

# ETHICS REVIEWS OF RESEARCH PROJECTS OUTSIDE THE FIELD OF BIOMEDICAL RESEARCH

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# Background: Status Quo



- scientific and technological innovations in biomedicine involving human participants in the research and development phases are considered by independent RECs in terms of ethics and law
- New developments:
  - ethics reviews are being requested by research funding bodies and scientific journals, even outside the field of biomedicine where they are not legally required
  - there are only a few RECs established to review research projects outside biomedical research
  - national structures for a joint exchange of non-medical RECs are often lacking
  - the demands on researchers to reflect ethically on their own research have grown more and more in recent years

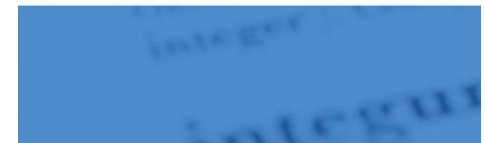


## New ethical requirements: Science within Society

- research is changing our world more and more profoundly
- this requires ethical reflection already in the research and development phase
- due to the worldwide interconnection of research institutions, the changes encounter different social contexts and value systems in a globalised world
- more and more human participants are involved in scientific projects outside the biomedical research
- broad responsibility of researchers:
  - „Respect for colleagues, research participants, society, ecosystems, cultural heritage and the environment.“ (ALLEA ECoC, 2017, p. 4)
- stronger normative interaction between science and society



**The European  
Code of Conduct for  
Research Integrity**  
REVISED EDITION



# Ethical Self assessments and ethical reviews in Europe: The needs

- ethics review outside biomedical research very heterogeneous in the EU
- often, not required by national laws, professional laws or guidelines.
- in some jurisdictions it is difficult for researchers to find an ethics committee to advise them and review their projects
- different systems in the Member States:
  - medical RECs review projects of other disciplines
  - specific RECs for non-medical disciplines of faculties
  - central RECs of universities or other research organisations
  - central national RECs
- need for an exchange of experience to harmonise the procedures between the member states, but also between the ethics review at the level of the European Commission and the member states



