Tecnobios Procreazione Srl
Via Dante, 15
40125 Bologna BO

Rev. 7 Data di appl. 18/05/2024

INFORMATION ABOUT THE TREATMENT

F.I.V.E.T. / I.C.S.I. EN

When you start the therapy, all the routine tests you will find in the following pages have to be already undergone and checked.

We kindly ask you to keep at you disposal the instructions during the phone calls that may take place.

In the meantime, we recommend you ask your doctor to prescribe the drugs in your treatment plan, which you will receive by post. The prescribed number of ampoules corresponds to the average dose needed by each patient. Please note that if the dosage is increased during monitoring at the Centre, the doctors there cannot make out prescriptions on Italian national health system (SSN) prescription pads.

Gonadotropin treatment protocol
initial treatment phase

Only begin the stimulation protocol after talking with a doctor at the Centre.

.....	Day 1	8 pm	… …IU of ……. ……
.....	Day 2	8 pm	… …IU of ……. ……
.....	Day 3	8 pm	… …IU of ……. ……
.....	Day 4	8 pm	… …IU of ……. ……
.....	Day 5	8 pm	… …IU of ……. ……
.....	Day 6	8 pm	… …IU of ……. ……
.....	Day 7	8 am	Come to the assisted reproduction Centre. **Patients staying away from home must bring all prescribed medications with them, as they will need to be administered during later phases.**

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.

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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 , THPA *(6-month validity)**
e) HIV 1/HIV 2 Antibodies *(3-month validity)**
f) Haemoglobin electrophoresis *(unlimited validity)**
g) Blood group *(unlimited validity)**

Only if specifically requested by the doctor

1. Y-chromosome microdeletion detection test *(unlimited validity)*
2. Karyotype *(unlimited validity)*
3. 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) Haemoglobin electrophoresis *(unlimited validity)**
g) Blood group *(unlimited validity)**
h) Rubella Virus 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) FSH between 3rd and 5th day of menstrual cycle and AMH *(6-month validity)*
l) Mammogram or breast ultrasound *(1-year validity)*
m) Electrocardiogram *(1-year validity)*
n) PT, PTT, full blood count with differential, creatinine, glucose, Antithrombin III *(6-month validity)*

Only if specifically requested by the doctor

o) Toxoplasma Antibody detection test *(6-month validity)*
p) Citomegalovirus Antibody detection test *(6-month validity)*
q) Karyotype *(unlimited validity)*
r) Screening for cystic fibrosis *(unlimited validity)*

**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.**

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FINAL PHASE OF TREATMENT

This takes in a week depending on the individual response, during which stimulation of multiple follicular growth is monitored by ultrasound and hormone levels are measured.

During this period, the patient must be fully prepared and available to be present at the Centre on the mornings requested by her doctor (usually alternate mornings) at dalle ore 8.30 ed entro le ore 10.00 so that the doctors and biologists can carry out all the tests necessary.

Every morning, the doctors who perform the ultrasound will tell the patient how the treatment cycle is going.

Her daily therapy will be notified to her in person or by phone in the afternoon.

The doctors will available for any clarification the patient might need about the treatment.

The patient must be free after the ultrasound and blood draw during the monitoring phase. On the day of the egg retrieval, she will be discharged 2 to 4 hours after the procedure.

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.

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.

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

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STATEMENT OF INFORMED CONSENT FOR IVF - ICSI (IVF WITH INTRACYTOPLASMIC SPERM INJECTION) AND EMBRYO TRANSFER

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 technique (in vitro fertilisation with intracytoplasmic sperm injection) and embryo transfer**.

