H E L L E N I C

N A T I O N A L B I O E T H I C S C O M M I S S I O N

R E C O M M E N D A T I O N

ENFORCEMENT OF THE LAW

FOR RESEARCH ETHICS COMMITTEES (RECs)

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I. Introduction

The Hellenic National Bioethics Commission dealt with the competence issue of the new Institution of Research Ethics Committees (RECs), which have been established or are about to be established in Universities, Research and Technological Institutes in our country, according to the law 4521/2018.

The present Recommendation deals, in particular, with the competence of RECs when it overlaps with that of another administrative Institution, according to relevant specific regulations. The coexistence of different Institutions over the same subject has sometimes led to ambiguity and uncertainty about the function of RECs. Therefore, it is necessary to define the limits of the relevant competences.

It is stressed that law 4521/2018 explicitly foresees that *"If, according to law, a project must be approved or licensed by another competent public service, administrative body or independent administrative authority, the REC's relevant decision does not substitute the aforementioned approval or licensing"* (Article 23, Paragraph 3).

The issue of RECs examining research projects that include laboratory animals and the possible, overlapping competency with other Bodies/Authorities was examined by the Hellenic National Bioethics Commission in collaboration with the National Committee for the Protection of Animals Used for Scientific Purposes. The relevant suggestions in the present Recommendation have been decided upon and approved by both National Bodies.

II. Specific Cases

The problem of overlapping competency of different administrative services, Bodies and Authorities is mostly found in the fields of: a) clinical trials, b) research in human reproductive material, and c) research in laboratory animals. In these fields, specific laws foresee approval or licensing of research proposals by the relevant administrative Institutions. The preventive inspection/control that is conducted by the later, concerns solely or includes the ethics evaluation of research proposals.

More specifically:

A) Clinical Trials

According to law, clinical trial proposals are assessed and approved -at a first level- by the hospitals' Research Ethics Committees (Law 2071/1992, Article 61) where the research is going to be conducted, or (if these committees do not operate) by the hospitals' Scientific Board (Law 2889/2001, Article 5). The Ethics Committee of the National Organization for Medicines subsequently provides the final approval. This assessment solely concerns compliance of the proposed clinical trials with the legislation and the internationally recognized ethical regulations (especially according to the principles of the WMA Declaration of Helsinki.)

B) Medically Assisted Reproduction

According to law 3305/2005, the Greek National Authority of Medically Assisted Reproduction assesses the scientific, legal and moral compliance of research proposals in human reproductive material (gametes and embryos).

C) Experiments in laboratory animals

Lastly, the Presidential Decree 56/2013, which incorporates the European Directive 2010/63, foresees compulsory licensing of research proposals concerning animals, by the competent Regional Authorities. These authorities come to a decision after the approval of the institutional Protocol Evaluation Committees (PEC).

In all the above cases, approval by the aforementioned relevant administrative institutions is obligatory in order for the research programme to be carried out.

III. Suggestions

1. The Commission deems that Law 4521/2018 describes the competency range of the RECs clearly, following the international standards.

In particular, in article 21 it is prescribed that:

"*RECs review whether a research project is carried out with respect to the value of human subjects, the autonomy of research participants, their private life and their personal data, as well as the natural and cultural environment*".

Besides, according to article 23 paragraph 2 a:

"It is compulsory for funded research projects which, according to the statement provided by the principal investigator, include research in human subjects, in human biologic material, such as genetic material, cells, tissues, and personal data, in animals or the environment - both natural and cultural, to be submitted for approval to the REC and the project cannot commence at the University or Research Institute unless the relevant approval is obtained".

Thus, there is no doubt that clinical trials, research in human reproductive material, as well as research in laboratory animals are under the competence of RECs. This means that there is a possibility of reaching contradictory decisions between RECs and the other relevant competent administrative Bodies/Authorities for the three fields that were mentioned above. Such a possibility is damaging to research, since it causes insecurity to the researcher and bureaucratic delays.

2. To avoid this kind of possibility, the Commission deems that:

a. Before a research proposal is submitted to RECs, it is better that *it has already been approved* by other relevant competent Bodies/Authorities. In this way, delays can be avoided and the researcher can be facilitated, considering the tight period within which RECs must reach a decision (within 15 days).
b. However, if the researcher chooses to submit the proposal to the REC first, the REC has to evaluate the proposal *without demanding the previous approval* from any other relevant Bodies/Authorities. In its decision, the REC should *remind the researcher of the necessity of this last approval,* in order for the research project to be conducted.
c. Provided that it is justified, the first decision (either from the REC or the other relevant administrative Bodies/Authorities) is non-binding but *must be seriously taken into consideration when the project is assessed by the second.* Only obvious,

unjustifiable decisions would vindicate a deviating position from the second Authority.

d. If the application to the REC comes after the application to other competent Bodies/Authorities, RECs can definitely make additional comments on the research proposal, in order to address the ethics issues. In any case, RECs are responsible for the evaluation of the ethical aspects of proposals that *are not covered specifically by the competency of other administrative institutions.* This happens, for example, in research proposals with laboratory animals, where RECs may assess additional ethics issues concerning the environment and public health.

e. Especially in the case of "overlapping" competency between RECs and institutional PECs regarding research in laboratory animals, *the close cooperation of the two Committees, as Bodies of the same University/Research Institution, is necessary.* This cooperation could take a more permanent form, either by integrating the PEC into the REC or even by the participation of PEC members in RECs.

f. A special case of "overlapping" competency takes place when, at the same Institute, Research Ethics Committees were previously established before law 4521/201, with a particular competency in a specified field (e.g. Committees that operate in medical schools). Even after the establishment of the REC according to law 4521/2018, the operation of the existent committees can continue at the same institute. By law, however, the relevant research proposals *must be submitted to the institute's REC, as well.* The need for cooperation -or even the institutional absorption of the two bodies- is also necessary in this case.

The Commission points out that, as a matter of principle, the need for a smooth adjustment of the new institution of RECs into the framework of the research community in our country. Views that could "disempower" their competency and weaken the role that they are expected to play are considered unacceptable. Finally, it is stressed that the limits for cooperation with already established Bodies/Authorities, which are already active in research ethics, are vast, and these limits should be utilized with an initiative by the research community itself

Athens, 11th December 2018