ISSN: 2358-1824

#### **Article**

# Analysis of embryo disposal in Brazil: bioethical, scientific and legal aspects

Análise do descarte de embriões no Brasil: aspectos bioéticos, científicos e legais

Análisis del descarte de embriones en Brasil: aspectos bioéticos, científicos y legalês

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Submitted on: 12/29/24 Revision on: 04/28/25

Approved on: 05/15/25

#### **Abstract**

**Objective:** to evaluate the findings regarding the human embryo produced in the laboratory, understand issues regarding its disposal and analyze the policies and regulations related to the subject in Brazil. **Methodology:** integrative review of the literature questioning sources related to marital infertility, assisted reproduction techniques, embryo disposal and current legislation in Brazil. The literature search was carried out in the PubMed, Lilacs, SciELO, Cochrane Library and VHL databases,

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using key terms "infertility", "assisted human reproduction", "embryo disposal" and "reproduction legislation". **Results:** being a recent practice in Medicine, there are constant discoveries regarding biological aspects regarding, for example, the development of embryos in the laboratory and the effects of cryopreservation on their viability. As a result, there is a constant update of the regulations on the subject. **Conclusion:** improvements in legislation should aim to strike a balance between respect for autonomy and individuals' reproductive choices, while addressing ethical issues and ensuring the safety and quality of reproductive services. A better understanding of the topic and attention makes it possible for assisted reproduction services to be accessible, safe and in compliance with ethics and law

**Keywords:** Infertility; Assisted Reproduction Techniques; Embryo Destination; Blastocyst.

#### Resumo

Objetivo: avaliar as descobertas referentes ao embrião humano produzido em laboratório, entender questões quanto ao seu descarte e analisar as políticas e regulamentações relacionadas ao assunto no Brasil. Metodologia: revisão integrativa da literatura questionadora de fontes relacionadas à infertilidade conjugal, técnicas de reprodução assistida, descarte de embriões e legislação vigente no Brasil. A busca por literatura foi realizada nas bases de dados PubMed, Lilacs, SciELO, Cochrane Library e BVS, utilizando termos-chave "infertilidade", "reprodução humana assistida", "descarte de embriões" e "legislação de reprodução". Resultados: sendo uma prática recente na Medicina, são constantes as descobertas a respeito dos aspectos biológicos referentes, por exemplo, ao desenvolvimento dos embriões em laboratório e efeitos da criopreservação na sua viabilidade. Com isso, observa-se constante atualização das regulamentações referentes ao assunto. Conclusão: as melhorias na legislação devem ter como objetivo encontrar um equilíbrio entre o respeito pela autonomia e as escolhas reprodutivas dos indivíduos, ao mesmo tempo que abordem questões éticas e garantam a segurança e a qualidade dos serviços reprodutivos. Uma melhor compreensão do tema e atenção possibilita que os serviços de reprodução assistida sejam acessíveis, seguros e em conformidade com a ética e lei.

Palavras-chave: Infertilidade; Técnicas de Reprodução Assistida; Destinação do Embrião; Blastocisto.

#### Resumen

Objetivo: evaluar los descubrimientos sobre los embriones humanos producidos en el laboratorio, comprender los problemas relacionados con su eliminación y analizar las políticas y regulaciones relacionadas con el tema en Brasil. Metodología: revisión integradora de la literatura cuestionando las fuentes relacionadas con la infertilidad conyugal, las técnicas de reproducción asistida, la disposición de embriones y la legislación vigente en Brasil. La búsqueda bibliográfica se realizó en las bases de datos PubMed, Lilacs, SciELO, Cochrane Library y BVS, utilizando los términos clave "infertility", "reproducción humana asistida", "eliminación de embriones" y "legislación sobre reproducción". Resultados: al ser una práctica reciente en Medicina, existen constantes descubrimientos respecto a aspectos biológicos referentes, por ejemplo, al desarrollo de embriones en el laboratorio y los efectos de la criopreservación en su viabilidad. Como resultado, hay una actualización constante de la normativa sobre el tema. Conclusión: las mejoras en la legislación deben tener como objetivo lograr un equilibrio entre el respeto de la autonomía y las opciones reproductivas de las personas, abordando al mismo tiempo las cuestiones éticas y garantizando la seguridad y la calidad de los servicios reproductivos. Una mejor comprensión del tema y una mayor atención hacen posible que los servicios de reproducción asistida sean accesibles, seguros y que cumplan con la ética y la ley.