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 with ICSI takes place across several phases.
The first phase involves stimulating the ovaries for multiple growth of follicles and hence oocytes. This increases the chances of fertilisation and development of an embryo into a normal foetus. During stimulation, follicular growth is carefully monitored by ultrasound and by oestradiol levels. Oestradiol is the hormone produced by the follicles as they develop. These examinations help determine the best time to retrieve the eggs. This takes from nine to twelve days, depending on the individual response. During this phase, the patient must be fully prepared and available to be present at the Centre on the mornings requested by her doctor (usually alternate mornings) so that the doctors and biologists can carry out all the tests necessary. When enough follicles have developed, the final phase of follicular maturation is induced.
The next phase involves aspirating the eggs from the follicles through a needle that has been inserted into the vaginal wall under ultrasound guidance. This procedure takes place under intravenous anaesthesia. The patient can usually be discharged two hours after the procedure. Once the eggs have been retrieved, the male partner is asked to produce a semen sample, which undergoes a certain preparation process before being used to inseminate the eggs.
In the insemination procedure, the sperm cells and eggs are in contact for about 16 to 18 hours (IVF)
or a single sperm cell is injected into the egg (ICSI). They eggs are then checked to see if insemination has taken place. Generally speaking, 70-80% of eggs are fertilised with this procedure.
If there are no sperm cells in the ejaculate or it is not possible, for other reasons, to obtain a semen sample from the ejaculate, the male partner can undergo testicular sperm aspiration (TESA). A needle is inserted through the skin of the testicle and sperm is aspirated so that it can be injected into the eggs using the ICSI microinjection technique. According to the literature, a complication that occurs in 7% of cases of testicular sperm aspiration is non-symptomatic transient intratesticular haematomas, detectable from scrotal ultrasound. These usually resolve spontaneously within three to six months of surgery (Hum. Repr. 15; 653-656, 2000; Fertil Steril 82; 442-444, 2004).
After the microinjection, the eggs are then checked to see if insemination has taken place. Generally speaking, 60-70% of eggs are fertilised in the IVF-ICSI-TESA process.
Eggs that show signs of having been fertilised are kept in culture: 2-5 days after retrieval of the eggs, the embryos are transferred to the patient's uterine cavity, unless the transfer is being deferred. 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 the 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 retrieval of eggs from the female partner.
This procedure is carried out transvaginally under intravenous anaesthesia and under ultrasound guidance. 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 ovarian stimulation therapy with drugs, the doctor may not consider it appropriate to proceed with egg harvesting, if the response was not sufficient.The rate of this occurring is reported in literature to range from 6.8% to 20.8% and depends on the age and the clinical condition of the patient (Abdalla HI et al.Reprod Biomed Online 2010, Nov. – Rep. Italian Ministry of Health on MAR, 2017). Data from the literature concerning the use of drugs to induce multiple ovulation show no increased risk of ovarian cancer or breast cancer in patients who have undergone this therapy (Breast Cancer Res Treat 2015, Tonday S., Lancet 2016, Van dem Belt er al., JAMA 2016, Zhao J. Et al. RBM Online 2015).Women who have experienced episodes of deep vein thrombosis or thrombophilia have an increased risk of experiencing an episode of thromboembolism during multiple follicular growth stimulation 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, Sine B. et al Hum Reprod Update 2019).

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

We declare that we have examined the rates of positive outcomes and have been informed of the actual likelihood of success in light of the limitations introduced by paragraphs 1 and 2 of Article 14 of Italian Law No 40/2004.
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: data from literature report percentages of TFF (Total Fertilization Failure) between 5 and 10% with IVF and between 2 an 3% with ICSI (kahiaoglu et al, J Assisted Reprod Genet 2015).We have also been informed of the possibility of non-retrieval of eggs even in the event of apparently normal ovarian stimulation. In the literature, the rate of this occurrence varies between 3.3% and 7% (Singh N. et al. 2018, J Hum Reprod Sci 2018– Rep. Italian Ministry of Health on MAR, 2017). We have been informed that, if the cyropresevation of the embyos is needed, the survival rate of the embryos to the thawing varies between 97 and 98.9% depending on the development stage (3rd or 5th day of colture)
We accept that there is a possibility that the treatment cycle may be suspended, if there are difficulties concerning the individual response to stimulation or if, before or after egg retrieval, the culture system is considered to be unreliable. We also accept that, if the parameters of the seminal fluid are assessed as unsuitable for IVF with embryo transfer, we will proceed with insemination of the eggs by ICSI (intracytoplasmic sperm injection).
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.

