Tecnobios Procreazione Srl
Via Dante, 15
40125 Bologna BO

INFORMATION ABOUT THE TREATMENT

IVF–ICSI
USING FROZEN DONOR EGGS FROM AN EGG BANK

Tecnobios Procreazione Srl
Via Dante, 15
40125 Bologna BO

TESTS REQUIRED FOR
MEDICALLY ASSISTED REPRODUCTION THERAPY

The test results must be presented to the doctors of the medically assisted reproduction centre at the start of treatment.We urge patients to pay the utmost attention to the validity period of the tests. Treatment will not be provided to patients presenting tests that are outside the validity period.

FOR THE MALE PARTNER

a) Hepatitis B Virus Australia Antigen (HBsAg) *(3-month validity)*°
b) Antibody to Hepatitis B Virus core Antigen (HBcAb tot) *(3-month validity)*°
c) Hepatitis C Virus Antibody (HCV) *(3-month validity)*°
d) VDRL, TPHA *(6-month validity)**
e) HIV 1/HIV 2 Antibodies *(3-month validity)**
f) Haemoglobin electrophoresis *(unlimited validity)**
g) Blood group *(unlimited validity)**
h) Y-chromosome microdeletion detection test *(unlimited validity)*
i) Karyotype *(unlimited validity)*
j) Screening for cystic fibrosis *(unlimited validity)*

FOR THE FEMALE PARTNER

a) Hepatitis B Virus Australia Antigen (HBsAg) *(3-month validity)*°
b) Antibody to Hepatitis B Virus core Antigen (HBcAb tot) (3-month validity)°
c) Hepatitis C Virus Antibody (HCV) *(3-month validity)*°
d) VDRL, TPHA *(6-month validity)**
e) HIV 1/HIV 2 Antibodies *(3-month validity)**
f) Blood group *(unlimited validity)**
g) Rubella Virus Antibody detection test *(6-month validity)*
h) Toxoplasma Antibody detection test *(6-month validity)*
i) Indirect Coombs test *(6-month validity)**
j) Cervical smear test *(3-year validity, 5-year validity for HPV test)**
k) Mammogram *(1-year validity)*
l) Electrocardiogram *(1-year validity)*
m) PT, PTT, full blood count with differential, creatinine, glucose, *(1-month validity)*
Only if specifically requested by the doctor: AST, ALT, Antithrombin III, LDL and HDL cholesterol, blood urea nitrogen, electrolytes, CPK, triglycerides, total protein, transferrin, serum iron, urine culture *(1-year validity)*
n) 3D ultrasound of the uterine cavity *(unlimited validity)*
o) Cardiology consultation and echocardiogram *(at doctor's discretion)*

Optional tests (not included in the pre-conception services of the SSN national health system)

a) Toxoplasma antibody detection
b) Cytomegalovirus antibody detection

**These are specialistic services for the protection of responsible motherhood, without participation to costs for preconception purpose, following DPCM on new Essential Level of Assistance 12/01/2017*

°*These tests are mandatory, following the D.Lgs 16/2010*

The above tests can be carried out at accredited laboratories in the patient's place of residence and must be checked before the start of therapy by the patient's general practitioner or by the doctors at the Centre, as agreed during the preliminary interview.

Please send the tests and the informed consent forms to the email address esami@9puntobaby.it or by fax to 0510822328 and always state which doctor is treating you and the place of treatment.

NOTE FOR PATIENTS

Patients requiring a medical certificate should ask for one at the start of treatment.

The certificate will indicate the actual days spent at the Centre.

If patients have insurance cover or are due to receive any other kind of reimbursement, they are kindly asked to inform reception at least 7 days before the start of treatment.

The patients have to send to the centre the together with the consent a copy of their identification documents.

To avoid any misunderstandings, patients are requested to read carefully the section of the consent form concerning payment and costs and to contact us by phone if further information is needed.

We reccomend, as signalled by the Ministry of Health, the assumption of at least 0.4 mg per day of folic acid to decrease the risk of congenital defects.

Beginning the assumption of folic acid at least one month before the conceiving and continuing the until the end of the first trimester of pregnancy is fundamental.

Tecnobios Procreazione Srl
Via Dante, 15
40125 Bologna BO

Statement of Informed Consent for IVF-ICSI (in vitro fertilisation with intracytoplasmic sperm injection) and embryo transfer with frozen donor eggs from an egg bank

IN ACCORDANCE WITH ITALIAN LAW NO 40 OF 19 FEBRUARY 2004

We, the undersigned,

Mr _____ _____ born on _____ in _____ **(____)**

Ms _____ _____ born on _____ in _____ **(____)**

agree to undergo a cycle of **IVF-ICSI (in vitro fertilisation with intracytoplasmic sperm injection) and embryo transfer with donor eggs from an egg bank**.