Palabras clave: Infertilidad; técnicas de reproducción asistida; Destino del embrión; Blastocisto.

# Introdução

Infertility is classified as a pathological condition that can affect both the female and male reproductive systems and is defined by the World Health Organization (WHO) as the inability to achieve pregnancy after 12 consecutive months of regular, unprotected sexual intercourse without the use of contraceptive methods. According to WHO estimates, around 186 million people around the world are affected by this condition, which qualifies it not just as an individual illness, but as a public health problem on a global scale<sup>(1,2)</sup>.

Based on data collected between 1990 and 2021, the global prevalence of infertility was estimated at 17.5% of the adult population in 2022 (95%CI: 15.0-20.3), corresponding to approximately one in six people who have experienced reproductive difficulties at some point in their lives<sup>(2)</sup>. The main female etiologies include ovulatory dysfunctions, tubal alterations, premature ovarian insufficiency and uterine anomalies, while in males, factors related to seminal quality and genetic alterations stand out<sup>(2)</sup>. It should be noted that the male factor is present in approximately 50% of cases of marital infertility, with azoospermia - total absence of sperm in the ejaculate sample after centrifugation - observed in 10 to 15% of these cases<sup>(3)</sup>.

The history of assisted reproduction dates back to unofficial reports involving early attempts at artificial insemination, such as those supposedly promoted by Henry IV of Castile (1425-1474), an episode that illustrates the beginnings of human intervention in fertility. However, it was only in the 1770s, in London, that the first documented procedure of artificial insemination in humans was recorded, carried out by John Hunter<sup>(4)</sup>. The decisive milestone, however, came in 1978, with the birth in Bristol (UK) of Louise Brown - the first baby conceived by *in vitro* fertilization (IVF), the result of Edwards and Steptoe's research, which revolutionized the field of assisted human reproduction (AHR) and began its scientific and bioethical consolidation<sup>(5,6)</sup>.

The available treatments known as 'low complexity' involve processes in which fertilization occurs in the woman's reproductive system, such as scheduled intercourse and intrauterine insemination<sup>(7)</sup>. Assisted reproductive technologies, as defined by the American Center for Disease Control (CDC), are any fertility-related treatments in which eggs or embryos are manipulated in a laboratory, including highly complex treatments in which fertilization occurs outside the body, such as IVF and Intracytoplasmic Sperm Injection (ICSI)<sup>(8)</sup>.

Since 1978, IVF and ICSI techniques have undergone significant improvement and global dissemination. ICSI, introduced in 1992, has become essential in cases of severe male infertility, allowing fertilization through the microinjection of a single sperm directly into the cytoplasm of the egg, with the aim of generating embryos suitable for uterine implantation<sup>(3,7)</sup>.

The steps involved in IVF and ICSI procedures include controlled ovarian stimulation with hormonal drugs, oocyte collection by transvaginal follicular puncture guided by ultrasound, laboratory insemination, embryo culture in incubators that simulate the intrauterine environment, and subsequent embryo transfer to the patient's uterus<sup>(9)</sup>. The morphological assessment of the embryos - considered one of the most important technical criteria - guides the medical decision as to which embryos will be transferred or cryopreserved. This morphological analysis, although relevant, is not enough to ensure genetic viability, which is why embryo biopsy and pre-implantation genetic diagnosis have been incorporated as complementary tools in embryo selection<sup>(3,10)</sup>.

