Chapter 1

In Search of an International Standard for the Use of Assisted Reproductive Technologies



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Abstract

The use of assisted reproduction techniques (ART) concerns one of the most intimate spheres of human life, which is procreation. It is therefore not surprising that ART is of interest not only to medicine, ethics and religion, but also to law. Lawyers are trying to answer the question, among others, whether it is possible to create an international complete and consistent standard (system) regulating the use of assisted reproductive technologies. Such a standard (at least in principle) should take into account both universal human rights based on the respect for and the protection of human dignity and freedom, as well as the specificity of regional and national ethical, cultural, religious and social and, of course, legal contexts. The aim of this study, which is the eponymous search for an international standard for the application of ART, will be achieved by means of a legal and comparative analysis taking into account acts of international law of a universal and regional nature, selected case law and literature on the subject.

Keywords: assisted reproductive technologies (ART), best interest of the child, dignity, human reproduction, human rights, international law

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1. Introduction

The World Health Organization (WHO)[1] defines infertility as a disease in which a woman does not get pregnant after 12 months of regular intercourse (2–4 times a week) without using any contraceptive methods.[2] *A contario* definition of reproductive health – developed at the International Conference on Population and Development in Cairo[3] – 'reproductive disease' is the inability of partners to have a satisfactory sexual life and the inability to fulfil their reproductive goals. What is more, the WHO also recognises infertility as a social disease, which means that it is a widespread, chronic, difficult to treat disease, requiring long-term and regular medical care. Infertility limits the ability to perform basic life tasks and poses a significant problem not only for the individual, but also for the entire society.[4] Such a position is criticised primarily due to the fact that the disease affects a single person, in its course there are several periods and the disease can be acute, subacute and chronic. As noted in the literature on the subject,

> Infertility is a completely different and quite specific disease, because its basic feature is the lack of a child in a partnership. It does not cause pain (in the physical sense), does not lead to disability and is not life-threatening. It concerns a married couple, and it often happens that each partner may, in a different relationship, have a child separately. The way to overcome it (cure) is to get pregnant and give birth to a healthy child.[5]

Regardless of the dispute outlined above on the classification of infertility as a disease, it has been recognised by the World Health Organization (WHO) as a significant health problem requiring action in the field of medical care, as well as the creation of an appropriate legal basis for the regulatory framework. Progress in the field of solving the problem of infertility (disease) has made it possible for many people who did not have such a chance to realise their dreams of parenthood.[6] However, the dynamic development of medical technologies in the area of assisted reproductive techniques (hereinafter: ART), such as *in vitro* fertilisation (hereinafter: IVF), embryo

1 The Constitution of the World Health Organization (WHO) was signed on July 22, 1946, in New York during the International Health Conference. As part of this conference, the Agreement establishing the Interim Commission and the Protocol concerning the International Office of Public Hygiene were also concluded.

2 Rowe et al., 2000; See pacjent.gov.pl, 2024; this position has been formulated in WHO documents such as the 'International Classification of Diseases' (ICD-10), where infertility is classified under codes N46 (male infertility) and N97 (female infertility).

3 Reproductive health is a state of physical, mental, and social well-being in all matters related to the reproductive system. Health population and development, See Cook and Fathalla, 1996, pp. 115–121.

4 Łepecka-Klusek et al., 2012, pp. 163–166.

5 Ibid.

6 Ibid.

cryopreservation or gamete donation, raises numerous legal, ethical and social challenges. The problem of infertility is solved on several levels.[7] The first is the national level, which is characterised by a variety of medical practices and legal standards. In some countries, assisted reproductive techniques are widely available and well regulated, while in others, the lack of legislation leads to the abuse or restrictions on access for individuals and couples wishing to use these methods.[8] The second level of solving the problem of infertility is the international level, both regional and universal.[9] Regional – supranational organisations, such as the European Union, and universal ones, such as the World Health Organization, in the absence of initiative on the part of some countries or the lack of a uniform approach to assisted reproductive techniques, are trying to create a certain standard for the use of assisted reproductive techniques. In this sense, among other things, it can be said that the application of ART is an international problem.[10]

An important aspect of international deliberations on ART is to ensure a balance between scientific progress and the protection of fundamental human rights, such as the right to start a family, privacy or individual dignity.[11] In addition, there are questions about the limits of permissible interventions in reproductive processes, such as genetic modification or cloning, which raise both hopes and ethical controversies.[12]

The aim of this Study is to answer the question whether it is possible to create a complete and coherent international standard (system) regulating the use of assisted reproductive techniques, which would take into account both the specificity of local ethical, cultural, legal, religious and social contexts, as well as universal human rights based on respect for and protection of human dignity and freedom.[13] The legal analysis will be carried out on the basis of acts of international law of universal and regional character, selected case law and literature on the subject. The Study will also attempt to identify the challenges and opportunities for the harmonisation of regulations in the face of the so-called globalisation of medical services and the dynamic development of reproductive technologies.

7 Cook and Fathalla, 1996, pp. 115–121.
8 Van Voorhis, 2007, pp. 379–386.
9 Lampman and Dowling-Guyer, 1995, pp. 213–222; Wischmann et al., 2001.
10 Griessler et al., 2022.
11 Klusek et al., 2012, pp. 163–166.
12 Szamatowicz, 2004, pp. 21–24.
13 Page, 2024.

2. The Concept and Classification of Assisted Reproductive Technologies

Analyses of the title issue should begin with the definition of assisted reproduction technologies. The key definition was formulated in 'The International Glossary on Infertility and Fertility Care, 2017' developed by an international team of scientists composed of: Fernando Zegers-Hochschild, G. David Adamson, Silke Dyer, Catherine Racowsky, Jacques de Mouzon, Rebecca Sokol, Laura Rienzi, Arne Sunde, Lone Schmidt, Ian D. Cooke, Joe Leigh Simpson and Sheryl van der Poel.[14] The glossary contains a set of 283 consensus-based and evidence-driven terminologies used in infertility, and fertility care has been generated through an inclusive consensus-based process with multiple stakeholders. It should be emphasised that the definitions contained in 'The International Glossary on Infertility and Fertility Care' were developed by a team of twenty-five experts who worked in five working groups examining: clinical definitions, outcome measurements, embryology laboratory, clinical and laboratory andrology and epidemiology and public health. The experts included in their research the first glossary of 53 terms, which was published by the International Committee for Monitoring Assisted Reproductive Technologies (ICMART) in 2006, and an extended version of this glossary, containing 87 terms, which was published by ICMART together with the WHO in 2009. However, it was recognised that there was a need for a new improved glossary that would address, among others, the male factor, demography, epidemiology and public health issues.

Assisted reproduction technology is defined as follows:

> All interventions that include the *in vitro* handling of both human oocytes and sperm or of embryos for the purpose of reproduction. This includes, but is not limited to, IVF and embryo transfer ET, intracytoplasmic sperm injection ICSI, embryo biopsy, preimplantation genetic testing PGT, assisted hatching, gamete intrafallopian transfer GIFT, zygote intrafallopian transfer, gamete and embryo cryopreservation, semen, oocyte and embryo donation, and gestational carrier cycles. Thus, ART does not, and ART-only registries do not, include assisted insemination using sperm from either a woman's partner or a sperm donor.

A broader term in relation to 'assisted reproduction technology, ART' is 'medically assisted reproduction, MAR'. This concept, in 'The International Glossary on Infertility and Fertility Care, 2017', is defined as follows:

> Reproduction brought about through various interventions, procedures, surgeries and technologies to treat different forms of fertility impairment and infertility. These include ovulation induction, ovarian stimulation, ovulation triggering, all ART

14 Zegers-Hochschild et al., 2017.

procedures, uterine transplantation and intrauterine, intracervical and intravaginal insemination with the semen of husband/partner or donor.

The definitions of ART and MAR referred to above are recommended by the European Society of Human Reproduction and Embryology (ESHRE) and the American Society for Reproductive Medicine,[15] therefore it is difficult to overestimate their importance for the further considerations contained in this study.

