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Legal Treatment of Embryos Created Through IVF

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Contents

Comparative Summary

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This report, prepared by staff of the Global Legal Research Directorate of the Law Library of Congress, surveys the rules in select jurisdictions regarding embryos created through artificial reproductive technology treatment cycles, such as those involving in vitro fertilization (IVF). The countries surveyed include **Australia** and **New Zealand**, the **United Kingdom**, and six European countries: **France**, **Germany**, **Italy**, **Poland**, **Portugal**, and **Sweden**.

The individual country surveys examine whether there is a legal limit on the number of embryos that can be created or transferred in a treatment cycle, and the actions that can be taken with respect to the embryos created (apart from transfer to a person's uterus as part of that cycle), including preimplantation genetic testing, sex selection for nonmedical purposes, cryopreservation and storage, donation to another person or couple, disposal or destruction, and allowing the embryos to be used for research purposes. This is intended to be a high-level survey, and it is recognized that countries may have detailed rules related to, for example, consent and counseling requirements, record-keeping and reporting, the collection and use of donor gametes, surrogacy, and restrictions and requirements related to embryo research.

Aspects of the country surveys are summarized in the table below. The storage time limits relate to the storage of embryos for the purpose of possible use in subsequent treatment cycles; some jurisdictions, such as the **United Kingdom** and **Sweden**, have separate time limits where storage is for the purpose of using the embryos for research. In addition, in almost all the countries that have a legal limit on storage duration, extensions may be granted by the relevant authorities.

As shown in the table, **Italy**, **Germany**, and **Poland** have the most restrictive rules of the jurisdictions surveyed. In these countries, the rules limit or discourage the creation of multiple excess embryos. However, while in **Italy** and **Germany** the ability to donate embryos to another person or couple is prohibited or highly restricted, such donation is required in **Poland** after the storage time limit is reached. These three countries do not permit research involving or disposal of excess embryos. Aspects of the laws in **Germany** are currently under review by a commission established by the government. The law in **Italy** is complex and there is uncertainty regarding some aspects, with certain restrictions having been declared unconstitutional by the Constitutional Court.

All the other jurisdictions surveyed allow for excess embryos to be discarded, and disposal is required in several jurisdictions when the storage limits have been reached. This includes one **Australian** state, **France**, **New Zealand**, **Portugal**, **Sweden**, and the **United Kingdom**.

Jurisdiction	Limit on Number of Embryos Created	Limit on Number of Embryos Transferred	Actions Related to Excess Embryos			
			Storage	Donation	Research	Disposal
Australia	No	1-2 depending on circumstances	No national limit; 10 years in two states	Yes	Yes	Yes
France	No	No	5 years	Yes	Yes	Yes
Germany	No more than will be transferred	3	No limit, but preservation only permitted as exception	Only if necessary to give chance to live	No	No

Jurisdiction	Limit on Number of Embryos Created	Limit on Number of Embryos Transferred	Actions Related to Excess Embryos			
			Storage	Donation	Research	Disposal
Italy	No more than strictly necessary for a single and contemporary implantation (limit of 3 declared invalid)	No (limit of 3 declared invalid)	No limit, but preservation only permitted as exception	No	No	No
New Zealand	No	1-2 depending on circumstances	10 years	Yes, requires approval	No	Yes
Poland	6	No	20 years	Yes, compulsory after 20 years	No	No
Portugal	Number necessary for success	No	3 years	Yes	Yes	Yes
Sweden	No	1, or 2 in special cases	10 years	Yes	Yes	Yes
United Kingdom	No	No	55 years	Yes	Yes	Yes

Australia

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SUMMARY In Australia, the use of artificial reproductive technology (ART) and research involving human embryos is governed by a combination of federal, state, and territory laws as well as nationally applicable quasi-legislative ethical guidelines and a code of practice used to audit fertility service providers. Under these instruments, there is no limit on the number of embryos that may be created in an ART treatment cycle. Providers are required to limit the number of embryos transferred to one or two, depending on the circumstances. Excess ART embryos may cryopreserved and stored, donated to another person for use in fertility treatment, donated for research purposes, or discarded, among other actions. The ethical guidelines do not include a specific limit on the duration of storage. Currently, two states have 10-year storage limits applicable to all ART embryos, and one state limits the storage of embryos created using donor gametes to 15 years. Extensions to these limits may be granted. Preimplantation genetic testing (PGT) is permitted in order to select against genetic conditions, diseases, or abnormalities that would "severely limit" the quality of life of the person who would be born; select an embryo with compatible tissue for subsequent stem cell therapy intended for a parent, sibling, or other relative; or increase the likelihood of a live birth. One state, Western Australia, has additional rules and approval requirements related to PGT. Sex selection for non-medical reasons is not currently permitted under the ethical guidelines, but is only specifically prohibited by two states.

I. Introduction

In Australia, the use of assisted reproductive technology (ART) is subject to specific laws enacted in four states: New South Wales, South Australia, Victoria, and Western Australia.[1] Proposed legislation has also recently been introduced in the Australian Capital Territory Legislative Assembly.[2] In all of the six states and two mainland territories, providers of ART services are accredited in accordance with the Reproductive Technology Accreditation Committee Certification Scheme (RTAC Scheme) of the Fertility Society of Australia and New Zealand.[3]

[1] See generally Isabel Karpin & Jenni Millbank, *Regulation of Assisted Reproductive Technology and Surrogacy in Australia,* in Routledge Handbook of Family Law and Policy 200–214 (John Eekelaar & Rob George eds., 2nd ed. 2020) (on file with author).

[2] Press Release, ACT Government, New Legislation to Better Support Donor-Conceived Canberrans (Nov. 28, 2023), https://perma.cc/45AF-VXA8; *Assisted Reproductive Technology Bill 2023*, ACT Legislation Register, https://perma.cc/E8XA-QBLR.

[3] See Fertility Society of Australia, *Reproductive Technology Accreditation Committee Certification Scheme (RTAC Scheme)* (rev. 1, Oct. 2010), https://perma.cc/MNX4-2PBG; Fertility Society of Australia and New Zealand, *Reproductive Technology Accreditation Committee Scheme (RTAC Scheme): Requirements for Bodies Providing Audit and Certification to the Code of Practice for Assisted Reproductive Technology Units* (Combined Australia, New Zealand and International Edition, Dec. 20, 2021), https://perma.cc/3UA6-4WN7.

Under this scheme, providers are audited against the RTAC's *Code of Practice for Assisted Reproductive Technology Units* (Code of Practice).[4] Under the Code of Practice, providers must comply with the National Health and Medical Research Council's (NHMRC's) *Ethical Guidelines on the Use of Assisted Reproductive Technology in Clinical Practice and Research* (Ethical Guidelines),[5] which therefore effectively act as a national ART framework.[6] The guidelines are subject to rolling review and were most recently updated in 2023.

The following state-level laws apply to the use of ART in the particular jurisdictions:

- New South Wales:[7] Assisted Reproductive Technology Act 2007 (NSW)[8] and Assisted Reproductive Technology Regulation 2014 (NSW)[9]
- South Australia:[10] Assisted Reproductive Treatment Act 1988 (SA)[11] and Assisted Reproductive Treatment Regulations 2010 (SA)[12]
- Victoria:[13] Assisted Reproductive Treatment Act 2008 (Vic)[14] and Assisted Reproductive Treatment Regulations 2019 (Vic)[15]
- Western Australia:[16] Human Reproductive Technology Act 1991 (WA)[17] and Human Reproductive Technology Regulations 1993 (WA)[18]

The New South Wales and South Australia laws largely cover matters such as clinic licensing and registration, the use of donor gametes, donor conception registers, the collection and release of donor information, and other record-keeping requirements. The Victoria legislation also includes

[4] Fertility Society of Australia and New Zealand, Reproductive Technology Accreditation Committee, *Code of Practice for Assisted Reproductive Technology Units* (rev. Oct. 2021) (Code of Practice), https://perma.cc/B6K7-G3CR.

[5] National Health and Medical Research Council (NHMRC), *Ethical Guidelines on the Use of Assisted Reproductive Technology in Clinical Practice and Research* (2017, updated 2023) (Ethical Guidelines), https://perma.cc/6YPD-PPNL.

[6] See *Your Legal Guide to IVF in Australia*, Ramsden Lawyers, https://perma.cc/L8RQ-5L38.

[7] *Assisted Reproductive Technology*, NSW Health, https://perma.cc/KUN4-CEZ3.

[8] Assisted Reproductive Technology Act 2007 (NSW), https://perma.cc/3LXL-VQJF.

[9] Assisted Reproductive Technology Regulation 2014 (NSW), https://perma.cc/284R-NPPF.

[10] *Assisted Reproductive Treatment Legislation*, SA Health, https://perma.cc/66S4-ZGEB.

[11] Assisted Reproductive Treatment Act 1988 (SA), https://perma.cc/A9LW-N2VB.

[12] Assisted Reproductive Treatment Regulations 2010 (SA), https://perma.cc/JPU5-DD4X.

[13] *Regulation*, Victorian Assisted Reproductive Treatment Authority (VARTA), https://perma.cc/UF9K-RDEJ.

[14] Assisted Reproductive Treatment Act 2008 (Vic), https://perma.cc/5G7N-23K6.

[15] Assisted Reproductive Treatment Regulations 2019 (Vic), https://perma.cc/W7F2-S6XL.

[16] *Legislation and Guidelines*, Reproductive Technology Council (WA), https://perma.cc/H3UX-3BHP; *IVF and Reproductive Technology*, WA Department of Health, https://perma.cc/G7UX-F9EA.

[17] Human Reproductive Technology Act 1991 (WA), https://perma.cc/GG2R-3BB4.

[18] Human Reproductive Technology Regulations 1993 (WA), https://perma.cc/BQ3M-5CRT.

provisions related to consent, counseling, the storage and disposal of embryos, and a ban on sex selection, among others. The Western Australia legislation covers both ART and research involving human gametes and embryos and is currently under review.[19] In other jurisdictions, embryonic research is subject to separate legislation.

Research involving human embryos is regulated at both the federal and state levels. At the federal level, the Prohibition of Human Cloning for Reproduction Act 2002 (Cth)[20] and Research Involving Human Embryos Act 2002 (Cth),[21] along with the Research Involving Human Embryos Regulations 2017 (Cth),[22] prohibit "human cloning for reproductive purposes and a range of other practices relating to reproductive technology. [The legislation] also regulates research activities that involve the use of human embryos created by assisted reproductive technology (ART) or by other means."[23] Pursuant to an agreement between the federal, state, and territory governments, all of the jurisdictions have passed nationally consistent legislation "to ban human cloning and other unacceptable practices and to regulate research involving excess ART embryos."[24]

This report provides information based on the state laws regarding ART, including the applicable non-statutory guidelines and code, and the federal laws regarding research involving excess or surplus embryos.

II. Rules Related to Embryos Created through Assisted Reproductive Technology

The Research Involving Human Embryos Act 2002 (Cth) establishes an offense of intentionally using an excess ART embryo unless certain exceptions apply, including that the use is an "exempt use," which includes the following:

> (a) the use consists only of:
> (i) storage of the excess ART embryo; or
> (ii) removal of the excess ART embryo from storage; or
> (iii) transport of the excess ART embryo; or
> (b) the use consists only of observation of the excess ART embryo; or
> (c) the use consists only of allowing the excess ART embryo to succumb; or
> (d) the use is carried out by an accredited ART centre, and:
> (i) the excess ART embryo is not suitable to be placed in the body of the woman for whom it was created where the suitability of the embryo is determined only on the basis of its biological fitness for implantation; and
> (ii) the use forms part of diagnostic investigations conducted in connection with the assisted reproductive technology treatment of the woman for whom the excess ART embryo was created; or

[19] *New Assisted Reproductive Technology and Surrogacy Legislation for WA*, WA Department of Health, https://perma.cc/QGF4-EL2V.

[20] Prohibition of Human Cloning for Reproduction Act 2002 (Cth), https://perma.cc/PA2K-KXH9.

[21] Research Involving Human Embryos Act 2002 (Cth), https://perma.cc/7RGZ-MAEU.

[22] Research Involving Human Embryos Regulations 2017 (Cth), https://perma.cc/FH9K-LLHC.

[23] *Embryo Research Licensing: Commonwealth and State Legislation*, NHMRC, https://perma.cc/RF7K-WK2H.

[24] Id.

(e) the use is carried out by an accredited ART centre, and:
  (i) the use is for the purposes of achieving pregnancy in a woman other than the woman for whom the excess ART embryo was created; and
  (ii) the excess ART embryo was not created using a mitochondrial donation technique as permitted under section 28B (carrying out activities authorised by mitochondrial donation licences); or
(f) the use is of a kind prescribed by the regulations for the purposes of this paragraph.[25]

The Ethical Guidelines set out the following overall approach regarding the use, storage, and discarding of embryos created through ART procedures:

> 4.1.3 Before gametes are collected or embryos are created, clinics must ensure that all responsible parties are provided with sufficient information to facilitate an understanding of the options they will have regarding the use, storage and discard of the gametes or embryos, including those which are legal, but are not available at the particular clinic. Options include:
> - use in their own or their partner's reproductive treatment (including the potential for posthumous use – see paragraph 8.22)
> - donation to another individual or couple for use in reproductive treatment (see Chapters 5 and 6) and the potential for this donation to be reallocated to a subsequent individual or couple (see paragraph 6.1.3)
> - use in research (see Part C of these Ethical Guidelines)
> - use in training or quality assurance activities (see paragraphs 10.3 – 10.6)
> - transfer to another clinic in cases where the desired option for the use or discard is not available at the initial clinic
> - discard of the gamete or embryo.[26]

A. Limit on Number of Embryos that Can Be Created or Transferred

There are no statutory limits in Australia on the number of embryos that can be created through an ART treatment cycle. The Ethical Guidelines also do not specify a limit. An Australian professor and fertility specialist commenting on the recent Alabama Supreme Court decision on the destruction of frozen embryos noted that the judge in that case "implied that in Australia, the only IVF cycles ethically permitted are stimulated cycles, where just one embryo is created and transferred, with no embryos being frozen."[27] The professor stated that

> this assertion is demonstrably false. There are no guidelines or regulations in Australia that discourage the creation of multiple embryos, as this practice enhances overall pregnancy rates, while making IVF safer and more cost-effective.
>
> What is discouraged is the *transfer* of multiple embryos at one time, as this increases the likelihood of multiple births, which carry heightened medical risks for both mothers and babies.[28]

[25] Research Involving Human Embryos Act 2002 (Cth) s 10.

[26] Ethical Guidelines ¶ 4.1.3.

[27] Alex Polyakov, *Alabama Ruling Frozen Embryos are Equivalent to Living Children has Worrying Implications for IVF*, The Conversation (Feb. 26, 2024), https://perma.cc/JR4S-Y9M4.

[28] Id.

With respect to the approach to limiting the number of embryos transferred at one time, the RTAC Code of Practice, against which fertility service providers are audited, includes requirements related to minimizing the incidence of multiple pregnancies, with providers needing to "provide evidence of implementation and review of policies and procedures that"

> a) Ensure a regular audit (at least annually) of multiple pregnancy rates and corrective actions that continuously attempt to reduce the incidence of multiple pregnancies in all treatment cycles, including artificial insemination even when the insemination is done offsite
> b) Recommend to patients that no more than one embryo or oocyte is transferred in the first treatment cycle where the oocyte is obtained from a woman aged less than 35 years at the time of oocyte collection
> c) Ensure that no more than two embryos or oocytes are transferred in any one treatment cycle in a woman under the age of 40 years at the time of oocyte collection
> d) Ensure that no more than two embryos or oocytes are transferred to a recipient woman, of any age, in any one treatment cycle, where the oocytes are donated from a woman aged less than 40 years at the time of oocyte collection
> e) Ensure single embryo transfer is mandatory for a gestational carrier in surrogacy arrangements
> f) Ensure that patients receive information on the risks to parents and babies associated with multiple pregnancies[29]

B. Preimplantation Genetic Testing

The Ethical Guidelines contain a section on preimplantation genetic testing (PGT) and state that

> 8.15.1 PGT may only be used to:
> - select against genetic conditions, diseases or abnormalities that would severely limit the quality of life of the person who would be born
> - select an embryo with compatible tissue for subsequent stem cell therapy intended for a parent, sibling or other relative
> - increase the likelihood of a live birth.
>
> 8.15.2 PGT may not be used to preferentially select in favour of a genetic condition, disease or abnormality that would severely limit the quality of life of the person who would be born.[30]

The guidelines set out additional paragraphs regarding assessing the acceptability of PGT to select against a genetic condition, disease, or abnormality. It provides a list of criteria that should be considered, stating that "[i]t is not possible to list the genetic conditions, diseases or abnormalities for which the use of PGT is ethically acceptable, as context is important and the assessment may change over time."[31]

[29] Code of Practice § 3.3.

[30] Ethical Guidelines ¶¶ 8.15.1 & 8.15.2.

[31] Id. ¶ 8.16.1.

Other paragraphs of the guidelines relate to assessing "the ethical acceptability of PGT to select an embryo with compatible tissue for subsequent stem cell therapy for a parent, sibling or other relative." These state that

> 8.17.1 PGT may only be used to select an embryo with compatible tissue for subsequent stem cell therapy for the planned treatment of an intended parent, sibling or other relative.
>
> 8.17.2 Clinicians must seek advice from an independent body before undertaking PGT to select an embryo with compatible tissue for subsequent stem cell therapy. The independent body should be satisfied that:
>
> - there is no evidence to suggest that the person who would be born would not be a welcomed, respected member of the family unit
> - the use of PGT will not significantly affect the welfare and interests of the person who would be born
> - the medical condition of the intended parent, sibling or other relative to be treated is serious and stem cell treatment is the medically recommended management of the condition.[32]

Additional paragraphs relate to the provision of information and counseling to individuals and couples who seek PGT, and to incidental findings and record keeping.[33]

Only Western Australia currently regulates the provision of PGT.[34] In that state, PGT is not considered part of a routine ART treatment cycle "and requires approval from the Reproductive Technology Council if"

> - the embryo is for use in the reproductive treatment of a woman; and
> - based on existing scientific and medical knowledge:
>   - the procedure is unlikely to leave the embryo unfit for implantation; and
>   - where, for genetic testing, there is a significant risk of serious genetic abnormality or disease being present in the embryo.[35]

The council maintains a list of pre-approved genetic conditions for testing, with clinics therefore able to "undertake testing with eligible patients without the need to seek further Council approval."[36] The approved conditions list was most recently expanded in January 2024.[37] In addition, preimplantation genetic testing for aneuploidy (PGT-A) does not require council approval if certain criteria are met.

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[32] Id. ¶¶ 8.17.1 & 8.17.2.

[33] Id. at 53–54.

[34] Karpin & Millbank, supra note 1.

[35] *Preimplantation Genetic Testing (PGT)*, WA Department of Health, https://perma.cc/GPQ9-GPK5. See Human Reproductive Technology Act 1991 (WA) s 14(2b).

