

The Current Status of Regulation Regarding Artificial Reproductive Technology in Japan and the Trends in Legal Development

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Abstract

The level of Artificial Reproductive Technology in Japan is high, and the country is at the forefront of the industry globally. However, the implementation of Artificial Reproductive Technology is self-regulated as per the guidelines of the Japan Society of Obstetrics and Gynecology. Nevertheless, given this situation, the need for legal regulation is currently being discussed. Many of the relevant judicial cases concern the determination of the parent-child relationship, and few have decided on the appropriateness of the implementation. Thus far, governmental review conferences and discussions have been carried out at the Science Council of Japan (1998-2008), and these talks have focused especially on the provision of sperm, ovum and surplus embryos, and surrogacy. While political parties have drafted legislative bills over recent years (2014-2016), it is still necessary to consider legislation. In this paper, we compare the guidelines and examination reports of governments, academic societies, and professional organizations, while also discussing recent trends and the perspectives of different political parties.

Introduction

The level of Artificial Reproductive Technology¹ in Japan is high, and there are many hospitals and clinics that perform the medical procedure. In recent years, advertisements for clinics that perform Artificial Reproductive Technology have become a common sight at stations and on streets. Gynecologists currently follow the guidelines of the Japan Society of Obstetrics and Gynecology to know what type of procedure is appropriate and what type should not be performed with respect to Artificial Reproduction Treatment.² However, there is an ongoing discussion regarding whether it is also necessary to establish legal regulations, and, since around 2000, such discussions have been held by public institutions (such as the Committee of the Ministry of Health, Labour and Welfare). As there are other countries that have enacted legislation concerning the regulation of Artificial Reproductive Technology,³ a focus has been placed on measures to be adopted in the future.

This paper organizes and introduces the status of both the development and diffusion of Artificial Reproductive Technology in Japan, the current status of the relevant regulations, and the status of discussions regarding the introduction of new regulations by government agencies and political parties.

I Development and Diffusion of Artificial Reproductive Technology

In 1948, Artificial Insemination by Donor (AID)⁴ was performed at Keio University, which led to the birth of a child the following year. This case is regarded as the first successful AID in Japan. Since then, spanning a period of more than 60 years, AID is being

* This paper is based on information published up to October 31, 2018. The last access date concerning Internet information is also the same date.

¹ In this paper, Artificial Reproduction Technology is assumed to include artificial insemination with donated sperm, In Vitro Fertilization-Embryo Transfer, Intracytoplasmic Sperm Injection, surrogacy, and gamete (sperm or ovum) or embryo (fertilized egg) cryopreservation, etc. The details of each of these technologies will be explained in the footnotes in the order they are presented in this paper.

² The specific guidelines are presented in “Table 2 Main Report of the Japan Society of Obstetrics and Gynecology Related to Artificial Reproductive Technology.”

³ 三輪和宏・林かおり「イギリスとフランスの生殖補助医療の制度」『レファレンス』788号, 2016.9, pp.29-51 (“The Legal Systems of Artificial Reproductive Technology in the UK and France”); 同「ドイツとイタリアの生殖補助医療の制度」『レファレンス』792号, 2017.1, pp.33-59 (“The Legal Systems of Artificial Reproductive Technology in Germany and Italy”); 泉真樹子「ドイツにおける生殖補助医療と出自を知る権利—精子提供者登録制度と血縁関係に関する立法—」『外国の立法』277号, 2018.9, pp.33-55 (“Artificial Reproductive Technologies and the Right of Donor-conceived Children to Know Their Biological Origins: Law on the Establishment of a Sperm Donor Registry and Amendments to the German Civil Code”).

⁴ A method in which sperm from a third party other than the partner (husband, etc.) is artificially injected into a female’s vagina, cervix, or uterine cavity for the purpose of achieving fertilization.

performed in Japan. In 1978, the world's first child conceived by In Vitro Fertilization-Embryo Transfer⁵ was born in the UK.⁶ In 1983, Japan's first case of childbirth by In Vitro Fertilization and Embryo Transfer was reported in Tohoku University Hospital.⁷

In the 1990s, treatment by Intracytoplasmic Sperm Injection (ICSI)⁸ for patients with refractory fertility disorders began to spread overseas. The first birth via Intracytoplasmic Sperm Injection (ICSI) was reported in 1994 at Fukushima Medical University Hospital.⁹ Recently, following advancements in technologies such as In Vitro Fertilization and Intracytoplasmic Sperm Injection (ICSI), the use of gametes (sperm or ovum) and embryos that have been cryopreserved¹⁰ has also increased. These changes are shown in Table 1, "The number of facilities providing Artificial Reproductive Technology and the number of birthed children in Japan." Both the number of facilities providing Artificial Reproductive Technology and the number of children born through Artificial Reproductive Technologies continue to increase,¹¹ and it is evident that Artificial Reproductive Technology is becoming more popular in Japan.

Given the above, Japan has a long history of Artificial Reproductive Technology, and

⁵ In Vitro Fertilization (IVF) is the fertilization of an ovum and sperm in an incubator. Embryo Transfer (ET) is the placement of an embryo into a female uterus. Similar to AID, there is In Vitro Fertilization and Embryo Transfer that use sperm, ovum, and embryo from a third party (individuals other than the couple (spouses, etc.)). A series of procedures in which Embryo Transfer is performed after In Vitro Fertilization is called "In Vitro Fertilization-Embryo Transfer (IVF-ET)."

⁶ A British couple who was unable to conceive naturally because of abnormalities in the fallopian tube succeeded in achieving conception and childbirth using In Vitro Fertilization Technology developed by Robert Geoffrey Edwards et al.

⁷ 「体外受精児 日本初の誕生」『毎日新聞』1983.10.14, 夕刊, p.1 ("Japan's First Childbirth Conceived by In Vitro Fertilization").

⁸ The technology called Intracytoplasmic Sperm Injection (ICSI), in which one sperm is directly injected into one ovum under a microscope, is used. ICSI is also called KENBI ZYUSEI. Strictly speaking, there are also other procedures, such as "YUSOHOU" (fenestration method) for KENBI ZYUSEI, but since ICSI is often used, ICSI and KENBI ZYUSEI are often synonymous. YUSOHOU is a method of helping the sperm pass through the zona pellucida by opening a hole in the zona pellucida, which surrounds the ovum, under the microscope.

⁹ 「卵細胞に精子注入し妊娠 福島の主婦、出産 国内初」『毎日新聞』1994.2.1, p.22 ("First in Japan: Fukushima Housewife Conceives through Intracytoplasmic Sperm Injection").

¹⁰ When the collected gametes or embryos are not used immediately, they should be stored frozen for a certain period using ultra-low temperature liquid nitrogen. Examples of the use of cryopreservation technology include: (1) If sperm of relatively good quality can be collected from a male infertile patient, it will be stored until the time of actual artificial insemination or In Vitro Fertilization; (2) The collected sperm will be stored until a negative result is obtained from the examination for infectious diseases; and (3) An embryo produced by In Vitro Fertilization will be stored until it is transplanted into a female body.

¹¹ However, this excludes the number of children conceived through AID. The number of children conceived through In Vitro Fertilization using frozen embryos and frozen ovum is increasing dramatically. Additionally, the reason why AID is not increasing is probably its low success rate (pregnancy rate). 「提供精子妊娠率 5%にとどまる 兵庫医大分析」『朝日新聞』2018.7.25, 夕刊, p.2 ("Hyogo Medical University Analysis: Pregnancy Rate of Donated Sperm at 5%").

the efficacy of such procedures is steadily increasing. From Chapter II onwards, the current status of Japan, as well as the discussions related to this status, will be introduced.

Table 1 The Number of Facilities Providing Artificial Reproductive Technology and the Number of Birthed Children in Japan

Year	Number of facilities ^{Note 1}	Number of birthed children ^{Note 2} (Unit: person)			
		Procedures using fresh embryos ^{Note 3} (In Vitro Fertilization except Intracytoplasmic Sperm Injection)	Procedures using fresh embryos (Intracytoplasmic Sperm Injection only)	Procedures using frozen embryos or frozen ovum (In Vitro Fertilization in general)	Artificial Insemination by Donor (AID)
1985	30	27	----	----	----
1986	30	16	----	----	----
1987	45	54	----	----	----
1988	92	114	----	----	----
1989	125	446	----	3	----
1990	156	1,031	----	17	----
1991	189	1,661	----	39	----
1992	237	2,525	35	66	----
1993	270	3,334	149	71	----
1994	303	3,734	698	144	----
1995	348	3,810	1,579	298	----
1996	388	4,436	2,588	386	----
1997	394	5,060	3,249	902	----
1998	442	5,851	3,701	1,567	188
1999	471	5,870	4,247	1,812	221
2000	511	5,447	4,582	2,245	121
2001	552	5,829	4,862	2,467	142
2002	578	6,443	5,486	3,299	133
2003	590	6,608	5,994	4,798	142
2004	627	6,709	5,921	5,538	129
2005	641	6,706	5,864	6,542	94
2006	575	6,256	5,401	7,930	117
2007	606	5,144	5,194	9,257	98
2008	609	4,664	4,615	12,425	76
2009	625	5,046	5,180	16,454	97
2010	591	4,657	5,277	19,011	53
2011	586	4,546	5,415	22,465	92
2012	589	4,740	5,498	27,715	120
2013	587	4,776	5,630	32,148	109

2014	598	5,025	5,702	36,595	100
2015	607	4,629	5,761	40,611	86
2016	604	4,266	5,166	44,678	99
2017	(605) ^{Note 4}	----	----	----	----
2018	(615) ^{Note 4}	----	----	----	----

(Note 1) The number of facilities refers to the number of facilities performing Artificial Reproductive Technology based on the system of the Japan Society of Obstetrics and Gynecology. The same organization asks facilities performing Artificial Reproductive Technology to register with them.

(Note 2) The results of the clinical outcomes have been published in academic journals since 1990 through the registration reporting system for Artificial Reproductive Technology, such as In Vitro Fertilization, which was initiated by the Japan Society of Obstetrics and Gynecology in 1986. Table 1 shows the number of children born through In Vitro Fertilization using fresh embryos, In Vitro Fertilization using frozen embryos (ovum), and Artificial Insemination by Donor. “Procedures using fresh embryos (In Vitro Fertilization excluding Intracytoplasmic Sperm Injection)” has been reported to date back to 1985. However, results for “procedures using frozen embryos or frozen ova,” “procedures using fresh embryos (Intracytoplasmic Sperm Injection only),” and “Artificial Insemination by Donor” have been published since 1989, 1992, and 1998, respectively.

(Note 3) A method in which, after In Vitro Fertilization is performed on an ovum collected from the body, the fertilized ovum is cultured without freezing and is transplanted into the patient’s body in the same menstrual cycle of ovum pick-up.

(Note 4) Numerical values for 2017 and 2018 are as of July 31 in both years. For other years, numerical values are as of December 31 of each year.

(Source) Created by the authors based on reports for each year, such as 「平成 29 年度倫理委員会 登録・調査小委員会報告（2016 年分の体外受精・胚移植等の臨床実施成績および 2018 年 7 月における登録施設名）」『日本産科婦人科学会雑誌』70 巻 9 号, 2018.9, pp.1822, 1826 (“FY2017 Ethics Committee: Registration and Survey Subcommittee Report (2016 Clinical Results of In Vitro Fertilization and Embryo Transfer, etc. and the Names of Registered Facilities as of July 2018”).

II The Current Status of Regulation regarding Artificial Reproductive Technology

1 *The Outline of Discussions on Regulations and the Current Status of Artificial Reproductive Technology*

(1) Characteristics of Regulations According to the Guidelines of the Society

As mentioned in the Introduction, obstetricians and gynecologists currently follow the guidelines of the Japan Society of Obstetrics and Gynecology¹² regarding what type of procedure is appropriate and what type of procedure should not be performed when it comes to artificial reproduction treatment. Before discussing the details of the guidelines of the Japan Society of Obstetrics and Gynecology, this section first explains the characteristics of the current regulations on Artificial Reproductive Technology. In order to create improved regulation, this paper will also explain the background of the discussion about the necessity of introducing some sort of legal regulation.

Physicians performing medical care are tasked with determining the appropriateness of how medical procedures, including Artificial Reproductive Technology, should be

¹² See Chapter II 2(1) for an explanation regarding the same society.

applied to patients. However, in terms of Artificial Reproductive Technology, the Japan Society of Obstetrics and Gynecology has compiled guidelines regarding both the techniques that are generally considered preferable and those that should not be performed. These guidelines were presented to obstetrician and gynecologist members, who were strongly encouraged to abide by them. Obstetricians and gynecologists perform actual artificial reproduction treatment procedures according to the guidelines set forth by the Society. Under these circumstances, this is considered a “voluntary guideline”¹³ that obstetricians and gynecologists can abide by at their own discretion.¹⁴

Looking at examples stated in the guidelines, the “Opinion on the Prevention of Multiple Pregnancy in Artificial Reproductive Technology” (April 2008)¹⁵ states that, in order to prevent the occurrence of multiple pregnancy, which will place excessive strain on the mother, the number of embryos to be implanted during Embryo Transfer should be limited to one embryo as a general rule. For In Vitro Fertilization-Embryo Transfer in general, the “Opinion on In Vitro Fertilization-Embryo Transfer” (revised in June 2014)¹⁶ compiles and indicates the qualifications and levels of technical proficiency required by the physicians and other people tasked with the implementation.

Furthermore, the guidelines provide not only technical guidelines regarding Artificial Reproductive Technology but also those considered to be beyond technical guidelines for procedures, such as the following: (1) Who can undergo the procedure; (2) What type of treatment methods are considered to be undesirable in Japan, even if technically possible; and (3) Is it possible to use gametes or embryos obtained from a third party (a donor other than a couple) rather than from the couple. This is because the application of Artificial Reproductive Technology is technically safe and should not be understood only from the perspective of the high success rate of treatment.

