

## Βιοηθικά

Τόμ. 5, Αρ. 1 (2019)

Bioethica



Η διττή σημασία των Επιτροπών Ηθικής και Δεοντολογίας της Έρευνας (ΕΗΔΕ): εξασφάλιση της ηθικής έρευνας αλλά και έμμεση εκπαίδευση των ερευνητών σε θέματα ηθικής και δεοντολογίας

Βασιλική Μολλάκη (Vasiliki Mollaki)

doi: [10.12681/bioeth.20831](https://doi.org/10.12681/bioeth.20831)

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### Βιβλιογραφική αναφορά:

Μολλάκη (Vasiliki Mollaki) Β. (2019). Η διττή σημασία των Επιτροπών Ηθικής και Δεοντολογίας της Έρευνας (ΕΗΔΕ): εξασφάλιση της ηθικής έρευνας αλλά και έμμεση εκπαίδευση των ερευνητών σε θέματα ηθικής και δεοντολογίας. *Βιοηθικά*, 5(1), 2–4. <https://doi.org/10.12681/bioeth.20831>

## The two-fold significance of Research Ethics Committees (RECs): ensuring ethical research but also providing indirect ethics training of researchers

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**Keywords:** Research Ethics Committees, RECs, bioethics, ethics review, ethics evaluation, ethics training.

## Η διττή σημασία των Επιτροπών Ηθικής και Δεοντολογίας της Έρευνας (ΕΗΔΕ): εξασφάλιση της ηθικής έρευνας αλλά και έμμεση εκπαίδευση των ερευνητών σε θέματα ηθικής και δεοντολογίας

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**Λέξεις κλειδιά:** Επιτροπές Ηθικής και Δεοντολογίας, ΕΗΔΕ, βιοηθική, αξιολόγηση, εκπαίδευση στην ηθική και δεοντολογία.

Recently, the law 4521/2018 required that Research Ethics Committees (RECs) must be established in all Higher Education and Research Institutes in Greece.<sup>1</sup> The purpose of RECs is to ensure that research including -but not limited to- research with human subjects, human biologic material, personal data or research posing risk to the environment, is in accordance with the principles of ethics, and meet the standards for research integrity and best practices. It is within the RECs' competence to examine whether a specific research project does not infringe the legislation in force and that it follows the generally accepted ethics principles. As a result, RECs review and assess each research project and may decide upon recommendations or require changes in the research content or methods, in order for the project to meet the higher ethical standards.

Nevertheless, at this point where most RECs have been recently or are currently being established in Higher Education and Research Institutes, there is also another, equally significant meaning of their establishment: RECs, through their procedures of applying for approval, assessment of research protocols, as well as through their decisions and recommendations, provide a chance to raise ethics awareness and training among researchers in Greece. Not to mention the continuous training and gain of experience in research ethics and governance of the Committee members themselves.

The importance of RECs in ethics awareness and training of researchers becomes even more critical, if one takes into account the fact that Ethics courses are sparse in undergraduate studies in Greece. Medical Ethics courses are still elective in some Medical Schools -even in top Universities-, whilst Ethics or Bioethics courses are elective or completely absent from the curriculum of some Departments of Biology. This emphasizes the lack of adequate ethics training and illustrates that raising awareness and training -in any form, even through the function of RECs- is imperative.

At this point, one should have a look at relevant aspects of how RECs or Institutional Review Boards (as they are mostly called in the United States of America) function in other countries. In many cases, RECs or IRBs have

established mandatory ethics training courses for their personnel staff who are engaged in research - at least with humans and/or human biologic material. This means that anyone involved in research design, conduct, data analysis or reporting is required to complete the relevant ethics training. Top-rated US and European Universities<sup>2-5</sup> have already put in place institutional policies requiring the completion of ethics training courses for personnel staff, including undergraduate students, research staff and Principal Investigators (PIs). In some cases, it is even a prerequisite to complete the ethics training for protocol approval by the REC or the IRB.

Of course, RECs requiring the completion of training courses before the submission of protocols for approval is far too optimistic and impractical at this point in Greece, where RECs have only been recently established by law. However, there are three realistic goals that need to be pursued and could be achieved at this point: a) Direct training of REC members, through continuing education sessions and workshops in ethics, and b) indirect training of research staff by completing the self-assessment forms during application for approval procedures and through the necessity to respond and adhere to the RECs' final recommendations and requirements, and c) direct training of researchers via seminars or workshops which will be organized by the RECs.

National Bodies with relevant expertise and know-how must have an active role in providing initial and continuous training of all stakeholders: both REC members and researchers. The Hellenic National Bioethics Commission<sup>6</sup> and the General Secretariat of Research and Technology<sup>7</sup> could have a major contribution to this effort, by providing expert training and body of knowledge for people involved in the process of ethics review of research, as well as practical workshops for researchers.

To conclude, through the establishment of RECs, researchers are now "obliged to stick to the rules of ethical conduct of research". However, we should not only rely on the obligatory nature of the ethics review process through RECs, but additional training must be provided to researchers and research staff. RECs will not only provide safeguards for better science and research

in Greece. RECs will also provide guidance for researchers with regards to the ethical conduct of research and will facilitate cultivating a research culture.

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