[36] Preimplantation Genetic Test (PGT), supra note 35.

[37] Reproductive Technology Council, *PGT Approved Conditions List: January 2024* (2024), https://perma.cc/2HLZ-48B6.

C. Embryo Selection

The Ethical Guidelines state in paragraph 8.14 that sex selection for non-medical purposes is "not currently supported." Therefore, "[s]ex selection techniques may not be used unless it is to reduce the risk of transmission of a genetic condition, disease or abnormality that would severely limit the quality of life of the person who would be born."[38] Clinics are required to "assess the ethical acceptability of selecting the sex of a human embryo" to reduce this risk, with the guidelines stating that there should be evidence to support "claims that the particular condition, disease or abnormality affects one sex significantly more than the other," and that "the risk of transmission is greater than the general risk of the condition, disease or abnormality occurring within the general population."[39]

The guidelines list different factors that the Australian Health Ethics Committee (AHEC) was cognizant of in considering the issue of sex-selection for non-medical purposes, and state that it had concluded that "in some circumstances, sex selection for non-medical purposes is consistent with the guiding principles" of the Ethical Guidelines.[40] The guidelines also note, although the states and territories have the capacity to legislate in this area, such sex-selection is currently only specifically prohibited in two Australian states. Therefore, "despite AHEC's majority view that there may be some circumstances where there is no ethical barrier to the use of sex selection for non-medical purposes, paragraph 8.14 applies until such time that wider public debate occurs and/or state and territory legislation addresses the practice."[41]

The two states that specifically prohibit sex selection for non-medical reasons are Victoria[42] and Western Australia.[43]

D. Embryo Preservation

Cryopreservation of embryos is permitted. The statutes and Ethical Guidelines do not include specific rules on this process, but cryopreservation more generally can be seen to be covered by rules related to embryo storage, outlined below. For example, in the New South Wales legislation, "store" means "(a) to freeze an oocyte, embryo or sperm; or (b) to otherwise preserve an oocyte, embryo or sperm by a prescribed method."[44] In the Western Australia legislation, a reference to "keeping [human gametes, a human egg undergoing fertilization or a human embryo], includes storing, whether by cryo-preservation or in any other way, in such a state as temporarily arrests

[38] Ethical Guidelines ¶ 8.14.1.

[39] Id. ¶ 8.13.1.

[40] Id. at 49–50; see also 107–108.

[41] Id. at 50.

[42] Assisted Reproductive Treatment Act 2008 (Vic) s 28; *Practical Guide to Legislation*, VARTA, https://perma.cc/SL8K-TR92.

[43] *Preimplantation Genetic Test (PGT)*, supra note 35; Human Reproductive Technology Act (WA) ss 7(1)(b) (prohibiting diagnostic procedures on any embryo where this is not authorized by the Code or specifically approved by the Council) & 14(2b)(iii) (stating that the Council cannot approve testing unless it is unless there is a significant risk of a serious genetic abnormality or disease being present in the embryo).

[44] Assisted Reproductive Technology Act 2007 (NSW) s 3 (definition of "store").

or suspends metabolic function" and "to any human gametes which are or a human egg or embryo which is, stored, means kept in such a state," and "store and storage shall be construed accordingly."[45]

E. Embryo Storage

According to a 2019 journal article, "[h]istorically in Australia, a ten year limit was imposed on the storage of frozen embryos (usually a five year limit with the option to extend this for an additional five years)."[46] This was based on previous versions of the Ethical Guidelines.[47] However, "it is now legally possible for those who create embryos to store them frozen for longer periods of time."[48] Currently, only two Australian states, Victoria and Western Australia, have broad statutory time limits on embryo storage. The limit in Western Australia is 10 years, unless an extension is approved by the Reproductive Technology Council.[49] In Victoria, the legislation provides that an ART provider must not cause or permit an embryo to remain in storage for later transfer for more than five years, or an additional five years if each responsible person consents to the longer period.[50] A Patient Review Panel may approve a longer or further period of storage.[51]

The New South Wales legislation includes a limit on the storage of an embryo created using a donated gamete, being 15 years plus any additional period authorized by the secretary.[52] In addition, written authorization is required for ART treatment using an embryo created from a donated gamete, or using a donated embryo, if the embryo was created more than 15 years before the treatment.[53]

[45] Human Reproductive Technology Act (WA) s 3(4).

[46] Clare Bartholomaeus & Damien W. Riggs, *Embryo Donation and Receipt in Australia: Views on the Meanings of Embryos and Kinship Relations*, 38(1) New Genetics & Society 1, 2 (2019) (on file with author).

[47] See NHMRC, *Ethical Guidelines on Assisted Reproductive Technology* 11 (1996), https://perma.cc/DFU4-KKWT; Anita Stuhmcke, *Tick Tock Goes the Clock: Rethinking Policy and Embryo Storage Limits*, 22 Feminist Legal Studies 285–306 (2014), https://perma.cc/9H6T-B5AA; Anita Stuhmcke & Eloise Chandler, *Storage Limits of Gametes and Embryos: Regulation in Search of Policy Justification*, 22 J. of L. & Med. 121–135 (2014), https://perma.cc/NMC9-PV86.

[48] Bartholomaeus & Riggs, supra note 46, at 2.

[49] Human Reproductive Technology Act 1991 (WA) s 25(1) & (1a). See also *Embryo Storage*, Reproductive Technology Council, https://perma.cc/7JGJ-BB2Q; *Storage of Sperm, Eggs and Embryos*, WA Department of Health, https://perma.cc/TM32-GZ4K.

[50] Assisted Reproductive Treatment Act 2008 (Vic) s 33.

[51] Id. s 33A. VARTA, *What to Do with Your Unused Embryos?* 3, https://perma.cc/3TFS-68FD; *Fertility Treatment Journey: Options for Unused Embryos*, VARTA, https://perma.cc/NBV6-RM5V.

[52] Assisted Reproductive Technology Act 2007 (NSW) s 25(3)(d).

[53] Id. s 26(1)(b).

Federal funding is available to eligible persons for embryo storage up to a 10-year limit, after which people would be required to pay for storage themselves.[54]
The Ethical Guidelines require that clinics discuss information related to embryo storage with people undertaking ART treatment, including "any limitations on storage times, specific to the clinic of the state or territory" and "any circumstances under which the clinic may dispose of the gametes or embryos before the end of the consent period, including the clinic's policy for managing disputes that may arise between a couple for whom an embryo is stored."[55] The guidelines also contain a chapter on the responsibilities of clinics for stored gametes and embryos. This includes the following requirements with respect to safe storage:

> 7.1.1 Clinics must have procedures in place to ensure all reasonable efforts are taken to maintain the safe storage and accurate identification of all gametes and embryos. All procedures should be consistent with current best practice.
>
> 7.1.2 Clinics must ensure that all reasonable efforts are made to keep gametes and embryos in safe storage for the period of storage specified in the consent form. After this time, if the individual or couple responsible for the stored gametes and embryos cannot be contacted to provide further direction and consent, clinics may discard the gametes or embryos, in accordance with the clinic's policy (see paragraph 7.6).[56]

Further paragraphs relate to assessing "the suitability for continued (long term) storage of gametes and embryos," stating that

> [d]ecisions about the continued (long term) storage of gametes or embryos involve both personal and clinical considerations. The suitability of gametes or embryos for continued storage is a clinical determination, however, if there is no evidence of deterioration, decisions about the continued storage of gametes or embryos may depend entirely on the personal preferences of the responsible party(ies).[57]

The RTAC Code of Practice also contains requirements to have policies and procedures regarding the safe management of cryopreserved embryos, such as maintaining records of temperature changes that may affect the viability of the stored material, and monitoring of storage vessels and detection of a failure.[58] The code also includes requirements related to the reporting of serious adverse events, including an event that "[c]auses a loss of viability of gametes or embryos or suspected deterioration (beyond accepted laboratory standards) that renders them unsuitable for use."[59]

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[54] *How the Assisted Reproductive Technology (ART) Storage Funding Program Works*, Department of Health and Aged Care, https://perma.cc/BF6T-C8U9.

[55] Ethical Guidelines ¶ 4.2.6.

[56] Id. ¶¶ 7.1.1 & 7.1.2.

[57] Id. ¶ 7.2.

[58] Code of Practice § 2.9.

[59] Id. § 3.2.2.

F. Embryo Donation

Embryo donation for use in fertility treatment is permitted under the Ethical Guidelines. Chapter 6 of the guidelines provide "additional guidelines for the use of donated embryos" and state that

> [e]mbryos that are no longer required by the individual or couple for whom they were created may be donated to another individual or couple for use in their reproductive treatment. Additionally, where a recipient individual or couple no longer requires a donated embryo for their own reproductive treatment, the donated embryo may be reallocated to another individual or couple.
>
> Embryos may be donated to a specific recipient who is known to the donor ('known donation') or to anyone who is receiving ART ('unknown donation').[60]

The guidelines contain requirements related to supporting the right to know the details of one's genetic origins in the context of embryo donation; responsibility for donated embryos; the donation of embryos with a known genetic condition, disease, or abnormality; and withdrawal of consent for donation.[61] These apply in addition to the extensive guidance on the use of donated gametes in chapter 5 of the guidelines.

In Australia, embryo and gamete donation must be altruistic, with direct or indirect inducements prohibited. The federal Prohibition on Human Cloning for Reproduction Act 2002 (Cth) establishes offenses of intentionally giving or offering, or receiving, "valuable consideration . . . for the supply of a human egg, human sperm or human embryo."[62] Reimbursement of "verifiable out-of-pocket expenses directly associated with the donation" is permitted.[63] The Ethical Guidelines also reflect these rules.[64]

Anonymous donation is also prohibited under the guidelines, with clinics being prohibited from using donated gametes and embryos in reproductive procedures "unless the donor has consented to the release of their identifying information to the person(s) born as a result of the donation."[65] Persons born from donated gametes or embryos may request information about the donor(s) at the age of 18 years.[66]

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[60] Id. at 37.

[61] Id. at 37–38.

[62] Prohibition on Human Cloning for Reproduction Act 2002 (Cth) s 21.

[63] Id.

[64] Ethical Guidelines ¶ 5.4.

[65] Id. ¶ 5.6.1.

[66] Id. ¶ 5.9. See also ¶ 6.1.1 ("Donated embryos (including those obtained from overseas, see paragraph 5.5.1) must only be used in reproductive treatment if all of the requirements in Chapter 5 for donated gametes are satisfied.")

G. Embryo Disposal

The Ethical Guidelines state the following with respect to the discard of stored gametes and embryos:

> 7.6.1 Clinics must have policies and procedures in place for discarding stored gametes and embryos. These policies should provide for the responsible party(ies) to determine the means of removal or discard of the embryos from the clinic, including those which are legal, but are not available at the particular clinic (see paragraph 4.1.3).
> 7.6.2 Clinics may, in limited circumstances, and in line with the clinic's policy, discard stored gametes or embryos without the consent of the individual or couple for whom the gametes or embryos are stored (see paragraphs 4.2.6, 7.1.2, 7.2.1 and 7.4.2).
> 7.6.3 Before a clinic may discard stored gametes or embryos without the consent of the responsible party(ies), clinics must make all reasonable efforts, and document all attempts, to notify the responsible party(ies) and allow reasonable time for the responsible party(ies) to take action.[67]

The legislation in Victoria includes a provision on the removal of embryos from storage, stating that an ART provider may not remove an embryo from storage unless it is to be used in a treatment procedure, written consent has been given by the responsible persons in relation to the embryo, the responsible persons cannot agree on the storage period and the Patient Review Panel has directed the removal, or removal is required due to the storage limit being reached.[68] A person who removes an embryo from storage must ensure that "it is disposed of in accordance with the regulations."[69] The relevant regulation then states that "an embryo must be disposed of by allowing the embryo to stand in its container, at room temperature, in a secure area for a period of not less than 24 hours."[70]

The Western Australia legislation requires that three months before the end of the permitted storage period, the provider "must take reasonable steps to notify each person for whom the human egg undergoing fertilisation or human embryo is being stored."[71] Subsequently, if the storage period comes to an end and no application for extension has been made, the provider may "allow . . . the human embryo to succumb and will not be liable to anyone for so doing."[72]

[67] Id. ¶¶ 7.6.1–7.6.3.

[68] Assisted Reproductive Treatment Act 2008 (Vic) s 34(1).

[69] Id. s 34(2)(b).

[70] Assisted Reproductive Treatment Regulations 2019 (Vic) reg 13.

[71] Human Assisted Reproductive Technology Act 1991 (WA) s 24(3).

[72] Id. s 24(4).

H. Use of Embryos for Scientific Research Purposes

The federal Research Involving Human Embryos Act 2002 (Cth) "requires that research involving human embryos, including excess embryos from assisted reproductive technology treatments and the creation and/or use of embryos arising by processes other than fertilisation, can only be conducted under a licence issued by the Embryo Research Licensing Committee (ERLC) [of the NHMRC]."[73] Part 2 of the act regulates the use of excess ART embryos and other material, with such an embryo defined as

> (1) . . . a human embryo that:
> (a) was created, by assisted reproductive technology, for use in the assisted reproductive technology treatment of a woman; and
> (b) is excess to the needs of:
> (i) the woman for whom it was created; and
> (ii) her spouse (if any) at the time the embryo was created.
> (2) For the purposes of paragraph (b) of the definition of excess ART embryo, a human embryo is excess to the needs of the persons mentioned in that paragraph at a particular time if:
> (a) each such person has given written authority for use of the embryo for a purpose other than a purpose relating to the assisted reproductive technology treatment of the woman concerned, and the authority is in force at that time; or
> (b) each such person has determined in writing that the embryo is excess to their needs, and the determination is in force at that time.[74]

As noted above, the Prohibition on Human Cloning for Reproduction Act 2002 (Cth) establishes certain prohibited practices, including the following:

- Placing a human embryo clone in the body of a human or animal;
- Importing or exporting a human clone embryo;
- Creating a human embryo for a purpose other than achieving pregnancy in a woman or for the purposes of a mitochondrial donation license;
- Developing a human embryo outside the body of a woman for more than 14 days;
- Collecting a viable human embryo from the body of a woman;
- Placing a human embryo in the body of an animal, or an animal embryo in the body of a human;
- Commercial trading in human eggs, sperm, or embryos; and
- Creating a hybrid embryo.[75]

[73] *Embryo Research Licensing: Commonwealth and State Legislation*, NHMRC, supra note 23.

[74] Research Involving Human Embryos Act 2002 (Cth) s 9.

[75] Prohibition on Human Cloning for Reproduction Act 2002 (Cth) pt 2.

Part C of the Ethical Guidelines sets out ethical principles applicable to ART research[76] and has a detailed chapter on research involving embryos, including excess ART embryos. This includes paragraphs on ensuring that an embryo has been declared an excess ART embryo; identifying all responsible persons; and obtaining consent.[77]

Recent developments in relation to embryo research in Australia include the implementation of "a new regulatory scheme to enable the phased introduction of mitochondrial donation into Australian clinical practice."[78] The ERLC also "licensed innovative research that creates human embryo-like structures from human skin cells."[79]

[76] Ethical Guidelines at 65–67.

[77] Id. at 71–74.

[78] *Spotlight on Embryo Research*, Australian Government Transparency Portal, https://perma.cc/9TZQ-QLC9.

[79] Id.

France

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SUMMARY France's 2021 Bioethics Law broadens access to medically assisted reproduction for all women and couples, regardless of medical reasons. It specifies that embryos can only be created in numbers essential for the success of medically assisted procreation. The law permits preimplantation genetic diagnosis but confines it to couples at risk of transmitting a serious genetic disease. The law permits the donation of embryos from a couple or single woman to another couple or single woman. Additionally, it allows the preservation of embryos for up to five years, restricts the development of embryos outside of storage to a maximum of 14 days, and permits scientific testing on donated embryos created within the context of a parental project.

I. Introduction

In France, medically assisted reproduction is governed by the 2021 Bioethics Law, which modified the provisions of the French Public Health Code (Code de la Sante Publique),[1] relevant to assisted reproduction.[2] The 2021 Bioethics Law is the fourth revision of the French Bioethics Law. The first Bioethics Law was passed in 1994,[3] and it was revised in 2004,[4] 2011,[5] and 2021.[6]

The 2021 Bioethics Law expands access to medically assisted procreation to all women with a parental project, including homosexual couples and single individuals. The previous requirement of infertility for access to assisted procreation is eliminated. Consequently, a woman can now freeze her oocytes without the need for medical reasons.[7]

The 2021 Bioethics Law also incidentally authorizes the possibility of creating an embryo through the use of donated sperm and oocytes during the same in vitro fertilization (IVF) attempt ("double donation"), which was previously prohibited.[8]

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[1] Code de la santé publique [Public Health Code], https://perma.cc/H5GF-CK69.

[2] Loi n° 2021-1017 du 2 août 2021 relative à la bioéthique (2021 Bioethics Law), Journal Officiel de la République Française [J. O.] [Official Gazette of France], Aug. 3, 2021, https://perma.cc/568Y-ECCG.

[3] Loi no. 94-654 du 29 juillet 1994 relative au don et à l'utilisation des éléments et produits du corps humain, à l'assistance médicale à la procréation et au diagnostic prénatal, J. O., July 30, 1994, https://perma.cc/EZS5-NYW2.

[4] Loi n° 2004-800 du 6 août 2004 relative à la bioéthique, J. O., Aug. 7, 2004, https://perma.cc/3JRA-SMRW.

[5] Loi n° 2011-814 du 7 juillet 2011 relative à la bioéthique, J. O., July, 8, 2011, https://perma.cc/595Z-KW4Z.

[6] Vie Publique, *Les questions de bioéthique: chronologie 1983-2023* (Oct. 17, 2023), https://perma.cc/P4BD-ZWBJ.

[7] Vie publique, *Bioéthique: l'ouverture de la PMA à toutes les femmes* (Sept. 8, 2023), https://perma.cc/GM99-2SCS.

[8] Id.

Additionally, the 2021 law regulates the preservation of embryos created through IVF as part of medically assisted reproduction. These embryos can be frozen upon the written request of the parents for later implantation in the mother's uterus. If they are no longer intended for a parental project, and if the parents consent to it, these embryos may be donated or used for research under certain conditions.[9]

The 2004 Bioethics Law created the Biomedicine Agency (Agence de la Biomédecine), a national government agency under the supervision of the Ministry of Health. The agency serves as the primary authority on medical, scientific, and ethical aspects related to procreation, embryology, and human genetics as well as organ, tissue, and cell recovery and transplantation issues.[10]

II. Rules Related to Embryos Created Through Assisted Reproductive Technology

An embryo can only be created in vitro within the framework and according to the objectives of medically assisted procreation.[11]

A. Limit on Number of Embryos That Can Be Created or Transferred

The French Public Health Code does not state a legal limit on the number of embryos that can be created or transferred in the context of an IVF treatment cycle. The Public Health Code states as follows:

> Taking into account the state of medical technology, the members of the couple or the unmarried woman may consent in writing to an attempt at fertilization of a number of oocytes which may make it necessary to preserve embryos, with the intention to subsequently carry out their parental project. In this case, this number is limited to what is strictly necessary for the success of medically assisted procreation taking into account the process implemented.[12]

B. Preimplantation Genetic Testing

The French public health code defines preimplantation diagnosis as a biological diagnosis performed on cells taken from the embryo in vitro.[13] Preimplantation diagnosis includes the following activities:

[9] 2021 Bioethics Law art. L2141-3.

