A GUIDE
for Research Ethics Committees for Biological Research (RECs)

In its effort to promote the creation of Research Ethics Committees for Biological Research Organisations in Greece – according to the model followed internationally for a number of years now – the National Bioethics Commission produced the following Guide which is expected to assist our research organizations (universities and research centres) to act accordingly. Obviously, the guide is intended only as a general framework of guidelines for the creation and operation of RECs. Each research organisation should complete it with more specialized rules depending on its mission and priorities.

I. Object of Research Ethics Committees

1. Which types of research must be subject to an ethical evaluation?

An ethics evaluation by a REC is currently recommended for the following types of research:

- clinical trials of medicines or other interventional forms of treatment,
- epidemiological studies,
- research on human behaviour and the behaviour of other primates,
- research of vulnerable population groups such as children, prisoners or mentally ill patients,
- research of groups with particular racial or cultural characteristics,
- research on the human embryo (*in vitro* or *in vivo*),
- research on human genetic or other biological materials,
- research on vertebrate animals,
- research in rare biological species (plants or animals),
- research on potentially dangerous organisms for humanity and the environment, including genetically modified organisms.

2. Why is an ethics evaluation by a REC necessary?

The above types of research put at risk fundamental values and social interests enjoying strict protection by international law, internationally recognized ethical rules, the legislation of the European Union and national legislation.
These are, in particular, the respect for human dignity, the protection of physical integrity, the respect for privacy, the right to health, the protection of personal data, the protection of the environment and of biodiversity, etc.
RECs must examine whether a research project – in addition to its scientific adequacy which is evaluated by other responsible bodies – includes sufficient safeguards to ensure that the above values and interests are respected.

3. What is the practical importance of an ethics evaluation?

At least for research funded by the European Union, a research proposal must pass the test of both, scientific and ethical evaluation.
Ethical evaluation, however, has become the standard practice for any respectable contemporary research organization – irrespective of the source of funding – because it is an essential safeguard of reliability and a prerequisite for its acceptance by the public.

4. What are the main legal instruments governing this evaluation?

A REC examines the specific compliance measures described in research proposals based mainly on the following instruments (laws and ethics codes):

I. Clinical trials of medicines or other aggressive forms of treatment

- Directive 2001/20/EC on the implementation of good clinical practice in the conduct of clinical trials on medicinal products for human use (particularly arts 3, 4, 5, 6),
- European Convention on Human Rights and Biomedicine (Oviedo Convention, Act 2619/1998) (particularly arts 15, 16, 17),

- Additional protocol to the Oviedo Convention concerning Biomedical Research,
- Helsinki Declaration of the World Medical Association regarding Ethical Principles for Medical Research Involving Human Subjects ,
- Act 2472/1997 on the Protection of Individuals with regard to the Processing of Personal Data (particularly arts 4 – 14).

II. Population (epidemiological) studies

- European Convention on Human Rights and Biomedicine (Oviedo Convention) (particularly arts 5, 10, 11, 12),
- Act 2472/1997 on the Protection of Individuals with regard to the Processing of Personal Data (only in case of sample processing that can reveal the identity of the person, particularly arts 4 – 14),
- UNESCO's Universal Declaration on the Human Genome and Human Rights (particularly arts 5 – 12),
- UNESCO's International Declaration on Human Genetic Data (particularly arts 4 – 22 if involving sample processing that can reveal the identity of the person).

III. Behavioural studies in humans

- European Convention on Human Rights and Biomedicine (Oviedo Convention) (particularly arts 15, 16, 17),
- Act 2472/1997 on the Protection of Individuals with regard to the Processing of Personal Data (particularly arts 4 – 14).

IV. Research in sensitive population groups such as children, prisoners or mental patients

- Directive 2001/20/EC on the implementation of good clinical practice in the conduct of clinical trials on medicinal products for human use (particularly arts 3, 4, 5, 6),
- European Convention on Human Rights and Biomedicine (Oviedo Convention) (particularly arts 15, 16, 17),
- Additional protocol to the Oviedo Convention concerning Biomedical Research,

- Helsinki Declaration of the World Medical Association regarding Ethical Principles for Medical Research Involving Human Subjects ,
- Act 2472/1997 on the Protection of Individuals with regard to the Processing of Personal Data (particularly arts 4 – 14).

