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RESEARCH ARTICLE

Legal Regulation of Donating Embryos for Scientific Research and for the Infertility Treatment in Ukraine

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ABSTRACT

The aim. The purpose of this study is based on a study of Ukrainian experience in the field of legal regulation of the use and donating of embryos in vitro for research purposes and infertility treatment, analyzing cases of European Court on human rights in this field, to suggest ways to fill the gaps in current legislation of Ukraine and bring it into line with international law.

The subject of the research was the legal regulation of donating embryos for scientific research and for the infertility treatment in Ukraine, which is an interesting experience for scientists from other countries, since Ukraine has become a candidate for European Union (EU) membership, and thus the peculiarities of the legal regulation of embryo donation in Ukraine will allow us to identify the positive and negative aspects of embryo donation and the possibility of conducting a comparative analysis with foreign regulation. In Ukraine, donation of gametes and embryos is a procedure according to which donors, with written voluntary consent, provide their reproductive cells-gametes (sperm, oocytes) or embryos for use in other persons within the treatment of infertility. The application of embryo donation is carried out according to medical indications, subject to the presence of written informed voluntary consent of the patients, ensuring the anonymity of the donor and maintaining medical secrecy. The study is based on an interdisciplinary approach to the analysis of the problem of legal protection of the embryo using dialectical, comparative legal, and systemic methods. The research used scientific developments in the field of problems of the legal status of the human embryo, international acts, the legislation of Ukraine, the practice of the European Court of Human Rights (ECHR).

Conclusion. The issue of legal protection of intellectual property rights, the object of which is the human genome, tissues or cells, is currently being hotly debated in the world. However, legal approaches to the possibility of patenting such objects can be divided into those that completely deny the patenting of the human genome, as well as other human tissues and cells, and those that cause such a process of certain restrictions of moral, ethical and legal nature, such as for example, the issue of ensuring the confidentiality of information about the person whose materials are being investigated. It seems that in view of the above practice of the ECHR, it would be appropriate to establish the possibility of free use of the results of such research, which would be in the interests of society and science.

Donors of embryos in Ukraine can be patients of the in vitro fertilization program, who have unused cryopreserved embryos left in the cryobank after the birth of a child. In case of fertilization of donor oocytes with donor sperm, their transfer into the recipient's uterine cavity or cryopreservation (with subsequent transfer in subsequent cycles) are possible. With the voluntary, informed, written consent of donor patients, these embryos may be used for donation to an infertile patient/recipient couple, as well as unmarried female recipients.

Assignment of embryos and embryo-fetal materials to the category of biological material does not mean that they are subject to the rules of property law, but they should be considered as special objects that are under state protection and are in close legal personal connection with the above mentioned persons, who are given the right to determine their future fate within the limits established by law. The right to dispose of embryos for research purposes may be granted by the woman and the man for whom the embryo was created, subject to informed consent and consent to the processing of personal data.

Keywords: human embryo, scientific research, donation, infertility treatment, embryonic stem cells, legislation.

INTRODUCTION

The embryo donation can take place in two different spheres: in reproductive medicine as the way of infertility treatment and in medical science to help understanding human being development, to treat certain disorders of embryonic development, to learn how to use the potential of embryonic tissues and cells for the treatment of incurable diseases, etc. The issue of specific legal regulation of gamete and embryo donation for scientific purposes and for the purpose of infertility treatment is debatable not only in national legal science, but also in foreign ones, affecting both legal and medical, ethical and religious aspects. Therefore, a comprehensive, systematic analysis is necessary, taking into account the right to life and the right to health care, as well as the right to abortion and the right to use assisted reproductive technologies.

The literature emphasizes that 95% of in vitro fertilized embryos die and some of them are deliberately destroyed: some due to unsuitability for implantation; others are initially stored as "spare" for further attempts to fertilize the same patient; they are discarded after their expiration date in the frozen state, or used in experimental studies of drugs, abortions, vaccines, oncogenic substances, etc[1]. Ukrainian scientists, focusing on the ethical issues of in vitro fertilization (IVF), include the following: biological rights of the embryo and social problems, as well as the problem of ownership of "extra" embryos[2].

In Ukraine, donation of gametes and embryos is a procedure according to which donors, with written voluntary consent, provide their reproductive cells-gametes (sperm, oocytes) or embryos for use in other persons in the treatment of infertility. The application of embryo donation is carried out according to medical indications, subject to the presence of written informed voluntary consent of the patients, ensuring the anonymity of the donor and maintaining medical secrecy. Donation of gametes and embryos is carried out in the presence of appropriate documentation: informed voluntary consent for sperm donation, statements of the patient/patients about the use of donor oocytes, informed voluntary consent for oocyte donation, informed voluntary consent for embryo donation[3].

The question is whether these live in vitro embryos, which have no prospects for further development due to the impossibility for some objective reasons to be implanted, and therefore, sooner or later, will inevitably die, can be used for research to expand knowledge about embryos development in the interests of reproductive medicine "and/or" the development of new treatment methods for the most severe and incurable diseases, mainly by obtaining embryonic stem cells from them. And is there a difference in embryo donation for the treatment of infertility, that is, if we use the embryo for scientific purposes, then according to most scientists it is immoral, in the case of donation and after use for the purpose of infertility treatment, it is moral.

When it comes to embryo research or infertility treatment, it is important to distinguish between «embryo research», «research on embryos» and «using embryo for infertility treatment». These are three different areas, which, legally and ethically, have their own characteristics. If we are talking about «embryo research», «using embryo for infertility treatment» then we are talking about research that is conducted in the interests of its healthy and full development, therefore, from an ethical point of view, there are no problems, because these kinds of using are positive for the embryo. Instead, the «research on embryos» raises much more questions in both legal and ethical spheres.

The analysis of the scientific literature in Ukraine and abroad shows that the problems of embryos in vitro research and using embryo for infertility treatment where studied by the following scientists, namely Buletsa S., Carrol J., Ehrenstein C., Gyöngyösi Z., Günther H.-L., Hyun I., Jobbágyi G., Ildikó V.R., Johnston J., Kaiser P., Kovaliova O., Kvit N., Mendzhul M., Mannix L., Matthews K. RW., Morali D., Neidert R., Sándor J., Soni S., Taupitz J., Varga R.I., Vicsek L., Wilkerson A., Zeller J. and others. Ukrainian legislation regulates only general questions of embryos usage in reproductive medicine. The research use of the in vitro embryo is unfortunately completely outside of the current legal regulation in Ukraine. The legislation, which is supposed to regulate the research involving human embryos, must undergo systematic analyzes and take into account the experience of the other legislations for improvement suggestions to be made. The study is based on an interdisciplinary approach to the analysis of the problem of legal

[1] Bachynska LIu Bioetychni problemy shtuchnoho zaplidnennia. *Porivnialno-analitychne pravo* 2016; 6: 296-299. (In Ukrainian).

