COUNCIL OF EUROPE

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# STEERING COMMITTEE FOR HUMAN RIGHTS IN THE FIELDS OF BIOMEDICINE AND HEALTH (CDBIO)

## Legislative developments on nuclear transfer

This document contains comments, by delegation, on the legislative developments on nuclear transfer and their relationship with Article 18.2 of the Convention on Human Rights and Biomedicine.

**The following delegations have submitted comments[1]:**

Armenia
Austria
Azerbaijan
Belgium
Bulgaria
**Cyprus**
Czech Republic
Denmark
Estonia
Finland
France
Georgia
Germany
Greece
**Hungary**
Iceland
Ireland
Italy
Latvia
Lithuania
Luxembourg
Malta
Moldova
Montenegro
The Netherlands
Norway
Poland
Portugal
Serbia
Slovak Republic
Slovenia
Spain
Sweden
Switzerland
**Türkiye**
Ukraine
United Kingdom
Canada
European Commission
Australia
Mexico
Belarus

[1] Countries which have sent contributions in November 2025 appear in bold.

**Armenia**
(Original version)

There is no separate law on nuclear transfer and/or cloning. Legal regulation of the given problem is within the framework of the Law on transplantation of human organs and/or tissue and the Law on Reproductive health and Reproductive Rights.

**Austria**
(Original version)

I will firstly consider the international situation in this field and then the Austrian one.

The European Court for Human Rights may give advisory opinions on legal questions concerning the interpretation of the Oviedo Convention, as stated in the treaty itself.

However, the explanatory report points out, that countries have to meet decisions concerning the interpretation of concepts such as “human being”, which are not defined by the text. We do not know what might be the opinion of the European Court of Human Rights, but it is sure that countries are entitled to a certain room for interpretation.

I agree with Mrs. Reusser (Switzerland): the Oviedo Convention does not envisage any disposition for the nuclear transfer.

I think that firstly the Convention should be interpreted according to its wording, then, as stated by the Vienna Convention on the Law of Treaties, an interpretation should be given according to the will of the parties. In my opinion nobody in the CDBI, at that stage, was aware of the possibilities of cloning. The gene manipulation brought into discussion was not “cloning”.

After Dolly, the Cloning Protocol to the Convention was elaborated and I agree with Mrs. Reusser that every kind of cloning, including nuclear transfer, is embedded in the text of the Protocol. This results from the history of the treaty. There had been attempts by some states to have an expressed formulation excluding non reproductive cloning from the field of application of the protocol**.** Other states were in favour of including all kinds of cloning in addition excluding any reservations to the protocol. In the end a compromise was reached: the member states were entitled to make an interpretation of the terms “human being”, this implying that all kinds of cloning were included but are allowed to ratify the protocol with reservations. This was an agreement reached at the end, but really important. Those who are now trying to interpret the treaty in a different way, excluding some kinds of cloning from the field of application of the treaty, are neglecting to take into consideration the history of the protocol and its correct interpretation. This is my private point of view, my country has not expressed itself on this issue.

As far as Austria is concerned, I would like to draw your attention to our Fortpflanzungsmedizingesetz (law on artificial procreation) that is characterized by a certain degree of caution towards the new medical techniques. In brief, this is what it states: all what is not necessary to achieve a pregnancy, is forbidden. The new law on procreation (Fortpflanzungsmedizingesetz 2015) allows the use of IPR in strictly limited requirements and subject to well-defined conditions (see in detail the basic document on preimplantation diagnosis). This new law has been in force since 24.2.2015. However, cloning, embryo research and stem cell creation are still prohibited, while importation of embryonic stem cell lines and research on their contents are allowed.

**Azerbaijan**
(Original version)

Azerbaijan Republic has not ratified the Oviedo Convention and the Additional Protocol on the Prohibition of Cloning of Human Beings. There is no separate law on nuclear transfer and/or cloning.

**Belgium**
(Translated from French)

The Belgian law prohibits research or treatment for the purposes of sex selection, except in the cases where the selection aims at avoiding sex-related disease.

The Law of 11 May 2003 on research on *in vitro* embryos allows research on supernumerary embryos, subject to a series of conditions set out in the same Law. The latter also allows the creation of embryos for research purposes in cases where such research cannot be conducted with supernumerary embryos. It prohibits human reproductive cloning.

Research on embryos is subject to two types of checks by two different bodies: the Local Ethics Committee, which is attached to the university in which the research project is being conducted, and a Federal Commission for Medical and Scientific Research set up under the same 2003 Law.

The Law of 6 July 2007 on medically assisted procreation and the use of supernumerary embryos and gametes specifies that *supernumerary* embryos may be included in a research protocol within the meaning of the Law of 11 2003, subject to the agreement of the initiators of the parental project. The period of their use for research purposes must be specified.

At all events, if Belgium were to sign and ratify the Oviedo Convention it would have to submit a reservation to Article 18.2 of this Convention.

**Bulgaria**
(original version)

The reproductive human cloning, including for the purpose of organ, tissue and cells donation is prohibited by a provision in the Health law (art.135).

**Cyprus**
(original version)

**In 2015, the Republic of Cyprus enacted Law No. 69(I)/2015, titled: "*The Law on the Application of Medically Assisted Reproduction*". This legislation establishes the legal framework governing assisted reproductive technologies within the country. Specifically, Article 18, Paragraph 1(ε) of the Law stipulates that "the replacement of the nucleus of a gamete cell with the nucleus of a cell from a human and the subsequent creation of an embryo is prohibited." This provision explicitly prohibits the practice of somatic cell nuclear transfer, a technique that involves replacing the nucleus of a reproductive (gamete) cell with that of a somatic (body) cell to produce a human embryo. In effect, the Law bans any form of human reproductive or therapeutic cloning and the artificial creation of embryos through nuclear substitution.**

**Czech Republic**
(original version)

The Czech Republic has ratified the Oviedo Convention and the Additional Protocol on the Prohibition of Cloning Human Beings in 2001. We have many laws regulating this area, such as Act No. 372/2011 Coll., The Act on Health Services, Act No. 373/2011 Coll., On Specific Health Services, Act No. 227/2006 Coll. on research on human embryonic stem cells, Act No. 285/2002 Coll., on donation, procurement and transplantation of tissues and organs, Act No. 296/2008 Coll., on human tissues and cells, Act No. 78/2004 Coll., on the handling of genetically modified organisms and products, etc.

The most important one is the Act No. 227/2006. It says for example: Research can only be carried out in authorised workplaces; During research on human embryonic stem cells, manipulation with these cells should not result in the creation of a new individual (reproductive cloning); Obtaining human embryonic stem cells for research purposes from surplus embryos is possible if (a) the woman and the

man from whom the surplus embryo has been obtained have given written consent; (b) the surplus human embryo has been provided by the assisted reproduction center. Human embryos for the purpose of obtaining human embryonic stem cells for the purpose of research may only be provided to a legal person conducting an authorized research under this Act.

But the development of legislation is not sufficient for the technical development of the field.

Changes in laws and regulation in area of biomedicine are debated for example in the Bioethics Commission, which is the expert and advisory body of the Council for Research, Development and Innovation (it is the advisory body to the Czech Government), in the Ethical Committee of the Czech Ministry of Health, in the Research Unit for Medical Law and Bioethics, founded by the Institute of Law and State of Czech Academy of Sciences.

## Denmark

(Original version)

The interpretation of the Danish law on assisted procreation is that nuclear transfer is not allowed; it is forbidden. In connection with the discussions on amendments to the regulation in order to allow stem cell research on surplus embryos, it was stated that if new treatment could be foreseen - and this would be based on nuclear transfer technology - the question would have to be reconsidered in Parliament; it was also stated that in this case the Danish authorities had to reevaluate the use of the provisions of the convention.