[10] *ABM (Agence de la biomédecine)*, Ministère de la Santé et de la Prévention (Mar. 7, 2023), https://perma.cc/LYX9-JKH2.

[11] Public Health Code art. L2141-3.

[12] Id. art. L2141-3.

[13] Public Health Code art. L2131-4.

- cell sampling of the embryo obtained by IVF,
- cytogenetic tests, including molecular tests, on the embryonic cell or cells, and
- molecular genetic tests on the embryonic cell or cells.[14]

Preimplantation diagnosis is allowed only in exceptional cases, requiring a doctor's certification that a couple or an unmarried woman, due to their family situation, have a high probability of giving birth to a child with a particularly severe genetic disease recognized as incurable at the time of diagnosis. The diagnosis is permissible when the anomaly responsible for such a disease has been precisely identified in one of the parents or in one of their immediate ascendants, specifically in cases of severely incapacitating, late-onset, and prematurely life-threatening diseases.[15] Both members of the couple, or the unmarried woman, must give their written consent to the testing.

Preimplantation diagnosis may also be authorized when the following conditions are met:

- the couple or unmarried woman previously produced a child suffering from a genetic disease causing death in the first years of life, recognized as incurable at the time of diagnosis,
- by applying a treatment that does not affect the integrity of the body of the child born from the transfer of the embryo in utero, the vital prognosis of the child can be significantly improved, and
- the sole purpose of the diagnosis is to identify the genetic disease and the means of preventing and treating it, as well as enabling the application of the mentioned treatment.[16]

C. Embryo Selection

As discussed in Section II.B, above, preimplantation diagnosis is strictly regulated in France by the 2021 Bioethics Law and is reserved for parents at risk of transmitting a serious genetic disease to their child. The law states that the only purpose of the preimplantation diagnosis is to identify this condition and the means to prevent and treat it.[17] It cannot be used to choose the sex of the future child.

When a legally administered preimplantation diagnosis reveals an anomaly or anomalies responsible for an incurable disease in an embryo, the couple or unmarried woman may signify their intention not to pursue their parental project regarding this embryo.[18]

[14] Id. art. R2131-22-2.

[15] Id.

[16] Id. art. L2131-4-1.

[17] Id. art. L2131-4.

[18] Id. art. L2131-4.

D. Embryo Preservation

Embryos can be preserved. A decree published on October 5, 2023, lays down rules of good practice concerning the possibility of embryo preservation for any medical reason. The 2023 decree mentions vitrification as a process used to conserve embryos.[19]

Article L2151-9 of the Public Health Code states that any organization that conserves embryos for research purposes must hold an authorization issued by the French Biomedicine Agency.[20] Annual reports from the agency indicate that clinical-biological centers and laboratories authorized to carry out medically assisted procreation activities perform embryo vitrification.[21] An information brochure from the agency outlines the vitrification process and summarizes the provisions of the 2021 Bioethics Law relevant to embryo preservation.[22]

E. Embryo Storage

Each year, individuals whose embryos are being preserved are asked whether they wish to continue storing them. If they no longer wish to continue storage or want to specify the conditions of preservation in the event of their death, they can provide written consent for the embryos to be donated, used for research, or for the storage to be terminated.[23] In principle, they cannot be kept for more than five years.[24]

Embryos donated to research and stored for more than five years on the date of publication of the Bioethics Act of 2021 are destroyed unless these embryos are of particular interest for research due to their storage at an early stage of development.[25]

F. Embryo Donation

Both members of a couple, or a single woman undergoing IVF treatment, can consent in writing for the stored embryos to be received by another couple or another unmarried woman.[26] The couple or unmarried woman receiving the embryo and the couple or unmarried woman who consented to donation of their embryo cannot know their respective identities.[27]

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[19] Arrêté du 5 octobre 2023 modifiant l'arrêté du 11 avril 2008 relatif aux règles de bonnes pratiques cliniques et biologiques d'assistance médicale à la procréation et abrogeant l'arrêté du 30 juin 2017 modifiant l'arrêté du 11 avril 2008, J. O., Oct. 10, 2023, Annexe I-8.3, https://perma.cc/E6CU-QXZA.

[20] Public Health Code art. L2151-9.

[21] Agence de la Biomédecine, *Rapport annuel 2021 sur le dispositif de vigilance relatif à l'assistance médicale à la procréation* (2021), https://perma.cc/D7QU-YLSM.

[22] Agence de la Biomédecine, *Assistance Médicale à la Procréation: Le Devenir des Embryons Congelés*, https://perma.cc/JY32-AVXC.

[23] Public Health Code art. L2141-12.

[24] Id. art. L2141-4.

[25] Id. arts. L2141-4, R. 2151-19.

[26] Id. art. L2141-5.

[27] Id. art. L2141-6.

G. Embryo Disposal

Embryos subjected to research may not be transferred for gestation purposes, and their in vitro development must be terminated no later than 14 days following their formation.[28] As mentioned above, stored embryos are terminated after five years of storage.[29]

The French Biomedicine Agency states that researchers must always destroy embryos once they have carried out their experiments.[30] The agency also states that, when a couple or single woman decide to put an end to the conservation of embryos, the medical team at their assisted reproduction center will destroy them after thawing the straws in which they are stored.[31]

H. Use of Embryos for Scientific Research Purposes

The Biomedicine Agency is responsible for approving all research protocols involving embryonic cells.[32] Article 511-19 of the French Penal Code provides for seven years' imprisonment and a 100,000 euro (around US$108,000) fine for carrying out embryo research without validation by the agency.[33]

According to article L2151-2 of the Public Health Code, the in vitro conception of a human embryo by gamete fusion or the cloning of a human embryo for research purposes is prohibited.[34] The modification of a human embryo by adding cells from other species is also prohibited. A human embryo may not be conceived, cloned, or used for commercial or industrial purposes.[35] Interventions designed to modify the genome of gametes or embryos are also prohibited.[36]

Research can only be carried out on embryos conceived in vitro as part of medically assisted procreation that are no longer the subject of a parental project and are offered for research by the couple.[37] Research on embryos conceived in vitro as part of medically assisted procreation, no longer intended for a parental project, is permissible under the following specific conditions:

- the scientific relevance of the research project is established,
- the research is likely to lead to major medical advances,

[28] Id. art. L2151-5-IV.

[29] Id. art. L2141-4.

[30] Agence de la Biomédecine, supra note 22, at 13.

[31] Agence de la Biomédecine, supra note 22, at 14.

[32] Public Health Code art. L2151-6.

[33] Code pénal [Penal Code] art. 511-19, https://perma.cc/DXU6-3TK5.

[34] Public Health Code art. L2151-2.

[35] Id. art. L2151-3.

[36] Id. art. L2141-3-1.

[37] Id. art. L2151-5.

- it is expressly established that it is impossible to achieve the desired result through research not using human embryos, and
- the research project and the conditions of implementation of the protocol respect the ethical principles relating to embryo research.[38]

The prior written consent of the originating couple or the surviving member is required. They must also be informed about the potential acceptance of embryos by another couple or the discontinuation of storage. If the couple or surviving member consents to research on their supernumerary embryos, detailed information about the planned research is provided to facilitate their free and informed consent. Consent must be confirmed after a three-month reflection period and may be withdrawn at any time.[39]

As discussed in Section II.G, above, embryos subjected to research may not be transferred for gestation purposes and their in vitro development must be concluded no later than 14 days following their formation.[40]

[38] Id. art. L2151-5-II.

[39] Id. art. L2151-5-III.

[40] Id. art. L2151-5-IV.

Germany

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SUMMARY Assisted reproductive technology and the use of human germ cells are regulated in several laws and ordinances, as well as specified in guidelines issued by the German Medical Association. Specific rules related to embryos are codified in the Embryo Protection Act. In order to avoid surplus embryos, Germany limits the number of embryos that may be created and transferred in one cycle to three. Preimplantation genetic diagnostics is generally prohibited with limited exceptions in select cases, such as if there is a high risk of severe hereditary diseases. Sex selection on embryos is generally prohibited, but may be performed on a sperm cell to prevent the child from getting Duchenne muscular dystrophy or a similar severe, sex-linked genetic disease. Cryopreservation must be performed by a physician and only as an exception, such as when the originally intended transfer to the woman cannot be performed due to medical reasons. Egg donations or embryo donations, defined as the extraction of an embryo before its implantation in the womb to transfer it to another woman, are prohibited. However, an embryo donation after in vitro fertilization to preserve the embryo, because the originally intended transfer has become impossible, is accepted. Embryos may not be disposed of or destroyed. Destruction would be an improper use not serving the preservation of the embryo. Lastly, German law completely bans the creation or use of embryos for scientific research. Likewise, the import and use of embryonic stem cells is generally prohibited. As an exception, the law allows the import and use of embryonic stem cells for research purposes if strict conditions are adhered to.

I. Introduction

Assisted reproductive technology (ART) and the use of human germ cells are regulated in several laws and ordinances, as well as specified in guidelines issued by the German Medical Association (Bundesärztekammer). Human germ cells, such as semen and ova, are considered human tissue within the meaning of the German Transplantation Act (Transplantationsgesetz, TPG).[1] The TPG rules are specified in the Transplantation Act Tissue Ordinance (TPG-Gewebeverordnung, TPG-GewV), which implements three different European Union regulations on the use of human tissue and cells.[2] Additional rules may be found in the Medicinal Products Act (Arzneimittelgesetz, AMG) and the Ordinance on the Manufacture of Medicinal Products and

[1] Transplantationsgesetz [TPG], Sept. 4, 2007, Bundesgesetzblatt [BGBl.] I at 2206, as amended, § 1a, no. 4, https://perma.cc/5J3K-9WQW.

[2] TPG-Gewebeverordnung [TPG-GewV], Mar. 26, 2008, BGBl. I at 512, as amended, https://perma.cc/XN6A-PKWP; Consolidated Text of Directive 2004/23/EC, 2004 O.J. (L 102), 48, https://perma.cc/MW29-WEX9; Consolidated Text of Commission Directive 2006/17/EC, 2006 O.J. (L 38), 40, https://perma.cc/S5ZP-6TFF; Consolidated Text of Commission Directive 2006/86/EC, 2006 O.J. (L 294), 32, https://perma.cc/VSD7-AW9Q.

Active Substances (Arzneimittel- und Wirkstoffherstellungsverordnung, AMWHV).[3] Lastly, the Guideline on ART issued by the German Medical Association, which was last revised in 2022, must be taken into account.[4] The Transplantation Act authorizes the German Medical Association to document the generally accepted state of medical knowledge regarding the extraction and transfer of human germ cells in guidelines.[5]

Specific rules related to embryos are codified in the Embryo Protection Act (Embryonenschutzgesetz, ESchG).[6] The ESchG was passed in 1990 and was last substantively amended in 2011 by the Preimplantation Diagnostics Act (Präimplantationsdiagnostikgesetz, PräimpG) to allow preimplantation genetic diagnostics in very limited cases.[7] The 2021 coalition agreement between the governing Social Democratic Party of Germany (Sozialdemokratische Partei Deutschlands, SPD), Green Party (Bündnis 90/Die Grünen), and the Free Democratic Party (Freie Demokratische Partei, FDP) provides in a section on "Reproductive Self-Determination" that the parties are planning to introduce rules to make the costs of preimplantation diagnostics be covered by health insurance, clarify that embryo donations at the pre-nucleus stage are legal, allow elective single embryo transfer, and form a commission on reproductive self-determination and ART to look into ways to legalize egg donations and altruistic surrogacy, among other things.[8] However, no concrete legislative proposals have been advanced so far, because the work of the commission is ongoing.[9]

Depending on the type of ART, other laws might be applicable, such as the Preimplantation Diagnostics Ordinance (Präimplantationsdiagnostikverordnung, PIDV), [10] the Genetic Diagnostics Act (Gendiagnostikgesetz, GenDG), [11] or the Sperm Donor Register Act (Samenspenderregistergesetz, SaRegG).[12]

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[3] Arzneimittelgesetz [AMG], Dec. 12, 2005, BGBl. I at 3394, as amended, https://perma.cc/YK2D-QANE (original), https://perma.cc/SZ75-NACF (English translation); Arzneimittel- und Wirkstoffherstellungsverordnung [AMWHV], Nov. 3, 2006, BGBl. I at 2523, as amended, https://perma.cc/RC3A-6EEN.

[4] Richtlinie zur Entnahme und Übertragungvon menschlichen Keimzellen oder Keimzellgewebe im Rahmen der assistierten Reproduktion, Mar. 18, 2022, Bundesanzeiger Allgemeiner Teil [BAnz AT], at B8, https://perma.cc/DR96-SF6K.

[5] TPG, § 16b.

[6] Embryonenschutzgesetz [ESchG], Dec. 13, 1990, BGBl. I at 2746, as amended, https://perma.cc/VK7J-3QMV.

[7] Präimplantationsdiagnostikgesetz [PräimpG], Nov. 21, 2011, BGBl. I at 2228, https://perma.cc/93M7-GGPZ.

[8] SPD, Bündnis 90/Die Grünen & FDP, *Koalitionsvertrag 2021 – 2025 zwischen der Sozialdemokratischen Partei Deutschlands (SPD), BÜNDNIS 90 / DIE GRÜNEN und den Freien Demokraten (FDP), Mehr Fortschritt wagen, Bündnis für Freiheit, Gerechtigkeit und Nachhaltigkeit* 92 (Koalitionsvertrag 2021-2025) (Dec. 7, 2021), https://perma.cc/37UB-5YNL.

[9] Deutscher Bundestag Drucksache [BT-Drs.] 20/5490, at 92, https://perma.cc/BN8B-L45Y.

[10] Präimplantationsdiagnostikverordnung [PIDV], Feb. 21, 2013, BGBl. I at 323, as amended, https://perma.cc/FRN7-9QT3.

[11] Gendiagnostikgesetz [GenDG], July 31, 2009, BGBl. I at 2529, 3672, as amended, https://perma.cc/3L4P-USYC.

[12] Samenspenderregistergesetz [SaRegG], July 17, 2017, BGBl. I at 2513, as amended, https://perma.cc/SJ9S-HTQG.

II. Rules Related to Embryos Created Through Assisted Reproductive Technology

Germany allows intrauterine insemination, in vitro fertilization (IVF), and intracytoplasmic sperm injection with both partner sperm (homologous insemination) or donor sperm (heterologous insemination). The Guideline on ART specifies the requirements for institutions that perform ART. The Embryo Protection Act defines an embryo as "the fertilized and viable human egg cell from the time of fusion of the nuclei; furthermore, each totipotent cell removed from an embryo that is assumed to be able to divide and to develop into an individual under the appropriate conditions for that."[13]

A. Limit on Number of Embryos That Can Be Created or Transferred

The Embro Protection Act prohibits the transfer of more than three embryos in one cycle or the insemination of more than three eggs through gamete intrafallopian transfer in one cycle.[14] A violation is punishable by a term of imprisonment of up to three years or a fine.[15] Anyone who inseminates more eggs than will be transferred to the woman in one cycle is equally liable.[16]

B. Preimplantation Genetic Testing

Preimplantation genetic diagnostics (PGD) is generally prohibited with limited exceptions in select cases. The Embryo Protection Act provides that anyone who performs genetic in vitro testing on cells of an embryo before its intrauterine transfer (preimplantation diagnostics) is punishable by a term of imprisonment of up to one year or a fine.[17] However, if there is a high risk of severe hereditary diseases, anyone who performs PGD with the written permission of the woman whom the egg belongs to according to the generally accepted state of medical knowledge does not act unlawfully. In addition, anyone who performs PGD with the written permission of the woman whom the egg belongs to in order to diagnose severe damage to an embryo that will most likely lead to a stillbirth or a miscarriage does not act unlawfully.[18]

C. Embryo Selection

Sex selection on embryos is generally prohibited.[19] It is punishable by a prison sentence of up to one year or a fine.[20] However, sex selection on a sperm cell is allowed if it is performed to prevent

[13] ESchG, § 8, para. 1.

[14] Id. § 1, para. 1, nos. 3, 4.

[15] Id. § 1, para. 1.

[16] Id. § 1, para. 1, no. 5.

[17] Id. § 3a, para. 1.

[18] Id. § 3a, para. 2.

[19] Id. § 3.

[20] Id.

the child from getting Duchenne muscular dystrophy or a similarly severe, sex-linked hereditary disease and the competent state authority has recognized the potential disease as severe.[21]

Elective single embryo transfer is prohibited, as discussed in Section I, above. In order to avoid "surplus" embryos, Germany prohibits the insemination of more ova than the number of embryos that will be transferred to the woman in one cycle and caps the number of embryos that may be transferred in one cycle to three.[22]

D. Embryo Preservation

In general, human embryos may be cryopreserved by physicians only.[23] However, embryos may not be created just to cryopreserve them; if a transfer is possible, they must be transferred. The Embryo Protection Act only allows uses that are targeted at preserving the embryo, such as when the originally intended transfer cannot be performed due to medical reasons.[24]

E. Embryo Storage

The Embryo Protection Act does not set any limits for the storage of embryos, as its goal is to avoid the creation of surplus embryos and, therefore, the need to cryopreserve embryos.

Facilities that process, handle, test, store, or place human germ cells or human germ cell tissue on the market as part of ART must have a license according to section 20c, paragraph 1 of the German Medicinal Products Act from the competent state authority in consultation with the Paul-Ehrlich-Institute.[25] However, if the human germ cells or human germ cell tissue remain with the same doctor for the entirety of the procedure and he or she uses them personally on the patient, no authorization is necessary; however, the doctor must notify the competent agency.[26]

F. Embryo Donation

The Embryo Protection Act does not allow egg donation, nor does it allow embryo donation, defined as the extraction of an embryo before its implantation in the womb to transfer it to another woman.[27] However, the act does not explicitly prohibit an embryo donation after IVF to a woman who is not supposed to be a surrogate mother if the embryo cannot be transferred to the original woman as intended.[28] The transfer of the embryo to the woman from whom the egg cell originates

[21] Id.

[22] Id. § 1, para. 1, nos. 3, 5.

[23] Id. § 9, no. 4.

[24] Id. § 2, para. 1.

[25] The Paul-Ehrlich-Institute is a German federal agency, medical regulatory body, and research institution for vaccines and biomedicines. See Paul-Ehrlich-Institut, https://perma.cc/HQ76-AY6W.

[26] AMG, § 20d; § 67, para. 1, sentence 2 in conjunction with § 67, para. 4.