# EUREC as a European Forum: The Future

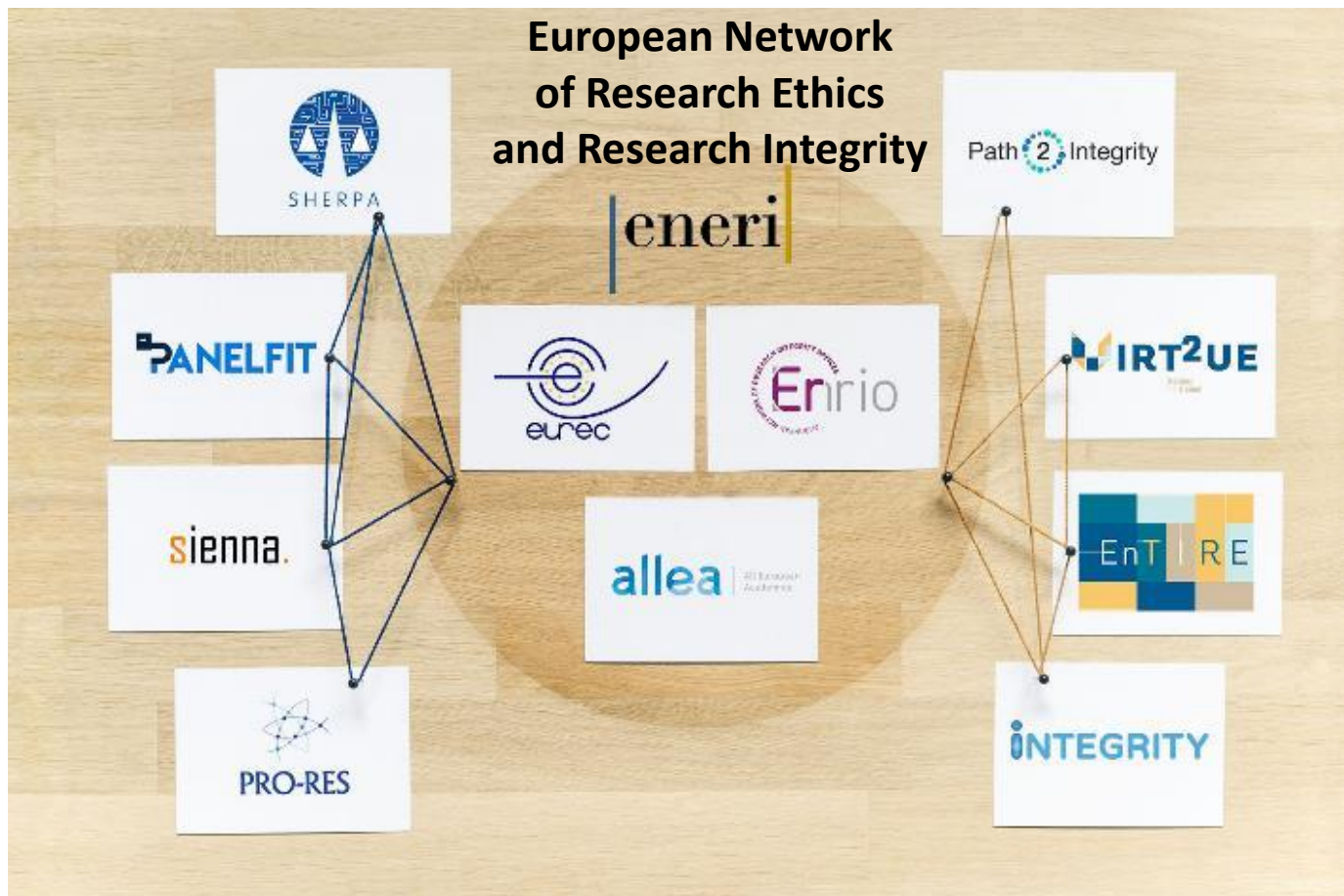
**Position of the  
European Network of Research Ethics Committees (EUREC)  
on Ethics Reviews of Research Projects involving Persons  
outside Biomedical Research**

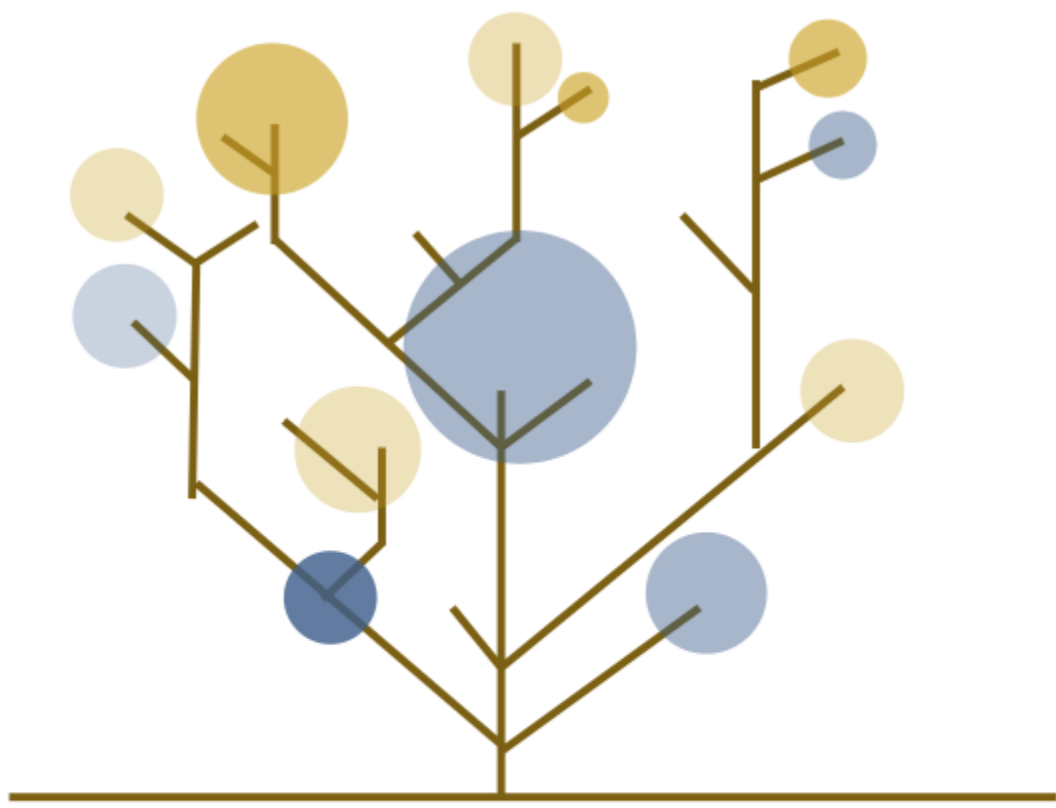
**to the attention of the  
the European Commission, the Council of Europe and the European Research Institutions**

