Ethics reviews in modern research: learning from medical RECs

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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 sciences, ethics and law
- New observations and developments:
    1. ethics reviews are being requested by research funding bodies and scientific journals, even outside the field of biomedicine where they are not legally required
    2. there are only a few RECs established to review research projects outside biomedical research
    3. national structures for a joint exchange of non-medical RECs are often lacking
    4. the demands on researchers to reflect ethically on their own research have grown more and more in recent years

reason why we are being asked these questions about extended forms of ethics reviews

- growing of society's sensitivity to ethical questions in the research process
- not only about social debates and political processes on the topic - i.e. the responsibility of national ethics councils - but also about an ethically sensitive research process itself
- not only physical interventions in the human body - as in medical studies - can cause harm, but also other methods, such as interviews with sensitive questions or the unauthorized use of personal data

critical views

Some scientist believe their work is being constrained and distorted by regulators of ethical practice who do not necessarily understand a methodology. Regulators are acting on the basis of biomedically driven arrangements that make little or no sense to scientists in other academic disciplines.

(Mark Israel / Ian Hay (2006). Research Ethics for Social Scientists: Between ethical conduct and regulatory compliance. London, p 1)

- even researchers who are generally in favour of institutionalised review procedures and actively participate in them indicate weaknesses in everyday procedures, such as incompetent, contradictory and poorly coordinated feedback and requirements
- willingness to reflect on questions of research ethics
- Nevertheless, many researchers would like more exchange and orientation that arise in connection with digital technologies, AI, social media and changes in the research situation due to the internet.
- Another concern is in technical disciplines: we provide methods and tools, but ethics starts with the application; this is the job on other agents.

New Ethical Requirements: Science within Society

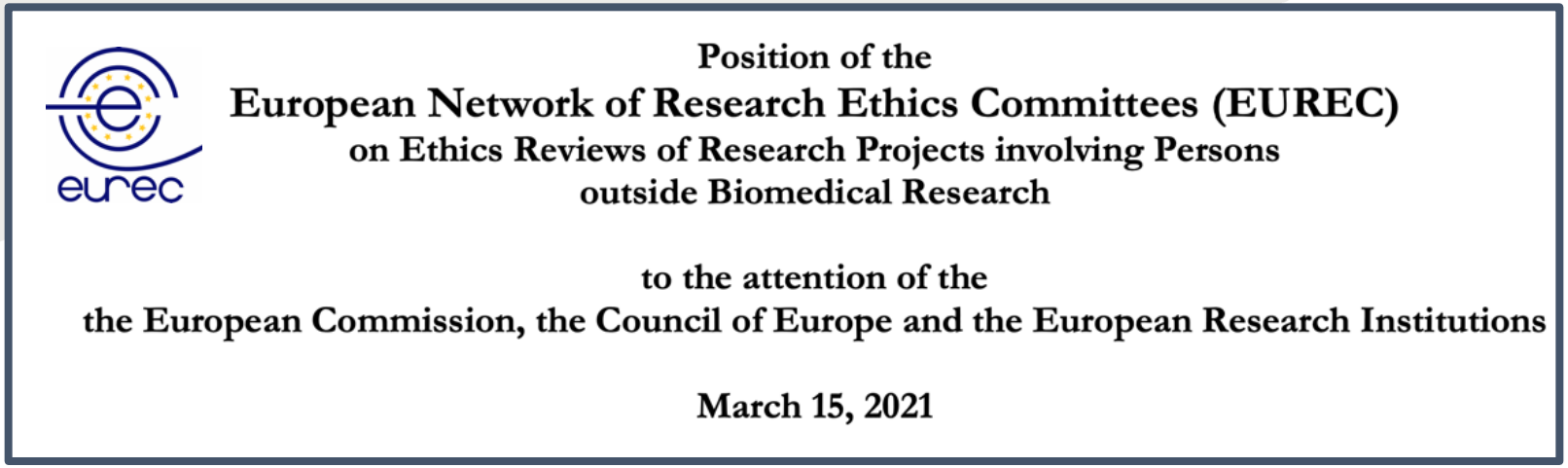
- research is changing the entire world more and more profoundly
- this requires ethical reflection already in the research and development phase
- due to the worldwide interconnection of research institutions, the changes encounter different social contexts and value systems in a globalised world
- human participants and personal data
- risks for society and environment
- 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

