International Legal Framework for the Application of Genetic Technologies: Main Features and Issues Open for Discussion

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Abstract: The objective of the present article is to determine the specific characteristics of the established international legal framework for the application of genetic technologies and to identify general guidelines that influence states’ policies in this area.

Genetic technologies evolve rapidly, raising a number of ethical and legal issues and directly affecting human rights. At the universal level, there is still no international treaty containing uniform rules in this field. At the regional level, the experience of the Council of Europe deserves further study. National approaches to the legal regulation of applying genetic technologies differ since States retain a great deal of discretion in regulating these issues.

Though the Council of Europe Member States enjoy a margin of appreciation in regulating the use of genetic technologies, a number of common distinctive features underlying the international legal framework in this area can still be singled out. These are informed consent, prohibition of reproductive human cloning, prohibition of germ line modification with certain exceptions. They arise primarily from the Oviedo Convention, the Protocols thereto and the ECtHR practice. Soft law documents adopted at the UN, UNESCO and the Council of Europe contribute to the process of their formation, too, but to a lesser extent. The efforts undertaken at the European and universal level shape modern international legal regulation in the field and set up the course of action for States to follow.

Keywords: genome; genetic technologies; bioethics; biomedicine; human rights; informed consent; genetic testing; human cloning; UN; UNESCO; Council of Europe; ECtHR

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I. Introduction

Genetic technologies are developing very rapidly and the scope of their application is expanding. Undoubtedly, the efforts of the United Nations (UN) and the United Nations Educational, Scientific, and Cultural Organization (UNESCO) aimed at regulating their application have borne some fruit. However, the documents developed by them at the universal level are not legally binding and constitute only the initial guidelines for humanity that faces the obvious need for international legal regulation of such new phenomena as genome research and the use of genetic technologies. At the regional level, the Council of Europe tries to resolve difficult issues that arise in the process of interaction between biomedicine and human rights and eliminate contradictions between ethical considerations and international law. The European Court of Human Rights (ECtHR) functioning under the auspices of the Council of Europe, has already established a notable practice of considering individual complaints on various aspects of the genetic technologies use.
Applying genetic technologies directly affect human rights and raises many legal and ethical issues. The range of these legal questions is fairly broad. Some of these problems would be considered in this article: the need to comply with appropriate ethical and legal standards in all research involving human beings; ensuring equal access to using genetic technologies in the context of the right to health; observing current prohibitions in the use of genetic technologies and searching for the answers what prohibitions are necessary and effective.

II. Regulating the Application of Genetic Technologies at the Universal Level

There is a number of international legal acts in the field of intellectual property protection that touched upon certain aspects of the applied use of genetics, namely the Berne Convention for the Protection of Literary and Artistic Works of 9 September 1886 and the UNESCO World Copyright Convention of 6 September 1952 (both of them were revised in Paris on 24 July 1971), the Paris Convention on the Protection of Industrial Property of 20 March 1883 (revised on 14 July 1967), the Budapest Treaty of the World Intellectual Property Organization (WIPO) on the International Recognition of the Deposit of Microorganisms for the Purposes of the Patent Issuance Procedure of 28 April 1977, the Agreement on Trade Aspects of Intellectual Property Rights (TRIPS), contained in the annex to the Agreement on the Establishment of the World Trade Organization of 15 April 1994, as well as in the UN Convention on Biological Diversity of 5 June 1992.

Over time the UN and its specialized agencies such as the UNESCO and the World Health Organization (WHO) started to regulate the use of genetic technologies and establish ethical principles that underlie the process more specifically. The UNESCO elaborated the Declaration on the Human Genome and Human Rights in November, 1997 and the Universal Declaration on Bioethics and Human Rights in October, 2005. In March, 2005 the UN General Assembly adopted the United Nations Declaration on Human Cloning. In 2016, International Ethical Guidelines for Human Health Research were developed jointly by the WHO and the Council for International Organizations of Medical
Sciences (CIOMS), an international non-governmental organization (NGO) that represents the biomedical scientific community.

The Universal Declaration on the Human Genome and Human Rights,\(^1\) adopted by the UNESCO General Conference on 11 November 1997, contains provisions concerning the human genome and its treatment, human rights in the context of genetic research, conditions for scientific activities, implementation of the above-mentioned provisions.

In section A “Human dignity and the human genome,” the human genome is declared the heritage of humanity. It forms the basis for the fundamental unity of all members of the human family, as well as the recognition of their inherent dignity and diversity (Article 1). The Declaration establishes everyone’s right to respect for their dignity and human rights, regardless of genetic characteristics, thereby introducing the prohibition of genetic discrimination (Article 2). Article 3 recognizes the possibility of mutations in the human genome due to its evolving nature: the potentialities contained in the human genome manifest themselves differently depending on the influence of natural and social environment. Article 4 bans receiving financial gains from the human genome. One should pay attention to the fact that the human genome should not serve as a source of financial gains only “in its natural state,” therefore we can conclude that the human genome if modified, can still become a source of financial enrichment. In addition, a ban is introduced in respect of receiving financial gains from the genome in its natural state, but not from the entire genomic turnover or any manipulations with the genome. Thus, it is worth emphasizing that the 1997 Universal Declaration on the Human Genome and Human Rights addresses the issues of genomic turnover and manipulation with genomes in a rather liberal way.

The provisions of Section B enshrine human rights in the use of the individual’s genome. Article 5 deals with some procedural issues of genome research, in particular, it covers issues of the prior, free and informed consent, control over research, as well as exceptions

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to these rules for the direct health benefit. Article 6 deals with genetic discrimination and its prohibition. Article 7 declares that the confidentiality of genetic data must be protected by law. Article 8 declares a right of a person to just reparation for any damage sustained as a direct and determining result of an intervention affecting his or her genome. The formulation in Article 8 raises questions of whether the human genome is viewed as a part of the human body or as an object of scientific research. Most probably, this article should be interpreted restrictively. In other words, the direct and determining impact can only take place in situations when the genome is considered a part of a person. Article 9 declares that within the bounds of public international law and the international law of human rights, limitations on the rights to confidentiality of information about genetic data and the procedure for obtaining informed consent may be imposed.