We declare that we have already had one/several interviews with **Dott./Dott.ssa _____** of the above centre, during which we were informed in a clear and exhaustive manner about the following points:

1. the possibility of using the instruments provided for by Italian Law No 184 of 4 May 1983 on fostering and adoption as an alternative to medically assisted reproduction;
2. the objective and subjective requirements for access to medically assisted reproduction techniques, in accordance with Article 1, paragraphs 1 and 2, Article 4, paragraph 1 and Article 5, paragraph 1, of Italian Law No 40 of 19 February 2004;
3. the legal consequences for the man, the woman and the unborn child, in relation to Articles 8, 9 and 12, paragraph 3 of Italian Law No 40 of 19 February 2004;
4. the penalties referred to in Article 12, paragraphs 2, 4, 5 and 6 of Italian Law No 40 of 19 February 2004;

Article 1. (Purpose)
1. In order to facilitate the resolution of problems stemming from human sterility or infertility, the use of medically assisted reproduction is permitted, in accordance with the conditions and the provisions set out in this Law, which safeguards the rights of all subjects involved, including the conceived child.
2. The use of medically assisted reproduction is permitted if there are no other treatment methods that can effectively remove the causes of sterility or infertility.

Article 4. (Access to the techniques)
1. The use of medically assisted reproduction techniques is only permitted when it is found that the causes impeding reproduction cannot be removed by other means; nevertheless it is restricted to cases of unexplained sterility or infertility that are documented in a medical report, or to cases of sterility or infertility with known causes certified in a medical report.

Article 5. (Subjective requirements)
1. Without prejudice to the provisions of Article 4, paragraph 1, access to medically assisted reproduction techniques is for adult heterosexual couples who are married or cohabiting, of a potentially fertile age and both living.

Article 8. (Legal status of the born child)
1. Children born as a result of medically assisted reproduction techniques have the status of legitimate children or recognised children of the couple that has expressed a willingness to use the said techniques in accordance with Article 6.

Article 9. (Prohibition against the denial of paternity and the anonymity of the mother).
1. If heterologous techniques are employed for medically assisted reproduction, the spouse or the cohabitant whose consent can be obtained from conclusive documentation may not deny paternity in the cases provided for in Article 235, paragraph 1, points 1) and 2) of the Italian Civil Code or have recourse to the appeal process referred to in Article 263 of the same Code.
2. The mother of the child born as a result of the application of medically assisted reproduction techniques may not refuse to be named, in accordance with Article 30, paragraph 1 of the Rules referred to in Decree of the President of the Italian Republic No 396 of 3 November 2000.
3. In the case of application of heterologous techniques, the gamete donor acquires no legal parental relationship with the born child and may exercise no rights or obligations relating to said child.

Article 12. (General prohibitions and penalties)
2. Anyone who, in any capacity, violates Article 5 by using medically assisted reproduction techniques with couples of partners who are not both alive or of whom one is a minor or who are of the same sex or unmarried or not cohabiting is punishable by a fine of 200,000 to 400,000 Euros.
3. To ascertain the requirements referred to in paragraph 2, the doctor uses a statement signed by the requesting parties. In the case of false statements, paragraphs 1 and 2 of Article 76 of the consolidated text of the legislative and regulatory provisions on administrative records, referred to in Decree of the President of the Italian Republic No 445 of 28 December 2000.
4. Anyone who applies medically assisted reproduction techniques without having obtained the consent in the manner provided for in Article 6 is punishable by a fine of between 5,000 and 50,000 Euros.
5. Anyone who, for whatever reason, uses medically assisted reproduction techniques at facilities other than those referred to in Article 10 is punishable by a fine of between 100,000 to 300,000 Euros.

6. Anyone who, in any way, produces, arranges or advertises the sale of gametes or embryos or surrogacy is punishable by imprisonment for between three months and two years and a fine of between 600,000 and one million Euros.

5. the bioethical problems resulting from application of the technique:

The use of MAR procedures can lead to problems centred on an individual's ethical sensitivity, e.g. concerning the distinction between sex life and reproductive life. Using a medical procedure to overcome obstacles to conception and accepting a procedure that entails extra-bodily fertilisation effectively means changing the traditional approach and, for some, the dignity of the reproduction process.
Another issue is the safeguard of the embryo. The principles on which Italian Law 40/2004 is based include the safeguard of the embryo, understood in a broader sense. This is because the philosophical theory and the interpretation of the biological data chosen in support of it state that the entire conception process should be protected at all stages and structures, right from the beginning, in other words from the moment when the sperm and egg meet. This protection should be identical at all stages of the process, for all the different structures that come together. In reality, the theory chosen is not the only one available. There are many others that are compatible with the biological data in our possession, which claim that the status of personhood should be assigned at different points along the timeline of conception.