Specifically, for example, an unmarried couple (or in some cases, an individual without a partner (spouse, etc.)) undergoes Artificial Reproductive Technology. A question, therefore, arises regarding whether or not to allow the couple or individual to bear a child. Situations similar to the aforementioned are tackled in the guidelines (“Opinion on In Vitro

¹³ 内閣府ホームページ「Q10 日本ではどの程度に不妊治療（生殖補助医療等）が普及していますか。」（“Q10: How Popular is Fertility Treatment (Artificial Reproductive Technology, etc.) in Japan?”).

¹⁴ This situation is called “self-regulation.” For example, “In Japan, the Opinion on In Vitro Fertilization and Embryo Transfer issued by the Japan Society of Obstetrics and Gynecology in October 1983, respects the limitation on the application of Artificial Reproductive Technology to married couples, and the use of donated gametes in In Vitro Fertilization and Embryo Transfer is subject to voluntary regulation by each facility.” 日本生殖医学会ホームページ「倫理委員会報告「第三者配偶子を用いる生殖医療についての提言」」2009.3 (“Ethics Committee Report: Recommendations on Reproductive Technology Using Donated Gametes”)

¹⁵ 日本産科婦人科学会ホームページ「生殖補助医療における多胎妊娠防止に関する見解」（“Opinion on the Prevention of Multiple Pregnancy in Artificial Reproductive Technology”）.

¹⁶ 日本産科婦人科学会ホームページ「体外受精・胚移植に関する見解」（“Opinion on In Vitro Fertilization-Embryo Transfer”）.

Fertilization-Embryo Transfer,” revised in June 2014).¹⁷ In other words, married couples can undergo the procedure since “the subject is a couple who strongly desires to bear a child and has adequate physical and mental condition to withstand pregnancy, childbirth, and childcare.” In addition to this, the guidelines also state that “the implementation of surrogacy¹⁸ is not permitted” in consideration of the physical dangers and mental strain borne by the subject of the procedure, as well as that “the contract of surrogacy is not ethically accepted by the society at large”¹⁹ in terms of the ethical factors. It also states that Artificial Reproductive Procedure through Embryo Transfer is not permitted since “the welfare of the child to be born should be given top priority” and that “the parent-child relationship is unclear,” which are reasons that extend beyond technical guidelines.²⁰ As detailed above, the guidelines set forth by the Japan Society of Obstetrics and Gynecology have a wide range of characteristics because they include both technical guidelines and ethical issues.

(2) Discussion on Regulations Based on Laws

Bearing such characteristics, the guidelines set forth by the Japan Society of Obstetrics and Gynecology function as a framework for the implementation of Artificial Reproductive Technology because obstetricians and gynecologists perform Artificial Reproductive Technology procedures according to them. As such, it is possible to evaluate the said guidelines. However, there are also discussions regarding the creation of a regulation based on laws designed to supplement the guidelines of the Society. The following points have been identified as examples based on this perspective: (1) The guidelines are not binding and cannot be sufficiently enforced; (2) Medical technology issues, as well as bioethical issues, must be addressed, making legal regulations preferable over academic guidelines; and (3) Civil Code issues, such as decisions on parent-child relationships, must be resolved. The Society has also called on the government to promptly create a framework for the proper implementation of reproductive procedures through sperm and ovum donation, such as the legislation on parent-child relationships under the civil law.²¹

¹⁷ *ibid.*

¹⁸ When a woman is unable to conceive because of having undergone a hysterectomy, a third party (surrogate (surrogate mother)) is asked to conceive and give birth to a child, which the requesting party takes.

¹⁹ 日本産科婦人科学会ホームページ「代理懐胎に関する見解」(“Opinion on Surrogacy”).

²⁰ 同上「胚提供による生殖補助医療に関する見解」(“Opinion on Artificial Reproductive Technology through Embryo Transfer”).

²¹ 「卵子提供「枠組み整備を」」『日本経済新聞』2013.1.19, p.34 (“Development of Framework for Ovum Donation”); 「産科学会「卵子提供で法整備を」」『朝日新聞』2013.1.19, p.37 (“Japan Society of Obstetrics and Gynecology Calls for Legislation on Ovum Donation”); 「適正な卵子提供へ 国に法整備求める 産科婦人科学会」『読売新聞』2013.1.19, p.38 (“Japan Society of Obstetrics and Gynecology: The Country Needs Legislation on Proper Ovum Donation”); 女性医局ホームページ「日本産科婦人科学会がコメント。「卵子の提供による生殖医療」

In particular, bioethical issues and Civil Code issues become more prominent when either the Artificial Reproductive Technology is not finalized between spouses or when a third party is involved. For example, the following questions arise: (a) Is the use of sperm, ovum, or embryo derived from a third party allowed?; (b) Is bearing a child through a third party surrogate allowed?; (c) Who is the legal parent of the child born?; (d) Is the child allowed the right to information that identifies their “biological parent”? There are several opinions stating that academic guidelines alone are not enough to provide a framework for the implementation of Artificial Reproductive Technology.²²

In response to such discussions, the Ministry of Health, Labour and Welfare, the Ministry of Justice, and political parties have conducted various studies. As a result of these studies, reports²³ outlining detailed considerations have been compiled. However, at present, no regulatory framework based on the law has been established. As for Artificial Reproductive Treatment, gathering opinions is an arduous task given that there is a wide variety of ideas that differ depending on the individual’s view of the family, etc.²⁴

The next section will introduce the outline of the guidelines of the Japan Society of Obstetrics and Gynecology, while also introducing the guidelines presented by other organizations (Japan Medical Association, Japan Society for Reproductive Medicine, Japanese Institution of Standardizing Assisted Reproductive Technology). At the end of this paper, we will publish Appendix 1 “Comparison of Guidelines by Academic and Professional Organization,” which compares the details of the guidelines compiled by the aforementioned four groups.

Next, in Chapter III, we will introduce the history of studies conducted by the Ministry of Health, Labour and Welfare, the Ministry of Justice, and different political parties. The introduction will deal specifically with parts related to Artificial Reproductive Technology (Artificial Reproductive Technology in the form of gametes and embryos donated from third parties (married couple, etc.), and surrogacy) involving third parties, which are often discussed in terms of implementation.

に関する報道について」2013.1.23 (“Japan Society of Obstetrics and Gynecology Comments Regarding Artificial Reproductive Technology through Ovum Donation”).

²² 「卵子提供の仲介 子供を守る法整備に踏み出せ」『読売新聞』2013.5.15, p.3 (“Ovum Donation Agency: A Step into Legislation Protecting Children”); 「生殖医療と子供 権利守るルールが必要」『毎日新聞』2013.12.15, p.5 (“Reproductive Treatment and Children: The Need for Rules that Protect Their Rights”); 「生殖医療 一線を引く議論を」『朝日新聞』2015.7.12, p.10 (“Reproductive Treatment: Discussions on Where to Draw the Line”); 「生殖医療は法の整備が急務だ」『日本経済新聞』2017.3.24, p.2 (“Reproductive Treatment Requires Urgent Legislation”). In particular, regarding the question who will be the “legal guardian,” there have been cases where parent-child relations were disputed in court. This point is described in detail in Chapter II-3.

²³ The report by the Ministry of Health, Labour and Welfare is discussed in Chapter III.

²⁴ 「凍結受精卵無断で使われ父親に」『日本経済新聞』2018.5.19, 夕刊, p.9 (“Frozen Fertilized Eggs Used without Permission of Father”).

2 Guidelines of the Japan Society of Obstetrics and Gynecology and other organizations

(1) Guidelines of the Japan Society of Obstetrics and Gynecology

The Japan Obstetrics and Gynecology Society was established in 1902. It is the largest academic society in the field of obstetrics and gynecology,²⁵ and aims to “contribute to the welfare of mankind and society through the advancement and development of obstetrics and gynecology” (Article 3 of the “Bylaws of the Japan Society of Obstetrics and Gynecology”). The Society not only prepares medical guidelines, such as “Gynecological Practice Guidelines-Obstetrics Edition 2017,” but also compiles guidelines in the form of reports to members of the Society,²⁶ especially for Artificial Reproductive Technology. The Society requires academic members to strictly adhere to the reports and takes appropriate measures if they are not observed.²⁷ The Society’s guidelines play a central role in the regulation of Artificial Reproductive Technology in Japan.

The Japan Society of Obstetrics and Gynecology has issued several notices (guidelines) on Artificial Reproductive Technology. Landmark examples are shown in Table 2 “Major Notices from the Japan Society of Obstetrics and Gynecology Related to Artificial Reproductive Technology.” The following is a summary of the content presented in these notices.

In the current notice from the Society, Artificial Insemination by Donor has been approved for Artificial Reproductive Technology using third-party gametes.²⁸ However,

²⁵ The Society has 16,552 members as of March 31, 2018. The Society was certified as a Public Interest Incorporated Association in 2011. 日本産科婦人科学会ホームページ「会員名簿」 (“List of Members”).

²⁶ The Japan Society Obstetrics and Gynecology issues a report indicating that they expect strict compliance from members. 由井秀樹「生命倫理と現代史研究 1—体外受精の臨床応用と日本産科婦人科学会の「見解」—」 (“Bioethics and Contemporary History Study 1: Clinical Application of In Vitro Fertilization and ‘Opinions’ of the Japan Society Obstetrics and Gynecology”) 吉田一史・由井秀樹編『生殖と医療をめぐる現代史研究と生命倫理』(生存学研究センター報告 25) 立命館大学生存学研究センター, 2016, p.21 (*Contemporary History Study and Bioethics Surrounding Reproduction and Medical Treatment*).

²⁷ 日本産科婦人科学会「臨床・研究遂行上倫理的に注意すべき事項に関する会告」 (“Report on Ethical Considerations for Clinical and Research Execution”); 同「会告 見解に違反した会員の処分について」『日本産科婦人科学会雑誌』69 巻 1 号, 2017.1, p.1 (“Notice: Regarding Disciplinary Actions for Members Violating the Society’s Opinion”). Some doctors have been dismissed from the Society in the past for violating the notice. In addition, those expelled from the Society for violating the notices will be unable to conduct academic presentations and will be unable to call themselves a specialist. 「着床前診断 『学会除名』でも診療は可能 実効性ある規制が課題」『読売新聞』2004.2.22, p.38 (“Pre-implantation Diagnosis: Performing Medical Treatment Possible Even When Expelled from the Society; Challenges in the Effective Implementation of Regulations”).

²⁸ 「「非配偶者間人工授精と精子提供」に関する見解」『日本産科婦人科学会雑誌』49 巻 5 号, 1997.5, pp.11-12 (“Opinion on Artificial Insemination by Donor”); 「提供精子を用いた人工授精に関する見解」『日本産科婦人科学会雑誌』67 巻 8 号, 2015.8, pp.1646-1648

Table 2 Major Notices from the Japan Society of Obstetrics and Gynecology Related to Artificial Reproductive Technology

Opinion on Registration and Reporting of Medical Institutions Performing Artificial Reproductive Technology	Revised in June 2016
Opinion on In Vitro Fertilization-Embryo Transfer	Revised in June 2014
Opinion on Intracytoplasmic Sperm Injection	Revised in April 2006
Opinion on Cryopreservation and Transplantation of Human Embryos and Ova	Revised in June 2014
Opinion on Cryopreservation of Unfertilized Ova, Embryos (Fertilized Ova), and Ovarian Tissues according to Medical Indication	Revised in June 2016
Opinion on Artificial Insemination Using Donated Sperm (Formerly “Opinion on Artificial Insemination by Donor”)	Revised in June 2015
Opinion on the Prevention of Multiple Pregnancy in Artificial Reproductive Technology	April 2008
Opinion on Cryopreservation of Sperm	April 2007
About the Deletion of “Marriage” in “Opinion on In Vitro Fertilization-Embryo Transfer/Cryopreservation and Transplantation of Human Embryos and Ova”	June 2014
Opinion on Research Dealing with Human Sperm, Ova, and Fertilized Ova	Revised in June 2013
Opinion on the Scope of Clinical Application of Human In Vitro Fertilization-Embryo Transfer	October 1998
Opinion on Pre-implantation Diagnosis	Revised in June 2018
Opinion on Genetic Test and Diagnosis Performed before Birth	Revised in June 2013
Opinion on Surrogacy	April 2003
Opinion on Artificial Reproductive Technology through Embryo Transfer	April 2004

(Source) Created by the author based on 日本産科婦人科学会「倫理に関する見解一覧」(“List of Opinions on Ethics”).

the notice states that “it does not explicitly ban” In Vitro Fertilization using donated sperm or ovum.²⁹ Regarding the pros and cons of In Vitro Fertilization using donated sperm and

(“Opinion on Artificial Insemination Using Donated Sperm”). Moreover, Artificial Insemination using donated sperm was already approved when the first notice regarding this procedure, “Opinion on ‘Artificial Insemination by Donor and Sperm Donation,’” was issued in May 1997. Even before this notice was issued, the Japan Society of Obstetrics and Gynecology did not see any problem with obstetricians and gynecologists practicing this procedure. 由井, *op.cit.* (26), p.22.