Assisted reproductive technology (ART) is a broad category of medical procedures and technologies that aim to support reproductive processes in individuals and couples experiencing difficulties in conceiving naturally.[16] ART includes a variety of methods that interfere with the natural biological processes of fertilisation, both through stimulation of ovulation, manipulation of reproductive cells, and fertilisation outside the mother's body.[17] Modern ART technologies are evolving dynamically, leading to an increasing number of available methods, but also to ethical and legal challenges.[18]

At the beginning it should be noted that 'assisted reproductive technologies' are not the same as 'assisted reproductive techniques' and 'medically assisted procreation'.[19] The concept of 'assisted reproductive techniques' includes specific medical procedures that help treat infertility by manipulating eggs, sperm, and embryos. These are methods used as part of assisted reproductive technologies.[20] 'Assisted reproductive technology', on the other hand, is a term that encompasses all tools, devices, equipment and procedures used in the treatment of infertility.[21] Technology is a broader concept that includes assisted reproduction techniques, but also other aspects, such as diagnostics, ovulation cycle monitoring, laboratory methods or new biotechnological solutions. Examples of assisted reproductive technologies include: embryoscope systems, i.e. devices that facilitate the continuous monitoring of embryos without removing them from the incubator; preimplantation genetic testing (hereinafter: PGT), i.e. the examination of embryos for genetic defects before transfer into the uterus; artificial intelligence technologies in embryology, i.e. algorithms that analyse the quality of embryos and predict their implantation potential, as well as automated systems for freezing and storing gametes and embryos.[22] Thus, 'assisted reproductive technologies' encompass the entire set of tools, procedures and devices that support fertility treatment, including both techniques and innovative technological solutions.[23]

15 ASRM, 2017.
16 Wołczyński, 2006.
17 Alon et al., 2019, pp. 1665–1681.
18 Czajkowska et al., 2015, pp. 57–69; Wołczyński and Radwan, 2011.
19 Trolice, 2011, pp. 12–19.
20 Łukaszuk et al., 2018, pp. 112–140.
21 Ibid.
22 Cybulska, 2019.
23 Łukaszuk et al., 2018, pp. 112–140.

Medically assisted procreation (hereinafter: MAR) is a technique and procedure used to treat infertility and assist in human reproduction. MAR covers both assisted reproductive techniques (ART) and other medical procedures to support conception. MAR is therefore a broader concept, covering not only laboratory technologies (part of the ART), but also procedures supporting natural conception.[24] Non-invasive methods of assisted reproduction include ovulation stimulation (pharmacological induction of ovulation in women with ovulation disorders), ovulation cycle monitoring (tracking natural fertility to increase the chances of conception) and intrauterine insemination (IUI – placing sperm in the uterine cavity at the time of ovulation).[25] On the other hand, advanced MAR techniques, which are part of ART, include: *in vitro* fertilisation (IVF – *In vitro* Fertilisation – combining an egg and sperm outside the woman's body), ICSI (Intracytoplasmic Sperm Injection – microinjection of sperm into an egg), cryopreservation of gametes and embryos (freezing of eggs, sperm and embryos for later use) and preimplantation diagnostics (PGT – genetic analysis of embryos before their implantation).[26] Thus, MAR is a comprehensive set of infertility treatment methods, including both natural and advanced assisted reproductive techniques (ART).[27]

Returning to the title 'assisted reproduction techniques', their classification is based on distinguishing basic and advanced assisted reproduction techniques.[28]

One of the basic and simplest methods of ART is intrauterine insemination (IUI), which involves introducing previously prepared semen into the uterine cavity during ovulation. It is used in the case of problems with sperm quality, cervical abnormalities or unexplained infertility.[29] *In vitro* fertilisation (IVF), on the other hand, involves the collection of eggs and their fertilisation in laboratory environment outside the woman's body. The embryos created by fertilisation are then transferred to the uterus. IVF is used in cases of obstruction of the fallopian tubes, endometriosis, problems with sperm quality, as well as other causes of infertility. Part of the *in vitro* (IVF) procedure is embryo transfer (ET), which involves inserting embryos into the uterus. The selection of embryos for transfer is often based on a prior assessment of their quality.[30]

The group of advanced assisted reproduction techniques includes, in the first place, Intracytoplasmic Sperm Injection (ICSI), which involves injecting a single sperm directly into the cytoplasm of the egg cell.[31] This technique is used in cases of severe male infertility when sperm counts are very low or have limited motility. Preimplantation genetic diagnosis (PGD), on the other hand, is a method that allows

24 Bączyk-Rozwadowska 2018.
25 Bagińska, 2020, pp. 321–331.
26 Kapelańska-Pręgowska, 2014.
27 Nadon et al., 2021, pp. 3021–3024.
28 Cohen, 2015, pp. 452–465.
29 Łukaszuk et al., 2018, pp. 112–140.
30 Safjan, 1990.
31 Kuczyński, 2005, pp. 109–113.

embryos to be tested for genetic defects before they are transferred to the uterus.[32] PGD is especially important for people with inherited genetic diseases. Embryo and egg freezing (Cryopreservation) is the process of freezing eggs, sperm or embryos for storage and use at a later time. This method increases time flexibility in family planning and is particularly important for people undergoing cancer treatment.[33]

The so-called advanced assisted reproduction techniques also include egg and embryo donation (oocyte donation and embryo donation), which is an alternative for couples who cannot use their own gametes. Like surrogacy,[34] however, it is an issue that raises numerous ethical and legal controversies, especially in the context of the anonymity of donors and the rights of children born from such procedures.

In creating a conceptual network related to assisted reproduction techniques and technologies, modern technologies and innovations used in infertility treatment are also worth mentioning.

Advances in molecular biology have made it possible to use technologies such as CRISPR-Cas9 to modify the genome of embryos. The introduction of genetic changes in embryos is aimed at eliminating genetic diseases, but it raises ethical controversies related to the possibility of abuse in the form of the so-called 'designer babies'.[35] Technologies related to the artificial uterus are currently in the experimental phase, but their potential in the future could completely change the way pregnancies are managed.[36] This solution could be used in cases when a natural pregnancy or surrogate pregnancy is not possible. In the absence of appropriate legal regulations, further development of gamete and embryo biobanks should also be expected. Biobanks provide the storage of reproductive cells and embryos for medical, scientific or social purposes. This solution is especially popular among women who want to delay motherhood, but maintain the possibility of getting pregnant at a later age.[37]

To conclude this part of the analysis, it should be noted that there is no uniform definition and classification of these methods, despite the fact that ART are used globally.[38] Each of these techniques is followed with specific legal, ethical and social challenges that require careful consideration at national and international levels. Differences in terminology, as well as in legal regulations between individual countries, make it difficult to harmonise international standards.[39]

32 Jain and Singh, 2021, pp. 1–10.
33 Mikuła and Rybczyński, 2006, pp. 145–163.
34 A procedure in which a woman (surrogate) agrees to carry a pregnancy to term for another person or couple. It can include both traditional surrogacy (where the surrogate also provides her egg) and gestational (where the embryo is entirely of the genetic origin of the future parents).
35 Nowacka and Kopania, 2016, pp. 107–130.
36 De Jonge and Barratt, 2002.
37 Stoczyńska-Fidelus and Rieske, 2021, pp. 175–182.
38 Łepecka-Klusek et al., 2012, pp. 163–166.
39 Safjan, 1990.

3. International Universal Legal Bases for The Application of ART

International and national laws that relate to assisted reproductive techniques (ART) are intrinsically linked to human rights issues.[40] Regulations at the international level, despite their diversity, provide an important framework for legislative activities and practical implementation in individual countries.[41] In this section, acts of international law of a universal nature, regional regulations and initiatives of international organisations that affect the standards of application of ART will be discussed in detail.

3.1. Acts of International Law of an Universal Nature Indirectly Affecting ART

3.1.1. Universal Declaration of Human Rights

The Universal Declaration of Human Rights was adopted by the UN General Assembly in 1948,[42] which means that it does not refer directly to assisted reproductive techniques for objective reasons. Although these technologies did not yet exist at the time of its adoption, several of its provisions may be applicable in the context of the right to use ART. Art. 16 should be considered elementary in this respect – the right to found a family, which reads 'Men and women of full age, without any limitation due to race, nationality or religion, have the right to marry and to found a family'. This provision can be interpreted as the right to access assisted reproduction methods for people who have difficulty conceiving a child naturally.[43] Art. 3 – The right to life, liberty and security of person 'Everyone has the right to life, liberty and security of person' can be interpreted in the context of the right to reproductive health, which includes access to fertility treatments.[44] Art. 12 of the Convention – Protection of Privacy and Family may serve to protect the right to make decisions concerning one's own reproductive health, including the use of assisted reproductive methods without interference from the state or society. It follows from its content that 'No one shall be subjected to arbitrary interference with his privacy, family, home or correspondence, nor to attacks upon his honour and reputation'.[45] Art. 25 of the Convention – The right to a standard of living ensuring health and well-being – also indirectly refers to the discussed issue: 'Everyone has the right to a standard of living adequate for the health and well-being of himself and of his family, including food, clothing, housing

