictly as they thought that a more open approach would be more fruitful, especially with social scientists.

## **Procedure**

Both tasks were realized either as in-person meetings or as online meetings via a suitable platform like Zoom. The events lasted from 45-60 minutes. In both tasks some of the interviews resp. focus groups were conducted in the vernacular while most of them were conducted in English. The Focus Groups were conducted between Fall 2024 and the first months of 2025 at a time and place chosen by the participants. The interviews were conducted between Fall 2024 and the first months of 2025 at a time and place chosen by the participants or online.

For the interviews and focus groups, data collection, processing and storage as well as ethics considerations were in accordance with the procedures and that are described in detail in D1.4 Data Management Plan and Reports of the Project's Ethical Management Responsibilities (submitted at M6).

## **Analysis**

All interviews and all focus groups were audiotaped. All audiotaped records were then transcribed into English word files. Those that were in other languages were translated using internet-based translation tools, like DeepL. IT-tools for transcriptions were used; NORSUS used Cuckatoo for this purpose. The transcriptions were double-checked for correctness. The audio files were stored by the partners conducting the interviews. After the end of the project these audiofiles will be destroyed. The transcripts of both focus groups and



interviews were analysed using codes both manually and with the support of IT-tools for analysing qualitative data (MAXQDA, Dedoose).

### **Ethical considerations**

All interviews / responses were thoroughly deidentified, and references to places, institutions or the like which could make the interviewees identifiable were removed. The question how to handle the issue of General data Protection regulation (GDPR) across the participating countries and research activities was addressed early. The lead-partners and those conducting the interviews (NORSUS, LMU, K&I, UB, MU) resp. the focus groups (MEFST, LMU, K&I, UB) obtained ethical approval from their home institution / country authority. NORSUS received clearance for the project information and a draft of the interview protocol from the Norwegian data protection service SIKT (15.08.2024; reference number 111120; standard assessment). The procedures followed are described in detail in D1.4 Data Management Plan and Reports of the Project's Ethical Management Responsibilities (submitted at M6). Additionally, a Joint Controller Agreement was established by the coordinator, which was signed by the participating project partners (see also Technical Report – 1<sup>st</sup> Reporting Period, Section 2.1, submitted in M20).

Selected excerpts from focus groups and interviews are here marked with identifiers like (X-FG1 = partner X Focus group 1; or: P#1 = interviewee #1). Large parts of the following reports are based on selected excerpts from the task reports for T2.3 and T2.4. (presented in Appendix 1 and 2).

In the remainder we shall report results from T2.3 and T2.4 together without separating them. More detailed analyses of each of them are to be found in respective task reports (Appendix 1 and 2).

## **4. Results**

As mentioned above, a major point of interest in both the focus groups and the interviews was to get insights into the experiences and perceptions of the respondents in relation to structural and institutional barriers of ethics review, to gauge the opinions of respondents

what ethics reviews miss out on, how the emergence of new technologies and new research formats presents ethical challenges, and what kind of tools or methodologies one could make use of in order to improve the situation. The analysis resulted in the identification of major concerns in regard problems and barriers in the work of RECs and ethics experts.

#### 4.1. Systemic and structural barriers

The effectiveness of ethics review systems is frequently undermined by institutional fragmentation, inertia, inconsistent practices, and limited support infrastructures. These structural limitations affect both how ethics review is practiced and how it is perceived across institutions, disciplines, and national borders. A majority of respondents identified structural and operational limitations in the RECs. In particular, they stressed that the method of ticking a box with ethical issues was imported from the medical sciences and is not useful if over-extended to all other spheres of research. What may be useful in the medical sciences does not do a good job in other areas. Across countries and institutions, ethics review processes differ markedly in scope, interpretation, and procedural rigor. The participants were of the opinion that these inconsistencies create inefficiencies and confusion, especially for researchers engaged in international or interdisciplinary work. The variation in how local, national, and EU-level ethics bodies operate reflects broader governance fragmentation and contributes to uncertainty and duplication in reviews.

In general, it is the lack of expertise, both within ethics and within the research fields they assess, which is seen as a major challenge. The participants / respondents emphasized that ethics reviewers frequently lack the up-to-date knowledge necessary to navigate rapidly advancing areas such as Artificial Intelligence (AI), data science, and participatory research. With limited access to ongoing training and a small pool of experts in the emerging research fields, many RECs struggle to provide meaningful oversight, leading to gaps in critical evaluation. Appointments to RECs often seem very opaque and mostly not built on competence in research ethics.

*"In my opinion, research ethics has become somewhat hyper-normatized - an over-reliance on rigid norms and rules." P#3*

*"Each agency that does ethics review does things a bit differently, makes the process less effective." (MEFST-FG3)*

*“Ethics committees seem almost like bureaucratic control apparatuses. But then they don't deal with the ethical specificity of a project.” P#5*

*“Individuals do not want to gain knowledge about ethics issues because incentives are poor... any implementation of solutions is more difficult.” (MEFST-FG1)*

*“Inertia is part of the review system... inflexibility of legal status quo – updating legislation is hard for new innovations.” (MEFST-FG4)*

*“It's not professionalized. Because the selection mechanism is simply this: each faculty nominates someone, and that's it...” P#4*

*“Each faculty has its own ethics committee... in theory they should meet, but in practice, nobody meets anybody.” (UB-FG1)*

#### 4.2. Insufficient resources

The experience of the participants / respondents was that ethics committees often function under constraints that compromise their quality and sustainability. Many RECs are staffed by unpaid or un-compensated volunteers, lack administrative support, and receive little investment in training or infrastructure. This chronic under-resourcing leads to inconsistent reviews and diminishes professionalization, especially in smaller institutions or in fields like the social sciences where ethics infrastructures are newer or less developed. All agreed that capacity building among members of RECs would be beneficial, but in practice it never takes place due to the lack of time and resources.

*“RECs rely on part-time or volunteer members, leading to inconsistent reviews and limited professionalization.” (LMU-FG1)*

*“The challenges mostly arise from the lack of necessary time. Let me add that they also stem from the purely voluntary contribution of the committee members, who aren't truly bound or obligated to participate in every consultation.” P#16*

*“We currently have no system to verify if researchers follow the ethical commitments outlined in their applications.” (UB-FG2)*

*“We lack the resources to enforce ongoing monitoring... once approval is granted, there's no follow-up.” (UB-FG2)*

*“The resources available to manage RECs are already limited... need for paid roles and investment in infrastructure.” (K&I-FG1)*

*“We [the committee] don't get into the content, either because of lack of time or because of lack of specific skills. When we talk about artificial intelligence, if you don't have an expert on the board, what are we talking about? If we talk about risk assessment and data protection, but no one has a high level of experience in that area [in the committee], it becomes a formal step.” P#5*

#### 4.3. Lack of recognition and distrust – the threat of ethics?

If ethical reviews are to have a lasting value within the research community, it must be built upon recognition of its principal importance for the quality of the research. In other

words, it needs to build upon trust between researchers and ethics committees in a manner that transgresses disciplinary divides and delivers transparent reviews. To quite some extent it should also be as participatory as possible, especially for research with a great public interest. The general public needs to be able to trust that ethical issues are handled independently and expertly.

However, for many researchers (and obviously others as well) the very term ethics is often perceived as somewhat challenging. There was an undertone that one should not overrate ethical deliberations and that there will always be some subjectivity. Rather than viewing ethics as a bureaucratic hurdle, framing it as an integral and empowering part of research can shift attitudes and encourage meaningful engagement. Participants emphasized that when ethics is connected to values like integrity, trust, and societal benefit, researchers are more motivated to integrate it into their work.

*“Look, the first experience is that people don’t know what ethics means.” P#21*

*“The need for ethics approval has generated a range of emotional responses among our colleagues - many are scared, angry, or confused, and they express a variety of reactions. Some of them comment extensively, questioning what we on the committee are actually doing and whether the process is a waste of time.” (UB-FG2)*

*“Should we follow strict guidelines, or should we be more flexible and case-oriented?” P#8*

*“Distrust between experts due to lack of knowledge beyond one’s field.” (MEFST-FG4)*

#### 4.4. Dominant Western ethics and inherent value conflicts

What is the relevant framework of ethical thinking that informs ethics reviews? This was a question that came up several times both in the focus groups and interviews. Ethics frameworks grounded in Western norms often fail to account for diverse cultural perspectives. This misalignment becomes especially problematic in global research collaborations or when engaging with communities whose ethical priorities differ from mainstream European values. The view was expressed that the current approach to research ethics is perhaps the result of some cultural imperialism from Anglo-Saxon countries, specifically the USA or be a specific Eurocentric view. This may have something to do with the recent history of medical ethics and the principles of bioethics. The tradition of ethical principles and principlism was mentioned but what follows from those deliberations for a wider range of research was much more uncertain.

*“Risk of keeping a Eurocentric view of research ethics... need to recognize and compare other ethical perspectives.” (K&I-FG1)*

*“Risk of losing focus on Western European values... due to global competitiveness and political polarization.” (K&I-FG1)*

*“...people in the US felt if they have to go through ethics reviews, everybody else should as well. Otherwise, the others are faster in doing research. And so, I think it was more/ I think this levelling playing field and also the question of who has the right ethics. I think that’s just, perhaps all the way to some cultural imperialism through ethics...” P#7*

*“Challenges in harmonising ethical values across societal actors with different perspectives.” (K&I-FG2)*

#### 4.5. Challenges from technological innovation

The lack of expertise was also mentioned in relation to research either aiming at or using technological innovation. Ethical guidelines often lag behind technological innovation, making it difficult to adequately address emerging challenges in rapidly evolving fields such as artificial intelligence. The participants noted that guidance is slow to adapt, leaving researchers and reviewers without clear frameworks for addressing novel ethical risks. New ethical guidelines take time to immerse in the community. Global research with Big Data and fragmentation of legal regimes and rules were recognized as particular challenges within current technological research.

Including experts from diverse academic and professional backgrounds, such as technical fields, law, humanities, social sciences, and medical ethics, enriches the deliberative process and would allow ethics committees to more effectively address complex and emerging ethical challenges. Such collaboration is especially crucial in areas involving new technologies, where ethical implications are not easily confined to a single domain.

Similar advantages apply to the inclusion of societal (non-academic stakeholders). This also improves the relevance of the research and fosters public trust.

*“Technology is developing faster than guidance and rules can be given.” (MEFST-FG1)*

*“Lack of appropriate guidelines to address ethical issues in new technology areas.” (K&I-FG1)*

*“Difficult to differentiate between technical and ethical issues... definitions are still developing.” (MEFST-FG6)*

*“...we often use eye trackers, face readers, that is, technologies that record the participant’s face. So afterwards, we have recordings, videos, emotions—even if they don’t tell us their name, which most of the time they do, we essentially have the person recorded. So, this is definitely a challenge....” P#15*

*“RECs do not evaluate end-products of a project... issues may emerge later.” (MEFST-FG6)*

*“Ethics committees still lack clear governance rules for fast-evolving areas like social media or AI-enhanced studies.” (K&I-FG1)*

#### 4.6. AI raises more questions than answers

One particular interest of the study was the extent to which new technologies, and here AI was the most prominent, create substantial challenges for RECs and may need new formats of ethical advice and assessment. In general, one notes a certain ambiguity in relation to AI. While many stated that AI presents some new challenges, some were of the opinion that these difficulties were not entirely new. They appear, however, as new as many of the committee members are not well informed about the power and the research characteristics of AI. To what extent AI would call for a revision of research ethics remained an open question.

*“Decision tree for an issue such as AI to guide researchers, designed by interdisciplinary team.” (MEFST-FG2)*

*“There is a need to somehow implement this [ethical integration and regulation of AI tools and practices in research] and... create an awareness of it, formulate guidelines and then adopt guidelines.” (LMU-FG2)*

*“Well, I think you're right that many of the (AI) challenges aren't entirely new, they've existed in other forms before. But I do think the scale at which these challenges now present themselves is really unprecedented.” P#12*

*“Yeah, maybe one of the reasons I find it hard to identify completely new ethical challenges specifically tied to AI is because, in my field, computational social science, this kind of co-dependence on companies, on corporate data, and on the systems they provide has basically existed since the field began.” P#12*

*“Not all AI is created equal... context determines ethical relevance.” (MEFST-FG4)*

#### 4.7. Ethics in the Social Sciences and Humanities is no less complex

It has long been recognized that researchers from within the Social Sciences and the Humanities have not been particularly pleased with the existing framework for ethics reviews or the structures of the RECs. In several countries these fields do not have RECs governing other issues than GDPR regulations. A majority of respondents / participants came from social science, so it was perhaps to be expected that this topic appeared among the concerns. One of the concerns was that the issues arise often only once you are already in the middle of the research project. Another concern was that there is legitimate research going on that does not easily fit with GDPR demands or create issues with standard anonymity. Covert research was mentioned as example of such research.

*“Ethical approval in social sciences must be approached differently... language, tools, and risks vary greatly from biomedical fields.” (UB-FG2)*

*“REC procedures, if modelled on medical frameworks, are frequently ill-suited to social science methodologies, requiring adaptation, especially for participatory research.” (LMU-FG1)*

*“...Or you go to an asylum camp, and someone tells you they’ve tricked the system, that they’re 25 years old and pretending to be 16. Okay. And then someone from the asylum service comes and asks you. What will you do? What protects the researcher at that point, and what protects the interviewee? And where does the need for research override the well-being or rights of a person?” P#21*

*“The humanities field— especially when referring to individuals on the autism spectrum—presents serious challenges and obstacles, as it relies on highly individualised data. As a result, research in this area involves qualitative elements that are difficult to assess, and there is a high degree of subjectivity depending on the personality of both the participant and the researcher or reviewer. Complexity arises from the fact that individuals on the autism spectrum are not patients in the strict medical sense.” P#19*

*“And when we research this, it means that we often have to ask ourselves to what extent we, ..., violate the contextual integrity of these people. So, do we have to get consent when we analyse publicly accessible Twitter comments? Can we just say that it is public communication or TikTok, the videos are posted publicly, these are not private accounts, can we analyse them?” P#11*

#### 4.8. The need for networking and support structures

Institutions that provide support structures such as dedicated ethics officers, helpdesks, ombudspersons, or advisory panels empower researchers to seek advice before problems escalate. These resources also relieve pressure on RECs and reinforce a culture of shared responsibility for ethics.