Ethics Reviews in Europe: The Needs

- ethics self-assessment and ethics review for researchers/research projects in FP7, HORIZON2020 and now also in HORIZON Europe
- ethics review outside biomedical research looks 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

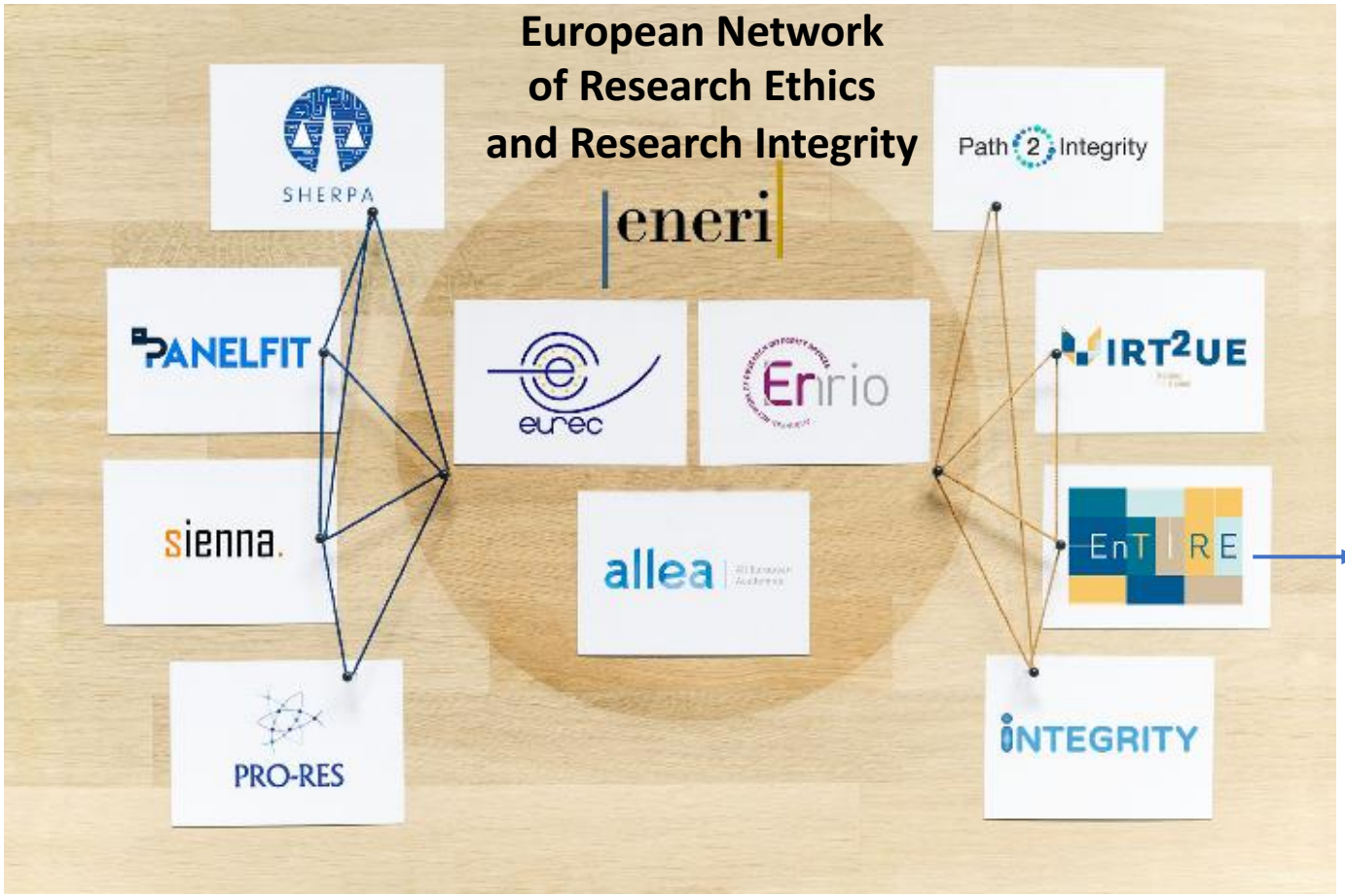
to the attention of the
the European Commission, the Council of Europe and the European Research Institutions

March 15, 2021

http://www.eurecnet.org/documents/EUREC_Positionpaper_March_2021.pdf

- 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.
- There are distinct topics between medical Research Ethics Committees and non-medical Research Ethics Committees, but there are also many overlapping topics, for example in the integration of AI or in data protection.

