

- Cluster randomized trials.
- Use of data obtained from the online environment and digital tools in health-related research.
- Requirements for establishing research ethics committees and for their review of protocols.
- Public accountability for health-related research.
- Conflicts of interest.

Bioethics and Human Rights

In October 2005, it was approved the Universal Declaration on Bioethics and Human Rights at the General Conference of the United Nations Educational, Scientific and Cultural Organization (UNESCO). The states members of this declaration (and the international community) engaged to respect and apply fundamental bioethical principles.

The declaration recognizes the relationship between ethics and human rights. It implies that every human being has the right to benefit from technological and scientific advances in a framework of respect to fundamental liberties of the person¹⁰.

This Declaration covers ethical aspects associated to the medical environment, life sciences and technologies applied to humans, always considering the social, legal and environmental sphere of individual, groups, communities and enterprises, both public and private¹⁰.

It establishes principles addressed to guide decision-making and practices, in the fields previously mentioned¹⁰ that are useful to guide the field of research with human beings:

- Human dignity and human rights.
- Benefit and harm.
- Autonomy and individual responsibility.
- Consent.
- Persons without the capacity to consent.
- Respect for human vulnerability and personal integrity.
- Privacy and confidentiality.
- Equality, justice and equity.
- Non-discrimination and non-stigmatization.
- Respect for cultural diversity and pluralism.
- Solidarity and cooperation.
- Social responsibility and health.
- Sharing of benefits.
- Protecting future generations.
- Protection of the environment, the biosphere and biodiversity.

Finally, it includes some provisions about interrelation and complementarity of principles, limitation to principles'

application, and some exceptions regarding interpretation (actions that are against human rights, fundamental liberties and human dignity)¹⁰ and that allow decision-making also regarding research.

Regulations of the General Health Law regarding Health-Related Research

They were published in 2014 in the Official Journal of the Federation. The regulations include 132 articles, distributed in 9 chapters and have the objective of having a legal framework for health-related research actions in Mexico. In general, these are the regulations:

1. General provisions.
2. Ethical aspects of research in human beings.
3. Research on Prophylactic, Diagnosis, Therapeutic and Rehabilitation Resources.
4. Biosafety research.
5. Internal commissions of health institutions.
6. Execution of research in health care institutions.
7. Research including use of animals for experimentation.
8. Safety measures.
9. Follow-up and compliance.

Discussion and conclusions

The relevance of human rights has to do with its function at an individual, social and structural level as they are fundamental to: achieve a comprehensive development of people, create conditions to actively participate in the democratic life and public affairs, establish limitations to the actions of institutions to prevent abuses or negligence, and increasing autonomy that allows making a desirable life plan.

The community of researchers, sponsors, ethics committee on research and health authorities, they have the obligation of evaluating the social and scientific value, the qualifications of research staff, and the respect of human rights and the good state of research protocols.

The scientific and social relevance has to do with the potential information quality, suitability to tackle important health problems, and the contribution in terms of clinical practices or public policies that improve the quality of health care services; besides, it must have a clinically solid design and provide ways to collect information that other