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CUMULATIVE RESULTS AMONG TECNOBIOS PROCREAZIONE CASES RELATED TO DIFFERENT AGE GROUPS AND NUMBER OF OOCYTES RETRIEVED

(For a better understanding, please refer to our website www.nove.baby)

	NUMBER OF OOCYTES RETRIEVED										
WOMAN'S AGE <34 YEARS	**1–2**	**3–4**	**5–6**	**7–8**	**9–10**	**11–12**	**13–14**	**15–16**	**17–18**	**19–20**	**>21**
No. of CYCLES	107	254	349	393	344	289	206	131	87	56	75
No. of PREGNANCIES	9	39	92	130	136	136	111	78	47	33	42
% CUMULATIVE PREGNANCY	8.4%	15.4%	26.4%	33.1%	39.5%	47.1%	53.9%	59.5%	54.0%	58.9%	56.0%
CUMULATIVE BIRTH RATE PER CYCLE (%)	**6.5%**	**12.2%**	**21.2%**	**27.7%**	**33.1%**	**38.4%**	**38.8%**	**44.3%**	**39.1%**	**51.8%**	**45.3%**

	NUMBER OF OOCYTES RETRIEVED										
WOMAN'S AGE 35–38 YEARS	**1–2**	**3–4**	**5–6**	**7–8**	**9–10**	**11–12**	**13–14**	**15–16**	**17–18**	**19–20**	**>21**
No. of CYCLES	188	407	476	434	372	316	190	107	76	43	53
No. of PREGNANCIES	15	59	129	147	131	139	89	52	49	19	36
% CUMULATIVE PREGNANCY	8.0%	14.5%	27.1%	33.9%	35.2%	44.0%	46.8%	48.6%	64.5%	44.2%	67.9%
CUMULATIVE BIRTH RATE PER CYCLE (%)	**6.9%**	**10.6%**	**19.1%**	**24.2%**	**23.4%**	**34.5%**	**35.8%**	**32.7%**	**43.4%**	**39.5%**	**49.1%**

	NUMBER OF OOCYTES RETRIEVED										
WOMAN'S AGE 39–42 YEARS	**1–2**	**3–4**	**5–6**	**7–8**	**9–10**	**11–12**	**13–14**	**15–16**	**17–18**	**19–20**	**>21**
No. of CYCLES	454	582	509	394	284	192	113	62	43	22	30
No. of PREGNANCIES	24	71	83	85	69	56	40	29	14	10	8
% CUMULATIVE PREGNANCY	5.3%	12.2%	16.3%	21.6%	24.3%	29.2%	35.4%	46.8%	32.6%	45.5%	26.7%
CUMULATIVE BIRTH RATE PER CYCLE (%)	**2.9%**	**7.4%**	**8.8%**	**14.2%**	**13.7%**	**21.4%**	**21.2%**	**32.3%**	**18.6%**	**22.7%**	**23.3%**

	NUMBER OF OOCYTES RETRIEVED		
WOMAN'S AGE 43–45 YEARS	**1–6**	**7–10**	**>11**
No. of CYCLES	368	90	47
CUMULATIVE BIRTH RATE PER CYCLE (%)	**3.3%**	**5.6%**	**4.3%**

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

Among Tecnobios Procreazione in vitro fertilisation cases in the period 2012–2017, 20.7% were twin pregnancies and 0.5% were triplet pregnancies. These percentages depend on the number of embryos transferred and the age of the patient. We acknowledge, however, that such occurrences are outside the realm of your competence and responsibility, hence, all decisions on whether or not to continue the pregnancy will be determined freely and personally by us.

Ovarian hyperstimulation syndrome

From the cases treated by Tecnobios Procreazione, the rate of ovarian hyperstimulation syndrome is around 0.1%. In the literature, the rate varies between 0.2% and 1.9% (Humaidan P. et al. Fertil Steril Jul 2010 - Rep. Italian Ministry of Health on MAR, 2017). This syndrome can lead to an abnormal increase in ovarian volume, ascites and various complications that could require admission to specialist clinics.