Section C deals with various issues of human genome research. Article 10 declares that no research and no research applications concerning the human genome, in particular in the fields of biology, genetics, and medicine, should prevail over respect for human rights, fundamental freedoms, and human dignity. Similar provisions were laid down in the acts of international NGOs, in particular, in the 1964 Helsinki Declaration of the World Medical Association “Ethical Principles for Medical Research Involving Human Subjects.” Article 11 states that practices that are contrary to human dignity shall not be permitted. However, it is not specified whether research or production practices are meant precisely. “Reproductive cloning of human beings” is cited as a specific example. Though this type of cloning of human beings is expressly prohibited, cloning for research purposes or for obtaining any biomedical products is hypothetically allowed. This is another confirmation of the liberal approach that guided the process of elaborating the Universal Declaration on the Human Genome and Human Rights back in 1997. We believe that this prohibition should bear a comprehensive character: any activity with the human genome

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that contradicts human dignity is unacceptable. Article 12 declares such principles of human genome research as the principle of availability of benefits from advances in biology, genetics, and medicine for all and the principle of freedom of research, which is an integral part of freedom of thought.

Section D indicates conditions for the exercise of scientific activities in this field. Article 13 declares that public and private science policy-makers should bear particular responsibilities in this respect. What is meant here is “meticulousness, caution, intellectual honesty and integrity” in carrying out genetic research. Articles 14, 15, and 16 characterize the role of the State in human genome research. States are obliged to undertake the following actions:

1) foster the intellectual and material conditions favorable to freedom in the conduct of research on the human genome and consider the ethical, legal, social and economic implications of such research, based on the principles set out in this Declaration;

2) provide the framework for the free exercise of research on the human genome with due regard for the Declaration principles, in order to safeguard respect for human rights, fundamental freedoms and human dignity and to protect public health;

3) recognize the value of promoting at various levels the establishment of independent, multidisciplinary and pluralist ethics committees to assess the ethical, legal and social issues raised;

4) seek to ensure that research results are not used for non-peaceful purposes.

Section E proclaims priority support for individuals, families and population groups who are particularly vulnerable to or affected by disease or disability of a genetic character (Article 17) and also covers some international cooperation issues (Articles 18 and 19). Sections F and G contain provisions on promotion and implementation of the 1997 Universal Declaration on the Human Genome and Human Rights.

Summing up, one should bear in mind that the 1997 Declaration on the Human Genome is one of the few international legal acts regulating the use of genetic technologies. The Declaration highlights a number of issues, such as the prohibition of genetic discrimination, procedures for genome research and obtaining informed consent, the
participation of ethics committees, the need to support individuals and
groups of the population most vulnerable to genetic diseases as well
as issues of international cooperation. The authors of this document
could have further elaborated on the issues of manipulations with the
human genome in light of their ethical acceptability, the legal status of
the human genome, the functioning of ethical committees. In the 1964
Helsinki Declaration “Ethical principles of conducting medical research
involving human subjects,” many of the issues mentioned above had
been laid down in a more detailed way.

In the fall of 2001 France and Germany made an appeal to the
UN General Assembly to develop a new global regulatory instrument,
more precisely an international convention against the reproductive
cloning of humans.3 On 8 March 2005, the UN General Assembly
adopted the United Nations Declaration on Human Cloning4 that is
often characterized as a purely political declaration — “as a way of
emphasizing the degree of compromise reflected in the text and also
as a way of minimizing its normative value” (Arsanjani, 2006, p. 164).
It does not directly prohibit human cloning, including for reproductive
purposes. Its main goals were to draw the attention of the public, the
international scientific community and governments to the problems
of bioethics and to promote the development of national legislation to
regulate stem cell research. In paragraph (a), the 2005 UN Declaration
on Human Cloning calls on Member States to take “all measures
necessary to protect adequately human life in the application of life
sciences,” which can be interpreted broadly even as a ban on abortion.
In paragraph (b), States are called upon to prohibit “all forms of human
cloning inasmuch as they are incompatible with human dignity and
the protection of human life.” In paragraph (c), Member States are
further “called upon to adopt the measures necessary to prohibit the

3 Legal Committee calls for Working Groups on human cloning, better protection
for UN, related personnel; other texts also approved. UN General Assembly Sixth

4 United Nations Declaration on Human Cloning, UN General Assembly
application of genetic engineering techniques that may be contrary to human dignity.” In paragraph (e), Member States are also “called upon to adopt and implement without delay national legislation” to bring into effect all the aforementioned provisions.

The UN General Assembly adopted the text by a vote of 84 in favor to 34 against, with 37 abstentions. During the negotiations at the UN on the possibility of human cloning, the states were divided into two groups. They held different views on cloning issues due to their predominant religious and ethical traditions (Arsanjani, 2004, pp. 151–157). Both groups were in favor of an unconditional ban on reproductive cloning of humans. However, the group of industrialized countries (France, Germany, Belgium, China, India, Japan, Russia, Singapore, South Korea, United Kingdom) pointed to the need for international legal regulation of stem cell research and therapeutic cloning, while the states supported by the Holy See, including the group of Latin American countries led by Costa Rica, the United States and European Catholic countries such as Italy, Portugal, Spain, were in favor of a comprehensive ban on all forms of cloning. The problem of “chimeric experiments” remained completely unresolved in the UN Declaration on Human Cloning. In this process human cells are implanted into organisms of other biological species, and it is not known whether the appearance of human-like consciousness, emotions and cognitive abilities would be possible.

In October 2005, UNESCO returned to the issues of international legal consolidation of the interests of the individual, society, and the State in the field of medicine based on the norms of bioethics and adopted the Universal Declaration on Bioethics and Human Rights. The Bioethics Declaration consists of four sections: general provisions, application of the principles, promotion of the Declaration and final provisions.

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6 The term “chimera” in ancient Greek mythology was used to denote a fire-breathing monster with a lion’s head, a goat’s body and a dragon’s tail.

The principles that should guide any medical research are set out in the sections “General provisions” and “Application of the principles.” The following principles are proclaimed as fundamental in the Declaration: human dignity and human rights, priority of the individual’s interests and welfare over the interest of science and society (Article 3), the right balance between benefit and harm in applying and advancing scientific knowledge, medical practice and associated technologies (Article 4), the need to respect personal autonomy (Article 5), prior, free and informed consent of the person concerned (Articles 6–7), non-discrimination and respect for human rights (Articles 9–11), cultural diversity and pluralism (Article 12), solidarity and cooperation (Article 13), the highest attainable standard of health as one of the fundamental rights of every human being (Article 14), protection of future generations, the environment, biosphere and biodiversity (Articles 16–17) and others. Article 16 contains a principle, according to which due regard should be given to the impact of life sciences on future generations, including on their genetic constitution. Such provisions are characteristic of acts regulating environmental protection, for example, the UN Declaration on the Human Environment of 1972, the Rio Declaration of 1992, the Convention on Biodiversity of 1992, etc. Most likely this principle should be interpreted as an indication of the need for precaution in order to prevent the negative consequences of an intervention in the genome of living beings and as an instruction to carry out further research to alleviate the fate of people suffering from genetic diseases.