*“And when we research this, it means that we often have to ask ourselves to what extent we, ..., violate the contextual integrity of these people. So, do we have to get consent when we analyze publicly accessible Twitter comments? Can we just say that it is public communication or TikTok, the videos are posted publicly, these are not private accounts, can we analyze them?” P#11*

*“...social scientists could complain: 'Oh, they're so strict here, the ethics committees at my university, why aren't they as liberal as at university X, Y, Z? So, I think we already need this kind of communication about what are the standards, how should we deal with dialogues between ethics committee members and researchers, and should there be some kind of clearinghouse or ombuds office when there are conflicts between ethics committees and researchers?’ P#9*

*“Working groups that support ethics and integrity – capacity building, mentoring, support structures.” (MEFST-FG5)*

*“We have a multi-level structure: ethics expert, faculty expert, and committee president... each offering different levels of support.” (UB-FG2)*

*“The provision of ethics advice on demand is essential...” (K&I-FG2)*

#### 4.9. Regulatory function or advisory role?

Many respondents / participants were not very favourably inclined towards the regulatory role of RECs. Some point out that real ethical learning often comes only once you are in the middle of the research, especially within social science. While the regulations in all European countries ask for such approval when dealing with clinical research, GDPR issues, or animal



experiments, other fields like the bulk of social science, humanities, or even technological research is not necessarily subjected to such legal demand of ex-ante approval.

*“Ethics oversight must become more proactive... not only reactive to emerging problems but supportive throughout the process.” (MEFST-FG6)*

*“Ethics should be seen as a strategic pillar guiding research... not just a remedial or compliance task.” (UB-FG1)*

*“[If] I were to approach a Research Ethics Committee with an ongoing project and I had some open questions or found myself navigating grey areas, my expectation, or maybe more of a hope, would be that the committee’s approach would be: How can we help make this project more ethical? So rather than giving a kind of blanket judgment, like “this is ethical” or “this is unethical”, I’d hope they would help identify problematic aspects and suggest ways to address them.” P#12*

*“Whereas what we in [REC] are attempting to promote is a continuous reflection on ethical issues throughout the lifetime of the research project, where, as you say, the ethical issues that come to the fore will change as the project develops, or the researchers will become aware of issues that they weren’t aware of at the outset of the project.” P#2*

*“The provision of ethics advice on demand is essential...” (K&I-FG2)*

*“Ethics review should not be a one-time event... ongoing advisory processes needed.” (LMU-FG3)*

#### 4.10. Solutions to improve ethical reviews?

One main complex of questions had to do with whether the participants / respondents had suggestions on how the challenges they were concerned about could be improved. The multi-disciplinarity of the composition of the RECs was a dominant theme here. Including experts from diverse academic and professional backgrounds, such as technical fields, law, humanities, social sciences, and medical ethics, enriches the deliberative process and allows ethics committees to more effectively address complex and emerging ethical challenges. In the biomedical area, including patient groups and lay persons was mentioned. Establishing channels for regular, transparent dialogue between ethics reviewers, applicants, and affected stakeholders, supported by appropriate digital or interpersonal tools, can reduce misunderstandings, enhance ethical clarity, and promote a culture of shared responsibility.

*“Post-grant award monitoring of projects suggested to ensure ethics is respected.” (MEFST-FG3)*

*“Ethics committees should therefore be ready to provide support to researchers when they request it (ethics helpdesk), monitor projects throughout their development and engage with researchers to anticipate ethical issues.” (K&I-FG1)*

*“I would say that committees—at least at [name of university], which does this quite well—should generally continue to be staffed by people from many different disciplines, specialisations. I think that’s good; it helps bring pluralism of perspectives and sheds light on an issue from different viewpoints. I very much believe—not so much in automation, let’s not go there—but in the systematisation of documents, policies, and procedures.” P#20*



*“Yes, the Delphi method, the ethics matrix, the consensualization conferences, and... ethical future scenarios? Yes, scenarios. All of these can be found in a book by the late Professor Valentin Mureşan, the founder of the Center for Applied Ethics Research. It’s called Management of Ethics in Organizations, and it explains all these methods, developed for the Romanian context. ... In fact, we were the ones who introduced that tool to University XX. We discussed it and promoted it. The ethics matrix. There’s also another tool called the “consensualization conference,” which is used alongside the ethics matrix. So yes, we’ve used these tools and actively promoted them at the university.” P#4*

*“Nevertheless, tools for ethical evaluation of research proposals are beginning to emerge, such as FERMI (Fake News Risk Mitigator), which offers guidelines and methodologies. However, designing and adopting such systems—especially in the absence of a broad consensus on what constitutes disinformation or the ethical meaning of certain actions—may provoke social resistance, particularly if perceived as an attempt to control expression or limit civil rights.” P#19*

*“And I was wondering, is there a space for human computer collaboration and maybe even AI in ethics review? What do you think, in the future?” P#7*

## 5. Outlook and Conclusions

The results of the two studies T2.3 and T2.4 contain valuable empirical information for the further work within the CHANGER project. In fact, most results directly or indirectly confirm or support the foundational assumptions which informed the design of the CHANGER project in the first place. This includes the analyses of main challenges of ethics reviews as also outlooks how to go forward and improve the system.

\* \* \* \*

## Appendix 1 - Report on Task 2.3: Expert interviews

### 1. Introduction

This report presents findings from 21 interviews which were conducted as part of WP2, Task 2.3 of the CHANGER project (CHALLENGES AND INNOVATIVE CHANGES IN RESEARCH ETHICS REVIEWS) in the period of 2024-2025. This task was subsequent to other tasks in WP2 the objective of which was to research perceptions and status quo of current activities and experiences with Research Ethics Committees (RECs). The results from these interviews are included in Deliverable D2.2. and D2.3, and complements other tasks related to the scoping reviews.

### 2. Methodology

#### 2.1. Initial planning of the interviews

The interviews connected to this task 2.3 are described in the project proposal in the following manner: “Stakeholder consultations to identify differences and best practices in ethics reviews to address new ethics challenges”. They were to be performed in a cross-country and multi-level interview study and be conducted with at least 20 individuals from different European RECs. The task aimed at exploring and understanding the decision making process for ethically challenging issues and the role of ethics experts. Best practices and risks were to be included.

Since all project partners were involved in this task, the Lead partner NORSUS sent out a message to all that each partner should plan one or several such interviews and report back to the Lead how many they plan to conduct (Fig. 1). This message was repeated at plenary consortium meetings.



This project has received funding from the European Commission Horizon WIDERA, under grant agreement No 101131683. Views and opinions expressed are those of the CHANGER consortium only and do not necessarily reflect those of the EU or the European Commission. Neither the EU nor the granting authority can be held responsible for them.

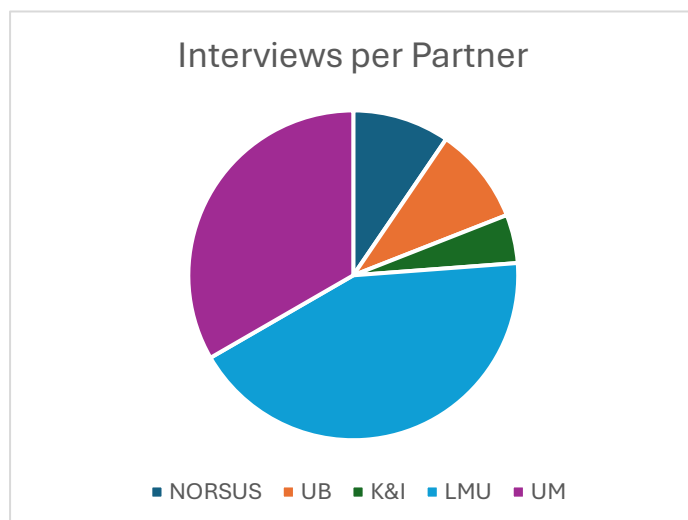


Fig.1 Interviews conducted per project partner.

One question that came up early was how the project handles the issue of GDPR across the participating countries and research activities. The Lead partner NORSUS received clearance for a draft of the interview protocol from the Norwegian data protection service SIKT (15.08.2024; reference number 111120; standard assessment). This included joint data controllers. However, in order to cover more of the CHANGER activities a Joint Controller Agreement (JCA) was necessary to be established. The coordinator NCSR-D prepared a JCA and initiated the process of approval by all partner organisations. There were delays by the legal offices of partner organisations in approving the JCA (see also Technical Report – 1<sup>st</sup> Reporting Period, Section 2.1, submitted in M20), and this whole process delayed the beginning of the interviews by 3-4 months.

A protocol for a semi-structured interview guide was developed by NORSUS and discussed with several project partners. The final version was communicated to the partners who indicated willingness to conduct interviews.

Despite repeated appeals to the consortium, only a small number of partners indicated that they would conduct such interviews. These were beside NORSUS, the partners UB, K&I, LMU, and UM. It was long unclear whether the target of 20 interviews would be reached. In the end we sampled 21 interviews from these partners.

The final interview protocol is attached as appendix 1. A standard information letter to prospective participants was devised and sent to the partners; see Appendix 2.

The recruitment was left to the best judgement of the partners in the respective countries. One of the partners decided not to follow the guide for semi-structured interviews but opted for a more open design focused on ethics in social science and AI.

## 2.2. Data handling and technical support

Interviews were conducted in person or online via a suitable platform like Zoom. The whole interview was recorded. Most of the interviews were in English, though some in the vernacular. Those that were performed in the vernacular were then translated into English with the help of internet-based translation tools (DeepL). All audiotapes of the interviews were transcribed into text. IT-tools for transcriptions were used; NORSUS used Cuckatoo for this purpose. The transcriptions were double-checked for correctness. The audio files were stored by the partners conducting the interviews. After the end of the project these files will be destroyed.

All interviews were thoroughly anonymized and references to places, institutions or the like which could make the interviewees identifiable were removed.

This resulted in 21 transcribed interviews of various lengths and content. These interviews were then analysed by the Lead partner (NORSUS) with the help of the analytic web-based program for data analysis Dedoose (<https://www.dedoose.com/>). A list of codes was prepared for the analysis of the interviews.

## 2.3. Participants

Altogether 21 persons were interviewed. They came from 7 countries (Fig. 2), 7 were female and 14 were male, and most in the age group 50-59 years of age (Fig. 3). All were either current or former members of RECs or were otherwise involved with them, e.g. as advisor or administrator. 15 members identified their academic background as Social Science, only 2 were from Humanities and the Arts, 2 was from Medicine and Health Science, and 2 from Engineering and technology (Fig. 4).

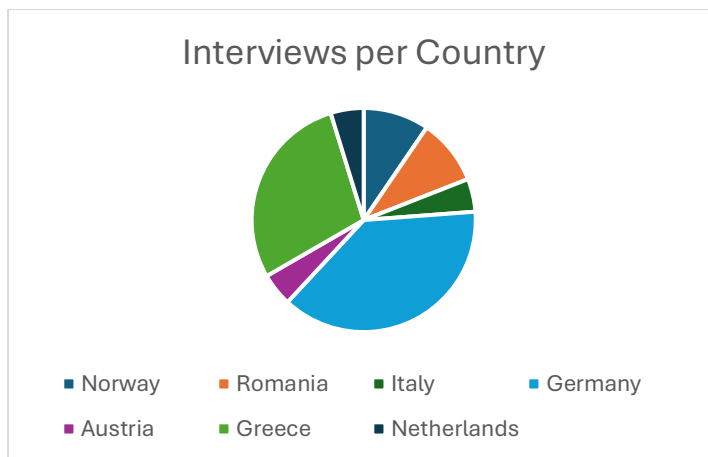


Fig. 2. Interviews per country.

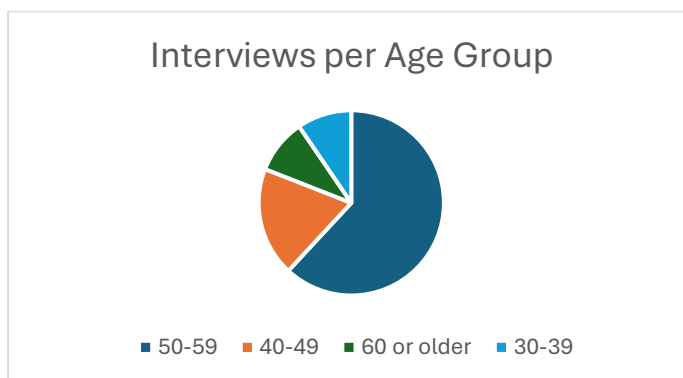


Fig. 3. Interviews per country.

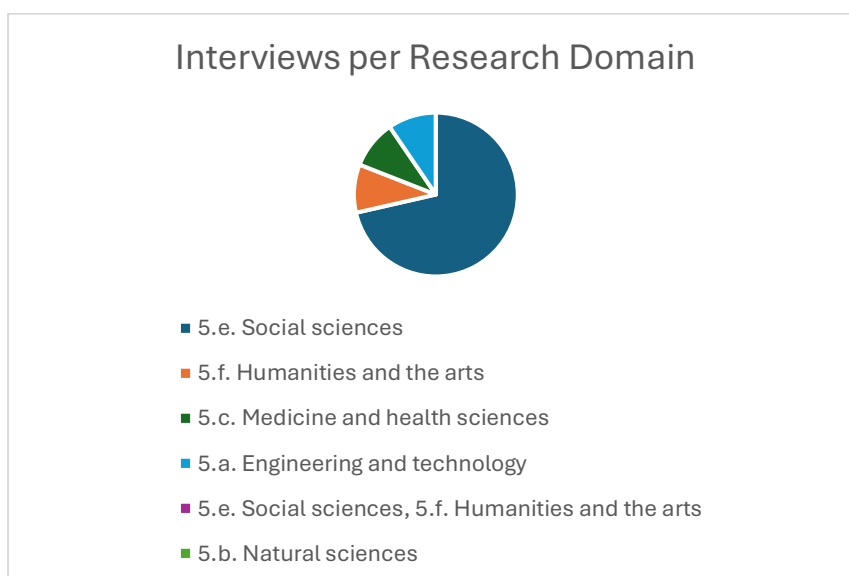


Fig. 4. Interviews per research domain.

### 3. Results from the interviews

The analysis of the interviews with the coding system (Fig. 5 and 6) and qualitative reading resulted in many common insights from the various interview partners.



Fig. 5. Interview codes.

