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Regulation of IVF and Related Issues

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Comparative Summary

Ruth Levush
Senior Foreign Law Specialist

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 **Israel**, the **United Kingdom** (UK), and six European countries: **France**, **Germany**, **Italy**, **Poland**, **Portugal**, and **Sweden**.

The report consists of this summary, individual country surveys and a table providing information on the legal treatment of embryos created through IVF. Among issues addressed by the report are the legal limits 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. Such actions include 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.

The reports further addresses countries' requirements for facilities where IVF procedures are conducted, registries of procedures and donors, funding of procedures, and the existence of restrictions in access to IVF procedures for certain groups of patients and couples.

Please note that the terms "embryos" and "fertilized ova" are used interchangeably in this report.

I. Access to IVF

Access to IVF is restricted by age in all countries, with different limits applied by each jurisdiction.

Israel provides wide access to IVF treatments regardless of marital status or gender. Reproductive care in that country is provided to spouses who do not have children in their current marriage, to same-sex male partners who do not have children, to childless women who wish to establish a single-parent family, and to childless men who wish to establish a single-parent family through surrogacy.

Germany's law does not put any restrictions on access to assisted reproductive technology. However, surrogacy is prohibited.

Under **Swedish** law, surrogacy is prohibited, and IVF treatments are available only to women who are part of stable heterosexual or same-sex relationships or are single, and who are unable to conceive a child.

France and **Portugal** limit IVF access to heterosexual couples and to same-sex female couples regardless of marital status but exclude singles and same-sex male couples.

In **Italy** and **Poland**, access is limited to heterosexual adult couples, married or cohabiting

In the **UK**, limiting IVF treatment to heterosexual couples would constitute unlawful discrimination punishable under the Equality Act.

II. Regulation of IVF Facilities

IVF facilities, either public or private, in **Germany**, **Israel**, **Italy**, **Poland**, **Portugal**, **Sweden**, and the **UK** need to be accredited by the state following a detailed approval process. In **France**, clinical and biological activities involving donated gametes are restricted to public health institutions or private, nonprofit health organizations, and practitioners cannot be compensated on a fee-for-service basis for these activities.

III. Funding

Public Funding of IVF treatments is available in all countries surveyed, including in **Poland**. In addition to state financing, **Italy** recognizes tax deductions for related expenses. **Portugal** authorizes the Ministry of Health to enter into agreements with authorized private centers to finance medically assisted procreation.

In **Germany**, IVF and ICSI treatments are partially covered by statutory health insurance for heterosexual married couples for up to three cycles. Eligible persons may apply for a grant from the federal government or the states to cover the remaining deductible.

The scope of IVF procedures that are funded by states' budgets vary. For example, **France**'s health insurance system covers a maximum of six inseminations (one per cycle), and four in vitro fertilization attempts to achieve pregnancy. In **Israel**, new rules limit the number of extraction cycles to six depending on the age of the woman and the number of ova extracted in prior treatments.

In addition to public funding, IVF treatments are covered by other sources. This is the case in **Sweden**, where IVF treatments are funded by public as well as by private sources. In **Israel**, 67% of the total IVF activities conducted in 2021 were funded by state resources, and 33% by health funds in accordance with subscribers' individual insurance plans and co-pay. A similar percentage of IVF treatments funded outside of state funding was reported in the **UK**, where in 2017, approximately 60% of IVF treatments was privately funded, and the remainder was funded through the National Health Service, the UK's taxpayer funded health care provider.

IV. Limits on the Number of Embryos Created and Transferred

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 donations are required in **Poland** after the storage time limit is reached. These three countries do not permit research involving, or disposal of, excess embryos. The

possibility of legalizing egg donation in **Germany** was reviewed by a commission established by the government, which published its final recommendations in April 2024. The law in **Italy** is complex and there is uncertainty regarding some aspects, with certain restrictions having been declared unconstitutional by the Constitutional Court.

Excess embryos may be discarded, and this is required in several jurisdictions when the storage limits have been reached. These jurisdictions include **France**, **Portugal**, **Sweden**, and the **UK**.

V. Storage of Embryos

The storage time limits relating to storing embryos for possible use in subsequent treatment cycles or for research vary among the jurisdictions surveyed. Some jurisdictions, such as **Sweden** and the **UK**, have separate time limits where storage is for using the embryos for research. In almost all the jurisdictions that have a legal limit on storage duration, extensions may be granted by the relevant authorities.

VI. Preimplantation Genetic Testing

In **Germany**, preimplantation genetic diagnostics are generally prohibited, with limited exceptions when there is a high risk of severe hereditary diseases. In **Poland**, 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. In **France**, 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. Preimplantation diagnosis may also be authorized in cases where a couple or unmarried woman previously produced a child suffering from a genetic disease-causing death in the first years of life, which was recognized as incurable at the time of diagnosis. In **Sweden**, genetic preimplantation testing is more limited and may only be carried out following approval from the National Board of Health and Welfare, in cases where the biological parents of the child both carry a predisposition for incurable hereditary diseases.

In the **UK**, preimplantation genetic testing is offered for monogenic disorders (PGT-M), for chromosomal structural rearrangements (PGT-SR), and for preimplantation tissue typing (PTT). Preimplantation genetic testing for aneuploidy (PGT-A) is permitted. Although preimplantation testing for specific hereditary disorders and chromosomal abnormalities in **Israel** is performed with public funding, PGT-P procedure, which screens for polygenic diseases such as diabetes, heart disease and cancer, is not permitted in that jurisdiction.

It should be noted also that preimplantation diagnosis for purpose of sex selection is prohibited in **Sweden** and restricted to medical reasons in jurisdictions such as **Poland** and the **UK**. In **Israel**, such testing may be approved based on a risk of substantial harm to the mental health of one of the parents or of the children who will be born if the gender selection procedure is not carried out, or, in extreme cases and for special reasons, when the applicants have at least four children in common of the same sex, and do not have children of the opposite sex.

Comparative Summary Table

						Actions Related to Embryos				
Jurisdiction	**Access Restrictions**	**Facility Requirements**	**Funding (Public, Private, Other)**	**Limit on Number of Embryos Created**	**Limit on Number of Embryos Transferred**	**Storage**	**Donation**	**Research**	**Disposal**	**Preimplantation Genetic Testing**
France	Yes; gender and age restrictions	Yes; authorized public or non-profit establishments	Public, reimbursed at 100% by the French health insurance system	No limit	No limit	Up to 5 years	Yes	Yes	Yes	Allowed only in exceptional cases, when the couple or unmarried woman previously produced a child suffering from a genetic disease causing death in the first years of life
Germany	Some states restrict access to heterosexual couples married or in committed relationship; currently no state medical associations explicitly block access for women who are single or in a same-sex relationship; same-sex male couples cannot use a surrogate mother	Must receive authorization from the competent state authority under conditions enumerated by law	Statutory health insurance in Germany covers 50% of the costs	Up to three in one cycle	Up to three	No limits	Generally prohibited, except for an embryo created through IVF that could not be transferred to original woman as intended	Prohibited	Prohibited	Allowed if there is a high risk of severe hereditary disease, or, with woman's consent, to diagnose severe damage to an embryo that will most likely lead to a still birth or a miscarriage

						Actions Related to Embryos				
Jurisdiction	**Access Restrictions**	**Facility Requirements**	**Funding (Public, Private, Other)**	**Limit on Number of Embryos Created**	**Limit on Number of Embryos Transferred**	**Storage**	**Donation**	**Research**	**Disposal**	**Preimplantation Genetic Testing**
Israel	No gender or marital status restrictions; age limit for public funding	Private or public hospitals and clinics must be accredited by Ministry of Health; notification in official gazette	Public funding; additional services funded through individual health insurance plans or direct payments by patients	Six cycles, if the number of ova extracted in prior ova extraction does not exceed 25 for women under age 36, or 35 for women age 36-41	Not specified	5 years; may be extended up to 5 additional years for a fee	Yes; requires committee approval subject to requirements by law	Ova may be donated; experimentation requires written approval by medical director	Yes; procedures not specified	Available for certain diseases; sex selection under limited conditions
Italy	Heterosexual couples, married or cohabiting, of potentially fertile age, both living	Public and private facilities authorized by the Italian regions and registered in the National Register of Facilities	Public funding; tax deductions for expenses up to 19% of costs	No fixed limit; not greater than necessary for a single implantation	Not greater than necessary for a single implantation	No limit	Prohibited	Prohibited	Unclear	Permitted
Poland	Only married or cohabiting opposite-sex couples with documented infertility are eligible	Infertility treatment centers must be officially registered and licensed by the Ministry of Health following consultation with the Council for Infertility Treatment	Public funding	Six	N/A	20-year limit	Yes, subject to conditions specified by the law	No	No	Only permitted when such a choice avoids a severe, incurable hereditary disease

						Actions Related to Embryos				
Jurisdiction	**Access Restrictions**	**Facility Requirements**	**Funding (Public, Private, Other)**	**Limit on Number of Embryos Created**	**Limit on Number of Embryos Transferred**	**Storage**	**Donation**	**Research**	**Disposal**	**Preimplantation Genetic Testing**
Portugal	Heterosexual or same-sex female couples, married or living in conditions similar to marriage, and women without a partner	Public or private facilities must be authorized by the Ministry of Health, after approval of the National Council of Medically Assisted Procreation	Public funding	Limited to number necessary in accordance with good clinical practice and informed consent	In consideration of the couple's clinical situation and prevention of multiple pregnancies	Three years; may be extended for additional three years	Yes	Yes	After six years	Permitted
Sweden	Stable heterosexual or same-sex female couples, and single women unable to conceive; age restrictions vary between public and private clinics	Yes	Public & private	No limit	One embryo at a time; two in special cases where there is a smaller risk for twin pregnancies	10 years	Yes	Embryos that are used for research must be discarded after 14 days of development, not counting the time they have been frozen	Mandatory after storage limit reached	No, unless both parents have a serious hereditary disease
United Kingdom	No gender or marital status restrictions; individual clinics have their own age eligibility criteria	Facilities must be licensed by the Human Fertilisation and Embryology Authority and comply with any conditions of the license	Self-funded or provided through the National Health Service	Multiple-births minimization strategy: multiple-births should not exceed 10% of annual birth rate for the center	Multiple-births minimization strategy	Up to 55 years for fertility treatment with consent from providers of ova and of sperm, renewed every 10 years	Yes	Yes; embryos stored for up to 10 years	Yes; procedures not specified	Testing for PGT-M, PGT-SR, PTT, and PGT-A permitted; sex-selection permitted under restricted circumstances involving gender-related serious medical condition of the child

France

Louis Gilbert
Foreign Law Specialist

SUMMARY The 2021 French Bioethics Law outlines regulations on medically assisted reproduction, expanding access to all women with a parental project, excluding male couples and single men. It sets age limits for participants and strict approval requirements for facilities handling gametes, embryos, and assisted reproduction. Embryo preservation is permitted with parental consent, while unused embryos may be donated, used for research, or destroyed under defined conditions. The law prohibits embryo cloning, genome modification, and commercial use, allowing research only on surplus embryos from assisted reproduction projects. Procedures are publicly funded within limits.

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 has been 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 conceiving an embryo by simultaneously donating 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.), J. O. [Official Gazette], 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 conceived during 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. Access to Assisted Reproductive Technology

Male couples and single men do not have access to medically assisted procreation. Both members of the couple must be alive and of childbearing age. There is no requirement for length of cohabitation or marriage.[11]

There are age limits for access to assisted reproduction. Sperm may be collected from men aged 29 to 45. Artificial insemination, the use of gametes or germ tissue collected, retrieved, or preserved for medically assisted procreation, and embryo transfer can be performed up to the 45th birthday of the woman who is intended to bear the child, whether she is unmarried or part of a couple. For the partner who is not intended to bear the child, these procedures can be carried out up to their 60th birthday.[12]

III. Requirements for Facilities

Facilities providing assisted reproductive care must meet specific requirements to gain approval for their operations. Clinical and biological activities involving donated gametes are restricted to public health institutions or private, non-profit health organizations, and practitioners cannot be compensated on a fee-for-service basis for these activities.[13] Additionally, clinical and biological activities related to medically assisted procreation may only be conducted in establishments that have received authorization from the director general of the regional health agency. This approval process includes consultation with the specialized commission of the regional health and autonomy conference responsible for healthcare and the Biomedical Agency.[14]

Health establishments, medical biology laboratories, and non-profit organizations wishing to engage in medically assisted procreation must apply to the regional health agency. The

[9] Public Health Code 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. L2141-2.

[12] Id. art. R2141-38.

[13] Id. art. L2142-1.

[14] Id. art. L6221-1.

application, as outlined in a 2007 order,[15] must include details about the procedures used for collecting, preparing, preserving, and distributing gametes, germ tissue, or embryos. It should also contain copies of agreements with external third parties involved in the process, specifying their responsibilities and the procedures they must follow to comply with quality and health safety standards, as well as documents verifying the competence of the practitioners involved.[16]

The director general of the Biomedicine Agency reviews the application and provides an opinion to the director general of the regional health agency within two months. The Biomedicine Agency also maintains and publicly shares an up-to-date list of authorized health establishments, organizations, health cooperation groups, and medical biology laboratories. If external third parties are involved, the application must include a copy of the agreements defining their roles and responsibilities.[17]

IV. Funding of the Procedure

Medically assisted procreation procedures are reimbursed at 100% by the French health insurance system (Assurance Maladie) for a maximum of

- six inseminations (one artificial insemination per cycle) to achieve pregnancy, and
- four IVF attempts to achieve pregnancy.

Coverage is the same for all (heterosexual couples, couples of two women, unmarried women).[18]

V. Rules Related to Embryos Created through Assisted Reproductive Technology

An embryo can only be conceived in vitro within the framework and according to the objectives of medically assisted procreation.[19] The 2021 Bioethics Law makes gamete preservation possible in the absence of a medical reason.[20]

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

The Public Health Code does not state a legal limit on the number of embryos that can be created or transferred in the context of IVF. The Public Health Code limits the number of embryos to

[15] Arrêté du 26 février 2007 fixant la composition du dossier prévu aux articles R. 2142-3 et R. 6122-32 du code de la santé publique à produire à l'appui d'une demande d'autorisation ou de renouvellement d'autorisation pour pratiquer des activités d'assistance médicale à la procreation, J. O. Mar. 24, 2007, https://perma.cc/5LKH-GPJ9.

[16] Public Health Code art. R2142-3.

[17] Id.

[18] *Procréation médicalement assistée (PMA),* Service Public (Aug. 17, 2023), https://perma.cc/D8DA-DF4E.

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

[20] 2021 Bioethics Law art. 3.

"what is strictly necessary for the success of the medically assisted procreation, taking into account the procedure used."[21]

However, medically assisted reproduction procedures are fully covered by the health insurance scheme, up to a limit of six inseminations and four IVF attempts.[22]

B. Preimplantation Genetic Testing

The Public Health Code defines preimplantation diagnosis as a biological diagnosis performed on cells taken from the embryo in vitro.[23] Preimplantation diagnosis includes the following activities:

- 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.[24]

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.[25] Both members of the couple, or the unmarried woman, must give their written consent to the diagnosis.

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.[26]

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

[22] Procréation médicalement assistée (PMA), supra note 18.

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

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

[25] Id.

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

C. Embryo Selection

As discussed in Part V(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.[27] 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.[28]

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.[29]

Article L. 2151-9 of the Public Health Code states that any organization that conserves embryos for research purposes must hold an authorization issued by the Biomedicine Agency.[30] Annual reports from the agency indicate that clinical-biological centers and laboratories authorized to carry out medically assisted procreation activities perform embryo vitrification.[31] An information brochure from the agency outlines the vitrification process and summarizes the provisions of the 2021 Bioethics Law relevant to embryo preservation.[32]

E. Embryo Storage

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.[33]

Each year, individuals whose embryos are being preserved are asked whether they wish to continue conserving them. If they no longer wish to continue conservation or want to specify the conditions of preservation in the event of their death, they can provide written consent for the

[27] Id. art. L2131-4.

[28] Id.

[29] 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.

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

[31] 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.

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

[33] Public Health Code arts. L. 2141-4, R. 2151-19.

embryos to be donated, used for research, or for the storage to be terminated.[34] In principle, they cannot be kept for more than five years.[35]

F. Embryo Donation and Registration

Both members of a couple, or a single woman undergoing IVF, can consent in writing for the stored embryos to be received by another couple or another unmarried woman.[36] 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.[37]

The Biomedicine Agency has set up a National Registry for Medically Assisted Procreation (Registre National d'Assistance Médicale à la Procréation). The aim of the registry is to

- analyze in quantitative and qualitative terms the activities of medically assisted procreation, IVF, and artificial insemination,
- compare the activities and results of medically assisted reproduction centers, and
- assess the consequences for people's health and ensure the transparency of activities.[38]

There is also a gamete donor register in France. This registry is managed by the Biomedicine Agency,[39] and notably enables

- the registration of donors,
- the traceability of donations, and
- the possibility for people born from a donation to access their origins when they come of age, in accordance with the 2021 bioethics law.[40]

G. Embryo Disposal

Embryos subjected to research may not be transferred for gestation purposes, and in vitro development must be terminated no later than 14 days following their formation.[41] As mentioned above, stored embryos are terminated after five years of storage.[42]

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[34] Id. art. L2141-12.

[35] Id. art. L2141-4.

[36] Id. art. L2141-5.

[37] Id. art. L2141-6.

[38] Agence de la Biomedecine, *Registre national d'Assistance Médicale à la Procréation* (May 14, 2021), https://perma.cc/LX62-FUUX.