**March 15, 2021**

- EUREC would like to encourage European institutions and European countries without established RECs of this kind and without existing national networks to initiate an ethics review system beyond biomedical research.
- EUREC will also work with national networks of RECs and European researchers to draft new guidance documents and revise established guidelines and codes for RECs outside biomedical research.

# Cooperation with Research: The Links

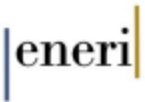




START WITH THE DECISION TREE

HOW TO USE THE DECISION TREE

# ENERI DECISION TREE



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European Commission

Horizon 2020  
European Union funding  
for Research & Innovation

Back to beginning

# PLANNING THE RESEARCH

CROSS-NATIONAL AND INTERNATIONAL MULTICENTRAL RESEARCH

RESPONSIBILITY IN AUTHORSHIP

RESEARCH WITH HUMAN PARTICIPANTS: GENERAL PROVISIONS

RESEARCH WITH ANIMALS

RESEARCH IN ENGINEERING, AI AND ROBOTICS

RESEARCH IN BIOTECHNOLOGY FOR AGRICULTURAL AND FOOD PURPOSES (OUTSIDE OF THE BIOMEDICAL SECTOR)

RESEARCH ON HUMAN REMAINS

STUDY DESIGN AND OBJECTIVES, AVOIDING BIAS

RESEARCH IN BIOTECHNOLOGY

THE ROLE OF THE FUNDERS

RESEARCH WITH PERSONAL DATA



## ASPECTS TO CONSIDER

General aspects to consider:

- ▶ How far is it possible to rise above bias?
- ▶ Who sets the agenda for my work?
- ▶ Whose voices are heard in setting that agenda?
- ▶ Whose interests are served by the research?
- ▶ Do any of the answers to these questions cause me, or others, concerns?
- ▶ Is it necessary for me (my institution, my funder, my colleagues, my friends and society) to be worried about what I am doing, or the reactions of others to what I do?
- ▶ How would I talk about, and defend what I do to others?

We need to ask ourselves, whom do we consult about our proposed work? This is a multi-layered question:

- ▶ How am I going to discuss the formal methodologies of my work, and with whom?
- ▶ If I am working in an area that might generate intellectual property that I (or my funder or institution) might wish to exploit commercially, will I need to maintain a circle of confidentiality around the work?
- ▶ How far can, and should, I share my ideas with colleagues as I develop them?

There are also a set of formal standards that are in place, with external regulators (often jurisdictionally specific):

- ▶ Do I know the ethics and law standards that apply in the different countries (or regions) where I am undertaking the work?
- ▶ What are the formal requirements?
- ▶ What permissions are needed, to whom do I apply, and when?
- ▶ Are there any informal requirements or expectations in the jurisdiction in which I will work?
- ▶ If I am going to challenge these, am I doing it deliberately and with good (defensible) reasons? (And am I prepared to face the cost of challenging the requirements?)

There are conceptual questions that we contribute to through the act of researching, and so must consider:

- ▶ What is the evidence that I will be creating?
- ▶ What am I claiming about that information?
- ▶ How am I justifying the claims that I am making?
- ▶ Why do I think that the claims that I am making are solid?
- ▶ What are the weaknesses in what I am doing and what I am saying?

Thank you for  
your attention