40 Safjan, 1990.
41 Griessler et al., 2022.
42 Universal Declaration of Human Rights. (adopted and proclaimed resolution of the United Nations General Assembly. 217 A (III) on 10 December 1948).
43 Kulczyk and Puppinck, 2018, pp. 18–30.
44 Gugla, 2018, pp. 107–126.
45 Babula, 2019, pp. 121–136

and medical care and necessary social services [...]'. It can be considered that the right to health also includes access to infertility treatment and assisted reproductive techniques.[46] The prohibition of discrimination is being increasingly noticed in the context of access to assisted reproductive techniques. In this context, Art. 7 of the Convention – Equality before the Law and Non-Discrimination 'All are equal before the law and are entitled without any discrimination to equal protection of the law'. Access to assisted reproductive techniques should not be restricted on the basis of gender, social status, sexual orientation or other factors.[47]

3.1.2. International Covenants on Rights of 1966

The standard of human rights protection created by convention guarantees relating to the most important spheres of human life has been developed under the UN system, among others, in the international Covenants on Human Rights of 1966.[48]

Thus, Art. 17 – Protection of Private and Family Life of the International Covenant on Civil and Political Rights contains the guarantee 'No one shall be subjected to arbitrary or unlawful interference with his privacy, family, home or correspondence, (...)'. It means that the state should not restrict access to assisted reproductive techniques and interfere in decisions regarding procreation.[49] On the other hand, Art. 23 – the right to marry and the right to found a family, which reads as follows: 'The family is the natural and fundamental group unit of society and is entitled to protection by society and the State' includes, among others, the right to have children, which could indicate the need to ensure access to infertility treatments.[50]

Furthermore, in the International Covenant on Economic, Social and Cultural Rights of 1966 it is possible to indicate two Arts indirectly referring to assisted reproductive techniques. The first of them is Art. 10 – Protection of the family and motherhood 'The States Parties to the Covenant recognise that the widest possible protection and assistance should be accorded to the family, which is the natural and fundamental group unit of society, (...)'. It is argued that supporting access to assisted reproduction methods is part of the protection of marriage and family.[51] Similarly, Art. 12 – Guarantee of the right to the highest attainable level of physical and mental health – refers only indirectly to the title issue. Access to ART can be seen as part of the implementation of this right, particularly in the context of reproductive health.[52]

46 Bucińska, 2003, pp. 121–136.
47 Florczak-Wątor and Kowalski, 2019.
48 International Covenant on Civil and Political Rights, opened for signature in New York on 19 December 1966, United Nations Treaty Series, vol. 999, p. 171.; International Covenant on Economic, Social and Cultural Rights, opened for signature in New York on 19 December 1966, United Nations Treaty Series, vol. 993, p. 3.
49 Kubicki, 1999.
50 Sękowska-Kozłowska, 2012.
51 Schulz, 2018, pp. 448–512.
52 B. Pawelczyk, 2018, pp. 595–624.

It is worth noting that in its General Comments the UN Committee on Economic, Social and Cultural Rights emphasises the need for equal access to health services, including reproductive health.[53] Of particular importance is General Comment No. 14 of 2000 – The Right to the Highest Attainable Standard of Health. The Committee defines the right to health as the right to enjoy a range of services, goods and conditions necessary to achieve the highest possible standard of physical and mental health.[54] It is pointed out that health services should be accessible to all, without any kind of discrimination, and they should take into account the principles of cultural acceptability and quality. In addition, the importance of reproductive health is highlighted, including access to sexual health education and information, as well as to family planning services. In General Comment No. 22 of 2016 – The Right to Sexual and Reproductive Health, the Committee points out that the right to sexual and reproductive health is an integral part of the right to health. It also stresses the obligation of states to ensure universal access to sexual and reproductive health services, including contraception, prenatal care and safe abortion where legal.[55] The Committee calls for the elimination of all forms of discrimination in access to these services, especially against women, young people, LGBTQ+ people and other marginalised groups. In the General Comments referred to above, the Committee stresses that states have a duty to ensure equal and non-discriminatory access to health services, including reproductive health, as a fundamental element of the implementation of the right to health.

3.1.3. Convention on the Rights of the Child

The Convention on the Rights of the Child, adopted by the United Nations in 1989, does not directly refer to assisted reproductive techniques, like the above-mentioned documents of international law, but it contains several provisions that can be interpreted in the context of children born through these methods and the rights related to their legal status and protection.[56] In this context, reference is primarily made to Art. 3 of the Convention – Best Interests of the Child: 'In all actions concerning children, whether undertaken by public or private social welfare institutions, courts of law, administrative authorities or legislative bodies, the best interests of the child shall be a primary consideration'.[57] The guarantee resulting from this provision is that regulations concerning assisted reproductive techniques should, first of all, take into account the good of children conceived as a result of these procedures. This

53 Unic Warsaw, 2018.
54 Committee on Economic, Social and Cultural Rights, General Comment 14, 2000.
55 Committee on Economic, Social and Cultural Rights, General Comment 22, 2016.
56 Convention on the Rights of the Child, adopted by the General Assembly of the United Nations on 20 November 1989, United Nations Treaty Series, vol. 1577, p. 3.
57 Cała-Wacinkiewicz and Szwed, 2022, pp. 111–124.

includes the creation of appropriate rules on parenthood, parentage rights, and legal protection for children born as a result of ART.[58]

Important guarantees regarding ART arise from Art. 7 of the Convention – Right to identity and to know one's parents

> The child shall be registered immediately after birth and shall have the right from birth to a name, the right to acquire a nationality and as far as possible, the right to know and be cared for by his or her parents.

This article addresses the issue of anonymous gamete donation and the child's right to know his/her genetic origins.[59] In many countries, there are debates about whether children born through gamete donation should have the right to know their donor.[60] An extension of these guarantees is Art. 8 – Preservation of Identity, in which 'States Parties undertake to respect the right of the child to preserve his or her identity, including nationality, name and family relations as recognised by law without unlawful interference'.[61] In the context of ART, this provision should refer to the protection of the identity of children born through assisted reproductive techniques, especially in cases of surrogacy and gamete donation.[62] In turn, in Art. 9 – Right to Parenting

> States Parties shall ensure that a child shall not be separated from his or her parents against their will, except when competent authorities subject to judicial review determine, in accordance with applicable law and procedures, that such separation is necessary for the best interests of the child.[63]

This provision should be addressed to surrogacy and the issue of the legal recognition of parenthood in the case of children born abroad as a result of ART.[64] The last provision of the Convention on the Rights of the Child that should be mentioned in the context of assisted reproductive technologies is Art. 24 – Right to Health 'States Parties recognise the right of the child to the enjoyment of the highest attainable standard of health (...)'.[65] Children, regardless of the method of conception, should have access to health care and monitoring of the long-term effects of these procedures.[66]

58 Kondratiewa-Bryzik, 2009.
59 Bosek, 2008, pp. 947–984.
60 Burtowy and Zajączkowska-Burtowy, 2020, pp. 101–115.
61 Schulz, 2012, pp. 79–118.
62 Łukasiewicz, 2023, pp. 58–101.
63 Holewińska-Łapińska, 2008, pp. 119–179.
64 Mostowik, 2019.
65 Kosińska, 2014, pp. 79–100.
66 Haberko 2010.

3.1.4. Universal Declaration on the Human Genome and Human Rights – UNESCO

International – universal guarantees concerning human rights are created as part of the activities of specialised United Nations organisations, which deal with diverse areas such as health care, agriculture and meteorology. These institutions coordinate their work with the UN through special agreements, but remain separate, autonomous organisations. These include: the International Labour Organization (ILO),[67] the Food and Agriculture Organization of the United Nations (FAO),[68] the Educational, Scientific and Cultural Organization of the United Nations (UNESCO),[69] and the World Health Organization (WHO).

It was the United Nations Educational, Scientific and Cultural Organization (UNESCO) that adopted the Universal Declaration on the Human Genome and Human Rights on November 11, 1997.[70] Although the declaration does not contain direct provisions on assisted reproductive technologies in general, *in vitro* fertilisation (IVF) or gamete donation in its actual form, it does introduce general principles for the protection of the human genome, which have an impact on the ethical and legal aspects of assisted reproductive techniques (ART).

