

# Challenges and innovative changes in research ethics review (CHANGER) – an overview

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## The Partnership



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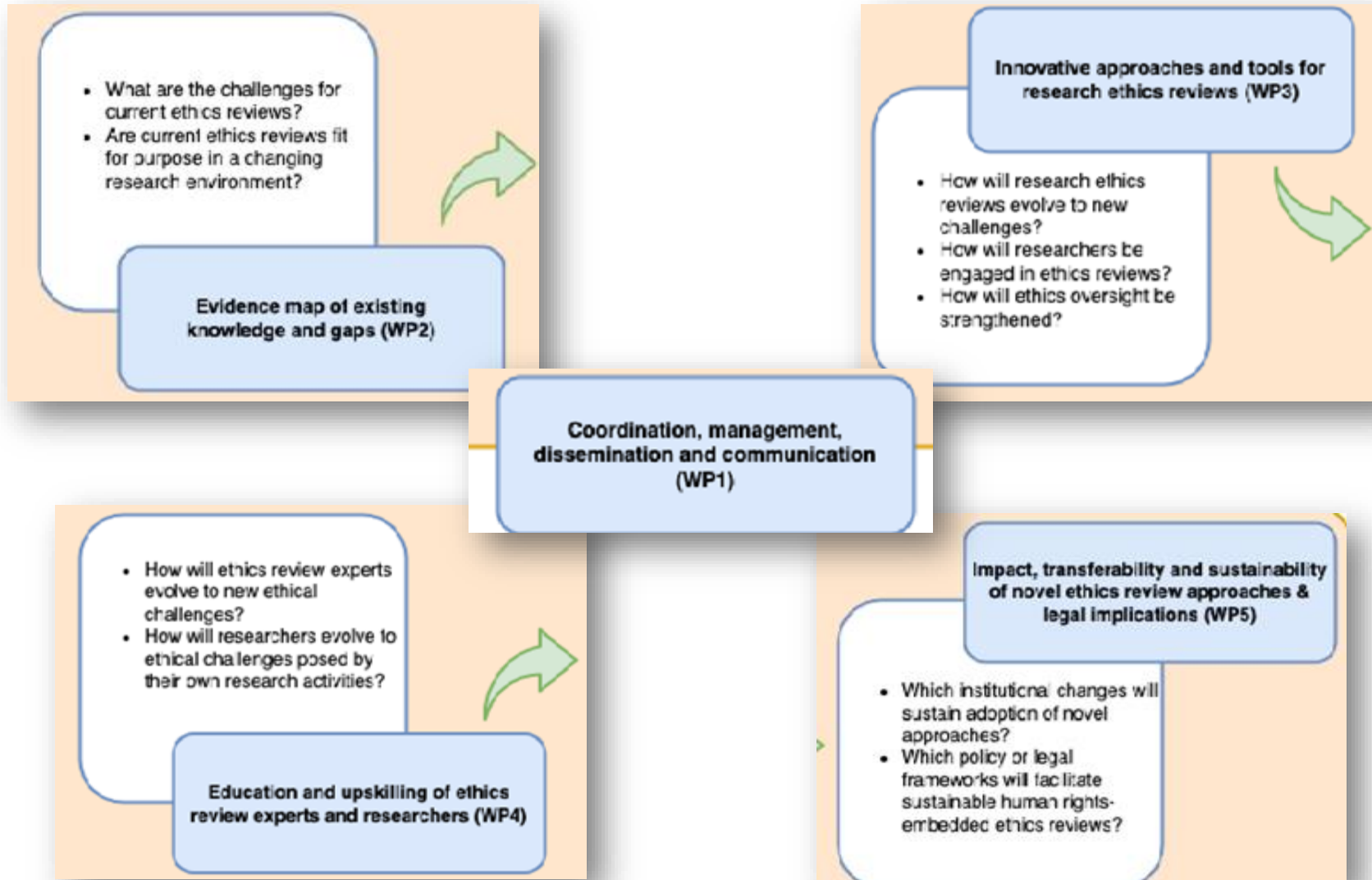
# Concept and overall objective

- **Trust** in science and responsible research is highly dependent on the ethical qualities of research
- This is why research projects are submitted to an **ethical review in Research Ethics Committees (RECs)**
- RECs are multidisciplinary, independent bodies, charged with reviewing research projects to ensure that they adhere to ethical standards and principles
- The continuous emergence of new technologies and new forms of research bring **new ethical concerns**
- This makes the functioning of RECs increasingly complex and emphasizes the **need to evolve** in order to cover this gap

## Overall objective

CHANGER aims to promote **innovative changes in research ethics reviews** that strengthen the capacities of researchers to incorporate ethical judgements in the project design and support ethics committees to address new challenges emerging from new technologies and new research practices

# WP Overview



## Expected outcomes

- **Capacity building** in RECs
- **Upskill** researchers and ethics experts
- Foster an **ethics-by-design** approach in researchers
- Promote **novel approaches** in ethics reviews that ensure ethical oversight
- Promote **policies** that embed human rights in research

## WP2 Evaluation of current ethics reviews in a changing research environment MEFST

### Objectives

1. To provide an **evidence base** for the challenges posed by contemporary research
2. To **assess the capacity** of existing RECs to assess and monitor innovative research projects

### Tasks

- 2.1 Scoping reviews, literature and public web document searches (M1-M6)
- 2.2 Creation of evidence- and gap-maps (M7-M9)
- 2.3 Stakeholder consultations to identify differences and best practices in ethics reviews to address new ethics (M1-M36)
- 2.4 Cross-disciplinary case study of ethics review experts (M4-M18)