²⁹ Professor KUJI Naoaki from the Department of Obstetrics and Gynecology of the Tokyo Medical University Hospital said they “do not currently perform In Vitro Fertilization using donated sperm.” He added that “while ovum donation is not prohibited in Japan, the Japan Society of Obstetrics and Gynecology has yet to release regulation for this procedure, so we are reluctant to perform it.” 久慈直昭ほか「わが国における不妊治療の現状」『小児科診療』78 巻 1 号, 2015.1, pp.24-25 (“The Current Status of Infertility Treatment in Japan”). While his statement saying they “do not currently perform In Vitro Fertilization using donated sperm” differs from the “Sperm and Ovum Donation Results (as of July 20, 2018)” published by the below-mentioned

ovum, there are opinions approving the procedure under certain conditions in research and examination within the Society.³⁰ However, the situation is as described above. On the other hand, regarding Artificial Reproductive Technology using donated embryos from a third party, “the welfare of the born child should be given top priority,” implying that it is not allowed because of “the parent-child relationship being unclear.”³¹ Regarding surrogacy, the Society has explicitly stated that “with or without compensation, the members of the Society must not perform or be involved in Artificial Reproductive Technology for individuals seeking surrogacy. Also, they must not be an agency for surrogacy.”³²

(2) Guidelines for Professional Ethics of the Japan Medical Association

Sections (2) and (3) introduce the guidelines of the Japan Medical Association and the Japan Society of Reproductive Medicine. The guidelines of these organizations clarify and present ideas from a professional standpoint, or indicate recommendations from a professional perspective. Compared to the guidelines of the Japan Society of Obstetrics and Gynecology, which requires strict adherence from its members, these guidelines are more lenient.

First to be discussed are the Guidelines for Professional Ethics of the Japan Medical Association, which published the first edition of the “Physician’s Professional Ethics Guidelines”³³ in 2004, followed by a revised edition in 2008, and a third edition in 2016. All three editions contain matters related to Artificial Reproductive Technology. As the name suggests, this is a guideline that shows the Japan Medical Association’s approach to matters involving ethical concerns when physicians perform their duties. Specific medical fields also include end-of-life care, in addition to Artificial Reproductive Technology. The following was stated in the guideline’s introduction (3rd edition): “To put it simply, ethics can be said as rules that we need to follow. However, it is important that each person

Japanese Institution for Standardizing Assisted Reproductive Technology (JISART) (see note (53)), the Artificial Insemination using donated sperm and ovum performed at JISART member facilities seems to be considered separately.

³⁰ In February 2001, the ethics council of the Society’s Ethics Committee submitted a report approving In Vitro Fertilization by Donor using donated sperm or ovum under certain conditions to the president of the Society and the chair of the ethics committee. In April 2001, the ethics committee also announced an opinion (draft) approving In Vitro Fertilization using donated sperm or ovum under certain conditions. 日本産科婦人科学会倫理委員会倫理審議会「倫理審議会答申書—卵子提供による非配偶者間体外受精・胚移植実施について—（追加審議事項を含む）」2001.2.23 (“Ethics Council Report: About the Implementation of In Vitro Fertilization-Embryo Transfer by Donor Using Donated Ovum (Including Additional Considerations)”); 「非配偶者間の体外受精に関する倫理委員会見解（案）」『日本産科婦人科学会雑誌』53 巻 4 号, 2001.4, pp.30-32 (“Ethics Committee Opinion on In Vitro Fertilization by Donor (Draft)”).

³¹ 「胚提供による生殖補助医療に関する見解」 *op.cit.* (20).

³² 「代理懐胎に関する見解」 *op.cit.* (19).

³³ Established after approval by the Board of Directors and distributed to members.

recognizes and observes the rule with awareness. We hope that you find this ethical guideline useful.” This guideline was not compiled to require strict adherence from its members. Physicians who perform Artificial Reproductive Technology can proceed with their own procedures while referring to these guidelines.

Regarding “Artificial Reproductive Technology using donated gametes from third parties,” this guideline says that “as a general rule, Artificial Reproductive Technology is performed using sperm and ova of the couple who will undergo the procedure.” However, it also states that “Artificial Reproductive Technology using donated gametes from third parties is not necessarily unethical if it has been medically determined that pregnancy cannot be achieved using medical procedures other than the one at hand, and if it is performed on a couple who has undergone counseling and with sufficient understanding of the necessary medical information.”³⁴ However, Artificial Reproductive Technology using donated gametes from third parties, “should be implemented only in medical institutions that have a well-developed system in view of addressing the child’s right to know their biological origins and of protecting the personal information of the donor.”³⁵ The guidelines also state that certain conditions should be met before the procedure can be performed.

As for surrogacy, both the first edition (2004) and the revised edition (2008) promote surrogacy “for commercial purposes,” adding that “being involved in recruitment... is unethical and must be avoided.”³⁶ The third edition (2008) states that “surrogacy may pose life-threatening risks to the surrogate mother. There were also cases where the requesting couple did not take charge of the child with Down syndrome. Some European countries have prohibited this procedure due to ethical reasons, and careful consideration is required in Japan.”³⁷

(3) Guidelines and Recommendations of the Japan Society for Reproductive Medicine

The Japan Society for Reproductive Medicine was established in 1956. It is an academic society composed of doctors, veterinarians, etc., conducts both basic and clinical research on the reproduction of humans, livestock, and other animals, and accredits

³⁴ 日本医師会『医師の職業倫理指針』（日本医師会雑誌・131 巻 7 号付録）2004, p.32 (*Physician's Professional Ethics Guidelines*); 同『医師の職業倫理指針 改訂版』2008, pp.41-42 (*Physician's Professional Ethics Guidelines Revised Edition*); 同『医師の職業倫理指針 第3版』2016, p.31 (*Physician's Professional Ethics Guidelines 3rd Edition*). None of the guidelines specifically mentions the scope of “donated gametes from third parties” (whether it includes both sperm and ovum, or allow embryos).

³⁵ 日本医師会『医師の職業倫理指針 改訂版』同上; 同『医師の職業倫理指針 第3版』同上

³⁶ 日本医師会『医師の職業倫理指針』*op.cit.* (34), p.34; 同『医師の職業倫理指針 改訂版』*op.cit.* (34), p.43.

³⁷ 日本医師会『医師の職業倫理指針 第3版』*op.cit.* (34), p.32.

reproductive medicine specialists.³⁸ The Society has also established the “Guidelines on Cryopreservation of Unfertilized Ova and Ovarian Tissue” (March 2018), “Guidelines on Cryopreservation of Unfertilized Ova and Ovarian Tissue” (November 2013), “Guidelines on the Number of Embryos for Transfer to Prevent Multiple Pregnancy” (March 2007), and “About the Cryopreservation of Sperm” (September 2006).³⁹ These guidelines aim to present recommendations from a professional standpoint. In terms of content, they deal specifically with methods for cryopreservation of gametes, etc., among Artificial Reproductive Technology procedures. Specifically, it suggests (1) when cryopreservation should be implemented, (2) requirements for cryopreservation facilities, and (3) that the buying and selling of cryopreserved gametes, etc. is not permitted.

In terms of surrogacy, the Society has also published the “Opinion of the Board of Director on the Issues concerning the ‘Surrogate Mother’” (1992),⁴⁰ which states that “this issue has a large social, ethical, and legal component, and the Committee [Ethics Committee of the Society] has not reached a clear conclusion on its implementation” ([] is the author’s supplement. The same shall apply hereafter). As such, the Society has deferred its standpoint on the matter.

The Society has yet to compile guidelines on Artificial Reproductive Technology involving third parties. However, with the advancement of the Society’s internal studies and research efforts, the ethics committee of the Society set forth the “Recommendations for Reproductive Medicine Using Third-Party Gametes”⁴¹ in March 2009. Since this recommendation is not a guideline, it does not present recommendations on medical care to academic members, but rather summarizes the results of studies and research efforts from a professional standpoint. In the future, it will be referred to as one perspective as we work towards a study on the regulation of Artificial Reproductive Technology. The contents of the recommendations are briefly introduced below.

The recommendation states that “there is clearly a certain number of couples in Japan who need treatment using third-party gametes. As such, we believe that the treatment is sufficiently reasonable, upon limiting medical indications for each provider and recipient, providing sufficient information to both parties and securing consent, and establishing strict conditions related to the welfare of the child born through this procedure by considering the right to know their biological origins.”⁴² As such, the recommendation approves In Vitro Fertilization using donated sperm or ovum from third parties.

³⁸ As of March 31, 2018, there were 5,118 general members. 日本生殖医学会ホームページ「日本生殖医学会とは」 (“What is the Japan Society for Reproductive Medicine?”).

³⁹ These guidelines are issued in the form of a report from the Society’s Ethics Committee (report to academic members).

⁴⁰ 日本生殖医学会ホームページ「倫理委員会報告『代理母』の問題についての理事見解」 1992.11.5 (“Opinion of the Board of Director on the Issues Concerning the ‘Surrogate Mother’”).

⁴¹ 「倫理委員会報告「第三者配偶子を用いる生殖医療についての提言」」 *op.cit.* (14).

⁴² *ibid.*

However, assuming this is the case, the recommendation states that “a regulated treatment based on certain conditions set forth by laws and guidelines is necessary in order to ensure the safety and benefit of the couple undergoing the procedure, and to protect the rights and welfare of the child and donor,” and that “the government needs to urgently work on the establishment of a publicly operated institution for reproductive treatment to management information on reproductive medicine using third-party gametes and on the development of laws that clarify the legal parent-child relationship under the Civil Code.”⁴³ Therefore, this proposal seeks the development of a framework for legal public regulation by the government. It should be noted that this recommendation is from the perspective of experts in the Society’s ethics committee.

(4) Guidelines of the Japanese Institution for Standardizing Assisted Reproductive Technology

In this section, while in accordance with the guidelines of the Japan Society of Obstetrics and Gynecology, the Japanese Institution for Standardizing Assisted Reproductive Technology (JISART) is an organization that creates guidelines for the aspects of the regulations that were not clearly presented to the members of the Society. However, there are a few critical opinions regarding the fact that JISART establishes its own guidelines for the parts that the Society could not clarify, while also performing procedures.⁴⁴

JISART was established in 2003 by clinics that support its founding philosophy of “achieving high standards of practice in infertility management by implementing a quality management system⁴⁵ in Japan, with the ultimate aim of improving the quality of patient care”⁴⁶ among facilities conducting Artificial Reproductive Technology. There are currently 30⁴⁷ member obstetrics and gynecology clinics, but hospitals (university hospitals, etc.) are not members. JISART member facilities are required to register as medical institutions for the implementation of Artificial Reproductive Technology in the Japan Society of Obstetrics and Gynecology, and are also required to comply with the

⁴³ *ibid.*

⁴⁴ 「第三者卵子提供 子どもの幸福が優先だ」『毎日新聞』2015.7.28, p.5 (“Third-party Donated Ovum: The Happiness of Children is the Top Priority”). See note (55).

⁴⁵ Specifically, member institutions are required to conduct regular internal audits to maintain the level of clinical practice, and conduct patient satisfaction surveys at least once a year. See 4.11 (Quality Control) section in 「JISART (Japanese Institution for Standardizing Assisted Reproductive Technology, 日本生殖補助医療標準化機関)における生殖補助医療を行う施設のための実施規定 2018 年 2 月改定」 (“Implementation Regulations for Facilities Performing Artificial Reproductive Technology in JISART (Japanese Institution for Standardizing Assisted Reproductive Technology) Revised on February 2018”).

⁴⁶ 「JISART 設立趣旨」 (“Purpose of the Establishment of JISART”).

⁴⁷ As of October 31, 2018. JISART 「メンバー情報 (地図および一覧)」 (“Member Information (Map and List)”).

ethical regulations of the Society. In addition, the director of a member facility is required to be a qualified reproductive medicine specialist certified by the Japan Society for Reproductive Medicine.⁴⁸

JISART has a basic guideline named “Implementation Regulation for Facilities Performing Artificial Reproductive Technology in JISART (Japanese Institution for Standardizing Assisted Reproductive Technology).”⁴⁹ Member facilities are required to abide by this guideline. In addition, whether or not these guidelines are actually followed by member facilities will be reviewed by a specialized committee (Reproductive Technology Accreditation Committee) established in JISART. These guidelines consist of items such as staff and facility equipment, provision of information to patients and their responses, consent forms, medical records, advertisements, etc. The guidelines also define the basic prerequisites for performing Artificial Reproductive Technology.

In addition, JISART also has the “JISART Guidelines on In Vitro Fertilization by Donor Using Donated Sperm or Ovum,”⁵⁰ which centers around Artificial Reproductive Technology based on donated sperm or ovum. This In Vitro Fertilization by Donor using donated sperm and ovum is an area that has not been clarified in the regulations imposed through a notice from the Japan Society of Obstetrics and Gynecology. Based on this guideline, JISART member facilities that intend to conduct In Vitro Fertilization by Donor using donated sperm and ovum must apply to the ethics committee⁵¹ in JISART for specific treatment cases, and the procedure can be performed only if approval has been granted. In JISART, there are only five clinics that are allowed to perform Artificial Reproductive Technology using donated sperm and ovum.⁵²

This guideline imposes certain requirements on In Vitro Fertilization using donated sperm and eggs (if the recipient has a medical reason for being unable to conceive by any other method, the recipient must be a married couple) (Guidelines 2-1). A child who is 15 years of age or older, and is born through In Vitro Fertilization by donor, can request that the implementing medical facility disclose information, including details that may identify the sperm or ovum donor, such as their name and address. The guidelines therefore

⁴⁸ JISART 「施設長の履歴書」 (“Resume of Facility Director”); 「JISART 入会希望施設代表者への質問状」 (“Questions to the Facility Director”).

⁴⁹ 「JISART (Japanese Institution for Standardizing Assisted Reproductive Technology, 日本生殖補助医療標準化機関)における生殖補助医療を行う施設のための実施規定」 *op.cit.* (50).

⁵⁰ 「精子・卵子の提供による非配偶者間体外受精に関する JISART ガイドライン 平成 30 年 9 月 1 日改定」 (“JISART Guidelines on In Vitro Fertilization by Donor Using Donated Sperm and Ovum September 1, 2018”).

⁵¹ The Ethics Committee and the Reproductive Technology Accreditation Committee are separate committees.