As follows from Art. 1 of the Declaration, 'The human genome is the common heritage of humanity', and Art. 2 reaffirms that 'Human dignity requires recognition and respect for the human genome'. It is difficult to overestimate the significance of these formulations, since they clearly indicate the need to respect human genetic material, including embryos created as a result of *in vitro* fertilisation.[71]

According to Art. 5 of the document, 'Any intervention concerning the human genome may be carried out only after obtaining the free and informed consent of the person concerned'. Therefore, each person participating in ART procedures (e.g. gamete donors, recipients, parents) must consciously consent to their involvement. This also applies to the examination of embryos before implantation and the storage of gametes and embryos. These guarantees may affect, for example, regulations on embryo storage, preimplantation testing (PGT) and gamete donation.[72] The declaration reiterates the provisions of the Universal Declaration of Human Rights and the International Covenant on Civil and Economic Rights regarding the right to privacy.

The above guarantees are to a certain degree complemented by Art. 12 of the Universal Declaration, which states that 'Research on the human genome should be

67 Constitution of the International Labour Organization, adopted in 1919, League of Nations Treaty Series (LNTS), vol. 1, p. 22.

68 Constitution of the Food and Agriculture Organization of the United Nations, signed in Quebec on 16 October 1945, United Nations Treaty Series (UNTS), vol. 1, p. 3.

69 Convention concerning the Establishment of the United Nations Educational, Scientific and Cultural Organization (UNESCO), signed in London on 16 November 1945, United Nations Treaty Series (UNTS), vol. 4, p. 275.

70 Universal Declaration on the Human Genome and Human Rights – UNESCO.

71 Tabaszewski, 2016.

72 Gradocka and Kowalski, no date.

conducted with respect for human rights and ethical and legal principles'. This way, UNESCO not only supports embryo genome research, which is conducted in accordance with ethical and legal principles, but also indirectly influences the permitted genetic research in the ART, e.g. the selection of embryos for health.[73]

Extremely important provisions from the aspect of the application of ART are contained in Art. 10 of the Declaration, which prohibits reproductive cloning: 'Practices contrary to human dignity, such as cloning human beings for reproductive purposes, must not be carried out'. This means, first of all, that cloning as a method of assisted reproduction is not permissible. Unfortunately, the document does not refer to therapeutic cloning, which can be used in medical research. This raises the question of the axiological coherence of the Declaration and its provisions contained in Arts 1 and 2 concerning respect for dignity.

The Universal Declaration on the Human Genome and Human Rights supports ensuring equal access to ART for all, regardless of economic status, as well as it can influence the regulation of ART's funding by health care systems. This primarily ensues from Art. 14, which reads as follows: 'Progress in genetics should be used to improve public health' and Art. 19 'States should cooperate to guarantee equal access to genetic therapies'.

In Art. 11 of the Universal Declaration on the Genome, UNESCO also formulated a prohibition of genetic discrimination in access to ART: 'It is not allowed to discriminate against individuals on the basis of their genetic characteristics'. This provision may be the basis for counteracting discrimination in access to ART, e.g. for people with genetic defects. It also applies to access to preimplantation diagnostics (PGT), which allows the detection of genetic diseases before embryo implantation.[74]

Thus, as the analysis of selected provisions demonstrate, the Declaration on the Human Genome and Human Rights does not refer directly to ART, but its provisions on the protection of human dignity, genetic privacy, the prohibition of cloning and equality in access to genetic therapies have a key impact on the ethical and legal aspects of assisted reproductive techniques.[75]

3.2. Examples of International Expert Documents on Assisted Reproductive Techniques

3.2.1. Declaration of Sexual and Reproductive Rights

The Declaration of Sexual and Reproductive Rights was adopted by the World Association for Sexual Health (WAS) in 1999 and updated in 2014. The purpose of this document is to define fundamental human rights in the area of sexual and reproductive health. It can therefore serve as a basis for national and international health

73 Kaźmierczak, 2022.
74 Krekora-Zając, 2014.
75 Birenbaum-Carmeli and Inhorn, 2009.

policies and actions for equality and human rights, which is why it is referred to as a reference document.[76]

The Declaration distinguishes 16 basic sexual rights, such as: the right to equality and non-discrimination (Everyone is entitled to enjoy all sexual rights free from discrimination on the basis of sex, sexual orientation, age, race, religion or social status), the right to autonomy and bodily integrity (Everyone has the right to make decisions about their own body and sexual health, including access to contraception, abortion and health care), the right to sexual and reproductive health (States should ensure access to sex education, medical care and treatment for sexually transmitted diseases), the right to sexual information and education (Everyone has the right to reliable, scientific and age-appropriate sexual education), the right to sexual freedom (Freedom from sexual coercion, exploitation, violence and intolerance), the right to a life free from sexual violence (Everyone has the right to protection from sexual violence, including rape, forced marriage, child exploitation and trafficking), the right to sexual privacy (Includes protection of gender identity, sexual orientation and intimate relationships), the right to decide about one's own fertility (Everyone should be able to freely decide whether to have children, use family planning methods and access ART (assisted reproductive techniques) services, the right to live in a society free from discrimination and sexual prejudice (Governments should prevent homophobia, transphobia and all forms of intolerance) and the right to equality in marriage and relationships (Everyone has the right to choose a partner and equality in the rights to marry and adopt children).[77]

The rights referred to above included in the Declaration of Sexual and Reproductive Rights may result in the impact of the document on at least three areas related to assisted reproductive techniques. Since the Declaration provides for the right to decide about one's own fertility, thus, support for the legality of *in vitro* fertilisation (IVF), gamete donation or even surrogacy can be concluded from the document. Indicating the right to privacy and bodily autonomy consequently leads to the fact that every person has the right to decide about his/her body, including the use of assisted reproductive techniques without unnecessary restrictions. The declaration guarantees equality in access to ART, so states should not discriminate, for example, against single women or same-sex couples in access to reproductive methods.

The content of the document clearly shows support for the rights of women, LGBTQ+ people and sexual minorities fighting discrimination and coercion in the field of sexual health, as well as the promotion of sex education, which should be based on science and devoid of ideology, knowledge about sexual health, which unfortunately is not lacking in the document.[78] In the Declaration of Sexual and Reproductive Rights there is too little content concerning respect for human dignity

76 Dobrowolska, 2016, pp. 163–181.
77 Bassa, 2012, pp. 363–377.
78 Birenbaum-Carmeli and Inhorn, 2009.

and the rights of conceived children, also with the use of assisted reproductive techniques.[79]

3.2.2. Casablanca Declaration

The Casablanca Declaration was announced on March 3, 2023 in Casablanca (Morocco) by an international group of experts, including lawyers, doctors and psychologists, from more than 75 countries.[80] The purpose of the declaration is to strive for the universal abolition of the practice of surrogacy (surrogacy). The parties of the Declaration emphasise that surrogacy violates the dignity of women and children, leading to their objectification and commercialisation,[81] and therefore call on states to take action to prohibit surrogacy at the national level, declare surrogacy agreements invalid, punish individuals and entities supporting such practices, and promote an international convention to prohibit surrogacy globally.

The Casablanca Declaration does not only refer to surrogacy related to the use of assisted reproductive techniques. It is an important step towards international cooperation to protect human rights and counteract the commercialisation of human reproduction. The parties of the Declaration call for a total prohibition of surrogacy, which directly affects ART practices that include surrogacy.[82]

The signatories of the Casablanca Declaration, by emphasising the need to protect the dignity and rights of women and children, can indirectly contribute to the tightening of regulations on ART procedures to prevent their potential abuse.

The postulate of adopting an international convention prohibiting surrogacy should be considered extremely valuable. The declaration may thus affect the harmonization of ART regulations at a global level. It can also lead to the revision of existing practices and regulations, especially in the area of surrogacy, and convince states to introduce stricter laws to protect human rights.[83]

79 Glińska, 2016, pp. 35–52.
80 Declaration-surrogacy-casablanca.org, 2023.
81 Ibid.
82 Horsey, 2024.
83 Ordoiuris, 2024.

4. European Guarantees

4.1. The European Convention for the Protection of Human Rights and Fundamental Freedoms and the Jurisprudence of the European Court of Human Rights

The unquestionable contemporary European foundation of the system of human rights protection is the European Convention on Human Rights, adopted by the Council of Europe in 1950.[84] It does not directly regulate assisted reproductive techniques, which is obvious due to the time of its creation, but at least five Arts. of the Convention have been repeatedly interpreted by the European Court of Human Rights in cases concerning, above all, *in vitro* fertilisation (IVF), surrogacy and rights to parenthood.