According to § 25 in the Danish law on assisted procreation, biomedical research on embryos and stem cells from embryos is only allowed if research using embryos fulfills the following purposes:

1. The purpose is to improve in-vitro fertilisation or similar techniques with the purpose of provoke pregnancy.
2. The purpose is to improve techniques for genetic examinations of a fertilised egg for the purpose of determining whether a serious genetic disease or a significant chromosomal abnormity exist (PGD).
3. The research using embryos and stem cells from the embryos with the purpose of gaining new knowledge which will create better possibilities for treatment of illness.

## Estonia

(original version)

Estonia has signed and ratified the Convention for the Protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine and signed and ratified the additional protocol on the Prohibition of Cloning Human Beings.

According to the Artificial Insemination and Embryo Protection Act:
(1) An embryo preserved in vitro shall be used (§ 31. Use of embryos):
1) for transfer to a woman pursuant to the procedure prescribed in this Act;
2) for scientific research under the conditions prescribed in § 32 of this Act.

§ 32:
(1) Embryos which, in order to ensure the success of the artificial insemination or to protect the health of the child or the mother, are not transferred to a woman, and embryos which have remained unused due to circumstances specified in subsection 4 (3) or 30 (2) of this Act may be used for scientific research.
(2) The consent of the persons who donated the gametes is necessary for using an embryo for scientific research.

Subsections:
4 (3) A woman has the right to refuse to undergo artificial insemination until it is carried out and declare her consent void.
30 (2) If an embryo is not transferred to a woman within the term specified in subsection (1) of

this section, the embryo shall be used for scientific research or destroyed.
30 (1) Embryos shall be frozen in vitro and preserved in frozen form for up to seven years only by providers of specialised medical care who organise artificial insemination. Within the specified term, the embryos may be used for the purposes prescribed in § 31 of this Act.

§ 34. Term for preservation or use of embryos
An embryo may be preserved or used on the grounds prescribed in § 31 or 32 of this Act within fourteen days after fertilisation of the ovum. Preservation or use of embryos after expiry of the specified term is prohibited.

It is prohibited to perform the following acts in connection with artificial insemination of a woman (§ 35. Prohibited acts with embryo):
1) artificial fertilisation of an ovum with a sperm which has been selected on the basis of the sex chromosome contained therein, except in the cases where a gamete is selected in order to avoid transmission of a serious sex-related inheritable disease to the child;
2) creation, by way of substitution of the nucleus of a fertilised ovum by a somatic cell of another embryo, foetus or living or dead person, of an embryo with genetic information identical to that of the embryo, foetus or living or dead person;
3) fusion of embryos with different genetic information in order to create a cell fusion if at least one of the embryos is a human embryo, or fusion of a human embryo with a cell which contains genetic information different from that of the cells of the embryo and which may develop further together with the embryo;
4) creation of an embryo capable of developing by fertilisation of a human ovum with animal sperm or animal ovum with human sperm.

Penal Code: New reduction get in force 20.07.2020
Illegal Treatment of Embryo or Foetus

§ 129. Damaging of embryo or foetus
(1) Damaging an embryo or foetus by injuring, administering a substance to or performing any other act with regard to the embryo or foetus while it is in the uterus of a woman if such act results in miscarriage or the death of the embryo or foetus is punishable by a pecuniary punishment or up to five years' imprisonment.
(2) The same act, if committed by a legal person, is punishable by a pecuniary punishment. [RT I, 23.12.2014, 14 - entry into force 01.01.2015]

§ 130. Prohibited acts with embryo
(1) Human cloning or creating a human hybrid or human chimera is punishable by a pecuniary punishment or up to three years' imprisonment.
(2) The same act, if committed by a legal person, is punishable by a pecuniary punishment. [RT I, 23.12.2014, 14 - entry into force 01.01.2015]

§ 131. Abuse of human embryo or foetus
(1) Creating of a human embryo or foetus in vitro without the intention to transfer the embryo or foetus to a woman, or outside an institution duly authorised by law or without the corresponding lawful right, or preserving of a human embryo or foetus in vitro in an unfrozen form for longer than the term provided by law or performance of unauthorised transactions with an embryo or foetus is punishable by a pecuniary punishment.
(2) The same act, if committed by a legal person, is punishable by a pecuniary punishment. [RT I, 23.12.2014, 14 - entry into force 01.01.2015]

**Finland**
(Original version)

Provisions on research on embryos have been written in the Medical Research Act (488/1999). It defines embryo as the product of fertilisation, of the fusion of sperm and ovum. Strictly interpreted, it means that the product of nuclear transfer is not an embryo.

The Medical Research Act forbids research aiming to clone a human being. According to the Act on Assisted Fertility Treatments (1237/2006), section 4, it is forbidden to use cloned embryos or genetically modified embryos in assisted fertility treatments.

Based on interpretation of these sections, reproductive cloning and research aiming at reproductive cloning are forbidden in Finland, but therapeutic cloning is allowed.

Update: There are no legislative changes in this area in our country. But to clarify the present situation we amended one sentence: According to medical research act the embryo has been defined as a group of cells formed in fertilization procedure i.e. fusion of an oocyte and sperm cell; therefore the cell and group of cells formed by nuclear transfer is not considered as an embryo.

According to this interpretation experiments on nuclear transfer would remain outside of this legislation. This interpretation, however, has not been challenged, i.e. nuclear transfer experiments on human cells has not been done in our country.

## France

(Translated from French)

The French law of 6 August 2004 established a strict and absolute prohibition on so-called reproductive cloning, going so far as to define it as a crime against the "human species", on an equal footing with eugenics.

As to the prohibition of creating embryos for research purposes, the law of 6 August 2004 incorporated the principle of Article 18 of the Oviedo Convention but did allow research, on an exceptional and transitional basis (for a five-year period), on so-called supernumerary embryos (created as a result of medically assisted procreation procedures and no longer part of any parental project). Such exceptional authorisation was only possible within a very strictly controlled framework.

Subsequently, Law No. 2011-814 of 7 July 2011 (Article 41), while retaining the general principle of a prohibition, substituted a permanent system of exceptional authorisation for the former temporary one.

The provisions of Law no. 2013-715 of 6 August 2013, amending the Law of 7 July 2011, lifted the general ban and now states that ‘ no research on the human embryo or on embryonic stem cells may be undertaken without authorisation ’. The legal system has thus moved from a prohibition with the possibility of derogations to a principle of highly supervised authorisation.

More recently, Law 2021-1017 of 2 August 2021 on bioethics differentiated the legal regime applicable to research on embryos from that applicable to research on embryonic stem cells. While the former remains subject to authorisation by the Agence de la biomédecine, the latter must now be declared to the same authority. This is due to the different nature of embryos and embryonic stem cells, which do not give rise to the same ethical issues.

Among the safeguards that the legislator has imposed on the granting of authorisation for embryo research are the following: in order to be authorised, the research must have a medical purpose or aim to improve knowledge of human biology; this research may only be carried out on embryos conceived in vitro, as part of medically assisted procreation, and which are no longer the subject of a parental project; research is subject to the prior written consent of the couple or the unmarried woman from whom the embryos are derived, or of the surviving member of the couple; embryos on which research has been conducted may not be transferred for the purpose of gestation; research protocols are authorised by the Biomedicine Agency (and not implicitly); the ministers responsible for health and research may request a re-examination of the file on which the decision was based.

In view of the principles enshrined therein, the new legislation is entirely in compliance with the requirements of paragraphs 1 and 2 of Article 18 of the Oviedo Convention. Research on embryos is restricted to embryos created in vitro as part of a medically assisted procreation procedure (Article 18.2) and subject to strict rules which ensure adequate protection of the embryo (Article 18.1).

**Georgia**
(Original version)

Human cloning is prohibited in Georgia according to two major legal instruments:

a) *Law on Health care* (#1139 Is, 1997), Article 142.1.

b) *Additional Protocol on the Prohibition of Cloning Human Beings* (entered into force in Georgia on the 1st March 2001). Georgia ratified the protocol with no reservations.

No difference is made between therapeutic and reproductive cloning.