[2] Kovalova O Deontolohiia v medytsyni: pidruchnyk. Deontology in medicine: a textbook. Kyiv: VSV «Medytsyna»; 2015. p.111. (In Ukrainian).

[3] Pro zatverdzhennya Poryadku zastosuvannya dopomizhnykh reproduktyvnykh tekhnolohiy v Ukrayini. Nakaz MOZ vid 09.09.2013 № 787. Available at: https://zakon.rada.gov.ua/laws/show/z1697-13#Text (In Ukrainian).

protection of the embryo using dialectical, comparative legal, and systemic methods. The research used scientific developments in the field of human embryo legal status problems, taking into consideration also international acts, the national legislation of Ukraine and foreign legislation, as well as the practice of the European Court of Human Rights.

The purpose of this study is based on a study of Ukrainian experience in the field of legal regulation of the embryos in vitro usage for research purposes and infertility treatment, analyzing cases of European Court on human rights in this field, to suggest ways to fill the gaps in current legislation of Ukraine and bring it into line with international law.

REVIEW AND DISCUSSION. The problem of the legal status of the embryo is raised in medical and legal scientific circles. Scientists believe that a human embryo can be an object of law[4] or cannot in any case be considered as an object of law, therefore using it for commercial purposes is simply unacceptable. Since a person and his rights are recognized as the highest social value, carrying out various manipulations with embryos devalues understanding of human life before birth. They note that the embryo belongs to the subjects of reproductive legal relations and needs proper legal protection from the state[5].

Another scientists determine the legal status of the "embryo" suppose, thnat it should be characterized as "pre-subjective", which provides for certain elements of legal protection, as well as in the case of transition to the subject status (during live birth) - protection of property rights, the grounds for which occurred during the "pre-subjective" state.

Ukrainian legislation, art. 1 of the Law of Ukraine "On the Prevention of Human Reproductive Cloning", designates an embryo as a human embryo at the stage of development up to 8 weeks. Such a definition is overtly undetectable and slanderous; looking back at the appearance of the indications of the initial moment, for which the embryo is the germ of a person. It is interesting that the legislator set the upper time limit of the concept - 8 weeks, i.e. 2 months. This line is important for the completion of the processes of organ formation in the embryo, and to that moment in time it is already important for the fetus, and not the embryo. However, the current legislation also defines the concept of "fetus" as an intrauterine product of conception, starting from the full 12th week of pregnancy until expulsion/removal from the mother's body. It is fixed, in particular, in clause 1.4. Order of the Ministry of Health of Ukraine dated March 29, 2006 No. 179 "On the approval of the Instructions for determining the criteria for the perinatal period, live births and stillbirths, the Procedure for registering live births and stillbirths"[6]. Therefore, the status of a conceived but unborn child in the period between 8 to 12 weeks of pregnancy remains unsettled.

In addition, the current Ukrainian legislation is characterized by a lack of unified terminology, since it uses, in addition to the above-mentioned terms "embryo" and "fetus", also the terms "conceived but not yet born child" (Part 2 of Article 1298 of the Civil Code of Ukraine), "conceived child" (Part 3 of Article 110 of the Family Code of Ukraine), without their definition[7]. In the literature, it is proposed to eliminate this problem by unifying the terminology and introducing a single term "unborn child" into legal circulation, which is proposed to be defined as "a human individual from the moment of conception (fertilization of an egg by a sperm) to the moment of birth"[8]. Such a definition fully covers all stages of the development of a human being from the moment of fertilization to the moment of birth, which will also cover embryos existing outside the mother's body (in vitro). It seems that such an approach will ensure the protection of the human embryo regardless of the form of its existence (implanted or non-implanted) and the stage of its development (embryo or fetus). For example, in the cases "Vo v. France" and A, B and C v. Ireland., the European Court of Human Rights confirmed that "an unborn child is not considered a 'person' whose rights are directly protected by Article 2 of the Convention. The Court noted that the 1950 Convention does not define the

[4] Valid Kamal′ Abdel′ Salam Atia. Pravove rehulyuvannya pravovoho statusu embrionu. *Seriya: Derzhavne upravlinnya 2019 p.,* № 3 (67).C.43-47 C. 46 (In Ukrainian); Korenha Y.U. Vyznachennya pravovoho statusu embriona. Istoryko-pravovyy chasopys. 2016. №2 (8). S.99-102 s.101 (In Ukrainian).

[5] Zabolotna M. Embrion – sub″yekt chy ob″yekt reproduktyvnykh pravovidnosyn? Yurydychnyy visnyk *2021. №1 C.225-234 C.231* (In Ukrainian).

[6] Pro zatverdzhennya Instruktsiyi zvyznachennya kryteriyiv perynatal′noho periodu, zhyvonarodzhenosti ta mertvonarodzhenosti, Poryadku reyestratsiyi zhyvonarodzhenykh ta mertvonarodzhenykh: nakaz Ministerstva okhorony zdorov″ya Ukrayiny vid 29 bereznya 2006 r. № 179. Available at: https://zakon.rada.gov.ua/laws/show/z0427-06 (In Ukrainian).

[7] Simeynyy kodeks Ukrayiny: Zakon Ukrayiny vid 10.01.2002 № 2947-III Available at: http://zakon4.rada.gov.ua/laws/show/2947-14 (In Ukrainian).

[8] Lyubych L.D. Pravovyy status nenarodzhenoyi dytyny u pravovidnosynakh shchodo realizatsiyi reproduktyvnykh prav lyudyny. Administratyvne pravo i protses. 2015. № 2(12). C. 262-273 263 (In Ukrainian).

term "human being" ("person"). At the same time, he noted that there is no consensus on the status of the embryo and/or fetus at the European level, but he recognized that the embryo/fetus belongs to the human race ("the human race")[9].