⁵² Kyono ART Clinic (Miyagi), Kyono ART Clinic Takanawa (Tokyo), St. Mother Hospital (Fukuoka), Hiroshima HART Clinic (Hiroshima), Hanabusa Women’s Clinic (Hyogo). 「JISART 会員施設における精子・卵子の提供による非配偶者間体外受精実施施設一覧」 (“List of Facilities Performing In Vitro Fertilization by Donor Using Donated Sperm or Ovum in JISART Member Facilities”).

recognize the right of the child to know their biological origins. Consequently, in cases where a request for disclosure is made, the implementing medical facility will notify the recipient, donor, and their spouse that this matter will be disclosed to the child prior to them consenting to the procedure. In addition, the recipient, donor, and their spouse must also understand the impact of the disclosure (Guideline 2-5 (4)-(1)).⁵³

Within this context, JISART itself has received a certain amount of external recognition for various activities⁵⁴ promoting In Vitro Fertilization by donor using donated sperm and ovum based on its own guidelines. On the other hand, under these circumstances, some critics have said that “Unlike usual medical procedures, Artificial Reproductive Technology is a procedure that creates new humans. Therefore, it is not appropriate for a private organization to follow its own rules.”⁵⁵

3 Cases Related to Artificial Reproductive Technology

As mentioned above (Chapter II-1), the regulation of Artificial Reproductive Technology in Japan is implemented in such a way that each doctor performing the treatment voluntarily observes the guidelines of the Japan Society of Obstetrics and Gynecology. Legal regulations based on public systems have not yet been established. However, cases related to Artificial Reproductive Technology may have been brought to court, where the propriety of the Artificial Reproductive Technology may be questioned. Cases may also be filed to dispute the parent-child relationship of children born through Artificial Reproductive Technology. Through such trials, judicial decisions related to the regulation of Artificial Reproductive Technology are accumulated, which may impact its regulation.

From this point of view, when examining cases related to Artificial Reproductive Technology, the following can be understood. In other words, most of these cases are related to Civil Code issues, such as the determination of parent-child relationships. More specifically, many of the precedents do not state whether the Artificial Reproductive Technology itself was performed, and only make decisions regarding the determination of

⁵³ According to the results that JISART has published (number of children conceived through In Vitro Fertilization using donated sperm and ova) on its website, the total number of children born through this procedure is 51. However, there is no distinction as to whether the procedure was performed using donated sperm or ovum. JISART 「精子・卵子提供実績 (2018年7月20日現在)」 (“Results of Donated Sperm and Ova, as of July 20, 2018”).

⁵⁴ In Vitro Fertilization by donor using donated sperm and ovum, long-term prognosis survey of children born through Artificial Reproductive Technology, awareness activities for medical students and young doctors by holding JISART Reproductive Medicine Forum, staff education seminars and cultural exchange meetings, etc. are listed as various activities by JISART. 「JISART 新理事長挨拶」『JISART NEWS』Vol.3, 2017.7.25, p.1 (“Greetings from the New Director of JISART”).

⁵⁵ 『毎日新聞』 *op.cit.* (44). However, this article does not directly refer to JISART. This article only refers to “one private organization.”

the parent-child relationship. Examples of cases that mentioned the pros and cons of Artificial Reproductive Technology include the cases in Chapter II 3 (3) (i) (decided on March 23, 2007, in the Supreme Court Petty Bench, Case 5)⁵⁶ and Chapter II 3 (3) (ii) (decided on May 20, 2005, in the Osaka High Court, case 6). Case 5 points out that (1) there is no regulation that clearly prohibits surrogacy and (2) that it is not possible to establish a socially accepted idea that denies surrogacy. On the other hand, Case 6 expresses an opinion that denies the contract of surrogacy. There is no other discussion about the pros and cons of Artificial Reproductive Technology. In terms of the determination of parent-child relationship, cases 5 and 6 present the idea that the “mother is the person who gave birth.” There are no precedents in which the person who donated the ovum (corresponding to the biological mother) is the mother in the Civil Code. This point is common to all cases.

It is also noteworthy that the case played a role in encouraging the legislature and executive government to consider Artificial Reproductive Technology. The case introduced in Chapter II 3 (1) (ii) (Osaka District Court, December 18, 1998, Case 2) prompted the Council of the Ministry of Health and Welfare (at that time) to study the regulation of Artificial Reproductive Technology.⁵⁷ In addition, as in the case introduced in Chapter II 3 (2) (Supreme Court 2nd Petty Bench, September 4, 2006, Case 4), some have claimed that the recognition of parent-child relationships is a problem that can be resolved by legislation. The latter case is noteworthy in that the court has expressed that it would be preferable for the legislature to improve related legislation. Case 5 also states that surrogacy requires both medical legislation and parent-child legislation. It also states that a quick response by legislation is strongly desired.

In the following, we will introduce the outlines of cases considered to represent cases related to Artificial Reproductive Technology.

(1) Cases related to AID

(i) A Case Concerning Custody after Divorce (Case 1)

With the consent of her husband, the wife used AID to give birth to a child (hereinafter referred to as “AID-born child”), but, after about two years, the couple divorced and fought over the custody of the child. The Tokyo High Court considers that if an AID is performed with the consent of the husband, the child is an AID-born child. Although it is reasonable to interpret an AID-born child as a child with presumption of legitimacy, it is also important to consider that the child is an AID-born child. Considering the circumstances of custody, etc., the mother was granted custody of the child (decided on September 16, 1998, in the Tokyo High Court, case 1).⁵⁸

(ii) A Case Concerning the Husband’s Denial of Legitimacy (Case 2)

⁵⁶ See note (58). The numbers given to the cases, such as Case 5, are given for the sake of convenience in the order of the cases introduced in Chapter II 3 (1) to (3).

⁵⁷ Mentioned later in Chapter III 1 (1).

⁵⁸ 家庭裁判月報 51 卷 3 号 165 頁 (*Court of Domestic Relations Monthly Report*).

During the implementation of AID, the wife was pregnant and gave birth after undergoing AID treatment without a written agreement signed by her husband. The husband named the child and submitted the birth notification himself. The wife argued that the husband had recognized the legitimacy of the child since he named and submitted the birth notification for the child. However, the Osaka District Court affirmed the husband's denial of the legitimacy, stating that even though the husband named the child and submitted the birth notification, in the absence of a written agreement (consent form) there was no prior comprehensive recognition of the pregnancy and birth by AID (decided on December 18, 1998, Osaka District Court, case 2).⁵⁹

(iii) A Case Concerning Artificial Reproductive Technology for Persons with Gender Identity Disorder (Case 3)

Based on Article 3 Paragraph 1 of the “Act on Special Cases in Handling Gender Status for Persons with Gender Identity Disorder” (Act No. 111 of 2003. Hereinafter referred to as “Act on Special Cases for Persons with Gender Identity Disorder”), a male who had transitioned from a female, married, and had a child by AID, requested that the family register be corrected because the section for the father was left blank. In accordance with Article 3, Paragraph 1 of the Act on Special Cases for Persons with Gender Identity Disorder, a person who undergoes a trial to change their sex to male can marry someone as a husband under the Civil Code. During the marriage, when the wife conceives a child, the child should be presumed to be the husband's child under the provisions of Article 772 of the Civil Code (decided on December 10, 2013, Supreme Court 3rd Petty Bench, Case 3).⁶⁰

(2) Cases Related to Posthumous Conception (Case 4)

A husband, who had undergone a bone marrow transplant to treat leukemia, was exposed to radiation before surgery. However, fearing the possibility of azoospermia, the husband decided to cryopreserve his own sperm. After the husband's death, the wife conceived and delivered a child (hereinafter referred to as “posthumously conceived child”) through In Vitro Fertilization using the cryopreserved sperm. The wife filed a case seeking posthumous recognition that the posthumously conceived child was the husband's child. The Supreme Court (2nd Petty Bench) examined the bioethics related to posthumous conception, the welfare of the child, the awareness of all parties involved, such as relatives,

⁵⁹ 家庭裁判月報 51 卷 9 号 71 頁 (*Court of Domestic Relations Monthly Report*). Moreover, the husband and wife in this case were divorced in November 1998 and were not married at the time the ruling was issued (December 18). However, in the text, they are referred to as husband and wife for convenience. 「夫の知らぬ間に AID 嫡出子認定せず 大阪地裁判決」『朝日新聞』1998.12.19, 夕刊, p.15 (“AID without the Husband's Knowledge: Denial of Legitimacy, Osaka District Court Ruling”).

⁶⁰ 最高裁判所民事判例集 67 卷 9 号 1847 頁 (*Supreme Court Reports (Civil Cases)*).

and the perspective of the general society. They ruled that although the recognition of parent-child relationship would be resolved by legislation, “there is no legal parent-child relationship between the posthumously conceived child and the deceased father” (decided on September 4, 2006, Supreme Court 2nd Petty Bench, case 4).⁶¹

(3) Cases Related to Surrogacy

(i) A case Concerning Surrogacy Using the Gamete of the Requesting Married Couple (Case 5)

The wife, who was unable to give birth because of a hysterectomy following cervical cancer, went to the state of Nevada, USA, and asked a local woman to be a surrogate mother using her ovum and the husband’s sperm. As a result, twin boys were born and submitted, and legitimate birth notification for the children was submitted to Shinagawa Ward, Tokyo, but was not accepted. Disagreeing with the non-acceptance of the birth notification, the couple filed for a cancellation of the disposition, but the Supreme Court (2nd Petty Bench) ruled that the “person who gave birth is the mother,” and the birth notification was not accepted.

This case refers to the propriety of surrogacy.⁶² In other words, this case points out that in Japan, (1) there is no regulation that clearly prohibits surrogacy contracts, and (2) it is not possible to establish a socially accepted idea that prevents surrogacy. At the same time, with regard to surrogacy, it was stated that “there are situations which the Civil Code has not anticipated and it is expected that such situations will continue to occur in the future,” and that “it is necessary to examine both medical legislation and parent-child legislation which required prompt action by legislation” (decided in March 23, 2007, Supreme Court 2nd Petty Bench, case 5).⁶³

(ii) A Case Concerning Surrogacy Using the Husband’s Sperm and Donated Ovum (Case 6)

In California, USA, a Japanese couple asked an American woman to be a surrogate using a fertilized ovum produced by In Vitro Fertilization of the husband’s sperm and a donated ovum, which led to the birth of twins. After returning to Japan, the couple submitted a birth notification to Akashi City, Hyogo, but this was not accepted, since there was no mother-child relationship between the wife, who did not give birth, and the children. The Osaka High Court did not accept the mother-child relationship between the wife and the children, based on the previous standard of determining whether there was a mother-child relationship as per childbirth. In addition, regarding surrogacy, the court denied the validity of the contract of the surrogacy as it was in contrast with public order and morals,

⁶¹ 最高裁判所民事判例集 60 卷 7 号 2563 頁 (*Supreme Court Reports (Civil Cases)*).

⁶² This was referred to as “surrogate birth” in the case.

⁶³ 最高裁判所民事判例集 61 卷 2 号 619 頁 (*Supreme Court Reports (Civil Cases)*).

stating that “with a human being treated exclusively as a means of reproduction and putting a third party at great risk from pregnancy and childbirth, not only is there a humanitarian problem, but there is also a risk of serious conflict over the children born between a couple of requested the surrogacy and a woman who performed the surrogacy, casting a prominent negative opinion for evaluation” (decided on May 20, 2005, Osaka High Court, case 6).⁶⁴

III The Current Status of Examinations regarding Artificial Reproductive Technology Regulation

1 Examinations conducted by the Ministry of Health, Labour and Welfare, etc.

(1) Examinations by the Council of Ministry of Health, Labour and Welfare, and Ministry of Justice, etc.

In 1998, the Ministry of Health and Welfare (at that time) established a special committee on Artificial Reproductive Technology (hereinafter referred to as the “Ministry of Health and Welfare Special Committee”) in the Health Science Council. In December 2000, the “Report on Artificial Reproductive Technology Using Donated Sperm, Ova, and Embryos”⁶⁵ was compiled. The report was based on the fact that the Ministry of Health, Labour and Welfare Special Committee needed to consider the state of regulation regarding Artificial Reproductive Technology. The following three points were raised stating the urgent need to develop a system for assessing the pros and cons of Artificial Reproductive Technology and the state of the existing regulation: (1) So far, artificial insemination and In Vitro Fertilization have been carried out under voluntary regulations centered on the Japan Society of Obstetrics and Gynecology, but there have been people⁶⁶ who violated the Society’s notice; (2) In December 1998, the Osaka District Court ruled that a child who was born by AID without the consent of the husband was denied a legitimate birth. This brings to light issues concerning the welfare of children born through Artificial Reproductive Technology⁶⁷; (3) Commercial acts, such as sperm trading and influencing

⁶⁴ 判例時報 1919 号 107 頁 (Case Report).

⁶⁵ 厚生科学審議会先端医療技術評価部会生殖補助医療技術に関する専門委員会「精子・卵子・胚の提供等による生殖補助医療のあり方についての報告書」2000.12.28 (“Report on the State of Artificial Reproductive Technology Using Donated Sperm, Ova, and Embryos”).

⁶⁶ An obstetrician in Suwa District, Nagano Prefecture, conducted In Vitro Fertilization using donated ovum, and was dismissed in 1998 because of a violation of the notice of the Japan Society of Obstetrics and Gynecology. This expulsion resulted in a great social response. 「社説 波紋広がる生殖医療問題」『読売新聞』1998.6.28, p.3 (“Editorial: The Rise of Reproductive Medical Problems”).

⁶⁷ Mentioned earlier in Chapter II-3 (1) (ii).

surrogacy, have been observed.⁶⁸

This report indicates the plan to (1) accept donation of sperm, ova, and surplus embryos (including donation from siblings), (2) protect the donor's anonymity (some information will be disclosed),⁶⁹ and (3) prohibit surrogacy (traditional type⁷⁰ and In Vitro Fertilization type).⁷¹ Regarding the regulatory methods, the following actions will be subject to legal regulation with penalties: (1) the donation and receipt of gametes and embryos, as well as their mediation for the purpose of profit; (2) the treatment and mediation of surrogacy; and (3) information leakage by a person with knowledge obtained from professional duties related to Artificial Reproductive Technology using donated sperm, ova, and embryos. In addition, the determination of the parent-child relationship will be provided by law. Regarding other implementation conditions in "All Artificial Reproductive Technology Using Donated Sperm, Ova, and Embryos," the report indicates that "from the perspective of ensuring flexibility in the reality of regulation, it is not appropriate to regulate by law with penal provisions, but it is appropriate to regulate by other means that can ensure the effectiveness of regulations based on law."

