



**Position of the
European Network of Research Ethics Committees (EUREC)
on Ethics Reviews of Research Projects involving Persons
outside Biomedical Research**

**to the attention of the
the European Commission, the Council of Europe and the European Research Institutions**

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Preamble

With this position paper, EUREC would like to acknowledge the increasing importance of ethics reviews of research projects outside the field of biomedical research, and to encourage policy makers and research institutions to pay more attention to this issue. EUREC, as the representative body of research ethics committees in Europe, is ready to welcome more members from non-medical research ethics committees and to support them in carrying out their tasks.

Background

Human participants are involved in scientific projects carried out by researchers outside the biomedical field independent of the type of funding. This includes not only the involvement of human individuals in research studies, but also their identifiable personal data or their stored materials in collections including biobanks. The researchers conducting those studies in the legal framework of their countries are in some cases not bound by specific provisions as are in force for medical research. Often an ethics review for such studies is not required either by national laws or by professional laws or guidelines. However, funding organisations and peer-reviewed journals are requesting ethics review for any studies with human research participants. In some jurisdictions it is difficult for these researchers to find an ethics committee that will review their projects. In contrast, there is a well-established structure for ethics reviews of biomedical research projects. In some European countries medical RECs have taken on the additional task of reviewing projects outside the field of biomedicine. EUREC is the European representation of national networks of medical research ethics committees in the European states. Therefore, the experience gained by these medical research ethics committees during the last decades can support the establishment of ethical review procedures outside the field of biomedical research.

Following the first establishments of “review committees” on request of authorities (1968 IRBs on request of the NIH in the US) or funding organisations (e.g. 1973 in Germany on request of the “Deutsche Forschungsgemeinschaft” at Universities), medical research ethics committees have been very much promoted since the Tokyo revised version (1975) of the Declaration of Helsinki of the World Medical Association.

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The competence of these committees to review a project covers three fields: scientific quality, conformity with law, and ethical acceptance.

The leading principles for an ethical research with humans, identified in the “Belmont Report” are: respect for persons - namely autonomy, beneficence, and justice. These were adopted in the four-principles approach by Beauchamp and Childress (Beauchamp T L, Childress J F., *Principles of Biomedical Ethic*, Oxford University Press, Eighth Edition 2019), where they were supplemented by the principle of non-maleficence – namely do-not-harm. These principles have a long provenance, with elements having been accepted for centuries (like beneficence and non-maleficence) and brought into force (e.g. in Germany in 1900, like autonomy). They have been adopted as a bedrock of ethics in medicine in several legally non-binding instruments like the Declaration of Helsinki (1964 – 2013) or Council for International Organizations of Medical Sciences (last version 2016) and by legal instruments like the Oviedo Convention of the Council of Europe (1997) or Regulations of the EU for drug trials or for trials with medical devices.

EUREC believes that these basic principles in the respect for the human dignity should also be adopted for the review of research projects outside the medical field. Knowledge gained with existing medical RECs may be helpful to consider the problem more practically.

- Principles in Research Ethics:

The four ethics principles of Beauchamp and Childress are general, such that almost anyone can agree with them. They sit between the systematic justifications of ethical theories, but above simple moral common sense. Therefore, these principles were argued to be mid-level principles mediating between deep-reflecting moral theory and practical common morality. The fact that they are cited and reflected in many research ethics contexts is evidence that they are readily applicable. The central aspect of their applicability is that the four principles bring different perspectives to bear on the evaluation of the study. They have to be balanced, and they are not subject to a predetermined hierarchy. This means, for example, that the principle of autonomy or the principle of justice cannot be the exclusive guiding principle in an application. The adoption of these biomedical ethics principles in many non-biomedical research settings should be extended and their interpretation needs to be more intensively placed in the European context, where ethical principles such as dignity or solidarity are particularly salient (e.g. European Group on Ethics in Science and New Technologies: Artificial Intelligence, Robotics and ‘Autonomous’ Systems, Luxembourg 2018).