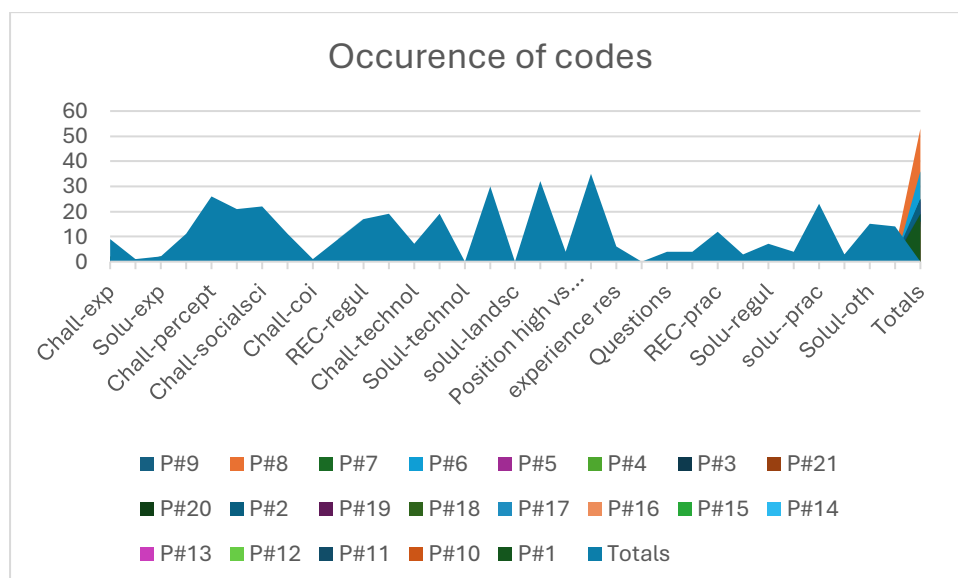


Fig. 6. Occurrence of codes.

### 3.1. Challenges faced by ethics committees

A majority of respondents identified structural and operational limitations in the RECs. In particular they stressed that the method of ticking a box with ethical issues was imported from the medical sciences and is not useful if over-extended to all other spheres of research. The “real” ethical challenges lie often beneath these questions, or they are not evident if assessed at the very start of a project. Committee members often see these challenges but have no time or opportunity to discuss them or to build up expertise about them. In general, it is the lack of expertise, both within ethics and within the research fields they assess, which is seen as a major challenge. Lack of expertise in emerging areas and especially within AI is a particular difficulty. Some complain that they cannot follow the ensuing practice in the projects they review and thus they have no feedback about the utility of the review. Also, there is the question who is to serve on RECs and under what condition. Appointments to RECs often seem very opaque and mostly not built on competence in research ethics.

*“In my opinion, research ethics has become somewhat hyper-normatized - an over-reliance on rigid norms and rules.” P#3*

*“...it's all good what we do in this ethics committee, but the real ethical challenges we cannot ask, because they are not part of the questions that are typical, or they are not related to any central norm or something like that, or our mandate.” P#1*

*“Ethics committees seem almost like bureaucratic control apparatuses. But then they don't deal with the ethical specificity of a project.” P#5*

*“It's not professionalized. Because the selection mechanism is simply this: each faculty nominates someone, and that's it...” P#4*

*“the coordination of the committee and the logistical aspects cannot be managed on a voluntary basis. We need a dedicated staff member for that.” P#8*

*“I think the further step that needs to be taken is that you can't delegate everything to the ethics committees because they don't have the resources [to deal with everything]. It's not even a question of skills. Even if it [the ethics committee] had them, it couldn't go into the details of this or that project and examine all the details of how the database is built, the parent sources, the false data, the consents and the legal basis.” P#5*

*“I find it unethical to waste people's time. I think if you waste researchers' time, I think about where they could do some good. And I think I want them to really think about ethics, but on a larger scale.” P#7*

*“The challenges mostly arise from the lack of necessary time. Let me add that they also stem from the purely voluntary contribution of the committee members, who aren't truly bound or obligated to participate in every consultation.” P#16*

Many respondents see the legal framework surrounding ethical reviews of research as problematic. The dividing line is not always clear, and the balance often favours only the legal aspects, e.g. GDPR regulations.

*“The increased awareness of ethics and deontology issues by the European Union itself has led to a legal framework that has become much stricter.” P#15*

*“Another institutionally relevant issue was whether there should be a prioritization among these categories, data protection, methodology, and research ethics. Since data protection has direct legal consequences, whereas research ethics is less legally binding and methodology is more flexible, we debated how to weigh these aspects. Given the legal framework, data protection is always relevant, meaning it cannot be considered separately from research ethics, as it ultimately involves liability issues. This is not the case for research ethics and methodology in the same way.” P#8*

*“A lot of people just care about the legal implications. They're not caring really about the ethics, but it's really/ also, I think if you look, who are the people in making laws, it's very clear. It's typically legal people because they understand how to do it, but they have very often a very basic view of technology. And they also see technology as something that's interchangeable. They are not really getting in depth into it because it doesn't really matter.” P#7*

### 3.2. Regulatory function or advisory role?

Most of the respondents were not very favourable towards enforced ethical judgements. This is, however, often the case when research projects need apply for ethical approval before starting the actual research. Some point out that real ethical learning often comes only once you are in the middle of the research, especially within social science. While the regulations in all European countries ask for such approval when dealing with clinical research, GDPR issues, or animal experiments, other fields like the bulk of social science, humanities, or even technological research is not necessarily subjected to such legal demand of ex-ante approval. One participating country, Norway, has therefore abolished the idea of ethical review of all projects by RECs and has its RECs, including national RECs, only giving selective advice on specialised topics. Else the researchers are required by the Research Council to submit ethical self-assessments.

But several respondents were favourably inclined to strengthen the advisory role of RECs, in particular also to different phases of the research. Overall, the impression is that there is a majority who would like to see the advisory roles strengthened.

*“I think you really need to give researchers that benefit of the doubt. To say: they're acting in line with certain recommendations, also from professional associations, they've had methodological training, they can demonstrate how they deal with ethical challenges. And when they do run into dilemmas, or when things really do become problematic, then they have other resources they can turn to, people or*



*places they can consult with to talk it through and decide how to proceed. I don't really see Research Ethics Committees as the actors or the bodies responsible at that stage anymore." P#14*

*"Anything more institutional would probably hinder research rather than help it. Because even as ethics committees, we weren't issuing certificates as quickly as we should have, so people were delayed. If we had additional institutional hurdles to go through, we'd never get anything done. I think everyone has to have ethics internalised, not wait for approval" P#21.*

*"[If] I were to approach a Research Ethics Committee with an ongoing project and I had some open questions or found myself navigating grey areas, my expectation, or maybe more of a hope, would be that the committee's approach would be: How can we help make this project more ethical? So rather than giving a kind of blanket judgment, like "this is ethical" or "this is unethical", I'd hope they would help identify problematic aspects and suggest ways to address them." P#12.*

*"We have the structure of the Ethical Advisor. It's a somewhat strange structure. We advise the projects. And at the same time, we also have a supervisory role towards the EU or the project officers involved. And to make it clear to them that they are effectively undermining the very research they are funding when they impose certain mandatory steps, referred to as deliverables in the EU, that can bring the research to a complete standstill." P#6*

*"in a lot of social science reviews, it's also only an advice and not a strict legal standard. But usually, the funder or the publisher might say, "Well, without a positive vote from an ethics committee, you won't get funding, or you can't publish your data. So, there is a secondary pressure. But overall, it is not as, legally not as strict as the core part of medical research. And that probably makes a difference here." P#9*

*"We have just assisted the [National] Research Council. Or consider when they now are required to do an ethical self-evaluation when they apply for funds from the Council – so - but it's not a checklist as such, it's more like questions to stimulate Reflections on research ethics, so you don't have to click the box." P#1*

*"Whereas what we in [REC] are attempting to promote is a continuous reflection on ethical issues throughout the lifetime of the research project, where as you say, the ethical issues that come to the fore will change as the project develops, or the researchers will become aware of issues that they weren't aware of at the outset of the project." P#2.*

### 3.3. Social science is not well represented in the REC?

Most of the respondents came from social science, including economy and psychology, ethnography etc. Consequently, there was quite a number of responses which stressed that the current practices in the REC are not well-adapted to the real issues in the social sciences. One of the concerns was that the issues arise often only once you are already in the middle of the research project. Another concern was that there is legitimate research going on that does not easily fit with GDPR demands or create issues with standard anonymity. Examples were mentioned as covert research or research with specially selected vulnerable groups. In general, the impression was given that there are indeed quite a number of really challenging issues in the social science, but that the current structures of the RECs do not accommodate them.

*“The problem I mentioned earlier, where some people reported to the Ethics Committee, came from sociology. The other sciences are less so because they mostly do desk research. There were also studies done with the police and studies in the urban environment — some such studies, yes, we had issues. But basically, the three departments that sent things to us were primarily psychology, sociology, and anthropology.” P#21.*

*“And then a prosecutor comes and says, “Give me the data.” What will you do? How do you ensure that anything they tell you stays confidential? He ultimately had to withdraw the plan. He said he wouldn’t do it. And this was an already funded project. Or you go to an asylum camp, and someone tells you they’ve tricked the system, that they’re 25 years old and pretending to be 16. Okay. And then someone from the asylum service comes and asks you. What will you do? What protects the researcher at that point, and what protects the interviewee? And where does the need for research override the well-being or rights of a person?” P#21*

*“The humanities field— especially when referring to individuals on the autism spectrum—presents serious challenges and obstacles, as it relies on highly individualised data. As a result, research in this area involves qualitative elements that are difficult to assess, and there is a high degree of subjectivity depending on the personality of both the participant and the researcher or reviewer. Complexity arises from the fact that individuals on the autism spectrum are not patients in the strict medical sense. Therefore, beyond the obvious and legally required protection of their personal data, increased safeguards are necessary to protect their privacy and that of their families. Furthermore, complexity increases significantly when the research sample comes from a different cultural context, as both explicit and implicit behavioural norms must be considered. For example, in the Middle East, openly displaying emotions (joy, sadness, anger, pain) is acceptable and expected. In contrast, in Western societies, similar expressions may be viewed as socially inappropriate and raise concerns about the individual’s mental health.” P#19*

*“And when we research this, it means that we often have to ask ourselves to what extent we, ..., violate the contextual integrity of these people. So, do we have to get consent when we analyze publicly accessible Twitter comments? Can we just say that it is public communication or TikTok, the videos are posted publicly, these are not private accounts, can we analyze them?” P#11*

*“I think one topic that is definitely gaining importance is participatory research, which is becoming more established at [RESEARCH INSTITUTE], especially research involving children.” P#8*

### 3.4. New research formats, AI and technology as challenges.

One particular interest of the study was the extent to which new technologies, and here AI was the most prominent, create substantial challenges for RECs and may need new formats of ethical advice and assessment. In general, one notes a certain ambiguity in relation to AI. While many stated that AI presents some new challenges, some were of the opinion that these difficulties were not entirely new. They appear as new as many of the committee members are not well informed about the power and the research characteristics of AI. To what extent AI would call for a revision of research ethics remained an open question.

*“Well, I think you're right that many of the (AI) challenges aren't entirely new, they've existed in other forms before. But I do think the scale at which these challenges now present themselves is really unprecedented.” P#12*

*“we [the committee] don't get into the content, either because of lack of time or because of lack of specific skills. When we talk about artificial intelligence, if you don't have an expert on the board, what*

*are we talking about? If we talk about risk assessment and data protection, but no one has a high level of experience in that area [in the committee], it becomes a formal step.” P#5*

*“Yeah, maybe one of the reasons I find it hard to identify completely new ethical challenges specifically tied to AI is because, in my field, computational social science, this kind of co-dependence on companies, on corporate data, and on the systems they provide has basically existed since the field began.” P#12*

*“Questions will arise, such as: Are we allowed to analyze data with AI? Can we use it for transcription? Can AI-generated content be considered research output? Are we allowed to write with it? I assume these issues will be clarified at some point.” P#8*

*“...so the AI question, especially weaponizing these technologies. And I think that that was much more under the surface. It was not called ethics at that time, but there were considerations what this means...” P#7*

*“...Artificial intelligence, as a phenomenon, certainly raises significant ethical issues and dilemmas, which are highly relevant. However, I don’t think we should impose excessive restrictions on researchers when it comes to studying these problems or dilemmas, including the use of artificial intelligence itself.” P#3*

*“However, it should be emphasised that as AI systems grow increasingly complex, they tend to become more autonomous from human intention. In AI discourse, this is known as the alignment problem. As a result, it is anticipated that a radical revision of ethical, deontological, and legal frameworks will be required. The direction this revision will take is not currently clear. The guiding principles set forth by national and supranational bodies (e.g., USA, China, EU, UN) are not legally binding and thus remain more aspirational than actionable. Solutions and practical tools are still under development.” P#19*

However, global research with Big Data and fragmentation of legal regimes and rules were also recognized as particular challenges within technological research.

*“...these fields use big data today. So, the framework is somewhat unclear. Another issue, which is closer to my own field, is that we often use eye trackers, face readers, that is, technologies that record the participant’s face. So afterwards, we have recordings, videos, emotions—even if they don’t tell us their name, which most of the time they do, we essentially have the person recorded. So, this is definitely a challenge: how do we manage to be ethical and follow deontological standards when we go into such depth, meaning we have the person recorded, their emotions, and how they reacted to particular situations.” P#15*

*“...the global legal framework is relatively fragmented, so if a university wants to conduct research in multiple countries, it has to adapt to many different legal systems, and that’s definitely a challenge. I’m not sure, especially at universities that aren’t technology leaders, if they have committee members capable of evaluating proposals that use new technologies.” P#20*

*“As a result, we also had private phone cards so that they could use a different number and of course absolutely no communication via WhatsApp, which was of course a huge challenge for everyone involved, because that was the most popular app. Oh, those were really big arguments, which made life more or less difficult for us.” P#10*

*“...that gives you [the healthcare institution] the possibility to deal with the industrial world. Because if you [the healthcare institution] are exposed, if you don’t have a risk assessment, if you don’t have a governance system [of the data], you can’t give data to third parties.” P#5*

### 3.5 Solutions for improvement?

Some respondents were clear about what it would take to improve the current situation of the RECs and aiming for best practice. The multi-disciplinarity of the composition of the RECs was a dominant theme so that there would be people in the committee who have a substantial insight in the kind of research they are looking at. When the question was raised whether the practical difficulties of ethical assessments could be supported by some methodological devices, some tools, many were very generally interested, but saw also some limitations in it. A respondent from Romania was the only one who was apparently well versed in some of the tools that CHANGER is using and developing. But respondents also expressed that the first responsibility of better ethics still lies with the individual researcher. Networking among the RECs, and a more professional support of the RECs, including some compensation scheme, were also mentioned. Basically, the respondents went against the outsourcing of ethics to a committee, but rather one should aim at a larger collaboration between many sections of the scientific community to get a better grasp on ethical issues.