6. illustration of the specific proposed technique and the related operational phases, with particular reference to its invasiveness for the woman and the man, in accordance with Article 6 of Italian Law No 40 of 19 February 2004:

IVF-ICSI with egg transfer involves several phases.Initially, the recipient couple must undergo a series of blood and diagnostic tests to verify whether they are suitable for treatment.Once the couple has been approved for treatment, the female partner is placed on oestrogen therapy to stimulate the endometrium to get it ready to receive the embryo.This therapy lasts for between 8 and 40 days. If no eggs are available during the course of this therapy, it may be interrupted and then resumed after menstruation. The effectiveness of the therapy is assessed with one or more transvaginal ultrasounds.Once the donor eggs are available, the male partner is asked to produce a semen sample, which is carefully prepared and then used to inseminate the eggs through ICSI. This technique consists in injecting a single sperm cell into the egg.After the microinjection, the eggs are then checked to see if insemination has taken place. Generally speaking, 50 to 70% eggs are fertilised in this process.Eggs that show signs of having been fertilised are kept in culture for a further 24 to 48 hours.During this period, the very first phases of development are set in motion, including one to three cell divisions leading to embryos, each made up of two to eight cells.Two to five days after insemination of the eggs, the embryos are transferred to the patient's uterine cavity.In the vast majority of cases, embryo transfer is fast and painless, involving the simple insertion into the cervical canal of a catheter containing the embryos.About two weeks after transfer, the outcome of the treatment is verified by measuring levels of β-HCG, a hormone produced by the implanted embryo. In accordance with Ruling No 162 of the Constitutional Court of Italy of 9 April 2014, the donation of one's gametes to another couple is permitted to enable their use in assisted fertilisation techniques.If a willingness to donate is expressed, the doctor will check whether the necessary requirements are in place, in accordance with legislation in force.
Invasiveness of the technique
The invasiveness of the technique is moderate and essentially concerns the embryo transfer in the female partner.
Embryo transfer consists in the introduction of the catheter into the cervical canal. It does not require anaesthesia and involves a very low degree of invasiveness.

7. commitment of the requesting parties (including with regard to completion times, pharmacological therapies, diagnostic and laboratory tests, outpatient visits and hospital admissions, including as day patients);

8. undesirable effects or side effects of treatment:

There is a chance that, after preparation of the endometrium, the doctor may not consider it appropriate to proceed with the transfer, if the there is insufficient endometrial development.There is no data in the literature concerning the risks related to short-term use of drugs for endometrial preparation like the one used in this method.These drugs are the same as those commonly used in oral hormone replacement therapy for menopause.Therefore, the data on the side effects of these drugs refer to long-term use of more than one year.Specifically, recent data reveal an increased risk in absolute terms of coronary heart disease after one year of use (AR 4/1000), venous thromboembolism after one year of use (AR 7/1000), infarction after three years of use (AR 18/1000), malignant breast cancer after five years of use (AR 23/1000) (Cochrane Database Syst Rev 2012 Jul). Women who have experienced episodes of deep vein thrombosis or thrombophilia have an increased risk of experiencing an episode of thromboembolism during endometrial preparation therapy and during pregnancy. Several papers in the literature highlight that pregnancies achieved using assisted fertilisation techniques have a worse obstetrical outcome than those resulting from natural conception, in terms of low birth weight, prematurity and perinatal mortality (Ombelet W et al. Facts, Views & Vision in ObGyn 2016, Qin JN et al. Arch Gynecol Obstet 2017).

9. likelihood of the success of the techniques, expressed as the possibility of a live birth:

The success rate reported in the literature for the IVF-ICSI method using frozen eggs from egg banks is around 50% (Hum Reprod 2014 Oct 10,29 (10):2099-113, "Assisted reproductive technology in Europe, 2010: results generated from European registers by ESHRE"). We have been informed that, since the ban on the use of this method has only recently been lifted, the relatively low number of total cases of this treatment at your Centre prevents a reliable estimate of the percentage of pregnancies. We are aware that, in the case of female partners aged ≥45, if more than one embryo is obtained, only one at a time will be transferred. This is to prevent serious complications in the event of a multiple pregnancy.
The pregnancy rate at 9Punto baby centres in the years 2019 to 2022 was 45% with the first transfer. The cumulative rate for the second transfer was 60%.
We have been informed that there are currently no tests on seminal fluid that can ascertain whether sperm cells (even from patients with normal sperm count) fertilise the eggs. Among cases dealt with by Tecnobios Procreazione, the rate of non-fertilisation was is 6.1% (Rep. Italian Ministry of Health on MAR, 2014: 4.9%).
We accept that there is a possibility that the treatment cycle may be suspended, if there are difficulties concerning the individual response to endometrial preparation therapy or if, before or after insemination of the eggs, the culture system is considered to be unreliable. We acknowledge that successful conception is outside the realm of your competence and responsibility. Thus, all decisions regarding the pregnancy will be determined freely and personally by us; hence, specifically, as pertains to the choice whether to proceed with prenatal diagnosis (amniocentesis, chorionic villus sampling, or others) to rule out possible foetal malformations, chromosomal anomalies and, generally, genetic disorders in the unborn child; that is, the choice to accept the possibility of such occurrences.

10. known or possible risks for the mother, as evidenced in the scientific literature:

Ectopic pregnancies
The percentage of ectopic pregnancies reported in the literature is 1.3% – 5.4 % (Muller V. et al. 2016 Gynecol Endocrinol - Rel. Ministero della Salute sulla PMA 2017); among Tecnobios Procreazione cases, the percentage is 2.9%. This condition almost always leads to the removal of the Fallopian tube.
Complications resulting from intrauterine embryo transfer
Although no cases have been reported in the literature, the possibility of complications from infection as a result of embryo transfer cannot be ruled out.

11. known or possible risks for the unborn child, as evidenced in the scientific literature:

It is very difficult to assess the risk of anomalies, malformations, neonatal diseases, not least because of the various problems involved. These include: higher than average age of the mother; possible parental sterility factors; evaluation of such diseases is not unequivocal and is certainly more accurate and prolonged in children born from assisted fertilisation. It is also difficult to estimate how often such disorders occur, since the figures for neonatal malformations vary between 1% and 6%, depending on the case populations examined. Currently, children born as a result of MAR techniques present a slightly greater risk of congenital abnormalities. Recent studies show that this risk tends to decrease over the years, probably thanks to general improvements in laboratory techniques. It should also be noted that children born spontaneously to couples with low fertility also have an increased risk of congenital abnormalities, when compared with those conceived by couples with normal fertility. Most case series show risks ranging from 5% to 6%, compared to the risk in the general population of between 4% and 4.4% (Pelkonen S. et al. Fertil Steril 2014, Bernsten S. et al Hum Reprod Update 2019). Most case series do not report an increase of cases of malignant tumors in babies born as a result of ART (Bernsten S. et al Hum Reprod Unpdate 2019). The 2017 Report of the Italian Ministry of Health reveals a rate of 0.7% of malformations among live births. At this Centre, the percentage of children born as a result of IVF with embryo transfer in the period in question who also had malformations was 0.4%.

12. risks related to heterologous MAR techniques and the measures taken to mitigate these risks, particularly with regard to the clinical examinations undergone by the donor, including the medical genetics consultation, and the tests performed, representing that these tests can in no way guarantee the absence of disease in the born child:

The main criteria for choosing a donor are good health and the absence of genetic abnormalities within his or her family. This must be established by means of a thorough investigation of their genetic history. No method can guarantee categorically that no infectious agent can be transmitted by insemination with donor eggs or sperm.

Nevertheless, the guidelines contained in the "Document on problems relating to heterologous fertilisation following Ruling No 162/2014 of the Constitutional Court of Italy" (Conference of Regions and Autonomous Provinces of 4 September 2014) which are applied at this Centre, combined with a proper investigation into medical history and the exclusion of individuals at high risk for HIV and other sexually transmitted diseases, can significantly reduce these risks.

Anonymity

The identity of the donor will not be made known to us the receiving parties or to any children born to us from this gamete donation programme. We are full aware that we are not entitled to know the donor, just as the donor will not know or be entitled to know our identity.

Number of donations

We have been informed that, in order to ensure that it is statistically unlikely for blood relations to engage, unaware, in sexual intercourse, no more than ten births may result from the eggs or the sperm of a single donor. This limit may be waived only in cases where a couple that has already had a child using heterologous medically assisted reproduction techniques wishes to undergo the same technique again using the eggs or sperm of the same donor, if available.

Choosing the phenotypic traits of the donor
We have been informed that, in order to prevent eugenic selection, which is illegal, it is not permitted to choose any particular phenotypic traits of the donor. However, your Centre undertakes to ensure reasonable compatibility between the main phenotypic traits of the donor and our own.