[27] ESchG, § 1, para. 1, nos. 1, 6.

[28] Id. § 1, para. 1, no. 7; Deutscher Ethikrat, *Embryo Donation, Embryo Adoption and Parental Responsibility. Opinion* 33-34 (Mar. 22, 2016), https://perma.cc/8AGN-74FA.

might have become impossible due to medical reasons or because she has died; impossibility might also result from the fact that the women retracts her consent to the procedure.[29] The Embryo Protection Act only explicitly penalizes the extraction of the embryo; it contains a legal loophole with regard to embryo donation to preserve it.[30] The explanatory memorandum to the Embryo Protection Act states that "the draft bill thereby seeks to make the need for a general prohibition of a so-called embryo donation redundant. Such a prohibition under criminal law would at least be worrisome in cases in which embryo donation is the only way of preventing the embryo from dying."[31]

The Bavarian Highest Regional Court (Bayerisches Oberstes Landesgericht, BayObLG) confirmed this view in 2020 and held that embryo donation is generally allowed in such cases.[32]

G. Embryo Disposal

Embryos may not be disposed of or destroyed. The Embryo Protection Act states that "[a]nyone who disposes of or hands over, acquires, or uses for a purpose not serving its preservation, a human embryo produced in vitro or removed from a woman before the completion of implantation in the uterus will be punished with imprisonment of up to three years or a fine."[33] Destruction would be an improper use not serving the preservation of the embryo.

H. Use of Embryos for Scientific Research Purposes

German law completely bans the creation or use of embryos for scientific research; egg cells may only be fertilized to achieve a pregnancy of the woman from whom the egg cells originated.[34]

Likewise, the German Stem Cell Act (Stammzellgesetz, StZG) generally prohibits the import and use of embryonic stem cells.[35] However, as an exception, the law allows the import and use of embryonic stem cells for research purposes under strict conditions.[36] Embryonic stem cells may be imported only if the approval authority is convinced that

- the embryonic stem cells have been derived in accordance with the relevant foreign law before May 1, 2007, have been kept in culture, or have been subsequently stored using cryopreservation methods (embryonic stem cell lines),

[29] Deutscher Ethikrat, supra note 28, at 33.

[30] Id.

[31] BT-Drs. 11/5460, at 8, https://perma.cc/AA9E-ED4W.

[32] BayObLG, Nov. 4, 2020, docket no. 206 St RR 1459/19-1461/19, paras. 66, 67, https://perma.cc/5D3Y-GN7W.

[33] ESchG, § 2, para. 1.

[34] Id. § 1, para. 1, no. 2.

[35] Stammzellgesetz [StZG], June 28, 2002, BGBl. I at 2277, as amended, § 4, para, 1, https://perma.cc/9UCN-AQZY.

[36] Id. § 4, para. 2.

- the embryos from which they were derived were created as a result of medically assisted IVF designed to induce pregnancy, were definitely no longer used for this purpose, and there is no evidence that this was due to reasons inherent in the embryos themselves,
- no compensation or other monetary benefit has been granted or promised for the donation of embryos used for the procurement of stem cells, and
- no other legal provisions, in particular those of the German Embryo Protection Act, conflict with the import or use of the embryonic stem cells.[37]

Additionally, the import must receive authorization from the competent agency, which will be granted if the above-mentioned requirements are complied with, the research project is "ethically acceptable," and an opinion by the Central Ethics Commission on Stem Cell Research has been submitted following a request by the competent agency to this effect.[38] A research project is "ethically acceptable" if it serves particularly important research aims to advance scientific knowledge in basic research or to increase medical knowledge for the development of diagnostic, preventive, or therapeutic methods to be applied to humans and, according to the state of the art, the questions have been clarified, as far as possible, through in vitro models using animal cells or animal experiments and the scientific knowledge to be obtained can only be gained by using embryonic stem cells.[39] Approval must not be given if the embryonic stem cells have been derived in contradiction to major principles of the German legal system.[40]

[37] Id.

[38] Id. § 6, para. 4.

[39] Id. § 5.

[40] Id. § 4, para. 3.

Italy

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SUMMARY Regulations concerning embryos created through in vitro fertilization are contained in Law No. 40 of 2004, as partially repealed and interpreted by successive decisions of the Italian Constitutional Court. The original text of Law No. 40 contains a restrictive approach to the such embryos, concerning, among other aspects, their number, commercialization, eugenic selection, cloning, cross-species fertilization, altering of the genetic heritage of the embryo, donation, and the embryonic reduction of multiple pregnancies (except as permitted by the law). Testing of embryos and gametes for diagnostic and therapeutic purposes is permitted. Cryopreservation and suppression or disposal of embryos is largely prohibited, except as conducted in accordance with law.

In 2009 the Constitutional Court declared invalid the legislative restriction on the number of embryos of three imposed by Law No. 40 and ruled that the transfer of embryos must also be carried out without prejudice to the health of the woman. Any experimentation on any human embryo is still prohibited, and their production for research or experimentation purposes is only allowed as permitted by Law No. 40, that is, exclusively for therapeutic and diagnostic purposes aimed at protecting the health and development of the embryo itself, in the absence of alternative methodologies. However, disagreements exist amongst legal and scientific experts in Italy concerning the scope of Law No. 40's ban on embryo experimentation, as the practice of research on embryonic material imported from abroad still continues.

I. Introduction

The legal framework on the use and protection of embryos resulting from artificial reproductive technology (ART) in Italy is highly complex. The main regulations are contained in Law No. 40 of February 19, 2004.[1] However, several crucial decisions of the Italian Constitutional Court have either interpreted or repealed some of Law No. 40's provisions. Therefore, to understand the current legal framework regarding embryos created through artificial reproductive technology (ART) procedures in Italy, it is necessary to refer to these decisions, not only concerning their express declarations, but also noting areas upon which the rulings were silent, as will be explained further in this report.

[1] Legge 19 febbraio 2004, n. 40 (Law No. 40), Norme in materia di Procreazione Medicalmente Assistita, https://perma.cc/VQ72-6P9K.

In particular, the following decisions of the Italian Constitutional Court are relevant: Decision No. 151 of 2009,[2] Decision No. 229 of October 22, 2015,[3] and Decision No. 84 of April 13, 2016.[4]

II. Rules Related to Embryos Created through Assisted Reproductive Technology

Law No. 40 of 2004 prohibits: (a) the carrying out, organizing, or advertising of the commercialization of gametes or embryos or maternity surrogacy;[5] (b) cloning interventions through nuclear transfer or early splitting of the embryo or ectogenesis for both procreative and research purposes;[6] (c) the fertilization of a human gamete with a gamete of a different species and the production of hybrids or chimeras;[7] and (d) embryonic reduction of multiple pregnancies.[8]

Through Decision No. 151 of 2009, the Italian Constitutional Court rejected a request for a declaration of the unconstitutionality of several provisions of Law No. 40 concerning embryonic reduction of multiple pregnancies.

Later, by Decision No. 84 of 2016, the same court rejected a request for a declaration of the unconstitutionality of several provisions of Law No. 40. This rejected request sought to eliminate the ban on the withdrawal of the couple's consent to medically-assisted procreation procedures beyond the moment of the egg's fertilization; the ban on experimentation on human embryos, except for therapeutic or diagnostic purposes; the prohibition of genetic selection; cloning; and the ban on the fertilization of a human gamete with a gamete of a different species.[9]

As a result, under Law No. 40, as sanctioned by the Italian Constitutional Court, permissible activities related to embryos include interventions for diagnostic and therapeutic purposes.[10] Furthermore, despite the general ban of Law No. 40, article 14.4 on the embryonic reduction of multiple pregnancies, this procedure is permitted under the circumstances established in Law No. 194 of 1978, related to the interruption of pregnancy.[11]

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[2] Sentenza del 8 maggio 2009, n. 151 (Decision No. 151 of 2009), https://perma.cc/T2GV-RVTB.

[3] Sentenza del 22 ottobre 2015, n. 229 (Decision No. 229 of 2015), https://perma.cc/Y7N6-PGSP.

[4] Sentenza del 13 aprile 2016, n. 84 (Decision No. 84 of 2016), Considerations of Law No. 1(a), https://perma.cc/D4K8-TC6Q.

[5] Law No. 40, art. 12.6.

[6] Id. art. 13.3(c).

[7] Id. art. 13.3(d).

[8] Id. art. 14.4.

[9] Decision No. 151 of 2009, Considerations of Law No. 1(b).

[10] Law No. 40, art. 13.3(b).

[11] Id. art. 14.4; Legge 22 maggio 1978, n. 194, Norme per la Tutela Sociale della Maternita' e sull'Interruzione Volontaria della Gravidanza, articles 4 and 6, https://perma.cc/JTD6-RLLC.

A. Limit on Number of Embryos that Can Be Created or Transferred

Under article 14.2 of Law No. 40 of 2004, embryo production techniques must not create a number of embryos greater than that strictly necessary for a single and contemporary implantation, and in any case not greater than three.[12]

However, Decision No. 151 of 2009 declared the unconstitutionality of article 14.2, which had established the mandatory maximum creation of three embryos, the obligation to proceed in a single and simultaneous implantation of embryos not exceeding three, and a ban on the cryopreservation of supernumerary embryos.[13] Later, Decision No. 84 of 2016 recalled that the possibility of creating embryos not brought to birth – commonly defined as supernumerary or residual – emerged with Decision No. 151 of 2009.[14] Decision No. 84 of 2016 also held that the constitutional protection of the embryo is subject to balancing vis-à-vis the protection of women's health,[15] and that this balance is reserved to the legislator.[16]

As a result, the current version of article 14.2 of Law No. 40 reads as follows:

> The embryo production techniques, taking into account the technical-scientific evolution and the provisions of article 7, paragraph 3, must not create a number of embryos greater than that strictly necessary for a single and contemporary implantation.

As already indicated, the original phrase "in any case not greater than three" was eliminated by Decision No. 151 of 2009.

Therefore, there is no fixed limit on the number of embryos that can be created or transferred in an ART treatment cycle, but there remains a restriction to a number no "greater than that strictly necessary for a single and contemporary implantation."

As a result of the Court's derogation of the ban on cryopreservation, currently embryos produced but not implanted are subject to freezing.[17]

B. Preimplantation Genetic Testing

As noted above, under Law No. 40, as sanctioned by the Italian Constitutional Court, permissible activities related to embryos include interventions for diagnostic and therapeutic purposes.[18]

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[12] Law No. 40, art. 14.2.

[13] Decision No. 151 of 2009, Considerations of Law No. 1, para. 1.

[14] Id. No. 8.2, para. 1.

[15] Id. No. 8.2.1, para 3.

[16] Id. No. 11, para 5.

[17] Id.

[18] Law No. 40, art. 13.3(b).

In 2012, the European Court of Human Rights (ECtHR) issued a decision concerning preimplantation genetic diagnosis (PGD) in Italy, stating that:

> Having regard to the above-described inconsistency in Italian legislation on PGD, the Court considers that the interference with the applicants' right to respect for their private and family life was disproportionate. Accordingly, there has been a violation of Article 8 of the Convention in the present case.[19]

Subsequently, the Italian Constitutional Court, in Decision No. 229 of 2015,[20] held that embryos can be the subject of preimplantation diagnosis.[21] Therefore, PGD seems to be permitted in Italy.

C. Embryo Selection

Law No. 40 of 2004 prohibits any form of selection, for eugenic purposes, of embryos and gametes or interventions which, through selection techniques, manipulation, or through artificial procedures, are aimed at altering the genetic heritage of the embryo or gamete or predetermining its genetic characteristics.[22]

In Decision No. 151 of 2009, the Constitutional Court declared article 14.3 of Law No. 40 to be unconstitutional because it did not provide that the transfer of embryos, to be carried out as soon as possible, must *also* be carried out without prejudice to the health of the woman.[23]

Later, in Decision No. 229 of 2015, the court addressed the constitutional legitimacy of the ban on the suppression of human embryos generated in test tubes, even if affected by genetic pathologies, stating that their "malformation does not justify, for this reason alone, a worse treatment compared to that of healthy embryos created in number . . . greater than what is strictly necessary."[24] In addition, this decision declared the unconstitutionality of the crime of selecting embryos for implantation.[25]

Therefore, embryo selection for implantation on the basis of preimplantation genetic testing seems to be permitted in Italy. Per the above-mentioned Constitutional Court decisions, the suppression of embryos is only abstractly admissible if it is justified by another constitutionally-protected interest.[26]

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[19] *Costa and Pavan v. Italy* (No. 54270/10), at 3, Conclusion 71, https://perma.cc/QAZ4-QK78.

[20] Elisa Chieregato, *La Resistenza del Divieto di Donazione di Embrioni alla Ricerca Scientifica tra Margine di Apprezzamento Europeo e Deferenza al Legislatore* (June 4, 2016), at 5, paras. 4 and 6, commenting on Decision No. 229 of October 22, 2015, at 5, para. 2, https://perma.cc/YQM2-UR7Y.

[21] Id. at 5, para. 2.

[22] Law No. 40, art. 13.3(b).

[23] Decision No. 151 of 2009, Considerations of Law No. 6.1, para. 8.

[24] Chieregato, supra note 20, at 5, paras. 4 and 6, commenting on Decision No. 229 of October 22, 2015.

[25] Id.

[26] Id. at 15, para. 3.

D. Embryo Preservation

Law No. 40 of 2004 prohibits the cryopreservation and suppression of embryos,[27] except as conducted in accordance with Law No. 40 and Law No. 194 of May 22, 1978.[28] Per this legislation, cryopreservation of the embryos themselves is permitted until the date of the transfer, which is to be carried out as soon as possible in situations where immediate transfer of the embryos into the uterus is not possible due to a serious and documented cause of *force majeure* relating to the woman's health, which could not have been foreseen at the time of fertilization.[29]

In addition, under Law No. 40, cryopreservation of male and female gametes is subject to informed and written consent.[30]

Decision No. 151 of 2009 of the Constitutional Court rejected a request for a declaration of the unconstitutionality of Law No. 40's provisions establishing a ban on cryopreservation and suppression of embryos.

Later, in its Decision No. 229 of 2015, the Constitutional Court held that "there is a need to protect the dignity of the embryo, to which, at present, no other response can be given than that of the cryopreservation procedure, and that the protection of the dignity of the embryo does not in itself allow the suppression of embryos."[31] However, the court left open the possibility of mitigating embryo protection when justified by significant conflicting interests.[32]

Therefore, cryopreservation appears to be potentially admissible in limited circumstances, where the embryos cannot be immediately transferred due to the health of the woman.

E. Embryo Storage

As stated above, presently, under Law No. 40 of 2004 (updated pursuant to the already-mentioned Italian Constitutional Court decisions), embryo production may not result in a number of embryos greater than that strictly necessary, as indicated in Part II.A above.[33]

As a consequence, as excess embryos may not be discarded, they must necessarily be stored according to the techniques accepted by current scientific knowledge, that is through freezing.[34]

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[27] Law No. 40, art. 14.1.

[28] Id.

[29] Id. art. 14.3.

[30] Id. art. 14.8.

[31] Chieregato, supra note 20, at 6.

[32] Id.

[33] Law No. 40, art. 14.2.

[34] Decision No. 151 of 2009, Considerations of Law No. 8.2, para. 1.

As discussed further below, Law No. 40 prohibits the donation of embryos.[35] However, Law No. 40 is silent on the fate of frozen and abandoned embryos, therefore leaving as the only option their conservation in a frozen state until the moment of their natural extinction[36] or until used, exclusively, by the couple who generated them.[37] This means that cryopreserved embryos – that is, embryos that have been frozen but not transferred – can remain stored for dozens of years and have virtually no expiry date.[38]

F. Embryo Donation

In Decision No. 229 of 2015, the Italian Constitutional Court did not alter the legal ban on killing embryos produced by medically-assisted procreation nor the legal ban on their donation for scientific research or reproductive purposes.[39]

Notably, the court mentioned the decision of the ECtHR in *Parrillo v. Italy*, concerning the ban on donating surplus embryos to scientific research. In the underlying ECtHR case, an Italian female citizen had asked to have five embryos, which had been created through medically-assisted procreation techniques (before the promulgation of Law No. 40), donated to scientific research, as she was not able to proceed with the transfer to the uterus due to her partner's death.[40] The ECtHR, as the Italian Constitutional Court recalled, declared the Italian ban on experimentation on embryos and the prohibition of embryo donation for experimentation purposes admissible under EU law.[41]

G. Embryo Disposal

Decision No. 229 of 2015 confirmed the constitutionality of Law No. 40's ban on embryo suppression, even if the embryo is "affected by genetic pathologies."[42] As, *de facto*, selection implies the choosing of some embryos to the detriment of others, the logical consequence of the admissibility of discarding the non-selected embryos appears to be negated by Law No. 40's rule against suppression and disposal.

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[35] Angela Arlotta, *Embriodonazione in Italia, Come Possiamo Utilizzare gli Embrioni Congelati?,* AngelaArlotta-Fertilità.com (July 3, 2019), https://perma.cc/54ZU-GX34.

[36] Chieregato, supra note 20, at 5, para. 3.

[37] Arlotta, supra note 35.

[38] Mario Mignini Renzini, *Cosa Succede agli Embrioni Congelati in Italia?*, EUGIN (May 26, 2021), https://perma.cc/FNC9-H7F5.

[39] Id.

[40] Id. at 6.

[41] Id. at 7, para. 2.

[42] Chieregato, supra note 20, at 5, para. 4 and 6.

On the other hand, an alternative interpretation sustains that under the already cited Constitutional Court decisions, the suppression of embryos is abstractly admissible if it is justified by the protection of another constitutionally-protected interest.[43]

As a result, the issue of whether embryos can be disposed of in Italy remains contentious and unclear.

H. Use of Embryos for Scientific Research Purposes

As noted above, Law No. 40 prohibits: (a) any experimentation on any human embryo,[44] and (b) the production of human embryos for research or experimentation purposes or for any purposes other than those set forth in Law No. 40.[45]

That is, under Law No. 40, clinical and experimental research on human embryos is permissible exclusively for related therapeutic and diagnostic purposes aimed at protecting the health and development of the embryo itself, when alternative methodologies are not available.[46]

As already stated, Decision No. 84 of 2016 rejected an unconstitutionality request regarding this absolute ban on any clinical or experimental research on embryos not resulting in the protection thereof.[47]

It should be noted that discrepancies still exist amongst legal and scientific experts in Italy concerning the scope of Law No. 40's ban on embryo experimentation. In particular, it is noted that Law No. 40 does not mention embryonic stem cells, but simply bans experimentation on human embryos.[48] As a result, after 2004, research continued in Italy on material imported from abroad as it has been interpreted that Law No. 40 does not contain an express ban on experiments on embryonic stem cells that are lawfully produced abroad.[49]

[43] Id. at 15, para. 3.

[44] Law No. 40, art. 13.1.

[45] Id. art. 13.3(a).

[46] Id. art. 13.2.