In April 2001, the Parent-Child Legislative Council for Artificial Reproductive Technology of the Legislative Council of the Ministry of Justice (hereinafter referred to as "Parent-Child Legislative Council of the Ministry of Justice") started deliberations regarding Artificial Reproductive Technology. In July of the same year, the Health Sciences Council for Evaluating Advanced Medical Techniques of the Ministry of Health, Labour and Welfare (hereinafter referred to as "Health Sciences Council for Advanced Medical Techniques") also started deliberations on Artificial Reproductive Technology. The Parent-Child Legislative Council of the Ministry of Justice specially deliberated on legislation to regulate the legal parent-child relationship of children born through donated

⁶⁸ 「走り出す生殖医療商業化 150 万円で精子あっせん インターネット通じ募集」『熊本日日新聞』1996.8.18, p.3 ("The Rise of the Commercialization of Reproductive Medicine; 1.5 Million Yen for Sperm Donation through the Internet"); 「代理母出産は是か否か 米あっせん業者が日本に本格上陸」『読売新聞』1992.6.20, 夕刊, p.1 ("The Appropriateness of Surrogacy: US Mediators Land in Japan").

⁶⁹ According to the report: (1) after adulthood, a child born by Artificial Reproductive Technology is allowed to know personal information regarding the donor of the sperm, ovum, or embryo that will not identify them within the scope of disclosure approved by the donor; (2) Before personal information is disclosed, donors can change the scope of personal information approved for disclosure; and (3) the child, regardless of (1) and (2), can ask for confirmation that the person they wish to marry is not closely related to them in order to prevent a consanguineous marriage. However, the report does not mention specific items that may be approved for disclosure.

⁷⁰ Traditional surrogacy is a method in which the ovum of the surrogate mother is fertilized by injecting the sperm of the partner (husband, etc.) of the requesting female into the uterus of the surrogate mother by Artificial Insemination.

⁷¹ In Vitro fertilization-type surrogacy uses (1) an ovum other than the surrogate mother's (the requesting female or third party) and (2) the sperm of the partner of the requesting female (such as the husband) or of a third-party for In Vitro Fertilization. The resulting embryo will be transferred to the surrogate mother. This is called gestational surrogacy.

gametes, etc. On the other hand, the Health Sciences Council for Evaluating Advanced Medical Techniques was intended to examine the implementation of the system based on the 2000 report by the Special Committee of the Ministry of Health and Welfare.

In 2003, the Health Sciences Council for Evaluating Advanced Medical Techniques compiled the “Report on the Development of a System for Artificial Reproductive Technology Using Donated Sperm, Ova, and Embryos.”⁷² Then, in the same year, the Parent-Child Legislative Council of the Ministry of Justice compiled the “Interim Draft of the Outline on Civil Code Special Cases Related to the Parent-Child Relationship of a Child Born through Artificial Reproductive Technology Using Donated Sperm, Ova, and Embryos”⁷³ (hereinafter referred to as Interim Draft of the Ministry of Justice). The report of the Health Sciences Council for Evaluating Advanced Medical Techniques came to the same conclusions as the Parent-Child Legislative Council of the Ministry of Justice regarding the acceptance of the donation of sperm, ova, and surplus embryos, as well as the prohibition of surrogacy (traditional and In Vitro Fertilization). On the other hand, the Special Committee of the Ministry of Health and Welfare banned the donation of gametes and embryos from siblings and allowed the disclosure of personal information of the gamete or embryo donor with special considerations (the child’s “right to know their biological origin”). Regarding regulatory methods, as with the Special Committee of the Ministry of Health and Welfare, information leakage by a person with knowledge obtained from professional duties related to Artificial Reproductive Technology using donated sperm, ova, and embryos will be subject to legal regulation with penalties. However, regarding other implementation conditions of the Artificial Reproductive Technology, the report states that “it is not appropriate to regulate by law with penal provisions, but it is appropriate to regulate by other means that can ensure the effectiveness of regulations based on law.” On the other hand, the “Interim Draft of the Ministry of Justice” presented the following three points regarding the parent-child relationship: (1) When a woman gives birth using a donated ovum, the person who gave birth will be the mother of the child; (2) When the consent of the husband is obtained and the child is conceived using the sperm of a man other than the husband, the husband will be the father of the child; and (3) Sperm

⁷² 厚生労働省ホームページ「精子・卵子・胚の提供等による生殖補助医療制度の整備に関する報告書」2003.4.28 (“Report on the Development of the Artificial Reproductive Technology Using Donated Sperm, Ova, and Embryos”).

⁷³ 法務省ホームページ「精子・卵子・胚の提供等による生殖補助医療により出生した子の親子関係に関する民法の特例に関する要綱中間試案」2003.7 (“Interim Draft of the Outline on Civil Law Special Cases Related to the Parent-Child Relationship of a Child Born through Artificial Reproductive Technology Using Donated Sperm, Ova, and Embryos”); 法務省民事局参事官室「精子・卵子・胚の提供等による生殖補助医療により出生した子の親子関係に関する民法の特例に関する要綱中間試案及び同補足説明」『民事月報』58 卷 8 号, 2003.8, pp.134-150 (“Interim Draft and Supplementary Explanation of the Outline on Civil Law Special Cases Related to the Parent-Child Relationship of a Child Born through Artificial Reproductive Technology Using Donated Sperm, Ova, and Embryos”).

donors cannot recognize the child as their own.

(2) Examinations Conducted by the Science Council of Japan and Efforts by Other Organizations

In January 2007, the Minister of Justice and the Minister of Health, Labour and Welfare, together with the request of the Science Council of Japan, following growing public demand for a clear direction on surrogacy, conducted further deliberations.⁷⁴ There was a call for a decision based on the insights of the Science Council of Japan, which was related to various fields.⁷⁵ In response, the Science Council of Japan set up a committee to examine the state of Artificial Reproductive Technology, and deliberated about various issues related to Artificial Reproductive Technology, focusing on In Vitro Fertilization-type surrogacy. In April 2008, the report on the “Problems of Artificial Reproductive Technology Focusing on Surrogacy: Toward Social Consensus”⁷⁶ was submitted to the Minister of Justice and the Minister of Health, Labour and Welfare. The report proposed the following 10 items: (1) Legal regulation is necessary for surrogacy (traditional and In Vitro Fertilization type) and, based on this, its prohibition is desired; (2) Surrogacy for commercial purposes should be subject to punishment for the practicing physician, agency, and client; (3) Trial implementation (clinical trials) of surrogacy under strict control, limited to women without a uterus and women who have undergone a hysterectomy, may be considered; (4) For surrogacy trials, a public organization should be established consisting of specialists in medicine, welfare, law, counseling, etc.; (5) the surrogate will be considered the mother of the child; (6) Through adoption or special adoption, a parent-child relationship should be established between the married couple, who requested

⁷⁴ 「“赤ちゃんがほしい” 代理母を求め渡米する夫婦が急増 日米の生殖医療事情」『毎日新聞』1995.8.16, 夕刊, p.2 (“I Want a Baby: The Rapid Increase of Couples Going to the U.S. in Search of Surrogate Mothers: The State of Reproductive Medicine in Japan and the U.S.”); 「第三者が介在する体外受精など、「利用しない」が7割超す 厚生省アンケート」『毎日新聞』1999.5.7, p.3 (“Ministry of Health, Labour and Welfare Survey: More than 70% Says They Won’t Use In Vitro Fertilization by Donor”); 「不妊治療の抵抗感低下 厚労省調査」『朝日新聞』2003.2.8, 夕刊, p.14 (“Ministry of Health, Labour and Welfare Survey: Reduced Resistance to Infertility Treatment”); 「代理出産を容認 54% 自分なら利用 10% 厚労省調査、国民 3400 人回答」『朝日新聞』2007.6.22, p.34 (“Ministry of Health, Labour and Welfare Survey: Out of 3,400 Respondents, 54% Accept Surrogacy, 10% Will Personally Opt for Procedure”); 「代理出産 「容認」 54%、初の過半数 協力拒否も 4 割」『毎日新聞』2007.11.7, p.2 (“54% Approve Surrogacy, the First Majority; 40% Say They Won’t Cooperate”).

⁷⁵ The deliberation request states that the Science Council of Japan, “composed of the best experts in various fields related to science,” is requested to conduct a multiperspective deliberation. 日本学術会議ホームページ「生殖補助医療をめぐる諸問題に関する審議の依頼」2006.11.30 (“Request for the Deliberation of Various Concern Surrounding Artificial Reproductive Technology”).

⁷⁶ 日本学術会議生殖補助医療の在り方検討委員会『対外報告 代理懐胎を中心とする生殖補助医療の課題—社会的合意に向けて—』2008.4.8 (*Problems of Artificial Reproductive Technology Focusing on Surrogacy: Toward Social Consensus*).

surrogacy, and the child; (7) The child's right to know their biological origin is subject for further examination; (8) Ovum donation and posthumous conception is subject for further examination; (9) Preferably, a public research institution related to bioethics should be created and policymaking should be handled by establishing a permanent public committee; (10) When discussing Artificial Reproductive Technology, child welfare should be given the top priority.

Apart from these items, with legislation by Diet members in mind, MASUZOE Yoichi, the Minister of Health, Labour and Welfare (at that time) said that "it is time for the Diet members to compile their ideas based their own philosophy" regarding the prohibition of surrogacy.⁷⁷

At about the same time, discussions led by academic societies had advanced, and, by this time, the "Proposal on Artificial Reproductive Technology Using Third-Party Gamete" was compiled by the Ethics Committee of the Japan Society for Reproductive Medicine, as previously mentioned (Chapter II-2 (3)). In addition, JISART also had the "JISART Guidelines on In Vitro Fertilization by Donor Using Donated Sperm or Ovum,"⁷⁸ which centers on In Vitro Fertilization based on donated sperm or ovum. It was also during this time that the Japan Reproductive Assistance Standardization Organization (JISART) compiled the "JISART Guidelines on In Vitro Fertilization by Donor Using Donated Sperm and Ovum."

At the end of this paper, Appendix 2, "Comparison of Examination Reports on Artificial Reproductive Medicine," compares the contents of the examination reports by the Health Science Council, etc.

In this way, various examinations have advanced, and reports have been compiled. However, although appeals have been made regarding the necessity of developing regulations related to Artificial Reproductive Technology, no legislation has been enacted that would lead to its creation. The following are the factors involved: (1) Complicating parent-child relationships; (2) Ethical concerns related to inflicting risks on third parties;⁷⁹ (3) It is strange for the state to regulate the right to give birth to children; and (4) Unfamiliarity with the legal regulation of reproductive medicine. Given the wide variety of ideas expressed above, reports have stated that it was difficult to aggregate the opinions expressed in the deliberations within political parties.⁸⁰ Points (1) and (2) are against

⁷⁷ 「代理出産「法律で原則禁止」 容認論 国民に強く 厚労省及び腰」『毎日新聞』2008.3.8, p.26 ("Legal Prohibition of Surrogacy: Citizens Side with Affirmative Side but Ministry of Health, Labour and Welfare Still Indecisive").

⁷⁸ See *op.cit.* (55). The first edition was compiled on July 10, 2008.

⁷⁹ In terms of Artificial Reproductive Technology involving third parties, such as gamete donation and surrogacy, the opinion assumes that the third party may experience some form of disadvantage or anxiety.

⁸⁰ 「生殖医療法 足踏み 法案提出を厚労省断念 自民内に反発」『中国新聞』2004.1.25, p.2 ("Reproductive Medicine Act: Ministry of Health, Labour and Welfare Abandons Reproductive Bill; Opposition within LDP"); 「キーワード 生殖医療の法整備」『朝日新聞』

Artificial Reproductive Technology involving third parties, while (3) raises doubts about the state and the law intervening in a private issue like reproduction.

2 Recent Trends and Discussions within Political Parties

(1) Recent Trends

In January 2013, an NPO “Oocyte Donation NETwork (OD-NET)” was launched, led by infertility treatment specialists and infertility patients. The organization announced that it would start recruiting free ovum donors.⁸¹ In response, TAMURA Norihisa, Minister of Health, Labour and Welfare (at that time), said he wanted to consider how to proceed with Artificial Reproductive Technology.⁸² Immediately after that, the Japan Society of Obstetrics and Gynecology issued a statement saying that the government should promptly establish a framework for the proper implementation of “reproductive medicine that uses donated sperm and ovum.”⁸³

In April 2015, based on its independent guidelines,⁸⁴ the JISART Ethics Committee approved the donation of ovum from anonymous third parties (2 people) and the implementation of In Vitro Fertilization-Embryo Transfer on two patients with premature menopause at a JISART member facility.⁸⁵ The anonymous third parties were people who registered in OD-NET to donate ova. It was revealed by OD-NET that the donated ova were fertilized in vitro in July of the same year. This was the first case in Japan, where an In Vitro Fertilization-Embryo Transfer was performed using donated ova from an anonymous third party.⁸⁶ Following this, an anonymous third party also donated ova

2011.7.27, p.2 (“Keyword: Legislation of Reproductive Medicine”); 「国内初の出産例はできたけど」『日本経済新聞』2017.5.11, p.2 (“The First Case of Birth in the Country but...”).

⁸¹ 「「卵子バンク」事業開始、民間団体、国内初、提供者募る」『日本経済新聞』2013.1.15, p.34 (“‘Egg Cell Bank’ Launched, First Private Organization in Japan Recruiting Donors”).