In addition, according to two Recommendations of the National Council on Bioethics of Georgia (Recommendations of 25.09.02 and 19.05.04), the Article 18.2 of the Convention on Human Rights and Biomedicine shall be interpreted so, that prohibition of creation of human embryo for research purposes shall include embryos created as a result of cloning.

**Germany**
(Original version)

The German Embryo Protection Act prohibits in Section 7 the formation of chimaerae[2] and hybrids. According to Section 7 of the German Embryo Protection Act the creation of human-animal hybrid embryos is prohibited in three different aspects.

It is prohibited
1) to unite embryos with different genetic material to a cell conglomerate using at least one human embryo or
2) to join a human embryo with a cell that contains genetic information different from the embryo cells and induces them further to develop, or
3) by fertilisation of a human egg cell with the sperm of an animal or by fertilisation of an animal's egg cell with the sperm of a man to generate an embryo capable of development.

Any violation will be punished with imprisonment up to five years or a fine.

On September, 29th 2017, the German Ethics Council delivered the Ad Hoc Recommendation „Germline intervention in the human embryo: German Ethics Council calls for global political debate and international regulation". The Council emphasizes that the technical opportunities offered by genome editing raise complex and fundamental ethical questions particularly where they are used to modify the human germline. Since research in this particularly sensitive area has been advanced at a great pace in some countries and as, however, this touches not only on national interests but also on the interests of mankind as a whole, the Ethics Council sees a need for a broadly-based discussion and for international regulation.

In its recommendation the Council mentions some of the numerous, as yet, unanswered questions and possible consequences of systematic genome manipulations in humans and requests that, in parallel to the discursive efforts on the part of the scientific community, political institutions should find ways and initiate processes to discuss the topic in an intensive, differentiated and, above all, global manner with the involvement of all relevant social groups and draw up the necessary regulatory standards as quickly and comprehensively as possible.

The full text of the ad hoc recommendation is available at
http://www.ethikrat.org/files/recommendation-germline-intervention-in-the-human-embryo.pdf
<http://www.ethikrat.org/files/recommendation-germline-intervention-in-the-human-embryo.pdf>

[2] Has been corrected according to the comments of the German delegation.

**Greece**
(Original version)

The Greek Law 3305 of 2005 concerning the application of Medically Assisted Reproduction strictly and absolutely prohibits the so called reproductive cloning (article 2.3). The Law, however, does not make any reference to therapeutic cloning.

In the articles dealing with research (articles 11 and 12), it is provided that research (either leading or not leading to pregnancy) is allowed only on *supernumerary* gametes or fertilized ova (the law does not include the word "embryo"), i.e. gametes or fertilized ova which derive from medically assisted reproduction procedures and which do not form part of a parental project any more). In these cases, authorization is required from the National Authority on Medically Assisted Reproduction, along with other conditions governing the legal framework of research.

It should be mentioned that the scientific community in Greece endorses the position of the law regarding the exclusion of an absolute prohibition of therapeutic cloning, as it is generally believed that the potential of these could be of great importance for the advancement of medicine.

The Greek National Bioethics Committee, in a recent report concerning stem cells has stated that, although the majority of the Committee's members agree with the provision of article 18 of the Convention, they believe that "the *creation of embryos using the method of nuclear transfer and the isolation of stem cells from them, should not be excluded since there exist no other alternative therapeutic techniques*". The Committee also states that albeit Article 18 of the Convention prohibits in general the creation of embryos for research purposes, nevertheless, according to the Preamble of the Additional Protocol on Cloning "some cloning techniques themselves may bring progress to scientific knowledge and its medical applications". This, according to the Committee could lead to the interpretation that therapeutic cloning be excluded from the general prohibition of article 18 of the Biomedicine Convention.

**Hungary**
(Original version)

There is no specific law dealing with nuclear transfer in Hungary.

A separate chapter (IX) of the Act CLIV of 1997 on Health Care deals with the human reproduction. Section 180 (3) prohibits the creation of embryos for research purposes. The prohibition of cloning is set in section 180 (5) and 182 (3).

**Amendment has been made in relation to the cryogenic preservation of oocytes.**

**A decree of the Minister of Internal Affairs has amended the decree of the Minister of Health (NM) 30/1998 on detailed rules for performing special procedures for human reproduction and for the disposal and cryogenic storage of oocytes and embryos.**

**The amendment to the NM decree adds a new point to the rules on the indications for the frozen storage of female oocytes, creating the possibility of freezing female reproductive cells for personal use on social grounds.**

**Annex 4 to Decree No. 30/1998. NM for "Indications for the frozen storage of reproductive cells and embryos" has been supplemented with point 1.7.**

**"1.7 *In the case of social indications – in the case of a person who is likely to experience a significant decline in the fertilization capacity of her oocyte in the future."***

**Iceland**
(Original version)

The Artificial Fertilisation Act No 55 1996 was amended in 2008 changing the definition of an embryo to include only ovum fertilised with sperm and allowing, under strict conditions, use of surplus embryos from IVF procedures to produce stem cell lines which can be used to enhance health or cure diseases. The law also allows nuclear transfer to produce stem cell lines for the same purposes.

The new definition of embryo is as follows: “Fertilised ovum at all stages of development, from fertilisation with sperm until the foetal stage.”

**Ireland**
**(Original version)**

In its ruling in the Roche v Roche case in 2009, the Irish Supreme Court found that in vitro embryos were not considered unborn under the Irish Constitution and ruled that the specific provisions of the Constitution relating to the unborn (i.e. Article 40.3.3) only applied following the implantation of an embryo in the womb. Based on this judgment embryonic stem cell research and the importation of embryonic stem cell lines created in other countries are not illegal in Ireland.

In February 2015 the Irish Government gave its approval to draft a General Scheme of legislative provisions for assisted human reproduction (AHR) and associated research. Following the completion of the General Scheme, the Government approved its publication and the drafting of a Bill on AHR based on this General Scheme. Under the proposed legislation embryonic stem cell research will be permitted in certain cases, but the creation of embryos for research (via IVF or research cloning) and other experimental practices (such as reproductive cloning) will be prohibited.

In January 2018 the General Scheme was submitted to the relevant parliamentary committee for review as part of the pre-legislative scrutiny process. This committee published the report of its review in July 2019, making recommendations which include proposals related to both broad policy objectives and more technical amendments. Its recommendations are being considered during the ongoing process of drafting the AHR Bill.

Notwithstanding the current absence of specific legislation in this area, medical practice is governed by the "Guide to Professional Conduct and Ethics for Registered Medical Practitioners" issued by the Medical Council. These guidelines state that a medical practitioner "must not take part in the creation of new forms of human life solely for experimental purposes" and "must not engage in human reproductive cloning".

**Italy**
(Original version)

Law No. 40/2004 on standards in the field of assisted procreation prohibits any kind of research on embryos, as the latter must be considered as an activity contrary to the embryo’s interests, with the sole exception of research that might (potentially) have a benefit for its health.

It is worthwhile mentioning Article 13 (experimentation on human embryos) of the Italian Law on assisted reproductive technologies N° 40 of 2004:

1. It clearly prohibits any experimentation and research on human embryos.
2. The only exception to this absolute ban is represented by research aiming at pursuing therapeutic and diagnostic purposes, intended to protect health and development of the embryo on which it is performed and when any other alternative methods are not available.

3. In any case, the law forbids:

a) production of human embryos for research or experimental purposes or for any other than that provided by this law;

b) any form of eugenic selection for the purpose of gametes or embryos and interventions that, through selection methods, manipulation or otherwise using artificial processes, are intended to alter the genetic heritage of the embryo or gamete or to predetermine genetic characteristics, except assistance with diagnostic and therapeutic purposes, under paragraph 2 of this article;

c) cloning interventions through nuclear transfer or embryo splitting or early ectogenesis, carried out both for procreation and research purposes;

d) fertilization of a human gamete with a gamete of different species and the production of hybrids or chimeras.