*"I would say that committees—at least at [name of university], which does this quite well—should generally continue to be staffed by people from many different disciplines, specialisations. I think that's good; it helps bring pluralism of perspectives and sheds light on an issue from different viewpoints. I very much believe—not so much in automation, let's not go there—but in the systematisation of documents, policies, and procedures. That is, there should be a process that reviews all the documents and all the procedures used by an ethics committee every year, to update them once, and then those should serve as the guide, the framework, for all research evaluated in a given year." P#20*

*"...go to the university's website, etc. So I think that's the most important thing: inevitably, they need to start there. Beyond that, every researcher should ensure they understand why they're submitting a proposal to an ethics committee and its importance. So, it's each researcher's responsibility to self-educate, to some extent, in this area: to do their own research and understand basic principles like integrity, confidentiality, and autonomy. All of these are things they need to know, not only to shape their research but also to prepare their application, so the application is easily understandable by committee members, aligns with key principles, aligns with the rules, and so on. As for other specific tools or solutions... I don't know, nothing else comes to mind right now, yes." P#20*

*"...social scientists could complain: 'Oh, they're so strict here, the ethics committees at my university, why aren't they as liberal as at university X, Y, Z? So, I think we already need this kind of communication about what are the standards, how should we deal with dialogues between ethics committee members and researchers, and should there be some kind of clearinghouse or ombuds office when there are conflicts between ethics committees and researchers?' P#9*

*"A basic proposal is that, precisely because of the scientific competence expected from committee members, it would be good if they received some compensation. In Greece, this work is unpaid at public universities, among the many duties a professor has to balance. Perhaps there should be collaboration, a network among the various university ethics committees, and a report or record of what is happening in each committee, so that the committee members can exchange views. Of course, law has different needs, medicine has others, theology, informatics, and so on. However, the sharing of knowledge among ethics committee members should become a priority." P#18*

*"I can't suggest specific tools. What I always say is that what helped me was to take and enter keywords based on my field — for example, "ethics and special education" — and look it up, because there are lots of articles on that. Focus on that to understand the logic: what ethics means in the field of special education, what it means when addressing socially vulnerable groups, and what you need to consider. Also, very important in all this is the language part — the inclusive language you should use." P#17*

*"But particularly in the northern countries, the Scandinavian countries, we have a long tradition of having clear roles for different types of ethics committees. And very often the secretaries of the ethics committees of different disciplines are on the same floor, which means that the members or the administrative staff of these ethics' committees are very likely to be able to talk to each other and have a good exchange about common issues and problems." P#9*

*"Yes, the Delphi method, the ethics matrix, the consensualization conferences, and... ethical future scenarios? Yes, scenarios. All of these can be found in a book by the late Professor Valentin Mureşan, the founder of the Center for Applied Ethics Research. It's called Management of Ethics in Organizations, and it explains all these methods, developed for the Romanian context. ... In fact, we were the ones who introduced that tool to University XX. We discussed it and promoted it. The ethics matrix. There's also another tool called the "consensualization conference," which is used alongside the ethics matrix. So yes, we've used these tools and actively promoted them at the university." P#4*

*"I'm not against these tools, but I think we are not at all in the process of developing those for use across the various research communities that we deal with, which include like child protection services, the police, social sciences and humanities. But it's a very diverse field. ... Well, as a PI of an ERC project, for European funded projects, as I'm sure you're aware, formulas that you need to go through at several steps in the research process. So I'm aware of such tools." P#2*

*"Nevertheless, tools for ethical evaluation of research proposals are beginning to emerge, such as FERMI (Fake News Risk Mitigator), which offers guidelines and methodologies. However, designing and adopting such systems—especially in the absence of a broad consensus on what constitutes disinformation or the ethical meaning of certain actions—may provoke social resistance, particularly if perceived as an attempt to control expression or limit civil rights. On the ethics side, training programs and seminars could contribute to a better understanding among researchers of what constitutes ethical practice in the research process. We should move in that direction since we now have the technological means for direct dialogue within the global scientific community on such matters." P#19*

*"And I was wondering, is there a space for human computer collaboration and maybe even AI in ethics review? What do you think, in the future?" P#7*

### 3.6. Ethics - the unknown field?

It may be a surprising fact that quite many respondents expressed that the very term ethics is somewhat challenging in the RECs. The tradition of ethical principles and principlism was mentioned but what follows from ethical deliberations was much more uncertain. There was an undertone that one should not overrate ethical deliberations and that there will always be some subjectivity. One expressed also the view that the current approach to research ethics is perhaps the result of some cultural imperialism from Anglo-Saxon countries, specifically the USA. This may have something to do with medical ethics and the principles of bioethics.

*“Look, the first experience is that people don’t know what ethics means.” P#21*

*“We talked a lot about principle-based ethics, for example, the kinds of principles that are laid out in the Belmont Report from the U.S., like Respect for Persons, Justice, and Beneficence. And that’s actually the ethical framework and approach I adopted back then, and I’ve been thinking along those lines ever since, so, really in terms of principle-based ethic.” P#12*

*“Should we follow strict guidelines, or should we be more flexible and case-oriented?” P#8*

*“...people in the US felt if they have to go through ethics reviews, everybody else should as well. Otherwise, the others are faster in doing research. And so, I think it was more/ I think this leveling playing field and also the question of who has the right ethics. I think that’s just, perhaps all the way to some cultural imperialism through ethics...” P#7*

*“I think it’s that ethics and academic integrity should be taken seriously, but not too seriously. (..) In the sense that it’s very easy to go overboard with these ideas about ethics and integrity. (.) You can become too harsh in your demands, too inflexible, overly moralistic, extremely judgmental, overly suspicious. (...) I’d prefer a balanced approach - not falling into indifference, but not into radicalism either.” P#4*

## 4. Summary of themes and comparative reflections

The round of 21 interviews gave a variety of viewpoints but also some surprising near-consensus on problematic issues. There was a widespread acknowledgement that the current system of RECs faced some serious challenges from various corners. There was also consensus that one often sees an over-formalization and some procedural rigidity of ethic assessment in the RECs. All complained the lack of training for the work in the RECs. Respondents were slightly divided whether an ex-ante approval of research projects is the best way to go (Fig. 7). Most were asking for a more continuous follow-up and advise through different phases of the research. In this sense, the approval system was seen as insufficient. Ethics bodies should have the capacity to act as advisory platforms, a function that they currently cannot have due to lack of resources.

Many expressed AI, social science, Big Data, technology research and inter- and transdisciplinary participatory research as challenges, although most also believed that they could be addressed given some more time and reflection.



| Theme                                    | Strong Consensus                                                                      | Notable Variation                           | Divergent Viewpoints                 |
|------------------------------------------|---------------------------------------------------------------------------------------|---------------------------------------------|--------------------------------------|
| <b>Ethics Committees Face Challenges</b> |  Yes | Causes range from capacity to training gaps | Some downplayed them as manageable   |
| <b>Approval System is Effective</b>      |  No  | Needed for journals/funders                 | Many feel it's overly bureaucratic   |
| <b>Advisory Role is Preferred</b>        |  Yes | Some committees use dual roles              | Some fear advisory lacks authority   |
| <b>Long-Term Project Challenges</b>      |  Yes | Monitoring differs by country/discipline    | Hard sciences often better organized |

Fig.7 Overall consensus and divergence in viewpoints in interviews.

#### Conclusions:

This multi-country interview synthesis shows that while ethics committees are increasingly present and structured across institutions, they are **widely perceived as bureaucratically rigid and under-resourced**. The **approval model remains dominant**, but its **legitimacy is weakening**, especially when it lacks capacity to guide evolving or complex research. **Advisory support is preferred**, and new models -such as **governance boards, embedded advisors, and training for early-career researchers-** are seen as promising.

The interviews suggest that **institutional reform is needed**, both to **build trust** and to make ethics governance more **collaborative and adaptive**.

## **Appendix 1, part 1: Interview guide for semi-structured interviews**

### **Draft protocol of interview in WP2 – Task 2.3 CHANGER project:**

1. Your gender (if supplied), and professional position?
2. How long have you been professionally active in this capacity, at your present or similar earlier institution?
3. What is your academic disciplinary background training?
4. Are you or have you been a member of an Ethical Review Board / Research Ethics Committee (REC)?
5. Or are you a member of any other ethical (advisory) board / committee, e.g. within a research project?
6. Could you please describe your background in ethics?
7. Did you receive any kind of training in practical ethics, like short seminars? In that case, how much and by whom?
8. Are you actively engaged in academic teaching?
9. Are you actively engaged in research? How much of your time?
10. What was your general experience about the work of an ERB? Describe the overall impression from the work.
11. Do you think the work of ethics committees in research (REC and others) receives the trust of your colleagues and /or other segments of the general society? Please elaborate.
12. Do you think that the REC in general addresses all the main ethical challenges in the research which it deals with? Here we ask if you can see ethical challenges in the dealings of the committee which are not sufficiently given attention (in the mandate of the REC for instance).
  - a. If no, why not?
  - b. If yes, do you think the concerned researchers share this view?
13. Are there new or evolving types of research which present a real challenge to an REC?

If yes: Can you be specific which kind of research possibly poses new challenges to the ethical assessments?



14. Do you have comments on the following types of research:
  - a. Research with or about artificial intelligence?
  - b. Research in social science in general?
  - c. Research which is essentially participative, like action research or participant observation?
  - d. Transdisciplinary research with societal partners?
  - e. Research with human induced stem cells derived from samples collected in another context?
  - f. Research with long time horizons?
  - g. Innovation projects where the final outcomes are highly uncertain and possibly socially controversial?
  - h. Any other types of research projects which you think may raise special ethical concerns?
15. Is there a structured way how your committee assesses ethical issues?
16. Are you aware of any assessment tools for ethics in research?
  - a. Have you heard of the ethical matrix, or do you know how to use it?
  - b. Have you heard of an ethical Delphi, or do you know how to use it?
  - c. Have you heard of ethical future scenario building, or are you aware how to use it?
  - d. Are you aware of useful ethical checklists, and if yes which?
  - e. Do you know of any other possible ethical assessment tool?
17. If more tools for ethics assessments were available, would you be interested in trying them out in a real case?
18. Would you be interested in additional capacity building on ethics in research? By this we aim at a more comprehensive process / training, typically via online activities, which could help sharpen the ethical assessments?
19. Any other comments on REC / committee practices?
20. Do you have any suggestions for policy changes to take place to improve ethics review practices?
21. Would you agree to be contacted again in a follow-up inquiry?

## Appendix 1, part 2: Info-letter and consent form

Are you interested in taking part in the research project

### ***“CHANGER: Challenges and innovative changes in research ethics reviews”?***

Purpose of the project: You are invited to participate in a research project where the **main purpose is described as**: “The overall objective of CHANGER is to promote changes in research ethics reviews that strengthen the

capacities of researchers to incorporate ethical judgements in the project design and implementation, and to support ethics committees in addressing new challenges posed by new technologies and new research.”

CHANGER is a research project funded by the European Commission. Its research tasks can be described briefly as: (i) **Evaluating** current approaches to assess ethics in research and identify best practice, (ii) **Developing** new approaches to assess ethical challenges, (iii) **Enhancing** knowledge and expertise about these aspects of research, and (iv) **Identifying** policy implications of an updated ethics agenda for research.  
**See also:** <https://changer-project.eu/>

In this context we will conduct interviews and focus groups. All personal data will only be used in an anonymized form within this project.

Which institution is responsible for the research project?

Norway: The Norwegian Institute for Sustainability Research (NORSUS) is responsible for the part (Work package) of the project where we seek your collaboration. The overall leadership of the project is by “Demokritos: National Center for Scientific Research, Athens” and coordinated by Dr. Vangelis Karakletsis; contact Dr. Vasiliki Mollaki: [vmollaki@iit.demokritos.gr](mailto:vmollaki@iit.demokritos.gr).

In **Norway** the contact at NORSUS is Prof. Matthias Kaiser, Contact: [Matthias.kaiser@uib.no](mailto:Matthias.kaiser@uib.no).

There are collaborating institutions in other countries helping with the collection of data from interviews and focus groups.

In **Germany** it is the Ludwig-Maximilians University of München; Prof. Hella von Unger, [unger@lmu.de](mailto:unger@lmu.de) and: KIT Academy for Responsible Research, Teaching, and Innovation; Prof. Rafaela Hillerbrand, [rafaela.hillerbrand@kit.edu](mailto:rafaela.hillerbrand@kit.edu)

In **Austria** it is the Technische Universität Wien; Dr. Marjo Rauhala, [marjo.rauhala@tuwien.at](mailto:marjo.rauhala@tuwien.at)

In **North Macedonia** it is University of Macedonia; Dr. Eda Starova Tahir, [edastarova@yahoo.com](mailto:edastarova@yahoo.com)

In **Croatia** it is Sveuciliste U Splitu Medicinski Fakultet; Prof. Ana Marusic, , [ana.marusic@mefst.hr](mailto:ana.marusic@mefst.hr)

In the **Netherlands** it is Rijksuniversiteit Groningen; Prof. Jeanne Mifsud Bonnici, [g.p.mifsud.bonnici@step-rug.nl](mailto:g.p.mifsud.bonnici@step-rug.nl)

In **Romania** it is Universitatea Din Bucuresti; Prof. Constantin Vica, [constantin.vica@filosofie.unibuc.ro](mailto:constantin.vica@filosofie.unibuc.ro)

In **Italy** it is Conoscenza Einnovazione societa aresponsabilita limitata semplificata, Dr. Alfonso Alfonsi, [alfonsi@knowledge-innovation.org](mailto:alfonsi@knowledge-innovation.org)

In **Belgium** it is Katholieke Universiteit Leuven, Prof. Pascal Borry, [pascal.borry@kuleuven.be](mailto:pascal.borry@kuleuven.be)

In **Greece** it is University of Macedonia, Prof. Ioannis Manis, [imanos@uom.edu.gr](mailto:imanos@uom.edu.gr).

In **Portugal** it is Universidade de Coimbra, Prof. Andre Dias Pereira, [andreper@fd.uc.pt](mailto:andreper@fd.uc.pt)

Why are you being asked to participate?

We ask you because we have identified your name through our knowledge of ethical committees in the country, or through our knowledge of experts on ethics in science, and relevant networks. All in all, our sample is restricted to a maximum of 100 persons. If you are situated outside of Norway, our foreign partner (see above) has identified your name building on the same criteria.

This letter is written by the coordinator of the interview tasks, but it may be sent you from our foreign partner. Please reply to the sender of this request.