[39] Agence de la Biomedecine, *Registre National de Donneurs de Gamètes et d'Embryons* (June 26, 2024), https://perma.cc/EU2R-TJWA.

[40] Public Health Code art. L2143-2

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

[42] Id. art. L2141-4.

The Biomedicine Agency states that researchers must always destroy embryos once they have carried out their experiments.[43] The agency also states that, when a couple or single woman decides 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.[44]

H. Use of Embryos for Scientific Research Purposes

The Biomedicine Agency is responsible for approving all research protocols involving embryonic cells.[45] Article 511-19 of the French Penal Code provides for seven years of imprisonment and a 100,000 euro (around US$108,000) fine for carrying out embryo research without validation by the agency.[46]

According to article L. 2151-2 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.[47] 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.[48] Interventions designed to modify the genome of gametes or embryos are also prohibited.[49]

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.[50] 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,
- 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.[51]

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

[43] Assistance Medicale a la Procreation le Devenir des Embryons Congeles, supra note 32, at 13.

[44] Id. at 14.

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

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

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

[48] Id. art. L2151-3.

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

[50] Id. art. L2151-5.

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

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.[52]

As discussed in Part V(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.[53]

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

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

Germany

Jenny Gesley
Foreign Law Specialist

SUMMARY 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. Specific rules related to embryos are codified in the Embryo Protection Act.

German law generally does not codify any restrictions for accessing ART. Facilities performing ART require an authorization from the competent authority. Statutory health insurance covers 50% of the costs of costs of in vitro fertilization and intracytoplasmic sperm injection for married heterosexual couples for up to three cycles.

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-

[1] Transplantationsgesetz [TPG], Sept. 4, 2007, Bundesgesetzblatt [BGBl.] I at 2206, as amended, § 1a, no. 4, https://perma.cc/2XF5-VSAC.

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 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 then-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) provided in a section on "Reproductive Self-Determination" that the parties were 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] The Commission on Reproductive Self-Determination and ART (Kommission zur reproduktiven Selbstbestimmung und Fortpflanzungsmedizin, Kom-rSF) presented its final report in April 2024.[9] It recommended, among other things, to allow egg

[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.

[3] Arzneimittelgesetz [AMG], Dec. 12, 2005, BGBl. I at 3394, as amended, https://perma.cc/9JGQ-3RF8 (original), https://perma.cc/SZ75-NACF (English translation); Arzneimittel- und Wirkstoffherstellungsverordnung [AMWHV], Nov. 3, 2006, BGBl. I at 2523, as amended, https://perma.cc/K9GP-TAE5.

[4] Richtlinie zur Entnahme und Übertragung von 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] Kom-rSF, Bericht der Kommission zur reproduktiven Selbstbestimmung und Fortpflanzungsmedizin (Apr. 2024), https://perma.cc/YX74-DMRV.

donation under limited circumstances.[10] However, no concrete legislative proposals have been advanced so far, because the respective ministries are still analyzing the commission's final report.[11]

Depending on the type of ART, other laws might be applicable, such as the Preimplantation Diagnostics Ordinance (Präimplantationsdiagnostikverordnung, PIDV), [12] the Genetic Diagnostics Act (Gendiagnostikgesetz, GenDG), [13] or the Sperm Donor Register Act (Samenspenderregistergesetz, SaRegG).[14]

II. Access to Assisted Reproductive Technology

German law generally does not codify any restrictions for accessing ART. The German Federal Fiscal Court (Bundesfinanhof, BFH), the supreme court for taxes and customs, has confirmed that performing assisted reproductive technology procedures on women who are in a same-sex relationship violates neither the Embryo Protection Act nor the guidelines of the medical associations.[15]

With regard to rules governing the medical profession, the non-binding 2006 (Model) Guideline on Performing ART ((Muster-)Richtlinie zur Durchführung der assistierten Reproduktion) from the German Medical Association stated that a doctor should generally only perform ART for married heterosexual couples and for single women who are living with a non-married man in a committed relationship if the man is likely to recognize paternity of the child.[16] The donor sperm used should be the sperm of the husband or partner.[17] Some state medical associations adopted these recommendations into their statutes, making them thereby legally binding for doctors practicing in that state.[18] The medical association of the state of Hamburg on the other hand,

[10] Id. at 493, 494. For a summary of the report, see Eva Dauke, *Germany: Expert Commission Recommends Reform of Laws on Abortion, Egg Donation and Surrogacy*, Global Legal Monitor (May 9, 2024), https://perma.cc/GX5B-EBRC.

[11] Deutscher Bundestag Drucksache [BT-Drs.] 20/13238, at 2, https://perma.cc/K44W-A9SJ.

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

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

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

[15] BFH, Oct. 5, 2017, docket no. VI R 47/15, ECLI:DE:BFH:2017:U.051017.VIR47.15.0, paras. 12, 22, 23, https://perma.cc/ZV74-HZ8E; BFH, Oct. 5, 2017, docket no. VI R 2/17, ECLI:DE:BFH:2017:U.051017.VIR2.17.0, paras. 12, 22, https://perma.cc/Z38R-ZUD9.

[16] Bundesärztekammer, *(Muster-)Richtlinie zur Durchführung der assistierten Reproduktion – Novelle 2006* (Feb. 17, 2006), para. 3.1.1., https://perma.cc/SVK4-BWYC.

[17] Id.

[18] Jochen Taupitz, *Donogene Insemination. Verwendung von Spender-Samen zur Herbeiführung einer Schwangerschaft bei homosexuellen (Ehe-)Paaren und alleinstehenden Frauen*, in Hessisches Ärzteblatt 9/2021, at 509, https://perma.cc/9AMY-G47K.

explicitly allowed ART for two women in a registered life partnership.[19] In other states, the statutes are silent.[20] The 2016 Model Guideline was replaced in 2018 with a Guideline on ART that stated in the preface that the previous recommendations have become redundant.[21] The 2018 guideline was then replaced by the abovementioned 2022 version.[22] The new Guideline on ART does not include any statements regarding who should have access to ART. It appears that there are currently no state medical associations that explicitly prohibit performing ART for single women or women in a same-sex relationship.[23]

It should be noted that couples cannot force a doctor to perform ART procedures for them even if it is legal. The Embryo Protection Act states that it is an individual decision for the doctor whether to perform assisted reproductive technology procedures.[24]

Lastly, it should be pointed out that surrogacy is prohibited in Germany, meaning that in particular male couples who would like to have a child that is genetically related to them cannot use a surrogate mother.[25] The German Federal Court of Justice (Bundesgerichtshof, BGH) has also not recognized foreign decisions recognizing a husband and a wife who used reproductive technologies via surrogacy in Ukraine as the genetic parents of the child.[26] The final report of the Commission on Reproductive Self-Determination and ART mentioned above recommended that the legislature either continue to prohibit altruistic surrogacy or allow it only under strict conditions to protect the surrogate mother and the child, such as when there is a close relationship of friendship or kinship between the surrogate mother and the intended parents.[27]

III. Requirements for Facilities

As mentioned, human germ cells, such as semen and ova, are considered human tissue.[28] Facilities that collect tissue intended for human applications or conduct the laboratory testing

[19] Id.

[20] According to the Federal Fiscal Court, Bavaria, Berlin, Brandenburg, and Hessen do not impose any restrictions. BFH, supra note 15, docket no. VI R 47/15, para. 22.

[21] Bundesärztekammer, *Richtlinie zur Entnahme und Übertragung von menschlichen Keimzellen im Rahmen der assistierten Reproduktion* (Apr. 20, 2018), https://perma.cc/XFT6-7M6X.

[22] *(Muster-)Richtlinie zur Durchführung der assistierten Reproduktion – Novelle 2006*, supra note 16.

[23] LSVD, *Ratgeber: Künstliche Befruchtung bei gleichgeschlechtlichen Paaren* (2023), https://perma.cc/XUX5-UCDX.

[24] ESchG,§ 10.

[25] ESchG § 1, para. 1, no. 7; Adoptionsvermittlungsgesetz [AdVermiG], Dec. 22, 2001, 2002 BGBl. I at 354, as amended, §§ 13a, 13b, 13c, 14, https://perma.cc/Z4KF-JYEB (original), https://perma.cc/NKX4-TS3Z (English translation).

[26] BGH, Mar. 20, 2019, docket no. XII ZB 530/17, ECLI:DE:BGH:2019:200319BXIIZB530.17.0, https://perma.cc/9S6Y-T9TY.

[27]Kom-rSF, supra note 9, paras. 2.1.2.3.3, 2.1.2.3.4.3, 2.2.1.5., 3.2, at 564, 568, 576, 604.

[28] TPG, § 1a, no. 4.

necessary for such collection must receive authorization from the competent state authority.[29] An authorization must be granted if

- an appropriately qualified person with the necessary professional experience is present;
- additional participating personnel is sufficiently qualified;
- appropriate rooms for the specific tissue collection or for the laboratory testing are available;
- it is guaranteed that the collection of tissues or the laboratory testing are conducted according to the latest standards prevailing in medical science and technology and according to the provisions contained in chapters 2, 3, and 3a of the Transplantation Act; and
- the person responsible or the applicant is sufficiently reliable in the performance of their job.[30]

No separate authorization is necessary if a person conducts such activities on a contractual basis for a manufacturer or a processor who is in possession of an authorization for the processing of tissue or tissue preparation.[31]

There are further requirements for facilities that extract and examine germ cells codified in the Transplantation Act and the Transplantation Act Tissue Ordinance.[32] In particular, the facility must employ a physician who has the required expertise according to the latest standards prevailing in medical science.[33] Additional rules are codified in the Ordinance on the Manufacture of Medicinal Products and Active Substances.[34]

Facilities that process, preserve, test, store, or place on the market tissues or tissue preparations within the framework of ART procedures also require authorization from the competent state authority in agreement with the Paul Ehrlich Institute.[35] Additional specific requirements are set out in the Ordinance on the Manufacture of Medicinal Products and Active Substances.[36] An authorization must be granted if

- a person with the necessary expert knowledge and experience responsible for ensuring that the tissue preparations and tissues are processed, preserved, tested, stored, or placed on the market in accordance with the statutory provisions in force is available;
- additional participating personnel is sufficiently qualified;

[29] AMG, § 20b, para. 1, sentence 1.

[30] Id. § 20b, para. 1, sentence 3.

[31] Id. § 20b, para. 2, sentence 1.

[32] TPG, § 8d; TPG-GewV, §§ 2-4

[33] TPG, § 8d, para. 1, sentence 1.

[34] AMWHV, §§ 32-34.

[35] AMG, § 20c, para. 1, § 77, para. 2. 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.

[36] AMWHV, §§ 32-41d.

- suitable premises and establishments are available for the envisaged activities;
- it is guaranteed that the processing, including the labelling, preservation, and storage, is conducted according to the latest standards prevailing in science and technology;
- a quality management system pursuant to the principles of good practice has been installed and been kept up to date; and
- the person responsible or the applicant is sufficiently reliable in the performance of their job.[37]

Expert knowledge must be shown by presenting a certificate testifying to the successful completion of university studies in human medicine, biology, biochemistry, or equivalent studies and by having at least two years' practical experience in the processing of tissues or tissue preparations.[38]

IV. Funding of the Procedure

Statutory health insurance in Germany covers 50% of the costs of in vitro fertilization (IVF) and intracytoplasmic sperm injection for married heterosexual couples for up to three cycles.[39] Eligible persons may apply for a grant from the federal government or the states to cover the remaining deductible.[40]

The German Federal Constitutional Court (Bundesverfassungsgericht, BVerfG) has held that limiting insurance coverage to 50% and to heterosexual married couples does not violate the equality clause, because the government is not constitutionally obligated to finance assisted reproductive technologies.[41]

V. 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 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."[42]

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[37] AMG, § 20c, para. 2.

[38] Id. § 20c, para. 3.

[39] Sozialgesetzbuch Fünftes Buch [SGB V], Dec. 20, 1988, BGBl. I at 2477, 2482, as amended, § 27a, https://perma.cc/37VK-6WXP.

[40] Richtlinie über die Gewährung von Zuwendungen zur Förderung von Maßnahmen der assistierten Reproduktion, Mar. 29, 2012, as amended, https://perma.cc/5HV4-Q4XL; *Unterstützung von Bund und Ländern*, Bundesministerium für Familie, Senioren, Frauen und Jugend, https://perma.cc/FL9M-5GW8.

[41] BVerfG, Feb. 27, 2009, docket no. 1 BVR 2982/07, para. 10, https://perma.cc/Y8NP-9T26.

[42] ESchG, § 8, para. 1.

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.[43] A violation is punishable by a term of imprisonment of up to three years or a fine.[44] Anyone who inseminates more eggs than will be transferred to the woman in one cycle is equally liable.[45]

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.[46] 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 still birth or a miscarriage does not act unlawfully.[47]

C. Embryo Selection

Sex selection on embryos is generally prohibited.[48] It is punishable by a prison sentence of up to one year or a fine.[49] However, sex selection on a sperm cell is allowed if it is performed to prevent 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.[50]

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.[51]

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[43] Id. § 1, para. 1, nos. 3, 4.

[44] Id. § 1, para. 1.

[45] Id. § 1, para. 1, no. 5.

[46] Id. § 3a, para. 1.

[47] Id. § 3a, para. 2.

[48] Id. § 3.

[49] Id.

[50] Id.

[51] Id. § 1, para. 1, nos. 3, 5.

D. Embryo Preservation

In general, human embryos may be cryopreserved by physicians only.[52] 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.[53]

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.[54] 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 state agency.[55]

F. Embryo Donation and Registration

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.[56] 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.[57] The transfer of the embryo to the woman from whom the egg cell originates 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.[58] 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.[59] 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."[60]

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[52] Id. § 9, no. 4.

[53] Id. § 2, para. 1.

[54] For information on the Paul-Ehrlich-Institute see supra note 35.

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

[56] ESchG, § 1, para. 1, nos. 1, 6.

[57] 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.

[58] Deutscher Ethikrat, supra note 57, at 33.

[59] Id.

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

The Bavarian Highest Regional Court (Bayerisches Oberstes Landesgericht, BayObLG), the supreme court for civil and criminal jurisdiction for the state of Bavaria, confirmed this view in 2020 and held that embryo donation is generally allowed in such cases.[61]

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."[62] 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.[63]

Likewise, the German Stem Cell Act (Stammzellgesetz, StZG) generally prohibits the import and use of embryonic stem cells.[64] However, as an exception, the law allows the import and use of embryonic stem cells for research purposes under strict conditions.[65] 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),
- 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.[66]

Additionally, the import must receive authorization from the competent state agency, which will be granted if the above-mentioned requirements are complied with, the research project is

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

[62] ESchG, § 2, para. 1.

[63] Id. § 1, para. 1, no. 2.

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

[65] Id. § 4, para. 2.

[66] Id.

"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.[67] 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.[68] Approval must not be given if the embryonic stem cells have been derived in contradiction to major principles of the German legal system.[69]

[67] Id. § 6, para. 4.

[68] Id. § 5.

[69] Id. § 4, para. 3.

Israel

Ruth Levush
Senior Foreign Law Specialist

SUMMARY In vitro fertilization (IVF) treatments are widely accessible to all Israelis. Until recently, the number of treatment cycles per woman has been almost unlimited, and the maximum age of patients exceeded that in other countries. New rules published by the Ministry of Health on December 2, 2024, limit the procedures for extraction of ova to women ages 30-41 as of the date of commencement of treatment, and the number of extraction cycles to six, if the number of ova extracted in prior ova extraction does not exceed 25 for women under age 36, or 35 for women aged 36 to 41.

IVF facilities need to be accredited by the state. Most procedures in 2021 were done in the four private recognized units rather than in the 21 public units.

Infertility treatments, including coverage for diagnostic procedures for ascertaining and treating infertility, artificial insemination, sperm enhancement treatments, and hormone therapy are provided through health funds and are covered by the state. A health plan may offer its members plans for additional health services in accordance with its insurance plans.

Although fertility treatments and preimplantation testing for specific hereditary disorders and chromosomal abnormalities are done with public funding, Israelis do not have access to the PGT-P procedure, which screens for polygenic diseases such as diabetes, heart disease, and cancer. Preimplantation screening to identify the gender of an embryo may be authorized under conditions enumerated by the law.

Fertilized ova may be kept frozen for five years free of charge and for an additional five years for a fee. The new rules published on December 2, 2024, establish procedures for storage and conditions for the disposal of frozen ova and embryos.

Ova may be donated and designated by a donor or a patient for implantation or for research with their consent. A medical experiment on an embryo requires written approval by the medical director of the hospital and must comply with the law and the principles in the Helsinki Declaration. The Israeli scientific community has been instructed by ethics advisory committees not to conduct experiments on embryos after the 14th day of their formation.