In the first place, it is necessary to point to Art. 8 of the Convention – Right to respect for private and family life:

> Everyone has the right to respect for his private and family life, his home and his correspondence. There shall be no interference by a public authority with the exercise of this right except such as is in accordance with the law and is necessary in a democratic society (...).[85]

The right to decide on starting a family also includes the right to use assisted reproductive techniques. States can regulate access to ART, but they cannot arbitrarily restrict these techniques if it would violate the right to private life.[86]

In the context of assisted reproductive techniques, reference should first be made to the judgement of the ECtHR Evans v. the United Kingdom of 10 April 2007.[87] The judgement was issued on the basis of the following factual and legal situation. Natallie Evans and her partner Howard Johnston submitted themselves to the *in vitro* fertilisation (IVF) procedure in 2001 because Evans was diagnosed with a tumour that required removal of her ovaries, which made her unable to conceive naturally. The couple mutually agreed to create and freeze embryos to use for implantation in the future.[88] After the breakup, Johnston withdrew his consent to the use of embryos. British law required the consent of both parties for each phase of the process,

84 Convention for the Protection of Human Rights and Fundamental Freedoms, signed in Rome on 4 November 1950, subsequently amended by Protocols No. 3, 5, and 8 and supplemented by Protocol No. 2, European Treaty Series (ETS) No. 5.

85 Kwiatkowski, 2019, pp. 179–192.

86 Łącki and Wróblewski, 2016, No. 3, pp. 21–37; Łącki and Wróblewski, 2013, pp. 51–74; Wiśniewski, 2011, pp. 433–450; Mirocha, 2018, pp. 164–188; Łukasiewicz 2023, pp. 58–101.

87 Nowicki, 2008.

88 Łącki and Wróblewski, 2016, pp. 21–37.

so the clinic had to destroy the embryos.[89] Natallie Evans claimed that the withdrawal of consent by her ex-partner violated her right to have a biological child, because after cancer treatment she had no other option to get pregnant. In her view, the destruction of the embryos violated the right to respect for private and family life[90] and that her interest in having a child outweighed her ex-partner's interest in refusing paternity.[91] The Court found that there was no violation of Art. 8 of the ECHR. It decided that the right to respect for private life includes both the right to have children and the right not to have them. Since the partner consented to the creation of embryos, but had the right to withdraw it later, the national law did not violate the ECHR. The Court found that the State had a wide 'margin of assessment' in regulating assisted reproductive techniques, and that British law was consistent with the principle of voluntary reproduction.[92] From the point of view of the relation between Art. 8 of the Convention and assisted reproductive technologies, the judgement confirmed that the consent of both partners is necessary at every stage of the ART. The Court in Strasbourg found that both the right to have children and the right not to have them are of equal importance, in other words, the decision of one partner not to use embryos cannot be imposed by the other.[93] From the point of view of ART, the ruling on the margin of assessment of states within the scope of ART is also extremely important, as the Court admitted that ART regulations differ between countries and there is no uniform international norm. Unfortunately, the judgement did not decide whether embryos have the right to legal protection as 'persons', but only indicated that their fate is subject to national law.[94]

The second extremely important case setting standards for the use of assisted reproductive techniques based on the provisions of the European Convention for the Protection of Human Rights and Fundamental Freedoms is S.H. and Others v. Austria.[95] The judgement in the first instance was issued on 1 April 2020, and the Grand Chamber decided on 3 November 2011. The Court found that Austria has the right to prohibit the donation of reproductive cells, leaving the decision on ART to the discretion of the Member States.[96] The judgement was issued on the basis of the following factual and legal situation. The case was about two couples from Austria who could not have children naturally and wanted to use assisted reproduction methods.[97] However, Austrian law prohibited the use of egg donation (oocytes) and sperm donation in combination with *in vitro* fertilisation (IVF). The couples argued that the

89 Human Fertilisation and Embryology Act 1990.
90 Art. 8 of the ECHR.
91 Mirocha, 2018, pp. 164–188.
92 Falski, 2016, pp. 9–24.
93 Kurosz, 2017, pp. 105–118.
94 Wiśniewski, 2011, pp. 433–450.
95 Nowicki, 2012.
96 Piaskowska and Piesiewicz, 2018, pp. 13–22.
97 Mirocha, 2018, pp. 164–188.

prohibition of Austrian law violates their right to private and family life[98] and the prohibition of discrimination[99] because the prohibition deprives them of the possibility of having a biological child, even though ART technology is sufficient enough to solve their health problem.[100] The couples also pointed out the disproportionality of the restriction, as other ART techniques (e.g. donor insemination) were legal, so the ban was not consistent.[101] With regard to the prohibition of discrimination,[102] the applicants argued that other European countries allow oocyte and sperm donation, so Austria should not restrict access to these methods.

At first instance, the Court found that the prohibition was disproportionate and violated Art. 8 of the ECHR and that Austria was inappropriately restricting access to ART, and that the technology should be accessible to those who needed it. The Court also noted that the State had not demonstrated sufficient reasons justifying the prohibition. With the judgement of the Grand Chamber, the Court radically changed its position and found that Austria had not violated the Convention. The Grand Chamber found that States have a wide 'margin of assessment' in regulating ART, because there are no uniform standards in Europe.[103] The lack of general consensus on the admissibility of gamete donation in ART justified that Austria could determine the rules of access to these technologies independently. The Court found that the prohibition in Austrian national law was intended to protect the child, family relationships and to avoid ethical problems related to the separation of genetic and biological parenthood.[104] Importantly, in the opinion of the Grand Chamber, a country cannot be forced to legalise a particular ART technique if the legal system considers it undesirable. The most important findings of the judgement, from the aspect of shaping the European standard for the use of assisted reproductive technologies, include the lack of a uniform standard in Europe,[105] and therefore States have the right to regulate access to ART according to their own value system and legal regulations,[106] consequently the right to family life[107] does not mean an automatic right to ART.[108] The Court also noted that the use of assisted reproductive techniques raises a number of problems, not only of a legal nature concerning, for example, the identity of the child and the risk of 'genetic selection'. Thus, the *judgement* of the Grand Chamber *of*

98 Art. 8 of the ECHR.
99 Art. 14 of the ECHR.
100 Wiśniewski, 2011, pp. 433–450.
101 Łącki and Wróblewski, 2013, pp. 51–74.
102 Art. 14 of the Convention.
103 Kwiatkowski, 2019, pp. 179–192.
104 Piaskowska; Piesiewicz, 2018, pp. 13–22.
105 In the opinion of the Court, legal differences within the scope of ART are admissible, which means that, for example, in France, Italy or Germany different regulations may apply than in Austria.
106 Not every restriction of ART is a violation of human rights, and as a result, States may prohibit gamete (sperm and oocyte) donation in IVF if they consider it in the public interest.
107 Art. 8 ECHR.
108 There is no 'right to the child' under the ECHR. The Court held that the right to family life includes the possibility of using the ART, but does not oblige the State to make it available.

S.H. and Others v. Austria confirmed that States have the right to regulate access to ART, including prohibiting certain methods (e.g. gamete donation) if they consider it in the public interest, and that the ECHR does not guarantee an automatic right to ART.[109]

The third case, which should be indicated as an important stage and element in the development by the European Court of Human Rights of the European standard for the use of assisted reproductive techniques, is Costa and Pavan versus Italy.[110] The Court decided on August 28, 2021, that the prohibition of preimplantation genetic diagnosis (PGT) in the case of the risk of transmitting genetic diseases violates the right to family life. The judgement was issued on the basis of the following factual and legal situation. Mrs. Costa and Mr. Pavan were carriers of cystic fibrosis, a genetic disease that they could pass on to their offspring.[111] However, Italian law prohibited preimplantation diagnosis (PGT) as part of *in vitro* fertilisation (IVF). Instead, the applicants could only conceive naturally and have prenatal diagnosis performed, and then – if the child had cystic fibrosis – they could decide to have a therapeutic abortion (which was legal).[112] As in the case referred to above, the applicants argued that the prohibition of PGT violated their right to private and family life, a right guaranteed by Art. 8 of the ECHR, because it prevented them from making a conscious decision about the health of their child. In Costa and Pavan's view, the prohibition of PGT, while at the same time legalising therapeutic abortion, is illogical and mutually contradictory, since it allows the late removal of the affected foetus, but not the early prevention of the disease. Moreover, the limitations in the ART in the Italian legal system – in their opinion – constitute discrimination,[113] because people who can become pregnant naturally have better opportunities to make decisions about the health of the child than couples who require ART.[114]

The Strasburg Court found that Italy had violated Art. 8 of the ECHR because the ban on PGT is disproportionate and does not give parents the opportunity to make conscious decisions about their child's health. The Court also pointed out the lack of legal coherence, since Italy allowed therapeutic abortion; therefore, the prohibition of preventing the disease before pregnancy was illogical. In the Court's view, excessive restrictions on ART violate the autonomy of parents and force them to make more difficult decisions in the later stages of pregnancy.[115]