4. Violation of the prohibitions referred to in paragraph 1 shall be punished with imprisonment of two to six years and a fine ranging from 50,000 to 150,000 euros. In case of violation of the prohibitions referred to in paragraph 3, the penalty is increased. Mitigating circumstances competing with aggravating circumstances provided for in paragraph 3 shall not be deemed equivalent or outweigh these ones.

5. Suspension of one to three years from professional practice shall be ordered to those performing a health profession convicted of offenses under this article.

Following two recent judgments of the Constitutional Court (n°96/2015 and 229/2015), Article 13, paragraph 3b) is no longer valid but exclusively limiting this interpretation to those cases regarding access to artificial reproductive techniques for fertile couples carriers of genetic diseases.

Particularly, the Constitutional Court of Italy (Judgment No. 96 of June 5th 2015), lifted the ban preventing fertile couples, known to be carriers of severe genetic diseases, from accessing pre-implantation genetic diagnosis. The mentioned diseases shall meet the severity criteria set out in Article 6, paragraph 1, letter b) of Law N° 194, 22 May 1978 (regulating cases of voluntary abortion interventions involving pregnancies beyond 90 days), and be detected by relevant public healthcare providers. However, there is still no regulation with respect to specific methods to access PGD. The Constitutional Court provided for clear limitations and ruled that it is incumbent upon the State legislature, namely Parliament, to act. The latter has not yet taken action in this regard.

**Latvia**
(Original version)

According to Section 16 “Prohibition of Human Cloning” of the Latvian Sexual and Reproductive Health Law (in force from 29 January 2004) “It is prohibited to use any medically assisted insemination and other technologies which could result in the birth of a human being genetically identical to another living or deceased human.”
The use of techniques aimed at creating genetically identical individuals is prohibited. The type of cloning is not directly specified.
According to Section 15 of the Law, it is prohibited to create human embryos for research purposes.

**Lithuania**
(Original version)

According to the Art. 3, Par 4. Of the Lithuanian Law on Ethics of Biomedical Research, “Cloning of a human being shall be prohibited”. The Law does not specify the type of cloning. In addition, the Art. 3, Par. 2. of the same Law states that Human embryos may be subjects only of clinical observations (non-interventional trials). Other biomedical research involving human embryos, also their creation for the purposes of biomedical research shall be prohibited (...)” http://www3.lrs.lt/pls/inter3/dokpaieska.showdoc_l?p_id=326057

Taking into account the mentioned legal provisions, it could be claimed that both reproductive and research cloning would not be allowed in the country.

**Luxembourg**
(Original version)

There is currently no regulation on nuclear transfer in Luxembourg.

**Malta**
(Original version)

The Embryo Protection Act 2012 – Chapter 524 of the Laws of Malta is the 'Parent' Act governing the Fertility Sector. The Bill was passed through Parliament and provides for the protection of human embryos through the establishment of the regulatory Authority (The Embryo Protection Authority. Ever since the enactment of the first Embryo Protection Act of Malta[3] there have recurrently been significant decisions to improve access to different categories of people who experience various problems with conception ranging from infertility (be it biological or social) to genetic disorders. This article intends to update the progressive development of this law.

At the time cryopreservation of embryos was introduced and although this required the freezing of ova, many of which would be lost during the thawing phase for fertilization purposes, and also given that fertilization would be more difficult and the procedure more expensive, the law was finally accepted. The law was introduced by the nationalist government in June of 2012 and allowed the government hospital to offer IVF services to couples for a limited number of attempts. Freezing of embryos was avoided as one would fertilize only two eggs. However, it was immediately pointed out that this was difficult at time. The important stumbling block was avoided.

The procedure, as pointed out, was offered only to infertile heterosexual couples. This was a historical moment in Malta and it is no surprise that the law was not called in terms of Reproductive Technology Act, but the *Embryo Protection Act.* This set the scene for any future developments.

Upon the election of the Labour party, one of the first items tackled was the recognition of gay and lesbian couples. One could not introduce 'marriage' but legal partnerships, giving all the rights as married couples, were introduced. This of course opened the door to heterosexual couples having a right to IVF services but this was not to come immediately. The first issue tackled by the Minister of Health was to introduce embryo freezing and surrogacy. The advice given to him was that eight fertilized eggs be allowed to be frozen. Of course, this did cause controversy but the public seemed to be on the side of modernizing this law. The Bioethics Consultative Committee advised that only five embryos be frozen, and, not to introduce surrogacy at that point in time as this would be tackling one moral problem with another. It was assumed that surrogacy was to be introduced not only to help infertile couples but to help those who are not biologically, but socially infertile, that is homosexual couples, the male gay couples being most likely to have to resort to surrogacy.

The first amendment to the 2012 law was therefore in 2018, under a different President, coming from the former labour party, who was willing to sign the law. This law therefore allowed for the freezing of a limited number of embryos provided the couple did not already have cryopreserved eggs, in which case they had to be used, or, that the couple requested themselves, on moral grounds, that they wished only for the cryopreservation of their eggs, as per the existing procedure. At this stage the application of the law still applied only to heterosexual couples. The law provided that the frozen embryos had to be used by the couple and should something happen that precluded this, the embryos would be given up for adoption by the authority in charge. This was upon the recommendation to the minister by the Chairman of the Bioethics Consultative Committee at the time, in order not to allow for the possibility or the misinterpretation of the law, that embryos which remained frozen would be given up for research or indeed killed. Thus, the title of the law would be protected. In 2015 the Embryo Protection Authority Regulations were introduced to define the responsibilities and duties of the Authority in charge of overseeing IVF[4].

[3] Chapter 524, Embryo Protection Act, Laws of Malta
[4] Embryo Protection Authority Act, chapter 524, Laws of Malta

More recent change

A radical change to the law came in 2018[5], which amendment allowed for the use of IVF services not only by homosexual couples but also by single mothers. Moreover, the introduction of sperm donation (and by implication sperm banking) was allowed with the information of the donor being kept confidential other than for essential information which prospective parents would want to know – such as age, sex, race, and family history of disease which is relevant etc. The authority reserved the right to reveal information however to the parents or the child when it reaches the age of eighteen, should this be required for reasons which the same authority considered legitimate, such as disease which can be helped if the biological parent is known.

The following are brief points which this radical change to the law introduced. The aticles focus on changing changing definitions in the beginning and also on defining the parameters of the new addtions as follows:

- Art 2. 'prospective parent' means any person regardless of gender or sexual orientation who has attained age of majority
- Art 4. 'medically assisted procreation' changed to 'medically assisted procreation and gamete donation'
    - 4.1.iii.g A register is to be kept of every medically assisted procreation procedure, germ line cell-donation, cryopreservation of germ line cells, cryopreservation of embryos and embryo donation and adoption
    - 4.2 authority may give for adoption to a third party who qualifies…

- Art. 6 para (b), provides provision for the fertilisation of more than two eggs, on permission of the authority, up to a maximum of 5 eggs.
- Art. 7 amended to
    - Allow cryopreservation of sperm cells during the life time of the person they originate from
    - Cryopreservation of embryos up to a maximum of five years renewable up to a maximum permissible age for the transfer thereof into the prospective parent. The authority shall authorise the donation.

- Art 9. was substituted to allow:
    - Donation of germ line cells given a contract between donor and licensee
    - That there shall be no link of filiation
    - Donor must be over eighteen
    - Donor must not have attained age of 36
    - Identity of donor shall remain confidential; prospective parents allowed to obtain only generic information (specified in the protocol), eg, age, sex, race, etc
    - Medical records may be accessible to the child once age of 18 is reached subject to the consent of the authority and in exceptional cases before.
    - If authority becomes aware of serious illness, it shall be obliged to disclose to the parents or the child if latter has attained age of 18.
    - Donation of germ line cells are limited to one donation only which shall be used in one prospective parent only.
    - No person shall pay consideration to a donor or to any other person involved in arranging for the services.
    - There may be compensation for costs and expenses of the stimulation treatments.

- Art. 12 stipulates that: nothing in the Act shall be construed or interpreted as impeding….the taking and freezing of sperm or egg of a person with the aim of making use of that same sperm or egg at a later stage for the generation of an embryo.

