The universal and European reference legal framework in the field of bioethics.

The realm of bioethics intersects with various aspects of human life, prompting a need for comprehensive legal frameworks at both universal and European levels. These frameworks aim to address ethical issues arising from advances in medicine, biology, and technology, ensuring that human rights, dignity, and ethical standards are upheld. This course explores the key legal instruments and principles that form the cornerstone of bioethics, highlighting the interplay between universal declarations and European regulations.

1. The universal referential legal framework :

This new area of law, because of its universal dimension, has naturally developed at international level, since a bioethics rule that would only apply within the borders of one state would remain without international authority. This research aims to bring together the most relevant international references in the field of bioethics.

1.1 Nuremberg Code -August 1947- :

The beginnings of an international code of ethics on human experimentation appeared as early as August 1947, when the Nuremberg Tribunal delivered its verdict in what was known as the "Doctors' Trial" from 20 November 1945 to 1 October 1946, during which Nazi doctors and officers involved in medical research appeared

The judges then proposed ten fundamental principles to govern medical research. They established as an absolute prerequisite the free and informed consent of the patient, as well as the principle of the necessity of the research. These principles form the "Nuremberg Code", the founding text of today's bioethics.

The principles set out in this text, as adapted by the CCNE in 1984 and the Conseil d'Etat in 1988, include: voluntary consent; the freedom of the human subject to undergo experimentation; the scientific soundness of the basis for experimentation; and the principle of the benefit/risk ratio.

1.2 Human rights and their universal declaration 1948 :

Adopted and proclaimed by the General Assembly of the United Nations in New York on 10 December 1948, the Universal Declaration of Human Rights comprises a preamble and thirty articles.

Among the principles cited in the declaration, and which find application in the field of bioethics, we should mention: the principle of non-discrimination (the exclusion of discrimination based on genetic characteristics follows from this), and the right to life (in bioethics, however, it should be noted that this right is poorly defined, particularly as regards the human embryo), the prohibition of the commercialisation of slaves and everything connected with human life. The protection of individual life against deliberate negative intervention or the crime of torture is also an affirmed right. All of these are considered to be ordering rules of international law.

1.3. Children's rights :

With regard to filiation, children have the right to know their origins, to know their parents and to be raised by them. Not only does this pose a problem in the case of adoption, but it is also a problem today in the case of children born through MAP.

On this point, French law is not entirely in line with the International Convention on the Rights of the Child.

It is important to remember that the preamble to this convention states that "the child, by reason of his physical and intellectual immaturity, needs appropriate legal protection before as well as after birth".

1.4. UNESCO's contribution :

UNESCO was the international framework within which the three founding texts of international bioethics were adopted, with the Universal Declaration on the Human Genome of 11 November 1997

the International Declaration on Human Genetic Data, 16 October 2003

and finally the Universal Declaration on Bioethics and Human Rights of 19 October 2005.

The importance of these little-known texts, which nevertheless form the framework of international bioethics, justifies the reproduction of large extracts from them.

1.4.1. **The Universal Declaration on the Human Genome and Human Rights 1997 :**

Genetic characteristics alone do not define individuals and human dignity should not be judged by reference to these characteristics. Everyone's character is unique and diverse. Throughout the declaration, it is always a question of respecting fundamental freedoms and individual rights, such as obtaining prior consent, guaranteeing confidentiality, and allowing everyone the right to know, or not to know, the results of research concerning them, for any action carried out on an individual's genome.

1.4.3. The International Declaration on Human Genetic Data and Human Rights 2003 :

The international declaration on human genetic data was adopted on 16 October 2003 by UNESCO. The aim of this second declaration is "to ensure respect for human dignity and the protection of human rights and fundamental freedoms in the collection, processing, use and storage of human genetic data". Such data is only used for the purposes of diagnosis and health care; medical and other scientific research, including epidemiological studies, in particular population genetics studies; forensic medicine and civil or criminal proceedings; and any other purpose compatible with the Universal Declaration on the Human Genome and Human Rights.

It also recognises that such data is of a "sensitive nature", which may in particular indicate genetic predispositions concerning individuals, and that it may have a significant impact on the family, including descendants, over several generations, and in some cases on the entire group concerned.

1.5. The contribution of non-governmental organisations NGOs :

Non-governmental organisations have also played a part in bioethics by setting up the rules laid down in numerous declarations and conventions, including guidelines, such as the World Medical Association: Declaration of Helsinki (1.5.1) and the Council for International Organisations of Medical Sciences (1.5.2).

1.5.1. World Medical Association: Declaration of Helsinki (1964-2000):

The WMA set out to develop ethical guidelines for research involving human subjects. This work took much longer than its predecessors, and it was not until 1964 that the Declaration of Helsinki was adopted.

This document was also revised periodically, most recently in 2000, under the title "Ethical Principles for Medical Research Involving Human Subjects". This text aims to establish ethical principles useful to doctors.

The many revisions it has undergone demonstrate the world association's concern to renew itself and adapt to developments in scientific and medical research. It recognises the fundamental distinction between medical (or therapeutic) research and pure scientific research, which offers no benefit to the person involved, and follows the twin principles of risk/benefit analysis and informed consent.

2. The reference legal framework in Europe :

The European landscape of bioethics is characterized by a rich tapestry of legal instruments, directives, and conventions that collectively form a robust framework for addressing ethical issues in medicine and the life sciences. This framework is designed to navigate the complex interplay between technological advances and ethical considerations, ensuring that the rights and dignity of individuals are safeguarded. Within this context, several key documents and regulatory mechanisms stand out for their impact and scope.