The section “Application of the principles” gives an understanding of how the principles set out in the 2005 Declaration should be implemented in practice. The Declaration brings up the issues of establishing independent, multidisciplinary and pluralist ethics committees (Article 19), previously mentioned in the 1997 UNESCO Declaration on the Human Genome and Human Rights, the need to address bioethical issues in decision-making (Article 18), etc. The provisions of Article 21 of the Declaration on transnational activities in health research deserve attention and further reflection. With the intensive development of transnational ties at the end of the 20th century — beginning of the 21st century, certain practices of transnational medical activity have
developed, creating a risk of violations of bioethical norms. Scientific research in this area can be carried out in countries with a low level of legal protection of their citizens. The provisions of Article 21 are aimed at reducing the risk of such abuses by making States responsible for ensuring the compliance of their professionals with bioethics standards in all cases when such activities are “undertaken, funded or otherwise pursued in whole or in part” by the State. Along with the requirement to comply with an appropriate level of ethical review in transnational medical practice in all States involved in such activities, the Declaration on Bioethics proclaims the need for transnational health research to be responsive to the needs of host countries. This indicates the intention of the authors of the Declaration on Bioethics to protect developing countries from exploitation by developed countries. In addition, the Declaration contains provisions on the need for interstate cooperation in the dissemination of useful research results and combatting bioterrorism and illicit traffic in organs, tissues, samples, genetic resources and genetic-related materials. To be able to take follow-up actions, the UNESCO will seek the help and assistance of the Intergovernmental Bioethics Committee (IGBC) and the International Bioethics Committee (IBC) (Article 25).

The UNESCO Declaration on the Human Genome and Human Rights of 1997 and the Universal Declaration on Bioethics and Human Rights of 2005, as well as the United Nations Declaration on Human Cloning of 2005 laid some international legal foundations for the subsequent use of genetic technologies. However, a number of burning questions remained unanswered. The legal status of the human genome was not determined with full certainty. Manipulations with the human genome did not receive an assessment in the light of ethical considerations. Legally binding bans of the reproductive cloning of humans and “chimeric experiments” were not introduced. Some of these gaps were subsequently filled in the process of international legal regulation at the regional level within the framework of the Council of Europe.
III. Regulating the Application of Genetic Technologies at the Council of Europe Level

For a long time the Council of Europe has been discussing, to varying degrees, the use of genetic technologies and related aspects in the context of ensuring human rights. This is evidenced by various publications of the Committee of Ministers and the Parliamentary Assembly of the Council of Europe prepared by expert groups (Le Bris, Knoppers, Luthera, 1997, pp. 1368–1369). In 1982, the Council of Europe became the first regional organization that initiated consideration of the concept of human dignity in the context of genetics, noting that “the rights to life and to human dignity protected by Articles 2 and 3 of the European Convention on Human Rights imply the right to inherit a genetic pattern which has not been artificially changed.”

In 1985, efforts in this direction were institutionalized, and under the leadership of the Committee of Ministers, the Ad Hoc Committee of Experts on Bioethics (CAHBI) responsible for interstate interaction on these issues was founded. In 1992, it became the Steering Committee on Bioethics (CDBI). The Steering Committee on Bioethics has carried out extensive work concerning various legal aspects of human genome research and provided important information concerning the legal implications of their impact on human rights (Jónatansson, 2000, p. 33).

In 2012, as a result of reorganization of intergovernmental bodies of the Council of Europe, the Steering Committee was transformed into the Committee on Bioethics (DH-BIO, hereinafter referred to as the Committee) and it was subordinated to the Steering Committee.

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Currently, the Committee performs the following functions:

— fulfilling tasks in the field of ensuring human rights when applying the achievements of biology and medicine;

— developing the Draft Additional Protocol concerning the protection of human rights and dignity of persons with mental disorder with regard to involuntary placement and involuntary treatment;

— monitoring the implementation of the Strategic Action Plan for 2020–2025 with a special focus on human rights issues arising from new technologies, such as neurotechnologies;

— studying ethical and legal issues arising in connection with the development of genome editing technologies in connection with Article 13 of the Convention on Human Rights and Biomedicine, etc.\(^\text{13}\)

The Committee meets at least two times a year at the headquarters of the Council of Europe. These meetings are attended by representatives of all 47 Member States of the Organization. In addition, representatives of observer States (Canada, Japan, Mexico, the USA and the Vatican), the European Union, WHO, UNESCO, OECD and a number of other organizations can participate in the meetings of the Committee without the right to vote. The Committee carries out its work by issuing various resolutions, recommendations, guidelines and reports. The documents in the field of legal aspects of the use of genetic technologies include Recommendation No R(90)13 on Prenatal Genetic Screening, Prenatal Genetic Diagnosis and Associated Genetic Counselling of 1990, Recommendation No R(92)3 on Genetic Testing and Screening for Health Care Purposes of 1992, Recommendation No R(94)1 on Human Tissue Banks of 1994, Recommendation No CM/Rec(2016)8 on the processing of personal health-related data for insurance purposes, including data resulting from genetic tests of 2016, Recommendation


\(^{13}\) Committee on Bioethics (DH-BIO), Information document concerning the DH-BIO, 16 March 2021. Available at: https://rm.coe.int/inf-2021-2-info-doc-dh-bio-e/1680a2cfbb [Accessed 15.02.2022].
No CM/Rec(2020)5 on the quality and safety of tissues and cells for human application, etc.\textsuperscript{14}

Since 1992, the Steering Committee on Bioethics has been actively working on a draft framework convention “establishing common standards for human protection in the context of the development of biomedical sciences.”\textsuperscript{15} Thus, the most significant result of the activities of the Steering Committee on Bioethics is the development and adoption within the Council of Europe of the first and, in fact, the only international treaty in the field of ensuring human rights in the use of genetic technologies — the Convention for the Protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine: Convention on Human Rights and Biomedicine of 1997 (hereinafter — the Oviedo Convention).\textsuperscript{16}

The Oviedo Convention reflects the consensus that existed at the time of its adoption on various issues of applying the achievements of medicine and technology to humans (Knoppers, Le Bris, 1991, pp. 329–361). It establishes the principles of human rights protection in the implementation of medical activities, as well as a number of norms regarding the use of genetic technologies in this context. In general, the Oviedo Convention contains general principles that were later developed in more detail in its additional Protocols.

