

**CONSENT FOR ASSISTED REPRODUCTION**

As approved by the Health Department of IRCCS Istituto Clinico Humanitas on 1 July 2013.

I, the undersigned \_\_\_\_\_

born in \_\_\_\_\_ on \_\_\_\_\_

and I, the undersigned \_\_\_\_\_

born in \_\_\_\_\_ on \_\_\_\_\_

after completing a diagnostic process aimed at pinpointing the causes and possible alternative treatments to assisted reproductive technologies (ART) and after being properly informed about the assisted reproductive technique and having read the patient information leaflet "*Medically Assisted Procreation programme- Instructions for couples*", **we hereby request to undergo the procedure as a possible solution to our problems of sterility/infertility.**

**Section A**

**I. We specifically ask to undergo an assisted reproductive procedure**, in light of the medical examinations performed and evaluated by a specialist of the Fertility Centre, Dr \_\_\_\_\_

who made/confirmed the diagnosis of the following type of sterility/infertility:

- |                        |                             |                      |
|------------------------|-----------------------------|----------------------|
| * tubal/adhesions      | * combined, male and female | * male               |
| * poor ovarian reserve | * multiple female factors   | * ovulation disorder |
| * immunological        | * endometriosis             | * idiopathic         |
| * _____                |                             |                      |

**II. We have been informed that the** assisted reproduction programme **for this pathology** requires a cycle of

IVF \* (in vitro fertilisation)

ICSI \* (intracytoplasmic sperm injection)

We are aware that the initial choice of one of these two techniques may be changed once the eggs are retrieved, depending on the quality and number of retrieved gametes. In both IVF and ICSI, the treatment programme consists of several stages, which we have been informed of through the disclosure document provided to all couples. These stages consists of:

1. desensitisation of pituitary gonadotropin secretion, through depot or daily **subcutaneous/ intramuscular injections or nasal sprays** or the administration of a drug used in induction therapy with the effect of inhibiting the spontaneous LH surge - which would require the stimulation therapy to be suspended. A preliminary progestin or estrogen and progestin therapy (pill) may be prescribed under special conditions to facilitate ovarian response and synchronise the ovarian cycle;
2. Ovarian stimulation to grow multiple follicles through a daily intake of drugs, the purpose of which is to induce the production of more than one follicle. Response to therapy will be monitored with blood tests to determine the level of hormones produced by ovarian follicles (namely 17 b-estradiol and progesterone) and serial ultrasound examinations ;
3. Eggs are retrieved trans-vaginally under ultrasound guidance, under either local or general anaesthesia (**deep sedation**);
4. Semen preparation through techniques designed to enhance its fertilising capacity. The retrieved eggs will be fertilised in vitro or injected with the treated sperm. After 2 to 6 days, embryos will be transferred through the vagina into the uterine cavity.

**III. We have also been informed of, and have fully understood**, the possible complications of ART, although rare:

1. increased ovary size depending on the various degrees of ovarian stimulation. Ovarian stimulation may involve swelling of the abdomen and some abnormal blood test results which, in the most severe cases, may require hospitalisation (<1 % in our experience, reflecting the results obtained by major international centres). In extreme cases, especially in women who have achieved pregnancy at the end of the treatment, it may cause permanent damage (kidney failure, thrombosis or embolism), and death;
2. complications associated with anaesthesia and the surgical removal of eggs (< 0.24% in our experience, reflecting the results obtained by major international centres);
3. uterine/ovarian infections (< 0.1% in our experience, reflecting the results obtained by major international centres);

4. chances of pregnancy settling in outside the uterus (ectopic pregnancy), with an estimated rate of up to 4%;
5. induction therapy results in a rise in endogenous estrogen and progesterone levels for approximately 15 to 30 days, comparable to what is normally reported in the early stages of pregnancy. Studies conducted to date have not shown any increased risk of cancer related to the administration of these drugs. However, it is known that in presence of hormone-sensitive cancers, a slight increase in tumor growth potential may be reported during the period of intake of the medication. There is currently no conclusive evidence in scientific literature that ovulation induction therapy and/or egg retrieval leads to an increased risk of cancer.