According to the protocols currently in force in Brazil, surplus viable embryos - not immediately transferred to the mother's uterus - can be cryopreserved, donated to third parties or discarded, with

the express prior and formal authorization of the parents<sup>(11)</sup>. However, embryo disposal remains one of the most controversial issues in bioethics and biolaw, especially given the lack of consensus on the legal and moral status of the human embryo<sup>(12)</sup>.

From the perspective of deontological bioethics, which is based on the principles of respect for human dignity and the non-instrumentalization of life, the disposal of embryos raises significant objections. This line of thought - influenced by the Kantian categorical imperative - attributes intrinsic value to human life from conception, which implies ethical restrictions on the use, research or disposal of embryos, even if they are viable and unused<sup>(12,13)</sup>. In contrast, utilitarian and consequentialist currents consider the social and scientific benefits arising from the use of surplus embryos for research or treatment purposes, which underpins more flexible positions regarding their destination<sup>(13,14,15)</sup>.

In the Brazilian legal system, the Biosafety Law (Law No. 11.105/2005) authorizes the use of embryos that have been frozen for more than three years for the purposes of scientific research, provided that the parents authorize it<sup>(16)</sup>. However, recent legislative and scientific debates have questioned this permissiveness, such as Senate Bill No. 4/2025 and the guidelines of the Federal Council of Medicine (CFM), which signal a possible tightening of regulations, moving closer to more conservative positions inspired by jusnaturalism<sup>(17,18)</sup>.

The aforementioned stance leads to regulation that is closer to conservative sectors who, based on justialist perspectives, argue that human dignity is inherent from conception, which reinforces ethical objections to embryonic disposal<sup>(19)</sup>. This controversy highlights the clash between the perspective that recognizes the rights of the embryo from fertilization and the view that conditions them on the development of cognitive and sensitive capacities. Thus, the deontological debate remains open, requiring a reconciliation between scientific advances, ethical principles and regulatory frameworks.

By definition, bioethics is the science "which aims to indicate the limits and purposes of human intervention on life, to identify rationally proposable reference values, to denounce the risks of possible applications" (20) Deontological bioethics, by emphasizing principles such as dignity and the non-instrumentalization of human life, often opposes utilitarian approaches, which justify the use of embryos on the basis of collective benefits<sup>(13)</sup>. Therefore, there are countless bioethical issues surrounding AHR, such as reproductive cloning, regulation of the commercialization and/or donation of gametes, *post-mortem* insemination<sup>(14)</sup> the right to knowledge of biological origin<sup>(15)</sup> among others. Each of these has numerous aspects that deserve to be understood and discussed.

This article aims to critically analyze the bioethical, scientific and normative foundations related to the disposal of human embryos in Brazil, with special attention to the dilemmas involving viable embryos, including those considered to be of inferior morphology, but with the potential to generate healthy pregnancies. The aim is also to identify legislative and regulatory proposals that promote reconciliation between advances in assisted reproduction techniques, the principles of human dignity and the effective legal protection of developing life.

# Methodology

In this study, the researchers carried out an integrative review of the literature<sup>(21)</sup> on the disposal of embryos produced in laboratories. The research was carried out in six stages: 1) formulation of the guiding question; 2) definition of the search descriptors; 3) definition of the inclusion and exclusion

criteria; 4) literature search; 5) critical analysis of the selected studies; 6) presentation and discussion of the results obtained.

The review was conducted based on the question "in view of the discoveries about embryos produced in laboratories and the methods used for this, how should we proceed with surplus embryos from assisted human fertilization treatments?".

The literature search took place between September and December 2024, in the following databases: PubMed; Latin American and Caribbean Health Sciences Literature (Lilacs); Scientific Eletronic Library Online (SciELO); Cochrane Database of Systematic Reviews (CDSR); Biblioteca Virtual em Saúde (BVS). The descriptors were selected from the Health Sciences Descriptors (DeCS) and Medical Subject Headings (MeSH): "infertility", "assisted reproduction techniques", "embryo loss" and "legislation", which were combined using the Boolean operator "AND". The term "embryo disposal" was also used in the search to specify the situation being investigated.

