**Bioethica**

Vol 10, No 1 (2024)

Bioethica


# The role of National Ethics Committees in the changing research environment

*Vasiliki Mollaki, Isidoros Karatzas, Charalambos Tsekeris, Vangelis Karkaletsis*

doi: 10.12681/bioeth.37386



**To cite this article:**

Mollaki, V., Karatzas, I., Tsekeris, C., & Karkaletsis, V. (2024). The role of National Ethics Committees in the changing research environment. *Bioethica*, *10*(1), 2–5. https://doi.org/10.12681/bioeth.37386

# The role of National Ethics Committees in the changing research environment

**Vasiliki Mollaki[1,2], Isidoros Karatzas[3], Charalambos Tsekeris[1,4], Vangelis Karkaletsis[1,2]**

[1] National Commission for Bioethics and Technoethics, Greece.
[2] Institute of Informatics and Telecommunications, National Centre for Scientific Research "Demokritos", Greece.
[3] Sector for Ethics and Research Integrity, European Commission, Brussels.
[4] National Centre for Social Research (EKKE), Greece.

✉ v.mollaki@bioethics.gr

**Keywords**: National Ethics Committee, Research Ethics Committee, research, ethics, new and emerging technologies.

# Ο ρόλος των Εθνικών Επιτροπών Βιοηθικής/Ηθικής στο περιβάλλον της έρευνας που μεταβάλλεται

**Βασιλική Μολλάκη[1,2], Ισίδωρος Καρατζάς[3], Χαράλαμπος Τσέκερης[1,4], Βαγγέλης Καρκαλέτσης[1,2]**

[1] Εθνική Επιτροπή Βιοηθικής και Τεχνοηθικής, Ελλάδα.
[2] Ινστιτούτο Πληροφορικής & Τηλεπικοινωνιών, Εθνικό Κέντρο Έρευνας Φυσικών Επιστημών «Δημόκριτος», Ελλάδα.
[3] Τομέας Ηθικής και Ακεραιότητας της Έρευνας, Ευρωπαϊκή Επιτροπή, Βρυξέλλες.
[4] Εθνικό Κέντρο κοινωνικών Ερευνών (ΕΚΚΕ), Ελλάδα.

**Λέξεις κλειδιά:** Εθνική Επιτροπή Βιοηθικής, Επιτροπή Ηθικής και Δεοντολογίας της Έρευνας, έρευνα, ηθική και δεοντολογία, νέες και αναδυόμενες τεχνολογίες.

In the rapidly evolving landscape of technology, new and emerging technologies are expected to disrupt research and have an impact not only on science but also on society. Big data and data analytics, gene editing, human organoids, Artificial Intelligence (AI) and quantum computing are some examples of innovations holding the potential to revolutionize research and address pressing global challenges. Nevertheless, as these technologies continue to evolve and -in many cases- intersect, as research becomes increasingly transformative and transdisciplinary, the unprecedented opportunities come with ethical challenges for human rights, privacy, autonomy, bias, justice, fairness, accountability, liability and impact on the environment.

The acceptability of rapidly advancing innovative technologies is dependent on the ethical qualities of research in these fields. Research Ethics Committees (RECs) (also known as Institutional Review Boards (IRBs)), are the link between researchers, research participants and society through the process of ethics review of research projects. RECs play a critical role in safeguarding the rights, well-being and dignity of research participants, but also animal welfare and nature's integrity. Despite the significant function of RECs in ensuring respect of values during research, existing models of ethics reviews come into question in light of the changing research practices and the disruptive technologies.

Most of these novel technologies cannot be ethically reviewed in the pre-funding phase, simply because during the life-cycle of such research projects several factors are not constant which can have an impact on the potential risks and the ethical issues raised by the research. Therefore, we need to reflect on whether the so called "*ex-ante* model" of ethics review is fit for purpose to assess research on new and emerging technologies or whether the changing research environment necessitates adaptations in the methodologies for ethics review. At the same time, "ethics-by-design" in research and capacity building of researchers themselves are promising approaches to complement the role of RECs in ensuring that ethical judgements and values are incorporated in the project design, fostering responsibility and accountability.

In this perspective, to mention a recent example, the EU-funded project CHANGER (https://changer-project.eu/) aims to support the idea of introducing ethical reflections upstream (i.e. before applying for approval to RECs) and of incorporating values and principles in the design of research protocols, fostering responsibility of researchers. "Learning by doing" and "ethics in dialogue" are the guiding principles for developing novel approaches in the ethics review process that can work even in a rapidly moving research reality, facing new challenges. EU and non-EU RECs will pilot test novel methodologies for the ethics review in various disciplines.

What is the role of National Ethics Committees/Councils (NECs) in addressing challenges in the changing research environment? A necessary step to adapt the ethics review process is, of course, to inform policy choices on the novel methodological approaches needed to be made for ethics oversight. In the new Ethics era, it is important that ethics is embedded early in the research processes but also early in the phases of policy design and not only as a "correctional" mechanism. Therefore, it is crucial to consider the ethical implications of new technologies in research and propose the relevant adaptations for a progressive process of change of present policy and legal framework, to better protect new and upcoming human rights in the changing research environment. Such changes in the ethics review process should be promoted at a worldwide level by NECs, to ensure equity in research both in lower-income and high-income settings based on the values of fairness, respect, care and honesty, as emphasized by the TRUST Code.[1]

[1] Global Code of Conduct for research in resource-poor settings. http://www.globalcodeofconduct.org.

NECs can and should play a significant role in proactively embracing adaptations in the ethics review process of research, in increasing the impact on policy and ensuring the sustainability of such changes as the new and emerging technologies advance.