**IV. We have also been informed of and we have fully understood the following.**

1. The medical team cannot guarantee that the treatment has a positive outcome. The success rates of the various treatments depend on many factors, such as the couple's age or the pathology that led to the treatment in the first place, and may greatly differ from a couple to another and from a cycle to another.
2. In the presence of ovarian cysts detected during the first ultrasound examination or later, it may be necessary to remove them through an aspiration procedure, or even to discontinue treatment.
3. If response to ovarian stimulation is thought to be in any way inadequate, the cycle may be discontinued at any time.
4. Even when monitored parameters are normal, there is a possibility that no egg will be retrieved.
5. Even when hormonal and biological parameters are normal for both male and female gametes, we cannot guarantee fertilisation, nor a successful division and subsequent development of fertilised eggs.
6. Not all follicles found during an ultrasound examination will produce eggs, and not all eggs retrieved are suitable for insemination. Also, the number of mature eggs used may, at the discretion of the medical team, be lower than the number of the viable eggs retrieved.
7. The number of embryos to be transferred will vary in relation to the clinical history and age of the female partner, so as to guarantee the best chance of success, reducing the risk of multiple pregnancies and all associated complications. To this end, mature surplus embryos will be cryopreserved (with the couple's consent), so as not to cause unnecessary discomfort for the patient through additional cycles of induced ovulation, anaesthesia and egg retrieval. The presence of frozen embryos will guarantee another chance of pregnancy if fresh transfer fails or if the patient seeks a second pregnancy after a successful fresh transfer.
8. The medical team will act according to:
  - a. the guidelines of the 'Practice Committee of the Society for Assisted Reproductive Technology' and 'Practice Committee of the American Society for Reproductive Medicine' (Fertil Steril 2013;99:44-6), that provide for a 2 embryo transfer in **good-prognosis patients aged 38 or younger**, while a **single embryo** transfer may be appropriate in good-prognosis patients aged 35 or younger (Good Clinical Treatment in ART, European Society of Human Reproduction and Embryology, 2008);
  - b. the directions on Assisted Reproductive Procedures provided by "Società Italiana di Medicina della Riproduzione" (Italian Society of Reproductive Medicine) after Constitutional Court decision no.151 of 8 May 2009, on Italian Law 40/2004. According to these directions, in all cases where repeated cycles of multiple follicular growth induction are not advisable because of a past or persistent, ongoing disease when the couple applies for an ART programme and has **agreed to embryo cryopreservation (freezing)**, the ART procedure will be optimised by using **all suitable eggs** (no more than 10-12 eggs, except under specific conditions), with the possible freezing of surplus embryos, to be transferred at a later date. More specifically, this approach will be adopted in the following cases:
    - previous Ovarian Hyperstimulation Syndrome (OHSS) or patients with high risk of OHSS;
    - repeated implantation failure and/or patients over the age of 38 years;
    - congenital or acquired thrombophilia;
    - non-obstructive azoospermia or cryptozoospermia and, in general, all cases of high risk of failing to retrieve male gametes or severely reduced fertilising capacity;
    - previous hormone-dependent cancer (ovary, breast, thyroid, etc.);
    - autoimmune diseases (lupus, multiple sclerosis, etc.);
    - previous pelvic surgery for stage III/IV endometriosis;
    - systemic diseases (cardiovascular, renal, hepatic etc.);
    - patients who underwent preimplantation genetic diagnosis;
    - patients who underwent organ transplantation;
    - history of failed fertilisation attempts.