The problem of research on embryos has long been intensively discussed at the international level and the conclusions from this discussion are very different. And today the hottest discussions revolve around the so-called "14-day rule", which provides for the possibility of embryo examination only within the first two weeks after fertilization. Many other countries worldwide permit human embryo research, e.g., on surplus in vitro fertilization embryos, until day 14 post fertilization. Countries around the world take a variety of approaches to human embryo research. Some – like Italy and Germany – don't allow it at all. Others, like the United Kingdom (hereinafter - UK), allow research to continue until the embryo is 14 days old, after which it must be destroyed. There are also some which permit embryo research without identifying a limit. Some, like the United States, do not have any law regulating it (but there are guidelines that contain reference to the 14-day rule). In South Africa, reference to the rule is found in the National Health Act (2003), which states that human embryo research may only be done with the permission of the minister and that the embryos must not be older than 14 days[10]. Four countries did not have a date limit: Brazil, France, Israel and the USA. Brazil's laws on human embryonic stem cells (hereinafter - HESC) research prohibit "*genetic engineering on human germ cells, human zygotes or human embryos*" but do not address a development limit or other restrictions on human embryo research. Israel has a 1999 law banning reproductive cloning and a set of guidelines for HESC research, but it does not address nor limit *in vitro* human embryo research. French law permits the use of leftover IVF embryos for scientific research if scientifically justified and with prior authorization by the Agency of Biomedicine. This bioethics law is under review in 2020, and the new version could include more permissive language related to human embryo research, including potentially adding a 21-day limit[11]. In at least 12 countries (Canada, Iceland, Spain, Slovenia, the United Kingdom, Denmark, the Netherlands, Sweden, Australia, New Zealand, South Korea, and Switzerland, it has set a legal limit of 7 days), this limit is implemented in national legislation that regulates assisted reproductive technologies and embryo research[12]. This rule was introduced in 2016 in the Guidelines for conducting such research by the International Stem Cell Research Association for the global scientific community. But on May 26, 2021, new guidelines came into force, which allowed each country to decide or limit such research. Therefore, since this document is not a normative act, but is of a recommendatory nature, such changes do not mean that researchers around the world will now be able to conduct in vitro embryo research without restrictions and grow embryos in the laboratory as much as they want. After all, as mentioned above, many countries have adopted this rule by implementing it in national legislation, and until they amend their legislation, such research will continue to be prohibited. However, for countries that did not have the appropriate legal regulation, which includes Ukraine, this will create the preconditions for the formation of legislation loyal to such ethically controversial research and the use of such countries as "raw material bases". It has been noticed that there is no specific legislation regarding human embryo research or human ES cell research: Belgium, Italy, Luxembourg and Portugal. Allowing by law for the creation of human embryos for research purposes: UK is for the moment the only Member State, which allows by law for the creation of human embryos either by fertilization of an egg by a sperm, or by somatic cell nuclear transfer (hereinafter - SCNT, also called therapeutic cloning) for stem cell procurement. The bill under discussion in the Belgian Parliament would allow for the creation of human embryos for research purposes including by SCNT. The Dutch Embryo Act of 2002 includes a five-year moratorium for the creation of embryos for research purposes including by SCNT.

Prohibiting the creation of human embryos for research purposes and for the procurement of stem cells by law or by ratification of the Convention of the Council of Europe on Human rights and Biomedicine signed in Oviedo on 4 April 1997:

[9] Case of Vo v. France 2004. Available at: http://hudoc.echr.coe.int/sites/eng/pages/search.aspx?i=001-61887; Case of A, B and C v. Ireland. 2010 Available at: http://hudoc.echr.coe.int/eng?i=001-102332

[10] Soni S Limits for human embryo research have been changed: this calls for public debate. *The Conversation*. 2021; June 30. Available at: https://theconversation.com/limits-for-human-embryo-research-have-been-changed-this-calls-for-public-debate-162305.

[11] Matthews K RW, Moralí D National human embryo and embryoid research policies: a survey of 22 top research-intensive countries. *Regenerative Medicine*. 2020; 15:7: 905-1917. Available at: https://www.futuremedicine.com/doi/10.2217/rme-2019-0138.

[12] Hyun I, Wilkerson A, Johnston J Embryology policy: revisit the 14-days rule. *Nature*. 2016; 533: 169–171. Available at: https://www.nature.com/polopoly_fs/1.19838!/menu/main/topColumns/topLeftColumn/pdf/533169a.pdf.

Austria, Denmark, Finland, France, Germany, Greece, Ireland, Netherlands, Portugal and Spain[13].

The basic norms in this issue at the level of international law are the norms of Part 1 and 2 of Article 18 (In vitro Embryo Research) of the Convention on Human Rights and Biomedicine, which was signed by Ukraine on March 22, 2002, but till today unfortunately not yet ratified. Article 18.1 states that "where the law allows research on embryos in vitro, it shall ensure adequate protection of the embryo." However, the term "adequate protection" is not defined in detail. Hence, Member States are at liberty to undertake the conditional authorization of research with "surplus" embryos. Thus, the admissibility at the national level of research on live embryos requires the unequivocal creation of legislative guarantees for their protection, although the wording "appropriate protection" does not contribute to a clear understanding of what issues need to be addressed to achieve the required level of protection. Although these provisions do not provide the human embryo with absolute protection from research, they create a certain framework and conditions for its protection during such research.

In the field of so-called foreign studies of human embryos (studies on embryos, but not in its interests) the most problems are caused by research and experiments conducted using embryonic stem cells, which are obtained from embryos at an early stage of their development, reproduce in the so-called cell cultures and creation of whole cell lines, which are then used to test and develop new drugs or treatment methods, which can even be patented. The question of embryo protection in the context of this issue is important because the production of embryonic stem cells from human embryos results in their destruction, and therefore the legality and ethics of such actions are debatable.

In this context, the decision of the ECHR from 18.10.2011 on the revocation of a patent for human Embryonic stem cells (ESCs), as a result of which the court generally prohibited such patenting (decision C-34/10)[14], the European Court of Justice ruled that German stem cell scientist Oliver Brüstle's patent on neural precursor cells derived from human ES cells violated Article 6 of the European Biopatent Directive, which specifies that "uses of human embryos for industrial or commercial purposes" cannot be patented. The judges argued that human embryonic stem cells could not be the subject of intellectual property rights because human embryos were destroyed to obtain them, in violation of the principle of protection of human dignity. However, there is no denying the possibility that use for therapy or diagnosis in the interests of the embryo (for example, in certain disorders of its development) - embryonic stem cells may be the subject of patents.