- Establishment of RECs:

RECs may be established in different ways and by different institutions, like Parliaments, Ministries, Universities, Authorities, Research Institutions, and others. Important points for the work of RECs that should be laid down in their establishing procedure are their independence, the scope of their legal competence, and the mandate of RECs. This should be clearly established, for example by statute or bylaws. The duty of researchers to submit research projects for a review should be clearly fixed by appropriate provisions within the jurisdiction. A system of appeal should be established for review of a REC's decision. The character of the decision of a REC should be stated: advice, favourable opinion or approval. Different aspects of a research project could be reviewed by different bodies, and it could be that the REC decision on the ethics aspect of a review is one in a number of reviews, and the composition of the final approval and the body that makes the decision of competence needs to be clear.

- Procedure of RECs:

The constitution of RECs requires some rules, including the following. A clear system for the appointment of REC members should be fixed, including an indication of bodies entitled to appoint the members and the duration of REC membership. The accepted principle of multidisciplinary of the composition of RECs should also be followed. The REC should invite external experts or ask for external expertise in case no member has scientific experience with the field of the submitted proposal or if a member with sufficient experience is excluded due to a conflict of interests. Clear conditions for the qualifications of REC members should be in place as well as initial and continued training of REC members in view of their professional qualifications and experience. There must be a procedure for REC members to declare any conflicts of interests either raised by their membership in a REC, or regarding a specific project. The formal conduct for meetings, including any voting process - unanimous or majority -, should also be established in the bylaws. Finally, RECs should display publicly to the researchers the procedures and the

contents of the submission dossier for evaluation of a project and inform about the right of the REC to ask additional documents or additional clarifications.

- Resources:

The establishment and the maintenance of RECs are costly. There is a need for not only expert time, but also for a robust administrative infrastructure to be in place. The existing medical RECs have experience in this that can be shared. Indeed, it could be a sensible first step for emerging non-medical RECs to be developed as “chambers” or “panels” within existing REC structures. Whilst respecting the need for different disciplinary approaches and skillsets, it would reduce the need to “reinvent the administrative wheel”.

Proposal

RECs have a highly valuable place in modern society ensuring that scientific and technological innovations that involve human participants in the research and development phases are considered independently in terms of ethics and law. Human dignity, it is agreed, must be protected in all science and technology development. RECs not only help to protect human participants in the research, but also the researchers themselves. EUREC, as the network of RECs across the EU has enormous experience in both the practical and substantive issues that relate to this enterprise. It is a space where that experience can be shared. Whereas RECs have grown in the area of biomedical research, and a strong biomedical ethics has emerged, EUREC recognises that it cannot only help to facilitate the development of RECs in other spheres, but it can ensure that those developments encourage a dialogue within bioethics about its understandings and presumptions. EUREC firmly believes that, whilst it has a lot to offer the broader REC process, it can also learn from those emerging non-medical RECs and those disciplinary understandings of ethics and law.

In order to promote the exchange of all kinds of RECs, EUREC could serve as a European umbrella organization of national networks of this type of RECs. EUREC will encourage the European institutions and European countries without established RECs of this kind to initiate an ethics review system beyond biomedical research. EUREC will also work together with national networks of RECs and European researchers to draft new guiding documents and to revise established guidelines and codes for RECs outside biomedical research. Such guidelines can be found, for example, in many professional associations and in the work of the European Commission already initiated in FP7 and HORIZON2020 projects. A basis for such guiding documents could be the “Guide for research ethics committee members” adopted by the Council of Europe in 2010 and the principles of the “European Code of Conduct” (ALLEA - All European Academies 2017). Whenever states prefer to stay with the existing system – different RECs competent for specific research fields – it will be useful to establish national networks for these RECs. These networks could become members of EUREC and for this the Statute of EUREC will have to be adapted accordingly.