Therefore, the two extremely important decisions of the Court in this case should be considered the link between preimplantation diagnosis (PGT), which is one of the key ART techniques, enabling the examination of embryos for genetic defects before implantation, with the right to privacy guaranteed by the Convention, since the

109 Łącki and Wróblewski, 2013, pp. 51–74.
110 Nowicki, 2013.
111 Łącki and Wróblewski, 2016, pp. 21–37.
112 Łącki and Wróblewski, 2013, pp. 51–74.
113 Art. 14 of the ECHR.
114 Kwiatkowski, 2019, pp. 179–192.
115 Łącki and Wróblewski, 2013, pp. 51–74.

prohibition of PGT violates the right to privacy and autonomy of parents in making reproductive decisions.[116] Second, in the context of the prohibition of discrimination, States cannot discriminate against couples using ART, since therapeutic abortion is legal, PGT should also be available as an alternative. ART should therefore be available on an equal basis for all couples. In *Costa and Pavan v. Italy*, the Court set a precedent for PGTs, indicating that the prohibitions on ART must be justified and proportionate.[117] In other words, the judgement in *Costa and Pavan v. Italy* confirmed that ART techniques, such as preimplantation diagnosis (PGT), are part of the right to private and family life, and that their prohibition, especially when the state allows therapeutic abortion, may violate the ECHR.

The Department for the Execution of Judgements of the European Court of Human Rights in its study on reproductive rights draws attention to another issue, important from the point of view of ART.[118] It is about the legal recognition of the parent-child relationship between biological fathers and their children born abroad thanks to surrogacy. Surrogacy is a separate and important legal problem occurring in the jurisprudence of the European Court of Human Rights, related to the title issue of ART. Although the issue of surrogacy goes beyond the scope of this study, it is worth pointing out the issues raised in the document prepared by the Department for the Execution of Judgements of the European Court of Human Rights.

Several cases decided by the ECtHR concerned the violation of the applicants' right to the private life of children born abroad as a result of surrogacy, due to the refusal by the authorities to recognise and thus establish a legal parental-animal bond with their biological fathers under national law.[119] The Strasbourg Court ruled that the consequences of the non-recognition of this legal family tie in French law are not limited only to the parents, but also affect the children themselves, whose right to respect for their private life – which means that everyone must be able to establish the essence of his/her identity, including the legal bond of kinship – is significantly violated.

The jurisprudence of the European Court of Human Rights in this area is important because the Court strongly stands on the side of the good interests of the child. It is to be hoped that this is the direction in which the next rulings related to the issues of ART and surrogacy will go.

116 Kwiatkowski, 2019, pp. 179–192.

117 As a consequence of the judgement, Italy had to change its law and allow PGT in certain cases.

118 Department for the Execution of Judgments of the European Court of Human Rights, Reproductive rights.

119 See ECtHR's ruling of 26 September 2014 in the case of *Mennesson v. France*, Application No. 65192/11; ECtHR's ruling of 26 September 2014 in the case of *Labasse v. France*, Application No. 65941/11; ECtHR's ruling of 19 January 2017 in the case of *Laboire v. France*, Application No. 44024/13; ECtHR's ruling of 21 September 2016 in the case of *Foulon and Bouvet v. France*, Application No. 9063/14.

In conclusion, it should be stated that the ECtHR had a great influence on shaping legal standards for ART in Europe through its jurisprudence.[120]

4.2. The Oviedo Convention

The Convention for the Protection of Human Rights and Dignity of the Human Being in the Context of Applications of Biology and Medicine regulates the applications of biology and medicine.[121] The purpose of the Convention is to protect human dignity and the resulting freedoms and rights of the individual in the context of new medical technologies and biomedical research. Art. 1 is of key importance in this respect, in which the principle of the primacy of human dignity and rights has been formulated, and science and medicine must serve the human being.[122] It is also worth noting the provisions of Art. 11 on the prohibition of genetic discrimination and Arts. 15 and 16, which state that scientific research on humans must be conducted in an ethical manner with respect for the rights of participants.[123]

120 See ECtHR's ruling of 15 September 2009 in the case of *Amato Gauci v. Malta*, Application No. 47045; ECtHR's ruling of 21 February 1975 in *Golder v. the United Kingdom*; Application No. 4451/70; ECtHR's ruling of 6 September 1978 in the case of *Klass and Others v. Germany*, Application No. 5029/71; ECtHR's ruling of 13 June 1979 in the case of *Marckx v. Belgium*, Application No. 6833/74; ECtHR, 22 October 1981, *Dudgeon v. the United Kingdom*, Application No. 7525; ECtHR, Judgement of 25 March 1983, *Silver and Others v. the United Kingdom*, Application No. 5947/72 and others; ECtHR's ruling of 26 March 1985 in *X and Y v. the Netherlands*, Application No. 8978/80; ECtHR, 28 May 1985, *Abdulaziz, Cabales and Balkandali v. the United Kingdom*, Applications Nos. 9214/80, 9473/81 and 9474/81, see also: ECtHR's ruling of 04 May 2021 in the case of *Jurčić v. Croatia*, Application No. 54711/15; ECtHR's ruling of 24 March 2014 in the case of *Topcic-Rosenberg v. Croatia*, Application No. 19391/11; ECtHR's ruling of 04 December 2007 in the case of *Dickson v. United Kingdom*, Application No. 44362/04; ECtHR's ruling of 11 February 2013 in the case of *Costa and Pavan v. Italy*, Application No. 54270/10; ECtHR's ruling of 14 March 2011 in the case of *Ternowszky v. Hungary*, Application No. 67545/09; ECtHR's ruling of 26 September 2014 in the case of *Mennesson v. France*, Application No. 65192/11 ECtHR's ruling of 26 September 2014 in the case of *Labassee v. France*, Application No. 65941/11; ECtHR's ruling of 19 January 2017 in the case of *Laborie v. France*, Application No. 44024/13; ECtHR's ruling of 21 October 2016 in the case of *Foulon and Bouvet v. France*, Application No. 9063/14; ECtHR's ruling of 16 December 2010 in the case of *A. B. and C. v. Ireland*, Application No. 25579/05; ECtHR's ruling of 29 October 1992 in the case of *Open Door and Dublin Well Women v. Ireland*, Application No. 14234/88; CtHR's ruling of 03 May 2009 in the case of *Women on Waves and Others v. Portugal*, Application No. 31276/05; ECtHR's ruling of 18 March 2013 in the case of *G.B. and R.B. v. Moldova*, Application No. 16761/09; ECtHR's ruling of 08 February 2012 in the case of V.*C. v. Slovakia*, Application No. 18968/07; ECtHR's ruling of 12 June 2012 in the case of *N.B. v. Slovakia*, Application No. 29518/10; ECtHR's ruling of 15 July 2014 in the case of *Radu v. Moldova*, Application No. 50073/07; ECtHR's ruling of 06 November 2009 in the case of *K.H. and Others v. Slovakia*, Application No. 32881/04; ECtHR's ruling of 10 June 2015 in the case of *Y.Y. v. Turkey*, Application No. 14793/08.

121 Convention for the Protection of Human Rights and Dignity of the Human Being with regard to the Applications of Biology and Medicine (Convention on Human Rights and Biomedicine), adopted by the Committee of Ministers on 19 November 1996).

122 Biesaga, 2006, pp. 24–28.

123 Winter, 1997, pp. 73–77.

Although the Convention does not refer directly to assisted reproductive techniques, its provisions may have an impact on their regulation, especially in the context of the protection of embryos. It follows from Art. 18 of the Convention that research on human embryos may be carried out only within the limits of national law, which has an impact on the issues of cryopreservation of embryos and their use.[124] The Convention also prohibits cloning in human reproduction. In addition, the prohibition of genetic discrimination refers, among others, to preimplantation genetic testing (PGT). The Oviedo Convention is relatively commonly considered to be a key document in the field of bioethics and human rights in medicine, although it does not comprehensively regulate issues related to assisted reproductive techniques.[125]

4.3. European Union Law

The European Union does not have a uniform legal act regulating assisted reproductive techniques, but certain standards result from the Charter of Fundamental Rights of the European Union,[126] the Treaty on European Union,[127] the Treaty on the Functioning of the European Union[128] and the directives on health and safety, in particular Directive 2004/23/EC[129] and Implementing Directives 2006/17/EC[130] and 2006/86/EC.[131]

The key provisions indirectly relating to assisted reproductive techniques are found primarily in the Charter of Fundamental Rights and in the Treaty on the Functioning of the European Union. In the first of these documents, modelled on the European Convention for the Protection of Rights and Fundamental Freedoms, the system of protection of individual freedoms and rights was based on the principle

124 Roscam Abbing, 1998, pp. 377–387.

125 Safjan, 2000, pp. 5–18.

126 Charter of Fundamental Rights of the European Union, Official Journal of the European Union, C 303/1, 14 December 2007.