13. commitment to inform the Centre, if undergoing heterologous MAR, of the onset of any illnesses or disorders, even after a long period of time, in the woman, in the unborn child or in the born child, and which it is reasonable to assume existed before the donation:

We are aware that only gametes from tissue institutes, banks or centres operating in accordance with Italian and European legislation in force and with the provisions of Chapter II of the Italian Ministerial Decree of 10 October 2012, which regulates the import and export of gametes and embryos, and of paragraph 298 of Article 1 of Italian Law No 190 of 23 December 2014, which establishes the "National register of reproductive cell donors for the purpose of heterologous medically assisted reproduction", in order to safeguard the health of all subjects involved in the process. The assisted reproduction centre is required to disclose to the regional authority and to the National Transplant Centre all available information regarding presumed serious adverse reactions, in accordance with Article 11 of Legislative Decree No 191/2007 and Articles 10 and 11 of Legislative Decree No 16/2010.

14. possibility that children born from heterologous fertilisation may, as adults, become the object of inappropriate investigation of medical history, if they are is not aware of the method used for their conception;

15. the voluntary and gratuitous donation of gametes, as defined in Article 12 of Legislative Decree No 191 of 6 November 2007, as well as the revelation of the identity of the receiving party or parties to the donor or to his or her family and vice versa, as defined in paragraph 3 of Article 14 of the same legislative decree:

Legislative Decree No 191/2007
Article 12 Principles of tissue and cell donation
1. The donation of cells and tissues is gratuitous. […]
Article 14 Protection of data and protection of confidentiality
[…]
3. In accordance with legislation in force on this subject, the identity of the receiving party or parties is not revealed to the donor or to his or her family and vice versa. […]

16. the possible psychological effects for the individual partners, for the couple and for the born child resulting from application of the technique, particularly with regard to the specific techniques of heterologous MAR:

Most couples are able to cope with their infertility on their own. Some, on the other hand, need psychological help at some point on their treatment path, especially if the number of failures increases.
In both men and women, infertility can be accompanied by emotional suffering, which has a significant impact on relationships, be it within the couple, with their families of origin; the relationship of the woman with other women; the couple's relationships in their wider social context.

Psychological therapy can help this suffering emerge so that it can be processed and contained, by facilitating the expression of emotions and the causes of anxiety.
An experienced psychologist can provide support as both partners share their reasons for entering into and continuing treatment and as they process their grief at the failures they might encounter. Therapy can help the couple come to terms with their experience and avoid the dangers of therapeutic obstinacy.
The scientific literature is divided about the concerns relating to the psychological problems that might affect children conceived with medical assistance.
Some authors claim that children could encounter psychological difficulties linked to the fact that their conception was "aided" by medicine. Others say that the only appreciable difference noted in these children stems from the worry and anxiety that their parents have been through.
These children are closely followed and are monitored by doctors more than children conceived spontaneously.
The numerous papers published agree that the cognitive and neuropsychological development of children born as a result of MAR is similar to that of children in the general population (Berry KZ et al.Am J Obstet Gynecol 2013; Hart R. et al. Hum Reprod Update 2013; Xing LF et al. J Zhejiang Univ Sci B 2014; Klausen T et Al Eur Child & Adolescent Psychiatry 2017).
Different opinions are reported regarding the impact of "disclosing the secret" on the structure of the family or on the serenity of the whole unit regarding whether or not the unborn child should be made aware of their biological origin. This aspect can be explored during counselling (Blake L. et al.Hum Reprod 2014, Ilioi E. et al. J Chil Psychol Psychiatry 2017). We are aware that psychological support is available at the Centre and accessible at any phase of treatment.

Taking all above into account, we declare we have been proposed a consultation with the centre psychologist and after a careful evaluation we have decided to:

☐ accept the consultation

☐ refuse the consultation

17. the possibility of cryopreserving male and female gametes for subsequent assisted fertilisation treatments and, possibly for donation for heterologous fertilisation.

Please see the specific informed consent forms for the cryopreservation of male and female gametes.

18. possibility for requesting parties to withdraw consent until fertilisation of the egg:

The willingness of both parties to have access to medically assisted reproduction techniques is provided by them in writing, jointly with the doctor in charge of the facility, in accordance with the procedures defined by Decree of the Ministers of Justice and Health, adopted in accordance with Article 17, paragraph 3 of Italian Law No 400 of 23 August 1988, within three months of the date of entry into force of this Law. There must be a period of at least seven days between the manifestation of willingness and application of the technique. The willingness to proceed may be withdrawn by either of the persons referred to in this paragraph before fertilisation of the egg.

