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Càtedra UNESCO de Bioètica de la Universitat de Barcelona

Observatori de Bioètica i Dret
Universitat de Barcelona

Guidelines for reviewing health research and innovation projects that use emergent technologies and personal data

Dr. Itziar de Lecuona,
Associate professor of the Department of Medicine, director of the ***Bioethics and Law Observatory*** *and co-director of the* ***Master in Bioethics and Law*** *at the University of Barcelona*

*[**Download guidelines**]* ***www.bioeticayderecho.ub.edu/en***

Research Ethics Committees (RECs)

RECs are legally established interdisciplinary collegiate bodies to review the **methodological, ethical and legal aspects** of research projects.
The RECs are **mechanisms to protect** the rights of individuals.

The **role of RECs** is to analyse the scientific soundness and the social value of health research and innovation projects in which people take part and personal data and/or biological samples of human origin are used.

RECs in health research and innovation projects

Initially, they were created to assess clinical trials of medicinal products.
Now, they also analyse projects that use emergent technologies, such as **artificial intelligence**, **big data**, **biometrics**, and **virtual reality**.

The interests of science, technology and society must not prevail over those of the individual

RECs are willing and able to act as guarantees that research, and the innovation that goes with it, complies with ethical principles and meets the established legal requirements

- Protect people by safeguarding their personal data
- Ensure their owners' privacy and confidentiality
- Promote and guarantee the exercise of autonomy to make free and informed decisions
- Avoid discrimination
- Guarantee fairness and transparency

Emerging technologies and intensive personal data exploitation

«**It is no longer possible to guarantee anonymity**»
We have ceased to be isolated pieces of data and have become datasets, stored in different databases that can be combined to improve decision-making.

The proper evaluation of these processes of gathering and processing data must be a priority for RECs.

The transfer of personal information must result in benefits and interventions for the data owner, or for patients and the future generations

This transfer must not lead to the digital surveillance of people or imply that governments and the major tech companies should have absolute control over personal data

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Challenges for a proper protection of individuals against intensive data exploitation

Develop public infrastructures in Europe
to make it possible to store, use and share data, and to ensure its interoperability and reuse.

Align the knowledge generation and transfer processes in which the public and private initiatives participate with the interests of the participants or those involved,
to avoid data markets disguised as health research and innovation.

Avoid the Europe's excessive dependence on the American tech companies;
the GAFAM Empire (Google, Apple, Facebook, Amazon and Microsoft).

Update the obsolete protocols for obtaining informed consent,
due to the fact that it was presumed not only that data were anonymous, but that they would remain so in the future.

Adapt the composition of RECs that lack the necessary knowledge and skills
to review research and innovation projects.
There is an urgent need for them to become **digitally literate**.

Prevent the commercialization of personal data in the field of health,
stimulated by the COVID-19 pandemic and the development and application of emerging technologies, such as AI, big data analytics, biometrics and health apps.

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Recommendations

To Research Ethics Committees

- Confirm and review compliance with the **principles of data protection**.
- **Ensure the non-identification of participants**, which will require the incorporation of experts in pseudonymization techniques, especially, as members or advisers.
- In the event of the institution not having its own specific protection system, the **conditions** guaranteeing personal data protection must be **agreed contractually**.
- Demand and review the **Data Protection Impact Assessment** (**DPIA**) in cases in which the General Data Protection Regulation demands it.
- Request and review the **Data Management Plan**.
- Check that the potential participants in health research and innovation projects are **informed about their rights** and the conditions for exercising them.
- Check that protocols and information and informed consent leaflets state explicitly and in detail **who the data controller is**.
- Request that **privacy policies** and **legal warnings** be included in the project report.
- Include **experts on emergent technologies**.
- Contribute to **generating a culture of respect for people's privacy** through personal data protection.

To research and innovation centres

- **Allocate enough funds** to equip RECs with the human and material resources for a proper assessment that makes the monitoring of health research and innovation projects feasible.
- Ensure **RECs' independence** for decision-making.
- Guarantee the **independence of the Data Protection Officer**.

To the legislator

- **Legally develop** the powers, duties, constitution, accreditation, composition and workings of RECs.
- **Create innovation ethics committees**.
- Incorporate the **Responsible Research and Innovation** (**RRI**) that Europe is advocating through the development of common guidelines.
- **Develop the 17th additional provision** concerning health data processing in the Organic Law on data protection and guarantee of digital rights.
- **Regulate the scope of telemedicine, telehealth and mHealth devices and applications**, apps included, in the processes of healthcare research that process personal data.
- Promote the **creation of public European data management infrastructures**.
- **Build a data management model** that ensure security and reliability.
- **Create data governance structures for data processing**.
- **Develop the legislation to**, and through the relevant actions, **achieve the digital literacy** and education established in the Organic Law on protection and guarantee of digital rights.
- **Reinforce the intelligibility of data analysis** and decision-making, avoiding so-called Black Box Artificial Intelligence.