The ECHR judges reached another important conclusion in the analyzed decision, noting that since the use of a human embryo for research purposes cannot be imagined without future commercial use, medicines based on embryonic stem cells cannot be the exclusive right to sell them. This conclusion provoked a wave of outrage in Europe, emphasizing that now pharmaceutical companies and investors will lose interest in such research, which will negatively affect the development of the medical and pharmaceutical industries. However, we share the position of European bio-patent expert Ingrid Schneider from the University of Hamburg, who noted that today such projects and research projects are still mostly funded by public funds, and the lack of patents that could limit the space for research will expand opportunities for researchers for the science development[15]. In addition, this solution will provide an impetus for the intensification and development of the adult human stem cells potential research.

The issue of legal protection of intellectual property rights, the object of which is the human genome, tissues or cells, is currently being hotly debated in the world. However, legal approaches to the possibility of patenting such objects can be divided into those that completely deny the patenting of the human genome, as well as other human tissues and cells, and those that cause such a process of certain restrictions of moral, ethical and legal nature, such as for example, the issue of ensuring the confidentiality of information about the person whose materials are being investigated. It seems that in view of the abovementioned practice of the ECHR, it would be appropriate to establish the possibility of free use of the results of such research, which would be in the interests of the society and science. Six EU Member States (Cyprus,

[13]Report on Human Embryonic Stem Cell Research. Available at: https://ec.europa.eu/commission/presscorner/detail/en/MEMO_03_81

[14] The decision of the European Court of Human Rights of 18.10.2011 № C-34/10. Available at: https://dejure.org/dienste/ver-netzung/rechtsprechung?Text=C-34/10

[15]Ehrenstein C. Kein Patent auf Embryo-Stammzellen. *Die Welt*. 2011. Available at: https://www.welt.de/print/die_welt/politik/article13668377/Kein-Patent-auf-Embryo-Stammzellen.html (In German).

Ireland, Poland, Luxembourg, Malta, Romania) do not have clear written legislation on embryo and embryonic stem cell research or cloning, one of them (Cyprus) refers to the biomedical convention. a means of filling the lack of national legislation.

In Ukraine, on the other hand, the legislator practically ignores the issue of creating guarantees for the protection of a live embryo in vitro, not to mention the existence of criminal liability for its illegal use. There is only an indirect ban on the use of live non-implanted embryos for non-reproductive purposes, which follows from a systematic analysis of the Procedure for the use of assisted reproductive technologies. The conclusion that can be drawn, in particular from the analysis of this act, is that the purpose of the creation and use of embryos in vitro is supposed to be exclusively reproductive.

Among the possible legally regulated forms of its use are:

• embryo transfer and storage for implantation in the future (in case of unsuccessful attempts or if you want to use reproductive services ones again);

• storage for the purpose of embryo transfer to recipients by donation;

• application of pre-implantation medical-genetic diagnostics to embryos for the prevention of genetic abnormalities and diseases, but the legislator did not regulate the possible consequences of such research (the need to destroy embryos containing genetic abnormalities, as neither implantation nor donation is possible);

• reduction (removal) of excess already implanted embryos, which can be carried out on the basis of a conclusion of the council (at least 3) doctors about its need, the number of embryos to be reduced is determined on the basis of a written application of the patient on the doctor's recommendation. The purpose of such destruction of already implanted viable embryos that develop in the mother's body is to prevent obstetric and prenatal complications associated with multiple births. This is the most problematic issue from both an ethical and a legal point of view. Therefore, we believe that it is necessary to amend Part 2 of paragraph 3.8. (Embryotransfer (hereinafter - ET)) The order of application of assisted reproductive technologies (hereinafter - ART) and state it in the following wording: "It is recommended to transfer no more than 2 embryos to the uterine cavity (if medically indicated and with the patient's consent) in order to avoid obstetric and prenatal complications associated with multiple births. ET of one selective embryo (with the patient's consent) and cryopreservation of the remaining embryos for use in subsequent cycles are recommended" and also to exclude from the Order Section 8 "Reduction of embryos"[16].

The analysis of the domestic legislation regulating the application of ART allows us to conclude that in legal sence the embryo becomes the object of legal relations. In particular, in clause 11.1. In order, embryos are defined as "biological material of the patient/patients". The right to control the fate of the embryo (regarding possible procedures and manipulations for in vitro fertilization and cultivation, embryo transfer (into the uterine cavity of a genetic or surrogate mother), cryopreservation and storage, transfer for reproductive technology programs to other persons, reduction) belongs to a woman (patient) - a female donor reproductive cells.

This legislative wording provokes a misunderstanding of the essence of non-implanted human embryos in vitro, until the moment of their implantation, as a thing that is owned by the biological parents, since in the case of in vitro fertilization, the right to the birth of such an embryo depends on the consent of the parents - customers of the reproductive program, which can be recalled before implantation.

This approach also does not correspond to the ECHR's vision of this issue, in particular the ECHR case of Parrillo v. Italy (No. 46470/11) dated August 27, 2015 is illustrative, the essence of which was that the plaintiff wanted to transfer unimplanted embryos that remained after the application to her and her husband assisted reproductive technologies, for their use for research purposes (at the time she discovered such an initiative, her husband died). The Italian courts refused to grant her the claim, because at the time of her appeal, the Law prohibiting the donation of embryos for scientific research came into force in Italy. Therefore, she appealed to the ECHR with a claim that this legal ban violated her right to respect for private life and the unhindered use of her property, arising from Art. 8 and Art. 1 of Protocol No. 1 to the European Convention on the Protection of Human Rights and Fundamental Freedoms. In its decision, the ECHR explained that in this case there was no violation of the above-mentioned rights. In particular, the right to respect for the plaintiff's

[16] Kvit N.M. (2020) Biobanky v Ukraini: tsyvilno-pravovyi aspekt: monohrafiia. [Biobanks in Ukraine: civil law aspect: monograph.] Lviv: Kvart; 2020. (In Ukrainian).

private life was associated with the fact that she has a genetic connection with the unimplanted embryos, which enables her to determine their future fate, and therefore is one of the aspects of her personal life and the right to self-determination. However, since this case did not involve the prospect of motherhood (since the husband died, and posthumous fertilization is prohibited), the court concluded that the right to research embryo donation in this case is not an important aspect of her personality. In addition, the national law ban on research donation of embryos takes precedence over her private life. As for the potential violation of Art. 1 of Protocol No. 1 of the Convention, the majority of judges supported the position that, taking into account the economic and monetary nature of property rights, the scope of providing human embryos is incompatible with these provisions of the Convention. Therefore, this aspect was not even considered by the court. Such a conclusion of the court once again confirms that human embryos cannot be considered as an object of property rights, and its parents can not be considered as owners. In addition, the court also emphasized that the claim cannot be satisfied also because it is impossible to establish the valid will of the plaintiff's husband (who is deceased) regarding such use of non-implanted embryos, which is important considering that the embryos contain the genetic information of both parents. Such a conclusion is definitely important and means that if national legislation allows the research use of unimplanted embryos, it must necessarily establish a requirement for obtaining written informed consent for such use from both parents, and not just the woman (potential mother) [17].