19. the possibility for the doctor in charge of the facility not to proceed with medically assisted reproduction on solely medical and health-related grounds, to be provided in writing:

Law No 40/2004
Article 6. (Informed Consent)
[…]
4. Without prejudice to the requirements of this law, the doctor in charge of the facility may decide not to proceed with medically assisted reproduction, solely on medical or health-related grounds. To this effect, he or she must provide the couple with a written justification for that decision.

20. the limitations on application of embryo techniques as referred to in Article 14 of Italian Law No 40 of 19 February 2004;

Law No 40/2004
Article 14. (limitations on the application of embryo techniques), as amended by Ruling No 151/2009 of the Constitutional Court of Italy
1. The removal and cryopreservation of embryos is prohibited, without prejudice to the provisions of Law No 194 of 22 May 1978.
2. Taking into account technical and scientific advances and the provisions of paragraph 3 of Article 7, embryo production techniques should create no more embryos than is strictly necessary for a single and simultaneous implantation, which in no circumstances should exceed three.

3. If embryo transfer is not possible for serious and documented reasons of force majeure relating to the health of the woman that were not foreseeable at the time of fertilisation, said embryos may be cryopreserved until the date of transfer, which should be performed as soon as possible.
4. For the purposes of this law on medically assisted reproduction, embryo reduction is not permitted in multiple pregnancies, except in the cases provided for by Law No 194 of 22 May 1978.
5. The subjects referred to in Article 5 are to be informed of the number and, at their request, the health of the embryos produced and to be transferred to the uterus.
6. Violation of the prohibitions and obligations referred to in the previous paragraphs is punishable by imprisonment of up to three years and a fine of between 50,000 and 150,000 Euros.
7. Health professionals convicted of any of the offences referred to in this article may be suspended from practising their profession for up to one year.
8. The cryopreservation of male and female gametes is permitted, subject to informed and written consent.
9. Violation of the provisions referred to in paragraph 8 is punishable by a fine of between 5,000 and 50,000 Euros.

21. the possibility of cryopreserving embryos in cases consistent with the provisions of Article 14 of Italian Law No 40 of 2004 and Ruling No 151 of the Constitutional Court of Italy of 2009. To this end, we have been informed that embryo production techniques should not create more embryos than are strictly necessary for reproduction and that the transfer of the created embryos should be carried out as soon as possible, without affecting the woman's health. We have also been told of the risk of producing supernumerary embryos, with the consequence of allocating surplus embryos to cryopreservation;

22. number of donated eggs and the total financial cost of the procedure:

We have been informed that the survival rate of frozen eggs is about 80% and that of the surviving eggs the average fertilisation rate is between 50% and 70%.

❒ Base treatment

At least one transfer at blastocyst stage (if there are no male factors and/or genetic factors) € 7.500,00 of which the initial sum of € 3.500,00 is to be paid to start the process of searching for the eggs and the remaining € 4.000,00 on the day the eggs are inseminated;

Any subsequent embryo transfer after the first will have a cost of € 1.750,00.

In case of delayed transfer an amount of 150,00 euro will be due for the embryo devitrification

Man’s signature_____Woman’s signature_____

❑ Treatment plus

At least a second transfer at blastocyst stage, if the first transfer failed (if there are no male factors and/or genetic factors) € 9.000,00 of which the initial sum of € 4.500,00 is to be paid to start the process of searching for the eggs and the remaining € 4.500,00 on the day the eggs are inseminated;

Any subsequent embryo transfer after the first will have a cost of € 1.750,00.

In case of delayed transfer an amount of 150,00 euro will be due for the embryo devitrification

Man’s signature_____Woman’s signature_____

❑ Egg donation treatment + aneuploidy screening

The cost of the procedure is € 11.350,00 of which the initial sum of € 4.500,00 is to be paid to start the process of searching for the eggs and the remaining € 6.850,00 Euros on the day the eggs are inseminated.
At least one embryo transfer at blastocyst stage (if there are no severe male factors and/or genetic factors). The cost includes up to 2 blastocysts. The cost of each additional blastocyst analysed will be € 400,00.

Any subsequent embryo transfer after the first will have a cost of € 1.750,00.

In case of delayed transfer an amount of 150,00 euro will be due for the embryo devitrification

Man's signature_____Woman's signature_____

- in addition to the cost of the procedure, we will be responsible for the cost of any drugs are not prescribed under the Italian national health system (SSN).
- if we withdraw from treatment for health or other reasons, we will only be required to pay the initial sum referred to above, instead of the entire cost of treatment;
- if treatment ends without a pregnancy, you will still be entitled to the above fees, which we are jointly committed to paying you.

Fully aware of the above, we hereby express our willingness to undergo the proposed technique of medically assisted reproduction, to be applied no earlier than seven days from the signing of this statement.