In accordance with the Oviedo Convention, human interests should be above the interests of the science or society, in connection with which a number of prohibitions are established in the field of bioethics, medical

\textsuperscript{14} Compendium of texts of the Council of Europe on bioethical matters. Available at: https://www.coe.int/t/dg3/healthbioethic/texts_and_documents/ [Accessed 16.02.2022].


research, obtaining consent for medical intervention, the right to privacy and information, the human genome and the removal of organs for transplantation. In particular, in the field of the human genome, the Oviedo Convention prohibits all forms of discrimination based on a person’s genetic heritage, permits only predictive genetic tests for medical purposes. According to Article 13 of the Convention, genetic engineering is permitted only for preventive, diagnostic or therapeutic purposes and only if it does not entail any modification in the genome of any descendants. As a rule, the Convention also prohibits the use of genetic technologies for the purpose of choosing the sex of a child.

As noted in the academic literature, the Oviedo Convention has become a model, a reference tool for the European Union, as well as the UNESCO and the WHO in matters of legal regulation of bioethics and the use of genetic technologies (Lwoff, 2009, pp. 1374–1377). At the same time, the object of regulation of the Convention divided the experts into two groups. The conservative-minded group focuses on the respect for human dignity and the inadmissibility of weakening ethical principles that can lead to the deterioration of moral standards. The liberal part of the expert community insists that people are constantly changing their environment in order to survive and provide a better standard of living, which involves some degree of risk. However, in their opinion, the mere probability of undesirable consequences should not exclude the possibility of using genetic technologies that help the humanity to survive (Jónatansson, 2000, pp. 35–36). Thus, the adoption of the Convention was the result of a compromise, the consequence of which is the inclusion of categories that are broad and vague to some extent, leaving freedom for national discretion. Nevertheless, there is an emphasis in the text of the Convention towards a “precautionary,” conservative approach.

Largely, this was the reason for the delay in the ratification procedure of the Convention by the Member States of the Council of Europe. The entry into force of the Convention on 1 December 1999 was preconditioned only by the maximum understated requirement for the number of ratifications required for this, up to five. After more than
20 years after the Oviedo Convention was drafted, 29 States ratified it, 7 States (including Italy, Sweden and Ukraine) signed it, but did not ratify, and 11 States (including the UK, Germany, Austria and Russia) did not even sign it out of 47 Member States of the Council of Europe.\(^{17}\)

To date, four protocols have been adopted to the Oviedo Convention:

1) the Additional Protocol on the Prohibition of Cloning of Human Beings of 1998 that entered into force in March 2001 (ratified by 24 States);\(^{18}\)

2) the Additional Protocol on Human Organ and Tissue Transplantation of 2002 that entered into force in May 2006 (ratified by 15 States);\(^{19}\)

3) the 2005 Additional Protocol concerning Biomedical Research that entered into force in September 2007 (ratified by 12 States);\(^{20}\)

4) the Additional Protocol to the Convention on Human Rights and Biomedicine concerning Genetic Testing for Health Purposes that entered into force in July 2008 (ratified by 6 States).\(^{21}\)

It should be noted that in accordance with Article 29 of the Oviedo Convention, the European Court of Human Rights (ECtHR) may issue advisory opinions on legal issues concerning its interpretation. However, the provisions of the Oviedo Convention have not been developed in the judicial practice of the ECHR.\(^{22}\) The Court referred to the norms


\(^{22}\) European Court of Human Rights. Vo v. France (GC), No 53924/00, 8 July 2004; Lambert and Others v. France (GC), No 46043/14, 5 June 2015; Vo v. Italy (GC), No 46470/11, 27 August 2015; Lopes de Sousa Fernandes v. Portugal (GC),
of the Convention in a number of cases, using previously expressed approaches to interpretation. Thus, in its judgment in *Vaux v. France* in 2004, the ECtHR confirmed the position of the Steering Committee on Bioethics and noted that the content of the word “everyone” in Article 1 of the Oviedo Convention, due to the lack of a unified approach, each State defines in its national legislation.23 Similarly in another case in a partially overlapping and partially dissenting opinion, J. Paulo Pinto de Albuquerque referred to the explanatory note of the Steering Committee on Bioethics and indicated that the purpose of Article 3 of the Oviedo Convention, guaranteeing equal access to health care of appropriate quality “is not to create individual rights which every person can refer to in the judicial processes against the State, but rather, prompting the latter to take the necessary measures in the framework of its social policy to ensure equal access to health services.”24

The content of the Convention and Protocols is criticized, in particular, in connection with the restrictions imposed on embryo research (Ponomareva, Kosilkin, and Nekoteneva, 2019, pp. 5408–5415), the prohibition of inherited genome editing (Boggio, Romano and Almqvist, 2020, pp. 201–236; Sykora and Caplan, 2017, pp. 1871–1872), human cloning and related aspects (McDaniel, 1998, pp. 543–581), that are discussed in more detail in the subsequent sections of this study. However, it can be stated that the experience of the legal regulation of the use of genetic technologies within the Council of Europe through specially established intergovernmental bodies and expert groups, as well as normative and regulatory acts developed on the basis of their recommendations, with the current level of scientific knowledge, meet modern requirements in the field of human rights protection.

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23 European Court of Human Rights. *Vo v. France* (GC), No 53924/00, 8 July 2004.

IV. Specific Human Rights Issues in the Application of Genetic Technologies

IV.1. Informed Consent in Genetic Research and Treatment

The principle of informed consent underlies the concept of personal autonomy; it is based on the ability and right of a person to make an independent choice and expresses one of the aspects of the human right to privacy. Any medical intervention, including genetic intervention, regardless of whether it is of scientific or therapeutic nature, can be carried out only with the consent of the patient or the person participating in the medical study. Article 5 of the Oviedo Convention contains a provision on the need for voluntary informed consent to a medical intervention. It is important to note that, unlike the 1947 Nuremberg Code and the 1964 Helsinki Declaration “Ethical Principles for Medical Research Involving Human Subjects” — the first documents that enshrined the principle of informed consent, the Oviedo Convention states that the need to obtain such consent is no longer limited to the conditions of a medical experiment, but extends to any medical intervention. Informed consent presupposes that a person receives relevant information in advance about the purpose and nature of the intervention, as well as about its consequences and risks, and can freely withdraw his consent at any time.

