Tecnobios Procreazione Srl
Via Dante, 15
40125 Bologna BO

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INFORMATION ABOUT THE TREATMENT

FREEZING AND STORAGE OF (OWN) EGGS

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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.

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) AMH (6-month validity)
e) VDRL, TPHA *(6-month validity)**
f) HIV 1/HIV 2 Antibodies *(3-month validity)**
g) Blood group *(unlimited validity)**
h) Cervical smear test *(3-year validity, 5-year validity for HPV test)**
i) Mammogram or breast ultrasound *(1-year validity)*
j) Electrocardiogram *(1-year validity)*
k) PT, PTT, full blood count with differential, creatinine, glucose, Antithrombin III *(6-month 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.**

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 THE FREEZING AND STORAGE OF (OWN) EGGS

I, the undersigned,

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

agree to the process of having **MY EGGS FROZEN AND STORED** and request the retrieval of my eggs by follicular aspiration, and ask you to freeze and store said eggs (cryopreservation).

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

1. illustration of the specific proposed technique at all stages of application:

CRYOPRESERVATION OF EGGS is a process with several phases.
The first phase involves stimulating the ovaries for multiple growth of follicles and hence oocytes. 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. 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.
After retrieval, the eggs that have suitably matured (metaphase II) are frozen and cryopreserved in liquid nitrogen.
The method used to fertilise frozen eggs after thawing is microinjection (ICSI), regardless of the quality of the semen sample.
The literature reports the survival rate of oocytes after thawing as varying between 70% and 84% (Argyle CE et al Hum Reprod Update Jun 2016 - Rel. Ministero della salute sulla PMA 2019).
The pregnancy chances, using criopreserved oocytes, are influenced by several variables: not leaving out specific factors, the most important variables are woman's age and total number of frozen oocytes**.**

2. possible side effects of application of the technique:

There is a chance that, after ovarian stimulation therapy, 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 6.7% 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, 2019).Data from the literature concerning the use of drugs to induce multiple ovulation show no increased risk of ovarian cancer in patients who have undergone this therapy. (Breast Cancer Res Treet 2015, Tonday S., Lancet 2016, Van den Belt et al., JAMA 2016, Zhao J. Et al RBM Online 2015).

3. possible risks to the woman resulting from the technique:

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, 2019). This syndrome can lead to an abnormal increase in ovarian volume, ascites and various complications that could require admission to specialist clinics.

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, 2019).

4. level of 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 on an outpatient basis.

5. financial cost of the entire procedure

- the cost of the procedure is 3.700,00 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 cost covers the freezing and safekeeping of the eggs for a period of 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.
- in addition to the cost of the procedure, I will be responsible for the cost of any drugs are not prescribed under the Italian national health system (SSN);
- if treatment is suspended because of a failed response to stimulation, I will only be required to pay the sum of 500,00, instead of the entire cost of treatment;
- if treatment is interrupted or if treatment is suspended because of failure to retrieve eggs, I will only be required to pay the reduced sum of 1.950,00, instead of the entire cost of treatment;
- the above mentioned cost of the procedures includes also the anaesthetist's fee;

I confirm that I relieve your Centre, as well as the doctors and technical staff in general operating on your behalf, of any liability, subject to the application of proper and professional diligence in all operations relating to the retrieval safekeeping of the oocytes. Notwithstanding, in the event of the eggs being stolen by third parties or of their damage or destruction for reasons attributable to you, I agree that your liability for damages will be limited to a maximum of three hundred Euros (€300).

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In the event of my death or in the event that I become untraceable – with regard to this, I undertake to inform you in a timely manner of any changes to my address – it is my request that your Centre proceed with one of the two options below, which I now indicate by ticking the relevant space:

☐ **using the oocytes for research purposes, or, at your own discretion, leaving them to degrade**

☐ **leaving the oocytes to degrade**

This application for the storage of my eggs will be effective for two years from the date of their freezing. Before that date, I undertake to provide you with written instructions regarding whether I intend to extend or discontinue the storage service. In the absence of any written communication from me by the end of the agreed period, your Centre will have the right to proceed with the option I have indicated above. The above will also apply in the event that I become untraceable.

Having considered the above, I freely express my will to have access to the proposed technique.

Date _____

Woman's signature _____

****

By confirming my signature and that this document, which I have sent to you by fax/post, comes from me, I also confirm that, from the date of the document to this day, my willingness as stated remains firm.

Date _____

Woman's signature _____

The Doctor _____

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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