Date _____

Man's signature _____

Woman's signature _____

****

By confirming our signatures and that this document, which we have sent to you by fax/post, comes from us, we also confirm that, from the date of the document to this day, our willingness as stated remains firm.

Date _____

Man's signature _____

Woman's signature _____

The Doctor _____

Tecnobios Procreazione Srl
Via Dante, 15
40125 Bologna BO

We, the undersigned,
Ms _____ _____ and Mr _____ _____

in accordance with the provisions of paragraph 1 of Article 5 and paragraph 3 of Article 12 of Italian Law 40/2004 “Rules on medically assisted reproduction” set out below:

Article 5.
(Subjective requirements)

1. Without prejudice to the provisions of Article 4, paragraph 1, access to medically assisted reproduction techniques is for adult heterosexual couples who are married or cohabiting, of a potentially fertile age and both living.

Article 12.
(General prohibitions and penalties)

3. To ascertain the requirements referred to in paragraph 2, the doctor uses a statement signed by the requesting parties. In the case of false statements, paragraphs 1 and 2 of Article 76 of the consolidated text of the legislative and regulatory provisions on administrative records, referred to in Decree of the President of the Italian Republic No 445 of 28 December 2000.

Note: The text of Article 76, paragraphs 1 and 2 of the Decree of the President of the Italian Republic No 445 of 28 December 2000 is as follows.
“1. Anyone who makes false statements, forms false documents or makes use of them in the cases provided for by this consolidated text is punishable under the Criminal Code and the special laws on this matter.
2. Displaying a document that contains information that no longer corresponds to truth is equivalent to using a false document.”

we declare that we are both aged over eighteen, of different genders, married or cohabiting and of potentially fertile age

Date _____

Signature _____ Signature _____

Tecnobios Procreazione Srl
Via Dante, 15
40125 Bologna BO

CHARACTERISTICS OF THE COUPLE

MAN		WOMAN
	FIRST NAME AND SURNAME	
o CAUCASIAN o AFRO o LATINO o ASIAN o OTHER:_____	**PHENOTYPE**	o CAUCASIAN o AFRO o LATINO o ASIAN o OTHER:_____
	BLOOD GROUP, RH	
	HEIGHT (cm)	
	Weight (kg)	
o BLOND o RED o BLACK o BROWN	**HAIR COLOR**	o BLOND o RED o BLACK o BROWN
o STRAIGHT o CURLY o WAVY	**HAIR TYPE**	o STRAIGHT o CURLY o WAVY
o BLUE o GREEN o BLACK o BROWN o GREY	**EYE COLOR**	o BLUE o GREEN o BLACK o BROWN o GREY
o LIGHT o DARK o OLIVE o OTHER:_____	**COMPLEXION**	o LIGHT o DARK o OLIVE o OTHER:_____
o LARGE o NORMAL o SLIGHT	**BUILD**	o LARGE o NORMAL o SLIGHT
Referring doctor:		

Date _____

Man's signature_____ Woman's signature_____

After completion, this form must be sent

to the email address eterologa@9puntobaby.it or by fax to 0510822328

Zika Virus Infections – Prevention and control measures

Summary of recommendations for pregnant women, women of reproductive age and their partners intending to travel to or returning from areas where there is currently Zika virus transmission or areas where historically Zika virus circulation has been reported.

TARGET POPULATION	**RECOMMENDATIONS**
Pregnant women	- Before you start your trip, consult your doctor to assess the individual risks and consider postponing non-essential travel to infected areas. - While travelling, take all measures possible to prevent mosquito bites. - Stay abstinent or have protected sex throughout the pregnancy. - When you get back from your trip, tell your doctor about your trip to areas with current Zika virus transmission and contact a doctor immediately if you develop symptoms that appear to be those of Zika virus.
Partners of pregnant women	- When you get back, stay abstinent or have protected sex throughout the pregnancy. - Contact a doctor immediately if you develop symptoms that appear to be those of Zika virus and tell them about how you may have been exposed to infection during your trip.
Women of reproductive age or women who are considering pregnancy	- Before your trip, consult your doctor to receive information about the possible effects of Zika virus during pregnancy and on the foetus, about how to prevent mosquito bites and sexual transmission, so you can make an enlightened choice as to whether to avoid conceiving during your trip and for two months once you return home.
Partners of women of reproductive age or women who are considering pregnancy	- Male sex partners returning from areas with current Zika virus transmission should have protected sex or stay abstinent for at least three months after their last possible exposure to Zika virus. - Get tested for Zika virus, if your partner asks you to

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The possibility of cryopreserving embryos in cases consistent with the provisions of Article 14 of Italian Law No 40 of 2004 and Ruling No 151 of the Constitutional Court of Italy of 2009.