The inclusion criteria adopted were: 1) articles related to the disposal of human embryos and their regulation in Brazil; 2) published between 2000 and 2024; 3) available in full; 4) published in scientific journals indexed in the selected databases; 5) quantitative, qualitative and reflective studies; 6) publications in Portuguese or English; 7) systematic reviews. Duplicate articles or those that did not have the desired scope were excluded.

The articles were selected in two stages. Initially, two researchers independently read the titles and abstracts found in the selected databases, based on the previously defined inclusion and exclusion criteria. The articles that met the criteria were then analyzed in full.

A total of 854 articles were found, distributed as follows: PubMed: 813 articles; Lilacs/BVS: 32 articles; SciELO: 1 article; Cochrane: 8 articles. Duplicate articles between the databases were then excluded, resulting in 12 excluded articles, mainly in the Lilacs and Cochrane searches. Due to the unavailability of the full text, 210 articles were excluded, followed by 37 articles by language (not Portuguese or English).

After reading the titles, 464 articles were excluded because they did not fit the desired scope of the research. After reading the abstracts, a further 118 articles were excluded because they did not provide data relevant to the study's objectives. This left 13 articles to read in full.

A consensus meeting was then held between the researchers to decide on the final inclusion of each article. In cases of disagreement, decisions were made by consensus, taking into account thematic pertinence, scientific relevance and suitability for the purpose of the review. This strategy sought to ensure greater methodological rigor and reduce selection bias. At this stage, 3 articles were excluded, so the review resulted in 10 articles to be analyzed.

Legislation, bills, government documents, professional council resolutions, court decisions and books on the subject were used to enrich the discussion. During the construction of the text, *Endote* was used as a reference management tool.

As this was a bibliographical study, it was not necessary to submit it to the Research Ethics Committee.

# Results and discussion

Ten articles were selected, as shown in Box 1, from 2005 to 2024

Box 1. Articles selected for review

Title	Author	Year of publication	Publication vehicle
Integrative review: causes of infertility and fertilization treatments <sup>(7)</sup>	Roller et al	2023	Brazilian Journal of Health Review
The right to knowledge of biological origin in assisted human reproduction: bioethical and legal reflections <sup>(15)</sup>	Vasconcelos et al	2014	Revista Bioética
Pregnancy of anencephalic fetuses and stem cell research: two themes about life and dignity in the constitution <sup>(24)</sup>	Barroso	2005	Revista de Direito Administrativo
The starting point of human life: ethical and legal perspectives in the context of biotechnological advances. (25)	Barreto and Lauxen	2017	Cadernos de Saúde Pública
Surplus human embryos or "created" from stem cells in Portugal and Brazil: the social relevance of legislating <sup>(26)</sup>	Barbas <i>et al</i>	2024	Revista Internacional Consinter de Direito
Comments on the case of Artavia Murillo et al. v. Costa Rica ("In vitro fertilization") and its possible impact on the Brazilian legal system <sup>(30)</sup>	Espinoza and Christopoulos	2018	Pensar - Revista de Ciências Jurídicas
The safety of long-term cryopreservation on slow-frozen early cleavage human embryos <sup>(33)</sup>	Liu et al	2014	J Assist Reprod Genet
The zinc spark is an inorganic signature of human egg activation <sup>(34)</sup>	Duncan <i>et al</i>	2016	Sci Rep
Guidance regarding gamete and embryo donation <sup>(35)</sup>	ASRM	2021	Fertil Steril
A reality outside the law: an ethical-legal analysis of the 30 years of deontological regulation of assisted reproduction technologies in Brazil <sup>(36)</sup>	Silva Netto	2023	BioLaw Journal - Rivista di BioDiritto

Source: own production

Based on the doctrinal, normative and empirical analysis of embryo disposal in Brazil, we have seen the persistence of a fragmented regulatory scenario, permeated by scientific, philosophical and legal controversies. On a legal level, there is no normative consensus that precisely defines the starting point for legal personality in Brazil. Article 2 of the Civil Code establishes that civil personality begins with live birth, although the rights of the unborn child are protected from the moment of conception. However, this provision does not expressly extend its application to embryos produced *in vitro*, nor does it deal with their destination in cases of cryopreservation and subsequent disposal<sup>(22)</sup>.