9. In addition to avoiding the repetition of ovarian stimulation cycles, embryo freezing is also necessary in cases of:

- serious impediment or risk to the patient;
- potential risk to the fetus;

In both cases (sections 8 and 9) it is intended to enable the couple to achieve optimal chances of a successful pregnancy, and to reduce the risks related to the onset of multiple pregnancies (risks for both the patient and the fetus);

10. Frozen embryos will be transferred as soon as possible after termination of the impediment (disease, specific risk) that led to their freezing, or after the negative outcome of a fresh transfer or the positive outcome of a pregnancy obtained following the transfer of fresh or frozen embryos. In any case, viable or evolutionary embryos will not be destroyed or discarded (see embryo cryopreservation consent form).

11. The couple must give their consent to the possibility of freezing surplus embryos after fresh transfer and/or to the freezing of surplus eggs. The couple may also give their consent to **cryopreserve surplus eggs and/or embryos**, as the two conditions are not mutually exclusive.

12. Denying the opportunity to freeze embryos implies that a small number of eggs can be used (3-4 eggs based on the couple's specific conditions) and that all developed embryos must be transferred.

13. Since the probability of egg fertilisation and cell division is in no way predictable, it may occur that there will be no embryos to transfer.

14. If microscopic analysis highlights irreversible abnormalities in the developing embryo (embryos developed after division of zygotes with abnormal pronuclear number), the couple will be informed before the transfer and shall indicate or confirm their determination not to proceed with the transfer of abnormal embryos (see separate section in this consent).

15. Once pregnancy is achieved, there is a higher incidence of spontaneous abortion (increased rate in relation to maternal age) and an increased risk of some obstetric complications has been observed (premature birth, abnormal implantation of the placenta, reduced birth weight ). It must be considered that such increased risk of obstetric complications can be observed in infertile patients who conceive, regardless of whether they underwent assisted reproductive techniques. There are numerous data confirming that infertile patients are at higher risk, regardless of how the pregnancy is achieved.

16. There is an increased incidence of multiple pregnancies (up to 30% in relation to maternal age) and this probability is directly proportional to the number of transferred embryos. The medical team shall endeavor to reduce this possibility, which poses a serious threat to both the mother and the future child.

17. Compared with spontaneous pregnancies and ART pregnancies of infertile show a significant increase, albeit modest (OR 1.28), of congenital malformations or birth defects in relation to the general population. A significantly increased risk has been found after ICSI treatment. It remains unclear whether this condition is related to the technique itself or the presence of a very severe male factor and the resulting transmission of risk factors related to the severity of the andrological status (Davies MJ et al, New England Journal of Medicine, 2012).

Assuming an incidence of congenital malformations between 1 and 3% in the general population, the risk of anomalies is estimated between 1.3% and 3.9%. The data of our study (1996-2009) indicate a risk of neonatal congenital abnormalities in a proportion of 3.7% (95/2578 children born), including both pregnancies resulting from fresh transfer and after freezing eggs and embryos.

18. We are aware that the Italian legislation (Law 40/2004 and the guidelines of the law itself) does not require couples undergoing high-tech assisted reproductive procedures to have tests other than those required for couples seeking natural pregnancy or who have achieved spontaneous pregnancy. Therefore couples are not required to undergo any additional tests for their own and their future child's safety, other than those commonly prescribed for preconception care. Special tests are indicated only in the presence of specific risk factors in the couple's history, which must be specified in the preliminary consultation with the medical team. In general, genetic tests are required (tests for karyotype and Y chromosome microdeletions) only in the presence of a severe dyspermia.

19. Maternal age can affect the outcome. Genetic counseling, amniocentesis or chorionic villus sampling are recommended when maternal age is 35 years and older or in cases where there is a **family history** of a **specific genetic condition**.

20. We are aware that the Italian legislation imposes an **obligation to follow-up** (defined as the set of examinations and tests carried out in a systematic manner as part of pre-defined programmes) of pregnancies and children born through assisted reproductive techniques. To this end, the couple:

- a. agrees to provide all useful information to learn about the evolution and the end of pregnancy and the postnatal development of the children born through these techniques;
- b. authorises the medical team, within the limits of law and patient privacy and confidentiality, to contact their doctors (gynecologist, pediatrician etc.) in order to complete the follow-up job.