What does participation involve for you?

The interviews will be conducted in two ways: either as an online interview or as a person-to-person interview. Please indicate which of these you prefer. If you chose to take part in the project, this would involve that you fill in some online questions ahead of the online interview. Alternatively, this will be done manually in the person-to-person meeting. The semi-structured interview with your experiences and assessments of ethics work will follow and will include questions about your experience with and your assessment of dealing with ethical issues in all walks of science / vitenskap / Wissenschaft, as it will include also social science and humanities. Your answers will be recorded electronically, and the researcher will take notes. All together it will take approx. 45 minutes, give or take some 15 minutes.

Participation is voluntary Participation in the project is voluntary. If you chose to participate, you can withdraw your consent at any time without giving a reason. All information about you will then be made anonymous. There will be no negative consequences for you if you chose not to participate or later decide to withdraw.

The answers you provide will not be made available to your employer or to any committee you are a member of.

Your personal privacy – how we will store and use your personal data

We will only use your personal data for the purpose(s) specified here and we will process your personal data in accordance with data protection legislation (the GDPR).

Only the persons (the project group) associated with the organisation which carries out the interviews will have access to your personal data, no others. Your personal data will be stored electronically on our local research server, without access to outside persons. We will replace your name and contact details with a code. The list of names, contact details and respective codes will be stored separately from the rest of the collected interview data. These will be shared in a pseudonymized form with research partners.

Only participating institutions in the above-mentioned research project will be able to access the project server. The personal identification data will all be pseudonymized. Therefore, you will not be recognizable in any publications, reports or oral presentations from this project. The only information we may provide in the reports are your gender, your professional role and occupation, disciplinary affiliation and/or area of expertise/nation/institution/organization.

A Data Management Plan is developed by the CHANGER Project as Deliverable D1.4.

What will happen to your personal data at the end of the research project?

The planned end date of the project is the end of 2026., with some reports coming out perhaps in the following year. After the reporting and publications all your personal information and the recordings of the interviews will be deleted from our records. Only the fully anonymized data may be stored for later use.

Your rights

So long as you can be identified in the collected data, you have the right to:

- access the personal data that is being processed about you
- request that your personal data is deleted
- request that incorrect personal data about you is corrected/rectified

- receive a copy of your personal data (data portability), and
- send a complaint to the Norwegian Data Protection Authority regarding the processing of your personal data (alternatively the relevant authority in the country of our partners if they conducted the interview).

What gives us the right to process your personal data?

We will process your personal data based on your consent.

Based on an agreement with The Norwegian Institute of Sustainability Research (NORSUS, The Data Protection Services of Sikt – Norwegian Agency for Shared Services in Education and Research - has assessed that the processing of personal data in this project task meets the requirements in data protection legislation.

Where can I find out more?

If you have questions about the project, or want to exercise your rights, contact:

- WP leader (prof.) Matthias Kaiser at NORSUS, e mail: [Matthias.kaiser@uib.no](mailto:Matthias.kaiser@uib.no) or
- Our Data Protection Officer: (prof.) Ellen-Marie Forsberg, director of NORSUS; [emf@norsus.no](mailto:emf@norsus.no).
- For countries outside Norway you may also contact the responsible researcher or the data protection officer at your participating institution (see the above list of participating institutions in different countries).

If you have questions about how data protection has been assessed in this project by Sikt, contact:

- email: ([personverntjenester@sikt.no](mailto:personverntjenester@sikt.no)) or by telephone: +47 73 98 40 40.

Yours sincerely,  
Project

Leader

(Researcher/supervisor)

---

**Consent form (NB: 2 copies)**

I have received and understood information about the project **CHANGER** and have been given the opportunity to ask questions. I give consent:

- ☐ to participate in the online interviews / focus groups as described above
- ☐ to participate in the person-to-person interviews / focus groups as described above

I give consent for my personal data to be processed until the end of the project.

-----  
(Signed by participant (electronically possible) , date)

## Appendix 1, part 3: Data overview

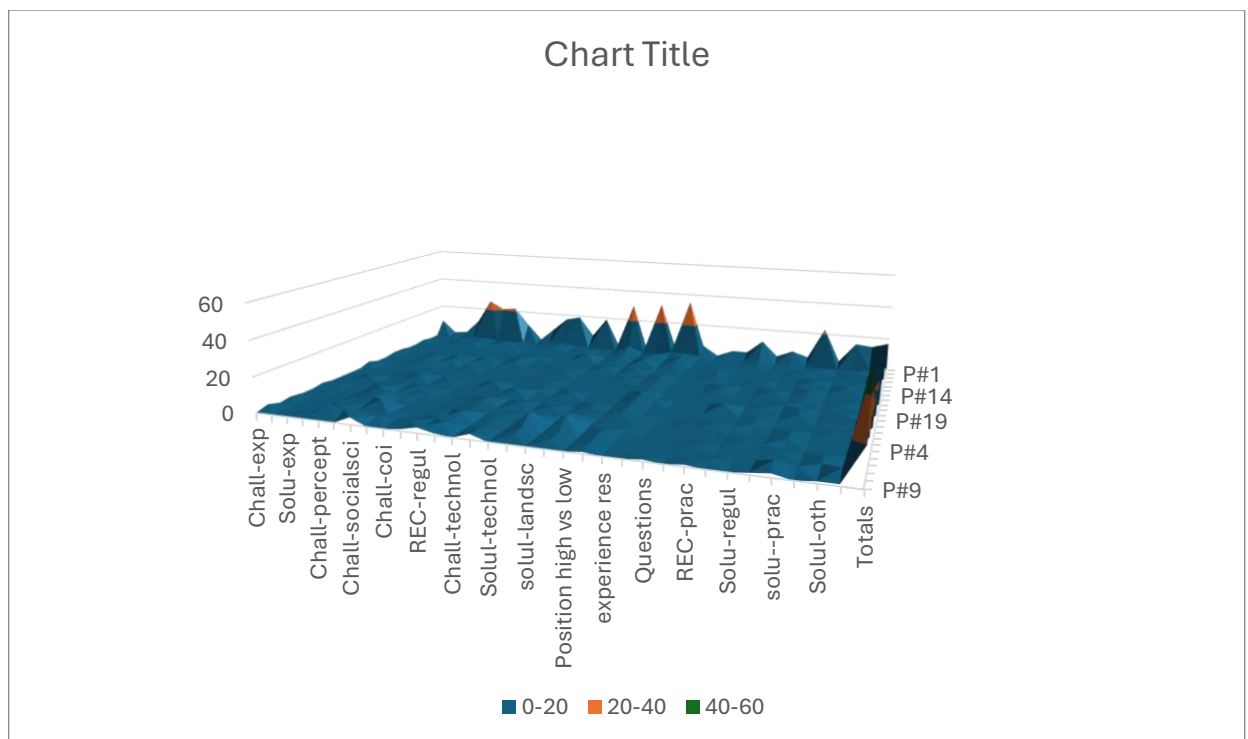


Fig. 1 Data overview.

## Appendix 2 - Report on Task2.4: Stakeholder consultation (Focus groups)

### 1. Introduction

This report presents the findings from the focus group interviews conducted under Task 2.4 of the CHANGER project (CHALLENGES AND INNOVATIVE CHANGES IN RESEARCH ETHICS REVIEWS). The objective of the study was to explore the experiences, challenges, and potential solutions perceived by ethics review experts across Europe in the context of evolving research practices. This work forms part of Work Package 2 (WP2), which contributes to Deliverables D2.2 and D2.3 and complements earlier tasks including scoping reviews and expert interviews.

### 2. Methodology

#### 2.1. Study design

The study employed a qualitative research design through the use of focus groups due to their ability to generate dynamic conversations and to reveal perspectives on ethics review challenges. To identify a wide range of facilitators and barriers to the implementation of new approaches in ethics review, we performed a cross-country and cross-disciplinary study with 13 focus groups of ethics review experts and researchers from different research fields. Although only 10 focus groups were initially planned, we were able to conduct 13 in total. The design of the focus groups was attentive to the diversity of the existing ethics review landscape (e.g. with more established review routines and infrastructures in some disciplines, such as the biomedical sciences, and more recent, interdisciplinary and evolving review infrastructures in other fields, such as the social sciences and humanities).

#### 2.2 Sampling and recruitment

A heterogeneous stratified purposive sampling strategy was employed to ensure representation from all major research domains (OECD Frascati classification): Natural Sciences, Engineering and Technology, Medical and Health Sciences, Agricultural Sciences, Social Sciences, and Humanities and the Arts. Purposive sampling is a non-



This project has received funding from the European Commission Horizon WIDERA, under grant agreement No 101131683. Views and opinions expressed are those of the CHANGER consortium only and do not necessarily reflect those of the EU or the European Commission. Neither the EU nor the granting authority can be held responsible for them.



probability sampling method widely used in qualitative research for the identification and selection of information-rich cases for the most effective use of limited resources in which elements selected for the sample are chosen by the judgment of the researcher. The purpose of a stratified purposeful sample is to capture major variations rather than to identify a common core, although the latter may also emerge in the analysis (Black, 2007, Patton, 1990). To supplement the scoping review (task 2.1) and better understand current challenges and solutions in more recently created and less researched ethics review infrastructures, e. g. in the social sciences and humanities, the purposive sampling strategy placed an emphasis on ethics experts in these fields. This focus aimed to counter their underrepresentation in existing research and to ensure that their distinct perspectives were captured.

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Participants were recruited via professional networks, CHANGER project partners, and ethical review boards across Europe. In the recruitment process, we invited potential researcher and stakeholder participants via an invitation letter that provided the information about the overall aim of the focus group. Before the focus group interview, all participants in the focus groups were presented with an invitation and information letter, as well as the informed consent form (see appendix), which

included the information on the project's purpose, funding, recruiting processes, methodologies, expected risks/adverse effects, beneficiaries of research results, communication of research results, all matters concerning data collection, analysis and protection of the participants personal information, the participants' opportunities for leaving the study and for viewing, and if relevant, commenting on transcriptions of interviews and quotations. In the informed consent form, it is very clearly described what the participants give their consent to by signing the form. The participants also filled in a brief demographic questionnaire before the start of the focus group (see Appendix). Each CHANGER partner was tasked with identifying and recruiting at least two experts.

### 2.3. Participants

A total of 57 individuals participated in 13 focus groups conducted for this study. Participants represented a diverse set of backgrounds and experiences related to ethics in research and review processes. The gender distribution was relatively balanced, with 31 female (54%) and 26 male (46%) participants. In terms of age, the majority fell within the 40–59 age range, with 17 participants aged 40–49 (30%) and 19 aged 50–59 (33%). A smaller number of participants were in the 30–39 age group (n=10, 18%), while 9 were 60 or older (16%), and only 2 participants (4%) were in the youngest age group of 18–29.

The majority (n=38, 68%) of participants identified themselves as researchers; 25 participants (44%) had experience participating in EU ethics reviews, and 23 (40%) were members of research ethics committees (RECs). A number of participants had more than one role. In addition to the three roles specified above (researcher, EU ethics expert, REC member), the participants reported the involvement in coordinating EU-funded ethics projects, managing or staffing the offices of ethics commissions, consulting in research management, and advocating for specific research communities.

The research domains represented among the participants covered a broad academic spectrum. Social sciences were the most common, with 24 participants (42%) working

in this area. Medicine and health sciences were represented by 18 participants (32%), while 12 participants (21%) worked in the humanities and the arts. Smaller numbers of participants came from engineering and technology (n=5, 9%), and natural sciences (n=4, 7%). About a half of the participants (n=29, 51%) had more than ten years of relevant professional experience. Thirteen participants (23%) had less than five years of experience, while 12 (21%) reported between five and ten years. Three participants (5%) did not specify the length of their professional engagement.

## 2.4. Implementation

Each focus group had 2 to 8 participants. The group discussions lasted around 60 minutes and were held either in-person or online, depending on logistical considerations. English was the default language, with translations and AI-assisted tools (DeepL) used for local-language groups upon consent.

## 2.5 Interview/moderator guide

The focus group interviews followed an interview/moderator guide (see Appendix), which in addition to a number of opening and closing interview questions, consisted of in-depth discussions on new challenges to ethics review identified in the scoping review, as well as further topics to supplement it, such as challenges and facilitators, drawing from selected articles within the scoping review that specifically discussed challenges faced by REC members.

## 2.6 Focus group questions

The questions for the focus group are outlined in the appendix and included fewer, more abstract discussion points and specific prompts to provide deeper insight into the topics. The questions addressed the challenges and solutions to ethics review. These included new technologies, new players, new forms of collaboration and partnerships, new human rights related frameworks, and specifically the barriers and facilitators for ethics evaluation of such emerging issues. The questions asked were

flexibly adapted to the group dynamic, discussion and composition of each focus group according to the methodological principles of qualitative research approaches.

## 2.7. Data collection and analysis

MEFST conducted six focus groups, all of which were held in English. Two focus groups took place in person, while the remaining four took place online. Participants (n=32 in total) were from a diverse range of research institutions across various European countries, including local research ethics committee (REC) members, and other experts exploring ethics in fields such as health technology assessment (HTA), research integrity, extended reality, and the use of artificial intelligence in medical education. All focus groups included a diverse mix of participants' roles – there was no single group involving, for example, only local REC members or members from a single discipline. Often, participants held multiple roles relevant to the topic and provided expertise from all of these contexts. All focus groups at MEFST were conducted by Marija Franka Žuljević (MFŽ), MD, PhD. MFŽ is a medical doctor employed as a teacher at MEFST at the time of the study. She had received previous training in qualitative research and had previous experience in conducting focus groups and interviews in her research. Nine participants knew of MFŽ through personal contacts. Antonija Mijatović, PhD, and Prof. Ana Marušić, MD, PhD, served as additional moderators/observers during the focus groups.

At LMU, three focus groups were conducted between January 8 and January 22, 2025. All three took place online and were held in German; they were subsequently translated into English. Participants (n=14) came from a range of disciplines, including anthropology, cultural studies, education, health and information sciences, linguistics, philosophy, psychology, and sociology. Most were based at academic institutions in Germany, including both universities and non-university research centers. The majority had served as chairs or members of Research Ethics Committees (RECs); three had acted as EU ethics experts, and three were in the process of establishing a REC at their institution. While most participants were researchers, four worked in science support roles. Recruitment took place via mailing lists—including NEKS (a network of RECs in the social sciences) and PartNet (a network of participatory health researchers in Germany)—as well as through the personal networks of LMU team members. The focus groups were moderated by experienced qualitative researchers: Anna Huber (FG1/moderator 1, FG3/moderator 2), Nevien Kerk (FG1/moderator 2, FG2/moderator 2), and Hella von Unger (FG2/moderator 1, FG3/moderator 1).