Also, in the literature, it is noted that cryopreserved in vitro embryos are special objects of civil rights, created from the biological material of patients participating in the ART procedure. Such objects are limited in circulation, given their specific nature of human embryo and biological origin, as well as due to the limited composition of participants in civil circulation to which they can belong. In addition, cryopreserved embryos can be the subject of a limited range of legal relations, in particular contracts for the provision of services for the implementation of ART programs, contracts for storage by health care institutions, as well as embryo donation, which by its legal nature is close to a contract of donation, after embryo transfer to the uterine cavity, he begins his intrauterine development and loses the features of an object of law, and his potential interests begin to be protected by law[18].

Ukrainian scientists, as an option for solving problems related to the use of embryos, propose to normatively determine the status of the embryo, but they cannot agree on exactly what this status should be. In particular, V.G. Tretyakov emphasizes that there is a question of determining the legal status of an embryo by law and the legal consequences of its use or destruction. It is believed that the law should establish all the necessary procedures, order and rules for handling embryos, especially with their use for artificial insemination.

In connection with this, the question also arises whether the embryo can be considered as biological material, and if so, whose. This question was also the object of research by German lawyers, whose opinions can be divided into two groups. In particular, some researchers believe that human eggs from the moment of their fertilization cannot be classified as biological material in the narrow sense, if they are considered as a new human life[19]. At the same time, German judicial practice indicates that it is still permissible to interpret a fertilized egg cell as biological material of the mother or biological parents, if one adheres to the position that human life does not arise immediately after fertilization, but only when the embryo reaches a certain stage of development (for example, from 14 days after the fusion of female and male reproductive cells)[20].

When it comes to biological material, these are tissues or cells separated from the donor's body and containing his genetic information. Although an in vitro embryo is newly created and has its own, although related to the parents, but unique genetic code, its creation would not be possible without the prior separation of reproductive cells from the body of the patient/patients (donors) and their fusion. It is also indisputable that he contains the genetic information of his biological parents, and therefore it cannot be denied that he, albeit indirectly, can still be considered the biological material of his biological parents. Note that there are no property relations regarding biological material, instead,

[17]Case Of Parrillo V. Italy (Application no. 46470/11). Available at: https://www.globalhealthrights.org/wp-content/uploads/2016/05/PARRILLO-v.-ITALY-.pdf

[18] Krushel′nyts′ka H.L. Kriokonservovani embriony in vitro yak ob″yekty tsyvil′nykh prav. Chasopys tsyvilistyky. Vypusk 37. 2020. S.36-41 S.40 (In Ukrainian).

[19] Fisahn A., Genetischer Code – Rechtlicher Schutzperspektiven, RDV 2002, S. 15-21. Available at: http://www.jura.unibielefeld.de/lehrstuehle/fisahn/veroeffentlichungen/2001/Genetischer_Code___rechtliche_Schutzperspektiven.pdf

[20] Das Bundesverfassungsgericht Entscheidung 1,37. Available at: http://www.servat.uni-be.ch/dfr/bv039001.html.

there is a legal personal connection between donors and their biological material, then it can be stated that the same legal relationship exists with the in vitro embryo and its future parents. Therefore, its interpretation as biological material in the broad sense does not mean that the regime of the thing applies to it. In addition, it is important to remember that the creation of an embryo is not always the result of the use of biological material of persons to whom assisted reproductive technologies are applied, instead it is often the result of the use of partially or completely donor biological material. Since the embryo is the result of the realization of the personal non-property reproductive rights of persons to whom assisted reproductive technologies were applied, it has an inseparable personal connection with them, which is not always based on genetic kinship. Therefore, the criterion of genetic kinship here, in our opinion, is not of primary importance, instead, the presence of a personal connection through the exercise by individuals of their personal non-property reproductive rights will be of decisive importance and influence the emergence of the right of these individuals to determine the further fate (dispose of) of the embryo, which was created as a result of realization of their non-property rights.

In connection with this, we consider it necessary to make changes to clause 11.1. The procedure for applying the ART, setting it out in the following version: "*11.1. Gametes of patients (sperm or eggs), testicular tissue or its appendages, ovarian tissue are the biological material of the patient/patients, and in vitro embryos created as a result of the use of assisted reproductive technologies are the result of the patient/patients exercising their reproductive rights and they have the right to determine the possibility of their use within the limits established by law*"[21].

As for the possibility of postmortem embryo creation or the use of reproductive biological material after the death of a person, to date, Ukrainian legislation does not regulate this issue. Such a significant gap can have a huge impact both in the area of personal non-property rights and inheritance rights, and in the area of family law. Instead, an analysis of Hungarian legislation in this area suggests that there is a clear ban on the use of gametes after death, without exception. If the gamete collection was performed during the life of the partner, with his or her valid, informed consent, specifically for reproductive purposes, this is unreasonable for the deceased donor, because the embryos can only be fertilized later. In such cases, it may be appropriate to establish measures to allow in vitro fertilization, even if the partner has died in the meantime[22]. The case law of the Hungarian Constitutional Court - which includes a very small number of judgments - has hardly dealt with ART proceedings, if so, it has mainly discussed restrictions on the right to reproduction. On the other hand, the Ombudsman's practice provides greater support for legal protection both in the use of the gametes of the deceased and in the donation of eggs[23].

So, in Ukraine, despite the lack of legal regulation of embryo disposal in vitro, an analysis of contractual and judicial practice in the field of assisted reproductive technologies allows us to conclude that managers of cryopreserved embryos are men and women together, so their death or the death of one of them if there is no joint written will for the event of the death of one of them to transfer their embryos to others by donation or a written order (so called biological will) from the husband to transfer after his death the right to dispose of the embryos to his wife for reproductive purposes, such embryos must be unfortunately destroyed.