[47] Decision No. 84 of 2016, Considerations of Law No. 1(a), https://perma.cc/D4K8-TC6Q.

[48] Filomena Gallo, *Embrioni alla Ricerca: il Paradosso della Legge 40* (Feb. 24, 2014), https://perma.cc/J8NE-PXUV.

[49] Id.

New Zealand

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SUMMARY New Zealand's approach to regulating assisted reproductive technology and human reproductive research involves three tiers: legislation, policy guidelines and advice by an advisory committee, and decisions on individual applications by an ethics committee. Certain "established procedures" do not require approval. Fertility services are audited against a non-statutory code of practice. There are no limits on the number of embryos that can be created in an IVF treatment cycle; preimplantation genetic testing is permitted for the diagnosis of genetic disorders only; sex selection is not permitted unless it is to prevent or treat a genetic disorder; and embryo cryopreservation and related actions are permitted. Currently, surplus embryos created during an IVF treatment cycle may either be stored, discarded, or donated for use in fertility treatment. There is a 10-year limit on cryostorage, unless the ethics committee grants an extension, after which embryos must be discarded. Embryo donation requires ethics committee approval in all cases and no payment is permitted. Surplus embryos cannot currently be used for scientific research purposes, although the advisory committee has sought public comment on whether to develop new guidelines that allow this.

I. Introduction

In New Zealand, the Human Assisted Reproductive Technology Act 2004 (HART Act)[1] governs the use of assisted reproductive technology such as in vitro fertilization (IVF), as well as research using human embryos. Additional rules under this legislation are contained in the Human Assisted Reproductive Technology Order 2005 (HART Order).[2]

The HART Act established the Advisory Committee on Assisted Reproductive Technology (ACART),[3] which issues guidelines and gives advice on any matter related to assisted reproductive procedures or human reproductive research to the Ethics Committee on Assisted Reproductive Technology (ECART), which was also established by the act.[4] In making decisions on applications, ECART must also consider a list of principles contained in section 4 of the HART Act.[5]

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[1] Human Assisted Reproductive Technology Act 2004 (HART Act), https://perma.cc/K9PY-2HX8.

[2] Human Assisted Reproductive Technology Order 2005 (HART Order), https://perma.cc/GZ8D-LMSV.

[3] HART Act s 32.

[4] Id. s 27. See also *Terms of Reference*, Advisory Committee on Assisted Reproductive Technology (ACART), https://perma.cc/U88E-2D29. Current guidelines are listed at *Guidelines and Advice Issued to ECART*, ACART, https://perma.cc/RTF3-998E.

[5] HART Act s 4.

Schedule 1 of the HART Order declares certain procedures and treatments to be "established procedures" under section 6 of the HART Act. Such procedures are not required to be approved by ECART.[6]

In addition, fertility services are governed by the Health and Disability Services (Safety) Act 2001,[7] and issues related to consent and other consumer rights for people undertaking fertility treatment are governed by the Health and Disability Commissioner (Code of Health and Disability Services Consumers' Rights) Regulations 1996.[8]

The New Zealand Ministry of Health mandates that providers of fertility services attain certification against NZS 8134:2021 – *Ngā Paerewa Health and Disability Services Standard*.[9] This standard includes high level requirements related to donation and surrogacy,[10] and to obtaining and caring for gametes and embryos.[11]

In addition, providers may be certified under the Reproductive Technology and Accreditation Committee (RTAC) Scheme of the Fertility Society of Australia and New Zealand.[12] The RTAC has developed the *Code of Practice for Assisted Reproductive Technology Units*,[13] which is "the standard against which ART Units in Australia and New Zealand are audited."[14] The Ministry of Health's *Designated Auditing Agency Handbook* for NZS 8134:2021 requires that auditors of fertility services be accredited by the RTAC under the RTAC Scheme and have an "in-depth understanding of RTAC code."[15]

[6] Id. ss 5 (definitions of "assisted reproductive procedure or procedure" & "established procedure") & 16.

[7] See id. s 80; Health and Disability Services (Safety) Act 2001 s 5, https://perma.cc/M8TN-MJ2H.

[8] Health and Disability Commissioner (Code of Health and Disability Services Consumers' Rights) Regulations 1996, https://perma.cc/Q9S7-QNQ9.

[9] *Services Standard*, Ministry of Health, https://perma.cc/UYH7-4G53; Standards New Zealand, NZS 8134:2021 (Incorporating Amendment No. 1): Ngā Paerewa Health and Disability Services Standard (on file with author).

[10] NZS 8134:2021 ¶ 1.10.

[11] Id. ¶ 3.8.

[12] See Fertility Society of Australia, *Reproductive Technology Accreditation Committee Certification Scheme (RTAC Scheme)* (rev. 1, Oct. 2010), https://perma.cc/MNX4-2PBG; Fertility Society of Australia and New Zealand, *Reproductive Technology Accreditation Committee Scheme (RTAC Scheme): Requirements for Bodies Providing Audit and Certification to the Code of Practice for Assisted Reproductive Technology Units* (Combined Australia, New Zealand and International Edition, Dec. 20, 2021), https://perma.cc/3UA6-4WN7.

[13] Fertility Society of Australia and New Zealand, Reproductive Technology Accreditation Committee, *Code of Practice for Assisted Reproductive Technology Units* (rev. Oct. 2021), https://perma.cc/B6K7-G3CR.

[14] *Australian and New Zealand Code of Practice*, Fertility Society of Australia and New Zealand, https://perma.cc/G6ML-PTRE.

[15] Manatū Hauora (Ministry of Health), *Designated Auditing Agency Handbook* 11 & 19 (2023), https://perma.cc/NCK6-QRBB.

II. Rules Related to Embryos Created through Assisted Reproductive Technology

A. Limit on Number of Embryos that Can Be Created or Transferred

The legislation does not contain limits on the number of embryos that can be created in an IVF treatment cycle, or the number of embryos that can be transferred to a person's uterus.

The RTAC Code of Practice includes requirements (i.e. non-statutory requirements upon which audits of fertility services are conducted) related to minimizing the incidence of multiple pregnancies, with ART Units required to "provide evidence of implementation and review of policies and procedures that":

> a) Ensure a regular audit (at least annually) of multiple pregnancy rates and corrective actions that continuously attempt to reduce the incidence of multiple pregnancies in all treatment cycles, including artificial insemination even when the insemination is done offsite
> b) Recommend to patients that no more than one embryo or oocyte is transferred in the first treatment cycle where the oocyte is obtained from a woman aged less than 35 years at the time of oocyte collection
> c) Ensure that no more than two embryos or oocytes are transferred in any one treatment cycle in a woman under the age of 40 years at the time of oocyte collection
> d) Ensure that no more than two embryos or oocytes are transferred to a recipient woman, of any age, in any one treatment cycle, where the oocytes are donated from a woman aged less than 40 years at the time of oocyte collection
> e) Ensure single embryo transfer is mandatory for a gestational carrier in surrogacy arrangements
> f) Ensure that patients receive information on the risks to parents and babies associated with multiple pregnancies[16]

The code does not include limits on the creation of embryos from an IVF cycle. It requires that ART Units minimize the incidence of medical and surgical risks, including ovarian hyperstimulation syndrome, and provide evidence of implementation and review of relevant policies and procedures.[17]

B. Preimplantation Genetic Testing

Preimplantation genetic diagnosis (PGD) is listed in the HART Order as an established procedure, defined as

> [a] procedure for genetically testing embryos for specific genetic conditions or chromosomal abnormalities prior to embryo transfer and that includes any of the following undertaken for, or in connection with, that procedure:
> (a) biopsy of embryos to remove 1 or more cells:
> (b) transportation of the cells to an approved laboratory:
> (c) analysis of the genetic or chromosomal constitution of cells obtained by biopsy:

[16] Code of Practice for Assisted Reproductive Technology Units, supra note 13, § 3.3.

[17] Id. § 3.1.

(d) selection of embryos for transfer on the basis of the results from analysis.[18]

However, if any of the following purposes *do not* apply, PGD will not be considered an established procedure and ECART approval will be required for its use:

(a) diagnosis of familial single-gene disorders where—
  (i) the disorder has been identified in the family or whānau; and
  (ii) there is a 25% or greater risk of an affected pregnancy; and
  (iii) there is evidence that the future individual may be seriously impaired as a result of the disorder; or
(b) sex determination where—
  (i) a familial sex-linked disorder has been identified in the family or whānau; and
  (ii) there is a 25% or greater risk of an affected pregnancy; and
  (iii) no specific test for the particular mutation that causes the disorder is available; and
  (iv) there is evidence that the future individual may be seriously impaired as a result of the disorder; or
(c) diagnosis of familial chromosomal disorders where—
  (i) the disorder has been identified in the family or whānau; and
  (ii) there is a 25% or greater risk of an affected pregnancy; and
  (iii) there is evidence that the future individual may be seriously impaired as a result of the disorder; or
(d) diagnosis of non-familial chromosomal disorders (aneuploidy testing) where—
  (i) the woman is of advanced reproductive age; or
  (ii) the woman has had recurrent implantation failure or recurrent miscarriage.[19]

ACART has issued *Guidelines on Preimplantation Genetic Diagnosis with Human Leucocyte Antigen Tissue Typing*.[20] These guidelines "expand New Zealand's policy on preimplantation genetic diagnosis (PGD) with human leucocyte antigen (HLA) tissue typing to allow its use to find a tissue match for a sick child with a non-genetic disease."[21] To approve such use of the procedure, in addition to considering the principles in the HART Act, ECART must be satisfied that, for example, the resulting child will be a brother or sister of the sick child; that the prospective parents have received the required medical advice, including what tissue may be potentially required, with the only two options being cord blood or bone marrow; that "the condition of the sick child for which PGD with HLA tissue typing is being undertaken is judged by the clinical team and prospective parents to be of sufficient severity to justify undertaking the procedure"; and that appropriate counseling and independent opinion has been received.[22]

[18] HART Order sch 1 pt 1.

[19] Id. sch 1 pt 2 cl 6.

[20] ACART, *Guidelines on Preimplantation Genetic Diagnosis with Human Leucocyte Antigen Tissue Typing* (Aug. 18, 2014), https://perma.cc/A46Z-TMM9.

[21] Id. at 2.

[22] Id. at 4–5.

C. Embryo Selection

The HART Act provides that an embryo may not be selected for implantation on the basis of the sex of an embryo, and no procedure may be performed that is aimed at ensuring or increasing the probability that an embryo will be of a particular sex. A person who contravenes this rule may be liable to imprisonment of up to one year or a fine of up to NZ$100,000 (about US$61,664), or both. However, it is a defense to such a charge "if the defendant proves that the act to which the charge relates was performed to prevent or treat a genetic disorder or disease."[23]

D. Embryo Preservation

Embryo cryopreservation is listed as an established procedure in schedule 1 of the HART Order, which defines it broadly as follows:

> A procedure in which embryos are maintained as potentially viable over a period of time by freezing them and that includes any of the following undertaken for, or in connection with, that procedure:
> (a) preparation of embryos for freezing:
> (b) freezing of embryos:
> (c) storage of embryos at low temperatures:
> (d) thawing of embryos:
> (e) in vitro culture of embryos:
> (f) inspection and grading of embryos:
> (g) alteration of hormonal control of the ovaries and uterus using drugs:
> (h) stimulation of multiple follicle development using drugs:
> (i) triggering ovulation using drugs:
> (j) embryo transfer into the uterus or Fallopian tubes:
> (k) discarding of embryos.[24]

All of these actions related to embryos are therefore permitted without prior approval from ECART.

E. Embryo Storage

The HART Act prohibits the "storage, manipulation, and use" of a human *in vitro* embryo beyond a period of 10 years,[25] unless ECART approves an extension in respect of the embryo.[26]

ACART has produced *Guidelines for Extending the Storage of Gametes and Embryos*,[27] which must be applied by ECART, along with the principles in the act, in determining whether to approve extensions to the storage period. The guidelines cover requirements related to informed consent

[23] HART Act s 11.

[24] Hart Order sch 1 pt 1.

[25] Id. s 10(1) & (4).

[26] Id. s 10A.

[27] ACART, *Guidelines for Extending the Storage of Gametes and Embryos* (June 2023), https://perma.cc/B3TA-GYZK.

and other considerations, including "any intergenerational effects on children where storage is for the purposes of fertility treatment or fertility preservation."[28]

The RTAC Code of Practice includes requirements on the cryostorage of gametes and embryos, as follows:

> [t]he ART Unit must provide evidence of implementation and review of policies and procedures to ensure the safe management of cryopreserved gametes, embryos and tissues. These records must include but are not limited to clear identification of the storage container in a form that is resistant to degradation during cryostorage, and the location of the container in the storage vessel. Records must be kept of temperature movements within the vessel that may affect the viability of any stored genetic material. Also, records must be kept including but not limited to the date of purchase of the storage vessel and its age. There must be a policy covering the monitoring of storage vessels and on detecting a failure and this must include a policy of renewal of storage vessels.[29]

The code also includes requirements related to the reporting of serious adverse events, including an event that "[c]auses a loss of viability of gametes or embryos or suspected deterioration (beyond accepted laboratory standards) that renders them unsuitable for use."[30]

F. Embryo Donation

Embryo donation to another person for use in fertility treatment is subject to ECART approval in all cases.[31] In addition, section 13 of the HART Act prohibits the commercial supply of human embryos, stating: "[n]o person may give or receive, or agree to give or receive, valuable consideration for the supply of a human embryo or human gamete."[32] Advertising in any way for such an action is also specifically prohibited.[33]

Among the matters that ACART is specifically tasked with providing advice on is "donations of human embryos." Current guidance, which must be applied by ECART, is contained in the 2020 *Guidelines for Family Gamete Donation, Embryo Donation, the Use of Donated Eggs with Donated Sperm and Clinic Assisted Surrogacy*.[34] This includes, for all procedures covered by the guidelines, a list of general requirements, including a requirement that "full genetic siblings are produced in no more than two families"; counseling requirements; consent requirements; legal advice requirements; and health advice requirements.[35]

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[28] Id. at 7.

[29] Code of Practice for Assisted Reproductive Technology Units, supra note 13, § 2.9.

[30] Id. § 3.2.2.

[31] See *Surplus Embryos*, Fertility New Zealand, https://perma.cc/U7RW-DMZH; Fertility Plus (Te Korito), *Information for Embryo Donation* (Oct. 2021), https://perma.cc/F42C-RYUA.

[32] HART Act s 13(1).

[33] Id. s 15.

[34] ACART, Guidelines for Family Gamete Donation, Embryo Donation, the Use of Donated Eggs with Donated Sperm and Clinic Assisted Surrogacy (2020), https://perma.cc/U2DZ-6QFD.

[35] Id. at 3–6.

Part 3 of the HART Act contains provisions related to information that must be provided to, and kept about, donors of donated embryos, and how information about donors may be accessed.

G. Embryo Disposal

As shown in subpart B above, discarding of embryos is permitted. In fact, after 10 years of storage, embryos must either be discarded or donated for use in fertility treatment unless a storage extension has been granted by ECART. The HART Act provides that "[f]or a 6-month period starting with the expiry of the applicable period [i.e. 10 years], any person may store for disposal or dispose of, but no person may in any other way store, manipulate, or use, the gamete or embryo."[36] After that six-month period, "no person may for any purpose store, manipulate, or use the gamete or embryo."[37]

H. Use of Embryos for Scientific Research Purposes

Currently, as explained below, viable human embryos cannot be used for scientific research purposes; therefore, people cannot choose for their "surplus" embryos from IVF treatment cycles to be donated for human reproductive research.[38]

The HART Act defines human reproductive research as "research that uses or creates a human gamete, a human embryo, or a hybrid embryo."[39] The act specifically prohibits the importation, use, and possession, for human reproductive research, of an *in vitro* human embryo that has been developed for a period longer than 14 days after the date of its formation, and prohibits doing anything to cause the further development of the embryo outside the body of a human being after that period.[40]

Schedule 1 of the HART Act contains specifically prohibited actions, including artificially forming, for reproductive purposes, a cloned embryo or hybrid embryo; implanting into a human being a cloned, animal, hybrid, or genetically modified embryo; and implanting into an animal a human or hybrid embryo.[41] These prohibitions "do not extend to lab-based or 'non-clinical' research not involving *implantation* in a human being or animal."[42]

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[36] HART Act s 10(2).

[37] Id. s 10(3).

[38] See Grace KA Williams, Embryo Research in Legal Limbo: A Critique of the Legal Framework for Embryo Research in New Zealand (LLB(Hons) dissertation, University of Otago, Oct. 2018), https://perma.cc/WS6F-AY9W.

[39] HART Act s 5 (definition of "human reproductive research").

[40] Id. s 9(2) & (4).

[41] Id. sch 1 ("prohibited actions").

[42] Jeanne M. Snelling, *Obstruction and Obfuscation: Regulatory Barriers to Human Embryo Research in New Zealand*, 20(4) Med. L. Int'l 339, 349 (2021) (on file with author).

Therefore, there are no express restrictions on "non-clinical" research involving human embryos of less than 14 days postfertilization.[43] However, section 16 of the HART Act provides that human reproductive research may only proceed with prior approval from ECART.

ECART can only approve applications to conduct such research "if it is satisfied that an application is consistent with the relevant guidelines, or advice, issued by ACART. If there are no guidelines governing the particular procedure proposed, ECART cannot approve applications."[44] The only guidelines related to embryo research that have been produced in New Zealand are the *Guidelines for Research on Gametes and Non-viable Embryos Research Guidelines*, published by the National Ethics Committee on Assisted Human Reproduction in 2005.[45] Under the HART Act, these guidelines have been taken to be applicable to ECART as "interim" guidelines.[46] Therefore, currently, ECART may only approve embryo research applications involving "non-viable" embryos – it is unable to consider any proposed research involving surplus donated embryos.[47]

In November 2022, ACART published a consultation document on research involving human gametes and embryos, with a view to providing updated guidelines. The closing date for feedback on the document was March 31, 2023.[48] The document includes discussion about using surplus embryos in research.

[43] Id.

[44] Id. citing HART Act ss 19(2) & 18(2).

[45] National Ethics Committee on Assisted Human Reproduction, *Guidelines for Research on Gametes and Non-viable Embryos* (2005), https://perma.cc/H6N6-WW9K.

[46] *Guidelines for Research on Gametes and Non-viable Embryos*, ACART, https://perma.cc/NY5U-SYW2; Snelling, supra note 42, at 351–52.

[47] See *Government Called to Define Law on Embryo Research*, University of Auckland (June 22, 2018), https://perma.cc/DH27-B7BV.

[48] *Research Involving Human Gametes and Embryos*, ACART (Nov. 29, 2022), https://perma.cc/BD26-JQLC; *Consultation on Research Involving Human Gametes and Embryos*, Ministry of Health (Nov. 29, 2022), https://perma.cc/3BNZ-YZVH; ACART, *Research Involving Human Gametes and Embryos: Consultation Document* (Nov. 2022), https://perma.cc/7APY-6PKP.