At UB, At the University of Bucharest (UB), two focus groups were conducted between 15 and 23 January 2025. The first focus group was national in scope, involving five researchers and experts from universities and research institutes across Romania. This session was held online via the Zoom platform. Participants in this group had experience in ethical analysis, were responsible for ethical compliance in international projects, or were members of research ethics committees (RECs) within their respective institutions. The second focus group took place in person at UB on 23 January and included six participants, all of whom were members of the institutional ethical review board. Both focus groups were conducted in Romanian and subsequently translated into English using DeepL. For recruitment, a list of potential participants was compiled, including all members of the UB institutional ethical review board and national ethics experts. Email invitations were sent out, and the personal networks of the UB project team were also leveraged to identify and recruit participants for both focus groups and interviews. The focus groups and interviews were moderated by sociologist Andrada Istrate-Luca. The in-person focus group at UB was supported by Alexandra Zorilă, a member of the CHANGER project team.

All focus groups were audio recorded, transcribed, pseudonymized/anonymized and translated into English, in case the focus groups were conducted in a different language. Transcription followed the guidelines by Dresing & Pehl (2024). The transcripts were analysed using thematic analysis (Braun & Clarke, 2006), combining deductive codes derived from the research protocol and literature, with inductive codes emerging from the data. Coding was conducted manually (MEFST) or by using qualitative analysis software: MAXQDA (LMU), <insert here for UB and K&I>.

Each focus group was referenced using a standardized code in the results and discussion sections. These codes indicate the partner institution and the number of the focus group conducted at that site. For example, “LMU-FG1” refers to the first focus group conducted by LMU, while “MEFST-FG6” indicates the sixth focus group conducted by MEFST. Similarly, “UB-FG#” refers to focus groups conducted by University of Bucharest, and “K&I-FG#” refers to those conducted by Knowledge and Innovation Srls.

## 2.8. Ethical considerations

Ethics approval for the study was obtained from the institutions of the partners conducting the focus groups (MEFST, LMU, K&I, UB). All participants provided informed consent. The

study adhered to GDPR requirements and EU data protection laws, with all data stored securely and in pseudonymized and anonymized form. To protect the privacy of participants, names were replaced with IDs (pseudonymization), and further identifying information (e.g., specific positions, names, and research project topics) was either anonymized or removed through generalization and omission.

## 2.9. Data management and privacy

Audio or audiovisual recordings and pseudonymized transcripts are stored locally, at the site they were created, according to the national and EU data protection rules and institutional policies (e.g., five (5) years for MEFST partner and ten (10) for KUL partner), and the CHANGER project's data management plan. Only translated, pseudonymized/anonymized transcripts were transferred between researchers in EU countries, according to National and EU law.

The following recommendation was followed for transcription (Dresing & Pehl, 2024):

|                  |                                                   |
|------------------|---------------------------------------------------|
| Mod              | Moderator (e.g., Mod 1 Mod 2)                     |
| S                | Speaker (e.g., S1, S2)                            |
| X                | Abbreviation (Names, Addresses, Institutions etc) |
| EMPHASIZED       | Emphasizes words                                  |
| (laughter)       | Non-verbal communication                          |
| [?]              | Inaudible word                                    |
| [??]             | Several words inaudible [unintelligible]          |
| [unintelligible] | Longer parts or sentence unintelligible           |
| [maybe?]         | Approximate wording                               |
| (...)            | Omission, parts not transcribed                   |
| ..               | Short pause                                       |
| (pause)          | Longer pause                                      |
| /                | Interruption                                      |

## 2.10. Translation

For focus groups conducted in a local language, additional consent was sought for AI-Assisted Translation, using a fully GDPR-compliant tool. We used DeepL Translator Pro to translate

anonymized transcripts (Appendix, part 4). This program processes data in accordance with the General Data Protection Regulation (GDPR). Data is stored by DeepL for 14 days only and is then deleted. All processing occurs exclusively on servers within the European Economic Area (EEA), and the data was not used for AI training purposes.

### 3. Results

The analysis of the focus group yielded a set of insights into the current challenges and evolving practices in research ethics review. Participants from diverse disciplinary and institutional backgrounds shared their experiences, highlighting both structural and contextual factors that influence ethics evaluations across Europe. We provide a list of key themes related to barriers and facilitators to ethics review process.

#### 3.1. Barriers in the ethics review process

The analysis identified a range of systemic, structural, capacity-related, and cultural barriers that hinder the effectiveness, fairness, and adaptability of ethics review processes across contexts and disciplines. Insights from focus groups across Europe reveal that these barriers are deeply embedded in systemic structures, cultural assumptions, institutional limitations, and evolving technological contexts. The challenges range from bureaucratic inefficiencies and lack of expertise, to fragmented oversight and insufficient engagement with ethical reflection, pointing to a system in need of reform both in substance and perception.

##### Systemic and structural barriers

The effectiveness of ethics review systems is frequently undermined by institutional fragmentation, inertia, inconsistent practices, and limited support infrastructures. These structural limitations affect both how ethics is practiced and how it is perceived across institutions, disciplines, and national borders.

##### *3.1.1.1. Lack of standardisation*

Across countries and institutions, ethics review processes differ markedly in scope, interpretation, and procedural rigor. The participants were of the opinion that these inconsistencies create inefficiencies and confusion, especially for researchers engaged in international or interdisciplinary work. The variation in how local, national, and EU-level ethics bodies operate reflects broader governance fragmentation and contributes to uncertainty



and duplication in reviews.

*"Each agency that does ethics review does things a bit differently, makes the process less effective." (MEFST-FG3)*

*"Discrepancy in views and approaches from different institutions (data protection office, local REC, EU level...)." (MEFST-FG6)*

*"Standardization across disciplines remains difficult, especially in resource-limited institutions." (LMU-FG1)*

*"There is a call for harmonisation and clear guidelines to address new ethical issues... At the same time, the evolution of ethical review seems to be moving towards an increase flexibility... These two needs may create tensions in the development and management of ethics reviews." (K&I-FG1)*

*"We've been discussing for about five years the need to redefine and adapt the concept of vulnerability... we haven't yet reached a definitive resolution..." (UB-FG2)*

### *Inertia and "administritis"*

Many participants emphasized that the efforts to improve ethics systems often stall due to entrenched bureaucratic cultures and legal rigidity. They highlighted how status quo adherence, lack of incentives for reform, and institutional resistance to innovation lead to passive or superficial engagement with ethical oversight. This institutional inertia not only delays adaptation to new challenges but also limits critical reflection within the system itself.

*"Inertia is part of the review system... inflexibility of legal status quo – updating legislation is hard for new innovations." (MEFST-FG4)*

*"Some colleagues rely on ethical definitions that are 10 to 20 years old, without recognizing the need for adaptation." (UB-FG1)*

*"Individuals do not want to gain knowledge about ethics issues because incentives are poor... any implementation of solutions is more difficult." (MEFST-FG1)*

*"RECs often use examples of unethical behaviour that are outdated, rather than trying to look at unethical behaviour in what is going on in research today." (K&I-FG1)*

*"Streamlining helps the reviewer... but risks include over-reliance on self-assessment, reduction in relevance of the review." (K&I-FG2).*

### *Insufficient resources*

The experience of the participants was that ethics committees often function under constraints that compromise their quality and sustainability. Many RECs are staffed by unpaid volunteers, lack administrative support, and receive little investment in training or infrastructure. This chronic under-resourcing leads to inconsistent reviews and diminishes professionalization, especially in smaller institutions or in fields like the social sciences where ethics infrastructures are newer or less developed.

*“RECs rely on part-time or volunteer members, leading to inconsistent reviews and limited professionalization.” (LMU-FG1)*

*“The resources available to manage RECs are already limited... need for paid roles and investment in infrastructure.” (K&I-FG1)*

*“No courses, no discussions... we assume they’re already trained, but that’s probably a disadvantage.” (UB-FG1)*

*“Universities reducing administrative and professional support staff... ethics support for researchers diminishing.” (K&I-FG2)*

### *Fragmentation of responsibilities*

The participants consistently identified confusion over the division of responsibilities between ethics committees, data protection offices, and research governance bodies. This overlap leads to role ambiguity, inefficient reviews, and places an undue burden on ethics bodies to serve reputational or regulatory functions that extend beyond their core purpose of fostering ethical research.

*“Overlap and confusion over responsibilities between RECs, data protection bodies, and other governance structures.” (LMU-FG1)*

*“Role confusion... unclear who is responsible for which part of review – local REC, EU level, or others.” (MEFST-FG6)*

*“RECs appear to have a role in research governance... but limited supporting role for researchers.” (K&I-FG2)*

*“Each faculty has its own ethics committee... in theory they should meet, but in practice, nobody meets anybody.” (UB-FG1)*

### *Conflicts of interest*

Concerns were raised about the lack of independence and transparency in some RECs. Institutional or interpersonal relationships, and unclear accountability mechanisms, can create real or perceived conflicts of interest, thereby undermining trust in the integrity of the review process.

*“The review system sometimes reproduces the same institutional interests... there’s a need for more independence and diversity in RECs.” (K&I-FG1)*

*“Sometimes institutional interests override ethical judgment, especially when institutional reputation is at stake.” (K&I-FG2)*

*“There’s a tendency to shift responsibility from research supervisors to the ethics committee... which is then expected to clarify unclear or complex situations.” (UB-FG1)*

## **Knowledge and capacity gaps**

### *Limited experience*

The participants emphasized that ethics reviewers frequently lack the up-to-date knowledge

necessary to navigate rapidly advancing areas such as AI, data science, and participatory research. With limited access to ongoing training and a small pool of experts in the emerging research fields, many RECs struggle to provide meaningful oversight, leading to gaps in critical evaluation.

*“RECs often lack the expertise to understand the ethical implications of many advanced technologies.” (K&I-FG1)*

*“Experts sometimes get caught up on wrong issues due to lack of detailed knowledge.” (MEFST-FG4)*

*“Experts/reviewers required to keep track of many topics at once, difficult to keep such a wide field of expertise.” (MEFST-FG4)*

*“Ethics commissions and researchers must constantly stay updated to understand complex AI systems.” (LMU-FG2)*

### *Lack of interdisciplinary understanding*

Modern research often spans multiple disciplines, yet RECs are not always equipped to address this complexity. Participants noted difficulties in achieving consensus on cross-cutting ethical issues, as well as the unrealistic expectation that individual reviewers should master a vast range of methods and theories.

*“Ethics experts expected to know a lot about many topics (sometimes not feasible).” (MEFST-FG2)*

*“Difficulty in consensus with interdisciplinarity.” (MEFST-FG3)*

*“RECs are not currently prepared to evaluate interdisciplinary projects... need new approaches.” (K&I-FG2)*

### *Researchers’ lack of awareness*

Despite the availability of training resources, many researchers still treat ethics review as a procedural requirement rather than a core part of responsible research. This lack of meaningful engagement, compounded by time pressures and incentive structures, limits ethical foresight and weakens the practical relevance of ethics approvals.

*“Researchers don’t have good understanding of ethics (e.g., informed consent, data sharing) despite available trainings.” (MEFST-FG5)*

*“Scientists are excited about their research, but don’t think about post-market impact.” (MEFST-FG3)*

*“Researchers often perceive ethics process as bureaucratic... submitting expected answers, conducting research differently in practice.” (UB-FG2)*

*“Some researchers write what they think we want to hear, but proceed differently in practice.” (UB-FG2)*

*“There is a risk that this will exclude researchers from thinking about the ethical*

*aspects of their own research...” (K&I-FG2)*

### *Poor ethical self-assessments*

Self-assessment processes often yield vague or perfunctory responses, making it difficult for ethics committees to evaluate projects rigorously. Researchers may include superficial statements that lack detail or misrepresent actual practices, undermining both the accuracy and value of the ethics review.

*“We currently have no system to verify if researchers follow the ethical commitments outlined in their applications.” (UB-FG2)*

*“Some of our colleagues perceive the application for research ethics approval as a mere formality... they simply write what they think we want to hear while, in reality, they proceed with their research as they wish.” (UB-FG2)*

*“In the ethics self-assessment, participants just put one word or general phrases... too little info provided.” (MEFST-FG4)*

*“Institutionalisation of ethics self-assessment risks excluding researchers from thinking ethically.” (K&I-FG2)*

*“Applicants say they follow guidelines but don’t practically say what this means.” (MEFST-FG4)*

## Cultural and perceptual issues

### *Ethics as a burden*

For many researchers, ethics review is perceived as a hurdle to be overcome rather than a valuable element of high-quality research. This perception, reinforced by bureaucratic structures and publication pressures, discourages genuine ethical reflection and can lead to superficial compliance.

*“Ethics is viewed as a necessary evil or bureaucratic checkbox.” (MEFST-FG2)*

*“Researchers’ perceptions of ethical review are generally negative... seen as limiting or slowing down research.” (K&I-FG1)*

*“Ethics review is seen as a terrible obstacle rather than an opportunity to improve research.” (K&I-FG2)*

*“Some researchers don’t understand the need for ethics approval and just want the process done quickly.” (UB-FG2)*

*“It adds another layer of bureaucracy to their workload... Some researchers respond with hostility, frustration, or fear toward the process.” (UB-FG2)*

### *Distrust*

Trust is lacking not only between researchers and ethics committees, but also from the public toward the research enterprise. Focus group participants reported that distrust can stem from disciplinary divides, opaque review processes, and past experiences of exploitation,

particularly in marginalized communities or participatory contexts.

*“The need for ethics approval has generated a range of emotional responses among our colleagues - many are scared, angry, or confused, and they express a variety of reactions. Some of them comment extensively, questioning what we on the committee are actually doing and whether the process is a waste of time.” (UB-FG2)*

*“Distrust between experts due to lack of knowledge beyond one’s field.” (MEFST-FG4)*

*“Distrust of white-led research, secondary data use, and institutional oversight.” (LMU-FG1)*

### *Eurocentrism and value conflict*

Ethics frameworks grounded in Western norms often fail to account for diverse cultural perspectives. This misalignment becomes especially problematic in global research collaborations or when engaging with communities whose ethical priorities differ from mainstream European values.