I. Introduction

For historical, social, and religious reasons, giving birth holds a central place in Israeli society.[1] Infertility treatments are widely accessible, with costs funded by the state.[2] Funding for in vitro fertility (IVF) treatments extends to married and unmarried couples as well as singles, including gay men who wish to start a single-parent family through surrogacy.[3] According to a report issued by Israel's State Comptroller's Office (SCO) in November 2024, the number of IVF treatment cycles per woman in Israel was almost unlimited, and the maximum age (45) exceeded that applicable in other countries.[4] The report also highlighted the lack of mandatory procedures for disposal of embryos, resulting in the long-term and costly preservation of a large number of unclaimed fertilized ova.[5]

The SCO report was issued following a thorough investigation of the implementation of IVF procedures in Israel. The investigation was prompted by the discovery of several irregularities in IVF units in the country. In one case disclosed in September 2022, a woman was mistakenly implanted with an embryo that was not biologically hers.[6] In another case, an embryo was found to have no genetic connection to the intended father. In two other cases, fertilized ovum dried up. A report by a Ministry of Health investigative commission appointed to review IVF procedures at facilities published on July 20, 2023, attributed the failures to the heavy workload in the units where these cases occurred.[7]

In its critical report, the SCO highlights existing legal and practical challenges faced by IVF units and makes recommendations for improvements.[8]

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[1] State Comptroller Off. Special Rep. (SCO report), *In Vitro Fertilization in Israel - Aspects of Regulation and Supervision* 5 (Nov. 2024), https://perma.cc/EB2Y-UXBY (in Hebrew). See also Ruth Levush, L. Libr. Congress, Global Legal Rsch. Ctr., *Israel: Reproduction and Abortion: Law and Policy* (2012), bibliographic information at https://lccn.loc.gov/2018299333.

[2] National Health Insurance Law, 5754-1994, 2d Supp. § 6(d), as amended by the National Health Insurance Order (Modification of the Second and Third Additions to the Law), 5783-2023, KT 10762, p. 2422, Nevo Legal Database, https://perma.cc/RX23-TJYA (in Hebrew, by subscription); full up-to date text of the law is available id. at https://perma.cc/WWA2-G5F9.

[3] National Health Insurance Law, 2d Supp. § 6(d).

[4] SCO report, supra note 1, at 44.

[5] Id. at 22.

[6] The genetic parents of the child who was later born by the non-genetic mother were identified in September 2023. In November 2024, the Rishon LeZion district court ordered the transfer of the child, who was already two years old by that time, from the parents who raised her to her biological parents. Fam. (DC Rishon LeZion) 61932-09-23 Anonymous v. Anonymous, Nevo Legal Database, https://perma.cc/89M7-6NW5 (in Hebrew, by subscription).

[7] SCO report, supra note 1, at 12.

[8] Id.

Shortly after the issue of the SCO report, on December 2, 2024, the Ministry of Health (MOH) published new rules for operation of IVF units[9] and additional guidelines for the treatment and preservation of fertilized ova.[10]

The new rules limit the number of treatment cycles for purpose of ova freezing to reduce the risk of age-related fertility loss in relation to the age of the woman, with the maximum age being 41, except to continue a process that began before she turned 41, and until the maximum number of treatments (six) is exhausted, or the maximum number of ova as prescribed by the rules is extracted.[11]

The new MOH requirements require attending physicians to inform patients and obtain their selection of one of four options regarding the preservation or disposal of their fertilized ova, on the day of ova retrieval, and no later than the day of the return of the fertilized ova. The MOH rules further provide for mandatory thawing under specified conditions.[12]

The following country study addresses various aspects of IVF treatments in Israel, including access to treatment, funding, regulation of IVF facilities, rules on freezing and discarding of embryos created through artificial reproductive technology, documentation, and oversight. References to the findings of the SCO in its November 2024 report, as well as to the new requirements introduced by the December 2, 2024, rules are included as relevant.

II. Access to Assisted Reproductive Technology

IVF treatment may be provided to the following:

- spouses who do not have children in their current marriage,
- a childless woman who wishes to establish a single-parent family,
- same-sex male partners who do not have children,
- a childless man who wishes to establish a single-parent family, through surrogacy.[13]

While IVF treatments subsidized by the state are limited to the birth of a first and second child, healthcare funds may authorize the provision of IVF services for the birth of additional children, subject to the terms of individual insurance plans managed by the healthcare funds. (This is discussed further in Section IV, below.) Additional services funded by the state include embryo preservation, ovum retention, and preservation and transplantation of ovarian tissue for girls and women that undergo chemotherapy or radiation treatment that may harm their fertility.[14] The

[9] Guidelines for In Vitro Fertilization (IVF) Units on the Treatment of Fertilized Ova, MOH Circular 12, 2024 (Dec. 2, 2024), https://perma.cc/TN4C-22WM.

[10] Ovum Freezing and Preservation, MOH Circular 13, 2024 (Dec. 2, 2024), https://perma.cc/38P2-AJVV.

[11] Id.

[12] Guidelines for in Vitro Fertilization (IVF) Units on the Treatment of Fertilized Ova.

[13] National Health Insurance Law, 2d Supp. § 6(d)(4).

[14] National Health Insurance Law, 2d Supp. § 6(d1).

treatment is provided "for the purpose of giving birth of a first and second child to spouses who do not have children in their current marriage and to a girl or a woman, without children [eligible recipients], for the purpose of fertility preservation."[15]

Treatments for preservation and transplantation of ovarian tissue are also provided if given "due to malignancy . . . for the purpose of fertility preservation (up to two children per family)."[16] Eligible recipients with an increased risk of early menstruation as defined by the law are also entitled to such treatments.[17]

IVF patients who are carriers of genetic diseases or chromosomal abnormalities due to fertility impairments and patients who underwent recurrent miscarriages due to chromosomal abnormalities are eligible for preimplantation genetic diagnostic services.[18]

Access to self-retention of sperm not for the purpose of donation is available in one of the following situations:

- Men who wish to retain sperm following malignant and systemic diseases.
- Retention due to sperm quality that does not allow fertilization naturally (OTA).
- Retention of testicular tissue as part of IVF treatments.
- Men who wish to retain sperm for a non-medical self-reason.
- Sperm retention after death.[19]

Sperm retrieval and retention posthumously requires court approval. The Ministry of Health has reportedly waived this requirement for soldiers who died in the Israel-Hamas war that began on October 7, 2023. According to a recent report:

> While retrieving sperm posthumously no longer requires legal permission, using it to conceive a child does. Families and spouses must petition a civil court and offer substantial evidence that the deceased wanted to have a child, whether in the form of diary entries, iPhone notes or something else. The standard of proof is far higher for parents, and cases can take up to 12 years, according to Irit Rosenblum, an Israeli fertility lawyer.
>
> Israel's Parliament could consider a law on using posthumous sperm for conception, but lawyers say this is unlikely to happen before the war ends.[20]

[15] Id.

[16] Id. § 6(d2).

[17] Id. § 6(d3).

[18] Id. § 21(a).

[19] *Self-Sperm Preservation*, Israel Ministry of Health, https://perma.cc/YP6N-LST2 (in Hebrew).

[20] Emma Goldberg, *Grieving Parents Ask: Should They Freeze Their Dead Son's Sperm?*, N.Y. Times (Nov. 20, 2024), https://perma.cc/4TNC-QNRK.

III. Requirements for Facilities

The National Health Regulations (IVF), 5747-1987, (hereafter IVF regulations) govern procedures associated with the provision of IVF services. [21]

A. Facilities in Israel

The taking of an ovum from a woman's body, and fertilizing, freezing, or implanting a fertilized ovum into a woman's body, may only be done in a "recognized unit" and in accordance with the regulations.[22] The regulations define a "recognized unit" as

> a unit in a hospital, including a government hospital or clinic, recognized by the Director [Director General of the Ministry of Health or a person authorized for the purposes of implementing the regulations], by notification in the Official Gazette, for the purpose of carrying out activities related to IVF, in whole or in part, and under conditions prescribed.[23]

By November 2024, the Ministry of Health recognized 26 IVF units in public and private hospitals throughout Israel.[24]

B. Foreign Facilities

The implantation of an ovum taken and fertilized outside of Israel may be authorized if done in a recognized facility in Israel and under conditions enumerated in the regulations. [25] Authorization requires submission of documentation to the director and to the attending physician, "proving that the pumping and fertilization were carried out in an institution authorized under the laws of the foreign country in which they were performed."[26]

Authorization for implantation further requires presentation of medical documents attesting to the suitability of the fertilized ovum for implantation, based on the following tests conducted on the donor:

- test for Tay-Sachs,
- blood count and liver and kidney function,
- urine tests for general indicators of infection and culture to identify the cause,

[21] National Health Regulations (IVF), 5747-1987, KT 5747 No. 5035 p. 978, as amended, https://perma.cc/ER7G-TFC5.

[22] Id. § 2.

[23] Id. § 1 (translation here and throughout this report by author.)

[24] SCO report, supra note 1, at 34.

[25] National Health Regulations (IVF) § 2A(1)(a).

[26] Id. § 2A(2)(b).

- serological tests – HbsAg, HCV, HIV, VDRL, and
- blood type and Rh test.[27]

The director and the attending physician must be satisfied based on the medical documents submitted that all measures were taken to protect the health of the donor, including by performing physical examinations, breast examinations, and appropriate gynecological examinations before ova retrieval; and by subjecting the donor to moderate, controlled ovulation-inducing treatment, where the daily dose in the first treatment did not exceed 225 follicle-stimulating hormone units.[28]

Approval of implantation of an ovum extracted and fertilized outside of Israel also requires presentation of a consent form signed by the donor in which she agrees to undergo any genetic test required of her in the future, or to preserve a blood sample for future genetic testing.[29]

IV. IVF Funding

As noted in Section III.A, above, by November 2024, the Ministry of Health recognized 26 IVF units in public and private hospitals throughout Israel.[30] According to the SCO report, in 2021, there were four private recognized units and 21 public units. Of the total 101,000 IVF activities that year, 60% were performed in the four private units' facilities, and 40% in the remaining 21 public ones. The SCO report also noted that 51% of the activities in private units in 2021 were funded as part of the state mandated "basket of health services." The report states that the private units provided additional services that were funded through individual health insurance plans or direct payments by patients.[31]

A. Basket of Health Services

Israel maintains a system of national health care. In accordance with the National Health Insurance Law, 5754-1994,[32] every resident must subscribe to a healthcare fund of their choice.[33] Healthcare funds cannot reject or make conditions for membership.[34]

Healthcare funds must provide subscribers services that are included in the "basket of health services" (the basket). The services included in the basket are authorized under the law and updated on an annual basis.[35]

[27] Id. § 2A(1)(b).

[28] Id. § 2A(1)(c).

[29] Id. § 2A(1)(d-e).

[30] SCO report, supra note 1, at 34; see also Section III.A. of this report.

[31] SCO report, supra note 1, at 62.

[32] National Health Insurance Law, 5754-1994, § 3.

[33] Id. § 4(a).

[34] Id. § 4(c).

[35] Id. § 3(c).

> The law establishes a mechanism that enables updating, expanding, and changing the health services basket from time to time, in accordance with various technological developments, subject to the government's priorities in the state budget, taking into account, inter alia, the total needs and resources available to the government, and subject to the financing capacity derived from the economic situation. Once a year, to the extent that a budget is set by the Israeli government for the purpose of adding new medical technologies to the basket and in accordance with the amount of the budget set, drugs and other medical technologies are added to the basket of services. Over the years, the need has arisen to formulate a mechanism that will assist the government in formulating its decision on which specific technologies should be added to the health services basket, within the framework of the budget set for this purpose. In response to this, it was decided to establish a special public committee – the "Public Committee for the Expansion of the Basket" or the "Basket Committee" . . . .
>
> The recommendations of the Basket Committee are presented to the Health Council in its plenum, and then they are submitted by the Minister of Health for approval by the Minister of Finance and for government approval . . . .[36]

The state is responsible for financing services that are included in the basket from sources listed in section 13 of the law.[37] These include mandatory health insurance dues collected under the National Insurance Law,[38] annual budget allocation for the Ministry of Health, additional allocations specified in the state annual budget, co-pay by healthcare funds' subscribers, etc.[39]

B. Publicly Funded IVF Procedures

The basket of Health Services includes infertility treatments such as coverage for diagnostic procedures for ascertaining and treatment of infertility, artificial insemination, sperm enhancement treatments, and hormone therapy.[40] Some services that are included in the basket, such as treatment with the fertility drug pergonal, however, require the patient to cover part of the cost as long as it does not exceed an amount specified in the law.[41]

Self-retention of sperm not for the purpose of donation that is performed for medical reasons such as cancer and radiation are covered through the respective healthcare funds. Applicants wishing to retain their sperm not for medical reasons will pay for the service in accordance with the Ministry of Health's tariff.[42]

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[36] *Public Committee to Expand the Healthcare Basket*, Ministry of Health, https://perma.cc/LG5L-DVUC (in Hebrew).

[37] National Health Insurance Law § 3(b).

[38] Id. § 14.

[39] Id. § 13.

[40] Id. 2d Supp. § 6(d)(1-3).

[41] Id. § 13(b-c).

[41] Id. 2d Supp. Part II § 9.

[42] *Self-Sperm Preservation*, supra note 14, at pt. II, eligibility for services.

C. Additional IVF Procedures Under Health Fund Plans

A health plan may offer its members plans for additional health services that are not included in the health plan's basket of services.[43] Such services are provided to subscribers under the fund's insurance plans with non-state funding sources such as co-pay fees.[44] According to the SCO report, 67% of the total IVF activities conducted in Israel in 2021 were funded through basket of services resources and 33% through other health fund plans.[45]

The Ministry of Health website contains a comparison table with detailed information on the type and terms, including co-pay, associated with the provision of IVF services by different healthcare funds' programs.[46] For example, the Klalit healthcare fund "Complete Gold" and the Leumit "Gold" plans partially cover IVF treatment for the birth of a third or subsequent child, with several plans covering private hospitals' stay.[47]

V. Rules Related to Embryos Created Through Assisted Reproductive Technology

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

Public funding existed for women until age 45, with the number of IVF treatment cycles is almost unlimited. According to the November 2024 State Comptroller's report, in 2019, for every 1,000 female patients at the "age of fertility (15-45)" the number of IVF treatment cycles was estimated at 27, reportedly much higher than in other countries.[48]

The new rules adopted by the MOH on December 2, 2024, reduce the age ceiling and the number of embryos that may be created or transferred in relation to reducing the risk of age-related fertility loss. Procedures may be authorized only for women who at the commencement of the treatment cycle were 30-41 years old, with the maximum number of treatment cycles of six, provided that the number of ova extracted in previous extractions was not more than 25 in a woman who at the time of the previous extraction was 30-36 years old; or up to 35 for a woman who at that time was 36-41 years old. If the maximum number of ova as stated was achieved in the first extraction, it is possible to allow one additional ova extraction. Under the rules, a woman who began the process before she turned 41 can continue it until the maximum number of treatments is exhausted, or the maximum number of ova is extracted if the process continues in accordance with the standards of medical practice.[49]

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[43] National Health Insurance Law § 10(a).

[44] Id. § 13(b-c).

[45] SCO report, supra note 1, at 58.

[46] *Eligibility, Choosing Insurers for Comparison*, *Artificial Insemination Treatments (IVF)*, Ministry of Health, https://perma.cc/XM3S-XBLX.

[47] Id. Detailed information available by clicking on links from the table.

[48] SCO report, supra note 1, at 41, 44.

[49] Ovum Freezing and Preservation, Rule 5, MOH Circular 13, 2024 (Dec. 2, 2024), https://perma.cc/38P2-AJVV.

B. Preimplantation Genetic Testing

Preimplantation screening for certain diseases is offered for patients seeking IVF treatments. While gender selection for nonmedical reasons is generally prohibited, preimplantation screening to identify the gender of an embryo may be authorized under conditions detailed by the law.

1. Screening Tests for Specific Hereditary Disorders and Chromosomal Abnormalities

The basket of healthcare services provides for the provision of free screening tests for common hereditary disorders (the list of disorders is updated periodically based on Ministry of Health decisions).[50] According to the current criteria, the following tests are included:

> Preimplantation genetic diagnosis –
>
> (a) The treatment will be given to patients who have one of the following conditions:
>
> (1) carriership of genetic diseases or chromosomal abnormalities in IVF patients due to fertility impairments;
>
> (2) recurrent miscarriages due to chromosomal abnormalities;
>
> (3) Women or couples at high risk of having a child with particularly severe chromosomal abnormalities or couples with carriership of mutations, which cause particularly serious genetic diseases, for which one of the following exists:
>
> (a) These two conditions:
>
> (1) There is a laboratory test that diagnoses carriership of the disease, and the disease can be detected in the embryo;
>
> (2) there is a 25% to 50% risk of particularly severe monogenic disease such as thalassemia major, cystic fibrosis, fragile X syndrome, Tay-Sachs, etc.;
>
> (b) in one partner there is a balanced chromosomal alteration such as translocation, which increases the risk of the fetus with severe chromosomal alteration;
>
> (4) carriership of mutations in genes that cause asymptomatic genetic deafness;
>
> Eligibility for treatment under this paragraph shall be limited to only two pregnancies that ended in childbirth;
>
> For the purposes of this paragraph, "particularly serious genetic disease" – a disease that causes mortality at an early age or morbidity and great suffering without the possibility of cure.
>
> (b) Eligibility for treatment will be determined according to the recommendation of a genetic counselor.[51]

2. Preimplantation Genetic Testing for Polygenic Diseases (PGT-P)

Although fertility treatments and preimplantation testing for certain diseases listed in the regulations are widespread and subsidized by the Israeli government, Israelis do not have access

[50] *Genetic Screening Tests*, Ministry of Health (Nov. 17, 2024), https://perma.cc/P2DD-4NKN.