From a biological point of view, authors such as Moore and Persaud recognize the beginning of human development at the moment of fertilization, when the zygote (the cell resulting from the union of the male and female gametes, at a stage prior to cell division) becomes an entity with its own unrepeatable genomic identity, endowed with the potential to develop into a complete human being, provided it is placed in a suitable environment and assisted by favourable conditions<sup>(23)</sup>.

However, there is a great deal of controversy associated with the first weeks of human life, their ontological nature and ethical and legal status. According to Luís Roberto Barroso: "The recognition

of a morally significant dividing line between fertilized egg and human person is one of the great questions of contemporary ethical debate"<sup>(24)</sup>.

With regard to ethical and legal issues concerning the starting point of human life, it can be seen that there are many different scientific criteria that point to different stages of human development as the beginning of life. There are also countless religious, cultural, philosophical and legal denominations that use different foundations and differing positions on the subject. Thus, there is no consensus on an exact answer regarding the starting point of human life<sup>(25)</sup>.

There are two main positions taken to define the significance of the embryo: one attributes the status of person to all human life from the moment of fertilization; the other establishes the appearance of the primitive streak, which occurs around the 14th day, when implantation in the uterine cavity ends, a phenomenon known as nidation, as the milestone for attributing the status of person to implantation<sup>(7)</sup>.

The group that values the formation of the primitive streak on the 14th day calls the zygote before this period a "pre-embryo", considering it to be in the presence of forms of human life, but not really a human being. Only after this period is the embryo, in this perspective, an individuality that will normally develop into an independent human being and, therefore, an ontological entity that must be respected and protected as a person<sup>(7)</sup>.

In the European Union it is generally accepted that the embryo should not be subjected to any form of experimentation after the appearance of the primitive streak. However, there is no overall European guideline on the procedures to be adopted in relation to 'human life' during the first two weeks. By considering the embryo as a person, human life should be respected and preserved from the 14th day after fertilization, after the appearance of the germ line<sup>(7)</sup>.

Considering the embryo as a human being only after nidation makes it possible for contraceptive methods that avoid this process, such as the morning-after pill and the Intrauterine Device (IUD), not to be considered abortifacients.

With regard to those who argue that, from an ethical-legal point of view, the embryo from the moment it is fertilized deserves the same respect and protection as the adult person, there are mainly two ways of explaining this. The first privileges the ontological belonging to the human species, that is, the genetic load would be enough to give it its own existence and intrinsic autonomy, which would make it a person who deserves due respect and legal protection. The second way favors the potential of human life from its very beginning, i.e. the ontological entity that arises from the fusion of the female and male gametes would have enough potential to become a person to be treated as such. The zygote is therefore seen as a potential person<sup>(7)</sup>.

Biological truth is a dynamic concept, shaped by the discoveries and innovations of science. The truths we accept today may be refined or even replaced as science advances<sup>(26)</sup>. While there is still no consensus on when the zygote, the product of fertilization, should be considered a human being with rights to be defended, in laboratories in Brazil and around the world, embryos continue to be produced at an exponential rate. According to data from the National Embryo Production System (SisEmbrio), in Brazil, while 32,181 embryos were frozen in 2012, in 2023 the number was already 115,359 embryos. Between 2020 and 2022, 110,075 cycles were carried out, 45,242 transferred, 284,232 frozen and 146,032 embryos discarded, noting that their viability was not researched before they were discarded<sup>(27)</sup>.