*“Risk of keeping a Eurocentric view of research ethics... need to recognize and compare other ethical perspectives.” (K&I-FG1)*

*“Risk of losing focus on Western European values... due to global competitiveness and political polarization.” (K&I-FG1)*

*“Challenges in harmonising ethical values across societal actors with different perspectives.” (K&I-FG2)*

*“When I worked in the U.S., it was well established that Research Ethics Committees were based on the specific disciplinary foundations relevant to their field. The same applied when I worked in [name of African country], where these foundational aspects also shaped the challenges of ethics review processes.” (LMU-FG1)*

## Challenges from technological innovation

### *Ethics lagging behind innovation*

Ethical guidelines often lag behind technological innovation, making it difficult to adequately address emerging challenges in rapidly evolving fields such as artificial intelligence. The participants noted that guidance is slow to adapt, leaving researchers and reviewers without clear frameworks for addressing novel ethical risks.

*“Technology is developing faster than guidance and rules can be given.” (MEFST-FG1)*

*“Lack of appropriate guidelines to address ethical issues in new technology areas.” (K&I-FG1)*

*“Difficult to differentiate between technical and ethical issues... definitions are still developing.” (MEFST-FG6)*

*“Lack of clarity on what AI research encompasses... complicates evaluation” (LMU-*

FG2)

*“Not all AI is created equal... context determines ethical relevance” (MEFST-FG4)*

*We need someone with expertise in AI and databases... Without this kind of specialized knowledge, it becomes much harder to navigate these challenges.” (UB-FG2)*

*“We’ve had one situation like this so far, but as AI tools are more and more used in research, then we have to keep up with the times.” (UB-FG2)*

### *Lack of long-term monitoring*

Ethics reviews typically occur only at the outset of projects, with little or no follow-up during or after research activities. This one-time model fails to account for ethical issues that emerge during implementation or in post-research consequences, particularly in dynamic areas like AI.

*“We lack the resources to enforce ongoing monitoring... once approval is granted, there’s no follow-up.” (UB-FG2)*

*“RECs do not evaluate end-products of a project... issues may emerge later” (MEFST-FG6)*

*“Post-grant award monitoring of projects suggested to ensure ethics is respected” (MEFST-FG3)*

*“Ethics review should not be a one-time event... ongoing advisory processes needed.” (LMU-FG3)*

### *Lack of governance*

Emerging research areas such as social media analysis or AI-enhanced studies often operate in legal and ethical grey zones. The participants suggested that the absence of comprehensive governance structures means these projects may proceed without informed consent or adequate ethical safeguards.

*“Ethical concerns arise around the use of public data without consent. While such data may be legally accessible, there is a risk of misuse.” (LMU-FG2)*

*“Ethics committees still lack clear governance rules for fast-evolving areas like social media or AI-enhanced studies.” (K&I-FG1)*

*“Participants discussed ambiguity over whether public data from social media can be ethically used without explicit consent.” (LMU-FG2)*

## **3.2 Facilitators in the ethics review process**

The focus group discussion suggested a range of practices, structures, and cultural shifts that can support more effective, inclusive, and responsive ethics review processes. These facilitators span interdisciplinary collaboration, stakeholder engagement, institutional

reforms, and innovations in oversight and education.

## Interdisciplinary and stakeholder collaboration

### *Interdisciplinary collaboration*

Including experts from diverse academic and professional backgrounds, such as technical fields, law, humanities, social sciences, and medical ethics, enriches the deliberative process and allows ethics committees to more effectively address complex and emerging ethical challenges. Such collaboration is especially crucial in areas involving new technologies, where ethical implications are not easily confined to a single domain.

*“Experts in specific fields such as AI can help circumvent some of the knowledge missing from other ethics experts.” (MEFST-FG1)*

*“Local RECs should enlist experts for new technology, more specialization.” (MEFST-FG2)*

*“We hold meetings... perspectives of experts in different fields intersect with those of philosophers... theology researchers, public administration specialists...” (UB-FG2)*

### *Stakeholder involvement*

Engaging laypeople, patients, community groups, and non-academic experts in ethics review helps incorporate real-world concerns and cultural perspectives that institutional actors may overlook. This inclusion not only improves the relevance of ethics assessments but also fosters public trust and reduces risks of marginalization or bias, such as Eurocentrism or structural racism.

*“Involvement of laypeople can provide a fresh perspective on what ethics issues are actually perceived as relevant, cultural context can be relevant too – different stakeholders have synergy.” (MEFST-FG1)*

*“Patient involvement important, especially in populations such as children.” (MEFST-FG1)*

*“More overall discussion of issues, in person (not just online) – more room for true discussion.” (MEFST-FG2)*

*“Our project included supervision, both for the academic team and for the co-researchers.” (LMU-FG3)*

### *Better communication*

Establishing channels for regular, transparent dialogue between ethics reviewers, applicants,

and affected stakeholders, supported by appropriate digital or interpersonal tools, can reduce misunderstandings, enhance ethical clarity, and promote a culture of shared responsibility. Improved communication structures also allow for iterative feedback and greater trust in the process.

*“Better dialogue should be enabled between VC and experts participating in review so conflicts are resolved faster.” (MEFST-FG4)*

*“More overall discussion of issues, in person (not just online) – more room for true discussion.” (MEFST-FG2)*

*“It wasn’t just a matter of submitting a paper and then getting a response saying, ‘Okay, everything is fulfilled’. Instead, it was a conversation. Of course, we did submit our paper, but afterward, we had a discussion. We talked things through right away. A colleague from the ethics department facilitated this process.” (LMU-FG3)*

*“There were several times when I wrote them an email saying: ‘This is how it is right now, does it still fit or is something critical?’ And that worked well.” (LMU-FG3)*

### *Standardization with flexibility*

Developing standardized tools, such as checklists, decision trees, and structured templates—can enhance consistency in ethics reviews. However, participants emphasized that these tools must remain adaptable to diverse disciplines and research contexts to avoid a "box-ticking" mentality that stifles critical reflection.

*“Standardized templates for addressing requirements (technical solution from ERC)” (MEFST-FG4)*

*“Decision tree for an issue such as AI to guide researchers, designed by interdisciplinary team” (MEFST-FG2)*

*“Tailored training and discipline-specific forms can streamline applications” (LMU-FG1)*

*“We have a standard evaluation report... along with clearly defined evaluation criteria.” (UB-FG2)*

*“There is a logic tree planned for our online platform to adapt ethics procedures to various research contexts.” (UB-FG2)*

### *Non biomedical foundations for ethics reviews in non-biomedical fields*

For disciplines beyond biomedical sciences, such as participatory action research and ethnography, new models of ethical review are needed that better reflect the nature of these methodologies. This includes alternative forms of informed consent, revised risk-benefit assessments, and the recognition of processual rather than fixed ethical commitments.



*“Ethical approval in social sciences must be approached differently... language, tools, and risks vary greatly from biomedical fields.” (UB-FG2)*

*“Forms and procedures have been developed especially for SSH disciplines... including separate review criteria and formats.” (UB-FG2)*

*“REC procedures, if modelled on medical frameworks, are frequently ill-suited to social science methodologies, requiring adaptation, especially for participatory research.” (LMU-FG1)*

### *Resources and funding*

A sustainable ethics review system requires long-term investment in REC staffing, infrastructure, and training. Focus group participants frequently highlighted how under-resourcing leads to inconsistent reviews, increased burden on volunteers, and poor institutional memory, all of which undermine quality and trust in ethics oversight.

*“The resources available to manage RECs are already limited... need for paid roles and investment in infrastructure.” (K&I-FG1)*

### **Integration and coordination of parallel review structures**

Efficient coordination among overlapping review structures, such as RECs, data protection bodies, research integrity offices, and safety review boards, reduces redundancy, clarifies responsibilities, and prevents contradictory feedback that frustrates researchers and overburdens committees.

*“There is a need to maintain a consistent approach to ethics review... despite national differences and the diversity of institutions now involved.” (K&I-FG2)*

*“CARFIA now coordinates with the other two committees, but they only met for the first time recently... we're still working on integration.” (UB-FG2)*

### **Capacity building and education**

#### *Ethics training and mentoring*

Efficient coordination among overlapping review structures, such as RECs, data protection bodies, research integrity offices, and safety review boards—reduces redundancy, clarifies responsibilities, and prevents contradictory feedback that frustrates researchers and overburdens committees.

*“Continuous education, incentivizing professional and personal growth at all levels.” (MEFST-FG1)*

*“Education on ethics of emerging technologies should begin early, already at*

*undergraduate level.” (MEFST-FG2)*

*“Researchers should be trained to think ethically... not only PhD students but also experienced researchers.” (K&I-FG2)*

### *Support structures*

Institutions that provide support structures such as dedicated ethics officers, helpdesks, or advisory panels empower researchers to seek advice before problems escalate. These resources also relieve pressure on RECs and reinforce a culture of shared responsibility for ethics.

*“Working groups that support ethics and integrity – capacity building, mentoring, support structures.” (MEFST-FG5)*

*“We have a multi-level structure: ethics expert, faculty expert, and committee president... each offering different levels of support.” (UB-FG2)*

*“The provision of ethics advice on demand is essential...” (K&I-FG2)*

### *Ethics by design*

Integrating ethical thinking into the earliest phases of project design, rather than approaching ethics as a retrospective requirement, promotes deeper reflection and more resilient research. Ethics by design is especially important in complex, interdisciplinary, or emergent areas where ethical risks evolve over time.

*“It seems necessary that researchers are increasingly trained to deal with the ethical issues involved in their research projects... This would also help to strengthen the ethics by design approach by enabling research teams to identify and address ethical issues at the research design stage.” (K&I-FG2)*

*“Ethics oversight must become more proactive... not only reactive to emerging problems but supportive throughout the process.” (MEFST-FG6)*

*“Ethics should be seen as a strategic pillar guiding research... not just a remedial or compliance task.” (UB-FG1)*

## **Institutional and cultural shifts**

### *Positive framing of ethics*

Rather than viewing ethics as a bureaucratic hurdle, framing it as an integral and empowering part of research can shift attitudes and encourage meaningful engagement. Participants emphasized that when ethics is connected to values like integrity, trust, and societal benefit, researchers are more motivated to integrate it into their work.

*“Ethics is part of an ecosystem... a general improvement in any aspect surrounding*

*ethics could also lead to an improvement in ethics.” (MEFST-FG1)*

*“Ethics should be framed not just as compliance but as strategic and pedagogical... a vision for the university.” (UB-FG1)*

### *Recognition of ethics complexity*

Ethics reviews must go beyond checklists and legalistic compliance to engage with complexity, uncertainty, and context. This means fostering a culture where nuance is valued, disagreement is acknowledged, and ethical judgment is developed rather than imposed.

*“Individuals do not want to gain knowledge about ethics issues because incentives are poor... any implementation of solutions is more difficult.” (MEFST-FG1)*

*“Ethical requirements are constantly evolving due to data, context, and shifting societal expectations.” (UB-FG1)*

### *Transparency and accountability*

Transparent decision-making, clear publication of ethics policies, and mechanisms for tracking implementation (such as midterm reviews or reporting audits) were seen as critical for building public and institutional trust.

*“Post-grant award monitoring of projects suggested to ensure ethics is respected” (MEFST-FG3)*

*“Clearer reporting expectations and checklists developed by a multidisciplinary team would improve assessments” (MEFST-FG6)*

*“Transparency in advance in who profits from what, terms of monetization” (MEFST-FG5)*

*“Ethics review should not be a one-time event... ongoing advisory processes needed.” (K&I-FG2)*

## **Reviewing new technologies**

### *Guidelines and governance structures development*

There is a need for clear guidelines and governance structures to support the ethical review of AI and AI-based research, including when informed consent and other ethical safeguards are or are not required.

*“Decision tree for an issue such as AI to guide researchers, designed by interdisciplinary team.” (MEFST-FG2)*

*“There is a need to somehow implement this [ethical integration and regulation of AI tools and practices in research] and... create an awareness of it, formulate guidelines and then adopt guidelines.” (LMU-FG2)*

## Innovative and participatory approaches

### *Democratization of review*

Expanding ethics oversight beyond academia to include civil society, NGOs, SMEs, and independent researchers increases the diversity of ethical perspectives and aligns review processes with the full range of research actors.

*“Opening up research review to non-university bodies (democratisation of research ethics review)” (K&I-FG1)*

*“Ethics should be able to deal appropriately with the diversification of actors and the broadening of ethical expectations” (K&I-FG2)*

*“We work very closely with civil society, so civil society organizations are continuously involved in the research.” (LMU-FG1)*

*“Opening up ethics review processes to other actors – NGOs, non-academic partners – is essential to match the broadening of ethical expectations.” (LMU-FG3)*

### *Co-creation and role reversal workshops*

Workshops where stakeholders reverse roles with researchers or co-design research protocols can foster empathy, accountability, and greater alignment between research aims and ethical priorities.

*“Role reversal workshops (can also go under training) to foster feeling of responsibility.” (MEFST-FG6)*

*“Co-creation with end-users, patients especially.” (MEFST-FG6)*

*“Role clarification is an ongoing process in participatory research... especially in highly sensitive areas...” (LMU-FG3)*

### *Long term monitoring*

Ethical oversight should not end with project approval. Participants advocated for ongoing reviews, midterm evaluations, and adaptive oversight mechanisms to catch emergent issues and support researchers throughout the lifecycle of a project.

*“Post-grant award monitoring of projects suggested to ensure ethics is respected.” (MEFST-FG3)*

*“Ethics review should not be a one-time event... ongoing advisory processes needed.” (LMU-FG3)*

*“Mandatory midterm review when something is questionable or carries potential unforeseen risks.” (MEFST-FG6)*

*“Ethics committees should therefore be ready to provide support to researchers when they request it (ethics helpdesk), monitor projects throughout their*

*development and engage with researchers to anticipate ethical issues.” (K&I-FG1)*

### *Peer-to-peer review and consultation*

Peer-to-peer consultation and informal ethics advice networks can supplement formal reviews, foster learning, and lighten the load on RECs by decentralizing ethical reflection.

*“Providing informal, on-demand ethics advice and promoting dialogue between researchers and ethics experts are essential steps toward a more consultative, responsive ethics system.” (K&I-FG2)*

*“We adapted the peer-to-peer process from the [Association for Ethnological Research] and modified it.” “In our four-year project [...] we therefore conducted three separate applications for ethics review or peer-to-peer ethics reviews, depending on the group we were working with at the time.” (LMU-FG3)*

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## Appendix 2, part 1: Focus group questions – interview guide

1. Please describe your areas of expertise concerning research ethics review and the context in which you have been actively involved in ethics review lately.
2. What would you say works well regarding these practices of ethics review? What are the strengths and benefits of the current ethics review system?
3. How would you describe the main challenges that currently exist for ethics reviews in your field?
  - a. Probe for one or more issues addressed in the scoping review: new technologies, new players, new forms of collaboration and partnerships, new human rights related frameworks
4. What do you see as main barriers to appropriate ethics evaluation of these emerging challenges in ethics review?
5. What do you see as main facilitators to the development of appropriate ethics evaluation of emerging challenges in ethics review?
6. What are possible future directions and solutions to the challenges described?
  - a. Probe for possible tools
  - b. Are there any policy changes that need to take place?
7. Is there anything else you would like to add?
8. Would you like to be further involved in the CHANGER project (e.g. piloting or dissemination activities)?