⁸² Minister Tamura’s remarks have been published as follows: “Individuals have different bioethics, views on family and various problems, so that’s why we could not create a law. The current situation came to be under such circumstances, so moving forward, I want to examine the current state of Artificial Reproductive Technology in the country, the current state of foreign law, and how we should proceed in Japan.” 厚生労働省広報室「田村大臣閣議後記者会見概要」2013.1.15 (Summary of the Post-Cabinet Meeting Press Conference of Minister Tamura).

⁸³ See note (21).

⁸⁴ See note (50) and (78).

⁸⁵ 「匿名第三者が卵子提供 国内初 2組 医療団体の倫理委承認」『読売新聞』2015.4.30, p.37 (“Anonymous Third Party Donates Ovum: First 2 Sets in the Country to Receive Approval from Ethics Committee of Medical Organization”); 「匿名の卵子提供 国内初の実施へ」『朝日新聞』2015.4.30, 夕刊, p.13 (“Anonymous Donates Ovum: First Case in the Country”); 「不妊治療 第三者卵子提供、承認 民間医療機関」『毎日新聞』2015.4.30, p.28 (“Infertility Treatment: Third Party Donates Ovum, Approved by Private Medical Organization”).

⁸⁶ 「匿名の第三者卵子 国内初の体外受精」『朝日新聞』2015.7.27, 夕刊, p.1 (“Anonymous Third Party Donates Ovum: The First In Vitro Fertilization in the Country”). Commenting on this In Vitro Fertilization, OD-NET chair KISHIMOTO Sachiko appealed to “understand that there are many pros and cons in ovum donation” and said “in order to be able to safely donate ovum,

through OD-NET, and a baby girl was born (in January the following year) via an In Vitro Fertilization-Embryo Transfer conducted in April 2016 at a JISART member facility. This birth was the first case in Japan that was announced as a birth that used an ovum provided by an anonymous third party.⁸⁷

According to the announcement of OD-NET in July 2018, there have so far been six cases where an In Vitro Fertilization-Embryo Transfer was performed using an anonymous third-party ovum provided through OD-NET. Among them, four cases have succeeded, one case led to a miscarriage, and one case achieved conception.⁸⁸ According to OD-NET, “Currently, the organization (OD-NET) has stopped recruiting new patients due to lack of progress in the legislation governing the rights and parent-child relationships of born children and due to the limited number of donated ovum.”⁸⁹ In addition, OD-NET chair KISHIMOTO Sachiko has said that “in order to popularize ovum donation in Japan, it is necessary to establish rules such as the right of the child to know their biological origin,” which makes legislation necessary.⁹⁰

(2) Examinations by the Liberal Democratic Party

In October 2013, a project team⁹¹ on Artificial Reproductive Technology (hereinafter referred to as “LDP PT”) was set up by the Liberal Democratic Party’s Policy Research Council Board to conduct a specialized study. In April 2014, the “Bill on Specific Artificial

the state must create rules as soon as possible.”「匿名第三者から受領、体外受精」『読売新聞』2015.8.5, p.13 (“In Vitro Fertilization Performed after Receiving Ovum from Anonymous Third Party”); 「第三者の卵子で体外受精」『読売新聞』2015.7.27, 夕刊, p.1 (In Vitro Fertilization Performed with Third-Party Ovum). On the other hand, she pointed out that this “tells the reality that trials in the medical field are ahead without any rules” and that “it is not appropriate for a private organization to proceed with its own rules.”「法整備に向けて議論深めよう」『読売新聞』2015.8.11, p.3 (“Deepening Discussions Towards Legislation”); 『毎日新聞』*op.cit.* (44).

⁸⁷ 「卵子提供 第三者卵子で初の出産 不妊女性、匿名提供受け」『毎日新聞』2017.3.22, 夕刊, p.1 (“Ovum Donation: The First Childbirth Using Third-Party Ovum, Infertile Woman Received Anonymous Donation”); 「匿名第三者卵子で出産 年内ほかに2人予定」『日本経済新聞』2017.3.23, p.43 (“Childbirth Using Anonymous Third-Party Ovum, Another 2 People Scheduled within This Year”).

⁸⁸ 「第三者卵子で出産 計4人に」『朝日新聞』2018.7.28, p.7 (“Childbirth Using Third-Party Ovum”). Presently, In Vitro Fertilization-Embryo Transfer is performed at JISART member facilities capable of conducting Artificial Reproductive Technology Based on Donated Sperm and Ova (five clinics, see note (52)). OD-NET introduces these JISART member facilities (5 locations) as implementing facilities. OD-NET ホームページ「非配偶者間体外受精実施施設一覧」 (“List of Facilities Performing In Vitro Fertilization by Donor”).

⁸⁹ 「第三者の卵子で新たに3人出産」『日本経済新聞』2018.7.28, 夕刊, p.8 (“3 Babies Born through Third-Party Ova”).

⁹⁰ 『朝日新聞』*op.cit.* (88).

⁹¹ Led by FUKUKAWA Toshiharu, a member of the House of Councilors.

Reproductive Technology) was compiled. The contents are as follows:⁹² (1) Specific Artificial Reproductive Technology refers to “Artificial Insemination, In Vitro Fertilization, In Vitro Fertilization-Embryo Transfer,⁹³ and other forms of treatment performed using reproductive procedures specified in a ministerial ordinance,⁹⁴ which uses donated sperm from a man other than the husband of the conceiving woman or using an ovum from a woman other than the conceiving woman.”; (2) The accredited medical facility is capable of performing Artificial Insemination, In Vitro Fertilization, and In Vitro Fertilization-Embryo Transfer using donated gametes from a third party (either a man other than the husband or a woman other than the wife) to a “couple whose sperm or ovum is unable to conceive a child.”; (3) If the wife “is clearly unable to conceive because she has no uterus as a result of a congenital condition or hysterectomy,” the embryo produced through In Vitro Fertilization using the sperm and ovum of the couple will be transplanted to a person other than the wife at a medical facility specifically identified by the Minister of Health, Labour and Welfare (In Vitro Fertilization Type Surrogacy). (4) “Buying and selling sperm, ova, and embryos” and “providing benefits related to surrogacy” are prohibited; and (5) Penalties will be established for violating prohibitions, such as performing medical treatment related to unpermitted surrogacy and sperm trading. In addition, the “necessity of regulation of Artificial Reproductive Technology between couples,” the “disclosure of information to know one’s biological origins,” and the “donation of embryos, and donation of ova in surrogacy” were considered as future issues.

In August 2015, the Judicial Affairs Division and the Health, Labour and Welfare Division of the Liberal Democratic Party Policy Research Council formed a joint subdivision and accepted a special bill that contained regulations on parent-child relationships under civil law. This bill stipulated that: (1) the mother will be the person who gave birth to the child born using donated ovum, and (2) the father of the child born using donated sperm is the husband of the woman who gave birth, provided that the husband gave his consent for the donation.⁹⁵ In March 2016, a joint subdivision of the Judicial

⁹² There are no documents on this bill on the LDP website, so above description is based on the following materials. 吉村やすのり生命の環境研究所ホームページ「特定生殖補助医療に関する法律案の概要」2014.6.24 (“Outline of the Bill on Specific Artificial Reproductive Technology”); 古川俊治「第三者が関与する生殖医療に関する法整備について」『日本医師会雑誌』144 巻 2 号, 2015.5, pp.289-291 (“About Legislation on Reproductive Medicine Involving Third Parties”); 平原興「生殖医療技術の法制化について」『自由と正義』65 巻 10 号, 2014.10, p.11 (“About Legislation on Reproductive Medicine Technology”).

⁹³ In above-mentioned 「特定生殖補助医療に関する法律案の概要」, “In Vitro Fertilization/Embryo Transfer” is written as “In Vitro Fertilization-Embryo Transfer.”

⁹⁴ At present, the Ordinance of the Ministry of Health, Labour and Welfare is assumed.

⁹⁵ 「卵子提供や代理出産 「産んだ女性が母」 自民部会が法案了承」『日本経済新聞』2015.8.5, 夕刊, p.14 (“Ovum Donation and Surrogacy: LDP Division Approves Bill Stating that the ‘Woman Who Gave Birth is the Mother’”); 「「産んだ女性が母」 法案了承」『読売新聞』2015.8.5, 夕刊, p.3 (“Woman Who Gave Birth is the Mother: Bill Is Approved”). For details regarding parent-child relationship in surrogacy, see 前澤貴子「民法上の親子関係を考える

Affairs and the Health Labour, and Welfare Divisions of the same party approved a special bill under the Civil Code with the same purpose. In response to the request of the Komeito Party, this bill also included other provisions, such as providing sufficient explanation to the couple, the consent of the corresponding couple when performing the Artificial Reproductive Technology, and establishing a consultation system by the state.⁹⁶

Although there are reports that these bills by the Liberal Democratic Party have been considered for submission to the Diet,⁹⁷ these have not yet been submitted to the Diet as of the time of writing (October 31, 2018).⁹⁸

(3) Examinations by the Komeito Party

The Komeito Party also compiled a “Draft Bill on Ensuring Appropriate Provision of Artificial Reproductive Technology,” and, in November 2014, took steps to approve it as a party. In this bill, Artificial Reproductive Technology refers to “a treatment using Artificial Insemination, In Vitro Fertilization and other medical techniques specified by the Ordinance of the Ministry of Health, Labour and Welfare.” Not limited to Artificial Reproductive Technology involving third parties, it also includes a wide range of Artificial Reproductive Technology approaches between couples. The bill consisted of basic principles, dissemination of knowledge and enlightenment, development of public awareness and consultation system, the formulation of guidelines by the Minister of Health, Labour and Welfare, registration of hospitals to designated academic societies, and guidance and recommendations made by the Minister of Health, Labour and Welfare. It also established a basic framework for providing Artificial Reproductive Technology.⁹⁹ At the request of the Komeito Party, some of the contents of this bill were reflected in the

—嫡出推定・無戸籍問題・DNA 検査・代理出産—『調査と情報—ISSUE BRIEF—』858号, 2015.3.24 (“Considering the Parent-Child Relationship in the Civil Code: Legitimate Birth, Concern over Non-registration, DNA Testing, and Surrogacy”).

⁹⁶ 「出産女性を母に」『日本経済新聞』2016.3.17, p.42 (“Woman Who Gave Birth is the Mother”); 「生殖医療の親子関係法案 自民部会が了承」『朝日新聞デジタル』2016.3.16 (“LDP Division Approves Bill on Parent-Child Relationships in Reproductive Medicine”).

⁹⁷ 「生殖補助医療 代理出産容認法案提出へ 不妊治療 禁止法案も作成 自民 PT」『毎日新聞』2014.4.25, p.1 (“Artificial Reproductive Technology: LDP PT Approves Draft Bill on Surrogacy, Will Also Create Law against Infertility Treatment”); 「不妊治療 「産んだ女性が母」特例法案、自民部会が了承」『毎日新聞』2015.8.5, 夕刊, p.1 (“Infertility Treatment: LDP Division Approves Special Bill Stating that the Woman Who Gave Birth is the Mother”); 『日本経済新聞』*op.cit.* (101).

⁹⁸ 「匿名者卵子で初の出産」『読売新聞』2017.3.23, p.3 (“First Birth Using Anonymous Ovum”).

⁹⁹ 秋野公造「生殖補助医療の適切な提供の確保に関する法律案」『日本医師会雑誌』144巻2号, 2015.5, pp.293-296 (“Draft Bill on Ensuring Appropriate Provision of Artificial Reproductive Technology”); 「生殖補助 公明案を公表」『読売新聞』2015.2.13, 夕刊, p.16 (“Artificial Reproduction: Komeito Draft”). In addition, on March 24, 2016, it was reported that the revised bill was approved by a joint division of the Komeito Health, Labour and Welfare Division, but there was no report on its contents. 「生殖補助で法整備必要」『公明新聞』2016.3.25, p.2 (“Artificial Reproduction Requires Legislation”).

special bill under civil law in March 2016 (approved by the joint division of the Liberal Democratic Party's Judicial Affairs Division and Health, Labour and Welfare Division).

Neither of the above-mentioned bills put forward by either the Liberal Democratic Party or the Komeito has been submitted to the Diet. As for the current situation regarding the lack of legislative progress, there is a press article stating that "it is difficult to collect opinions due to themes related to family views, so the legislation has not materialized yet."¹⁰⁰

Conclusion

It can be said that Japan's accumulation of technology and experience regarding Artificial Reproductive Technology is at the forefront globally. In addition, according to a study¹⁰¹ by the International Federation of Fertility Societies (IFFS), after India, Japan has the second largest number of facilities providing Artificial Reproductive Technology in the world. On the other hand, Artificial Reproductive Technology is self-regulated based on the notices (guidelines) of the Japan Society Obstetrics and Gynecology, and, although new regulations based on laws have been studied, the relevant legislation is still yet to materialize. Considering this state of affairs, while the spread of Artificial Reproductive Technology has been remarkable, Japan can be described as a country that has yet to establish regulations on Artificial Reproductive Technology, despite the fact that public systems based on legislation have been considered. Artificial Reproductive Technology continues to advance day by day. As such, it is necessary to keep an eye on its future progress in terms of the regulatory system that will be formed, while simultaneously understanding the current state of its progress.¹⁰²

¹⁰⁰ 『朝日新聞』 *op.cit.* (24).

¹⁰¹ Steven J. Ory et al., eds., "IFFS Surveillance 2016," *Global Reproductive Health*, Volume 1 Issue e1, September 2016, p.6. This document states that the number of facilities performing Artificial Reproductive Technology in India is 1,000 (as of 2016).