In Brazil, Article 2° of the Brazilian Civil Code states that "a person's civil personality begins with the birth of life, but the law protects the rights of the unborn from conception". From reading this article, we can see that the starting point for a natural person's legal existence is birth with life, the moment when legal capacity begins. However, Brazilian legislation does not specifically define the legal status of the human embryo and how it should be protected<sup>(22)</sup>.

In 2005, Biosafety Law Nº·11.105 was created in Brazil. Article 5 states that "For research and therapy purposes, the use of embryonic stem cells obtained from human embryos produced by *in vitro* fertilization and not used in the respective procedure is permitted, provided that the following conditions are met: I - they are non-viable embryos; or II - they are embryos that have been frozen for three years or more on the date of publication of this Law, or that, having already been frozen on the date of publication of this Law, after completing three years, counted from the date of freezing"<sup>(16)</sup>.

However, França draws attention to the need for a correct policy to protect cryopreserved preembryos, preventing them from being targeted by speculators in programs of experimentation and genetic manipulation of human embryos. According to the author, many have said that the fertilization program is just a smokescreen to cover up the real interests of experimentation in human genetics projects, without the ethical and legal problems<sup>(28)</sup>.

In 2012, the Inter-American Court of Rights ruled in the case of Artavia Murillo et al ("In Vitro Fertilization") v. Costa Rica that "every person has the right to have their life respected. This right must be protected by law and, in general, from the moment of conception. No one may be deprived of life arbitrarily" <sup>(29)</sup>. The ruling sparked intense discussion by establishing the interpretation and scope of the right to life, provided for in Article 4.1 of the Inter-American Convention on Human Rights, as well as setting a precedent on the legal status of the unborn in the Convention<sup>(30)</sup>.

Seeking to respond to requests from fertility clinics for a position on the disposal of frozen embryos, which, according to them, were being abandoned and cluttering up their services, in 2013 the CFM created Resolution 2·013. The resolution established the five-year freezing period for embryo donation for the purposes of stem cell research, which the Biosafety Law sets at three years, but also for the disposal of embryos<sup>(31)</sup>.

The scientific community's attention was drawn to the successful use of embryos that had been frozen for 20 years when, in 2010, a technique was applied at the Jones Institute for Reproductive Medicine at the Eastern Virginia Medical School. After thawing five anonymously donated embryos, the two embryos that survived the process were transferred into the uterus of a 42-year-old woman diagnosed with low ovarian reserve. The procedure resulted in a single pregnancy with the birth of a healthy boy<sup>(32)</sup>.

In view of this event, there was an interest in understanding the effects of cryopreservation on the embryo. Contrary to the initial hypothesis, studies have shown that longer freezing times do not seem to have a negative influence on the survival and pregnancy outcomes of human embryos. One study evaluated 3,367 embryos transferred after being frozen for at least 12 months. They were used in four groups, depending on how long they had been cryopreserved. The highest rate of high-quality embryos was found in the group that remained in cryopreservation for 24 to 35 months. The highest rates of clinical pregnancy and implantation occurred in the group frozen between 36 and 47 months. And surprisingly, the highest rates of live births and pregnancies lasting 38 weeks or more were in the group cryopreserved for more than 48 months<sup>(33)</sup>.

Then, in 2022, the CFM issued Resolution 2<sup>,</sup>320, where the conditional disposal of cryopreserved embryos was no longer included in the text, and determined that, per cycle and in laboratories, the maximum number of embryos could be no more than eight. In the section on Cryopreservation of gametes and embryos, it is determined that surplus embryos should be cryopreserved, authorizing the donation for research or disposal only of embryos diagnosed with genetic alterations that cause disease<sup>(18)</sup>.