[51] National Health Insurance Law, 2d Supp. § 21A.

to the PGT-P procedure, which screens for polygenic diseases such as diabetes, heart disease, and cancer. According to an October 2022 article,

> PGT-P is different from prior technology in important ways, creating new opportunities and challenges for parents while raising profound ethical dilemmas for society. Similar to older forms of testing, PGT-P relies on analyzing genetic material from embryos created through IVF before implantation and checking them for certain diseases and conditions. The information then helps the parents and doctors decide which embryos to implant.
>
> However, the biggest difference between PGT-P screening and earlier forms of genetic testing is that the prior tests checked for genetically simple conditions such as Down syndrome, cystic fibrosis, or Tay Sachs disease. These diseases, which are serious or fatal, have extremely high "penetrance," which means that if the gene mutation is seen in the embryo's DNA, it is nearly certain that the child will have that condition. The appearance of the disease-linked gene is the basis of a clear diagnosis.
>
> This "simple" genetic screening has already borne fruit in the Jewish community: Decades ago, babies in the Ashkenazi Jewish community were nearly 100 times more likely to be born with Tay Sachs than babies in the general US population. Today, because of genetic screenings, the disease is "virtually wiped out."
>
> In contrast, PGT-P screening can't tell you with assurance if an embryo will develop a genetic disease such as cancer or Crohn's disease. That's because this new screening checks for polygenic diseases – complex conditions caused by the combined impact of possibly thousands of different genes, as well as lifestyle and other environmental factors.
>
> Instead of a clear diagnosis, prospective parents receive a "polygenic risk score," basically the probability of a child developing a certain disease or condition. . . .
>
> The "relative risk reduction" projected to be accomplished by PGT-P varies depending on the disease. However, according to a 2021 research paper by Carmi and his collaborators, for schizophrenia and Crohn's disease, around a 45% relative risk reduction is achievable for parents testing five embryos and choosing the best scoring, compared to implanting a randomly chosen one of the five.[52]

The article suggests that there are grave ethical concerns about the impacts of PGT-P technology on the society. These include

> fears of stigmatizing those living with genetic diseases, and questions about equitable access to these technological advances.
>
> Perhaps the most significant ethical concern, and one that looms larger with polygenic screening than with older tests for monogenic diseases, is the potential for eugenics. This is the infamous and dangerous philosophy, practiced in Nazi Germany and elsewhere, that society should try to promote the creation of the most genetically "superior" babies.[53]

[52] Nirit Sandman Eriksson, *Designer Babies? Hi-Tech Preimplantation Genetic Testing May Soon Come to Israel*, Sci. (Oct. 14, 2022), https://perma.cc/QE5D-GAZM.

[53] Id.

3. Sex Selection in Preimplantation Diagnosis

Persons wishing to choose the gender of their newborn may apply to the National Committee for Gender Selection of the Newborn in Preimplantation Genetic Diagnosis (the committee). Applications may be filed by single women, couples who are lawfully married to each other, or who are "known to others as married"[54] who are not married to others.[55]

The Ministry of Health provides that the committee will be able to approve the process only if all the following conditions are met:

- There is a real risk of substantial harm to the mental health of one of the parents or of the children who will be born if the gender selection procedure of the newborn is not carried out.
- The applicants have at least four children in common of the same sex, and do not have children of the opposite sex, except in exceptional and extremely rare cases and for special reasons to be recorded in the decision of the committee.
- The applicants received genetic counseling in which the following details were clarified:
    - Details of the procedure and advice from a fertility doctor regarding the chances and risks.
    - The ethical considerations involved in choosing the sex, including the status and fate of embryos of the unchosen sex.
- The applicants gave their written informed consent to perform the procedure and separate informed consent was given by the parents to perform an IVF (in vitro fertilization) procedure.
- It was explained to the applicants that if the created embryos are not of the requested sex, no further fertilization cycle for the purpose of sex selection will be approved before all the normal embryos created are used.
- The committee was convinced that there was great justification for choosing the sex of the newborn in this case.[56]

C. Freezing of Embryos

The rules issued by the MOH on December 2, 2024, regulate the treatment and preservation of fertilized ova.[57] According to the rules, ova freezing will be performed in accordance with the

[54] Israeli law does not recognize cohabitation as fully equivalent to a legal marriage. Persons who cohabit and are "known to others as married," however, may be eligible under specific laws to the financial benefits to which married persons are entitled. See Ruth Levush, L. Libr. Congress, Global Legal Rsch. Ctr., *Israel: Common-Law Marriage,* (1997), bibliographic information at https://lccn.loc.gov/2019670754.

[55] *National Committee for Newborn Sex Selection in Preimplantation Diagnosis*, Ministry of Health, https://perma.cc/N9PF-TCDX (in Hebrew).

[56] Id.

[57] Ovum Freezing and Preservation, MOH Circular 13, 2024, supra note 10.

medical indication for preservation of fertility or during IVF treatment. The guidelines provide for ova freezing as follows:

> 4.1. Fertility preservation
>
> 4.1.1. Cancer patients or patients with benign diseases prior to gonadotoxic treatment;
>
> 4.1.2. Patients with diseases that may be associated with the risk of early menopause;
>
> 4.1.3. Genetic conditions associated with the risk of premature menopause;
>
> 4.1.4. Prior to surgery that may involve the removal of ovarian or ovarian cysts;
>
> 4.1.5 Before Gender Adjustment treatment;
>
> 4.1.6 To reduce the risk of age-related fertility loss.
>
> 4.2 During IVF treatments:
>
> 4.2.1 When the partner does not give sperm on the day of ova retrieval for various reasons.
>
> 4.2.2. When not enough sperm was found to fertilize all the extracted ova.
>
> 4.2.3 According to medical indication.[58]

D. Disposal of Fertilized Ova and Embryos

The basket of healthcare services includes freezing of fertilized ova among services that are provided through healthcare funds. Fertilized ova may be kept frozen for five years free of charge. The duration of the freeze can be extended for an additional five years with a fee. Under the IVF regulations,

> 9.(a) An ovum, including a fertilized ovum, shall be frozen for a period not exceeding five years.
>
> (b) If a written request to extend the freezing period is received, signed by the woman from whose body it was taken and by her husband, and certified by the signature of the responsible physician, the hospital may extend the freezing period by an additional five years.[59]

The IVF regulations, however, do not address the disposal of frozen ova and embryos.

In 2008, the Ministry of Health published a directive requiring IVF units to request new patients to choose between three options: freezing fertilized ova or embryos for five additional years for

[58] Id. rule 4.

[59] National Health Regulations (IVF), 5747-1987, §9 (a-b), KT 5747 No. 5035 p. 978, as amended, https://perma.cc/ER7G-TFC5.

additional cost, discarding them, or donating them for research. The directive instructed the units to reach out to patients again at the end of the first five-year period and to thaw the embryos or the ova if no response has been received. Units were similarly instructed to reach out to patients whose embryos and ova were already preserved prior to 2008. Although the ministry stated it intended to publish a final directive regarding unclaimed ova and embryos, by December 2023, no such directive has been issued. Significantly, large number of ova and embryos have reportedly been accumulated over the years at storage facilities, some from the 1980s. Some of the patients have passed the age when they can use their frozen ova or embryos or have died.[60]

The SCO report called on the Ministry of Health to complete the adoption of rules with regard to locating patients, the circumstances where frozen ova and embryos may be thawed, such as in relation to patients' ages, and the method of providing consent to thawing ova and embryos, for example, by allowing digital signatures to prevent the need for patients to show up in person to the IVF unit. According to the SCO report, the need for the adoption of such rules had become clearer in recent years, considering the shortage of storage places at the IVF treating units caused, among other reasons, by the sharp increase in the number of IVF procedures performed and the difficulties and risks in continuing to preserve abandoned ova and embryos.[61]

In response to the SCO's recommendation, the MOH December 2, 2024, rules define the periods for the preservation of fertilized ova according to patients' wishes, as well as in the absence of requests for continued preservation.[62]

Under the new requirements, prior to the start of the IVF treatment cycle or the return of frozen fertilized ova (including from a gamete donation), the attending physician must provide all patients with a detailed explanation and obtain signed informed consent indicating patients' awareness that at the end of the treatments, fertilized ova may remain suitable for freezing for future use. Patients must choose on the day of ova extraction or of the return of fertilized ova one of the following alternatives regarding the future of the remaining fertilized ova:

> 2) a. Freezing for a period not exceeding five years without additional payment;
>
> b. freezing for a period of five years without additional payment, and in addition a request to extend the freezing period for an additional five years, subject to arrangement of advance payment;
>
> c. thawing or refraining from freezing the fertilized ova, resulting in inability to to use them for the purpose of procreation; or

[60] SCOs report at 98; for societal and cultural reasons attributed to the avoidance of discarding embryos, see Netta Ahituv, *Revealed: Israel Is Storing 1 Million Frozen Embryos, Some From the '80s*, Haaretz (Apr. 7, 2022), https://perma.cc/5LGA-H63T (by subscription).

[61] SCO report, supra note 1, at 99.

[62] Guidelines for in Vitro Fertilization (IVF) Units on the Treatment of Fertilized Eggs, MOH Circular 12, 2024 (Dec. 2, 2024), https://perma.cc/TN4C-22WM.

> d. Donation of the fertilized ova to a study that was duly approved.[63]
>
> 3) Failure to choose any of the options means consent to the thawing of the fertilized ova after 5 years.[64]

Patients must also confirm that they know that they can provide instructions on what to do with the fertilized ova if any of them die. They must provide an exact address and additional contact information such as telephone number or e-mail address and must be informed of their responsibility to update the facility in writing of any change in their contact information and/or marital status.[65]

At the end of the storage period, they will be notified of their ability to choose an extension of the freezing period for an additional five years with pay, thawing, or use of their ova for legally approved research.[66]

Additional guidelines issued by the MOH in response to the SCO report address the rules that apply to thawing embryos. Accordingly,

> 12 The defrosting procedure:
>
> When removing the test tubes/straws with the eggs from the storage tanks, special care is required for the entire process.
>
> 12.1. The thawing procedure will be performed by two embryologists.
>
> 12.2. Since the freezing containers contain test tubes/straws with eggs and fertilized eggs from different dates, a comprehensive examination of each test tube/straw is required and its suitability for defrosting.
>
> 12.3. The removal of the biological material will be done similarly to the procedure of removing fertilized ova that are not intended for return to the uterus, in accordance with the procedures for the disposal of biological waste.[67]

E. Storage of Embryos

The Ministry of Health March 2024 Draft Standards for In-Vitro Fertilization (draft) state that quality assurance is essential in the IVF laboratory and includes, among other things,

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[63] Id. Rule 4.1.1. 2).

[64] Id. Rule 4.1.1. 3).

[65] Id. Rule 4.1.1. 4) & 4.1.2.

[66] Id. Rule 4.4.

[67] Ovum Freezing and Preservation, Rule 12., MOH Circular 13, 2024 (Dec. 2, 2024), https://perma.cc/38P2-AJVV.

> 6.1.3. Retrievable recording and monitoring of each ovum and sperm sample, growth substrates, equipment and staff responsible for laboratory operations. Ensure that all solutions / reagents / consumables have passed all required quality tests.
>
> 6.1.4. Proper maintenance, service and calibration of all laboratory equipment . . .
>
> 6.1.6. Carrying out preventive and corrective actions if necessary and monitoring their effectiveness.
>
> 6.1.7. Continuous monitoring of fertilization rates, embryo distribution and survival of thawed embryos for continuous improvement.
>
> 6.1.8. Existence of a risk management system for all laboratory activities.[68]

The draft proposes the following quality control guidelines to be implemented in IVF laboratories:

> 6.2.1. For every activity performed in the laboratory, a standard execution procedure (SOP) must be established.
>
> 6.2.2. The laboratory shall have procedures for single-value identification of tissues, gametes and fertilized ova in relation to patients.
>
> 6.2.3. The laboratory shall have a procedure describing the marking of test tubes, growing plates and freezing straws containing gametes or fertilized ova. The marking will be clear and durable and will include the patient's full name and a single-value identification code that can be retrieved.
>
> 6.2.4. The laboratory shall have a procedure for recording exceptional events resulting from malfunctions, human errors, emergency situations and complaints. It is necessary to document the corrective actions and monitor the effectiveness of the corrective action. In such cases, it is necessary to write down the dates of the start and end of monitoring the effectiveness of the actions taken. Any exceptional case will be reported to the unit manager and transferred to the medical institution's risk management unit.
>
> 6.2.5. Any relevant information related to the laboratory's activity should be registered in an electronic database with or without a physical draft.
>
> 6.2.6. Periodic analysis of laboratory results must be performed at least once a year. Results should be discussed periodically at least once a year and corrective action should be taken as necessary.
>
> 6.2.7. Participants must participate in internal and external quality control audits, or inter-laboratory. Every finding should be documented, the results of quality audits discussed, and corrective action should be taken if necessary.[69]

The draft includes procedures for univalent verification and identification of gametes and fertilized ova in relation to patients, as well as for the handling of tinctures and equipment.[70]

[68] Draft Standards for In-Vitro Fertilization Supp. 2 § 6.1.

[69] Id. § 6.2.

[70] Id. §§ 7-9.

F. Embryo Donation and Registration

In accordance with the Ova Donation Law, 5770-2010, a physician who treats an Israeli resident between the ages of 18 to 54 and who is unable to conceive or has another medical problem that justifies the use of another woman's ova for the purpose of giving birth to a child, should inform the patient that she could apply for ovum donation.[71]

The extraction and implantation of donated ova requires authorization by an approval committee appointed in accordance with the law, consisting of representatives of both genders including two physicians, a clinical psychologist, a social worker, an attorney, and a public representative or cleric who belongs to the donor's religious, social, or cultural denomination at her request. [72]

1. Donor's Consent

Prior to the committee hearing, the donor must be provided with a written explanation, in a language she understands, of the following:

> (1) details of the direct and indirect medical risks involved in ovum retrieval and alternatives to retrieval methods;
>
> (2) the details that will be stored in the database and in the neonatal registry and the conditions for providing the information from the database or registry;
>
> (3) the rights of the donor and the prohibitions applicable to her under the provisions of this Law;
>
> (4) the donor's rights to designate ova for implantation, freezing for future use by her, for research or destruction purposes, and to change the purpose of the ova . . . [before fertilization];
>
> (5) the [legal] status of the newborn;
>
> (6) The circumstances under which the approval of the exceptions committee is required . . . .[73]

The law further requires the volunteer donor to undergo a medical and psychological examination to check her suitability for ova donation.[74]

2. Committee's Authorization

Authorization for the retrieval of ova from the body of a volunteer donor for transplantation may be granted after specifying to the donor, orally, the contents of the explanatory statement, and verifying that the donor signed the consent form of her free will, she is a resident of Israel who is 21 to 35 years old, has legal capacity, and is not incarcerated. When a donor has designated in

[71] Ovum Donation Law, 5770-2010, § 11, SH 5771 No. 2264 p. 86, as amended, available at the Nevo Legal Database, https://perma.cc/N8BQ-CTMA (in Hebrew, by subscription).

[72] Id. § 12(b-c).

[73] Id. § 12(d).

[74] Id. § 12(e).

advance that the ova extracted from her body is for a particular donee, the committee must verify that the donor's consent was not given for monetary or any other consideration, directly or indirectly.[75]

3. *Implantation of Donated Embryo*

The allocation and implantation of donor ova requires the head of the IVF department (responsible physician) to verify that the man with whose sperm the ova will be fertilized has given his prior written consent to do so for one or more actions as indicated, including consent to the inclusion of his personal details in the database and in the neonatal registry, in a consent form ordered by the responsible physician. These requirements do not apply to a sperm donation received from the sperm bank.[76]

Approval of implantation of donated ovum in the body of a donee or a surrogate requires verifying that the recipient is a resident of Israel who is 18 to 54 years old and unable to conceive from her own ova due to a medical reason or has another medical problem that justifies the use of another woman's ova to give birth to a child.[77]

In addition, approval requires receipt of confirmation from the database established under the law that all of the following have been fulfilled:

> 13.(e)(3)
>
> (a) the donor is a member of the donor's religion and is not her relative;
>
> (b) the donor is not a relative of the person intended to be the genetic father of the newborn;
>
> (c) the donor is not married;
>
> (d) if the ova extracted from the donor were intended for fertilization with the sperm of a sperm donor – the sperm donor is not a relative of the donor or the recipient; 13.(e)(4)
>
> If the ova intended for implantation were donated from a donor who is married or from a donor who is not of the donor's religion – the responsible physician [must have] informed the donor and her spouse that the donor is married or is not of the donor's religion, as the case may be, and received the consent of the donor and her spouse, in writing, to receive the ova from such a donor.[78]

4. *Conditions for Extraction of Ova from a Donor*

Before extracting ova from a donor, the treating physician must ensure that approval for the allocation and implantation of the ova has been granted. The physician must also receive confirmation from a data bank established under the law that no more than two ova retrieval operations have been performed on the volunteer donor before the date of retrieval, and that at least 180 days have passed since the last date on which such ova retrieval was performed on the

[75] Id. § 12(f).

[76] Id. § 12(d).

[77] Id. § 13(e)(1-2).