Thus, in practice, a large number of "embryos" can be created, which are not affected by potential mothers or donors, in part because they do not even know how many fertilizations have taken place. It should also be taken into account that in the field of ART there is also the possibility or likelihood of an abuse in order to create human embryos, obviously not for their further implantation into a woman's body, but for research purposes. The proposed changes to the legislation will help prevent such abuses. Part 2 of Article 18 of the Convention on Human Rights and Biomedicine was formulated, which enshrined the need to establish a legislative ban on the creation of human embryos for the purpose of their study.

It is important to note that research on non-implanted embryos, as well as on embryos that were known to be created for research purposes, is

[21] Kvit N.M. Problema vyznachennya pochatku lyuds'koho zhyttya y rehulyuvannya mezh vykorystannya embriona yak ob"yekta zberihannya v biobanku. Naukovyy visnyk Mizhnarodnoho humanitarnoho universytetu. Ser: Yurysprudentsiya. 2019. № 40. S. 83-91. (In Ukrainian).

[22] Sándor J. A humán reprodukciós orvosi eljárások jogi szabályozásáról. [On the legal regulation of medical procedures for human reproduction.] *Acta Humana*. 1996; 25:36. (In Hungarian).

[23] Zeller J A testen kívül létrejött embriók morális és jogi státusa a reprodukcióhoz való jog és a tudományos kutatás tükrében. [The moral and legal status of out-of-body embryos in the light of the right to reproduction and scientific research]. PHD értekezés tézisei. Pécs; 2009. (In Hungarian).

clearly their non-targeted (alien) use, therefore it is opposed both from a legal and ethical point of view by the principle of protection of life. However, the question of whether the need to help seriously ill people (the right to health care and protection of the life of existing subjects) can outweigh the right to protect the life of an unimplanted embryo, which is still doomed to death, remains debatable. Such a juxtaposition would be incontrovertible only if the norm regarding the protection of life is subordinated to the human right to self-determination based on the autonomy of the will. However, this presupposes the individual's ability to be informed and make informed decisions. And this, in the context of the implementation of the principle of protection of life, means that such decisions can only be made by a person independently, and cannot depend on the will of other persons. It is quite clear that the embryo does not have such an ability. That is why, if the status of human life is extended to it, then the principle of protection of life cannot be applied to it[24].

Researchers who provide the so-called graduated right to protect the life of the embryo in the first 2 weeks from the moment of fertilization. In this case, although the embryo cannot be used for any purpose, the protection of its life during this period of time can be compared with the norms that serve to help patients or the needs of research in the framework of the treatment of unwanted infertility. The decision to match or not to match the principle of protection of the life of the human embryo depends on its definition and weight both from the legal and moral side.

In view of this, another debatable question arises whether the same right to protection of life can be given to an embryo in vitro and an embryo in vivo. Juxtaposing the right to life of these two types of embryos requires a decision to "be" (depending on the natural course of events) or "could be" (when there is permission to decide on the basis of human will what should happen naturally). The latter is called the "naturalistic fallacy" in the literature and is unacceptable from both an ethical and a legal point of view[25].

The most rational and balanced from both legal and moral-ethical point of view is the establishment of the possibility of using unimplanted embryos in vitro, but within a very strict and clearly defined framework, which must be established by law and subject to constant state control and only if enshrining a complete ban on the creation of embryos solely for research purposes (including therapeutic cloning). Therefore, in the context of creating legal guarantees for the protection of living unimplanted embryos, we support the position that they should be given the right to "species" rather than "individual" human dignity, which should be manifested in the possibility of their use only after their legal viability ceases, in particular due to the impossibility of their use for reproductive purposes for various (established in the legislation) reasons, only for the social needs defined in the legislation (development of new methods of treatment and diagnosis of serious diseases, etc.) [26].

Another possible way out of this ethically and legally difficult situation may be the use of artificially created embryonic cells instead of human embryos for research purposes. In particular, importance to Australian science is the International Society of Stem Cell Research (hereinafter - ISSCR's) recommendation to address the creation of embryo-like or model structures from human stem cells, like the iBlastoids generated by Professor Jose Polo and his team at Monash University. The model embryos, created in a laboratory by researchers at Melbourne's Monash University, do not use egg or sperm, but ordinary cells that are reprogrammed to replicate the first few days of human life[27]. The new guidelines state that – given that these embryo models are not considered equivalent to human embryos under most legislation globally – they are not subject to the restrictions of the 14-day rule[28].

Today in Ukraine, there is an objective need to create guarantees for the protection of live, non-implanted embryos in the legislation with the

[24] Beckmann J.P. Der Schutz von Embryonen in der Forschung im Bezug auf Art.18 Abs.1,2 des Menschenrechtsübereinkommen zur Biomedizin. Das Menschenrechtsübereinkommen zur Biomedizin des Europarates: taugliches Vorbild für eine weltweit geltende Regelung? Hrsg. Johen Taupitz; Institut für Deutsches, Europäisches und Internationales Medizinrecht, Gesundheitsrecht und Bioethik der Universitäten Heidelberg und Mannheim: Springer Verlag, 2002. 833s.

[25] Stefanchuk R.O. Vyznachennya momentu vynyknennya prava na zhyttya: prodovzhuyuchy dyskusiyu. Yurydychna Ukrayina. 2005. № 10. S. 38-43. C.39-40 (In Ukrainian).

[26] Kvit N.M. Problema vyznachennia pochatku liudskoho zhyttia y rehuliuvannia mezh vykorystannia embriona yak obiekta zberihannia v biobanku [The problem of determining the beginning of human life and regulating the boundaries of the use of the embryo as an object of storage in a biobank]. *Scientific Bulletin of the International Humanities University. Ser: Jurisprudence.* 2019; 40:83-91. (In Ukrainian).

[27] Mannix L. Scientists create model embryos in lab, raising major ethical questions. *The Age*. 2021; March 18. Available at: https://www.theage.com.au/national/scientists-create-model-embryos-in-lab-raising-major-ethical-questions-20210317-p57bkc.html.

[28] Carrol J Embryo research law needs tweaking to catch up with science. *The Age.* 2021; June 7. Available at: https://www.monash.edu/discovery-institute/news-and-events/news/2021-articles/embryo-research-law-needs-tweaking-to-catch-up-with-science.

aim of implementing Article 18 of the Convention on Human Rights and Biomedicine into national legislation, in particular with the aim of: excluding the possibility of embryonic cloning; ensuring the prohibition of obtaining embryonic stem cells from live cryopreserved non-implanted embryos in vitro, resulting in their death and the creation of embryos in vitro for research purposes; determination of the procedure according to which the death of embryos will be subject to registration with the establishment of the causes and determination of the procedure for ascertaining the death on the basis of expert verification of the irreversibility of the termination of the processes of cell division of the embryo.