Bill 4/25 to revise and update the Civil Code is currently before the Federal Senate. Article 1.629-V, in its sole paragraph, states that "cryopreserved embryos may be used for research or given to other people who seek treatment and need genetic material from third parties; they may not be discarded" (17). It thus seeks to resolve the scenario of legal uncertainty and emptiness regarding the disposal of cryopreserved embryos produced by assisted reproduction techniques. However, it still leaves open the fact that it would be important to assess the viability of these embryos before they are used for research.

A 2016 study showed that when activated by sperm penetration, the egg releases a 'zinc spark'. This activation involves events such as blocking polyspermy, completion of meiosis, maternal mRNA recruitment and pro-nuclear formation, all of which are fundamental to the successful evolution of the embryo. By observing the simultaneous fertilization of several eggs in the laboratory, a difference was observed in the presence and intensity of the 'zinc spark' produced by them. It was concluded that the ability and intensity of the fertilized egg to emit this spark is associated with its meiotic maturation. Furthermore, the chelation (i.e. the chemical interaction involving organic molecules and metal ions) of intracellular zinc alone was sufficient to induce the resumption of the cell cycle and the transition from a meiotic to a mitotic cell. Together, these results demonstrate critical functions for zinc dynamics and establish the zinc spark as an extracellular marker of early human development<sup>(34)</sup>.

França suggests two ethical options to avoid the inadvertent production of human embryos in this relationship: one would be to fertilize only the eggs to be implanted, and thus not have surplus embryos. The other would be to accept the adoption of cryopreserved embryos by adopting couples<sup>(28)</sup>.

This second suggestion is already being made, for example, in the United States. In order to help with embryo donation, the American Society for Reproductive Medicine (ASRM) has published a protocol with minimum criteria aimed at guiding topics such as: screening, testing and counseling of potential embryo donors and recipients; criteria for choosing a donor embryo; suggested psychoeducational counseling for donors and recipients; genetic screening and counseling and family history screening for unidentified donors<sup>(35)</sup>.

Among the practical guidelines, the ASRM emphasizes that the medical professional should have knowledge of the storage, thawing and transfer of frozen embryos. It points out that there may be costs for recipients for thawing embryos, the embryo transfer procedure, coordinating and documenting the cycle, and screening and testing recipients and donors for infectious diseases. However, the sale of embryos in itself is ethically unacceptable<sup>(35)</sup>.

It also advises that attention must be paid to the physical and mental health of all those involved. The embryo donor cannot be the temporary owner of the uterus. Users are solely responsible for selecting donors when using a gamete or embryo bank. In the event of embryos formed from gametes from different patients or donors, the embryo transfer must be carried out with embryos from a single source for the safety of the offspring and traceability<sup>(35)</sup>.

In Brazil, the most recent CFM Resolution<sup>(18)</sup> determines the criteria for the donation of embryos and gametes. These are:

- a) The donation must not be for profit or commercial in nature;
- b) Donors must not know the identity of the recipients or vice versa, except in the case of gametes or embryos being donated to a relative of up to the fourth (4th) degree of one of the recipients, as long as there is no consanguinity involved (first degree of kinship: parents and children; second degree: grandparents and siblings; third degree: uncles and nephews; fourth degree: cousins);
- c) The identity of gamete and embryo donors must be kept confidential. In special situations, information about donors, for medical reasons, can be provided exclusively to doctors, safeguarding the civil identity of the donor.
- d) Clinics, centers or services where donations are made must keep a permanent record of general clinical data and phenotypic characteristics, in accordance with current legislation.
- e) In the region where the unit is located, the registration of births will prevent a donor from having produced more than two births of children of different sexes in an area of 1 million inhabitants. Except when the same recipient family chooses the same donor, who can then contribute as many pregnancies as desired.

According to the quote by Conill Sancho, in the face of scientific progress, it is necessary to reflect and propose measures that value the relevant contribution of the respective advances, but which also promote a responsible orientation of its growing power. It is also necessary to confront moral pluralism and its inevitable conflicts, especially in the face of scientific freedom<sup>(25)</sup>.