Poland

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SUMMARY Medically assisted reproduction in Poland is regulated by several laws, most notably the 2015 Act on Infertility Treatment, the Medical Profession Act of Dec. 5, 1996, the Code of Medical Ethics, and the Ministry of Health Regulation of October 20, 2015, on Training in the Collection, Processing, Storage, Testing and Distribution of Reproductive Cells and Embryos Intended for Use in the Medically Assisted Procreation Procedures.

In vitro fertilization treatment is only available to those who have attempted other means of treatment for at least 12 months or those who have not completed the full 12-month period of other treatments because, based on current medical knowledge, achieving pregnancy through these methods is deemed unfeasible.

According to the Act on Infertility Treatment, the number of oocytes fertilized during a single IVF attempt is limited to no more than six female reproductive cells, unless the recipient is over 35 years old or for medical reasons.

In Poland, embryos may be cryopreserved and stored in germ cells and embryos banks for up to 20 years, after which they are to be transferred for donation if they meet two conditions: first, that the rate and the sequence of cell division and morphological structure make proper embryo development probable, and second, if the embryo has not been diagnosed with a defect that would result in severe and irreversible impairment or an incurable disease. The Act on Infertility Treatment stipulates compulsory embryo donation after 20 years of storage if surplus embryos are not utilized by the couple for their own embryo transfer.

The Act on Infertility Treatment bans the destruction of embryos and their use in scientific research.

I. Introduction

In Poland, medically assisted reproduction is regulated by the Act on Infertility Treatment, enacted in 2015. [1]

This legal act limits assisted reproduction to those with clinically proven infertility, and stipulates the conditions for the use of reproductive technologies, establishes the rules and procedures for donation, collection, processing, testing, storage, and distribution of reproductive cells and embryos intended for use in medically assisted procreation procedures, sets up the requirements

[1] Act of June 25, 2015, on Infertility Treatment, effective Nov. 1, 2015, last amended in 2020, https://perma.cc/6SKW-8SFZ (in Polish).

for donations of gametes and embryos, and provides the conditions for the national register of medically assisted procreation centers, as well as reproductive cell and embryo banks.[2]

Additional rules on assisted reproduction are contained in the Medical Profession Act of December 5, 1996, the Code of Medical Ethics, and the Ministry of Health Regulation of October 20, 2015, on Training in the Collection, Processing, Storage, Testing and Distribution of Reproductive Cells and Embryos Intended for Use in the Medically Assisted Procreation Procedures.[3]

Provisions of the Code of Medical Ethics oblige doctors to treat the process of transmitting human life with a sense of special responsibility, to provide information consistent with medical knowledge regarding fertilization processes and methods of regulating conception, considering their effectiveness, mechanism of action, and risk, and to familiarize patients with the possibilities of modern medical genetics, and prenatal diagnosis and therapy.[4]

Notably, in November 2023, Poland reinstated the government funding for in vitro fertilization (IVF) treatment for couples unable to naturally conceive children. The Act on the Amendments to the Act on Health Care Services Financed from Public Funds of November 29, 2023, requires the Minister of Health to allocate annually no less than 500 million Polish złoty (PLN) (about US$125,917,500) from the state budget for the implementation of a health policy program for infertility treatment covering medically assisted reproduction procedures, including in vitro fertilization conducted in a medical establishment recognized as a reproduction center.[5]

According to this act, the first health policy program for infertility treatment shall commence on June 1, 2024.[6]

In Poland, official registration and licensing is required for infertility treatment centers. Article 14 of the Infertility Treatment Act outlines the procedure for granting the status of an infertility treatment center through an administrative decision made by the Ministry of Health, following consultation with the Council for Infertility Treatment.[7] To apply for this status, the medical entity must provide specific information including its name, address, organizational structure, scope of activities related to infertility treatment, and involvement in teaching and research activities aimed at health promotion and innovation in medical technologies.[8]

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[2] Id. art. 2(1-5).

[3] Medical Profession Act of Dec. 5, 1996, art. 30, https://perma.cc/WPY7-R422 (in Polish); National Congress of Doctors, Code of Medical Ethics of Jun. 18, 2013, https://perma.cc/5M6C-UP7F (in Polish); Regulation of the Ministry of Health of Oct. 20, 2015 on the Training in the Collection, Processing, Storage, Testing and Distribution of Reproductive Cells and Embryos Intended for Use in the Medically Assisted Procreation Procedures, https://perma.cc/7KMA-2VEJ (in Polish).

[4] Code of Medical Ethics, ch. Procreation, art. 38.

[5] Act on Amendments to the Act on Health Care Services Financed from Public Funds of November 29, 2023, arts. 1 & 2, https://perma.cc/NSP6-H3LU (in Polish).

[6] Id. art. 2.

[7] Infertility Treatment Act, art. 14, para. 1.

[8] Id. art. 14, para. 2(1-5).

The Infertility Treatment Council is a consultative and advisory body to the Ministry of Health. It consists of experts from various scientific disciplines, especially law and medicine, as well as philosophy in the field of ethics.[9]

A license can be revoked by the Ministry of Health if the center in question loses its permit, stops performing infertility treatments, or discontinues teaching and research linked to innovative medical technologies for infertility diagnosis and treatment.[10]

II. Rules Related to Embryos Created through Assisted Reproductive Technology

In Poland, IVF treatment is only available to patients who can prove they attempted other methods of treatment for a period of at least 12 months.

Article 5 of the Act on Infertility Treatment specifies that IVF procedures must be performed only after exhausting other treatment methods over a minimum period of 12 months, or without completing the full 12-month period of other treatments if, based on current medical knowledge, achieving pregnancy through these methods is deemed unfeasible.[11]

The Act on Infertility Treatment outlines the rules governing infertility procedures.[12] These rules include providing medical counseling; conducting diagnoses to ascertain the causes of infertility; administering conservative pharmacological treatment; performing surgical interventions; carrying out medically assisted reproduction techniques, such as IVF, conducted within a medically assisted reproduction center; and ensuring the preservation of future fertility.[13]

The procedures governing the handling of reproductive cells and embryos in medically assisted procreation consist of the transfer of male reproductive cells into the recipient's body; extracorporeal creation of embryos (IVF); and testing of reproductive cells and embryos.[14]

Medically assisted reproduction procedures that require dealing with reproductive cells and embryos can be carried in a center for medically assisted reproduction. An institution designated as a center for medically assisted reproduction conducts the collection of reproductive cells from donors and their subsequent use in procreation, including processing, testing, preservation, and distribution. [15] However, handling reproductive cells and embryos for such procedures,

[9] *What about the Infertility Treatment Council - the Commissioner asks the Ministry of Health,* (Aug. 21, 2023), Public Information Bulletin of the Commissioner for Human Rights, https://perma.cc/4FUH-G7PY (in Polish).

[10] Infertility Treatment Act, art. 15(1)-(3).

[11] Id. art. 5, para. 2.

[12] Id. art. 5.

[13] Id. art. 5, paras. 1 & 2.

[14] Id. art. 17(1)-(3).

[15] Id. art. 44, para. 1(1), (2).

specifically involving the direct use of donated reproductive cells from partners, can occur in other medical facilities such as hospitals or health care centers.[16]
According to the Medical Profession Act, doctors are obligated to obtain consent for the use of Assisted Reproductive Technologies (ART),[17] and to maintain confidentiality to safeguard patient-related information.[18]

A. Limit on the Number of Embryos that Can Be Created or Transferred

According to the Act on Infertility Treatment, the number of oocytes fertilized during a single IVF attempt is limited to no more than six female reproductive cells, unless the recipient is over 35 years old or for medical reasons, such as a disease coexisting with infertility, or if there have been two previous unsuccessful IVF treatments, which would justify fertilizing a larger number of oocytes.[19]

Article 21 stipulates that the transfer of embryos generated from reproductive cells collected for partner or non-partner donation into the recipient's body is prohibited if

> the recipient has revoked her written consent.
>
> In the case of partner donation, the reproductive cell donor has not consented to the embryo transfer.
>
> In the case of non-partner donation, the recipient's husband has not consented to the embryo transfer, and if the recipient is in cohabitation, the man has not submitted a specific declaration in accordance with the Family and Guardianship Code.
>
> There are medical contraindications for transferring the embryo to the recipient's body.[20]

In addition, if the husband or the donor of reproductive cells collected for partner donation, from which an embryo was created, does not consent to the transfer of the embryo, the guardianship court shall issue a permit for the transfer.

Furthermore, anyone who creates an embryo for purposes other than medically assisted procreation procedures is subject to imprisonment from six months to five years.[21] The same term shall be prescribed to those individuals who produce an embryo containing genetic information in its cell nucleus that is identical to the genetic information found in the cell nucleus of another embryo, fetus, living human, deceased human, or human remains.[22] Any individual who engages in the creation of a chimera or hybrid through medically assisted procreation methods, or

[16] Id. 44, para. 2.

[17] Medical Profession Act, art. 32, para. 1.

[18] Id. art. 40.

[19] Act on Infertility Treatment, art. 9, paras. 2 & 3.

[20] Id. art. 21, para. 1(1).

[21] Id. art. 85.

[22] Id. art. 87.

performs an intervention with the intent of introducing heritable changes in the human genome that can be inherited by future generations is subject to imprisonment ranging from six months to five years.[23]

B. Preimplantation Genetic Testing

Article 2 of the Act on Infertility Treatment defines testing as activities aimed at assessing the suitability of reproductive cells or embryos for use in human medically assisted procreation.[24]

Under this act, it is prohibited to restrict reproductive possibilities based on a person being found to be the carrier of genetically determined diseases.[25]

The preimplantation genetic diagnosis within medically assisted procreation is permissible solely for medical reasons and must be preceded by genetic counseling as part of the medical guidance. This genetic testing must be conducted in a medical diagnostic laboratory.[26]

C. Embryo Selection

The use of preimplantation genetic diagnosis for non-medical reasons, such as selection of phenotypic traits, including the sex of the child, is prohibited except in cases when such a selection would prevent a severe, incurable, hereditary disease.[27] These actions are punishable by a fine, restriction of liberty, or imprisonment for up to two years.[28] The Act on Infertility Treatment also provides that anyone who destroys a viable embryo capable of normal development, resulting from a medically assisted procreation procedure, must be punished by imprisonment for a period of six months to five years.[29]

D. Embryo Preservation

In Poland, embryos may be cryopreserved. It is also possible to secure fertility for the future by freezing eggs, semen, and ovarian tissue. Embryos may be stored in germ cells and embryos banks for up to 20 years, after which they are to be transferred for donation if they meet two conditions cumulatively: first, that the rate and the sequence of cell division and morphological structure make proper embryo development probable, and second, if the embryo has not been diagnosed with a defect that would result in severe and irreversible impairment or an incurable disease.[30]

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[23] Id. art. 86.

[24] Id. art. 2, para. 25.

[25] Id. art. 3, para. 2.

[26] Id. art. 26, para. 1.

[27] Id. art. 26, para. 2.

[28] Id. art. 82.

[29] Id. art. 3.

[30] Id. art. 23, paras. 1 & 2(1), (2).

E. Embryo Storage

Poland has a 20-year storage limit. The Act on Infertility Treatment stipulates compulsory embryo donation after 20 years of storage if surplus embryos are not utilized by the couple for their own embryo transfer. After this period, all frozen embryos must be transferred to a clinic acting on behalf of the state and donated to another heterosexual couple.[31] Consent for this donation must be given before commencing the medically assisted procreation procedure.[32] Additionally, if embryos generated from reproductive cell donations for partner purposes need to be stored, consent for their use is required each time before restarting a medically assisted procreation procedure.[33]

A conclusion of an agreement between the donor and the reproductive cell and embryo bank is required for storing reproductive cells or embryos.[34]

F. Embryo Donation

According to the Act on Infertility Treatment, the reception of an embryo can happen with a partner donation or a non-partner donation. The first one concerns married couples or people who have an intimate physical relationship. The second refers to the donation of reproductive cells or of embryos by people who are not spouses or partners (anonymous donors). Sperm, egg, and embryo donation are all allowed. Strict anonymity is enforced by law, although clinics are required to keep personally identifiable data of both the donor and the recipient as part of their case documentation.

The transfer of an embryo to an anonymous recipient is allowed and requires medical justification by a doctor based on individual medical information.[35] Risk assessments must be conducted to ensure recipient safety and minimize adverse events.[36]

Recipients must be fully informed and confirm the accuracy of provided information via written declaration. Written consent from spouses or partners is required if a couple is in a marital or cohabiting relationship.[37]

Embryos must be used within 14 months of consent submission. Donors must be informed about the legal consequences of donation.[38] Couples who have concluded their fertility treatments, but

[31] Id. art. 97; art. 21, para. 3(1), (2).

[32] Id. art. 21.

[33] Id. art. 20.

[34] Id. art. 46, para. 1.

[35] Id. art. 36, para. 1(1-4).

[36] Id.

[37] Id. art. 36, para. 1(5)(a-b).

[38] Id. art. 36, para. 1(1—10).

still have extra embryos can store them for up to 20 years or give them up for adoption.[39] After 20 years, the embryos are automatically given up for adoption, and the process does not require the patients' consent.[40] Consent to embryo donation may be withdrawn until the recipient begins the medically assisted procreation procedure in which the embryo is to be used.[41] Destroying viable embryos is illegal and can be punished by up to five years in prison.[42]

Under Polish law, the reproductive cells collected from a donor for purposes other than partner donation may be used for partner donation if the donor withdraws consent for other purposes in writing and provides written consent for partner donation.[43] In such cases, a doctor assesses the medical justification for using reproductive cells collected for non-partner donation for partner donation.[44] In addition, embryos resulting from reproductive cell donations for partner or non-partner purposes are eligible for donation under the following circumstances:

- if the storage contract period expires, not exceeding 20 years from the date of embryo transfer to the reproductive cell and embryo bank;
- in case of the demise of both embryo donors, or in instances of non-partner donation, upon the death of the recipient and her spouse or cohabiting partner.[45]

Legal limits in third-party donation, when permitted, are limited to 10 embryos. The sale, purchase, or intermediation in the paid sale or purchase of a reproductive cell or embryo is prohibited. No payment, other financial benefit, or personal benefit may be demanded or accepted for reproductive cells collected from a donor or for embryos used.[46]

G. Embryo Disposal

The Act on Infertility Treatment bans the destruction of embryos and their use in scientific research. Article 23 provides for a prohibition on destroying embryos capable of proper development, created in the procedure of medically assisted procreation, and not transferred to the body of the recipient.[47] Anyone who destroys an embryo capable of proper development, and resulting from a medically assisted procreation procedure, is subject to imprisonment from six months to five years.[48]

[39] Id. art. 36, para. 2.

[40] Id. art. 36, para. 1(1-10).

[41] Id. art. 36, para. 5.

[42] Id. art. 83.

[43] Id. art. 18, para. 3.

[44] Id. art. 21.

[45] Id. art. 21, para. 3(1), (2).

[46] Id. art. 28, paras. 1 & 2.

[47] Id. art. 23, para. 3.

[48] Id. art. 83.

H. Use of Embryos for Scientific Research Purposes

In Poland, it is prohibited to create human embryos for purposes other than medically assisted procreation (IVF). According to article 26 of the Medical Profession Act, unborn children cannot be involved in scientific experiments.[49] The Act on Infertility Treatment also creates a ban on handing embryos over for scientific research.[50] No mention is made regarding therapeutic experiments, which would make the practice permissible, even if there is no regulation on this subject.

[49] Medical Profession Act, art. 26.

[50] Act on Infertility Treatment, art. 19.

Portugal

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SUMMARY In 2006, medically assisted reproduction was regulated in Portugal. The law regulates the use of embryos through assisted reproduction, determines that embryos should be created in a number that guarantees the success of the process, allows preimplantation genetic diagnosis, prohibits choice of sex (except in certain cases), and allows cryopreservation for a maximum period of six years and donation of cryopreserved embryos after that period. If embryos are not used for any purpose, they can be discarded.

I. Introduction

Medically assisted procreation (*Procriação Medicamente Assistida*, PMA) became regulated in 2006 by Law No. 32/2006,[1] which also created the National Council of Medically Assisted Procreation (*Conselho Nacional de Procriação Medicamente Assistida*, CNPMA) as a regulatory body for the practice of this activity. In June 2016, Law No. 17/2016 amended Law No. 32 and extended the scope of beneficiaries, guaranteeing access for all women to PMA techniques.[2] Law No. 90/2021 amended articles 8 (surrogacy), 14 (consent), and 39 (surrogacy) of Law No. 32.[3]

II. Rules Related to Embryos Created Through Assisted Reproductive Technology

Article 9 of Law No. 32/2006 states that the creation of embryos through PMA with the deliberate aim of their use in scientific research is prohibited.[4] It is, however, legal to carry out scientific research on embryos with the aim of "prevention, diagnosis or therapy" of embryos, the improvement of PMA techniques, the establishment of stem cell banks for transplantation programs, or for any other therapeutic purposes.[5]

The use of embryos for scientific research can only be permitted if it is reasonable to expect that it will result in benefits for humanity, with each scientific project subject to an assessment and decision by the CNPMA.[6]

For the purposes of scientific research, only the following may be used:

[1] Lei No. 32/2006, de 26 de julho, https://perma.cc/3DJA-P7ZV.

[2] Lei No. 17/2016, de 20 de junho, https://perma.cc/5WL9-G2HH.

[3] Lei No. 90/2021, de 16 de dezembro, https://perma.cc/ZC9W-Z7FU.

[4] Lei No. 32/2006, art. 9(1).

[5] Id. art. 9(2).

[6] Id. art. 9(3).

a) Cryopreserved, surplus embryos, for which there is no parental plan;

b) Embryos whose condition does not allow transfer or cryopreservation for procreation purposes;

c) Embryos that carry a serious genetic anomaly, within the framework of preimplantation genetic diagnosis;

d) Embryos obtained without resorting to sperm fertilization.[7]

The use of embryos under the conditions of subparagraphs (a) and (c) above depends on obtaining prior, express, informed, and conscious consent from the beneficiaries for whom they were intended.[8]

Anyone who, through PMA, uses embryos in scientific research and experimentation outside of the cases permitted in Law No. 32/2006 is punishable by a prison sentence of one to five years.[9] Anyone who transfers an embryo used in scientific research and experimentation to the uterus will incur the same penalty outside the cases provided for in Law No. 32/2006.[10]

A. Limit on Number of Embryos That Can Be Created or Transferred

Article 24 of Law No. 32/2006 determines that during in vitro fertilization, embryos should only be created in a number considered necessary for the success of the process, in accordance with good clinical practice and the principles of informed consent.[11] The number of oocytes to be inseminated in each process must consider the couple's clinical situation and the general indication for preventing multiple pregnancies.[12]

B. Preimplantation Genetic Testing

Preimplantation genetic diagnosis (PGD) aims to identify embryos that do not have a serious anomaly, before their transfer to the woman's uterus using PMA techniques, or for the purposes set out in section 3 of article 7.[13] The application, under the guidance of a responsible specialist doctor, of genetic screening of embryos to be transferred is permitted to reduce the risk of chromosomal alterations and thus increase the chances of success of PMA techniques.[14]

The application, under the guidance of a responsible specialist doctor, of PGD techniques that have recognized scientific value for the diagnosis, treatment, or prevention of serious genetic

[7] Id. art. 9(4).