¹⁰² As for the most recent trend on the matter, the first meeting of the "Research Group on Legislation of Parent-Child Relationship Centered on the Birth Legitimacy System" was held on October 18, 2018, involving researchers and practitioners. The research group is held at the Japan Institute of Business Law Research Group, and staff from the Ministry of Justice, as well as related organizations, also participate. The research group discusses the development of parent-child relationship legislation for children born through Artificial Reproductive Technology, while also reviewing the birth legitimacy system. 商事法務研究会ホームページ「嫡出推定制度を中心とした親子法制の在り方に関する研究会」("Research Group on Legislation of Parent-Child Relationship Centered on the Birth Legitimacy System"); 法務省「法務大臣閣議後記者会見の概要 平成 30 年 10 月 19 日(金)」("Summary of the Post-Cabinet Meeting Press Conference of the Minister of Justice: October 19, 2018 (Fri)").

Appendix 1 Comparison of Guidelines by Academic Societies and Professional Organizations

	Japan Society Obstetrics and Gynecology	Japan Medical Association	Japan Society for Reproductive Medicine	Japanese Institution for Standardizing Assisted Reproductive Technology (JISART)
Guideline Title (Including the proposal of the Japan Society for Reproductive Medicine)	Notice of the Japan Society Obstetrics and Gynecology (hereinafter referred to as "JSOG")	Japan Medical Association "Physician's Professional Ethics Guidelines 3rd Edition" Oct. 2016	Japan Society for Reproductive Medicine Ethics Committee Report "Director's Opinion on Concerns Related to the Surrogate Mother" Nov. 1992, and "Recommendations on Reproductive Technology Using Donated Gametes" Mar. 2009	"Implementation Regulations for Facilities Performing Artificial Reproductive Technology in JSART" Revised in Feb. 2018 "JISART Guidelines on In Vitro Fertilization by Donor Using Donated Sperm and Ovum" Revised in Sep. 2018
Requirements for Implementing Facilities and Personnel	<ul style="list-style-type: none"> ○ Registration to JSOG ○ Meet the standards presented by JSOG for facilities and equipment. ○ Establishment of Ethics Committee and Safety Management Committee. ○ Assignment of one person in charge of implementation in accordance with the standards of JSOG, implementing physicians (1 or more), nurses (1 or more), and a technician handling embryos. However, the person responsible for implementation and the implementing physician can be the same person. ○ Preferably, they must have close cooperation with urologists and counselors. (Note 1) 	<p>[In cases of In Vitro Fertilization-Embryo Transfer]</p> <ul style="list-style-type: none"> ○ Facilities that perform in vitro fertilization and embryo transfer must be registered to JSOG. 	<p>[In cases of Artificial Reproductive Technology using donated gametes]</p> <ul style="list-style-type: none"> ○ Preferably, a treatment facility must be accredited upon examination by this organization after a publicly managed organization has been established. ○ Each facility should have a case review and ethics committee. ○ Requires a counselor with sufficient expertise within the facility or a continuous and comprehensive partnership with an external specialist counselor. ○ All documents and information, including the consent of the gamete donor and the recipient married couple, must be stored for at least 80 years. 	<ul style="list-style-type: none"> ○ A medical institution that has been accredited as a facility performing Artificial Reproductive Technology (ART) by JISART. The accreditation review is conducted by the JISART Reproductive Technology Accreditation Committee. ○ Meet JISART standards for staff and facility equipment, patient information provision and response, consent forms, medical records, advertisements, etc. <p>[In cases of In Vitro Fertilization by Donor]</p> <ul style="list-style-type: none"> ○ The person in charge or doctor must have general knowledge of reproductive medicine, including reproductive physiology, embryology, and genetics, and have at least five years of experience in Artificial Reproductive Technology in an appropriate facility performing Artificial Reproductive Technology.

<p>Treatment indication requirements</p>	<p>[In Vitro Fertilization-Embryo Transfer]</p> <ul style="list-style-type: none"> ○ The subject is a couple who strongly desires to have a baby and be able to withstand pregnancy, childbirth, and childcare, both physically and mentally. ^(Note 2) <p>The propriety of sperm or ovum donation for In Vitro Fertilization is not explicitly prohibited in the notice. ^(Note 3)</p> <p>[In cases of Artificial Insemination by Donor]</p> <ul style="list-style-type: none"> ○ This is intended for those who are not likely to become pregnant through procedures other than AID or couples who have attempted other methods but for whom it was judged that the procedure would pose serious risks to the mother or child. ○ A legally married couple who can endure pregnancy, childbirth and childcare both physically and mentally. ○ Artificial insemination using donated sperm is a medical practice performed as a treatment for infertility, and when implementing it, careful attention must be paid to the ethical, legal, and social structures in Japan. ^(Note 4) <p>[Embryo Donation]</p> <ul style="list-style-type: none"> ○ Artificial Reproductive Technology with embryo donation is not allowed. ^(Note 5) 	<ul style="list-style-type: none"> ○ It should be recognized that Artificial Reproductive Technology is in principle performed on couples who suffer from infertility using their gametes. ○ However, if medically determined that Artificial Reproductive Technology using a gamete donated by a third party is not likely to achieve conception with any other procedure, it is not necessarily unethical to perform the procedure on a couple that has fully understood the necessary medical information after counseling. 	<p>[In cases of Artificial Reproductive Technology using donated gametes]</p> <ul style="list-style-type: none"> ○ Currently, women receiving ovum donations should be limited to legally married women who are unable to produce ova in the body because of medical reasons. They must also have a functioning uterus, be 45 years of age or younger, be in good health, and have no hindrance to childbirth or childcare. ○ Men receiving sperm donation should be unable to produce mature sperm from testis or have sperm that are medically incapable of fertilization and embryogenesis. If the wife does not need In Vitro Fertilization-Embryo Transfer, artificial insemination using the provided sperm will be first conducted. If artificial insemination does not lead to conception, In Vitro Fertilization-Embryo Transfer can be performed. 	<p>[In cases of In Vitro Fertilization by Donor]</p> <ul style="list-style-type: none"> ○ Those who can undergo In Vitro Fertilization by donor using donated sperm (the recipient) should have medical reasons for undergoing In Vitro Fertilization instead of artificial insemination. In addition, medical reasons for being unable to conceive without receiving sperm from a third party other than her husband are recognized. The recipient of the ovum donation must have a medical reason for being unable to conceive unless she is provided with an ovum from a third party and undergoes In Vitro Fertilization. ○ The upper limit of the age of the wife should be about 50 years old. ○ The couple should be in a stable condition (health and economic status) to raise the child. ○ It must be confirmed in the family registry that the recipients are a legal couple.
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<p>Requirements for donating sperm and eggs</p>	<p>[In cases of Artificial Insemination by Donor]</p> <ul style="list-style-type: none"> ○ Mental and physical health, no infectious or genetic diseases, and normal semen findings. ○ No more than 10 births from the same sperm donor. ○ Sperm donation should not be for profit. ^(Note 4) 		<p>[In cases of Artificial Reproductive Technology using donated gametes]</p> <ul style="list-style-type: none"> ○ Sperm donors should be physically and mentally healthy adults under the age of 55. In principle, donors who are an anonymous third party to the recipients are given priority. It is necessary to prove that there is no obstacle to sperm donation through various tests, including infectious disease screening. ○ No more than 10 children are born from sperm from the same donor. However, this does not apply if the recipient wishes to obtain the second and subsequent children from the same donor. ○ An ovum donor is a physically and mentally healthy adult under the age of 35, and, in principle, should preferably be an anonymous third party to the recipient. ○ The number of recipients per ovum pick-up is limited to two, and no more than 10 children should be born from the ovum of the same donor. ○ The provision of compensation for the donation of gametes is not allowed. However, it is assumed that a reasonable amount of compensation will be paid. In the case of sperm donation, a reasonable amount of compensation is considered to be the same 	<p>[In cases of In Vitro Fertilization by Donor]</p> <ul style="list-style-type: none"> ○ In principle, the sperm donor must be an adult under 55 years old. ○ The ovum donor must be an adult under 35 years old who already has a child. ○ The number of babies who have given birth support by sperm or eggs provided by the same person has not reached five. ○ The number of children birthed by the person undergoing Artificial Reproductive Technology using donated sperm or ovum from the same donor should not reach five. ○ Giving or receiving any compensation related to the donation of sperm or ovum is not allowed. However, this does not apply to compensation for the expenses related to sperm and ovum donation, the medical expenses of the donor (including compensation when a risk occurs), and for cases that cause loss of income due to the work absence related to counseling or ovum pick-up.
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			as the standard amount currently paid to donors in Artificial Insemination by Donor. In the case of ovum donation, payment of medical expenses, leave expenses, etc. is considered to be a reasonable scope of compensation in consideration of the loss of time and physical stress.	
Surrogacy	<ul style="list-style-type: none"> ○ Surrogacy is not allowed. Members should not conduct or be involved in surrogacy with or without compensation. ○ Not allowed to be an agency for surrogacy. ^(Note 6) 	<ul style="list-style-type: none"> ○ Surrogacy has life-threatening risks to the surrogate mother. There were also cases where the requesting couple did not take charge of the child with Down syndrome. Some European countries have prohibited this procedure because of ethical reasons, and careful consideration is required in Japan. 	<ul style="list-style-type: none"> ○ This issue has a large social, ethical, and legal component, and a clear conclusion on the implementation of the surrogate mother has yet to be achieved. 	
Protection of anonymity and the right to know one's biological origin	<p>[In cases of Artificial Insemination by Donor]</p> <ul style="list-style-type: none"> ○ The sperm donor will remain anonymous to protect the privacy of the person, but the physician shall keep a record of the donor. ^(Note 4) 	<p>[In cases of Artificial Reproductive Technology using a gamete provided by a third party that may be performed]</p> <ul style="list-style-type: none"> ○ The procedure should be implemented only in medical institutions that have a well-developed system in view of addressing the child's right to know their biological origins and of protecting the personal information of the gamete donor. 	<p>[In cases of Artificial Reproductive Technology using donated gametes]</p> <ul style="list-style-type: none"> ○ Proposal to maintain a non-disclosure principle for the married couple. ○ When a child reaches adulthood, basic information other than the donor's address and name should be disclosed in principle. The address and name that identifies the donor will remain undisclosed at the request of the person. However, depending on future legislative trends, disclosure of addresses and names may also be permitted. In that case, it must be explained in advance to the donor that such information may 	<p>[In cases of In Vitro Fertilization by Donor]</p> <ul style="list-style-type: none"> ○ In principle, the donor must be an anonymous third party. ○ According to the agreement signed by more than two-thirds of the members of the JISART Ethics Committee, if no anonymous donors are found, it is considered medically and socially inevitable to use sperm or ovum from relatives or friends. ○ A child who is 15 years of age or older and born through In Vitro Fertilization by donor can request to the implementing medical facility to disclose

			also be disclosed.	information, including details that may identify the sperm or ovum donor, such as their name and address. In case of a request, the implementing medical facility will notify the recipient, donor, and their spouse that this matter will be disclosed to the child prior to consenting to the procedure. In addition, the recipient, donor, and their spouse must understand the impact of the disclosure.
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(Note 1) 日本産科婦人科学会「生殖補助医療実施医療機関の登録と報告に関する見解」(会告) 2016.6 改定 (“Opinion on Registration and Reporting of Medical Institutions Performing Artificial Reproductive Technology”).

(Note 2) 日本産科婦人科学会「体外受精・胚移植に関する見解」(会告) 2014.6 改定 (“Opinion on In Vitro Fertilization-Embryo Transfer”).

(Note 3) Professor KUJI Naoaki from the Department of Obstetrics and Gynecology of the Tokyo Medical University Hospital said they “do not currently perform In Vitro Fertilization using donated sperm.” He added that “while ovum donation is not prohibited in Japan, the Japan Society of Obstetrics and Gynecology has yet to release regulation for this procedure, so we are reluctant to perform it.” 久慈直昭ほか「わが国における不妊治療の現状」『小児科診療』78 巻 1 号, 2015.1, pp.24-25 (“The Current Status of Infertility Treatment in Japan”).

(Note 4) 日本産科婦人科学会「提供精子を用いた人工授精に関する見解」(会告) 2015.6 改定 (“Opinion on Artificial Insemination Using Donated Sperm”).

(Note 5) 日本産科婦人科学会「胚提供による生殖補助医療に関する見解」(会告) 2004.4 (“Opinion on Artificial Reproductive Technology through Embryo Transfer”).

(Note 6) 日本産科婦人科学会「代理懐胎に関する見解」(会告) 2003.4 (“Opinion on Surrogacy”).

(Source) Created by the author based on 日本医師会『医師の職業倫理指針 第 3 版』2016, pp.31-32 (*Physician's Professional Ethics Guidelines 3rd Edition*); 日本生殖医学会「倫理委員会報告『代理母』の問題についての理事見解」1992.11.5 (“Ethics Committee Report: Opinion of the Board of Director on the Issues Concerning the ‘Surrogate Mother’”); 同上「倫理委員会報告 第三者配偶子を用いる生殖医療についての提言」2009.6.19 (“Ethics Committee Report: Recommendations on Reproductive Technology Using Donated Gametes”); 日本生殖補助医療標準化機関「JISART (Japanese Institution for Standardizing Assisted Reproductive Technology, 日本生殖補助医療標準化機関) における生殖補助医療を行う施設のための実施規定 2018 年 2 月改定」 (“Implementation Regulations for Facilities Performing Artificial Reproductive Technology in JISART (Japanese Institution for Standardizing Assisted Reproductive Technology), Revised on February 2018”); 日本生殖補助医療標準化機関「精子・卵子の提供による非配偶者間体外受精に関する JISART ガイドライン 平成 30 年 9 月 1 日改定」 (“JISART Guidelines on In Vitro Fertilization by Donor Using Donated Sperm or Ovum, Revised on September 1, 2018”).

