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Challenges to ethics review of emerging technologies

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Background: The aim of the study was to provide a broad overview of the challenges faced by research ethics review bodies concerning new technologies, stakeholders, collaborations, and frameworks, in response to evolving research environment. The study was conducted as part of the Horizon Europe project Challenges and innovative changes in research reviews (CHANGER).

Methods: We used scoping review methodology. A literature search was performed using major bibliographic databases – Scopus, Web of Science, and PubMed – as well as grey literature sources. The SyRF (Systematic Review Facility) platform was used for screening, and a Large Language Model (LLM) was employed for data extraction. We implemented a methodology that included three iterations of GPT-4 text analysis: 1) piloting phase with refinement of the LLM prompts and output validation; 2) a topics extraction phase where we identified ethical and legal issues, technologies, new forms of collaborations, and frameworks/guidelines mentioned in the articles; and 3) categorization of extracted data and binary coding to allow comparative analysis across all documents. The collected evidence base was used to create Evidence and Gap Map (EGM) – systematic and visual presentation of the availability of evidence for the identified challenges to ethics review. The map was created in Python (version 3.8.19).

Results: In total, 756 academic articles, 65 deliverables from 46 Horizon 2020 projects and 13 deliverables from 8 Horizon Europe were included in this scoping review. We identified most common ethical challenges across various scientific fields. Key issues include informed consent (mentioned as a primary focus in 119 articles), privacy (196 articles), data sharing (32 articles), security (64 articles), and transparency (47 articles), which are tightly related to technological advancements. The EGM offered a visualization of these challenges, indicating areas where ethical concerns were most prevalent. For example, AI faces risks related to bias and privacy, while biomedical engineering and genomics highlight the need for legal and regulatory frameworks, and for ensuring informed consent. Similarly, robotics and automation show concerns around safety, security, and regulatory gaps. Big data analytics presents challenges in data privacy and security, while digital health involves risks on privacy, transparency, and public trust.

Conclusion: Our findings highlight the need for interdisciplinary and adaptable ethics review mechanisms that can address emerging ethical challenges. The EGM provides a visual guide for ethics review improvements and regulatory development in evolving research environments.