- Art. 19 Status of the Child: 'shall be considered to be the child of the prospective parent or prospective parents who have expressed their consent in writing…and shall for all intents and purposes of law be deemed to have been naturally born of the same prospective parent or prospective parents…any such child shall be registered in any act of civil status as the direct

[5]Embryo Protection Amendment Act, 2018, Laws of Malta

descendent of such prospective parent of prospective parents who shall enjoy such rights and bear such duties according to law in respect of such child.

- In sub-regulation (1) of regulation 2 of the Leave for Medically Assisted Procreation National Standard Order the definition of 'prospective parents' shall be substituted by the following:
  - 'prospective parent' means any person regardless of gender of sexual orientation, who has attained the age of majority and is a receptor or user of the medically assisted procreation techniques regulated under the Embryo Protection Act…

Genetic disorders

The final act in the law to date came in 2022 when changes to allow people with genetic diseases in their family, such as Huntington's disease, would be allowed to use IVF services to eliminate any fertilized eggs containing a gene which brings about a genetics disorder.

There were two significant points in the controversy to be mentioned. The incumbent President of the Republic had frequently expressed, even before he was appointed President, that he would not sign any law to do with abortion or euthanasia and that if the government had to provide such a Bill he would resign. He was not comfortable with signing this law but on the other hand it did not provide for the freezing of embryos. This was resolved by his official visit to another country where he provided for the Agent-President (an acting President in his place during his absence) to sign the law.
Secondly the Nationalist party, as point out before, had opposed the law. It suggested the use of polar body biopsy on the ovum instead of testing a developing embryo. (Usually the cells are taken following a few days from the outer cell mass which goes on to develop the placenta and not the embryo, which will not be harmed). However, such a procedure can only detect disease from the mother's side. It is significant that following dialogue of the two parties, the Nationalist party accepted the law on the grounds that it promoted life. Having changed position took courage of course and indeed marked a probable historical event. It also proved to move itself away from a more conservative approach, which seems to be the will of the people.

Recent Bill to decriminalize Abortion for a medical reason.

A more recent Bill, indirectly affecting the Embryology Act is a Bill to amend the Criminal Code (Chapter 9, Laws of Malta). In this Bill the Minister for Health and Deputy Prime minister is proposing to decriminalise medical termination when there is danger to life of the mother. Such cases were never deemed criminal by the court but a recent case in which a non-viable pregnancy was not terminated as there was still a heartbeat created controversy. The reasoning is that once the baby is deemed to be dying, a heartbeat should not push the gynaecologist, on moral grounds, to put the woman at further risk, such as Sepsis. In ectopic pregnancies the heartbeat is ot taken into consideration so it should not affect these cases.
The Bill also contemplate situations in which grave health outcomes can be envisioned. This is still under debate.

## Moldova

(Original version)

Research on embryos is banned in the Republic of Moldova. The creation of human embryos for research purposes is prohibited.

## Montenegro

(original version)

Genetic procedures with the purpose of diagnostics, prevention and treatment are being conducted in Montenegro. Two private and one public medical facility conduct methods of medically assisted procreation. For now, Montenegro does not have the technical means for the nuclear transfer. Having in mind the importance of development of biology and medicine and possible ethical problems and dilemmas that could be encountered in practice, Article 27 of the Constitution, in its paragraph 2 states that any intervention aimed at creating a human being that is genetically identical to another human being, living or dead shall be prohibited.

Also, Paragraph 3 of the Article 38 of the Bill on medically assisted reproductions will prohibit the creation of embryo with the same heritance base or embryos which are identical in heritance bases with other living or dead persons, with the purpose of reproductive cloning. Bill will be signed into Law in forthcoming days.

**The Netherlands**
(Original version)

The **current** Embryo Act defines `embryo' as a cell or a complex of cells with the capacity to develop into a human person'. This implies that according to Dutch law, the entity created after cell nuclear transfer is considered to be an embryo, **if it has the capacity to develop into a human person.**

**The Embryo Act contains a temporary prohibition on the creation of embryos for research. This prohibition covers embryos created by cell nuclear transfer (i.e. if an embryo is created by the process of cell nuclear transfer).**

**The legal definition of embryo is currently under review as a result of an evaluation of the Embryo Act. It was recommended to modify the definition to take into account scientific developments such as the possibility to create embryolike structures using stem cells. However, this will not affect the statement above: also under the possible new definition the entity created after nuclear transfer will still be considered to be an embryo if it has the capacity to develop into a human person.**

**Norway**
(Original version)

The issues of embryonic stem cells and cloning are regulated under the Act relating to the application of biotechnology in human medicine (Biotechnology Act).

Use of embryonic stem cells

A change in the Biotechnology Act that entered into force 1st of January 2008 allows research on surplus human embryos and human embryonic stem cells originating from surplus embryos if the following conditions are met

- the purpose of the research is to develop and improve methods and techniques used in relation to medically assisted procreation or PGD, or to provide new knowledge that may contribute to develop treatment for serious diseases in humans
- the research has been approved by a regional committee for research ethics. In cases where human embryonic stem cells /cell lines are used in clinical trials or medical treatment, and additional approval from the Ministry of Health will be required.
- an informed consent has been obtained from the couple donating the embryo. If the embryo has been created from donor sperm, consent from the donor is also required.

Embryos can be used for research until 14 days after creation, and should then be destroyed. Cell lines can be grown for a longer period of time.

**Cloning**
Reproductive cloning and therapeutic cloning is forbidden.

The relevant passages of the Act are cited below:

§ 3-5 Prohibition against creating human embryos by cloning, etc.
It is prohibited:
to create human embryos by cloning,
to carry out research on cell lines derived from human embryos by cloning,
to create embryos by cloning by the technique of inserting human genetic material into an animal oocyte.

Cloning is here understood to mean techniques for creating copies that are genetically identical.

§ 3-6 Prohibition against techniques designed to create genetically identical individuals
The use of techniques designed to create genetically identical individuals is prohibited.

**Poland**
(Original version)

In Poland there are no direct legislative regulations according to the nuclear transfer in respect to art. 18,2 of the European Convention on Biomedicine. Poland still has not ratified the Convention.

The public discussion about the ratification of Convention is going on in Poland, and possibly the document will be ratified (however I can not guarantee it will happen). Polish Parliament is working on the legislative regulations of in vitro fertilization – we have no legal regulations in this field until now. The debate is of course connected with art. 18.2 of the Convention.

According to the interpretation of Polish Constitution by Polish Constitutional Tribunal the dignity of human life must be esteemed from its biological beginning; so the life of human embryo must be protected. Dr Jerzy Umiastowski thinks that according to this official opinion of the Constitutional Tribunal the procedure of nuclear transfer in human embryo is against Polish Constitution. However, this is his private point of view, and until now there is no official opinion of Polish Authorities about art.18,2 of the Convention and about nuclear transfer.

**Portugal**
(Translated from French)

Portugal has adopted a Law on medically assisted procreation which allows research on supernumerary embryos under certain conditions, as well as on the results of nuclear transfer technique, which the Law does not describe as embryos. Provision is also made for using the said results for reproductive purposes, but the Delegate is almost certain that this is a mistake or a misunderstanding.

The question of the constitutionality of this Law, which has been raised before the Constitutional Court by a group of parliamentarians, is still open.

**Serbia**
(Original Version)

The Constitution of Serbia (2006) anticipates a new paragraph on the prohibition of human cloning within the Right to life provision (Article 24).

The Law on public Health, blood transfusion, cell, tissue and organ transplantation, and AMP (2009) regulate storing and forming of biobanks. Articles 67-88 regulates research on collected cells and embryos only for improvement of therapy.

**Slovak Republic**
(Original version)

Non-therapeutic research on a living human embryo or foetus is prohibited (§26 ind. (10) lett. a) of the Law No. 576/2004 Coll. on health care, and §116 ind. (1) of the Law No. 300/2005 Coll. – Penal Code). Only research aiming at the direct health benefit of the living human embryo or foetus concerned would be allowed.