In the world practice of using genetic technologies, the case of Jesse Gelsinger that occurred in 1999, is widely known. 18-year-old Jesse was ill with a rare genetic disease. When the doctor informed that clinical trials in the field of gene therapy aimed at treating this disease in children were conducted, Jesse decided to take part in clinical trials and gave his consent. The study of new methods of gene therapy led to the death of the patient. During the investigation, the US Food and Drug Administration found out that the researchers did not tell Jesse about serious side effects in previous patients and that two laboratory monkeys died from similar gene manipulations. If he had been properly...

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informed about these problems, he could have refused to participate in the study and stayed alive. Serious violations of the principle of informed consent (failures in the informed-consent procedure) were revealed, despite the fact that formally a participant in clinical trials gave his consent to the trial of gene therapy. This case greatly influenced the organization of research in the field of gene therapy (many studies were stopped or taken under serious state control), and it resulted in the more detailed elaboration of the requirements for informed consent in different countries.

At the moment, in many jurisdictions, the requirements for the information to be provided to persons giving their informed consent are quite clearly formulated. For example, in the USA, the requirements for the form of expression of consent are defined in detail in §§ 50.25, 50.27 of Title 21 of the Code of Federal Regulations. In Russia, the procedure for giving informed voluntary consent to a medical intervention and refusal to a medical intervention is approved by the Order of the Ministry of Health of the Russian Federation. Voluntary informed consent in relation to children has its own characteristics. The general approach is that the consent to the treatment of the child, including the use of genetic technologies, is given by the parents.

This procedure is illustrated in Glass v. United Kingdom considered in the European Court of Human Rights. The child was hospitalized several times with a respiratory system disease. There were disagreements between the hospital staff and Ms. Glass about the methods of child’s treatment in the event of a crisis — whether to conduct intensive therapy or not. In one case, doctors believed that the child was in a near-death state, and in order to reduce pain, they injected diamorphine against the mother’s wish. In addition, “Do Not Resuscitate” order was included in the child’s medical card without the

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27 Sec. 50.25, 50.27. Title 21. Code of Federal Regulations. Available at: https://www.ecfr.gov/cgi-bin/ECFR?page=browse [Accessed 01.05.2021].


29 European Court of Human Rights. Glass v. the United Kingdom, No 61827/00, 6 March 2004.
knowledge of his mother. There was a serious conflict between doctors and family members of the child. The child survived.

The ECHR held that imposing the course of treatment on a child, despite the constant objections of the mother, was an act of interference in the exercise of the child’s right to respect for his private life. The fact that the doctors dealt with a crisis situation for the child’s life did not justify the fact of such an intervention. The Court noted that at the initial stages of the applicant’s conflict with the hospital, the hospital administration did not attempt to resolve this conflict by resorting to judicial intervention. The burden of the initiative to resolve the conflict at the threshold of the next crisis of the patient lay on the hospital administration. Instead, doctors used the limited time available to them in that situation to try to impose their point of view on the mother. The Court considered that the decision of the medical authorities to ignore the objections of the mother of a minor patient about the proposed treatment in the absence of permission from the judicial authorities led to the violation of Article 8 of the Convention.

At the same time, there are situations when the doctors’ actions against the will of the parent or the legal representative of the child were recognized as permissible. In Jehovah’s Witnesses in Moscow v. the Russian Federation30 the ECtHR pointed out that the provision of the Russian legislation31 in force at the time of the case that the decision of parents to refuse treatment provided to a child in order to save his life can be overcome by a court decision that protects the rights of the child.32

The situation of saving a patient’s life may be directly related to gene therapy. Thus, one of the most expensive medicines in the world, 

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30 European Court of Human Rights. Jehovah’s Witnesses of Moscow v. Russia, No 302/02, 10 June 2010.
32 European Court of Human Rights. Jehovah’s Witnesses of Moscow v. Russia, para. 137.
Zolgensma®, is a gene therapy drug developed for the treatment of patients with spinal muscular atrophy, and it is used to treat children under 2 years old (Zolgensma® is a prescription gene therapy used to treat children younger than 2 years old with spinal muscular atrophy. Some countries implement policies for free provision of such expensive drugs for the treatment of severe hereditary diseases.

It can be concluded that the decision on a medical intervention in relation to a minor, who in accordance with the national legislation does not have the right to make such a decision independently, lies with his parents (legal representatives). At the same time, in cases requiring medical personnel to respond immediately in order to save a child, when a parent (legal representative) prevents it, doctors can act at their discretion after applying to the court.

Consent may be required not only in cases of treatment or participation of a person in biomedical research, but also when using his genetic material by third parties: by medical, scientific institutions or family members, spouses, partners. Thus, in Evans v. United Kingdom33 the Court considered the legality of the prohibition to use embryos by one partner — the carrier of genetic material — without the consent of the second partner. Natalie Evans suffered from the ovarian cancer. Before the removal of the ovaries, she and her partner D. resorted to in vitro fertilization. The resulting embryos were placed in storage. The couple’s joint relationship did not work out. D. withdrew his consent to the use of embryos since he did not want to become the genetic father of the applicant’s children. According to the national law, the embryos had to be destroyed. Natalie Evans was deprived of the opportunity to ever have her own, genetically native children.

Expressing sympathy for the applicant, the ECtHR found no violation of Articles 2 (right to life), 8 (right to respect for private and family life) and 14 (prohibition of discrimination) of the European Convention on Human Rights. One of the criteria for the Court’s making of such a decision was a clearly formulated rule in national law on the consent of the partner, with which Ms. Evans was acquainted before the

33 European Court of Human Rights. Evans v. the United Kingdom (GC), No 6339/05, 10 April 2007.
fertilization procedure. Absence of the spouse’s consent to the use of embryos containing his genetic material prevented the applicant from becoming a mother, which undoubtedly affected her right to privacy protection. However, the Court declared that the notion of a “private life” incorporates the right to respect for both the decisions to become and not to become a parent.\textsuperscript{34} The Court concluded that, given the lack of a European consensus on this point, the fact that the domestic rules were clear and brought to the attention of the applicant and that they struck a fair balance between the competing interests, there was no violation of Article 8 of the Convention.\textsuperscript{35}

Voluntary informed consent is a prerequisite for a person to participate in a genetic examination, to undergo genetic testing or treatment. Informed consent is not just a document signed by a patient or his legal representative; it is a procedure that requires compliance with certain criteria.