[78] Id. § 13(e)(3-4).

donor. The attending physician must also receive confirmation from the database that the ova intended for implantation were extracted from one donor, in one ova retrieval operation, and that no ova were allocated from this retrieval for transplantation in more than two other women. Additionally, the treating physician must ensure that the ova retrieval operation does not involve risks to the volunteer donor that exceed the usual risks involved in such an operation.[79]

5. Disclosure of Information to Donors After Ova Retrieval and Consent to Perform Procedures on Them

The donor must be informed of the number and quality of the ova extracted from her body. She then will be asked to sign a form providing her consent regarding the ova extracted from her body, the number of ova she agrees to designate for implantation, for freezing for her own future use, for research, or for destruction.[80]

The law requires, however, that the number of ova designated by a volunteer donor for freezing for her future use or for research purposes will not exceed 20% of the number of ova extracted from her body or two ova, whichever is lower. The donor's consent for the implantation or freezing of ova may be given for a certain period, after which the ova is destroyed, or for an indefinite period resulting in the ova not being destroyed for at least 10 years.[81]

6. Donors' Identification and Registration of Procedures

The law requires preservation of extracted ova intended for transplantation, freezing, research or destruction in a manner that enables their identification until they are implanted, allocated for research purposes, or destroyed. For that purpose, the responsible physician and the attending physician must document their actions in the donor's medical record, including the number of ova extracted from the donor and the number of ova allocated to each of the actions designated by the donor. The medical record must be accompanied by the letter of consent signed by the donor as well as instructions given to her regarding withdrawal of consent and change of designation as provided in the law.[82]

G. Use of Embryos for Scientific Research Purposes

1. Use of Ova

Embryos created through IVF may be donated by the donor for scientific research. As noted in Section V.F.5, above, a donor may allocate up to two ova or 20% of her extracted ova, whichever is lower, for research.[83] As noted above, the donor's consent must be given in writing in a form designated by the head of the IVF unit.[84]

[79] Id. § 14.

[80] Id. § 16(b).

[81] Id. § 16(c-d).

[82] Id. § 18.

[83] Id. § 16(c).

[84] Id. § 16(b).

Both donors and non-donor patients may grant consent for extraction of their ova for an approved study or for certain types of studies that have been duly approved before the grant of consent. The donor or patient, as relevant, will indicate on the form whether her consent extends to designation of ova for the purpose of research to be conducted abroad, and the period in which it can be used. The ova will be destroyed at the end of the designated period or no later than 10 years after extraction if an earlier period had been designated.[85]

2. Use of Embryos

Public Health Regulations (Medical Trials on Human Subjects), 5741-1980, defines a "medical experiment in humans" as

> (1) Making use of a drug, radiation or chemical, biological, radiological or pharmacological substance, contrary to the approval given for that use under legislation, or when such use is not acceptable in Israel for the purposes sought to be intended for them, or has not yet been tried in Israel, and has or is intended to affect the health, body or soul of a person or *embryo*, or part thereof, including the genetic makeup;
>
> (2) Doing any procedure, action or examination on a person that is unacceptable . . . .[86]

A medical experiment on a human being requires written approval by the medical director of the hospital. No medical experiment may be performed on a human being in a hospital contrary to the regulations and contrary to the Helsinki Declaration.[87]

According to the Israel Academy of Science and Humanities,

> Due to the sensitivity of the research topic on embryos, the scientific community has been instructed by ethics advisory committees not to conduct experiments on embryos after the 14th day of their formation. The directive became known as the "14-day rule." The 14th day of fetal development is determined by a combination of several reasons: some are practical – the need to set a certain boundary after which the embryo is more like a human creature and should not be experimented on; Some of them are biological and related to the stages of fetal development. The incision line is also determined because day 15 is the primitive streak – the earliest point in time after which the embryo cannot divide into twins (i.e., a marker of individuality). Also, after the 14th day, the nervous system begins to develop, and the rationale was to prevent suffering from a creature capable of sense. Recently, with the advancement of the scientific ability to grow human embryos in the laboratory up to day 13, a heated debate has arisen in the scientific community as to the correctness of the 14-day rule. Some voices call for "distancing" the incision line, after which experiments on embryos can no longer be performed for moral reasons, while others

[85] Id. § 27.

[86] Public Health Regulations (Medical Trials on Human Subjects), 5741-1980, KT No. 4189 p. 292, as amended (emphasis added); up-to-date text available at the Nevo Legal Database, https://perma.cc/B2SR-JAB7 (in Hebrew, by subscription).

[87] Id.; Helsinki Declaration, recommendations guiding physicians in biomedical research involving humans – as adopted at the 18th World Medical Assembly, Helsinki, Finland, 1964, and amended at the 29th World Medical Assembly, Tokyo, Japan, 1975.

fear a slippery slope that will allow for more expansion of experiments on embryos, even at later stages of development.[88]

[88] *Research in Embryos*, Israel Acad. Sci. & Human., https://perma.cc/F33Y-WVEL (in Hebrew).

Italy

Dante Figueroa
Senior Legal Information Analyst

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 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 Law No. 40's three-embryo limit invalid 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 among 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.

Under current Italian legislation, medically assisted procreation procedures are carried out in public and private facilities that are authorized by the Italian regions and registered in the National Register of Facilities Authorized to Apply Medically Assisted Procreation Techniques, of Formed Embryos, and of Children Born as a Result of the Application of the Techniques. The register allows the National Health Institute to collect data and disseminate information enabling the transparency and publicity of medically assisted procreation techniques carried out throughout the country. The Health Ministry, through the National Health Institute, defines guidelines on the procedures and techniques for medically assisted procreation. The legislation created a fund to facilitate access to medically assisted procreation techniques. Finally, only adult couples of different genders, married or cohabiting, of potentially fertile age, and both living, may access medically assisted procreation techniques.

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 ART procedures in Italy, it is necessary to refer to these decisions concerning not only their express declarations, but also the areas on which the rulings were silent, as will be explained further in this report.

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. Access to Assisted Reproductive Technology

Under current Italian legislation, only adult couples of different sexes, married or cohabiting, of potentially fertile age, both living, may access medically assisted procreation techniques.[5]

Access to ART is further restricted to persons up to 46 years old, and a minimum of 18 years of age and a maximum of 40 years old regarding third-party donations.[6]

III. Requirements for Facilities

Per current Italian legislation, medically assisted procreation procedures are carried out in public and private facilities authorized by the Italian regions,[7] and they are registered in the National Register of Facilities Authorized to Apply Medically Assisted Procreation Techniques, of Formed Embryos, and of Children Born as a Result of the Application of the Techniques (National Register).[8]

The regions and the autonomous provinces of Trento and Bolzano are directed to regulate the following matters in their own regional legislation:

- the technical-scientific and organizational requirements of the facilities,
- qualification criteria for facilities staff,
- factors for determining the length and revocation of authorizations, and

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

[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), https://perma.cc/D4K8-TC6Q.

[5] Law No. 40 art. 5(1).

[6] C. Calhaz-Jorge et al., *Survey on ART and IUI: Legislation, Regulation, Funding and Registries in European Countries*, Hum. Reprod. Open (Feb. 20, 2020), https://perma.cc/AD24-XJ83.

[7] *World Fact Book: Italy – Administrative Divisions*, CIA, https://perma.cc/F639-U29X.

[8] Law No. 40 arts. 10(1), 11(2).

- the criteria for monitoring compliance with Law No. 40 of 2004 and the technical-scientific and organizational requirements of the facilities.[9]

The National Register is established at the National Institute of Health (*Istituto Superiore di Sanita* (Institute)), and registration for organizations is mandatory.[10] The Institute's mission is to collect and disseminate, in collaboration with the regional epidemiological observatories, the information necessary to enable the transparency and communication of the medically assisted procreation techniques adopted and the results obtained.[11] The Institute gathers requests, information, suggestions, and proposals from scientific communities and users regarding medically assisted procreation.[12]

Further, the National Register's purposes are

- listing facilities and centers present on the national territory, identifying the facilities' technical characteristics and the services offered; collecting in a centralized manner the data on the efficacy and safety and results of techniques, allowing comparisons and all citizens to make informed choices regarding the centers and treatments;[13]
- carrying out scientific studies and evaluations;[14]
- conducting long-term follow-up studies on children born through ART to assess their health and well-being;[15] and
- recording produced and cryopreserved embryos, enabling, through a complex database, epidemiological analyses to monitor the evolution of phenomena and conduct comparisons with other countries.[16]

The National Register uses a website where registered organizations enter anonymous data in aggregate form, which is freely accessible.[17] The website provides users with data collection, information dissemination, connection between the centers and the Institute, promotion of studies, research and debate on the topics of human reproduction, and professional collaboration.[18] In addition, the general public may obtain information on the facilities operating in the national territory, by region.[19]

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[9] Id. art. 10(1).

[10] Id. art. 11(2).

[11] Id. art. 11(3).

[12] Id. art. 11(4).

[13] *Il Registro Nazionale della PMA*, Istituto Superiore di Sanita' (Oct. 24, 2006), https://perma.cc/6733-K9TA.

[14] Id.

[15] Id.

[16] Id.

[17] Id.

[18] Id.

[19] Id.

Law No. 40 mandates quality audits of facility operators' professionalism and requires measures to ensure that equipment and applied technologies are used appropriately.[20]

Regulated facilities must provide regional epidemiological observers and the Institute with data and information so the Institute may communicate the data annually to the Health Ministry.[21] The National Registry uses specific software to help centers enter data on treatment cycles.[22] The Institute and the Health Ministry monitor the data of all facilities.[23]

The Institute must submit an annual report to Parliament, based on the data collected, regarding the activity of authorized facilities, in particular, the epidemiological evaluation of the techniques and interventions performed; based on this report, in turn, the Health Ministry presents its annual report to Parliament.[24]

The Italian National Health System covers the majority of ART treatments, although there are minor regional differences.[25]

IV. Registries of Procedures and Donors

The Health Ministry, through the Institute, and after consulting the Higher Council of Health, must define guidelines on the procedures and techniques for medically assisted procreation.[26] All data collected at the Institute are kept anonymously and used only for scientific purposes.[27]

Facilities and centers must transmit to the Health Ministry a list containing the numerical indication of the embryos produced following the application of medically assisted procreation techniques in the period established by the law, with an indication of the persons who have used the techniques according to which the embryos were formed, in compliance with personal data protection legislation.[28]

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[20] Olivia McDermott et al., *A Comparison of Assisted Human Reproduction (AHR) Regulation in Ireland with Other Developed Countries* (Reproductive Health 2022), https://perma.cc/S3KF-FECT, citing V. Fineschi et al., *The New Italian Law on Assisted Reproduction Technology*, 31 J. Med. Ethics. 536-39 (2005), https://perma.cc/4LAD-FNWC.

[21] Law No. 40 arts. 11(5), 15.

[22] Istituto Superiore di Sanita', *Il Registro Nazionale della PMA*, supra note 13.

[23] Id.

[24] Law No. 40 art. 15(1).

[25] McDermott et al., supra note 20, citing E. Chelo, *Assisted Reproduction: Historical Background* 14(2–3) Global Bioethics 69–74, https://perma.cc/536M-V5MX.

[26] Law No. 40 art. 7(1).

[27] Istituto Superiore di Sanita', supra note 13.

[28] Law No. 40 art. 17(2).

The National Registry is generally regarded as a valuable tool to collect information on the cycles of assisted reproduction treatment performed annually in Italy,[29] as it collects anonymous data from all Italian centers that apply assisted reproduction techniques regarding treatment cycles, therapeutic protocols, complications, results obtained, and follow-up of pregnancy and births.[30] Thus, the National Registry allows for the improvement of treatments in conditions that guarantee users greater safety regarding assisted reproduction techniques.[31]

In case of heterologous techniques conducted in violation of the law,[32] the gamete donor does not acquire any legal parental relationship with the child and cannot assert any rights or hold any obligations concerning the child.[33]

V. Funding of the Procedure

Law No. 40 established the Fund for Medically-Assisted Procreation Techniques at the Ministry of Health, to facilitate access to medically assisted procreation techniques.[34] The fund is divided among the regions and the autonomous provinces of Trento and Bolzano on the basis of criteria determined by the Health Ministry after consultation with the Permanent Conference for Relations Between the State, the Regions and the Autonomous Provinces of Trento and Bolzano.[35]

"The Italian law does not stipulate to what extent procedures will be funded and what, if any, conditions are necessary to receive funding."[36]

Tax deductions for expenses resulting from ART are permitted in Italy up to 19% of the costs involved.[37]

[29] Istituto Superiore di Sanita', supra note 13.

[30] Id.

[31] Id.

[32] That is, "[A]chieving pregnancy with the help of a third party to provide gametes or the uterus provided by a family member; also called intrafamilial medically assisted reproduction." Paola Delbon & Adelaide Conti, *Medically Assisted Procreation and Fast-Moving Developments in Science and Law: Ethical and Legal Issues in Heterologous Procreation in Italy*, 4 J. Pub. Health Rsch. 109-12 (2015), https://perma.cc/66FK-WY7Y.

[33] Law No. 40 art. 9(3).

[34] Id. art. 18(1).

[35] Id.

[36] Memorandum from White and Case LLP to Center for Reproductive Rights on European Laws Governing in Vitro Fertilization (Feb. 25, 2009), https://perma.cc/BR9D-JZ44.

[37] C. Calhaz-Jorge et al., supra note 6.

VI. Rules Related to Embryos Created Through Assisted Reproductive Technology

Law No. 40 of 2004 prohibits the following activities:

- carrying out, organizing, or advertising the commercialization of gametes or embryos or maternity surrogacy,[38]
- cloning interventions through nuclear transfer or early splitting of the embryo or ectogenesis for both procreative and research purposes,[39]
- the fertilization of a human gamete with a gamete of a different species and the production of hybrids or chimeras,[40] and
- embryonic reduction of multiple pregnancies.[41]

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

Later, by Decision No. 84 of 2016, the Constitutional Court rejected a request for a declaration of the unconstitutionality of several other provisions of Law No. 40. This rejected request sought to eliminate the ban on the withdrawal of a 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; the ban on cloning; and the ban on the fertilization of a human gamete with a gamete of a different species. [42]

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.[43] 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.[44]

[38] Law No. 40 art. 12.6.

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

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

[41] Id. art. 14.4.

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

[43] Law No. 40 art. 13.3(b).

[44] Id. art. 14.4; Legge 22 maggio 1978, n. 194, Norme per la Tutela Sociale della Maternita' e sull'Interruzione Volontaria della Gravidanza, arts. 4, 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.[45]

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.[46] Later, Decision No. 84 of 2016 noted that the possibility of creating embryos not brought to birth—commonly defined as supernumerary or residual—emerged with Decision No. 151 of 2009.[47] 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,[48] and that this balance is reserved to the legislature.[49]

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 Constitutional Court's derogation of the ban on cryopreservation, currently, embryos produced but not implanted are subject to freezing.[50]

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.[51]

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[45] Law No. 40 art. 14.2.

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

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

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

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

[50] Id.

[51] 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.[52]

Subsequently, the Italian Constitutional Court, in Decision No. 229 of 2015,[53] held that embryos can be the subject of preimplantation diagnosis.[54] 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.[55]

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.[56]

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 [a] number . . . greater than what is strictly necessary."[57] In addition, this decision declared the unconstitutionality of the crime of selecting embryos for implantation.[58]

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.[59]

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[52] *Costa and Pavan v. Italy*, Appl. No. 54270/10, Eur. Ct. H.R. 3, Conclusion 71 (2012), https://perma.cc/QAZ4-QK78.

[53] Elisa Chieregato, *La Resistenza del Divieto di Donazione di Embrioni alla Ricerca Scientifica tra Margine di Apprezzamento Europeo e Deferenza al Legislatore* 5 (June 4, 2016), https://perma.cc/YQM2-UR7Y, commenting on Constitutional Court Decision No. 229 of Oct. 22, 2015.

[54] Chieregato, supra note 53, at 5, para. 2.

[55] Law No. 40 art. 13.3(b).

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

[57] Chieregato, supra note 53, at 5, paras. 4, 6, commenting on Decision No. 229 of October 22, 2015.

[58] Id.

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

D. Embryo Preservation

Law No. 40 of 2004 prohibits the cryopreservation and suppression of embryos,[60] except as conducted in accordance with Law No. 40 and Law No. 194 of May 22, 1978.[61] 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 extraordinary cause relating to the woman's health, which could not have been foreseen at the time of fertilization.[62]

In addition, under Law No. 40, cryopreservation of male and female gametes is subject to informed and written consent.[63]

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."[64] However, the court left open the possibility of mitigating embryo protection when justified by significant conflicting interests.[65]

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

Under Law No. 40 of 2004 as updated after the Italian Constitutional Court decisions discussed above, embryo production may not result in a number of embryos greater than that strictly necessary, as indicated in Section VI.A, above.[66]

As a consequence, as excess embryos may not be discarded, they must necessarily be stored according to the techniques accepted by current scientific knowledge, namely, freezing.[67]

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[60] Law No. 40 art. 14.1.

[61] Id.

[62] Id. art. 14.3.

[63] Id. art. 14.8.

[64] Chieregato, supra note 53, at 6.

[65] Id.

[66] Law No. 40 art. 14.2.

[67] 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.[68] 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,[69] or until used, exclusively, by the couple who generated them.[70] This means that cryopreserved embryos—that is, embryos that have been frozen but not transferred—can remain stored for dozens of years with no official expiration date and theoretical viability up to 50 years.[71]

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 or the legal ban on their donation for scientific research or reproductive purposes.[72]

The court cited 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.[73] The ECtHR, as the Italian Constitutional Court noted, declared the Italian ban on experimentation on embryos and the prohibition of embryo donation for experimentation purposes allowable under EU law.[74]

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."[75] As selection is a de facto choosing of some embryos to the detriment of others, the logical consequence of allowing unselected embryos to be discarded appears to be negated by Law No. 40's rule against suppression and disposal.

On the other hand, an alternative interpretation maintains that, under the Constitutional Court decisions discussed above, the suppression of embryos is abstractly allowable if it is justified by observance of another constitutionally protected interest.[76]

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

[69] Chieregato, supra note 53, at 5, para. 3.

[70] Arlotta, supra note 68.

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

[72] Id.

[73] Id. at 6.

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

[75] Chieregato, supra note 53, at 5, paras. 4, 6.