127 Treaty on European Union, Official Journal of the European Union, C 325, 24 December 2002.

128 Treaty on the Functioning of the European Union, Official Journal of the European Union, C 325, 24 December 2002.

129 It sets out quality and safety requirements for the collection, storage and use of human cells, including gametes and embryos. Directive 2004/23/EC of the European Parliament and of the Council of 31 March 2004 on setting standards of quality and safety for the donation, procurement, testing, processing, preservation, storage and distribution of human tissues and cells, Official Journal of the European Union, L 102, 7 April 2004.

130 Commission Directive 2006/17/EC of 8 February 2006 implementing Directive 2004/23/EC of the European Parliament and of the Council as regards certain technical requirements for the donation, procurement and testing of human tissues and cells, Official Journal of the European Union, L 327, 24 November 2006.

131 Commission Directive 2006/86/EC of 24 October 2006 implementing Directive 2004/23/EC of the European Parliament and of the Council as regards traceability, notification and notification requirements for serious and adverse reactions and occurrences and certain technical requirements for the coding, processing, preservation, storage and distribution of human tissues and cells, Official Journal of the European Union, L 294, 25 October 2006.

of respect and protection of human dignity formulated in Art. 1 – Human dignity: 'Human dignity is inviolable. It must be respected and protected'.[132] This principle affects the regulations on embryo protection and ethical aspects of assisted reproduction methods.[133] Consequently, the obligation to respect human dignity prohibits inhumane treatment of persons using ART, including forced donation of gametes or the use of ART in a manner contrary to ethics. Human dignity sets a specific standard for the implementation of individual freedoms and rights guaranteed by the Charter.[134]

A right that is undoubtedly associated with the use of assisted reproductive techniques is the right to the integrity of the person. According to Art. 3 of the Charter,

> In the fields of medicine and biology, the following must be respected, in particular: (a) the free and informed consent of the person concerned, according to the procedures laid down by law; b) the prohibition of eugenic practices, in particular those aiming at the selection of persons; c) the prohibition on making the human body and its parts as such a source of financial gain; d) the prohibition of the reproductive cloning of human beings.[135]

These guarantees indicate the right to conscious consent for medical procedures, including those related to the use of ART, the prohibition of genetic selection and reproductive cloning, which affects the genetic testing of embryos, and limits the commercialisation of ART, e.g. the sale of eggs and commercial surrogacy.[136]

As in the case of the European Convention on Human Rights and Fundamental Freedoms, Art. 7 of the Charter of Fundamental Rights of the EU implies respect for private and family life, which includes the possibility of using ART methods, if Member States deem it compatible with health policy.[137] The right related to the use of assisted reproductive techniques is the right to marry and found a family,[138] included in Art. 9 of the Charter of Fundamental Rights. The last of the rights that should be indicated as forming the basis of the ART standard in the European Union is formulated in Art. 35 – Right to health care: 'Everyone has the right of access to preventive health care and the right to benefit from medical treatment under the conditions established by national laws and practices'.[139] The meaning of these regu-

132 Stefanicki, 2009, pp. 6–22.
133 Kondratiewa-Bryzik, 2009.
134 Koncewicz, 2012, pp. 171–181.
135 Pyziak-Szafnicka, 2016, pp. 21–26.
136 Wnukiewicz-Kozłowska, 2012, pp. 55–76.
137 Schulz, 2012, pp. 79–118.
138 This law is at times interpreted to mean that States can regulate access to ART, but cannot arbitrarily restrict this right, e.g. by prohibiting ART from same-sex couples or single people. See Osiejewicz, 2015, pp. 24–30.
139 Wróbel, 2014, pp. 104–108.

lations leads to the statement that EU Member States can regulate the availability of ART independently, but equality in access to healthcare should be ensured.[140]

In addition to the above-mentioned provisions of the Charter of Fundamental Rights of the EU, which obligate to respect and protect human dignity and guarantee the right to the integrity of the person, respect for private and family life, the right to marry and establish a family, and the right to health care, the prohibition of discrimination is of key importance from the EU perspective. According to Art. 21 of the Charter of Fundamental Rights,

> Any discrimination based on any ground such as sex, race, colour, ethnic or social origin, genetic features, language, religion or belief, political or any other opinion, membership of a national minority, property, birth, disability, age or sexual orientation shall be prohibited.[141]

Therefore, EU Member States must not discriminate against unmarried women, same-sex couples or people with disabilities in access to ART. The prohibition of discrimination may also be grounds for challenging restrictions on access to ART in individual countries.[142]

Legal analyses concerning the standard of assisted reproductive techniques in the European Union law cannot omit several provisions of the Treaty on European Union and the Treaty on the Functioning of the European Union. In the first of them, Art. 5, the principle of subsidiarity (subsidiarity) was formulated.[143] The European Union has no competence to impose uniform regulations in the field of ART. The Union can only coordinate health policies and ensure that national regulations do not violate the fundamental rights of citizens.[144] This means that it is up to the Member States to decide whether to allow surrogacy, IVF, gamete donation or PGT.

In the TFEU, on the other hand, the issue of ART is indirectly addressed by a provision concerning public health.[145] It follows from Art.icle168 TFEU ('The Union's actions shall be aimed at improving public health, preventing diseases and eliminating sources of threat to physical and mental health'.) that the EU may coordinate health policies concerning ART, but may not impose uniform regulations on the Member States. Provision on the harmonisation of rules[146] ('The Union may adopt measures for the harmonisation of national law if this is necessary for the proper functioning of the internal market'[147]) may be the basis for the introduction of common regulations

140 Kuciński, 2011, pp. 19–46.
141 Maliszewska-Nienartowicz, 2021, pp. 35–48.
142 Szpunar, 2015, pp. 4–10.
143 Tomaszewski, 2020, pp. 171–184.
144 Gagatek, 2013, pp. 31–39.
145 Jończyk, 2007, pp. 4–9.
146 Art. 114.
147 Czapliński, 2004.

on ART in the field of cross-border procedures, e.g. the donation of reproductive cells or the recognition of parenthood in the case of surrogacy.[148]

In addition to the above-mentioned provisions of the Treaty of Lisbon, the European Union has introduced directives aimed at establishing quality and safety standards for the collection, testing, processing, storage and distribution of human tissues and cells, which also include gametes and embryos. An example is Directive 2004/23/EC of the European Parliament and of the Council of 31 March 2004.[149] It lays down quality and safety standards for the donation, procurement, testing, processing, preservation, storage and distribution of human tissues and cells intended for human use. Although the Directive does not directly address assisted reproductive techniques, some of its provisions address this issue.[150] Firstly, the Directive sets out the eligibility criteria for donors of tissues and cells, including germ cells, to ensure that the risk of transmission of infectious diseases to recipients is minimised. Second, it sets standards for methods of tissue and cell collection and mandatory testing to ensure their quality and safety. Third, the Directive imposes the obligation to apply appropriate procedures and conditions for the processing, preservation, storage and distribution of tissues and cells in order to maintain their integrity and functionality. Fourth, it requires the establishment of a system for monitoring and reporting serious adverse events and responses related to the collection, testing, processing, storage and distribution of tissues and cells. Finally, the Directive requires that all tissues and cells be traceable from donor to recipient and vice versa, in order to ensure safety and responsiveness when hazards are detected.[151]

As it can be observed from these decisions, the Directive in the context of ART aims to ensure that all procedures related to the use of reproductive cells meet high standards of quality and safety, thus protecting the health of both donors and recipients.

The analysis of European Union law on assisted reproductive techniques should be complemented by the European Parliament resolution of 24 June 2021 on the situation of sexual and reproductive health and rights in the EU, in the light of women's health.[152] The European Parliament treats reproductive health (along with sexual health) as an essential element of good health.[153] In this regard, the Member States

148 Malczewska, 2020, pp. 4–19.

149 By way of example, it should be pointed out that, for example, Poland, implementing these directives, introduced appropriate legal regulations, such as the Act on Infertility Treatment and the regulations of the Minister of Health on training in the collection, processing, storage, testing and distribution of reproductive cells and embryos intended for use in the procedure of medically assisted procreation.

150 Grabowska, 2015, pp. 245–252.

151 Ibid.

152 The resolution was adopted on the basis of the Report of the Committee on Women's Rights and Gender Equality on the situation of sexual and reproductive health and rights in the EU in the context of women's health, A9-0169/2021.