At the level of international conventions and legislation Ukraine already has elements of legal protection of the embryo, but there are also collisions. In particular, there are contradictions on the definition of the end of the period of embryonic development in Ukraine. For example, have been noticed that the part 2 of Art. 2 of the Law of Ukraine "On the Prohibition of Human Reproductive Cloning" should be worded as follows: human embryo - a human embryo at the stage of development up to eight weeks (up to 12 weeks of pregnancy)", with such a legislative formulation, if it is impossible to conduct a reliable diagnosis regarding the period of embryo development, it will also be possible to calculate it for the weeks of pregnancy[29].

The question of determining the moment of death of the embryo remains relevant. In 2004, a scientific article "Embryonic death and the creation of human embryonic stem cells" was published in the American "Journal of Clinical Investigation", which is published by the American Association for Clinical Investigation, where the authors carried out a detailed analysis of human embryonic development and drew a parallel with already existing criteria for human death, aiming to determine the criteria for the irreversible death of a human embryo at the embryonic stage of its development, regardless of whether it exists in vitro or in utero[30]. As a result of the study, the authors proposed to take the irreversible cessation of cell division processes as the criterion for the death of the embryo, reasonably refusing to define as a criterion the death of each of the cells of the embryo, since the conducted studies showed that even after the complete and irreversible cessation of cell division of the embryo, some cells retained their viability, which, however, did not mean the possibility of further development of the embryo itself.

Since fertilization and the possibility of further development of a human embryo are defined as a universally accepted condition of human existence, it is quite logical to think that the termination of its existence (death) at this stage of its development will be determined from the moment of the irreversible termination of its further development, that is, the irreversible termination of the processes of cell division of the embryo .

However, even if this criterion is fixed at the legislative level, in case of doubts, for example, that the stem cells were really removed after the death of the embryo, the state of science today does not allow to check this retrospectively, and therefore it is impossible to exclude the possibility of abuse in the form of illegal use live unimplanted embryos, especially since the current legislation does not contain either a direct prohibition or a criminal penalty for carrying out such activities.

In connection with this, it is proposed to include Chapter VIII entitled "Procedure and conditions for ascertaining the death of cryopreserved non-implanted embryos and transferring them for further research" to the Procedure for the Application of ART. We propose to present this section in the following version:

"8.1. It is allowed to stop taking measures to preserve and artificially support the life of non-implanted embryos in vitro in the presence of informed voluntary written consent to stop storing cryopreserved non-implanted embryos only in the following cases:

a) if a mutation of any isolated gene or chromosomal abnormality of the embryo was detected during the legitimate application of pre-implantation medical and genetic diagnostics, as well as if there is a credible risk of development after implantation of hereditary diseases, which makes its further implantation and normal development impossible;

b) in case of refusal of the patient/patients on the basis of his/her written application for refusal of further storage of embryos that were created and cryopreserved in his/her interests for reproductive purposes, provided he/she has written application for refusal of embryo donation;

c) in the case of the death of the patient and the absence of his/her voluntary written consent to the donation of cryopreserved embryos;

[29]Dorofeyeva L.M., Karabin T.A., Mendzhul M.V., Khokhlova I.V. Embrion i plod cheloveka: problemy pravovoy zashchity. *Georgian Medical News*. No 9 (306) 2020 C. 164 C.162-166 (In Ukrainian).

[30] Laundry D.W., Zucker H.A. Embryonic death and the creation of human embryonic stem cells. *Jouurnal of Clinical Investigation*. 2004. Vol. 114(9). P.1184-1186

d) in case of non-fulfillment by the patient/patients of the terms of the agreement on payment for the storage of cryopreserved non-implanted embryos and the impossibility of contacting the patient/patients within 1 year from the moment of payment delay with mandatory written confirmation of monthly attempts within 1 year to obtain her/their will for extension or termination storage or donation of cryopreserved non-implanted embryos; in compliance with these requirements, the termination of taking measures for the preservation and artificial life support of non-implanted embryos in vitro is allowed without the presence of informed voluntary written consent to the termination of storage of cryopreserved non-implanted embryos.

8.2. Termination of storage and artificial support of the viability of cryopreserved non-implanted embryos and their death shall be ascertained on the basis of an independent expert opinion on the irreversibility of the termination of the processes of cell division of the embryo, and shall also be subject to registration in the record book of storage and use of cryopreserved embryos with the addition of an expert opinion, informed voluntary written consent to termination storage of cryopreserved non-implanted embryos (except for the case provided for in clause 8.1.d), as well as relevant documents confirming the reasons, namely: for clause 8.1.a. - the results of the Preimplantation genetic diagnostics (PGD) examination and the doctor's conclusion about the impossibility of further implantation and normal development of the embryo; for item 8.1.b. – written statement of the patient/patients about refusal of embryo donation; for item 8.1.c. – death certificates of the patient/patient/patients; for item 8.1.g. - written documents confirming monthly attempts within 1 year from the time of overdue payment for storage of cryopreserved embryos established by the contract, to obtain the patient's will to extend or terminate storage or to donate cryopreserved non-implanted embryos, as well as documents confirming payment overdue.

8.3. The transfer of anatomical materials of deceased embryos for their further research and/or obtaining embryonic stem cells can be carried out only on the condition of having informed (about the purpose) voluntary written consent of the patient/patients for such a transfer and compliance with the requirements established by the Procedure for conducting clinical trials of tissue and cell transplants and examination of clinical trial materials. Such a transfer is subject to registration in the record book of the storage and use of cryopreserved embryos with a mandatory indication of the date of transfer, data about the researcher, the purpose of further research with the mandatory attachment of the written voluntary informed consent of the patient/patients to such a transfer and an act of

8.4. The cryobank is obliged to ensure the confidentiality of data on the patient/patients who have given consent to the transfer of embryo-fetal materials for their further research and/or obtaining embryonic stem cells and data on researchers, in order to avoid their direct contact.

8.5. Any financial incentive or material compensation to the patient/patients who consented to the transfer of deceased embryos for their further research and/or obtaining embryonic stem cells, as well as the sale of embryofetal materials of deceased cryopreserved non-implanted embryos or the purchase and sale of live non-implanted cryopreserved embryos in vitro is prohibited and subject to qualification as illegal trade in human organs or tissues in accordance with Part 4 of Article 142 of the Criminal Code of Ukraine."