The Penal Law prohibits human cloning, without distinguishing between the “reproductive” or “therapeutic” cloning (§116 ind. (2) of the Law No. 300/2005 Coll. – Penal Code).

**Slovenia**
(Original version)

The law on medical and assisted procreation from 2000 allows research on surplus embryos but not creation of embryos for research. Regarding cloning, Slovenia has signed the additional Protocol. Up to now, only one proposal for research on embryos was received by the Medical Ethics Committee and the Committee for medical and assisted procreation, but the authorisation was not granted, because the same research was equally possible and less ethically problematic if carried out on animal embryos.

**Spain**
**(Original version)**

Update:
In November 15th 2010 was approved the Royal Decree 1527/2010 regulating the Guarantee Commission for the Donation and Use of Human Cells and Tissues and the Register of Research Projects was published in 2010.

The Royal Decree 1527/2010 establishes the procedures to assure the scientific, ethical and legal guarantees that may be demanded in relation with the research in some of the most sensitive aspects related with biomedical research. This Royal Decree includes a list of research which must be informed favourably by the Guarantee Commission for the Donation and Use of Human Cells and Tissues: a) the research that required the use of pre-embryos, b) human embryonic stem cells research, c) activation of ovocites by nuclear transfer for use for therapeutic and research purposes, d) other techniques that using human biological samples obtain pluripotent stem cell, including nuclear transference and nuclear reprogramming, e) the research with human embryonic cells and tissues obtained when it does not entail the creation of a pre-embryo or an embryo exclusively for this purpose, f) any other line of research that includes cell material of human embryonic origin or other functionally similar, and g) the research with embryonic stem cell lines that come from another country, within the EU countries or those outside the EU.

In this sense, it is interesting to point out that a research project included in the above paragraph requires the favourable report of the Ethics Committee of the research institution, the authorization of the director of the Research Centre, and finally, it is necessary the favourable report of the Commission for the Guarantees on the Donation and Use of Human Cells and Tissues. So, this regulation guarantees that any research with the participation of human beings or with biological samples of human origin should be done to fulfil with the methodological, ethical and legal provisions.

(Translated from French)

Professor Romeo-Casabona pointed out that the Law on medically assisted procreation was amended in May 2006, attaching major importance to the National Commission on Medically Assisted Reproduction, which must now give a binding prior favourable opinion on any application for authorisation of human reproduction research involving embryos and embryonal cell lines. Furthermore, a similar opinion is also required for other research goals from the Commission responsible for supervising the use of human tissues and cells.

In July 2007 Medical Research Bill was approved by the Spanish Parliament. This text concerns, *inter alia*, authorisation of research projects on stem cells and techniques for producing such cells, including nuclear transfer and other techniques capable of reprogramming somatic cells in order to obtain stem cells. The Bill refers to Article 18.2 of the Oviedo Convention.

Specifically, the Article 33 says: 1. The creation of human preembryos and embryos exclusively for experimentation purposes is prohibited. 2. The use of any technique for obtaining human stem cells for therapeutic or research purposes is allowed, always when it does not entail the creation of a pre-embryo or an embryo exclusively for this purpose, in the terms provided in this Law, including the activation of ovocites through nuclear transfer.

The Delegate has presented his Government with an opinion intended to demonstrate this Bill's

conformity with Article 18.2. He considers that it is possible to legitimate the regularisation of nuclear transfer and other cell reprogramming techniques in order to obtain stem cells for research or future treatment, with full respect for the Convention and Additional Protocol. He points out that in 1997 reproductive cloning was not on the agenda, and that no one could have envisaged at the time that stem cells would one day be used to produce regenerative cells; and that non-reproductive cloning lies outside the scope of the Protocol on cloning, because the use of such techniques is not geared to creating a human being genetically identical to another; and finally that the Additional Protocol leaves it to States Parties to decide whether the immediate outcome of cloning (i.e. the initial phases of development), whatever the desired aim, is a human being or not within the meaning of the said Protocol – Professor Romeo recalls that when the Netherlands signed the Additional Protocol they defined a human being as an individual who had already been born. This meant that the use of this technique for non-reproductive purposes was not subject to the prohibition of creating a human being genetically identical to another. An extensive interpretation of the Convention, and more specifically of Article 18, beyond what might reasonably be deduced from its interpretation in its own spatiotemporal context, might involve a non-consented limitation of the sovereignty of States Parties by setting out restrictions that are more far-reaching than those voluntarily accepted under the act of ratification and acceptance of the Convention (see 1969 Vienna Convention on the Law of Treaties).

(Original version)

Professor Alonso said that the cell resulting from the nuclear transfer is qualitatively different from that generated by fertilization of an oocyte by a spermatozoid and therefore it would be difficult to call that cell an embryo. These two entities differ from the biological and biochemical point of view and also when considering their potential. The sperm fertilized oocyte (embryo) has a nucleus formed at singamy from the fusion of the haploid female and male pro-nuclei while the cell resulting from the transfer of a nucleus from a somatic cell has a different nature, having a diploid nucleus already formed before the transfer. Also, the DNA of the male and female haploid nuclei does not have the epigenetic transformations that are present in the nucleus transferred to the oocyte. In addition, the movement of the male and female chromatin-chromosomes along a mitotic plaque (metaphase spindle) necessary for the formation of the diploid nucleus of the sperm-oocyte embryo does not occur in the oocyte after nuclear transfer. These two peculiarities lead obviously to the existence of biochemical differences between both cells. In addition, an oocyte that has been fertilised by a spermatozoid becomes a blastocyst by virtue of its own biochemical mechanisms while the cells resulting from nuclear transfer to oocytes will very rarely reach a blastocyst stage, and only under very particular conditions. The delegate said that, even if these cells may form a blastocyst, the original cell should not be considered an embryo at the time of the transfer. To behave as an embryo the cell resulting from nuclear transfer has to go through profound changes such as de-differentiation and trans-differentiation. Similar changes do not occur in the sperm-oocyte embryo. He added that these may be some reasons why the Spanish bill, if adopted, could allow nuclear transfer for non-reproductive purposes.

**Sweden**

(Original version)

Since 2005 nuclear transfer is permitted in Sweden, as to create fertilised eggs solely for research purposes. So, when ratifying the Convention which they haven't done yet, they will have to make a reservation on article 18.2.

Concerning the scientific situation, there is at the time being about 50 embryonic stem cell lines established from left over eggs from in vitro fertilisation. Concerning research on eggs solely done for research purposes, there's no project admitted or submitted to ethical research committee.

**Switzerland**
(Translated from French)

The Convention provides no definition of the concepts of “human being” and “embryo”, which is why the concept of embryo as used in Article 18 requires interpretation.

The rules on interpreting international conventions are set out in the Vienna Convention on the Law of Treaties of 23 May 1969. To the best of my knowledge, all Council of Europe member States have adhered to this Convention. Article 31 (1) provides that a treaty must be interpreted in good faith in accordance with the ordinary meaning to be given to the terms of the treaty in their context and in the light of its object and purpose. In addition to context, consideration should also be given to any relevant rules of international law applicable in the relations between the parties [Article 31 (3) (c)]. Recourse may also be had to supplementary means of interpretation, including the preparatory work of the treaty and the circumstances of its conclusion (Article 32).

Work began on drafting the Convention on Human Rights and Biomedicine in 1990. In June 1996 the CDBI transmitted the text of the Convention to the Committee of Ministers for decision. The Committee of Ministers adopted the Convention in November 1996. When the various provisions were being drawn up, no one could have known that human life could also be created by transferring the nucleus of a somatic cell into an ovum from which the nucleus had been removed. The explanations set out in the explanatory report on Article 18 para. 2 of the Convention are very concise. It is traditionally accepted that an embryo is the result of the merger of the nuclei of the spermatozoon and the ovum. The Swiss Federal Law on medically assisted procreation provides the same definition of the embryo.