**IV.2. Genetic Diagnostic Technologies and Reproductive Rights**

Despite the rapid development of technologies, patients’ access to genetic technologies is not always open, it is provided, restricted and prohibited by national legislation. Genetic testing technologies allow carriers of serious genetic diseases to avoid transmitting the disease to their future children, make it possible to detect fetal development pathologies in time and make an informed decision about maintaining or terminating pregnancy, help doctors to determine pregnancy follow-up or treatment strategies. Prenatal (antenatal), in particular pre-implantation genetic diagnostics (testing/screening) allow parents to ensure the protection of reproductive rights and, as a consequence, the right to health and the right to respect for private and family life.

Prenatal testing may be offered to women during pregnancy to determine if the fetus has a possibility to be born with a genetic condition or a birth defect. Performing prenatal testing may be useful in

\textsuperscript{34} European Court of Human Rights. Evans v. the United Kingdom (GC), para. 71.

\textsuperscript{35} European Court of Human Rights. Evans v. the United Kingdom (GC), para. 92.
determining different options for the pregnancy or special management of the pregnancy and delivery to improve the outlook for the baby (Genetic Alliance, 2009). Preimplantation genetic testing (PGT) is an early form of prenatal genetic diagnosis where abnormal embryos are identified, thereby allowing transfer of genetically normal embryos (Parikh, Athalye, Naik and Naik, 2018, pp. 306–314).

Let us turn to the ECHR jurisprudence concerning access to prenatal genetic diagnosis. In cases related to reproductive health, the ECtHR quite often refers to the concept of a “broad margin of discretion” of States.36 Due to the lack of a pan-European consensus on such sensitive issues as reproductive rights, States can use wide opportunities for legal regulation in this area. Despite this, the Court quite often recognizes a violation of rights related to reproductive health on the part of the participating States. In some cases, national legislation is applied (or not applied) in such a way that it leads to a violation of the right to privacy. In others, the national legislation itself is so vague or contradictory that its application naturally leads to a violation of human rights in the reproductive sphere.

In R.R. v. Poland37 the medical staff deliberately refused to conduct timely genetic tests for a woman pregnant with a third child, even though the fetus was suspected of having a serious genetic defect. After considerable delay, the examination took place. By the time she received the results confirming that the foetus was suffering from Turner Syndrome, it was too late for R.R. to have a legal abortion under Polish law. The Court found a violation of Article 3 (prohibition of inhuman and degrading treatment) of the Convention as the applicant, who was in a very vulnerable position, had been humiliated and “shabbily” treated. The determination of whether she should have had access to genetic tests, as recommended by doctors, was marred by procrastination, confusion and lack of proper counselling and information. The Court concluded that the authorities had failed to comply with their positive obligations to secure effective respect for the applicant’s private life.

36 European Court of Human Rights. Parrillo v. Italy (GC), No 46470/1, 27 August 2015, para. 180.

and that there was therefore a breach of Article 8 (right to respect for private and family life) of the Convention.

The case of A.K. v Latvia\textsuperscript{38} is quite similar to the previous one. The applicant was 40 years old at the time of pregnancy. Under domestic law she should have been treated as a patient with a high-risk pregnancy. The applicant claimed that her gynaecologist had failed to ensure that she would have an antenatal screening test. She gave birth to a daughter with Down’s syndrome. Relying on Article 8 (right to respect for private and family life), A.K. alleged that she had been denied adequate and timely medical care in the form of an antenatal screening test which would have indicated the risk of a genetic disorder in the foetus and would have allowed her to choose whether to continue the pregnancy. The Court stated that the cumulative effect of the failings identified was that the domestic courts did not properly examine the applicant’s claim that she had not received medical care and information in accordance with domestic law in a manner sufficient to ensure the protection of her interests. Consequently, there was a violation of Article 8 of the Convention in its procedural aspect.\textsuperscript{39}

Despite the broad discretion in cases related to reproductive health, in Costa and Pavan v. Italy\textsuperscript{40} the Court recognized the inconsistency of Italian national legislation in the regulation of preimplantation diagnostics and the use of assisted reproductive technologies, which led to human rights violations. The applicants were healthy carriers of cystic fibrosis and they had a child with the disease. Before having any more children, the applicants sought access to medically-assisted procreation techniques so they could have the embryos screened prior to implantation. In Italy, however, medically-assisted procreation was available only to sterile or infertile couples or where the man had a sexually transmissible viral disease, and the embryo screening (or pre-implantation diagnosis) was prohibited. The Court discovered that Italian domestic law lacked consistency: on the one hand, it prohibited the screening of embryos, a technique that made it possible to select

\textsuperscript{38} European Court of Human Rights. A.K. v Latvia, No 33011/08, 24 June 2014.

\textsuperscript{39} European Court of Human Rights. A.K. v. Latvia, para. 94.

\textsuperscript{40} European Court of Human Rights. Costa and Pavan v. Italy, No 54270/10, 28 August 2012.
only those not infected with cystic fibrosis for implantation, on the 
other hand, it permitted the abortion of a foetus infected with the 
same disease. The applicants did not have an opportunity to use pre-
implantation diagnosis and in vitro fertilisations. The only option they 
had was to conceive a child naturally, make a prenatal testing and 
terminate pregnancy in case of discovering the foetus development 
abnormalities. The Court concluded that there had been a violation of 
Article 8 of the Convention.

In cases where artificial insemination and termination of pregnancy 
for medical reasons are permitted in national legislation, prenatal 
diagnostics should not be prohibited, which makes it possible to make 
a decision on keeping or terminating pregnancy if a fetal defect is 
detected.

IV.3. Human Cloning 
and Germ Line Modification Prohibition

Genetic technologies are developing so fast that law falls behind 
with responding to these changes. Nevertheless, in modern conditions, 
there are still certain restrictions and prohibitions in the use of such 
technologies that can be considered quite justified. Thus, it is forbidden 
to carry out reproductive human cloning and edit the germline in such 
a way that the change becomes hereditary. We will attempt to find out 
what acts constitute the international legal framework regulating human 
cloning and germline modification and identify national approaches to 
the regulation of these issues.