We, the undersigned,

Mr **_____ _____** born on **_____** in **_____ (____)**

Ms **_____ _____** born on **_____** in **_____ (____)**

having been informed by **Dott./Dott.ssa _____** that we should produce the number of embryos considered strictly necessary for a useful result in the specific scenario. This number is chosen to protect reproductive needs and women's health rights. Notwithstanding the general prohibition of cryopreservation, any supernumerary embryos must be cryopreserved, if transferring them would go against reproductive needs (after a useful outcome has already been achieved) and/or would go against the patient's health (danger of multiple pregnancies). We are aware of the obligation that frozen embryos are to be transferred as soon as possible, without prejudice to the health of the woman.

We are well aware that the consensus to the Assisted Reproduction Treatment cannot be revoked and that the woman can ask the embryo transfer even if the partner is dead (Court of Cassation, 15/05/19, n. 13000) or the relationship has come to an end (Constitutional Court n. 161/2023).

Aware of the above

❒ we agree to the insemination of the number of oocytes that the centre's team of doctors and biologists considers appropriate.

❒ we do not agree to the insemination of the number of oocytes that the centre's team of doctors and biologists considers appropriate.

If the laboratory results indicate that it would be suitable, we have been thoroughly informed of the possibility of keeping the embryos in culture until the blastocyst stage. We are aware that, while on the one hand, embryo transfer at this stage of development provides a higher probability of implantation and reduces the likelihood of a multiple pregnancy, on the other, it can lead to non-transfer, if none of the embryos develops to the blastocyst stage. The survival rate of embryos frozen at our Centre varies from 97% to 98.8%, depending on the stage of development (3rd or 5th day of culture) (Esher Special Interest Group of Embryology and Alpha Scientists in Reproductive Medicine. Repord Biomed Online, 2017)

In this regard:

❒ we agree to the embryos being kept in culture.

❒ we do not agree to the embryos being kept in culture.

We are aware that Article 14 of Italian Law 40/2004 prohibits the destruction of the said supernumerary embryos and that cryopreservation is regulated by the provisions of the Decree of the Italian Minister of Health of 4 August 2004 set out here below:

Article 1

1. For the purposes of Article 17, paragraph 3 of Law No 40 of 19 February 2004, concerning the rules governing medically assisted reproduction, this decree identifies two different types of cryopreserved embryos: embryos that are awaiting future implantation; embryos whose abandonment has been ascertained.
2. The abandonment of an embryo is ascertained when one of the following conditions occurs:
   a. the centre for medically assisted reproduction gets a written waiver of the future implantation of cryopreserved embryos from both parents from the woman alone (in the case of embryos produced before the current regulations on donor sperm and in the absence of a male partner);
   b. the centre performing the medically assisted reproduction techniques records the repeated attempts made, for at least one year, to contact the couple or the woman who has asked for the cryopreservation of embryos; only in the case of an actual, documented impossibility of tracing the couple can the embryo be defined as abandoned.

The Centre is entrusted with the storage and safekeeping of the cryopreserved material and all relevant health records, at its own premises or at third-party premises authorised for the purpose by the Ministry of Health and used by the Centre in accordance with articles 21 and 24 of Legislative Decree no. 191/2007.

We have been informed of the payment conditions and agree to the following:

- No amount will be invoiced for the embryos cryopreservation and the activities of embryos conservation and custody for the first year after the treatment and/or pregnancy and birth.
- if, at the end of this period, the embryos are still in storage at your facility, we hereby undertake to pay you the sum of €671 (six hundred and seventy-one Euros) annually in proportion to the number of months elapsed from that time until the end of storage due to the transfer of the embryos or until we abandon the embryos by means of a written statement of relinquishment in accordance with the provisions of letter a), paragraph 2 of Article 1 of the aforecited decree.
- the cost of the service of thawing and transfer of embryos is € 1,750 (one thousand seven hundred fifty Euros).
- If we decide to terminate the arrangement for the storage and safekeeping of the embryos in order to place them at another facility, we will be invoiced €220 (two hundred and twenty Euros) for the specialist medical and biological services of preparing the biological material for withdrawal.

At the same meeting, we were also proposed the possibility of cryopreserving any supernumerary oocytes and we were provided with thorough explanations of the technique and of the chances of success. In this regard, we hereby:

❒ agree to freeze our supernumerary eggs, for which we will sign a separate informed consent letter

❒ do not agree to freeze our supernumerary eggs

Date _____

Man's signature _____ Woman's signature _____

Doctor's signature _____