Donors of embryos in Ukraine can be patients of the in vitro fertilization program, who have unused cryopreserved embryos left in the cryobank after the birth of a child. In case of fertilization of donor oocytes with donor sperm, their transfer into the recipient's uterine cavity or cryopreservation (with subsequent transfer in subsequent cycles) are possible. With the voluntary, informed, written informed consent of donor patients, these embryos may be used for donation to an infertile patient/recipient couple, as well as unmarried female recipients. Data on the use of cryopreserved embryos are entered in the record book, storage and use of cryopreserved embryos. The use of donor gametes and embryos is carried out at the request of the patient/patients regarding the use of assisted reproductive technologies with donor gametes/embryos, the patient/patients' request for the use of donor oocytes, informed voluntary consent to embryo donation.

Ukrainian legislation needs to be improved in the context of supplementing and expanding the content of Art. 290 P.1 of the Civil Code of Ukraine, which regulates the right to donate, in order to close the gap in regulating the right to donate embryos, which is currently not covered by this article. In this regard, it is proposed that paragraph 1, part 1 of Article 290 of the Civil Code of Ukraine be worded as follows: "An adult person has the right to be a donor of blood, its components, as well as organs and other anatomical materials, including

reproductive cells, tissues, as well as cryopreserved embryos, which were created for the customers of reproductive services, but were not used for their treatment".

In the literature, the position is expressed that the donation of in vitro embryos is an act, in particular, a voluntary act of subjects of civil rights, which consists in giving written consent to the use of embryos belonging to them for the treatment of other patients of in vitro fertilization programs, as a result of which the authority to dispose of embryos in vitro, aimed at terminating their ownership by alienation in favor of other persons. The subject of donation is cryopreserved embryos in vitro, regardless of the presence of a genetic link with patients who consent to donation. The subject composition of the embryo donation deed depends on the anonymity or non-anonymity of the donation. If the donation is anonymous, the parties to the transaction are the donor and the health care institution. In the case of non-anonymous addressed donation, the parties to the transaction are the donor and the recipient, and the health care institution performs exclusively intermediary functions, without acquiring ownership rights to the donor embryos. If the donors are a spouse or a man and a woman who are not in a registered marriage, then the donation of embryos is carried out with their mutual consent. At the same time, consent to embryo donation can be withdrawn before the recipient's implantation, provided that the costs of embryo storage in the cryobank are compensated. Considering the legal nature of embryo donation as the free provision by donors of their biological material for the purpose of using in vitro fertilization programs for the treatment of infertility of other patients, which is close to the legal construction of donati, it seems that the payment of monetary compensation to donors for donor embryos will be contrary to the norms of the law[31].

Therefore, in our opinion, it would be most correct to consider that in vitro embryos created as a result of the use of assisted reproductive technologies are the result of the patient/patients exercising their reproductive rights and they have the right to determine the possibility of their use within the limits established by law. From the proposed wording, firstly, it will follow that in vitro embryos, which are created as a result of partial or complete use of donor biological material at the request of persons to whom assisted reproductive technologies are applied, will have this personal connection only with the customer-parents and not there will be an ethical dilemma concerning biological parents (donors of reproductive cells) as to who should have the right to determine their future fate. Second, it would also mean that embryos could only be created for reproductive purposes, and an assisted reproduction facility would not have the discretion to create or dispose of in vitro embryos without the proper written consent of the requesting parents. And, thirdly, it will exclude the possibility of treating such embryos as objects of real property law[32].

CONCLUSIONS

Note that not every cell we receive will become an embryo. Only 30-50% of cells grow to a certain stage of the embryo, which can be transferred by reproductive specialists to the cavity of the woman's uterus. Others are filtered out due to genetic diseases or mutations. Therefore, not every cell will become an embryo and not every embryo is implanted and therefore cannot be considered a subject of law, but it cannot be attributed to the object of law. Considering the above, we can determine that a human embryo is a special object with the characteristics of a creature. Embryo donation is a free expression of the will of donors in compliance with the legal conditions defined by the regulatory act.

Today in Ukraine the issues of using unimplanted embryos are outside the legal field. From this we can conclude that the anatomical materials of the dead (dead) embryo, whether implanted or not, can be removed both for scientific research within the statutory (subject to approval of the study by the ethics committee) and for therapeutic purposes (for cell transplantation), subject to the relevant proposed amendments to the legislation to comply with the requirements of Article 18 of the Convention on Human Rights and Biomedicine. Instead, the creation and further use of embryos for any purpose other than reproduction is illegal and should be prohibited by law with the imposition of appropriate criminal penalties.

Non-implanted embryos and embryo-fetal materials, as well as cells derived from them, are biological material of individuals, a carrier of genetic information of the patient/patients to whom assisted reproductive technologies were applied, and in the case of embryos or fetuses removed from

[31] Krushel'nyts'ka Hanna. Tsyvil'no-pravovi aspekty donatsiyi embrioniv lyudyny in vitro. Pidpryyemnytstvo, hospodarstvo i pravo. 2021. №3. С.43-49 С.48 (In Ukrainian).

[32]. Kvit N.M. Pravovyy rezhym neimplantovanoho embriona in vitro z pozytsiy doktryny, tsyvil'noho zakonodavstva ta sudovoyi praktyky. *Chasopys Kyyivs'koho universytetu prava*. 2020. №2 С. 241 С.238-242(In Ukrainian).

a woman's body - it is a woman's biological material. Assignment of embryos and embryo-fetal materials to the category of biological material does not mean that they are subject to the rules of property law, but they should be considered as special objects that are under state protection and are in close legal personal relationship with the above entities, who are given the right to determine their future fate within the limits established by law.

The right to dispose of embryos for research purposes may be granted by the woman and the man for whom the embryo was created, subject to informed consent and consent to the processing of personal data. The healthcare facility/medical research center as the owner determines the level of access of health workers to the information of personal data of embryo managers by restricting a certain range of subjects (researcher, doctor, junior specialists with medical education, members of consultations, consultants, etc.). Each of these workers has access only to the embryo examination data that he needs in connection with the performance of his professional/official/work duties. The healthcare professional, as the person who has access to the embryo examination, must sign a written commitment to medical confidentiality and give a written commitment not to disclose personal data and information about the embryo examination entrusted to them or which became known to them in connection with the implementation. professional/official/labor duties. All requests for access to the results of the embryo examination must be in writing.

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