V. Research in groups with particular racial or cultural characteristics

- European Convention on Human Rights and Biomedicine (Oviedo Convention) (particularly arts 5, 6, 11, 12).

VI. Research in the human embryo

- European Convention on Human Rights and Biomedicine (Oviedo Convention) (particularly art. 18),
- Act 2472/1997 on the Protection of Individuals with regard to the Processing of Personal Data (particularly art. 7 on sensitive data of gamete donors),
- Act 3089/2002 on assisted reproduction (particularly art. 1459 of the Civil Code),
- Act 3305/2005 on assisted reproduction (particularly arts 11, 12).

VII. Research on human genetic or other biological materials and research involving access to sensitive personal data

- European Convention on Human Rights and Biomedicine (Oviedo Convention) (particularly arts 5, 6, 10, 21, 22),
- Act 2472/1997 on the Protection of Individuals with regard to the Processing of Personal Data (particularly arts 4 – 14 if involving sample processing that can reveal the identity of the person),

- Presidential decree 26/2008, transferring Directive 2004/23/EC on setting standards of quality and safety for the donation, procurement, testing, processing, preservation, storage and distribution of human tissues and cells (particularly arts 12 – 14).

VIII. Research in vertebrates

- Presidential decree 160/1991 transferring Directive 86/609/EC on the protection of animals used for experimental and other scientific purposes, (particularly arts 3 - 11),
- Act 2015/1992 on the protection of vertebrates used for experimental and other scientific purposes (particularly arts 5 – 12).

IX. Behavioural studies in primates other than humans

- Presidential decree 160/1991 transferring Directive 86/609/EC on the protection of animals used for experimental and other scientific purposes (particularly arts 5, 6, 7, 10),
- Act 2015/1992 on the protection of vertebrates used for experimental and other scientific purposes (particularly arts 5, 6, 7, 9, 10).

X. Research in rare species (plants or animals)

- Presidential decree 160/1991 transferring Directive 86/609/EC on the protection of animals used for experimental and other scientific purposes (particularly art. 4).

XI. Research in genetically modified organisms and micro-organisms

- UN Convention on Biological Diversity (Rio Convention – preamble),
- Directive 2001/18/EC on the deliberate release into the environment of genetically modified organisms (particularly art. 4),
- Directive 98/81/EC on the contained use of genetically modified micro-organisms (particularly art. 5).

II. Creation and operation of ECBRs

The composition of a REC must ensure on the one hand a thorough examination of the ethical issues raised by a research proposal and, on the other hand, the independence of relevant deliberations from conflicts of interests.

1. Number of members

A relatively small number of members is recommended (e.g. from seven to nine persons)

The optimal number of members is to be defined by each organization taking into account the workload of the Committee, especially the number of anticipated research proposals to be evaluated annually and the fact that members will be basically volunteers with another full-time employment.
If a big number of research proposals is anticipated, the composition may be enlarged so that evaluations can be performed by subcommittees.

2. Composition

Committees should include medical and biology experts, specialists from the social sciences (e.g. legal experts, philosophers, theologians, sociologists) and lay persons.

The composition of the Committee must ensure impartial evaluation, the capacity to comprehend the questions under consideration and adequate justification of the scope of the proposals so that it is comprehensible by the general public.
At least one third of the members should not be involved with biological research.
Members should not be in any relation of dependence with the persons submitting the research proposal or have any other vested interests that may interfere with their judgment.
It is useful to provide for deputy members to ensure a full composition in the case that members are prevented from attending due to any of the above-mentioned conflicts of interest.

3. Appointment of president and members

The president and the members of the REC are appointed by the Rector of the University or the General Director of the Research Centre.

Each organization will decide depending on its specificities if members will be appointed directly by the head (rector or general director) of the organization or by decision of the central administrative body (university senate or board of directors).

4. Term of office

The suggested term of office is from one (1) to three (3) years.

The term of office is to be determined on the basis of the expected workload and in a way that allows as many members of the academic community as possible to gain experience on the ethical evaluation of research proposals.