153 European Parliament Resolution of 24 June 2021 on the situation of sexual and reproductive health and rights in the EU, in the frame of women's health.

are called to establish effective monitoring strategies and programmes to ensure universal access to the full range of quality and affordable sexual and reproductive health and rights services, in line with international health standards, regardless of the financial, practical and social obstacles and in a non-discriminatory manner, with a particular focus on marginalised groups, including women belonging to ethnic, racial and religious minorities, migrant women, women from rural areas and outermost areas where geographical restrictions prevent direct and immediate access to such services, women with disabilities, women without health insurance, LGBTI people and victims of sexual and gender-based violence. However, the part entitled 'Access to infertility treatment' is crucial from the aspect of ART. In issue 39 according to the Resolution, the European Parliament calls on the Member States to ensure that all persons of childbearing age have access to fertility treatment, regardless of their socio-economic situation, marital status, gender identity or sexual orientation; stresses the importance of comprehensive research into fertility in the EU as a public health issue and the prevalence of infertility and reduced fertility, which are difficult and painful for many families and individuals; calls on the Member States to adopt a holistic, rights-based, inclusive and non-discriminatory approach to fertility, including measures to prevent infertility and ensure equal access to services for all people of childbearing age, and to make artificial insemination available in Europe.[154]

It should be called to mind that European Parliament resolutions are official positions or appeals of the European Parliament adopted on specific political, social, economic, international or legal issues. However, they are legally non-binding in nature, although they can have a political influence on decisions taken in the European Union. Hence, the Resolution of 24 June 2021 'calls' on Member States to eliminate barriers to access to ART and to counteract all forms of discrimination in this regard, and 'highlights' the need to take into account the gender perspective and ensure equal access to health services for all, regardless of gender identity, sexual orientation or socio-economic status.[155]

To conclude the part of the discussion concerning the Treaty of Lisbon, it should be stated that it does not contain provisions directly referring to ART, but it introduces principles affecting the reproductive policy of EU countries. The provisions of the Charter of Fundamental Rights of the European Union protecting human dignity, the right to integrity, privacy and health protection, and prohibiting discrimination should be considered as the most important decisions concerning the title issue.[156] Moreover, it follows from the TEU and TFE that the EU cannot impose uniform regulations on ART, but it can influence the protection of human rights and the

154 European Parliament Resolution of 24 June 2021 on the situation of sexual and reproductive health and rights in the EU, in the frame of women's health (2020/2215(INI)), Official Journal of the European Union, C 81/4, 24 February 2022.

155 Staszczyk, 2013, pp. 251–263.

156 Stefanicki, 2009, pp. 6–22.

elimination of discrimination, which means – in accordance with the principle of subsidiarity – maintaining a certain autonomy of the Member States in the field of ART.[157]

5. Conclusions

The conducted legal analyses allow us to formulate ten conclusions regarding the eponymous search for an international standard for the use of assisted reproductive technologies.[158]

Firstly, international law instruments of a universal nature concerning the protection of human rights, such as the Universal Declaration of Human Rights of 1948, the International Covenant on Civil and Political Rights of 1966 and the International Covenant on Economic, Social and Cultural Rights of 1966, do not contain provisions directly relating to assisted reproductive technologies. This is mainly due to the time of their adoption by the United Nations and the fact that at the time these types of reproduction methods were unknown. In legal analyses based on these documents, assisted reproductive technologies are usually indirectly referred to by provisions concerning the right to privacy, the right to establish a family or the right to health protection.[159]

Secondly, the same is true for The Convention on the Rights of the Child. Although this document was adopted by the United Nations in 1989, the Arts. on the best interests of the child,[160] the right to identity and knowledge of one's parents,[161] the right to parenting[162] refer to ART only indirectly.

Thirdly, the general principles of human genome protection that affect the ethical and legal aspects of assisted reproductive technologies are contained in the Universal Declaration on the Human Genome and Human Rights of 11 November 1997 adopted by the United Nations Educational, Scientific and Cultural Organization (UNESCO). The provisions of this Declaration referring to human dignity should be considered extremely important: 'The human genome is the common heritage of humanity'[163] and 'Human dignity requires recognition and respect for the human genome'.[164]

Fourthly, it should be noted that the issue of the use of assisted reproductive technologies is addressed by so-called expert documents, such as: the Declaration

157 Kruk, 2016, pp. 28–51.
158 Cahn, 2015, pp. 751–765
159 López et al., 2021, pp. 1–12.
160 Art. 3 of the Convention.
161 Arts 7 and 8 of the Convention.
162 Arts 9 and 24 of the Convention.
163 Art. 1 of the Declaration.
164 Art. 2 of the Declaration.

of Sexual and Reproductive Rights was adopted by the World Association for Sexual Health in 1999, updated in 2014, and the Casablanca Declaration announced on March 3, 2023. In the first document, the rights of women, LGBTQ+ people and sexual minorities were reaffirmed. Unfortunately, it lacks guarantees concerning respect for human dignity and the rights of conceived children, also with the help of assisted reproduction techniques. The goal of the signatories of the Casablanca Declaration is to strive for the universal abolition of the practice of surrogacy (surrogacy).

Fifthly, in addition to universal documents, regional regulations are important for the development of international standards for the use of assisted reproductive technologies. Due to the perspective of the Central European countries, European regulations are of key importance in this respect, created both at the level of the Council of Europe (European Convention for the Protection of Human Rights and Fundamental Freedoms) and the European Union (the Treaty of Lisbon and other documents).

Sixthly, the 1950 European Convention on Human Rights and Fundamental Freedoms – because of its similarity to the Universal Declaration of Human Rights of 1948 and the International Acts of Rights of 1966 – does not contain provisions relating directly to ART.

Seventhly, in the case of the 'living instrument', which is the European Convention for the Protection of Human Rights and Fundamental Freedoms, the European Court of Human Rights plays an increasingly important role in the application of its Art. 8 (on the right to privacy) to ART. Examples of such a broad interpretation of the right to privacy are the judgements indicated in this study: Evans versus the United Kingdom, S.H. and Others versus Austria and Costa and Pavan versus Italy. The analyses allowed us to conclude that 'ECtHR had a great influence on shaping legal standards for ART in Europe through its jurisprudence'.

Eighthly, the key document in the field of bioethics and human rights in medicine in Europe is The Convention for the Protection of Human Rights and Dignity of the Human Being in the Context of Applications of Biology and Medicine, adopted by the Committee of Ministers on 19 November 1996. Although it does not refer directly to assisted reproductive techniques, its provisions may nevertheless have an impact on their regulation. It follows from Art. 18 of the Convention that research on human embryos may be carried out only within the limits of national law, which has an impact on the issues of cryopreservation of embryos and their use. The Convention also prohibits cloning in human reproduction.

Ninthly, the European Union has some references in its law to the issue of assisted reproductive technologies. The Charter of Fundamental Rights of the European Union contains provisions protecting human dignity, the right to integrity, privacy and health protection, and prohibiting discrimination. On the other hand, the TEU and TFE show that the EU cannot impose uniform regulations on ART, but it can influence the protection of human rights and the elimination of discrimination, which means – in accordance with the principle of subsidiarity – maintaining a certain autonomy of the Member States in the field of ART testing, processing, storage and

distribution of human tissues and cells, which also include gametes and embryos.[165] In addition, in the European Parliament Resolution of 24 June 2021 on the situation of sexual and reproductive health and rights in the EU in the frame of women's health, the European Parliament considers reproductive health (alongside sexual health) as an essential element of good health.

Tenthly, it should be expected that the Court of Human Rights in Strasbourg, which has a creative approach to its activities and is constantly striving to expand its competences, will attempt to influence the sphere of human life, which is reproduction, creating (or at least strive to create) specific standards in the field of assisted reproduction techniques.

In conclusion, the title research leads to the conclusion that the process of shaping the international standard for the use of assisted reproductive technologies, which has been ongoing since at least 1948 (the adoption of the Universal Declaration of Human Rights), has not ended. Moreover, the cultural, religious, social, and consequently legal pluralism of the contemporary world (including the European region) is unlikely to contribute in the coming years to the adoption of a single universal model for the application of ART.[166] Nevertheless, it remains imperative to persistently and unwaveringly advocate – contrary to the prevailing narrative – for the protection of the dignity and rights of not only parents but also, and perhaps most importantly, children, in the name of respecting their inherent dignity and best interest…

165 Directive 2004/23/EC, Implementing Directives 2006/17/EC and 2006/86/EC.
166 McDermott et al., 2022, pp. 1–12.

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