The Council of Europe reacted quickly to the public concerns expressed after the birth of Dolly, the first cloned sheep, in February 1997. In June 1997 the CDBI tabled a draft Additional Protocol prohibiting the cloning of human beings. On 7 November 1997 the Committee of Ministers adopted this protocol. According to paragraph 1 of the Explanatory Report, the Additional Protocol builds on certain provisions of the Convention on Human Rights and Biomedicine, particularly Article 18 (2). Paragraph 2 of the Report states that the Additional Protocol targets the “cloning of human beings, for example by utilising the techniques of embryo splitting or nuclear transfer”, regardless of whether the clones are created for the purposes of research or reproduction.

The genesis of the Convention on Human Rights and Biomedicine shows that Article 18 para. 2 does not apply to nuclear transfer, which is why an Additional Protocol was adopted to settle this specific point. Although the provisions of the Convention may be further developed under a “contemporary” interpretation, the fact that the Additional Protocol settles the issue of nuclear transfer means that an extensive interpretation of the embryo concept in accordance with Article 18 para. 2 of the Convention would, in my view, be incompatible with the principle of good faith.

**Türkiye**
**(Original version)**

“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” was ratified into our domestic law by the Law No. 5013 dated 03.12.2003 on the “Ratification of 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”.

In this context There is no regulation in our legislation that is contrary to the Oviedo Convention and on matters related to “The creation of human embryos for research purposes" and " The use of techniques of medically assisted procreation shall not be allowed for the purpose of choosing a future child's sex, except where serious hereditary sex-related disease" as specified in the Oviedo Convention.

**Regarding medically assisted reproductive treatments;**

With the Law dated 15.11.2018 and numbered 7151, an additional article was added to the "Law on Organ and Tissue Procurement, Storage, Vaccination and Transplantation" dated 29.5.1979 and numbered 2238, and with this article; "*In cases where it is not possible to have a child naturally or there*

*is a medical necessity, reproductive cells or embryos can be applied to the expectant mother by making the reproductive cells of the woman and/or man suitable for fertilisation by medical methods and ensuring fertilisation inside or outside the body. This method can only be performed between spouses who are married. These treatment applications can only be performed by physicians authorised by the Ministry and in assisted reproductive treatment application centres licensed by the Ministry within the framework of the medical principles determined by the Ministry. The procedures and principles of opening, operating and inspecting assisted reproductive treatment centers are regulated by the regulation issued by the Ministry. It is forbidden to have children and engage in surrogate motherhood by applying the reproductive cells taken from one or both spouses and the embryos obtained from these cells to other people. It is forbidden to carry out a donation process by using someone else's reproductive cells and/or embryos, and to donate, sell, keep, use, store, transport, import, export and mediate these transactions*." provisions have been introduced.

In addition, with the "Regulation on Assisted Reproductive Treatment Practices and Assisted Reproductive Treatment Centers"; the principles of the implementation for married couples unable to have children, who are deemed medically appropriate, to have children through assisted reproductive treatment methods, and the procedures and principles regarding the opening, operation and supervision of the centers that will carry out this practice are regulated.

Besides, in subparagraph (e) of the 3rd paragraph of Article 18 of the "Regulation on Genetic Diseases Evaluation Centers" published in the Official Gazette dated 10.01.2020 and numbered 31004;

"*In preimplantation genetic diseases diagnosis and prenatal diagnosis applications, genetic examination cannot be performed only for the purpose of sex determination without medical indication. Gender cannot be specified in preimplantation examination reports in cases other than gender anomaly. The licence of the Centre that acts contrary to this shall be cancelled."* and in subparagraph (h); "*Identification using STR or other polymorphic markers is not permitted in the Centre except for medical reasons (maternal contamination in prenatal diagnosis, suspicion of material adulteration, chimerism, etc.). In case of identification for medical reasons, there shall be a signed note from the doctor and the person's informed explicit consent is obtained*."

**Türkiye remains a Party to the Oviedo Convention and maintains its alignment with Article 18.2, which prohibits the creation of human embryos for research purposes.**

**National legislation continues to regulate assisted reproduction, genetic research, and embryological studies under the Regulation on Assisted Reproductive Treatment Centres (ÜYTE) and the Embryology Laboratory Standards Regulation, both under the Ministry of Health's oversight.**

**There have been no legislative changes authorising or expanding nuclear transfer or cloning practices for biomedical purposes. Such activities remain prohibited under existing ethical and medical research frameworks.**

**Türkiye's legal environment therefore remains fully consistent with Article 18.2 of the Convention, ensuring that all research involving human embryos adheres to principles of dignity, safety, and non-creation for research purposes.**

**Ukraine**

(Original version)

The Law on Health Protection and the Criminal Law prohibit non-therapeutic cloning and non therapeutic research on embryo.

**United Kingdom**
(Original version)

In 2004, the United Kingdom began a major review of its legislation on assisted reproduction and embryo research. This review resulted in the passing of the Human Fertilisation and Embryology Act 2008 (2008 Act), which received Royal Assent in November 2008. The 2008 Act amends and updates the Human Fertilisation and Embryology 1990 Act. The majority of the 2008 Act came into force on 1 October 2009, and the remaining sections relating to Parental Orders came into force 6 April 2010.

One of the key changes brought about by the 2008 Act concerned the definition of a human embryo. The 2008 Act amends the 1990 Act to include embryos created by processes other than fertilisation, such as cell nuclear transfer. The 1990 Act, as amended, now specifically prohibits the use for reproductive purposes of any embryo not created by fertilisation. The Human Reproductive Cloning Act 2001 was repealed on 1 October 2009.

The 1990 Act, as amended, also refers to inter-species embryos, described in the 1990 Act, as amended, as "Human Admixed Embryos". The 1990 Act, as amended, permits the creation of human admixed embryos for research purposes only. This followed extensive public consultation and debate in both Houses of the UK Parliament. The creation of human admixed embryos can only take place under a licence from the UK national regulator, the Human Fertilisation and Embryology Authority (HFEA). Licences for embryo research will only be issued where the HFEA is satisfied that the use of embryos, including human admixed embryos, is necessary and that the research is necessary or desirable for the purposes specified in the Act. There is no change to the requirement that embryos may only be used by researchers for a maximum of 14 days or until the appearance of the primitive streak if earlier.

**Canada**
(Original version)

The *Assisted Human Reproduction Act* (AHR Act) received Royal Assent on March 29, 2004. On December 22, 2010, the Supreme Court of Canada (SCC) issued its ruling on the constitutionality of certain sections of the *Assisted Human Reproduction Act* (AHR Act) and ruled that some key sections exceed the legislative authority of the Parliament of Canada. The prohibitions against cloning were not subject to the court challenge and remain in force. The use of nuclear transfer technologies for the purposes of cloning continues to be prohibited under the AHR Act where no person shall knowingly create a human clone by using any technique, or transplant a human clone into a human being or into any non-human life form or artificial device (s. 5(1)(a)). The AHR Act thus prohibits the use of any technique, which includes nuclear transfer,for the purposes of creating a human clone whether it would be for the purpose to derive stem cells (also known as therapeutic cloning) or for the purpose of creating a cloned human being (also known as reproductive cloning).

The Act requires that certain conditions be met before an *in vitro* embryo can be used for research, including:
- the donor(s) of the *in vitro* embryo must have given fully informed and written consent to the use of the embryo for the purpose of research (s. 8);
- the *in vitro* embryo must no longer be needed for reproductive purposes, as an *in vitro* embryo can only be created for the following purposes: to create a human being or improving or providing instruction in assisted reproduction procedures. An *in vitro* embryo must not be specifically created for research purpose (s.5(1)(b)); and
- no one must have purchased, sold or advertised for the purchase or sale of the *in vitro* embryo(s) (s. 7(2)).

**European Commission**
(Original version)

On 30 September 2002, the Council adopted the specific programme implementing the Sixth Framework Programme for research, technological development and demonstration: *"Integrating and*

*strengthening the European Research Area"* (2002-2006) (Decision 2002/834/EC30 — hereinafter referred to as "the specific programme").