It is important that the term of office allows the acquisition of necessary experience on evaluation but also deters the development of dependence relations between REC members and the researchers who submit proposals.

5. Meetings and quorum

A REC meets frequently and at regular intervals depending on the number of submitted proposals. A quorum exists when at any one meeting the present members (indispensably including the president) outnumber the absent members and at least one present member does not come from the biological sciences.

RECs must hold frequent meetings to avoid unnecessary delay in the onset of implementation of research proposals. For the efficient operation of the evaluation system, meetings should be held at regular intervals and on prefixed dates and the deadlines for the submission of proposals to be evaluated at each meeting should be determined well in advance. The usual practice internationally is for RECs to publish the schedule of their meetings for a whole academic or calendar year.
The authority of RECs decisions is enhanced by the participation of members outside the biological sciences and laypersons outside the scientific community. It is desirable that decisions are made with interdisciplinary participation.

6. Members financial compensation

The question of financial compensation is to be decided by individual research organizations.

The members of the scientific community should consider their participation in the research organization's REC as a duty. Especially scientists who submit proposals for evaluation by the REC should consider it as a return of services they have enjoyed and will enjoy in the future.
At all events, it is at the discretion of the research organization to decide whether the members of the REC (especially those not working for the organization) are to be compensated.

7. Decisions

The REC decides if in quorum and provided that all supporting documents have been submitted by the principle investigator. The REC may, if necessary, call in independent experts or the National Bioethics Commission for assistance. Decisions are made without the presence of independent guest experts and, if possible, unanimously. Members with conflict of interest must abstain from the decision-making process and be substituted with deputy members.

During the evaluation procedure researchers submitting research proposals are warned of eventual ethical problems so that they may modify the research protocol appropriately.
At all events, the aim of evaluation should be to improve on the ethics of research proposals and not to raise bureaucratic obstacles. A total rejection of proposals is justified only exceptionally if the ethical problems are insurmountable (e.g. proposals for research in the reproductive cloning of human beings which is against the law).

To achieve transparency, the REC members who participate in the evaluation should expressly declare (in writing) at each meeting that they do not stand to gain any benefit whatsoever and are in no way involved in the proposals under consideration.

8. Obligations of RECs

a) Justification of decisions

The REC must justify its decisions and the justification must be communicated in writing to the researchers concerned.

Decisions and evaluation procedures must be transparent and justified to ensure good cooperation between the ethics committee and researchers.

b) Records – monitoring of proposals

RECs must keep records of research applications and corresponding decisions and monitor the course of approved proposals.

To monitor the progress of proposals, RECs may ask the research team to submit progress reports and may evaluate the project anew if they think there is cause to do so.

For the sake of transparency and the provision of information to the scientific community, RECs should produce annual reports including the categorization of the main ethical problems they encountered with and the solutions they offered. These reports will be submitted to the head of the research organization, communicated to the National Bioethics Commission, which may suggest ways of improvement on the operation of the institution, and publicized (e.g. on the website of the organization). The National Bioethics Commission may have access to the records if the REC so decides.

c) The educational role of RECs

RECs organize seminars and debates on ethical issues on their own initiative in order to provide information to and stimulate awareness amongst the staff of the research organizations in which they operate.

Compliance with ethical principles in biological research depends above all on proper information and training of researchers.

For this reason, RECs play a crucial educational role by providing constant information to the scientific personnel of research organizations on the ethics of research and the practical aspects of submission of research proposals for evaluation.

9. Funding of RECs

The expenses of RECs are expected to be covered by the research account or another similar fund of the research organization.

RECs have operating expenses as they require support by full-time or part-time staff (depending on the conditions of each research organization) to collect applications, organize meetings, keep records, coordinate and promote training actions and to meet their other obligations. Therefore, when a REC is created, the necessary funds for its unhindered operation must be ensured. Since the operation of RECs supports research, the necessary funds should at best originate from the research account.

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(International documents and Greek Legislation on bioethics, grouped in thematic sections, can be consulted on the website of the Commission at **http://www.bioethics.gr/category.php?category_id=63**)