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

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

- any experimentation on any human embryo,[77] and
- the production of human embryos for research or experimentation purposes or for any purposes other than those set forth in Law No. 40.[78]

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.[79]

As already stated, Decision No. 84 of 2016 rejected a challenge to the constitutionality of the absolute ban on any clinical or experimental research on embryos that does not maintain the protection of the embryos.[80]

It should be noted that disagreements still exist among 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.[81] 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.[82]

[77] Law No. 40 art. 13.1.

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

[79] Id. art. 13.2.

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

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

[82] Id.

Poland

Iana Fremer
Legal Research Analyst

SUMMARY In Poland, medically assisted reproduction is regulated by several laws, most notably the Act on Infertility Treatment, the Medical Profession Act, the Code of Medical Ethics, and the Ministry of Health Regulation 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 2023, health care services legislation was amended with provisions mandating public funding of infertility treatment. This program includes medically assisted reproduction procedures, such as in vitro fertilization (IVF), conducted at medical establishments recognized as reproductive centers. IVF treatment is available only to those individuals who have attempted other means of treatment for at least 12 months, or to those who, based on current medical knowledge, are incapable of achieving pregnancy through other methods. 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 embryo banks for up to 20 years, after which they must be transferred for donation if they meet conditions specified by the law and were not utilized by the couple for their own embryo transfer. The use of preimplantation genetic diagnosis to select phenotypic traits (including the child's sex) is only permitted when such a choice would avoid a severe, incurable hereditary disease. Destruction of embryos and their use in scientific research is prohibited.

In June 2024, the Polish government introduced a state-funded IVF treatment program for the years 2024-2028. The program outlines the categories of individuals eligible to use procreation techniques and provides a list of public or private medical facilities that will receive public funding. All clinics performing assisted reproductive procedures must be accredited by the Ministry of Health and submit treatment data for statistical purposes.

I. Introduction

In Poland, medically assisted reproduction is governed by the Act on Infertility Treatment of 2015.[1] It regulates the issues concerning the treatment of infertility and the functioning of assisted reproduction facilities.

The act sets up the rules governing infertility procedures and declares the preservation of future fertility as one of its goals. The rules prescribe providing medical counseling, conducting

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

diagnoses to ascertain the causes of infertility, administering conservative pharmacological treatment, performing surgical interventions, and carrying out medically assisted reproduction techniques, such as IVF, conducted within a medically assisted reproduction center.[2]

II. Access to Assisted Reproductive Technology

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

This legal act limits assisted reproduction to those with clinically proven infertility. It 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 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.[3]

Additional rules on assisted reproduction are contained in 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.[4]

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.[5]

III. Requirements for Facilities

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.[6] To apply for this status, the medical entity must provide specific information including its name, address, organizational structure,

[2] Id.

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

[4] Medical Profession Act of Dec. 5, 1996, art. 30, https://perma.cc/WPY7-R422 (in Polish); Nat'l Congress of Doctors, Code of Medical Ethics (June 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 Medically Assisted Procreation Procedures, https://perma.cc/7KMA-2VEJ (in Polish).

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

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

scope of activities related to infertility treatment, and involvement in teaching and research activities aimed at health promotion and innovation in medical technologies.[7]

The Council for Infertility Treatment 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.[8]

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.[9]

The data on accredited assisted reproduction units and embryo banks in Poland can be found in the Register of ART Units and Germ Cells and Embryo Banks Registry.[10]

IV. Funding of the Procedure

In November 2023, Poland reinstated the government funding for IVF treatment for couples unable to naturally conceive children.

The Act on Amendments to the Act on Health Care Services Financed from Public Funds of November 29, 2023, requires the Ministry of Health to allocate annually no less than 500 million Polish złoty (PLN) (about US$126 million) from the state budget for the implementation of a health policy program for infertility treatment covering medically assisted reproduction procedures, including IVF conducted in a medical establishment recognized as a reproduction center.[11] Under the act, the first health policy program for infertility treatment began on June 1, 2024.[12] On that day, the Polish government introduced a state-funded IVF treatment program for the years 2024-2028.[13] The government has set the program budget at 2.5 billion Polish zloty (PLN), which is about US$620 million.

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

[8] *What About the Infertility Treatment Council: The Commissioner Asks the Ministry of Health* (Aug. 21, 2023), Pub. Info. Bull. Comm'r for Hum. Rts., https://perma.cc/4FUH-G7PY (in Polish).

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

[10] E-Health Registry, ROiB, *Register of Medically Assisted Procreation Centers and Reproductive Cell and Embryo Banks*, https://perma.cc/WA8S-D74M (in Polish). In the registry, a person can check the scope of activity of the facility or bank, its address and the addresses of places where the facility carries out activities covered by the permit of the Ministry of Health, and the validity of the permit.

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

[12] Id. art. 2.; see also Ministry of Health, *Funding for in Vitro Treatments from June 1, 2024* (Dec. 20, 2023), https://perma.cc/D7QT-QZF5 (in Polish).

[13] Ministry of Health & Nat'l Health Fund, *Website of the Infertility Treatment Including Medically Assisted Procreation Procedures, Including in Vitro Fertilization Conducted in a Medically Assisted Procreation Center, for the Years 2024-2028*, https://perma.cc/B57G-ZXKB (in Polish); the text of the program is available at https://perma.cc/YEH6-JENZ (in Polish).

According to the Ministry of Health and the National Health Fund, 58 centers across the country where patients can apply for treatment have been selected. Clinics will receive public grants ranging from more than PLN 2 million (about US$489,000) to nearly PLN 10 million (about US$2.4 million) annually for their treatment. The exact amount received by the clinic depends on how many patients a given center estimates it will care for.[14]

The government's IVF treatment program covers married couples and cohabiting couples with infertility diagnosed or unsuccessfully treated within 12 months before registering for participation. The support is also applied to people suffering from cancer. The program covers expenses for harvesting and freezing the patients' reproductive cells before the cancer therapy starts, so they can be used in the future.[15]

Furthermore, the program covers the financing of six assisted reproduction procedures, including up to four cycles of fertilization with one's own reproductive cells or sperm donation and up to two cycles of fertilization with donor oocytes. There is also the possibility of fertilizing six reproductive cells within one cycle and up to six cycles with sperm donation.

The qualification criteria for the program are the woman's age, which is up to 42 years for women using their own eggs or sperm donation and up to 45 years for women using donor oocytes or embryos. The age limit for men is 55 years of age.

In the framework of this program, support will also be provided to patients before or during cancer treatment. Under this program, funding for so-called oncofertility, procedures such as the collection, freezing, and storage of reproductive cells will be financed. Women up to 40 years old and men up to 45 years old can benefit from this.[16]

V. Rules Related to Embryos Created Through Assisted Reproductive Technology

A. Limit on 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.[17]

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 non-partner donation, the recipient husband's consent to the embryo transfer is also required. A transfer will not be performed if there are medical contraindications for this

[14] Id.

[15] Id.

[16] Id.

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

procedure.[18] If the husband or the donor of reproductive cells collected for partner donation does not consent to the transfer of the embryo, the guardianship court must decide whether to permit the transfer.

The law punishes everyone who creates an embryo for purposes other than medically assisted procreation procedures by imprisonment from six months to five years.[19] The same punishment is prescribed for 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, or who create a chimera or hybrid through medically assisted procreation methods or perform an intervention with the intent of introducing heritable changes in the human genome that can be inherited by future generations.[20]

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.[21] The act prohibits restricting a person's reproductive possibilities because the person is a carrier of genetically determined diseases.[22]

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.[23]

C. Embryo Selection

The use of preimplantation genetic diagnosis for nonmedical 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.[24] Prohibited use is punishable by a fine, restriction of liberty, or imprisonment for up to two years.[25]

The Act on Infertility Treatment also provides that anyone who destroys a viable embryo capable of normal development that resulted from a medically assisted procreation procedure must be punished by imprisonment for a period of six months to five years.[26]

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

[19] Id. art. 85.

[20] Id. art. 87.

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

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

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

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

[25] Id. art. 82.

[26] Id. art. 3.

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 the following two conditions cumulatively:

- the rate and the sequence of cell division and morphological structure make proper embryo development probable, and
- the embryo has not been diagnosed with a defect that would result in severe and irreversible impairment or an incurable disease.[27]

Polish law prevents single women from accessing treatment and prevents them from using previously frozen embryos unless they have a male partner.[28] Their cryopreserved embryos can be given to a married couple without their consent after 20 years.[29]

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 used 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.[30]

Consent for this donation must be given before commencing the medically assisted procreation procedure.[31] 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.[32]

A conclusion of an agreement between the donor and the reproductive cell and embryo bank is required for storing reproductive cells or embryos.[33]

F. Embryo Donation and Registration

Egg and sperm donation in Poland is usually anonymous. 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

[27] Id. art. 23, paras. 1, 2(1)-(2).

[28] Id.

[29] Bridget Brennan, *Single Woman in Poland? Your Embryos Could be Given to Another Couple*, ABC News (Nov. 24, 2019), https://perma.cc/BTH4-5WYK.

[30] Id. Act on Infertility Treatment art. 21, para. 3(1)-(2), art. 97.

[31] Act on Infertility Treatment art. 21.

[32] Id. art. 20.

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

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 the 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.[34] Risk assessments must be conducted to ensure recipient safety and minimize adverse events.[35]

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.[36]

Embryos must be used within 14 months of consent submission. Donors must be informed about the legal consequences of donation.[37] Couples who have concluded their fertility treatments, but still have extra embryos can store them for up to 20 years or give them up for adoption.[38] After 20 years, the embryos are automatically given up for adoption, and the process does not require the patients' consent.[39]

Consent to embryo donation may be withdrawn until the recipient begins the medically assisted procreation procedure in which the embryo is to be used.[40] Destroying viable embryos is illegal and can be punished by up to five years in prison.[41]

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.[42] In such cases, a doctor assesses the medical justification for using reproductive cells that were collected for non-partner donation for partner donation.[43] 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, and

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

[35] Id.

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

[37] Id. art. 36, para. 1(1)—(10).

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

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

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

[41] Id. art. 83.

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

[43] Id. art. 21.

- 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.[44]

Third-party donation, when permitted, is legally 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.[45]

The act requires the Ministry of Health to keep records of the reproductive cell and embryo donors for the purpose of donation other than partner donation, and records of the recipients using this type of treatment. The system guarantees a high level of data safety and security.

The Regulation of the Minister of Health of October 23, 2015, outlines the medical criteria a person must meet to be eligible as a donor or recipient of reproductive cells (sperm or eggs) used in assisted reproductive technology (ART) procedures, including both partner and non-partner donations, and specifies the detailed procedures for collecting these cells.[46] This regulation serves as the legal basis for managing reproductive cell donation in Poland, ensuring ethical and safe practices in ART procedures.

This regulation details the health requirements for potential sperm and egg donors, including age limits, medical history checks, genetic screening, infectious disease testing, and psychological evaluations to ensure suitability for donation.[47] Additionally, the regulation provides the protocols for collecting reproductive cells, encompassing details like the collection methods, storage conditions, and quality control measures to be followed in a medical facility.[48] All healthcare providers performing ART procedures in Poland must adhere to the guidelines outlined in this regulation.[49]

G. Embryo Disposal

The Act on Infertility Treatment bans the destruction of embryos and their use in scientific research. Article 23 of the act prohibits destroying embryos capable of proper development that were created in the procedure of medically assisted procreation and not transferred to the body

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

[45] Id. art. 28, paras. 1, 2.

[46] Regulation of Ministry of Health of 23 October 2015 on Health Requirements for a Candidate for a Donor of Reproductive Cells for the Purpose of Partner Donation and Donation Other than Partner Donation and for the Recipient of Reproductive Cells and Embryos and Detailed Conditions for the Collection of Reproductive Cells for the Purpose of Use in the Procedure of Medically Assisted Reproduction, https://perma.cc/AF9A-CYJB (in Polish).

[47] Id. arts. 1,2, & 3, para. 1(1)-(3), para. 2.

[48] Id. arts. 4, 5, paras. 1(1)-(4), 2 & 3.

[49] Id. see Annex to the Regulation.

of the recipient.[50] Anyone who destroys such embryos is subject to imprisonment from six months to five years.[51]

H. Use of Embryos for Scientific Research Purposes

Poland prohibits creating human embryos for purposes other than IVF. According to article 26 of the Medical Profession Act, unborn children cannot be involved in scientific experiments.[52] The Act on Infertility Treatment also creates a ban on handing embryos over for scientific research.[53] Article 19 of the act permits research on "reproductive cells that were not used in the procedure of medically assisted procreation" but not on embryos, and article 25 prohibits creation of embryos for purposes other than procreation.[54] No mention is made regarding therapeutic experiments, which would make the practice permissible, even if there is no regulation on this subject.

[50] Id. Act on Infertility Treatment art. 23, para. 3.

[51] Id. art. 83.

[52] Medical Profession Act art. 26.

[53] Act on Infertility Treatment art. 19.

[54] Id. arts. 19, 25.

Portugal

Eduardo Soares
Senior Foreign Law Specialist

SUMMARY In 2006, medically assisted reproduction became regulated in Portugal. The law regulates the use of embryos through assisted reproduction, states 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.

Portuguese legislation regulates the functioning of public or private facilities that make use of assisted reproductive technology. A regulatory decree defines the protocol for keeping data related to the application of medically assisted procreation techniques. Authorized public centers involved with these techniques are financed by the government, and private ones may be financed if an agreement is made with the Ministry of Health. The law defines who can make use of procreation techniques.

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. Access to Assisted Reproductive Technology

A. Law No. 32 of July 26, 2006

Couples of different sexes or female couples, who are married or living in conditions similar to marriage can use PMA techniques, as can women regardless of their marital status and sexual orientation.[4] The techniques can only be used for the benefit of those who are at least 18 years of age and "as long as there is no accompanying sentence prohibiting the use of such techniques."[5]

[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. 6(1).

[5] Id. art. 6(2).

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

Different waiting times for PMA treatments based on whether the beneficiary is a couple of different sexes, a couple of women or women without a partner are prohibited, without prejudice to the priorities established based on objective criteria of clinical severity.[6]

III. Facilities Requirements

A. Law No. 32 of July 26, 2006

Law No. 32 of July 26, 2006, regulates the use of medically assisted procreation ((*Procriação Medicamente Assistida*, PMA) techniques.[7] Article 2 states that Law No. 32/2006 is applicable to the following PMA techniques:

a) Artificial insemination;

b) In vitro fertilization;

c) Intracytoplasmic sperm injection;

d) Transfer of embryos, gametes or zygotes;

e) Pre-implantation genetic diagnosis;

f) Other equivalent or subsidiary laboratory techniques for gametic or embryonic manipulation.[8]

Law No. 32/2006 also applies to the surrogate pregnancy situations provided for in article 8.[9]

Article 5 states that PMA techniques, including those carried out in the context of surrogate pregnancy situations provided for in article 8 of Law No. 32, can only be administered in public or private centers expressly authorized for such purpose by the health minister.[10] Article 5 further states that the following will be defined in the proper regulation:

a) The qualifications required of the medical equipment and health personnel;

b) The mode and criteria of periodic evaluation of technical quality;

c) The situation in which the operating authorization may be revoked.[11]

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[6] Decreto Regulamentar No. 6/2016, de 29 de dezembro, art. 7, https://perma.cc/KR77-ZGRC.

[7] Lei No. 32/2006, de 26 de julho, art. 1, https://perma.cc/LD6R-TPLA.

[8] Id. art. 2(1).

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

[10] Id. art. 5(1).

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

As stated in Section I, above, Law No. 32/2006 created the CNPMA, which is responsible, generally, for issuing opinions on the ethical, social, and legal issues of the PMA.[12]

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.[13]

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

Regulatory Decree No. 6 of December 29, 2016, regulates, inter alia, article 5 of Law No. 32/2006.[14] Article 2 defines a center authorized to provide PMA techniques as the set of human, material and organizational means that allow PMA to be carried out, which are authorized in the terms of article 5 of Law No. 32/2006.[15]

The centers can be public or private and must be expressly authorized for such purpose by the member of the government responsible for the health area, after receiving approval of the CNPMA, in the terms provided in article 30(2)(b) of Law No. 32/2006.[16]

The centers may be authorized to carry out the set of PMA techniques provided for in article 2 of Law No. 32/2006, for the exclusive execution of the artificial insemination technique or for the selection of donors and preservation of gametes.[17]

The application of the PMA techniques provided for in article 2 of Law No. 32/2006 to female couples and women, regardless marital status, sexual orientation or a diagnosis of infertility, , who meet the requirements set forth in article 6(2) of Law No. 32/2006 (minimum age of 18 years), can only be administered in PMA centers, public or private, duly authorized by the Ministry of Health, after approval of the CNPMA, according to the terms of Regulatory Decree No. 6.[18]

IV. Registries

A. Law No. 32 of July 26, 2006

According to article 30(2)(p) of Law No. 32/2006, the CNPMA's duties include, but are not limited to, centralizing all relevant information on the application of PMA techniques, in particular donor registration, including surrogate mothers, beneficiaries, and born children.[19]

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[12] Id. art. 30(1).

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

[14] Decreto Regulamentar No. 6/2016, de 29 de dezembro, art. 1(a).

[15] Id. art. 2(1).

[16] Id. art. 2(2).

[17] Id. art. 2(3).

[18] Id. art. 2(4).

[19] Lei No. 32/2006 art. 30(2)(p).