Current regulation of the AHR technique in Brazil is fragmented, scarce and sectoral. In order to visualize the Brazilian bioethical legal model that guarantees the right to access and use AHR techniques, it is necessary to carry out a process of connecting the norms found and originating from different sources.

It can be seen that the absence of a normative reality, with a specific law regulating the techniques, has led to a great appreciation of the deontological Resolutions issued by the CFM, which, despite not being a law in the formal sense, end up establishing guidelines for the use of these procedures. They have been updated over time in order to keep up with advances in AHR technologies, but they still lack the cogent force that only a law in the formal sense would have the power to make possible, with the judiciary and its administrative bodies, in most cases, having the role of making up for this absence<sup>(36)</sup>.

In view of what has been assessed in this article, since the production of embryos through IVF and ICSI is something recent in science, it is necessary for legislation to keep pace with discoveries on the subject, keeping up to date. As Vasconcelos *et al* say, "in their proposal to build a new ethic for technological civilization, (...) attention is drawn to the fact that the consequences of the decisions and measures taken today will fall on future generations, who will have the burden of facing them and paying their price<sup>(15)</sup>.

# Conclusion

The analysis carried out in this article allows us to conclude that the disposal of cryopreserved embryos in Brazil remains shrouded in deep bioethical, philosophical and legal controversies, especially in the absence of specific legislation that clearly regulates the fate of surplus embryos generated in AHR procedures.

Despite the infralegal regulations issued by the Federal Council of Medicine and the parameters established by the Biosafety Law, there is a significant regulatory gap regarding the legal status of the embryo, its legal protection and the circumstances that would ethically and legally justify its disposal. The lack of an express legal provision on disposal, coupled with the absence of objective criteria for assessing embryonic viability before its destination, compromises the principle of the dignity of human life in its most embryonic form and accentuates the legal uncertainty that falls on health professionals, patients and institutions.

Among the most relevant findings is the lack of consensus on the initial ontological framework of human life, the divergence between justiaturalist and utilitarian approaches, and the weakness of public policies aimed at monitoring, donating or researching cryopreserved embryos. Equally worrying is the significant increase in the number of embryos discarded in recent years, with no clarity as to the criteria used for such disposal.

As a limitation of this research, we recognize the difficulty of accessing standardized clinical data on embryo viability screening in Brazil, as well as the scarcity of public technical regulations governing disposal based on transparent scientific parameters. Furthermore, the narrative nature of the review, although appropriate to the proposed approach, does not allow for statistical generalization of the findings.

For future studies, it is recommended that empirical research be carried out to assess the disposal criteria used in the country's main assisted reproduction centers, as well as the effectiveness of ethical and health inspection mechanisms. It is also suggested that the comparative analysis between international regulatory models and the Brazilian legal system be deepened, in order to support the formulation of specific national legislation, systematized and compatible with the constitutional principles of human dignity, the right to life, health and reproductive self-determination.

Finally, it is suggested that the construction of a robust and ethical regulatory framework on the fate of cryopreserved human embryos is an urgent and urgent measure, in order to ensure not only the legal protection of human life in its early stages, but also the predictability and legal certainty necessary for the exercise of reproductive medicine in the Democratic State of Law.

### **Conflict of interest**

The authors declare that there is no conflict of interest.

#### Authors' contribution

Assis CR contributed to the conception/design of the article, data analysis and interpretation, writing of the article, critical review of its content and approval of the final version. Salutti V contributed to writing the article. De Souza LP contributed to the conception/design of the article, revision and approval. Khamis RBM contributed to the critical revision of the content and approval of the final version. Lamy M contributed to the critical review of the content and approval of the final version.

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# How to cite

Assis CR, Salutti V, De Souza LP, Khamis RBM, Lamy M. Analysis of embryo disposal in Brazil: bioethical, scientific and legal aspects. Cadernos Ibero-Americanos de Direito Sanitário. 2025 jul./sep.;14(3):68-81 https://doi.org/10.17566/ciads.v14i3.1319

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