[8] Id. art. 9(5).

[9] Id. art. 40(1).

[10] Id. art. 40(2).

[11] Id. art. 24(1).

[12] Id. art. 24(2).

[13] Id. art. 28(1).

[14] Id. art. 28(2).

diseases, as considered by the CNPMA, is permitted.[15] PMA centers that wish to apply PGD techniques must have or work with a multidisciplinary team that includes specialists in reproductive medicine, embryologists, medical geneticists, cytogeneticists, and molecular geneticists.[16]

C. Embryo Selection

According to article 7 of Law No. 32/2006, reproductive cloning with the aim of creating human beings genetically identical to others is prohibited.[17] PMA techniques cannot be used to improve certain nonmedical characteristics of the unborn child, namely, the choice of sex.[18]

Section 3 of article 7 states that exceptions to the choice of sex are cases in which there is a high risk of a genetic disease linked to sex, and for which direct detection by preimplantation genetic diagnosis is not yet possible, or when there is a need to obtain an HLA (human leukocyte antigen) group compatible for the purpose of treating serious illness.[19]

D. Embryo Preservation

Embryos that, under the terms of article 24 of Law No. 32/2006, do not have to be transferred, must be cryopreserved, with the beneficiaries committing to use them in a new embryo transfer process within a maximum period of three years.[20] At the request of the beneficiaries, in duly justified situations, the director of the center may assume the responsibility of extending the period for cryopreservation of embryos for a new three-year period.[21]

E. Embryo Storage

1. Regulatory Decree No. 6 of December 29, 2016

Article 13 of Regulatory Decree No. 6 of December 29, 2016, states that, in conjunction with the CNPMA, the General Inspection of Health Activities (*Inspeção-Geral das Atividades am Saúde*) carries out audits, inspections, and oversights of public and private centers that provide PMA techniques.[22] The operating authorization granted to the PMA center may be revoked in situations of bad practice resulting from the violation of Law No. 32/2006, as well as the lack of technical and safety conditions, defined by the CNPMA under the terms of article 30(2)(b) of Law No. 32/2006.[23]

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[15] Id. art. 28(3).

[16] Id. art. 28(4).

[17] Id. art. 7(1).

[18] Id. art. 7(2).

[19] Id. art. 7(3).

[20] Id. art. 25(1).

[21] Id. art. 25(2).

[22] Decreto Regulamentar No. 6/2016, de 29 de dezembro, art. 13(1), https://perma.cc/KR77-ZGRC.

[23] Id. art. 14.

2. Law No. 32 of July 26, 2006

Law No. 32/2006 created the CNPMA, which is responsible, generally, for giving opinion on the ethical, social, and legal issues of the PMA.[24] Article 30(2)(b) of Law No. 32/2006 states that the CNPMA is responsible for establishing the conditions under which centers must be authorized where PMA techniques are taught, as well as centers where gametes or embryos are preserved.[25]

F. Embryo Donation

As determined by section 3 of article 25 of Law No. 32/2006, after the three-year period has elapsed (article 24), without prejudice to the situations set out in section 2 of article 25 of Law No. 32/2006 (new three-year extension), embryos may be donated to other beneficiaries whose medical indication of infertility so advises, with the determining facts being subject to registration, or donated for scientific research under the terms set out in article 9 of Law No. 32/2006.[26]

G. Embryo Disposal

Once a donation is made under the terms set out in section 3 of article 25, if the embryos have not been used by other beneficiaries or in a research project approved under article 9 in the six years following the moment of cryopreservation, they can be thawed and disposed of, as determined by the center director.[27] If a donation is not made under the terms set out in section 3 of article 25, as soon as any of the deadlines indicated in sections 1 or 2 of article 25 have elapsed, the embryos may be thawed and eliminated, as determined by the director of the center, after communication to the CNPMA.[28]

H. Use of Embryos for Scientific Research Purposes

As stated in Section II, above, it is legal to carry out scientific research on embryos with the aim of prevention, diagnosis or therapy of embryos, the improvement of PMA techniques, the establishment of stem cell banks for transplantation programs, or for any other therapeutic purposes.[29] The use of embryos for scientific research can only be permitted if it is reasonable to expect that it will result in benefits for humanity,[30] and only specific embryos can be used.[31]

[24] Lei No. 32/2006, art. 30(1).

[25] Id. art. 30(2)(b).

[26] Id. art. 25(3).

[27] Id. art. 25(6).

[28] Id. art. 25(7).

[29] Id. art. 9(2).

[30] Id. art. 9(3).

[31] Id. art. 9(4).

Sweden

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SUMMARY The Act on Genetic Integrity regulates the use of embryos created through in vitro fertilization (IVF) and in research. The National Board of Health and Welfare also publishes regulations, recommendations, and standards for IVF treatments. The National Board of Health and Welfare has published a regulation limiting IVF implantation to one embryo to avoid twin pregnancy risks to the mother. In special circumstances where the risk of a twin pregnancy is particularly low, implantation of two embryos is allowed. Preimplantation genetic testing is only allowed when the biological parent has a serious hereditary disease. Embryos may be frozen for up to 10 years. In special circumstances, the National Board of Health and Welfare may extend the duration an embryo is frozen. If an embryo is not used or frozen, it must be immediately discarded. Frozen embryos may be donated for IVF treatment of another woman or for research. Compensation for donated embryos is not allowed. Embryos used for research must be destroyed after 14 days of development. Stem cells derived from the embryo need not be destroyed after 14 days.

I. Introduction

In vitro fertilization (IVF) and research using stem cells are regulated in the Act on Genetic Integrity.[1] In addition, Socialstyrelsen (The National Board of Health and Welfare) issues supplemental regulations pertaining to assisted productive technology.[2] There are no current amendments to the Act on Genetic Integrity pending in parliament and the most recent amendment was made through amendment 2023:40 in 2023.[3] The storage of all human materials, including eggs, sperm, and embryos, is regulated in the Bio Bank Act.[4] This act was adopted in 2023, overhauling the previous Bio Bank Act of 2003.[5] IVF treatment is also subject to the Act on Quality and Safety Norms for the Handling of Human Tissues and Cells.[6] The most current

[1] Lag om genetisk integritet m.m. [Act on Genetic Integrity] (SFS 2006:351), https://perma.cc/A3FS-2HBJ.

[2] Senaste version av SOSFS 2009:32 Socialstyrelsens föreskrifter och allmänna råd om användning av vävnader och celler i hälso- och sjukvården och vid klinisk forskning m.m. (SOSFS 2009:32), https://perma.cc/7VRC-TYJE.

[3] Lag om ändring i lagen (2006:351) om genetisk integritet m.m. [Act Amending the Act on Genetic Integrity (SFS 2006:351)] (SFS 2023:40), https://perma.cc/XT6Q-YHRH.

[4] Biobankslag [Bio Bank Act] (SFS 2023:38), https://perma.cc/9MMG-6HGF.

[5] Id.

[6] Lag om kvalitets- och säkerhetsnormer vid hantering av mänskliga vävnader och celler [Act on Quality and Safety Norms for the Handling of Human Tissues and Cells] (SFS 2008:286), https://perma.cc/33RR-7TLG.

recommendation on the use of tissue and cells in health care and clinical research is the SOSFS 2009:32, which was most recently amended in 2022.[7]

Under Swedish law, women have the right to receive IVF treatment if they are part of a stable heterosexual couple, part of a stable homosexual couple, or are single, and unable to conceive a child in either of these family constellations. Women who are in a cohabiting relationship must seek fertilization treatment together with their significant other, who must consent to the treatment in writing.[8] Treatment can be carried out using the woman's own eggs, donor eggs, the significant other's sperm, donor sperm, or through so-called double-donation where the woman is implanted with a donated embryo, where both the egg and sperm are donated and thus the child has no biological connection to either intended parent.[9] Before 2019, Swedish law required that one intended parent had a biological connection to the child, allowing for either donor eggs or donor sperm to be used, not both. Surrogacy is not legal in Sweden.

II. Rules Related to Embryos Created through Assisted Reproductive Technology

A. Limit on Number of Embryos that Can Be Created or Transferred

The Act on Genetic Integrity does not set a limit on embryos that can be created or transferred. However, the National Board of Health and Welfare have issued regulations and national guidelines which specify that, during IVF procedures, women should only be implanted with one embryo at a time.[10] In special cases where there is a smaller risk for twin pregnancies, two embryos may be transferred.[11]

B. Preimplantation Genetic Testing

Preimplantation genetic diagnosis (PGD) is only permissible if there is a risk of serious hereditary illnesses, meaning only the embryos of couples that carry a predisposition for hereditary diseases may be tested.[12] Couples who do carry these genetic diseases may opt to instead screen for the disease once there is a confirmed pregnancy. Tests can only be performed to test and rule out the specified hereditary disease.[13] Testing with the purpose of creating a sibling with stem cells that could cure a sibling from a serious disease can only be done in exceptional cases and requires

[7] Senaste version av SOSFS 2009:32 Socialstyrelsens föreskrifter och allmänna råd om användning av vävnader och celler i hälso- och sjukvården och vid klinisk forskning m.m. (SOSFS 2009:32), https://perma.cc/7VRC-TYJE, includes amendments through HSLF-FS 2022:52.

[8] 6 ch. 1b §; 7 ch. 3 § Act on Genetic Integrity.

[9] 7 ch. 2 § Act on Genetic Integrity.

[10] 4 ch. 15 § SOSFS 2009:32.

[11] Id.

[12] 4 ch. 2 § Act on Genetic Integrity.

[13] Id.

approval from the National Board of Health and Welfare.[14] Per the Swedish National Council on Medical Ethics, approximately 100 PGD tests are performed per year in Sweden.[15]

C. Embryo Selection

Sweden does not allow for embryo selection by the parent. The responsible doctor must choose the most viable embryo. As mentioned above in Part II(B), PGD testing is limited by law.

D. Embryo Preservation

Following an IVF treatment cycle, all embryos may be frozen for up to 10 years.[16] In contrast, embryos used for research that have been subject to a somatic cell nuclear transfer may be frozen for up to five years.[17] The National Board for Health and Welfare may extend these periods subject to special reasons and must then specify how long the embryo may continue to be frozen.[18]

E. Embryo Storage

Storage of embryos is regulated in the Bio Bank Act and the Act on Quality and Safety Norms for the Handling of Human Tissue and Cells.[19] Embryo storage facilities are subject to inspection and those operating such facilities may be fined for noncompliance of the rules.[20] As mentioned above under Part II(D), embryos can be frozen for up to 10 years.[21] Embryos used in research may be frozen for up to five years.[22] By law, Inspektionen för vård och omsorg (IVO) (the Health and Social Care Inspectorate) must keep a registry of all biobanks in Sweden.[23]

F. Embryo Donation

Since 2019, donations of embryos resulting from IVF treatment cycles have been permitted.[24] In 2019, the Swedish Parliament removed a prior requirement that embryos must have a genetic connection with one of the intended parents. As a result, prospective parents undergoing IVF treatment can agree to donate their surplus embryos to other persons seeking IVF treatment.[25] In

[14] Id.

[15] Statens Medicinskt Etiska Råd (SMER) [Swedish National Council for Medical Ethics], Preimplantatorisk genetisk diagnostik, https://perma.cc/A5F8-CFDR.

[16] 5 ch. 4 Act on Genetic Integrity.

[17] Id.

[18] Id.

[19] Bio Bank Act (SFS 2023:38), https://perma.cc/9MMG-6HGF.

[20] 15-19 §§ Lag om kvalitets- och säkerhetsnormer vid hantering av mänskliga vävnader och celler, (SFS 2008:286), https://perma.cc/33RR-7TLG.

[21] 5 ch. 4 Act on Genetic Integrity.

[22] Id.

[23] 3 ch. 1 § Bio Bank Act.

[24] 7 ch. 3a § Act on Genetic Integrity.

[25] 5 ch. 1, 3 §§ Act on Genetic Integrity.

addition, "double donation" is now permitted, where embryos are created using both donated sperm and eggs.

A special assessment must be carried out by the responsible physician in cases where donor embryos are being used for IVF treatment.[26] In addition, the child's right to know his or her heritage must be guaranteed through special journal references where donor information is included.[27] Donations where there is no biological link to either parent remain rare, in 2021 only 25 children were born without a biological link to either parent.[28]

Donors may not donate embryos, eggs, or sperm to more than six families.[29] There are no restrictions on the number of donations that one family receives. Donors cannot be compensated for donating their embryos, and compensation is criminalized.[30] However donors of eggs and sperm may receive compensation.[31]

G. Embryo Disposal

Embryos must be disposed after they have been frozen for 10 years.[32] Embryos subject to somatic cell nuclear transfer as part of research may only be frozen for five years.[33] Embryos that are used for research must be discarded after 14 days of development, not counting the time they have been frozen.[34] In 2012, the IVF treatment center at the Karolinska Institute in Stockholm destroyed embryos belonging to a couple by mistake, resulting in a *Lex Maria* (internal) investigation, as required by Chapter 3 Section 5 of the Patient Safety Act.[35] There was no legal recourse.

[26] 4 ch. 11 § Socialstyrelsens föreskrifter (SOSFS 2009:32).

[27] 6 ch. 4 §; 7 ch. 6 § Act on Genetic Integrity.

[28] Fertilitetsbehandlingar i Sverige, Årsrapport (Annual Report) 2021, (2023), https://perma.cc/5ZKE-VKVH. See also Ann Thurin-Kjellberg, Donation av ägg och spermier, Läkartidningen (Dec. 15, 2022), https://perma.cc/Z4J6-765A.

[29] SKR, Meddelande från styrelsen – Rekommendation assisterad befruktning – dubbeldonation och embryodonation Ärendenr: SKR2022/00072, https://perma.cc/7SZM-L6J6.

[30] 8 ch. 6 § Act on Genetic Integrity.

[31] Statens medicinskt-etiska råd, Uttalande: Schablonersättning vid äggdonation – etiska aspekter, Dnr S1985: A/2016/15 (February 17, 2016), https://perma.cc/58YW-GZQ2.

[32] 5 ch. 4 § Act on Genetic Integrity.

[33] Id.

[34] 5 ch. 3 § Act on Genetic Integrity;

[35] SVT Nyhter, Frysta embryon förstördes av misstag (July 11, 2012), https://perma.cc/ZA77-LTUF.

H. Use of Embryos for Scientific Research Purposes

Stem cell research using fertilized eggs has been legal in Sweden since 2005.[36]

Research using embryos is subject to prior ethical review and requires the consent of the embryo donors.[37] Thus, embryos that have been created as part of an IVF procedure and are not used – for example if the parents do not want to make another attempt at implantation – may be used in scientific research. If the embryos were created using donated eggs or sperm, such use is subject to approval by the donor.[38]

Embryos used for research must be destroyed at 14 days of development.[39] However, stem cells that have been derived from the embryo may be researched and made to live longer than those 14 days.[40]

In 2002, Sweden became the second country in Europe, after the United Kingdom, to create a stem cell biobank.[41]

[36] Lag (2005:39) amending Lag (1991:115) om åtgärder i forsknings- eller behandlingssyfte med ägg från människa, https://perma.cc/42GC-ULYJ.

[37] 5 ch. 1 § Act on Genetic Integrity; 4, 6, 17 §§ Lag om etikprövning av forskning som avser människor (SFS 2003:460), https://perma.cc/3W4H-45WW.

[38] 5 ch. 1 § Act on Genetic Integrity; 17 §§ Lag om etikprövning av forskning som avser människor (SFS 2003:460).

[39] 5 ch. 3 § Act on Genetic Integrity; See also Statens Medicinsk-Etiska Råd, *Kort om Embryomodeller* (Smer 2023:2) (June 2023), https://perma.cc/L2PT-3SKV.

[40] See Regeringens proposition 2021/22:257 En ny biobankslag (Prop. 2021/22:257), https://perma.cc/KQ2W-EFLN explaining how cell lines are exempt from biobank rules under the modified samples rule.

[41] Pew Research Center, *Stem Cell Research Around the World* (July 17, 2008), https://perma.cc/67X7-QPJL.

United Kingdom

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SUMMARY The Human Fertilisation and Embryology Act 1990 regulates the use of embryos in the United Kingdom. The Human Fertilisation and Embryology Authority is responsible for issuing licenses for the creation, use, and storage of human embryos. To help reduce the number of multiple births caused by in vitro fertility treatments, each clinic is required to have a multiple birth minimization strategy and attempt to ensure that its birth rate does not include more than 10% of multiples. There is a wide variety of preimplantation testing available to prospective parents to rule out specified conditions. Genetic testing to select the sex of the embryo for purely social reasons is not permitted. Surplus embryos can be donated, stored, or disposed of. The storage time limit is 10 years for research purposes and up to 55 years for treatment purposes. There are very limited payments available to individuals who wish to donate their unused embryos to either research or other prospective parents. The use of embryos for research purposes is limited to eight purposes specified in the act.

I. Introduction

The Human Fertilisation and Embryology Act, enacted in 1990, is the main piece of legislation regulating the use of embryos in the United Kingdom (UK). The act prohibits the creation, use, or storage of a human embryo or gametes (germ cells containing chromosomes of one sex)[1] without a license issued by the Human Fertilisation and Embryology Authority (HFEA),[2] a regulatory body established by the act. If a person creates a human embryo without a license from the HFEA, they are guilty of an offense and are liable, upon indictment, to imprisonment for up to two years, a fine, or both.[3] The HFEA is accountable to the UK Parliament and ensures, through a system of licensing, that human embryos are used only for the purposes specified in the act.

To ensure that the act maintains pace with scientific and technological developments, it includes a provision that allows the scope of research for which licenses can be granted to be expanded through secondary legislation.[4] It is unusual to allow the expansion of the scope of primary legislation through secondary legislation. In this case, to ensure that secondary legislation on such a contentious issue cannot quietly be passed without debate, a draft must be placed before both the House of Lords and House of Commons and approved by a resolution in each house.[5]

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[1] Human Fertilisation and Embryology Act 1990, c. 37, §§ 3, 4, https://perma.cc/CF2N-TLX8.

[2] Id. sched. 2, § 2.

[3] Id. § 41.

[4] Id. § 45(4).

[5] See generally Erskine May, *Erskine May's Treatise on the Law, Privileges, Proceedings and Usage of Parliament* 666-701 (William McKay et al. eds., 2004), https://lccn.loc.gov/2004615623.