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

Article 17(1) of Regulatory Decree No. 6/2016 states that data relating to PMA are maintained in PMA centers for a period of 30 years after the end of their clinical use.[20]

The information centralized in the CNPMA on the application of PMA techniques, in particular the registration of donors, beneficiaries and born children provided for in article 30(2)(p) of Law No. 32/2006 is maintained for a period of 75 years.[21]

If any PMA center closes before completing the period referred to in article 17(1) of Regulatory Decree No. 6/2016, the person responsible for it communicates the situation, six months in advance, to the member of the government responsible for the health area, who determines the destination of data relating to PMA, gametes, and cryopreserved embryos.[22]

In the cases provided for in the previous paragraph, the recipient entity guarantees the protection and security of data and information under the same conditions required for the center that has ceased its activities.[23]

Personal data relating to PMA may be deleted in the following circumstances:

> a) At the end of the conservation period;
>
> b) By court decision;
>
> c) At the request of the beneficiary who has revoked the consent until the beginning of PMA therapeutic processes;
>
> d) In other legally foreseen situations.[24]

V. Funding of the Procedure

Article 15 of Regulatory Decree No. 6/2016 states that authorized public centers are financed through a contract with the Central Administration of the Health System (*Administração Central do Sistema de Saúde*),[25] while article 16 states that the Ministry of Health may enter into agreements with authorized private centers to finance the use of PMA techniques.[26]

[20] Decreto Regulamentar No. 6/2016 art. 17(1).

[21] Id. art. 17(2).

[22] Id. art. 17(3).

[23] Id. art. 17(4).

[24] Id. art. 20.

[25] Id. art. 15.

[26] Id. art. 16.

VI. 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.[27] 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.[28]

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.[29]

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

> 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.[30]

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.[31]

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.[32] Anyone who implants an embryo used in scientific research and experimentation in a uterus will incur the same penalty outside the cases provided for in Law No. 32/2006.[33]

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

Article 24 of Law No. 32/2006 states 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

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

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

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

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

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

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

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

clinical practice and the principles of informed consent.[34] 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.[35]

B. Preimplantation Genetic Testing

Preimplantation genetic diagnosis (PGD) aims to identify embryos that do not have a serious anomaly, before their transfer to a woman's uterus using PMA techniques, or for the purposes set out in section 3 of article 7.[36] 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.[37]

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 diseases, as considered by the CNPMA, is permitted.[38] 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.[39]

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.[40] PMA techniques cannot be used to improve certain nonmedical characteristics of the unborn child, namely, the choice of sex.[41]

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.[42]

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

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

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

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

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

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

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

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

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

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

process within a maximum period of three years.[43] 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.[44]

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.[45] 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, and for the lack of technical and safety conditions defined by the CNPMA under the terms of article 30(2)(b) of Law No. 32/2006.[46]

2. Law No. 32 of July 26, 2006

As stated in Section VI.E.2, above, Law No. 32/2006 created the CNPMA, which is responsible, generally, for issuing opinions on the ethical, social, and legal issues of the PMA.[47] 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.[48]

F. Embryo Donation

As stated 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.[49]

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

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

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

[45] Decreto Regulamentar No. 6/2016, de 29 de dezembro art. 13(1).

[46] Id. art. 14.

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

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

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

by the center director.[50] 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.[51]

H. Use of Embryos for Scientific Research Purposes

As stated in the first paragraph of Section VI, 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.[52] 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,[53] and only specific embryos can be used.[54]

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

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

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

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

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

Sweden

Elin Hofverberg
Foreign Law Specialist

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 period 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 of development.

I. Introduction

The first child born as a result of in vitro fertilization (IVF) techniques in Sweden was born in 1982.[1] Approximately 25,000 treatments are provided annually.[2]

IVF and research using stem cells are regulated in the Act on Genetic Integrity.[3] In addition, Socialstyrelsen (the National Board of Health and Welfare) issues supplemental regulations pertaining to assisted productive technology.[4] 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.[5] The storage of all human materials, including eggs, sperm, and

[1] Nationallet kvalitetsregister för assisterad befruktning, Fertilitetsbehandlingar i Sverige Årsrapport 2024 Gäller behandlingar startade 2022, [Q-IVF annual report 2024 for 2022], https://perma.cc/9PP4-824Y.

[2] Id. at 2.

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

[4] 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.

[5] 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.

embryos, is regulated in the Bio Bank Act.[6] This act was adopted in 2023, overhauling the previous Biobank Act of 2003.[7] IVF treatment is also subject to the Act on Quality and Safety Norms for the Handling of Human Tissues and Cells.[8] The most current 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.[9]

II. Access to Assisted Reproductive Technology

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 any 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.[10] 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.[11] 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.

IVF treatments are subject to age restrictions. For example, in Region Stockholm, publicly funded IVF treatments are restricted to single women between the ages of 25 and 40, and to couples where the partner is between 25 and 56 years old.[12] Private clinics may have slightly more generous age restrictions. For example, a clinic in Stockholm allows for three successive treatments to commence when a woman is no older than 41 years of age.[13]

In addition, access to IVF treatments is subject to a number of other restrictions, including no prior children and no psychological issues, and the woman seeking the treatment must have a

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

[7] Id.

[8] Lag om kvalitets- ouch 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.

[9] 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.

[10] 6 ch. 1b §; 7 ch. 3 § Act on Genetic Integrity.

[11] 7 ch. 2 § Act on Genetic Integrity.

[12] *Regler och grundkrav - Assisterad befruktning (IVF/ICSI)*, Karolinska Universitetssjukhuset, https://perma.cc/2WDJ-X5LD.

[13] See for example an IVF-clinic in Stockholm offering to start IVF treatments for women until age 41. *IVF-gruppen, Priser*, Ackrediterad Vårdgivare, Sophiahemmet, https://perma.cc/V86Q-D9S9.

body mass index (BMI) between 18 and 35.[14] Couples seeking a procedure must have tried to conceive for a year and be in a stable relationship for at least two years.[15]

Moreover, for persons who receive embryos from a third party, additional requirements must be fulfilled. Specifically, the treating doctor must determine whether it is appropriate that the treatment takes place in consideration of the medical, psychological, and social conditions of the couple, and it may only be completed if it can be assumed that the child will grow up under good conditions.[16]

III. Requirements for Facilities

Fertility treatments can only be performed at approved hospital clinics.[17] Before 2019, procedures with donated sperm could only be performed at public clinics.

IV. Funding of the Procedure

As mentioned in Section II, above, both public and private IVF facilities are available in Sweden. Publicly funded IVF treatments still come with visit costs, but are subject to the Swedish *högkostnadsskydd*, i.e., the maximum amount that a person must pay for public care within a 12-month period.[18] For 2024, it is currently set at SEK 1400 (about US$130).[19] Private clinics set their own prices but may also provide some publicly funded treatments under contract with the region.[20]

V. 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 the embryos that can be created or transferred. However, the National Board of Health and Welfare has issued regulations and national guidelines, which specify that, during IVF procedures, women should only be implanted with one embryo at a time.[21] In special cases where there is a smaller risk for twin pregnancies, two embryos may be transferred.[22]

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[14] Karolinska universitetssjukhuset, supra note 12.

[15] Id.

[16] SKL (now SKR), *Assisterad Befruktning*, https://perma.cc/TZ6V-FVGY.

[17] 9 § Lag om kvalitets- och säkerhetsnormer vid hantering av mänskliga vävnader och celler, (SFS 2008:286); 3 ch. 1 § Genetic Integrity Act.

[18] *Högkostnadsskydd för öppenvård*, 1177, https://perma.cc/V3JE-6RMN.

[19] *Patientavgifter i hälso- och sjukvården i alla regioner 2024*, SKR, https://perma.cc/JA7J-J5M3.

[20] See, e.g., price list of Sophiahemmet, supra note 13.

[21] 4 ch. 15 § SOSFS 2009:32.

[22] Id.

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.[23] 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.[24] 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 approval from the National Board of Health and Welfare.[25] Per the Swedish National Council on Medical Ethics, approximately 100 PGD tests are performed per year in Sweden.[26]

C. Embryo Selection

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

D. Embryo Preservation

Following an IVF treatment cycle, all embryos may be frozen for up to 10 years.[27] In contrast, embryos used for research that have been subject to a somatic cell nuclear transfer may be frozen for up to five years.[28] 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.[29]

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.[30] Embryo storage facilities are subject to inspection and those operating such facilities may be fined for noncompliance with the rules.[31] As mentioned in Section II.D, above, embryos can be frozen for up to 10 years.[32] Embryos used in research may be

[23] 4 ch. 2 § Act on Genetic Integrity.

[24] Id.

[25] Id.

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

[27] 5 ch. 4 Act on Genetic Integrity.

[28] Id.

[29] Id.

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

[31] 15-19 §§ Lag om kvalitets- och säkerhetsnormer vid hantering av mänskliga vävnader och celler, (SFS 2008:286), https://perma.cc/33RR-7TLG.

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

frozen for up to five years.[33] By law, Inspektionen för vård och omsorg (IVO) (the Health and Social Care Inspectorate) must keep a registry of all biobanks in Sweden.[34]

F. Embryo Donation

As of 2019, donations of embryos resulting from IVF treatment cycles are permitted.[35] At that time, 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 could accept donor embryos without a biological link. Prospective parents undergoing IVF treatment can agree to donate surplus embryos either to research or to other persons seeking IVF treatment.[36] However, according to reports, the donor rules, which require that the child resulting from IVF treatment has a right to know his or her biological heritage, have meant that very few such "double donations," where both the egg and sperm are unrelated to the intended parents, have taken place. A special assessment must be carried out by the responsible physician in cases where donor embryos are being used for IVF treatment.[37] In addition, the child's right to know his or her heritage must be guaranteed through special journal references where donor information is included. [38] According to reports, the number of donations of eggs are approximately 100 per year.[39] In 2019, there were four double donations, and in 2020 there were 39.[40] In 2021, the number of double donations had increased to 122, resulting in 25 births.[41]

Donors may not donate embryos, eggs, or sperm to more than six families.[42] 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.[43] However donors of eggs and sperm may receive compensation.[44]

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[33] Id.

[34] 3 ch. 1 § Bio Bank Act.

[35] 7 ch. 3a § Act on Genetic Integrity.

[36] 5 ch. 1,3 §§ Act on Genetic Integrity.

[37] 4 ch. 11 § Socialstyrelsens föreskrifter (SOSFS 2009:32).

[38] 6 ch. 4 §; 7 ch. 6 § Act on Genetic Integrity.

[39] Ann Thurin-Kjellberg, Donation av ägg och spermier, Läkartidningen (Dec. 15, 2022), https://perma.cc/Z4J6-765A.

[40] Fertilitetsbehandlingar i Sverige, Årsrapport (Annual Report) 2020 (2022), https://perma.cc/4P96-EX5S.

[41] Fertilitetsbehandlingar i Sverige, Årsrapport (Annual Report) 2021, (2023), https://perma.cc/5ZKE-VKVH.

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

[43] 8 ch. 6 § Act on Genetic Integrity.

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

G. Registry of Procedures and Donors

The Q-IVF Registry is a qualitative registry which keeps a record of all performed IVF treatments. The information is used for research purposes. The Q-IVF Registry in turn reports its data to the Nordic organization NFS (Nordic Fertility Society) and the European organization ESHRE (European Society of Human Reproduction and Embryology).[45]

H. Embryo Disposal

Embryos must be discarded after they have been frozen for 10 years.[46] Embryos subject to somatic cell nuclear transfer as part of research may only be frozen for five years.[47] Embryos that are used for research must be discarded after 14 days of development, not counting the time they have been frozen.[48] However, the time limits for how long an embryo may be frozen may be extended by the National Board for Health and Welfare on a case-by-case basis if there are special reasons for an extension.[49] 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.[50] There was no legal recourse.

I. Use of Embryos for Scientific Research Purposes

Stem cell research using fertilized eggs has been legal in Sweden since 2005.[51]

Research using embryos is subject to prior ethical review and requires the consent of the embryo donors.[52] 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 donors.[53]

[45] Q-IVF annual report 2024 for 2022, supra note 1, at 3.

[46] 5 ch. 4 § Act on Genetic Integrity.

[47] Id.

[48] 5 ch. 3 § Act on Genetic Integrity.

[49] 5 ch. 4 § Act on Genetic Integrity.

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

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

[52] 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.

[53] 5 ch. 1 § Act on Genetic Integrity; 17 §§ Lag om etikprövning av forskning som avser människor (SFS 2003:460).

Embryos used for research must be destroyed at 14 days of development.[54] However, stem cells that have been derived from the embryo may be researched and made to live longer than those 14 days.[55]

In 2002, Sweden became the second country in Europe, after the United Kingdom, to create a stem cell biobank.[56]

[54] 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.

[55] 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.

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

United Kingdom

Clare Feikert-Ahalt
Senior Foreign Law Specialist

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. Access to Assisted Reproductive Technology

There do not appear to be age limits for fertility treatment in the laws that govern IVF across the UK, but individual clinics have their own eligibility criteria for treatment.

The Equality Act 2010 is the main piece of legislation that prohibits discrimination.[9] It applies to the government and a wide range of organizations, including education providers, employers, associations, membership bodies, service providers, and those who provide public functions. There are nine characteristics that are protected by the act, which include gender reassignment, marriage and civil partnership, sex, and sexual orientation.[10]

Any behavior that discriminates against, harasses, or victimizes a person due to one or more of these characteristics is prohibited. Indirect discrimination, which occurs where an individual with a protected characteristic is disadvantaged without a reasonable justification, is also prohibited.[11] Limiting IVF treatment to heterosexual couples would constitute discrimination under the Equality Act,[12] which includes a number of offenses that are committed if the provisions of the act are not complied with.

III. Requirements for Facilities

The act provides a general framework for the creation and use of embryos created through assisted reproductive technology, requiring facilities that provide these services to be licensed by

[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] Equality Act 2010, c. 15, https://perma.cc/PD2X-D8AJ.

[10] Id. § 4.

[11] Id. § 19. See further Douglas Pyper et al., HC Libr., CBP 9061, *Disability Discrimination* (Jan. 4, 2023), https://perma.cc/LL58-BH4P.

[12] Id.

the HFEA and comply with any conditions of the license.[13] 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.[14] The HFEA has also issued a code of practice under section 25 of the act to provide guidance on the activities it licenses.

The HFEA is required to maintain a register of licenses held by clinics, research facilities, and storage centers. The act requires that certain conditions be attached to every license issued by the HFEA, including a requirement that certain activities may only occur on the premises the license relates to under the supervision of a responsible person, that records be maintained in a form that the HFEA specifies in directions, that no money or benefit be provided or received for the supply of gametes, embryos or human admixed embryos unless authorized by HFEA-issued directions, and that information be recorded to facilitate the traceability and safety of gametes and embryos.[15] Licensed facilities that provide treatment are also required to keep information about individuals to whom services are provided, the type of services provided to them, children born as a result of the treatment, and the mixing of egg and sperm and the taking, or otherwise acquiring, of an embryo.[16]

IV. Funding of the procedure

IVF may be self-funded or provided through the National Health Service (NHS), the UK's taxpayer funded health care provider. In 2017, approximately 60% of IVF treatment was privately funded, and the remainder was funded through the NHS.[17] The cost of private treatment is not regulated and varies at clinics across the UK.[18] There is no legal age limit for the use of fertility treatment; it is up to the discretion of each clinic, which, in addition to costs, sets its own eligibility criteria.[19]

The criteria for eligibility for NHS-funded IVF varies somewhat across the countries of the UK and, in England, the local regions. It should be noted that the act provides

> A woman shall not be provided with treatment services . . . unless account has been taken of the welfare of any child who may be born as a result of the treatment (including the need of that child for supportive parenting), and of any other child who may be affected by the birth.[20]

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[13] Human Fertilisation and Embryology Act 1990 § 11. See further Dep't Health, *Triennial Review of the Human Fertilisation and Embryology Authority*, (Apr. 2017), ¶ 1.14, https://perma.cc/Z6XT-K94Q.

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

[15] Human Fertilisation and Embryology Act 1990 § 12. `

[16] Id. § 13.

[17] Dep't Health, *Triennial Review of the Human Fertilisation and Embryology Authority*, supra note 13, ¶ 5.6.

[18] *Costs & Funding*, Hum. Fertilisation & Embryology Auth., https://perma.cc/X9X8-LB2F.

[19] *Finding the Best Fertility Clinic for You*, Hum. Fertilisation & Embryology Auth., https://perma.cc/VS85-NCB7.

[20] Human Fertilisation and Embryology Act 1990 § 13(5).

A. England

In England, Integrated Care Boards (ICBs) are responsible for determining who receives NHS-funded IVF treatment. ICBs are local, and there can be variances, not only in the eligibility criteria, but also in the number of attempts at IVF a person may be allowed.[21]

To help provide some consistency, the National Institute for Clinical Excellence (NICE) has issued guidelines for access to IVF that ICBs typically follow and, in many instances, add to.[22] The guidelines recommend that three cycles of IVF should be offered to women under 40 years of age who have not conceived after two years of regular unprotected intercourse or 12 cycles of artificial insemination, with six or more of these being intrauterine insemination. If the woman turns 40 during treatment, any cycle in process should be continued, and no more cycles should be offered.[23] Any previous IVF treatment, whether undertaken privately or through the NHS, counts toward the total number of three cycles that should be offered through the NHS.[24] The guidelines recommend that women aged 40 to 42 who meet the criteria above and who have not previously had IVF, who show no evidence of low ovarian reserve and who have undergone a discussion about the implications of IVF and pregnancy at this age, be offered one cycle of IVF.[25] In all cases, if there is no chance of pregnancy without IVF, the woman should be directly referred for IVF treatment.[26] The outcome of previous IVF treatment should be taken into account when assessing the effectiveness and safety of any further IVF treatment.[27]

As noted above, ICBs in England may have additional criteria, or more stringent criteria, than the NICE guidelines, such as not having received any NHS-funded or self-funded IVF treatment, having children from current or previous relationships, being in a certain weight range, both partners being nonsmokers, and being under 35 years of age.[28] Many ICB policies require same sex female couples to have undergone at least six, and many require 12, cycles of self-funded artificial insemination.[29] The ICBs' policies on cryopreservation also vary, with some not covering it at all, and others covering it for between one to three years.[30]

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[21] *Availability, IVF*, NHS, https://perma.cc/N69C-3MDK.