## Appendix 2, part 2: Focus group – Demographic questionnaire

1. Which category below includes your age?

- ☐ 18-29
- ☐ 30-39
- ☐ 40-49
- ☐ 50-59
- ☐ 60 or older

2. What is your gender?

- ☐ Female
- ☐ Male
- ☐ Other (specify)
- ☐ Prefer not to answer

3. What is your country of residence?

\_\_\_\_\_

4. What is your experience in ethics review? (tick all that apply)

- ☐ I am a member of an institutional ethics committee/research ethics committee
- ☐ I participate in EU ethics reviews
- ☐ I am a researcher
- ☐ Other, please specify: \_\_\_\_\_
- ☐

5. What is your main research domain? (please select one from below):

☐ **5.a. Engineering and technology**

(Civil engineering, Electrical, electronic and information engineering, Mechanical engineering, Chemical engineering, Materials engineering, Medical engineering, Environmental engineering, Environmental biotechnology, Industrial biotechnology, Nano-technology, Other engineering and technologies)

☐ **5.b. Natural sciences**

(Mathematics, Computer and information sciences, Physical sciences, Chemical science, Earth and related environmental sciences, Biological sciences, Other natural sciences,

☐ **5.c. Medicine and health sciences**

(Basic medicine, Clinical medicine, Health science, Medical biotechnology, Other medical science)

\_\_\_ 5.d. **Agricultural and veterinary sciences**

(Agriculture, forestry, and fisheries, Animal and dairy science, Agricultural biotechnology, Other agricultural sciences)

\_\_\_ 5.e. **Social sciences**

(Psychology and cognitive sciences, Economics and business, Education, Sociology, Law, Political science, Social and economic geography, Media and communications, Other social sciences)

\_\_\_ 5.f. **Humanities and the arts**

(History and archaeology, Languages and literature, Philosophy, ethics, and religion, Arts – arts, history of arts, performing arts, music, Other humanities)

6. What is the duration of your expertise in your research field/work as ethics expert or ethics committee member?

\_\_\_ <5 years

\_\_\_ 5-10

\_\_\_ >10



## Appendix 2, part 3: Information Letter and Consent Form

### Are you interested in taking part in a research project?

#### *“CHANGER: Challenges and innovative changes in research ethics reviews”?*

##### **Purpose of the project:**

You are invited to participate in a research project where the **main purpose is described as:** “The overall objective of CHANGER is to promote changes in research ethics reviews that strengthen the capacities of researchers to incorporate ethical judgements in the project design and implementation, and to support ethics committees in addressing new challenges posed by new technologies and new research.”

CHANGER is a research project funded by the European Commission. Its research tasks can be described briefly as: (i) **Evaluating** current approaches to assess ethics in research and identify best practice, (ii) **Developing** new approaches to assess ethical challenges, (iii) **Enhancing** knowledge and expertise about these aspects of research, and (iv) **Identifying** policy implications of an updated ethics agenda for research.

**See also:** <https://changer-project.eu/>

In this context we will conduct a study involving qualitative research in the form of focus groups. All personal data will only be used in an anonymized form within this project.

##### **Which institution is responsible for the research project?**

**Croatia:** University of Split School of Medicine (MEFST) is responsible for the part (Work package) of the project where we seek your collaboration. The overall leadership of the project is by “Demokritos: National Center for Scientific Research, Athens” and coordinated by Vangelis Karakletsis; contact Dr. Vassiliki Mollaki: [v.mollaki@bioethics.gr](mailto:v.mollaki@bioethics.gr).

In **Croatia**, the contact at MEFST is Prof. Ana Marušić, Contact: [ana.marusic@mefst.hr](mailto:ana.marusic@mefst.hr).

There are collaborating institutions in other countries helping with the collection of data from interviews and focus groups.

| Country | Institution                              |                                                                                               |
|---------|------------------------------------------|-----------------------------------------------------------------------------------------------|
| Austria | Technische Universität Wien              | Dr. Marjo Rauhala,<br><a href="mailto:marjo.rauhala@tuwien.at">marjo.rauhala@tuwien.at</a>    |
| Belgium | Katholieke Universiteit Leuven           | Prof. Pascal Borry,<br><a href="mailto:pascal.borry@kuleuven.be">pascal.borry@kuleuven.be</a> |
| Germany | Ludwig-Maximilians University of München | Prof. Hella von Unger,<br><a href="mailto:unger@lmu.de">unger@lmu.de</a>                      |

|                 |                                                                        |                                                                                                                        |
|-----------------|------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------|
|                 | KIT Academy for Responsible Research, Teaching, and Innovation         | Prof. Rafaela Hillerbrand,<br><a href="mailto:rafaela.hillerbrand@kit.edu">rafaela.hillerbrand@kit.edu</a>             |
| Greece          | University of Macedonia                                                | Prof. Iwannis Manis,<br><a href="mailto:imanos@uom.edu.gr">imanos@uom.edu.gr</a>                                       |
| Italy           | Conoscenza Einnovazione societa aresponsabilita limitata semplificata, | Dr. Alfonso Alfonsi,<br><a href="mailto:alfonsi@knowledge-innovation.org">alfonsi@knowledge-innovation.org</a>         |
| Netherlands     | Rijksuniversiteit Groningen                                            | Prof. Jeanne Mifsud Bonnici,<br><a href="mailto:g.p.mifsud.bonnici@step-rug.nl">g.p.mifsud.bonnici@step-rug.nl</a>     |
| North Macedonia | University of Macedonia                                                | Dr. Eda Starova Tahir,<br><a href="mailto:edastarova@yahoo.com">edastarova@yahoo.com</a>                               |
| Norway          | Norwegian Institute for Sustainability Research (NORSUS)               | Prof. Matthias Kaiser,<br><a href="mailto:Matthias.kaiser@uib.no">Matthias.kaiser@uib.no</a>                           |
| Portugal        | Universidade de Coimbra                                                | Prof. Andre Dias Pereira,<br><a href="mailto:andreper@fd.uc.pt">andreper@fd.uc.pt</a>                                  |
| Romania         | Universitatea Din Bucuresti                                            | Prof. Constantin Vica,<br><a href="mailto:constantin.vica@filosofie.unibuc.ro">constantin.vica@filosofie.unibuc.ro</a> |

### Why are you being asked to participate?

We ask you because we have identified your name through our knowledge of ethics review experts or research experts in your country, or through our knowledge of experts on ethics in science, and relevant networks. If you are situated outside of Croatia, a project partner (see above) has identified your name, according to the same criteria.

This letter is written by the coordinator of the interview tasks, but it may be sent you from our foreign partner. Please reply to the sender of this request.

### What does participation involve for you?

Focus groups are a method used in qualitative research study designs. In this study we aim to collect the opinion of different stakeholders on the new challenges in ethics reviews emerging from new technologies and from new research practices, which are not sufficiently covered in the current review process. Based on the consultations with stakeholders, we hope to develop innovative training to ethics review experts, members of ethics review committees and researchers, and propose innovative approaches and tools to ethics review reform and new understandings to practice ethics by design, supported by guidelines and a policy roadmap.

If you would like to participate, you will join one of the approx. 10 focus groups that will be organized during the project. The focus groups will be led by an experienced researcher, and the discussion will be focused on research questions regarding the barriers and facilitatory related to address emerging challenges in ethics review. The focus groups will last approx. 60 minutes each. They will be audiorecorded and transcribed. The data will be treated confidentially. Names of persons and institutional affiliations will be deleted and replaced by codes or pseudonyms (see below).

Before participating in the focus group, we will ask you to complete a brief questionnaire about your background: gender, age, role, years of experience as an ethics expert or researcher, country of residence/work, and research area.

The overall results from the focus group will be presented and reported within a final study report, and you will receive a copy of this report.

### **Benefits and risks of participating in the study**

While participants directly gain valuable insights into research ethics and ethics reviews by sharing experiences and contributing to knowledge-building, the broader benefits extend to the entire research community, ultimately enhancing their own professional growth and opportunities. There are no known risks to participation beyond those encountered in everyday life. There is a slight risk that cases of misconduct may be revealed and we ask you not to provide any identifying information if you want to describe a specific case. Your responses during the focus group interview will remain confidential and anonymous. Data from this research will be kept at a secure server.

There will be no fee for the participation in the study.

### **Participation is voluntary**

Participation is voluntary. If you do not want to participate, you do not have to do anything, and you are not required to let us know. If you decide to participate, you will be asked to sign the informed consent form. By signing the consent form you agree to the following:

1. You have read the information provided about the study. You have had the opportunity to ask questions and your questions have been sufficiently answered. You have had enough time to decide whether you would like to participate.
2. You are aware that participation in the study is voluntary. You also know that you can decide at any moment to not participate or withdraw from the study. You do not have to provide any reasons for not participating or terminating enrolment in the study.
3. You give consent to the collection and use of your data as described in this document.
4. You give consent to having some of your quotes from the focus group discussions publicly available in an anonymous format.
5. You want to participate in this study.

If you have agreed to participate but change your mind, you can withdraw at any point (including during the focus group interview), we would ask you kindly to inform us if this is

the case. You do not have to provide us with reasons for the termination of your participation. When you withdraw from the study, all your non-anonymised data will be destroyed. If your data has already been analysed, the results will be used but the source of the data will not be retrievable.

The answers you provide will not be made available to your employer or to any committee you are a member of.

### **Your personal privacy – how we will store and use your personal data**

Only the researchers that lead the focus group study (Prof. Ana Marušić, [ana.marusic@mefst.hr](mailto:ana.marusic@mefst.hr), and partners conducting the focus groups in their country/field will have access to your personal information during the conduct of the study, for the purposes of correspondence.

The audio or audio-visual recordings of the focus groups will be transcribed and pseudonymised by replacing individual names with codes such as participant 1, 2,3 etc. These codes will also be used when presenting the results of the focus groups.

Storage and use of the data collected during the study will be in alignment with the data protection procedures contained in the European Union Law, specifically Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data (General Data Protection Regulation).

Audio or audiovisual recordings and pseudonymized transcripts will be and stored locally, at the site they were created, according to the national and EU data protection rules and institutional policies (e.g., five (5) years for MEFST partner and ten (10) for KUL partner). Only pseudonymized transcripts will be transferred between researchers in EU countries, according to National and EU law.

If you would like your data deleted from the transcripts, please contact the principal researcher, Prof. Ana Marušić or the University of Split School of Medicine Data Protection Officer.

We will only use your personal data for the purpose(s) specified here and we will process your personal data in accordance with data protection legislation (the GDPR). We will follow the Data Management of the CHANGER project. Only the persons (the project group) associated with the organisation which carries out the interviews will have access to your personal data, no others. Your personal data will be stored electronically on our local research server, without access to outside persons. We will replace your name and contact details with a code. The list of names, contact details and respective codes will be stored separately from the rest of the collected interview data. These will be shared in a pseudonymized form with research partners.

Only participating institutions in the above-mentioned research project will be able to access the project server. The personal identification data will all be pseudonymized. Therefore, you will not be recognizable in any publications, reports or oral presentations from this

project. The only information we may provide in the reports are your gender, your professional role and occupation, disciplinary affiliation and/or area of expertise/nation/institution/organization.

### *Your rights*

So long as you can be identified in the collected data, you have the right to:

- access the personal data that is being processed about you
- request that your personal data is deleted
- request that incorrect personal data about you is corrected/rectified
- receive a copy of your personal data (data portability), and
- send a complaint to the Norwegian Data Protection Authority regarding the processing of your personal data (alternatively the relevant authority in the country of our partners if they conducted the interview).

### *What gives us the right to process your personal data?*

We will process your personal data based on your consent.

### **Where can I find out more?**

If you have questions about the project, or want to exercise your rights, contact:

- WP leader (Prof.) Ana Marušić at MEFST, e mail: [ana.marusc@mefst.hr](mailto:ana.marusc@mefst.hr) or
- MEFST Data Protection Officer: (Ms) Ivana Ružić Urlić, secretary of MEFST, [dpo@mefst.hr](mailto:dpo@mefst.hr).
- For countries outside Croatia you may also contact the responsible researcher or the data protection officer at your participating institution (see the above list of participating institutions in different countries).

Yours sincerely,

Task Leader (Researcher/supervisor)

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## Consent form

(in two copies, one for the participant and one for the researcher)

I have read the information above about the study and have had an opportunity to ask questions about the focus group study methodology and how my information will be used. I understand the purpose of this study and what my participation involves.

- I agree to take part in focus group study.
- I understand that anonymised data about me may be published within the final project report, which may be published online, and that published material may be used and distributed for training and service design and development.
- I know that my participation is voluntary and that I can choose to withdraw from the research at any point.
- Also, I confirm that I do not have any conflict of interest and if I would think otherwise throughout the research, I will inform the lead person of this activity.

NAME and SURNAME of the participant:

DATE:

\_\_\_\_\_

\_\_\_\_\_

SIGNATURE:

\_\_\_\_\_

NAME and SURNAME of the focus group moderator:

DATE:

\_\_\_\_\_

\_\_\_\_\_

SIGNATURE:

\_\_\_\_\_

## Appendix 2, part 4: Focus group – Additional consent for AI-assisted translation

**Additional consent for AI-assisted translation** If you prefer your focus group to be conducted in [language], we kindly request your consent to use AI-assisted translation to convert the transcripts into English for further analysis as part of the CHANGER project. We use DeepL Translator Pro to translate anonymized transcripts. This program processes data in accordance with the General Data Protection Regulation (GDPR). Data is stored by DeepL for 14 days only and is then deleted. All processing occurs exclusively on servers within the European Economic Area (EEA), and the data will not be used for AI training purposes.

For further details, please see DeepL's privacy policy: [DeepL Privacy Policy](#).

The AI-assisted translation will be reviewed and corrected by the [team].

If you have any questions, please contact [local contacts].

Providing consent to use this program is voluntary.

By signing below, I consent to the data processing with DeepL.

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Date

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Name (please type)

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Signature