Cooperation with Research: The Links



the embassy of good science

What can we learn from medical RECs?

- starting national and European **networking** at an early stage to exchange experiences and set standards.
- inclusion of dialogues with **stakeholders** (publishers, funders, lay people, users...)
- **avoiding administrative burden** for researchers and RECs (often it depends on the legal and institutional requirements; but strict administration can also be a parameter of a fair treatment of researchers by ethics committees)
- considering ethical review as a **consultative process** rather than a controlling process
- thinking about more than just an ex ante review: consider **procedural advice**
- **using the freedom of not having everything regulated in a law** as an advantage (as opposed to drug research/research with medical devices)
- **providing training** programmes / cooperation with trainers

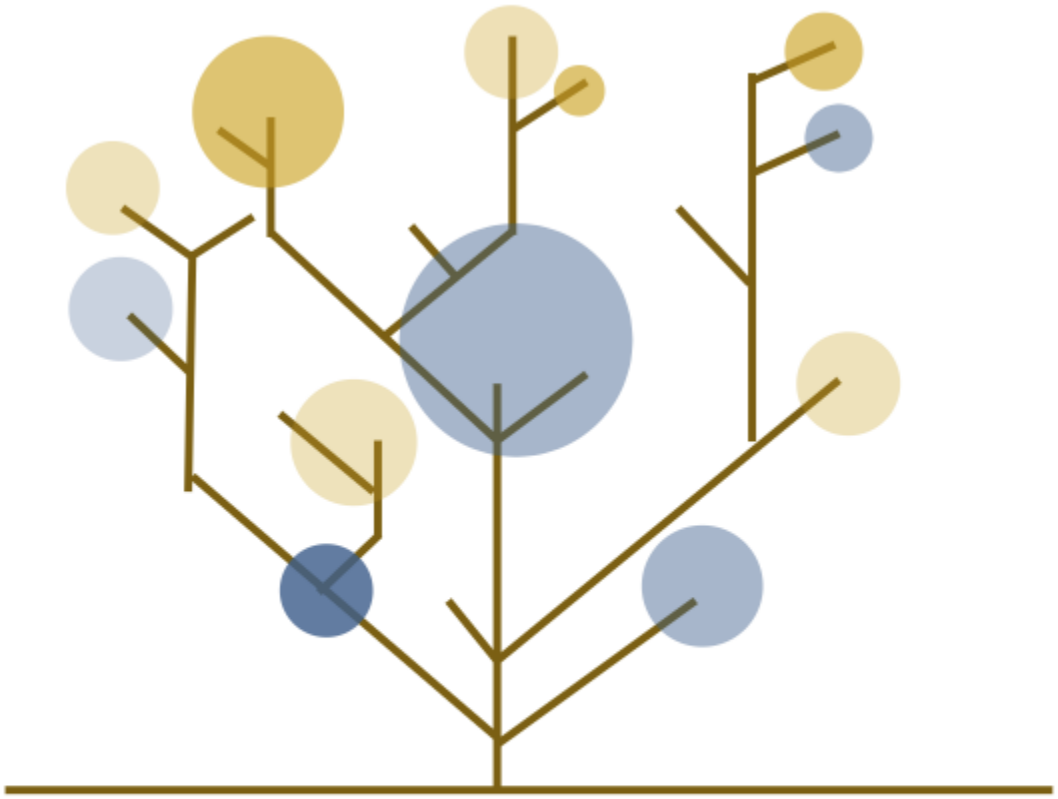
Considering ethical principles

- Autonomy
- Nonmaleficence
- Beneficence
- Justice

(Tom Beauchamp/James Childress: Principles of Biomedical Ethics, 8th rev. ed. 2019, OUP)

Which **risk** is acceptable, which is not, which is minimal?

START WITH THE DECISION TREE



HOW TO USE THE DECISION TREE

ENERI DECISION TREE

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PLANNING THE RESEARCH

- CROSS-NATIONAL AND INTERNATIONAL MULTICTENRAL 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

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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?

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?)

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 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?

Back to *Research as a social practice*

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Thank you for your attention