Ectopic pregnancies

The percentage of ectopic pregnancies reported in the literature is 1.3% – 5.4% (Muller V. et al. 2016 Gynecol Endocrinol – Rep. Italian Ministry of Health on MAR, 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

Complications resulting from ultrasound-guided egg retrieval occur at a very low rate and include pelvic infections (0.02%) and abdominal bleeding (0.1%–0.4%), (Bodri D. et al. Reprod Biomed 2008 Aug - Rep. Italian Ministry of Health on MAR,

2017). 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. point omitted because treatment is homologous;

13. point omitted because treatment is homologous;

14. point omitted because treatment is homologous;

15. point omitted because treatment is homologous;

16. the possible psychological effects for the individual partners, for the couple and for the born child resulting from application of the technique:

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).
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. the total financial cost of the procedure:

- the cost of the standard procedure is 5.195,00 Euros of which an initial sum of 1.500,00 Euros is to be paid when the therapeutic plan is issued and the balance before the retrieval of eggs;
- the “2nd cycle" rate of 4.895,00 Euros is applied if the cycle is repeated within six months;
- 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). Any medicines prescribed under the SSN will be subject to the following conditions: women no older than 45 and/or with FSH values of no more than 30 mIU/ml on the third day of their cycle.

- if treatment is interrupted or suspended because of a failed response to stimulation, we will only be required to pay the sum of 500,00, instead of the entire cost of treatment;
- if treatment is suspended because of failure to retrieve eggs, we will only be required to pay the reduced sum of 2.650,00, instead of the entire cost of treatment;
- if treatment is suspended before insemination of eggs for health or other reasons, we will only be required to pay the reduced sum of 3.700,00, instead of the entire cost of treatment;
- if the embryo transfer is delayed temporarily for health or other reasons, we will be required to pay the entire cost of treatment; an added amount of 150 euro will be due for the embryo devitrification.
- the above mentioned treatment cost includes the anaesthetist's fee;
- if we decide to proceed with the thawing of any supernumerary eggs, we will be required to pay an additional sum of 500,00 Euros for the freezing of our eggs and their storage for two years from the date of freezing; after this period of time, for the economics, the reference will be the agreement undersigned by myself on the preservation and storage.
- If we later decide to use the eggs, we will be required to pay the sum of 1.950,00 Euros for each thawing procedure if the eggs are fertilised, or the reduced sum of 750,00 Euros if the eggs are not fertilised.
- If the male partner undergoes a TESA procedure, we will be required to pay the sum of 500,00 €
- if treatment ends without a pregnancy, you will still be entitled to the above fees, which we are jointly committed to paying you.

DOUBLE STIMULATION

- If double stimulation is used during treatment, we will be required to pay a 'forfait' amount of 8.195,00 Euros, of which an initial sum of 1.500,00 Euros is to be paid when the therapeutic plan is issued and the balance before the retrieval of eggs; the paid amount will be due regardless of both procedures' results.
- if treatment is suspended because of a failed response to first stimulation, we will only be required to pay the sum of 500,00, instead of the entire cost of treatment;
- if we decide to proceed with the thawing of any supernumerary eggs, we will be required to pay an additional sum of 500,00 Euros for the freezing of our eggs and their storage for two years from the date of freezing; after this period of time, for the economics, the reference will be the agreement undersigned by myself on the preservation and storage.
- If we later decide to use the eggs, we will be required to pay the sum of 1.950,00 Euros for each thawing procedure if the eggs are fertilised, or the reduced sum of 750,00 Euros if the eggs are not fertilised.
- If the male partner undergoes a TESA procedure, we will be required to pay the sum of 500,00 €
- if treatment ends without a pregnancy, you will still be entitled to the above fees, which we are jointly committed to paying you.

IVF/ICSI with PGT-A

- If we choose to undergo an IVF/ICSI with PGT-A (up to 2 blastocysts), the amount due for the treatment will be 7.045,00 euros, of which an initial sum of 1.500 Euros is to be paid when the therapeutic plan is issued, a second sum of 3.695,00 Euros will be due before the retrieval of eggs and the balance will be due at the moment in which the exact number of obtained blastocysts fit for the genetic testing will be defined.
- the cost of IVF/ICSI with PGT-A includes the analysis PGT-A up to 2 blastocysts;400 euros will be due for any added analysis.
- if treatment is suspended because of a failed response to stimulation, we will only be required to pay the sum of 500,00, instead of the entire cost of treatment;
- if treatment is suspended because of failure to retrieve eggs, we will only be required to pay the reduced sum of 2.650,00, instead of the entire cost of treatment;
- For other economic details, we will refer to above paragraphs.
- 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_____

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 _____