[22] Id.

[23] Nat'l Inst. for Health & Care Excellence, *Fertility Problems: Assessment and Treatment* (last updated Sept. 6, 2017), ¶ 1.11.1.3, https://perma.cc/DU5W-YB8P.

[24] Id. ¶ 1.11.1.6.

[25] Id. ¶ 1.11.1.4.

[26] Id. ¶ 1.11.1.5.

[27] Id. ¶ 1.11.1.7.

[28] *Guidance: NHS-Funded in Vitro Fertilisation (IVF) in England*, Dep't Health & Social Care, https://perma.cc/N82H-3X9N.

[29] Id.

[30] Id.

B. Wales

Wales offers two cycles of NHS-funded fertility treatment where the following criteria, set by the Welsh Health Specialised Services Committee, are met:

- heterosexual couples must have failed to conceive after two years of regular, unprotected intercourse, or have a fertility problem,
- same sex couples or single women and men must have had "no live birth following insemination at or just prior to the known time of ovulation on at least six non-stimulated cycles or a fertility problem demonstrated at investigation,"[31]
- female partners must be aged 20 to under 40 years of age, and male partners must be 55 years of age or younger,
- neither partner must have any living children, either biological or adopted,
- a female partner must have a body mass index (BMI) between 19-30; if the BMI is under 19, treatment may be approved at the discretion of the clinician, provided the patient is ovulating normally,
- neither partner can have been sterilized, even if this has been reversed,
- both partners must be nonsmokers at the time of treatment,
- neither partner must have undergone three or more IVF treatments, either self-funded or through the NHS,
- patients must conform to the HFEA Code of Practice, which includes being assessed and meeting the requirements in the "Welfare of the child" appendix.[32]

Women aged between 40-42 years old who meet the access criteria above are entitled to one cycle of IVF if they have never previously had IVF treatment, there is no evidence of low ovarian reserve, and there has been a discussion about the implications of both IVF and pregnancy at their age.[33]

C. Scotland

Three cycles of IVF funded by NHS Scotland may be offered where the following criteria are met:

- heterosexual couples must have had unexplained infertility for two years, or infertility with a cause for any duration,
- same sex couples must have had unexplained infertility following six to eight cycles of NHS-funded donor insemination, or infertility with a cause for any duration,

[31] Welsh Health Specialised Services Committee (WHSSC), *Specialised Services Commissioning Policy: CP38 Specialist Fertility Services*, (Jan. 2017, ver. 9.2), ¶ 3.2.7, https://perma.cc/99YY-T3S4.

[32] Id. ¶ 3.2.

[33] Id. ¶ 3.2.3.

- there must be a reasonable expectation of a live birth,
- both partners must be free for a minimum of one year prior to referral from methadone, be nonsmoking and nicotine free for at least three months before and during treatment, and abstain from illegal and abusive substances,
- both partners must not drink alcohol before and during treatment,
- a female partner must have a BMI above 18.5 and below 30,
- neither partner must have undergone voluntary sterilization, or had this reversed, even if the reversal was self-funded,
- neither partner must have a living biological child,
- neither partner must have received the maximum number of IVF treatment cycles funded by NHS Scotland, regardless of where in the UK they received treatment,
- fresh treatment cycles must be completed before a female partner's 40th birthday, any frozen embryo transfers must occur prior to the female partner's 41st birthday, and
- couples must be cohabiting in a stable relationship for a minimum of two years at the same address.[34]

NHS Scotland does fund IVF treatment if the above criteria are met, even if the individual seeking treatment have previously self-funded IVF treatment provided the clinician believes the individual clinical circumstances warrants further treatment.[35]

Women aged 40-42 may be eligible for one cycle of NHS Scotland funded IVF treatment if they meet the above criteria if neither partner has previously had any IVF treatment, either NHS or self-funded, there is no evidence of poor ovarian reserve, the clinician believes that treatment is in the patients' interests and there has been a discussion of the implications of both IVF and pregnancy at this age. If these criteria are met, the couples must have been screened for treatment by the time of the female partners 42nd birthday and all treatment, including the transfer of frozen embryos, must be completed before the day before the female partner's 43rd birthday.[36]

D. Northern Ireland

Northern Ireland provides one cycle of NHS-funded IVF treatment if the following criteria are met:

- there must be a demonstrated fertility problem, or a woman has not conceived after two years of regular unprotected intercourse or eight cycles of artificial insemination, with at least four of these being by intrauterine insemination,[37]

[34] *Access Criteria NHS IVF Treatment Scotland*, fertility.scot, https://perma.cc/R8RE-T4G9.

[35] Id.

[36] Id.

[37] *Eligibility for HSC Funded IVF and Related Treatments Effective from 1st June 2019*, Belfast Health & Social Care Trust (last updated Jan. 13, 2020), https://perma.cc/VER2-9D5M.

- the woman must be either under 40 years of age or between 40-42 years of age and have never previously had IVF treatment, show no evidence of low ovarian reserve, and have undergone a discussion of the implications of IVF and pregnancy in her age group,
- the woman must have a BMI of between 19-30,
- neither partner must have had three or more prior IVF cycles, whether through the NHS or self-funded,
- neither partner must have undergone voluntary sterilization, or had this reversed, unless this occurred as a result of another medical problem,
- both partners must have been assessed and met the HFEA requirements on the welfare of the child,
- smokers should be advised to abstain from smoking for three months prior to IVF,
- women "should be informed that drinking no more than 1 - 2 units of alcohol once or twice per week and avoiding intoxication reduces the risk of harming a developing foetus. Men should be advised that excessive alcohol intake is detrimental to semen quality."[38]

V. 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.[39] 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. [40] 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.[41]

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.

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[38] Id.

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

[40] 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.

[41] 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),[42] and preimplantation genetic testing for aneuploidy (PGT-A)[43] 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."[44] 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.[45]

Currently, PGT-M has been licensed by the HFEA for over 600 genetic conditions,[46] and its use is limited to solely screen out disorders, thus not permitting people to create "designer babies."[47] 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.[48]

C. Embryo Selection

The act does not permit sex selection for social purposes.[49] 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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[42] *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.

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

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

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

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

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

[48] *Approved PGT-M and PTT Conditions*, supra note 46.

[49] 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.[50]

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.[51]

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,[52] which includes a number of conditions.[53] 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.[54] Embryos may be stored for up to 10 years for research or training purposes.[55]

F. Embryo Donation and Registration

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.[56] 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.[57] Embryo donors are also required to go through the same health checks as sperm or egg donors.[58] Consent must be provided by both parties, and counseling is offered. In cases where the embryo was created using donor sperm or

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

[51] Hum. Fertilisation & Embryology Auth., *Code of Practice*, supra note 49, ch. 17.

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

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

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

[55] Id. § 14(3)(c).

[56] Id. sched. 3.

[57] Hum. Fertilisation & Embryology Auth., *Code of Practice*, supra note 49, ch. 17.

[58] *Donating Your Embryos*, Hum. Fertilisation & 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.

As noted above, license conditions provide that "[n]o money or other benefit must be given or received in respect to any supply of gametes, embryos or human admixed embryos unless authorised by Directions."[59] 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."[60] Providing money or benefit to a person to donate gametes, embryos or human admixed embryos that is not authorized by the HFEA directions is a criminal offense, punishable with a fine, imprisonment for up to six months upon summary conviction, or both.[61] There is limited compensation available to individuals who wish to donate their embryos to be used in fertility treatment. Up to 45 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.[62]

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.[63] The HFEA is required by law to keep a register of:

> (a) the provision for any identifiable individual of treatment services other than basic partner treatment services,
> (b) the procurement or distribution of any sperm, other than sperm which is partner-donated sperm and has not been stored, in the course of providing non-medical fertility services for any identifiable individual,
> (c) the keeping of the gametes of any identifiable individual or of an embryo taken from any identifiable woman,
> (d) the use of the gametes of any identifiable individual other than their use for the purpose of basic partner treatment services, or
> (e) the use of an embryo taken from any identifiable woman, or if it shows that any identifiable individual is a relevant individual.[64]

[59] Hum. Fertilisation & Embryology Auth., *Standard Licence Conditions, Treatment & Storage Licences* (GB), supra note 53, at T69. For Northern Ireland, see Hum. Fertilisation & Embryology Auth., *Standard Licence Conditions, Treatment & Storage Licences* (NI), (July 1, 2022) T69, https://perma.cc/278W-KVVQ.

[60] Hum. Fertilisation & Embryology Auth., *Directions Given Under the Human Fertilisation and Embryology Act 1990 (as Amended) Gamete and Embryo Donation* (Oct. 29, 2015), § 3, https://perma.cc/TQS5-AJY3.

[61] Human Fertilisation and Embryology Act 1990 §§ 12(1)(e), 41.

[62] Hum. Fertilisation & Embryology Auth., *Directions Given Under the Human Fertilisation and Embryology Act 1990 (as Amended) Gamete and Embryo Donation,* supra note 60, § 7, as amended by *Chair's Letter*, CH(24)02, (July 30, 2024), https://perma.cc/J7N4-FD3H.

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

[64] Id. § 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.[65] 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.[66]

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")[67] appears, whichever occurs first.[68] 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.[69]

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:

(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.[70]

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.[71]

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

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

[66] Id. § 17; Hum. Fertilisation & Embryology Auth., *Code of Practice*, supra note 49, § 17.9.

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

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

[69] 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.

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

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

to a research project.[72] 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.[73]

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

[73] Id.

Regulation of IVF and Related Issues

Table of Primary Sources

Jurisdiction	Type of Law	Citation	URL
France	Code	Code Penal (Penal Code)	https://perma.cc/DXU6-3TK5
		Code de la santé publique (Public Health Code	https://perma.cc/H5GF-CK69
	Statute	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, J. O., Aug. 3, 2021	https://perma.cc/568Y-ECCG
	Ministerial Order	Arrêté du 26 février 2007 fixant la composition du dossier prévu aux articles R. 2142-3 et R. 6122-32 du code de la santé publique à produire à l'appui d'une demande d'autorisation ou de renouvellement d'autorisation pour pratiquer des activités d'assistance médicale à la procreation, J. O. Mar. 24, 2007	https://perma.cc/5LKH-GPJ9
		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	https://perma.cc/E6CU-QXZA

Jurisdiction	Type of Law	Citation	URL
Germany	Statute	Arzneimittelgesetz [AMG], Dec. 12, 2005, BGBl. I at 3394, as amended	https://perma.cc/9JGQ-3RF8 (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
		Präimplantationsdiagnostikverordnung [PIDV], Feb. 21, 2013, BGBl. I at 323, as amended	https://perma.cc/FRN7-9QT3
		Samenspenderregistergesetz [SaRegG], July 17, 2017, BGBl. I at 2513, as amended	https://perma.cc/SJ9S-HTQG
		Sozialgesetzbuch Fünftes Buch [SGB V], Dec. 20, 1988, BGBl. I at 2477, 2482, as amended	https://perma.cc/37VK-6WXP
		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/2XF5-VSAC
	Ordinance	Arzneimittel- und Wirkstoffherstellungsverordnung [AMWHV], Nov. 3, 2006, BGBl. I at 2523, as amended	https://perma.cc/K9GP-TAE5
		TPG-Gewebeverordnung [TPG-GewV], Mar. 26, 2008, BGBl. I at 512, as amended	https://perma.cc/XN6A-PKWP
Israel	Statute	National Health Insurance Law, 5754-1994, as amended by the National Health Insurance Order (Modification of the Second and Third Additions to the Law), 5783-2023, KT 10762, p. 2422	https://perma.cc/WWA2-G5F9; https://perma.cc/RX23-TJYA (in Hebrew)
		Ovum Donation Law, 5770-2010, SH 5771 No. 2264 p. 86, as amended	https://perma.cc/N8BQ-CTMA (in Hebrew)

Jurisdiction	Type of Law	Citation	URL
	Regulations	National Health Regulations (IVF), 5747-1987, KT 5747 No. 5035 p. 978, as amended	https://perma.cc/ER7G-TFC5 (in Hebrew)
	Guidance	Guidelines for In Vitro Fertilization (IVF) Units on the Treatment of Fertilized Ova, MOH Circular 12, 2024 (Dec. 2, 2024)	https://perma.cc/TN4C-22WM (in Hebrew)
		Ovum Freezing and Preservation, MOH Circular 13, 2024 (Dec. 2, 2024) https://perma.cc/38P2-AJVV	https://perma.cc/38P2-AJVV (in Hebrew)
	Report	State Comptroller Off. Special Report, In Vitro Fertilization in Israel - Aspects of Regulation and Oversight (Nov. 2024)	https://perma.cc/EB2Y-UXBY (in Hebrew)
Italy	Statute	Legge 19 febbraio 2004, n. 40, Norme in materia di Procreazione Medicalmente Assistita	https://perma.cc/VQ72-6P9K
	Court Decision	Sentenza del 8 maggio 2009, n. 151	https://perma.cc/T2GV-RVTB
		Sentenza del 22 ottobre 2015, n. 229	https://perma.cc/Y7N6-PGSP
		Sentenza del 13 aprile 2016, n. 84	https://perma.cc/D4K8-TC6Q
Poland	Statute	Act on Amendments to the Act on Health Care Services Financed from Public Funds of Nov. 29, 2023	https://perma.cc/NSP6-H3LU (in Polish)
		Act of June 25, 2015, on Infertility Treatment, effective Nov. 1, 2015, last amended in 2020	https://perma.cc/6SKW-8SFZ
		Medical Profession Act of Dec. 5, 1996, art. 30	https://perma.cc/WPY7-R422 (in Polish)
	Regulations	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 Medically Assisted Procreation Procedures	https://perma.cc/7KMA-2VEJ (in Polish)
Portugal	Statute	Lei No. 32/2006, de 26 de julho	https://perma.cc/3DJA-P7ZV
		Lei No. 17/2016, de 20 de junho	https://perma.cc/5WL9-G2HH
		Lei No. 90/2021, de 16 de dezembro	https://perma.cc/ZC9W-Z7FU
	Regulatory Decree	Decreto Regulamentar No. 6/2016, de 29 de dezembro	https://perma.cc/KR77-ZGRC

Jurisdiction	Type of Law	Citation	URL
Sweden	Statute	Lag om genetisk integritet m.m. [Act on Genetic Integrity] (SFS 2006:351)	https://perma.cc/A3FS-2HBJ
		Biobankslag [Bio Bank Act] (SFS 2023:38)	https://perma.cc/9MMG-6HGF
		Lag (2005:39) amending Lag (1991:115) om åtgärder i forsknings- eller behandlingssyfte med ägg från människa	https://perma.cc/42GC-ULYJ
		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
		Lag om etikprövning av forskning som avser människor (SFS 2003:460	https://perma.cc/3W4H-45WW
		Lag om kvalitets- ouch 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
	Regulations	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	Equality Act 2010, c. 15	https://perma.cc/PD2X-D8AJ
		Human Fertilisation and Embryology Act 1990, c. 37	https://perma.cc/CF2N-TLX8
	Regulations	Directions, Hum. Fertilisation & Embryology Auth.	https://perma.cc/V53V-BYJ5
		Human Fertilisation & Embryology Auth., Directions Given Under the Human Fertilisation and Embryology Act 1990 (as Amended): Gamete and Embryo Donation (Oct. 29, 2015)	https://perma.cc/TQS5-AJY3
		Human 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

Jurisdiction	Type of Law	Citation	URL
		Hum. Fertilisation & Embryology Auth., Standard Licence Conditions — GB – 1 July 2022 onwards, Treatment and Storage Licences (July 1, 2022)	https://perma.cc/P29A-THU6
		Hum. Fertilisation & Embryology Auth., Standard Licence Conditions, Treatment & Storage Licences (NI), (July 1, 2022)	https://perma.cc/278W-KVVQ
		Human Fertilisation and Embryology Authority (Disclosure of Donor Information) Regulations 2004, SI 2004/1511	https://perma.cc/JX7R-YRNM
		Standard Licence Conditions: Research Licences, Hum. Fertilisation & Embryology Auth. (July 21, 2022)	https://perma.cc/98V5-L2B4
	Guidance	Access Criteria NHS IVF Treatment Scotland	https://perma.cc/R8RE-T4G9
		Eligibility for HSC Funded IVF and Related Treatments Effective from 1st June 2019, Belfast Health & Social Care Trust (last updated Jan. 13, 2020)	https://perma.cc/VER2-9D5M
		Guidance: NHS-Funded in Vitro Fertilisation (IVF) in England, Dep't Health & Social Care	https://perma.cc/N82H-3X9N
		Hum. Fertilisation & Embryology Auth., Code of Practice (rev. Oct. 2023)	https://perma.cc/969R-TVUD
		Nat'l Inst. for Health & Care Excellence, Fertility Problems: Assessment and Treatment (last updated Sept. 6, 2017)	https://perma.cc/DU5W-YB8P
		Welsh Health Specialised Services Committee (WHSSC), Specialised Services Commissioning Policy: CP38 Specialist Fertility Services, (Jan. 2017, ver. 9.2)	https://perma.cc/99YY-T3S4