2.1. The Oviedo Convention

Formally known as the Convention for the Protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine, the Oviedo Convention is the only binding international instrument dedicated to the protection of human rights in the biomedical field. Adopted in 1997 under the auspices of the Council of Europe, the convention sets forth fundamental principles applicable to daily medical practice and research, including:

- **Consent:** The necessity of informed and free consent prior to any medical intervention.
- **Privacy and confidentiality:** The right to privacy and the protection of personal health data.
- **Non-discrimination:** The prohibition of any form of discrimination based on genetic heritage.
- **Protection of the human genome:** Prohibiting interventions aimed at modifying the human genome except for preventive, diagnostic, or therapeutic reasons and only if they do not aim to introduce any modification in the genome of descendants.

The Oviedo Convention also addresses sensitive issues such as organ transplantation, public health, and scientific research, making it a cornerstone of European bioethics and human rights law.

2.2. The Charter of Fundamental Rights of the European Union

Enacted in 2000 and gaining binding legal force in 2009 with the Treaty of Lisbon, the Charter of Fundamental Rights of the European Union represents a pivotal moment in the integration of fundamental rights into the European legal framework. The Charter encompasses a wide range of rights directly relevant to bioethics, including:

- **Dignity:** Article 1 of the Charter proclaims human dignity as inviolable, laying the ethical groundwork for all biomedical practices.
- **Integrity of the person:** Article 3 specifically addresses bioethical concerns, stipulating that everyone has the right to respect for their physical and mental integrity. It outlines consent requirements for medical or biological research and bans eugenic practices and the making of human bodies and their parts as such a source of financial gain.
- **Protection of personal data:** Article 8 protects personal data, including health-related information, ensuring its processing is done for specified purposes and based on the consent of the person concerned or other legitimate bases laid down by law.

2.3. European Union Directives and Regulations

The European Union (EU) has issued several directives and regulations that significantly impact bioethical considerations:

General Data Protection Regulation (GDPR): Enacted in 2018, the GDPR provides a comprehensive framework for data protection, including health data, which is of paramount importance in medical research and practice. It reinforces individuals' rights to privacy and control over their personal data, setting a global benchmark for data protection standards.

Clinical Trials Regulation: The Clinical Trials Regulation (EU) No 536/2014 aims to ensure a high level of human health protection and the smooth functioning of the internal market, with specific provisions to guarantee transparency, informed consent, and the safety of participants in clinical trials.

3. Case Studies and Ethical Dilemmas

This module explores practical applications of bioethical principles through the analysis of real-life scenarios and the examination of ethical dilemmas presented by emerging technologies. By dissecting these cases, students are encouraged to apply ethical theories and legal frameworks to complex situations, fostering a deeper understanding of bioethical issues.

3.1 Analyzing Real-Life Scenarios

- **Genetic Testing and Discrimination**

Genetic testing offers unprecedented opportunities for disease prevention and personalized medicine but also raises significant ethical concerns related to privacy and discrimination. A case in point involves a hypothetical scenario where an individual undergoes genetic testing that reveals a predisposition to a serious, incurable disease. This information, while valuable for the individual's health planning, could lead to discrimination by employers or insurance companies if not adequately protected by privacy laws. This scenario underscores the need for robust legal protections to prevent genetic information misuse and the ethical obligation to respect individuals' privacy and autonomy.

- **End-of-Life Decisions and Autonomy**

End-of-life care presents profound ethical dilemmas centered on the principles of autonomy and dignity. Consider the case of a patient with a terminal illness who expresses the wish to refuse life-sustaining treatment, opting instead for palliative care. This decision challenges healthcare providers to balance respect for patient autonomy with their professional obligations to preserve life. The case highlights the ethical importance of advance directives and the need for clear communication and understanding between patients, families, and healthcare professionals to honor the patient's end-of-life wishes.

- **Access to Healthcare and the Principle of Justice**

Access to healthcare is a fundamental ethical issue, reflecting the principle of justice in the distribution of health resources. An illustrative case might involve a healthcare system where access to a life-saving treatment is limited by socioeconomic status, leading to unequal health outcomes. This scenario prompts a discussion on the ethical responsibilities of societies to ensure equitable access to healthcare services, regardless of individuals' ability to pay, and explores potential strategies to address health disparities.

3.2 Ethical Dilemmas in Emerging Technologies

- **Challenges Posed by Artificial Intelligence**

Artificial intelligence (AI) in healthcare, from diagnostic tools to treatment recommendation systems, offers immense potential but also introduces ethical challenges related to accountability, transparency, and informed consent. A pertinent dilemma arises when an AI system recommends a treatment plan that deviates from standard care, raising questions about the reliability of AI decision-making, the protection of patient autonomy, and the need for transparency in AI algorithms.

- **Gene Editing and Biotechnology**

The advent of CRISPR-Cas9 and other gene-editing technologies has ignited a debate on the ethical boundaries of genetic modification. A case that encapsulates the ethical quandaries involves the use of gene editing to prevent hereditary diseases versus enhancements or non-therapeutic modifications. This scenario forces a confrontation with questions about the definition of "normal" human traits, the potential for social inequality, and the long-term consequences of altering the human genome.

To conclude, this course has illuminated the critical importance of both universal and European legal frameworks in guiding the ethical compass in bioethics. As we venture into the future, the collective engagement of the international community in evolving these frameworks is essential. Together, we must ensure they continue to provide a robust ethical and legal guidepost, safeguarding human dignity and rights amid the ceaseless advance of biomedical and technological innovation.