Challenges and areas of focus defined

Systematic review under preparation



## WP3 Novel approaches and tools to support the ethics reviews TUW, NORSUS

### Objectives

1. To **develop** and **pilot** innovative approaches in research ethics reviews aiming to embed ethics-by-design (foster support rather than policing of research)
2. To integrate into already existing platforms an interactive, web-based resource of new ethics review approaches
3. To develop **new tools** for RECs and researchers to assess their own capacities to address new challenges and new human rights

### Tasks

- 3.1 Development and piloting of novel ethics review approaches (M1-M30)
- 3.2 Linking novel ethics review approaches into existing infrastructure of networks and portals support in research ethics reviews (M1-M30)
- 3.3 Development of an ethics assessment methodology focused on AI (M25-M36)
- 3.4 Development of a benchmarking tool focused on AI (M25-M36)

### Conceptualization of framework

Novel methodologies under development

Literature review for ethics assessment methodology and benchmarking tool



## WP4 Innovative training material to address new challenges in ethics reviews and training KUL

### Objectives

1. To develop **guidelines** for RECs and professionals involved in research ethics reviews
2. To develop novel, digital **training material**, focused on specific new technologies and practices for ethics review experts, researchers and students
3. To provide **training** to stakeholders involved in the ethics review process of funders (EC), focused on specific new technologies and practices

### Tasks

- 4.1 Development of review guidelines (M13-M24)
- 4.2 Development of digital training and educational material (M13-M24)
- 4.3 Intensive course for Framework Programme ethics appraisal scheme experts (M31-M36)

### Skeleton of MOOCs created

Draft of eIC MOOC

Expert list for interviews/participation have been drafted







## WP5 Generation of impact and transferability of new models, operational tools, and approaches for RECs RUG, K&I

### Objectives

1. To identify the **policy implications** of the proposed innovative approaches and tools
2. to promote policy choices supporting the **uptake and dissemination** of novel ethics review approaches in the ERA at different levels (EU, national, research organisations)

### Tasks

- 5.1 Dialogue Events to identify institutional changes favouring the adoption of the novel methodological approaches and sustainable options (M13-M24)
- 5.2 Research Ethics Playbook addressed to researchers, research organisations and RECs providing guidance to the design and implementation of institutional changes (M25-M36)
- 5.3 Policy Roadmap proposing changes in present policy and legal framework (M25-M36)



## What has been done so far

### Scoping review of challenges to ethics review in the evolving research landscape

by **Ana Marušić**, Professor of Anatomy and Chair of the Department of Research in Biomedicine and Health at the University of Split School of Medicine, Croatia, **Antonija Mijatović**, postdoc, MEFST & **Lana Barać**, PhD, MEFST

- ✓ **Why a scoping review methodology?** (The Campbell Collaboration, 2020 and Joanna Briggs Institute (JBI) Review's Manual (Peters et al., 2015a)
- ✓ to provide an overview of the existing literature on a broader topic, identify knowledge gaps and clarify concepts, rather than a systematic review approach, which is designed to answer specific research questions using rigorous and transparent methods



## Scoping review of challenges to ethics review in the evolving research landscape

by **Ana Marušić**, Professor of Anatomy and Chair of the Department of Research in Biomedicine and Health at the University of Split School of Medicine, Croatia, **Antonija Mijatović**, postdoc, MEFST & **Lana Barać**, PhD, MEFST

- ✓ **Creation of search strategies** (categorization of key search terms into 6 concepts :1. ethics committees; document types (such as guidelines, regulations, and consent forms); ethical considerations; virtues and values; other critical issues (such as social justice and data protection);various advanced technologies (including neurotechnology, artificial intelligence, and gene editing).
- ✓ **Conduct of a comprehensive literature search** across three major academic databases (Scopus, Web of Science and PubMed)
- ✓ **Screening and selection process** (SyRF online platform)
- ✓ **Data analysis, validation and quality control**



### Scoping review of challenges to ethics review in the evolving research landscape

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#### Results

- ✓ Identification of the **most common ethical challenges** : AI, Privacy, Consent and Bias/Fairness, Regulatory gaps and challenges, Safety and security, Transparency, Data sharing and management
- ✓ Identification of the **most frequently discussed technologies** : AI, Biobanking and Genomics, Big Data and Analytics, Privacy-enhanced Technologies, IoT, Robotics, Neurotechnologies
- ✓ Identification of **key challenges faced by ethics committee members** : low confidence in the issue/topic, lack of training and resources, lack of consistency in the review process, terminology misconceptions, dealing with undisclosed information or material misconduct, lack of clarity of the legal frameworks applied, ensuring that protocols are scientifically and ethically sound while not overburdening researchers with excessive bureaucracy

## What are the on going activities

- ✓ **Stakeholder consultations** to identify differences and best practices in RECs
- ✓ Cross-country and cross-disciplinary **focus group study** (-10 focus groups) focusing on the facilitators and barriers to the implementation of new approaches
- ✓ Developing and exploring the suitability of **5 novel ethics review approaches**:
  - Institutional capacity building
  - Inclusion of Ethics Mentors in project management structures
  - Iterated ethics reviews for multiple phases in a research design
  - Two-step consent as obligatory input in the ongoing data to organoid biobanks

# Thank you

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## Project partners



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