The possibility of human cloning is both an ethical and a legal 
problem: you can never know for sure what consequences may be brought 
about by the interference in the natural process of human creation. Prof. 
Paul A. Kalinichenko notes that “from a legal point of view, human 
cloning conflicts with a number of the most important rights of the 
individual, with the right to human dignity and the resulting right to 
the integrity of the individual. There is no need to even talk about the 
legal problems that the appearance of a human clone will lead to. The 
first problem will be the question of whether a human clone will be 
a subject of law, and if so, whether its legal personality will coincide
with the legal personality of the original. A colossal legal puzzle will be provoked by the settlement of relations between the original personality and his clone, at least in terms of identity identification (who is who), succession, family relations, etc.” (Kalinichenko, 2002, pp. 45–48).

There are two types of cloning, namely: reproductive and therapeutic. Reproductive cloning refers to artificial reproduction in laboratory conditions of a genetically exact copy of any living being (Dolly the sheep, born at the Roslin Institute in Edinburgh, is an example of the first case of such cloning of a large animal). Therapeutic cloning is carried out for medical purposes (embryo development is limited to a period of 14 days; the embryonic cells formed during this time can later turn into specific tissue cells of individual organs: heart, kidneys, liver, pancreas, etc. and be used in medicine for the treatment of many diseases).

Reproductive cloning is prohibited in many countries at the legislative level (Lo, Parham and Alvarez-Buylla, 2010, pp. 16–20). Moreover, such a prohibition is enshrined in international legal instruments. Carmel Shalev, an academic lawyer and ethicist, who specializes in health, medicine, biotechnology and human rights, wrote, “A ban on cloning constrains two important liberties: freedom of reproduction and freedom of science. The essence of liberty is that it may not be constrained, except to protect the liberty of another person or a strong public interest. Proposed justifications to prohibit reproductive cloning are based primarily on concern for human dignity and the moral status of the human embryo” (Shalev, 2002, pp. 137–151).

Reproductive cloning is prohibited by such international instruments as the Universal Declaration on the Human Genome and Human Rights of 1997 (Article 11 of the Declaration states that “practices contrary to human dignity, such as human reproductive cloning, are not allowed”), the United Nations Declaration on Human Cloning of 2005, the Additional Protocol to the Convention on the Protection of Human Rights and Dignity in Connection with the Application of Advances in Biology and Medicine concerning the Prohibition of Cloning of Human Beings (SED No 168) (hereinafter the Protocol on the Prohibition of Cloning). The Protocol establishes an absolute prohibition on human cloning. Article 1 of the Protocol on the Prohibition of Cloning states,
“Any intervention seeking to create a human being genetically identical to another human being, whether living or dead, is prohibited.”

The preamble of the Protocol on the Prohibition of Cloning emphasizes that “the instrumentalisation of human beings through the deliberate creation of genetically identical human beings is contrary to human dignity and thus constitutes a misuse of biology and medicine,” human cloning can give rise to “serious difficulties of a medical, psychological and social nature.” The Protocol on the Prohibition of Cloning is mandatory for its participants. It is the only binding international treaty banning reproductive cloning. It entered into force for 24 States of the Council of Europe. Russia is not a party to this international treaty.

Though there exist only one international treaty and several declarative acts prohibiting reproductive cloning, such a prohibition is contained in many national laws (at least 50 countries) (Matthews, 2009, p. 20), including Russia. In countries where the prohibition is not explicitly established, as a rule, this issue is not settled at all. At the same time, it will be difficult to find a State that has directly allowed such a practice at the legislative level. In general, there is a consensus between countries on the issue of reproductive cloning: it is either prohibited or not regulated at the national level.

Despite the fact that the Protocol on the Prohibition of Cloning has entered into force for a small number of States, and not all States have an outright prohibition concerning such activities, the provision on the prohibition of human reproductive cloning exists as an opinio juris. This statement is supported by the existence of a large number of countries that enshrined a prohibition on reproductive cloning in their legislation, the absence of opposing opinions of States on this issue, and the existence of a number of international recommendation acts indicating inadmissibility of human reproductive cloning.

At the same time, the regulation of therapeutic cloning differs significantly from one jurisdiction to another. There is no ban on therapeutic cloning at the international level, and there are no strict restrictions for this activity, which means that States retain ample opportunities to address this issue at the national level in accordance
International acts do not explicitly prohibit therapeutic cloning. The Council of Europe Convention for the Protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine: Convention on Human Rights and Biomedicine (SED No 164) in Article 18 establishes that “where the law allows research on embryos in vitro, it shall ensure adequate protection of the embryo.” The UN Declaration on Human Cloning calls for prohibiting “all forms of human cloning in as much as they are incompatible with human dignity and the protection of human life.” The phrase “all forms” can also be attributed to therapeutic cloning, but “human dignity” and “human life” in many European countries are protected since the moment of birth rather than at the stage of embryonic development. In the Inter-American Human Rights protection system, where the beginning of life is determined by the moment of conception, an embryo created and maintained \textit{in vitro} and not implanted into a woman’s body is not recognized as a “human being.”\footnote{Inter-American Court of Human Rights. Artavia Murillo et al. v. Costa Rica. Judgment of 28 November 2012.} In this regard, the ambiguous provisions of the UN Declaration on Human Cloning that need interpretation, can hardly be applied in matters of therapeutic cloning permissibility.

The issues of therapeutic cloning are not regulated in many jurisdictions, national laws do not contain either a direct prohibition or permission for such activities, \textit{e.g.}, Denmark, India, China, Finland, South Korea (Matthews, 2009, p. 20). Russia can also be classified as a country where there is no unambiguous regulation of therapeutic cloning. Although the existing Federal Law No 180-FL of 23.06.2016 “On Biomedical Cell Products” partially regulates the issues of therapeutic cloning, due to substantive, technical and legal imperfections, it does not provide legal certainty in this area. There are States where therapeutic cloning is prohibited along with reproductive cloning, despite the fact that the purpose of such cloning is not to create a human being identical to another. Such prohibition exists in Austria, Italy, Canada, Latvia, Lithuania, the Netherlands, France, Switzerland. At the same time, in

with social and scientific priorities, as well as cultural, religious, ethical characteristics of individual countries.
some States, therapeutic cloning is directly permitted and regulated in legislation. Such countries include Belgium, Great Britain, Spain, Saudi Arabia, Singapore, Sweden (Matthews, 2009, p. 20). In addition, many States have the rule that allows research involving human embryos up to the 14th day after fertilisation (the stage of development equivalent to the time of completion of embryo implantation), which allows to achieve both practical and ethical goals. At the same time, there are discussions about increasing this period up to 28 days in order to expand scientific opportunities (Appleby and Bredenoord, 2018).