Appendix 2 Comparison of Examination Reports on Artificial Reproductive Technology

	Health Sciences Council Special Committee for Medically Assisted Reproduction	Health Sciences Council Japan Society of Reproductive Medicine	Science Council of Japan Review Committee on the State of Artificial Reproductive Technology
Report Title	“Report on the State of Artificial Reproductive Technology Using Donated Sperm, Ova, and Embryos” Dec. 2000	“Report on the Development of the Artificial Reproductive Technology Using Donated Sperm, Ova, and Embryos” Apr. 2003	“Problems of Artificial Reproductive Technology Focusing on Surrogacy: Toward Social Consensus” Apr. 2008
Basic Ideas	<ul style="list-style-type: none"> ○ Prioritize the welfare of the born child. ○ Do not treat people exclusively as a means of reproduction. ○ Give sufficient consideration to safety. ○ Eliminate the idea of eugenics. ○ Eliminate commercialism. ○ Protect human dignity. 	<ul style="list-style-type: none"> ○ Prioritize the welfare of the born child. ○ Do not treat people exclusively as a means of reproduction. ○ Give sufficient consideration to safety. ○ Eliminate the idea of eugenics. ○ Eliminate commercialism. ○ Protect human dignity. 	<ul style="list-style-type: none"> ○ When discussing Artificial Reproductive Technology, such as surrogacy, the welfare of the born child should be given top priority.
Establishment and role of regulatory agencies and administrative agencies	<ul style="list-style-type: none"> ○ Establish a public deliberation organization to examine the use of each Artificial Reproductive Technology from the ethical, legal, and technical aspects, and make necessary recommendations. ○ Establish a public management organization to manage and administer Artificial Reproductive Technology using donated sperm, ova, and embryos. 	<p>Operation of public management organization</p> <ul style="list-style-type: none"> ○ Information management <ul style="list-style-type: none"> • Storage of consent form (of the married couple undergoing Artificial Reproductive Technology, the donor and their spouse) • Responding to requests for disclosure of consent forms • Storage of personal information • Protection of anonymity and the right to know one’s biological origins • Collection of reports, such as medical results, and preparation and publication of statistics ○ Sperm, ovum, and embryo coordination and matching ○ Screening related to embryo donation ○ Consultation services after a child is born 	<ul style="list-style-type: none"> ○ For surrogacy trials, a public management organization should be established, consisting of specialists in medicine, welfare, law, counseling, etc. ○ Considering the importance of bioethical issues ^(Note 1), preferably, a public research institution should be created, and a new public permanent committee should be established to process these issues, including policy planning.
Regulation Method	<ul style="list-style-type: none"> ○ The following are regulated by law with penalties. <ul style="list-style-type: none"> • The giving and receiving of sperm, ovum, and embryo and acting as an agent for commercial purposes • Conducted procedures for surrogacy and acting as an agent for the procedures • Improper information leakage 	<ul style="list-style-type: none"> ○ The following are regulated by law with penalties. <ul style="list-style-type: none"> • The giving and receiving of sperm, ovum, and embryo and acting as an agent for commercial purposes • Conducted procedures for surrogacy and acting as an agent for the procedures • Improper information leakage 	<ul style="list-style-type: none"> ○ For surrogacy, regulation by law (for example, the Artificial Reproductive Technology Act (tentative name)) is required. ○ Surrogacy that is performed for commercial purposes will be punished.

	that violates the privacy of people with knowledge gained through their professional duties related to Artificial Reproductive Technology using donated sperm, ova, and, embryos	that violates the privacy of people with knowledge gained through their professional duties related to Artificial Reproductive Technology using donated sperm, ova, and embryos	
Implementing Facilities	<ul style="list-style-type: none"> ○ Based on designated standards established by the government after listening to the opinions of the public deliberation organization, a medical facility that performs Artificial Reproductive Technology using donated sperm, ova, or embryos should be designated by the government. Otherwise, the Artificial Reproductive Technology cannot be performed. 	<ul style="list-style-type: none"> ○ Artificial Reproductive Technology using donated sperm, ova, or, embryos can only be carried out by a medical facility designated by the Minister of Health, Labour and Welfare or the head of the local government. ○ Donating sperm, ova, and embryos can be done only in a medical facility designated by the Minister of Health, Labour and Welfare or the head of the local government. ○ The person in charge of implementation at the actual medical facility must establish an ethics committee. 	
Those who are qualified to receive the treatment	<ul style="list-style-type: none"> ○ Limited to legally married couples who want a child but cannot conceive because of infertility. ○ Married couples who cannot conceive because of advanced age are not eligible. ○ Couples who are able to produce their own sperm and ovum cannot receive donated sperm and ovum. 	<ul style="list-style-type: none"> ○ Limited to legally married couples who want a child but cannot conceive because of infertility. Couples who are able to produce their own sperm and ovum cannot receive donated sperm and ovum. ○ Married couples who cannot conceive because of advanced age are not eligible. 	
Sperm Donation	<p>[AID]</p> <ul style="list-style-type: none"> ○ Only couples who are unable to conceive, unless receiving donated sperm, can undergo artificial insemination using donated sperm. <p>[In Vitro Fertilization using Donated Sperm]</p> <ul style="list-style-type: none"> ○ Only married couples who have medical reasons for receiving In Vitro Fertilization, and who cannot conceive unless receiving donated sperm, can undergo In Vitro Fertilization using donated sperm. 	<p>[AID]</p> <ul style="list-style-type: none"> ○ Only couples who are unable to conceive unless receiving donated sperm can undergo artificial insemination using donated sperm. <p>[In Vitro Fertilization using Donated Sperm]</p> <ul style="list-style-type: none"> ○ Only married couples who have medical reasons for receiving In Vitro Fertilization, and who cannot conceive unless receiving donated sperm, can undergo In Vitro Fertilization using donated sperm. 	<ul style="list-style-type: none"> ○ There are issues that have not been discussed, such as the donation of ovum and becoming pregnant with cryopreserved sperm after the death of the husband, while new problems may also emerge in the future. Continuous review surrounding Artificial Reproductive Technology is required.
Ovum Donation	<ul style="list-style-type: none"> ○ Only couples who are unable to conceive unless receiving donated ovum can undergo In Vitro Fertilization using donated ovum. 	<ul style="list-style-type: none"> ○ Only couples who are unable to conceive unless receiving donated ovum can undergo In Vitro Fertilization using donated ovum. 	

Embryo Donation	<ul style="list-style-type: none"> ○ Only a married couple who cannot get pregnant unless receiving an embryo, or a married couple who cannot get pregnant unless receiving a donated ovum and has difficulty obtaining donated ovum, can receive a surplus embryo. ○ If it is difficult to receive surplus embryos, embryos obtained from donated sperm and eggs can be transplanted. 	<ul style="list-style-type: none"> ○ On the condition that the married couple is able to provide a stable environment for the welfare of the child, married couples, who cannot conceive without receiving embryos, are allowed to transfer donated embryos as a last resort. ○ Embryos that can be provided are limited to those obtained by other couples for their own embryo transfer, and embryo transfer obtained by providing both donated sperm and eggs is not allowed. 	
Requirements for donating sperm, ovum, and embryo	<ul style="list-style-type: none"> ○ Persons who can provide sperm are adults under 55 years of age. ○ Only adults under 35 years of age who already have a child can donate ova. ○ Ova from the same donor can be provided up to three times. ○ Giving or receiving compensation related to the donation of sperm, eggs, or embryos is prohibited. However, this does not apply to the amount equivalent to actual expenses. ○ If there is no person who can donate sperm, ovum, or embryo other than siblings, etc., siblings, etc. will be permitted to donate on condition that sufficient explanation and counseling are provided. ○ If a person who has undergone Artificial Reproductive Technology with sperm, ovum, or embryo donated by the same person reaches 10 pregnancies, they may no longer use the sperm, ovum, or embryo from the same donor for Artificial Reproductive Technology. 	<ul style="list-style-type: none"> ○ Persons who can provide sperm are adults under 55 years of age. ○ Only adults under 35 years of age who already have a child can donate ova. ○ The maximum number of ovum pick-up from the same person is limited to three times. ○ If a person who has undergone Artificial Reproductive Technology with sperm, ovum, or embryo donated by the same person reaches 10 pregnancies, they may no longer use the sperm, ovum, or embryo from the same donor for Artificial Reproductive Technology. ○ When collecting and using sperm, ova, and embryos, preventive measures, such as sufficient screening for infectious diseases like HIV or checking for hereditary diseases, must be performed. ○ Giving or receiving compensation related to the donation of sperm, eggs, or embryos is prohibited. However, this does not apply to the amount equivalent to actual expenses and medical expenses. ○ For the time being, the donation of sperm, ova, or embryo from siblings is not allowed. 	

Surrogacy	<ul style="list-style-type: none"> ○ Surrogacy (surrogate mother and gestational surrogacy) is prohibited. (Note 2) 	<ul style="list-style-type: none"> ○ Surrogacy (surrogate mother and gestational surrogacy) is prohibited. (Note 2) 	<ul style="list-style-type: none"> ○ Surrogacy (traditional and In Vitro Fertilization) should in principle be prohibited by law. (Note 2) ○ Trial implementation (clinical trials) of surrogacy may be considered in accordance with the provisions of the law under the regulation of a public agency. ○ Surrogacy for commercial purposes should be punished. Those who are subject to punishment are practicing physicians, agents, and clients, while the surrogate person is excluded from punishment.
Protection of anonymity and the right to know one's biological origins	<ul style="list-style-type: none"> ○ Anonymity is provided when donating sperm, ova, or embryos. ○ After adulthood, a child born by Artificial Reproductive Technology using donated sperm, ovum, or embryo is allowed to know personal information regarding the donor of the sperm, ovum, or embryo that will not identify them within the scope of the disclosure approved by the donor. ○ Before personal information is disclosed, donors can change the scope of the personal information approved for disclosure ○ The child born by Artificial Reproductive Technology using donated sperm, ovum, or embryo can ask for confirmation that the person they wish to marry is not closely related to them to prevent a consanguineous marriage. 	<ul style="list-style-type: none"> ○ Anonymity is provided when donating sperm, ova, or embryos. ○ A child born through Artificial Reproductive Technology using donated sperm, ovum, or embryo, or those who think they may have been born through Artificial Reproductive Technology and are 15 years of age or older, can request to disclose personal information of the donor, including information that may identify the donor, such as their name and address. ○ A child born through Artificial Reproductive Technology using donated sperm, ovum or embryo, or those who think they may have been born through Artificial Reproductive Technology and are 18 years old (male) or 16 years old (female), can ask the public management organization to confirm that the person they wish to marry is not closely related to them to prevent a consanguineous marriage. 	<ul style="list-style-type: none"> ○ The right to know one's biological origin should be respected as much as possible from the perspective of child welfare. However, for this purpose, Artificial Insemination by Donor (AID), which has been conducted for many years, should be first considered before surrogacy. This is an important future issue to be considered.
Parent-Child Relationship	<ul style="list-style-type: none"> ○ Specify the following in the law: <ul style="list-style-type: none"> • The mother of a child born by Artificial Reproductive Technology using donated ovum or embryo is the person who gave birth. • The child conceived and born 	<ul style="list-style-type: none"> ○ In the Special Committee Report ("Report on Artificial Reproductive Technology Using Donated Sperm, Ovum or Embryo, etc." Dec. 2000), regarding the parent-child relationship, it should also be clarified in the law that "the 	<ul style="list-style-type: none"> ○ For the parent-child relationship of a child born by surrogacy, the surrogate person is considered to be the mother. ○ For couples who request surrogacy, the parent-child relationship is established through

	<p>through Artificial Reproductive Technology using donated sperm or embryo upon obtaining the consent of the husband is considered to be the husband's child.</p> <ul style="list-style-type: none"> • If a wife conceives or gives birth through Artificial Reproductive Technology using donated sperm or embryo, her husband's consent is presumed. • A person who donates sperm, ovum, or embryo will not be considered the parent of the child because of the fact that they donated the sperm, ovum, or embryo. 	<p>husband's consent is presumed if the wife conceives and gives birth through Artificial Reproductive Technology using donated sperm or embryo."</p>	<p>adoption or special adoption.</p>
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(Note 1) This refers not only to the issue of surrogacy, but also to various issues related to bioethics.

(Note 2) According to the Glossary of Terms for Obstetrics and Gynecology, "surrogacy" is classified into "traditional surrogacy and gestational surrogacy. In the former case, the husband's sperm is injected into a woman other than his wife (surrogate) through a medical procedure, and the conceived and born child will be the child of the requesting couple. The ovum is derived from the surrogate mother. The latter refers to fertilizing the gamete of the infertile couple through In Vitro Fertilization. The fertilized ovum is placed in the womb of a woman other than the wife for pregnancy and childbirth. The surrogate in this case is also called gestational carrier." 日本産科婦人科学会編・監修『産科婦人科用語集・用語解説集 改訂第4版』日本産科婦人科学会事務局, 2018, pp.235-236 (*Glossary of Terms for Obstetrics and Gynecology Revised 4th Edition*). Surrogacy using a surrogate mother is sometimes called "traditional surrogacy," and gestational surrogacy is sometimes called "In Vitro Fertilization surrogacy."

(Source) Created by the author based on 厚生科学審議会先端医療技術評価部会生殖補助医療技術に関する専門委員会「精子・卵子・胚の提供等による生殖補助医療のあり方についての報告書」2000.12 ("Report on the State of Artificial Reproductive Technology Using Donated Sperm, Ovum or Embryo"); 厚生科学審議会生殖補助医療部会「精子・卵子・胚の提供等による生殖補助医療制度の整備に関する報告書」2003.4 ("Report on the Development of a System for Artificial Reproductive Technology Using Donated Sperm, Ovum, or Embryo"); 日本学術会議 生殖補助医療の在り方検討委員会「対外報告 代理懐胎を中心とする生殖補助医療の課題—社会的合意に向けて—」2008.4 ("External Report: Problems of Artificial Reproductive Technology Focusing on Surrogacy: Toward Social Consensus").