The law has remained relatively unchanged since its enactment. The HFEA completed a review of the law in November 2023, in which it determined the law was flexible and remained fit for its purpose, but made some recommendations to expand areas involving consent, such as to create a research bank of embryos created through in vitro fertilization (IVF), increase the powers of the HFEA, improve the access to donor information, and give the HFEA more discretion to support scientific developments.[6]

The UK is also a signatory to international treaties that impose obligations relating to bioethics, including the Universal Declaration on the Human Genome and Human Rights, adopted in 1997,[7] and the Universal Declaration on Bioethics and Human Rights, adopted in 2005.[8]

II. Rules Related to Embryos Created Through Assisted Reproductive Technology

The act provides a general framework for the creation and use of embryos created through assisted reproductive technology, requiring facilities that provide these services be licensed by the HFEA and comply with any conditions of the license. Sections 23-24 of the act provide the HFEA with the ability to introduce directions, which are rules that licensed facilities must comply with. Failing to comply with a direction is a breach of a statutory license condition.[9] The HFEA has also issued a code of practice under section 25 of the act to provide guidance on the activities it licenses.

A. Limit on Number of Embryos That Can Be Created or Transferred

The HFEA has issued a direction on the transfer of multiple embryos for the purposes of fertility treatment.[10] The direction requires licensed centers to have a written multiple-births minimization strategy that is regularly audited and evaluated to determine the effectiveness of the strategy, with the aim being to not exceed multiple births in 10% of the annual birth rate for the center. The HFEA monitors and inspects clinics to assess compliance with the strategy.[11]

Licensed centers are required to log cases where three or four embryos are transferred to a patient, or where multiple embryos are transferred to a patient who only meets the requirements of the strategy's single embryo transfer. The reasons for this transfer must be included in the log.

[6] Hum. Fertilisation & Embryology Auth., *Modernising Fertility Law* (Nov. 2023), https://perma.cc/6PNC-KW4H.

[7] Universal Declaration on the Human Genome and Human Rights (Nov. 11, 1997), https://perma.cc/WG5F-5683.

[8] Universal Declaration on Bioethics and Human Rights (Oct. 19, 2005), https://perma.cc/6FBE-W5LB.

[9] *Directions*, Hum. Fertilisation & Embryology Auth., https://perma.cc/V53V-BYJ5.

[10] Hum. Fertilisation & Embryology Auth., *Directions Given Under the Human Fertilisation and Embryology Act 1990 (As Amended): Multiple Births* (Oct. 1, 2012), https://perma.cc/NK3X-B9UD.

[11] Id. § 5.

B. Preimplantation Genetic Testing

Preimplantation genetic testing for monogenic disorders (PGT-M), preimplantation genetic testing for chromosomal structural rearrangements (PGT-SR), preimplantation tissue typing (PTT),[12] and preimplantation genetic testing for aneuploidy (PGT-A)[13] is permitted in the UK under the Human Fertilisation and Embryology Act, which provides the HFEA with the authority to license treatment, including "other practices designed to secure that embryos are in a suitable condition to be placed in a woman."[14] The HFEA reasons that an applicant is entitled

> to regard an embryo as unsuitable unless it is both free of abnormality and tissue compatible with [a sibling]. Without such testing, [the applicant] cannot make an informed choice as to whether she wants the embryo placed in her body or not. The authority considers it desirable for the purpose of providing [the applicant] with treatment services, ie IVF treatment, that she should be able to make such a choice . . . the Act does not require that PGD or HLA typing should constitute treatment services. They must be activities in the course of such services, ie in the course of providing IVF treatment.[15]

Currently, PGT-M has been licensed by the HFEA for over 600 genetic conditions,[16] and its use is limited to solely screen out disorders, thus not permitting people to create "designer babies."[17] The decision to license a condition is made by the HFEA, which considers whether the treatment is lawful under the Human Fertilisation and Embryology Act and that the decision to provide treatment is in accordance with the Code of Practice and HFEA policy.[18]

C. Embryo Selection

The act does not permit sex selection for social purposes.[19] It does permit sex selection for limited circumstances, which are restricted to cases:

> where there is a particular risk that a woman will give birth to a child who will have or develop—

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[12] *Pre-implantation Genetic Testing for Monogenic Disorders (PGT-M) and Pre-implantation Genetic Testing for Chromosomal Structural Rearrangements (PGT-SR)*, Hum. Fertilisation & Embryology Auth., https://perma.cc/Y87Q-7RMV.

[13] *Pre-implantation Genetic Testing for Aneuploidy (PGT-A)*, Hum. Fertilisation & Embryology Auth., https://perma.cc/4PCG-L3ZF.

[14] Human Fertilisation and Embryology Act 1990, sched. 2 § 1(d).

[15] Quintavalle v. Human Fertilisation and Embryology Authority [2005] UKHL 28, para. 12, https://perma.cc/XG8K-42BY.

[16] *Approved PGT-M and PTT Conditions*, Hum. Fertilisation & Embryology Auth., https://perma.cc/Q8TM-45W7.

[17] *PGT-M Conditions*, Hum. Fertilisation & Embryology Auth., https://perma.cc/XHM5-QLHJ.

[18] *Approved PGT-M and PTT Conditions*, supra note 16.

[19] Human Fertilisation and Embryology Act 1990, c. 37, sched. 1ZB; Hum. Fertilisation & Embryology Auth., *Code of Practice* (rev. Oct. 2023), § 10.20, https://perma.cc/969R-TVUD.

(a) a gender-related serious physical or mental disability,
(b) a gender-related serious illness, or
(c) any other gender-related serious medical condition.[20]

D. Embryo Preservation

Embryos may be stored for reproductive or research purposes. The HFEA's Code of Practice sets out several requirements for centers storing embryos, such as the requirement for inspections, alarms and monitoring systems (including alarms for both temperature and liquid nitrogen levels and systems that can contact staff outside of working hours), and spare storage space to enable the transfer of embryos if the original storage location fails.[21]

E. Embryo Storage

The Human Fertilisation and Embryology Act prohibits the storage of a human embryo or gametes without a license issued by the HFEA,[22] which includes a number of conditions.[23] The law permits the storage of embryos for up to 55 years for fertility treatment purposes with consent from both the provider of the egg and the provider of the sperm. These individuals must renew their consent every 10 years.[24] Embryos may be stored for up to 10 years for research or training purposes.[25]

F. Embryo Donation

Embryos created in the course of fertility treatment can be donated to others to be used in fertility treatment, and these can be stored for up to 55 years. Embryos can also be donated to research infertility and genetic diseases or be used in training, and these can be stored for up to 10 years.[26] There are typically no eligibility criteria for the donation of embryos for research, but there are certain requirements that must be met in order to donate embryos to be used in fertility treatment. The egg the embryo was formed from should be from a donor between 18 to 35 years old, and the sperm donor should be between 18 to 45 years old, although, in exceptional circumstances, clinics accept donors from outside this age range.[27] Embryo donors are also required to go through the same health checks as sperm or egg donors.[28] Consent must be provided by both parties, and counseling is offered. In cases where the embryo was created using donor sperm or

[20] Human Fertilisation and Embryology Act 1990, § 13 & sched. 1ZB.

[21] Hum. Fertilisation and Embryology Auth., *Code of Practice*, supra note 19, ch. 17.

[22] Human Fertilisation and Embryology Act 1990, §§ 3, 4.

[23] Hum. Fertilisation and Embryology Auth., *Standard Licence Conditions Treatment and Storage Licences* (July 1, 2022), https://perma.cc/P29A-THU6.

[24] Human Fertilisation & Embryology Act 1990, § 14.

[25] Id. § 14(3)(c).

[26] Id. sched. 3.

[27] Hum. Fertilisation and Embryology Auth., *Code of Practice*, supra note 19, ch. 17.

[28] *Donating Your Embryos*, Hum. Fertilisation and Embryology Auth., https://perma.cc/P2Z3-6K39.

eggs, whether the embryo can be donated depends upon the consent provided by the donor and whether the individual's donations have already been provided to the maximum of 10 families for treatment.

There is limited compensation available to individuals who wish to donate their embryos to be used in fertility treatment. Up to 35 British pounds (approximately US$45) for each clinic visit, such as for screening tests, is available for those who wish to donate their unused embryos.[29] The HFEA has issued a direction to refuse to accept a "donor who is known (or is reasonably suspected) by that centre to have received or to be about to receive money or other benefits not in line with these Directions."[30]

Donors are no longer able to remain anonymous, and individuals conceived from donations made after April 1, 2005, can obtain their donor's name, date of birth, and last known address upon turning 18 years old.[31]

G. Embryo Disposal

As noted above, embryos created for IVF that are not used can be stored for up to 55 years with the consent of both the mother and father, which must be renewed every 10 years.[32] If consent is not provided or renewed, the embryos will be disposed of. Section 17 of the act provides that "proper arrangements" must be made for the disposal of embryos and that "suitable practices are used in the course of the activities" but does not specify the procedures that should be used.[33]

H. Use of Embryos for Scientific Research Purposes

Embryos created through IVF can currently be donated and used for scientific purposes until the embryo is 14 days old, or when the primitive streak ("a collection of cells from which the central nervous system eventually develops")[34] appears, whichever occurs first.[35] This time frame does not apply to the time embryos are kept in storage. The donated embryo must be for a specific, named project and can be stored for up to 10 years for use in the named project.[36]

The Human Fertilisation and Embryology Act limits the use of human embryos in research by specifying the following purposes for which the HFEA can issue a license:

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[29] Hum. Fertilisation and Embryology Auth., *Directions Given Under the Human Fertilisation and Embryology Act 1990 (As Amended) Gamete and Embryo Donation* (Oct. 29, 2015), § 7, https://perma.cc/TQS5-AJY3.

[30] Id. § 3.

[31] Human Fertilisation and Embryology Authority (Disclosure of Donor Information) Regulations 2004, SI 2004/1511, https://perma.cc/JX7R-YRNM.

[32] Human Fertilisation and Embryology Act 1990, §§ 3, 14.

[33] Id. § 17; Hum. Fertilisation and Embryology Auth., *Code of Practice*, supra note 19, § 17.9.

[34] Select Committee on Stem Cell Research, Report, 2001-2002, HL 83(i), n. 3, https://perma.cc/U69T-8H4S.

[35] Human Fertilisation and Embryology Act 1990, §§ 3(3)(a), 3(4).

[36] Id. § 14(3)(c); *Clinic FAQs on New Storage Legislation Effective From July 2022*, Hum. Fertilisation & Embryology Auth. (last updated Feb. 14, 2023), https://perma.cc/8D25-L2YT.

(a) increasing knowledge about serious disease or other serious medical conditions,
(b) developing treatments for serious disease or other serious medical conditions,
(c) increasing knowledge about the causes of any congenital disease or congenital medical condition that does not fall within paragraph (a),
(d) promoting advances in the treatment of infertility,
(e) increasing knowledge about the causes of miscarriage,
(f) developing more effective techniques of contraception,
(g) developing methods for detecting the presence of gene, chromosome or mitochondrion abnormalities in embryos before implantation, or
(h) increasing knowledge about the development of embryos.[37]

The HFEA has discretion to ensure that embryos are not arbitrarily used in research. Not only must a license applicant meet one of the purposes above, but the HFEA also must be satisfied that the use of the embryo is necessary or desirable for that purpose.[38]

A recent review of the law by the HFEA recommended that the act be amended to allow patients to donate embryos to a research bank, which would store embryos without the need to link them to a research project.[39] It also recommended the 14-day development time limit for use of the embryo be removed and the HFEA be allowed to approve research on a case-by-case basis.[40]

[37] Human Fertilisation and Embryology Act 1990, sched. 2, § 3A(2).

[38] Id. sched. 2, § 3A(1). See further *Standard Licence Conditions: Research Licences*, Hum. Fertilisation & Embryology Auth. (July 21, 2022), https://perma.cc/98V5-L2B4.

[39] Hum. Fertilisation & Embryology Auth., *Modernising Fertility Law*, supra note 6, Proposal 13.

[40] Id.

Legal Treatment of Embryos Created Through IVF

Table of Primary Sources

Jurisdiction	Type of Law	Citation	URL
Australia	Statute	Human Reproductive Technology Act 1991 (WA)	https://perma.cc/GG2R-3BB4
		Assisted Reproductive Technology Act 2007 (NSW)	https://perma.cc/3LXL-VQJF
		Assisted Reproductive Treatment Act 1988 (SA)	https://perma.cc/A9LW-N2VB
		Assisted Reproductive Treatment Act 2008 (Vic)	https://perma.cc/A9LW-N2VB
		Prohibition of Human Cloning for Reproduction Act 2002 (Cth)	https://perma.cc/PA2K-KXH9
		Research Involving Human Embryos Act 2002 (Cth)	https://perma.cc/7RGZ-MAEU
	Regulation	Assisted Reproductive Technology Regulation 2014 (NSW)	https://perma.cc/284R-NPPF
		Assisted Reproductive Treatment Regulations 2010 (SA)	https://perma.cc/JPU5-DD4X
		Assisted Reproductive Treatment Regulations 2019 (Vic)	https://perma.cc/W7F2-S6XL
		Human Reproductive Technology Regulations 1993 (WA)	https://perma.cc/BQ3M-5CRT
		Research Involving Human Embryos Regulations 2017 (Cth)	https://perma.cc/FH9K-LLHC

France	Statute	Code pénal [Penal Code]	https://perma.cc/ZJ2U-6MES
		Code de la santé publique [Public Health Code]	https://perma.cc/H5GF-CK69
		Loi no. 94-654 du 29 juillet 1994 relative au don et à l'utilisation des éléments et produits du corps humain, à l'assistance médicale à la procréation et au diagnostic prénatal, J. O., July 30, 1994	https://perma.cc/EZS5-NYW2
		Loi n° 2004-800 du 6 août 2004 relative à la bioéthique, J. O., Aug. 7, 2004	https://perma.cc/3JRA-SMRW
		Loi n° 2011-814 du 7 juillet 2011 relative à la bioéthique, J. O., July, 8, 2011	https://perma.cc/595Z-KW4Z
		Loi n° 2021-1017 du 2 août 2021 relative à la bioéthique (2021 Bioethics Law), Journal Officiel de la République Française [J. O.] [Official Gazette of France], Aug. 3, 2021	https://perma.cc/568Y-ECCG
Germany	Statute	Arzneimittelgesetz [AMG], Dec. 12, 2005, BGBl. I at 3394, as amended	https://perma.cc/YK2D-QANE (original), https://perma.cc/SZ75-NACF (English translation)
		Embryonenschutzgesetz [ESchG], Dec. 13, 1990, BGBl. I at 2746, as amended	https://perma.cc/VK7J-3QMV
		Gendiagnostikgesetz [GenDG], July 31, 2009, BGBl. I at 2529, 3672, as amended	https://perma.cc/3L4P-USYC
		Präimplantationsdiagnostikgesetz [PräimpG], Nov. 21, 2011, BGBl. I at 2228	https://perma.cc/93M7-GGPZ
		Samenspenderregistergesetz [SaRegG], July 17, 2017, BGBl. I at 2513, as amended	https://perma.cc/SJ9S-HTQG
		Stammzellgesetz [StZG], June 28, 2002, BGBl. I at 2277, as amended	https://perma.cc/9UCN-AQZY
		Transplantationsgesetz [TPG], Sept. 4, 2007, Bundesgesetzblatt [BGBl.] I at 2206, as amended	https://perma.cc/5J3K-9WQW

	Regulation	Arzneimittel-und Wirkstoffherstellungsverordnung [AMWHV], Nov. 3, 2006, BGBl. I at 2523, as amended	https://perma.cc/RC3A-6EEN
		Präimplantationsdiagnostikverordnung [PIDV], Feb. 21, 2013, BGBl. I at 323, as amended	https://perma.cc/FRN7-9QT3
		TPG-Gewebeverordnung [TPG-GewV], Mar. 26, 2008, BGBl. I at 512, as amended	https://perma.cc/XN6A-PKWP
Italy	Statute	Legge 19 febbraio 2004, n. 40, Norme in materia di Procreazione Medicalmente Assistita	https://perma.cc/VQ72-6P9K
		Legge 22 maggio 1978, n. 194, Norme per la Tutela Sociale della Maternita' e sull'Interruzione Volontaria della Gravidanza	https://perma.cc/JTD6-RLLC
	Constitutional Court Decision	Sentenza del 8 maggio 2009, n. 151	https://perma.cc/T2GV-RVTB
		Sentenza del 13 aprile 2016, n. 84	https://perma.cc/D4K8-TC6Q
		Sentenza del 22 ottobre 2015, n. 229	https://perma.cc/Y7N6-PGSP
New Zealand	Statute	Human Assisted Reproductive Technology Act 2004	https://perma.cc/K9PY-2HX8
		Health and Disability Services (Safety) Act 2001	https://perma.cc/M8TN-MJ2H
	Regulation	Health and Disability Commissioner (Code of Health and Disability Services Consumers' Rights) Regulations 1996	https://perma.cc/Q9S7-QNQ9
		Human Assisted Reproductive Technology Order 2005	https://perma.cc/GZ8D-LMSV
Poland	Statute	Act of June 25, 2015, on Infertility Treatment	https://perma.cc/6SKW-8SFZ
		Act of November 29, 2023 on Amendments to the Act on Health Care Services Financed from Public Funds	https://perma.cc/NSP6-H3LU
		Medical Profession Act of Dec. 5, 1996	https://perma.cc/WPY7-R422
	Regulation	Code of Medical Ethics	https://perma.cc/5M6C-UP7F

		Regulation of the Ministry of Health of Oct. 20, 2015 on the Training in the Collection, Processing, Storage, Testing and Distribution of Reproductive Cells and Embryos Intended for Use in the Medically Assisted Procreation Procedures	https://perma.cc/7KMA-2VEJ
Portugal	Statute	Guaranteed access for all women to medically assisted procreation techniques, Lei No. 17/2016, de 20 de junho	https://perma.cc/5WL9-G2HH
		Medically Assisted Procreation, Lei No. 32/2006, de 26 de julho	https://perma.cc/3DJA-P7ZV
Sweden	Statute	Biobankslag [Bio Bank Act](SFS 2023:38)	https://perma.cc/9MMG-6HGF
		Lag om genetisk integritet m.m. [Act on Genetic Integrity] (SFS 2006:351),	https://perma.cc/A3FS-2HBJ
		Lag om kvalitets- och säkerhetsnormer vid hantering av mänskliga vävnader och celler [Act on Quality and Safety Norms for the Handling of Human Tissues and Cells] (SFS 2008:286)	https://perma.cc/33RR-7TLG
	Regulation	Senaste version av SOSFS 2009:32 Socialstyrelsens föreskrifter och allmänna råd om användning av vävnader och celler i hälso- och sjukvården och vid klinisk forskning m.m. (SOSFS 2009:32)	https://perma.cc/7VRC-TYJE
United Kingdom	Statute	Human Fertilisation and Embryology Act 1990, c. 37	https://perma.cc/CF2N-TLX8
	Regulation	Human Fertilisation and Embryology Authority (Disclosure of Donor Information) Regulations 2004, SI 2004/1511	https://perma.cc/JX7R-YRNM