The conclusion is that the analysis of existing legislation on cloning in different jurisdictions indicates strong evidence of state practice and *opinio juris* supporting the prohibition of reproductive cloning. At the international level, there are no legally binding documents prohibiting therapeutic cloning. States enjoy a wide margin of appreciation to determine regulation in this area.

Another prohibited action refers to germline modification. Most countries with the legal framework for the regulation of biomedical developments either prohibit or severely restrict the use of human germline editing technologies (Isasi, Kleiderman and Knoppers, 2016; Araki and Ishii, 2014). The prohibition is enshrined in the Universal Declaration on the Human Genome and Human Rights and the Oviedo Convention. Under Article 13 of the Oviedo Convention, “an intervention seeking to modify the human genome may only be undertaken for preventive, diagnostic or therapeutic purposes and only if its aim is not to introduce any modification in the genome of any descendants.” The Parliamentary Assembly of the Council of Europe highlighted in its Recommendation 2115(2017), “Deliberate germline editing in human beings would cross a line viewed as ethically inviolable.”

The Oviedo Convention has entered into force in only 29 of the 47 Council of Europe Member States. Countries have different opinions of the regulation proposed by the Oviedo Convention. The United Kingdom did not sign the Convention because it was considered too restrictive, on the contrary, Germany deemed it too permissive.

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The EU regarded germline gene modification as conflicting with the fundamental values of the European legal order. In the words of the Preamble of the “Biotech Directive” (1998), there is “a consensus within the Community that interventions in the human germline and the cloning of human beings violate ‘ordre public and morality’.” Correspondingly, Article 6 of the Biotech Directive excludes from patentability “processes for modifying the germline genetic identity of human beings” and “processes for cloning humans” (Van Beers, 2020). Due to the fact that at the moment no country authorizes direct editing of the germline, taking into account the acts of soft law and the Oviedo Convention, it can be stated that editing the germline is prohibited. However, researchers and States differ in their opinions on this issue more than on the issue of reproductive cloning.

In 2020, the CRISPR Journal published the results of the research on germline editing regulation in different countries. Scientists identified five counties where germline modifications are prohibited with some exceptions: these are Belgium, Colombia, Italy, Panama, United Arab Emirates (Baylis, Darnovsky, Hasson and Krahn, 2020, pp. 365–377). For example, in Belgium “germline genome editing is permitted for corrective purposes (meaning elimination or correction of genetic diseases), if approval of the local ethics committee and the Federal Commission on scientific research on embryos in vitro is obtained” (Pennings, 2020, pp. 266–280). The official statement of the Chinese scientist He Jiankui about the birth of children with the edited DNA in 2018 represents a vivid illustration of the weakness of this prohibition. In the Report of the Second International Summit on Human Genome Editing where this statement was made, the actions of the scientist were assessed as irresponsible and failing to conform to international norms (The National Academies of Sciences Engineering Medicine, 2018). It is reported that He Jiankui was sentenced in China to 3 years in prison. Nonetheless, it is obvious that the announcement of the birth of children with the modified DNA attracted even a greater interest of scientists and certain countries to the development and application of new genetic technologies. One would like to hope that the existing national and international legal mechanisms will develop together with technologies and it will prevent their uncontrolled and unsafe use.
V. Conclusion

The UNESCO Declaration on the Human Genome and Human Rights of 1997 and the Universal Declaration on Bioethics and Human Rights of 2005, as well as the UN Declaration on Human Cloning of 2005 defined initial contours of international legal regulation for the use of genetic technologies. However, a number of vital problems, such as the lack of certainty in defining the legal status of the human genome, the absence of legally binding bans on the reproductive cloning of humans and “chimeric experiments,” no legal consolidation of ethical principles regulating manipulations with the human genome, to name a few, were not resolved. Some of these lacunae were filled later on as the process of international legal regulation of these issues continued at the regional level within the framework of the Council of Europe.

The Oviedo Convention and its additional Protocols specified the principles of human rights protection in carrying out medical activities and applying genetic technologies. Despite the fact that the Oviedo Convention and the Protocols thereto entered into force for a comparatively small number of countries, they have become a reference standard for the legal regulation of bioethical issues and the use of genetic technologies carried at the UNESCO, WHO and the European Union.

Informed consent is a fundamental principle that protects human rights in the circumstances of genetic treatment or in a situation when individuals are engaged in genetic research. This principle is not only enshrined in the Oviedo Convention but also reflected in the European Court of Human Rights jurisprudence. The ECtHR interpretation of this principle sheds light on how countries should apply it. The ECtHR is also a major instrument in protecting reproductive rights, including the situations of access to genetic diagnostic technologies.

The analysis of the existing national legislation on cloning in different countries indicates strong evidence that the state practice and opinio juris supporting the prohibition of reproductive cloning have been formed, but within the Council of Europe states enjoy a great deal of discretion in regulating therapeutic cloning. Germline modifications are prohibited by the Oviedo Convention and the soft law, but de facto
legal regulation in this field is a developing process and it is hard to predict what positions on these issues would be taken by various countries in the near future.

In conclusion, one can single out the following main features that constitute the basis of today’s international legal framework regulating the application of genetic technologies:

— the prohibitions of reproductive human cloning and germline modifications have been firmly established;

— informed consent has become a feature of fundamental importance in the field under study;

— at the regional level, the Council of Europe plays a significant role establishing its guidelines in the sphere of biomedicine and human rights. At present they are laid down in the Oviedo Convention and the Protocols to it, as well as in the ECtHR jurisprudence and the soft law provisions on the use of genetic technologies (such as ensuring the protection of the embryo where law allows research on embryos in vitro; the recognition of the fact that prenatal genetic diagnostics should not be prohibited if artificial insemination and termination of pregnancy for medical reasons are permitted in national legislation, etc.). The prohibitions and restrictions mentioned above set the limits of what is legally permissible at the global and the European level. Apart from this, the Council of Europe Member States keep enjoying a wide margin of appreciation in determining their national approaches to regulating such a sensitive sphere as the application of genetic technologies.

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