The specific programme allowed the funding of research activities involving the use of human embryos and human embryonic stem cells except in three areas:

– research activity aiming at human cloning for reproductive purposes (reproductive cloning),

– research activity intended to modify the genetic heritage of human beings which could make such changes heritable (germline gene therapy)31,

– research activities intended to create human embryos solely for the purpose of research or for the purpose of stem cell procurement, including by means of *somatic cell nuclear transfer* (commonly referred to as therapeutic cloning).

DECISION No 1982/2006/EC OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

of 18 December 2006 concerning the Seventh Framework Programme of the European Community for research, technological development and demonstration activities (2007-2013)

Article 6 (2nd §):

The following fields of research shall not be financed under this programme:

– research activity aiming at human cloning for reproductive purposes,

– research activity intended to modify the genetic heritage of human beings which could make such changes heritable,

– research activities intended to create human embryos solely for the purpose of research or for the purpose of stem cell procurement, including by means of somatic cell nuclear transfer.

**Australia**
(Original version)

Background

The National Health and Medical Research Council (NHMRC) is Australia's peak body for the support of health and medical research, the maintenance of ethical standards for research involving humans and the development of authoritative health advice and guidelines. The functions of NHMRC come from the statutory obligations conferred by the *National Health and Medical Research Council Act 1992* (NHMRC Act). NHMRC comprises its Council, Principal Committees, staff and Chief Executive Officer (CEO of NHMRC).

In addition to its roles listed above, NHMRC is responsible for administering national legislation for the regulation of research involving human embryos and the prohibition of human cloning for reproduction. The NHMRC Embryo Research Licensing Committee, a Principal Committee of NHMRC, was established under the *Research Involving Human Embryos Act 2002* (RIHE Act) to oversee human embryo research in accordance with the regulatory framework required by the RIHE Act. It is also responsible for administering the *Prohibition of Human Cloning for Reproduction Act 2002* (the PHCR Act).

Effect of the Amendment Act

Following a review of the 2002 legislation in 2005, the passage of *Prohibition of Human Cloning for Reproduction and the Regulation of Human Embryo Research Amendment Act 2006* (the Amendment Act) in December 2006 expanded the range of licensable activities as summarised below.

The Amendment Act retained existing prohibitions on activities such as:

- placing a human embryo clone in the human body or the body of an animal;
- importing or exporting a human embryo clone;
- creating a human embryo by fertilisation of a human egg by human sperm, for a purpose other than achieving pregnancy in a woman;
- creating or developing a human embryo by fertilisation of human egg by human sperm which contains genetic material provided by more than 2 persons;
- developing a human embryo outside the body of a woman for more than 14 days;
- making heritable alterations to a human genome;
- collecting a viable human embryo from the body of a woman;
- creating a chimeric embryo;
- developing a hybrid embryo beyond 14 days;
- placing a human embryo in an animal, a human embryo into the body of a human other than into the female reproductive tract or an animal embryo in a human; and
- importing, exporting or placing in the body of a woman, a prohibited embryo.

The Amendment Act also permitted researchers to:

- use excess ART embryos;
- create human embryos other than by fertilisation of a human egg by a human sperm, and use such embryos for research;
- create human embryos (by a process other than fertilisation of a human egg by human sperm) containing genetic material provided by more than 2 persons, and use such embryos for research;
- create human embryos using precursor cells from a human embryo or a human foetus, and use such embryos for research;
- undertake research and training involving the fertilisation of a human egg, up to but not including the first mitotic division, outside the body of a woman for the purposes of research or training;
- create hybrid embryos by the fertilisation of an animal egg by human sperm, and develop such embryos up to, but not including, the first mitotic division provided that the creation or use is for the purposes of testing sperm quality and will occur in an accredited ART centre.

The legislation was reviewed again in 2011 and we are currently awaiting the Government's response to the report of the legislative review which was chaired by The Hon Peter Heerey QC.

## Mexico

(original version)

### EMERGING ISSUES IN BIOETHICS

### 1. Spindle transfer and assisted reproduction

#### Bioethical aspects of Mitochondrial Replacement Techniques

The latest advances in attention to infertility have forced to consider many aspects of human reproduction under a new light. Beside the undoubted benefits that these techniques suppose, there are also different ethical and legal issues that must be resolved.

#### The National Bioethics Commission (CONBIOETICA) on assisted human reproduction

Regarding the case of spindle transfer in Mexico, an official statement was issued in 2017,[6] which offers an assessment on the bioethical aspects of the procedure. In this regard, the statement emphasizes that, as an experimental technique, the legal framework in place at the time for the conduction of

[6] CONBIOETICA (2017). Bioethical assessment on human reproduction, with a focus on spindle transfer techniques [Consideraciones bioéticas en torno a la reproducción humana asistida, con referencia específica a la técnica de reemplazo mitocondrial].
https://www.gob.mx/cms/uploads/attachment/file/470839/9._RHA_reemplazo_mitocondrial_2017.pdf

research protocols with human subjects was more than sufficient to ensure protection for the participant and ensure the integrity of the process; however, these legal criteria were omitted.

**Normative Framework in Mexico**

Considering that spindle transfer still constitutes an experimental procedure, there is no specific legislation required in our country at all. In this regard, the General Health Law, the regulations on health research, the regulations on the provision of health care services and other secondary rules, are all instruments that police every aspects of the conduction of scientific research in health, including requirements for the participation of human subjects and the supervision of diverse committees.

In Mexico, conducting research with human subjects is a well-regulated process, to ensure that the research process is conducted with scientific rigor, as well as in an ethical manner, protecting participants and guaranteeing the validity of the results. Regulations seek to guarantee the dignity, well-being and safety of research subjects. They consider the following aspects:

- Study Design: Researchers develop a detailed research protocol, which includes objectives, methodology, and ethical considerations. Research must be scientifically and ethically justified, to ensure that the subject is not exposed to unnecessary risks, while contributing to advance our knowledge on health and disease.

- Institutional Review: The protocol requires approval by a Research Committee, a Research Ethics Committee and, if necessary, also by a Biosecurity Committee. These committees ensure that the study complies with ethical and scientific regulations.

- Informed Consent: It is essential to obtain informed consent from all participants, clearly explaining the risks, benefits, and nature of the research. informed consent must be obtained from the research subject or his or her legal representative.

- Regulatory Approval: Depending on the nature of the study, approval from the appropriate health authorities, such as the Federal Commission for the Protection against Sanitary Risks (COFEPRIS), may be necessary.

- Study Execution: The study is conducted according to the approved protocol, always keeping an eye on the well-being of the participants.

- Monitoring and Reporting: During and after the study, results are monitored and reported to the appropriate committees and authorities, ensuring transparency and ethical compliance.

One of the main goals of the National Bioethics Commission consists in fostering scientific innovation in healthcare in line with ethical principles. In this regard, CONBIOETICA has contributed in the construction of a regulatory framework in the field of assisted human reproduction, to ensure these procedures are carried out on the basis of scientific evidence, informed consent and within a framework of legal certainty, in order to address infertility and the prevention of genetic diseases. To this day, technical opinions have been issued on at least 36 reform initiatives.

**Belarus**
(Original version)

There is no separate law on nuclear transfer and/or cloning. Legal regulation of the given problem is within the framework of the Law of Assisted Reproductive Technologies/ART (2012).
According to the ART Law of Republic of Belarus № 341-3 from 7.01.2012 germ cells (gametes) may be used in research purposes. Using embryos in research purposes is prohibited.
In the law of Assisted Reproductive Technologies (art.18) the use of embryo in research is forbidden. The Law allows research on supernumerary embryos, only if supernumerary embryos are used to improve ART and only up to 14 days of embryo development and according to consent of the donors of germ cells for this embryo.
*The germ cells can be used in research aims. The consent of the persons who donated the gametes*

*is necessary, the consent of anonymous donors of germ cells is not necessary for research.*
Cloning is not prohibited by law in Belarus.