21. Prenatal and postnatal care will be offered with full respect for the couple's privacy, and the specific information about the technique that allowed the conception will not be disclosed.

22. Embarking on an assisted reproductive technique does not relieve couples seeking pregnancy from undergoing all the routine screening tests that are considered appropriate and prescribed by their own doctor, gynecologist or any other specialists with whom the couple must regularly remain in contact. L'équipe medica dell'Istituto è disponibile in ogni momento a collaborare con i medici di fiducia della coppia e, ove richiesto espressamente, di farsi carico di richiedere o eseguire gli accertamenti di loro competenza.

23. Pursuant to art. 11 of Italian Law no. 40 dated 19.1.2004, the National Institute of Health has established a register of the centres authorised to operate as human assisted reproduction centres, of developed embryos and those born as a result of applying assisted reproductive techniques. Registration is mandatory.

## **Section B**

### **EMBRYO CRYOPRESERVATION CONSENT**

**I.** We have been informed of and we understand the reasons for and implications of embryo cryopreservation (freezing):

1. where the simultaneous transfer of all in-vitro fertilised and developed embryos may lead to a high risk of multiple pregnancy with all its inherent complications, for both the patient and the fetus;
2. where the patient's health conditions do not allow for embryo implantation, except with serious risks of complications for both the patient and the embryo itself.
3. that this technique allow to proceed with one additional attempt in case of failure of the first attempt, thereby avoiding a new cycle of ovarian stimulation;
4. that survival rates for frozen embryos cannot be predicted and may range from 0 to 100%;
5. that chances of implantation cannot be guaranteed and may vary depending on embryo number and quality;
6. that no increase in birth defects or development abnormalities has been reported in pregnancies achieved with frozen embryos compared to spontaneous pregnancies of infertile couples;
7. that the transfer may be performed during natural cycles or, alternatively, taking fertility hormones (estrogens and progesterone) by oral, transdermal, vaginal or intramuscular administration, to enhance endometrial development. We are also aware of the side effects of this therapy, although rare.
8. a valid consent from both partners is required to request embryo cryopreservation.
9. The couple will not be entitled to any compensation in case of loss or deterioration of the stored material, for any reason and/or despite the care taken by the Centre;

**II.** We acknowledge that we had a preliminary consultation with the medical team, during which health professionals answered our questions and clarified our doubts concerning the procedure we are about to undergo, including its success rate.

**III.**

1. We have read, fully understood and agree to all the clauses in this consent form, including the clause in sect. A, point IV, no. 10, which makes clear that viable or evolutionary cryopreserved embryos will in no case be destroyed or discarded.
2. The Centre will not store frozen embryos indefinitely, except under specific conditions to be individually agreed upon with the Directors of the Centre. The Centre may at any time decide to give the frozen embryos back to the couple/patient, who shall bear the cost of their transfer to another Tissue Bank, in compliance with the Italian Law on embryo transportation and storage.
3. We are aware that the frozen embryos will have to be transferred to the woman's uterus in the future. Unused (abandoned) embryos will be stored at the Centre for a period of time not specified by the current law or moved to another bank/centre, in the event of changes to the law.

4. At the present time, and subject to changes to the current law, embryo freezing does not require the couple to pay for any costs related to the embryo cryopreservation and storage process from the date of cryopreservation to the date of their transfer to the woman's uterus or to another authorised Centre.
5. The couple shall **renew this agreement on an annual basis.**

We have read and understood the above and:

\* **YES** We agree to the cryopreservation of any embryos developed in the laboratory of Istituto Clinico Humanitas and not transferred to the uterus as a result of the assessments made by the medical team. We therefore agree to the cryopreservation of any surplus embryos.

\***NO** We do not agree to the cryopreservation of any surplus embryos. We are therefore aware of the conditions requiring the medical team to use a reduced number of oocytes.

### Section C INFORMED CONSENT TO THE EGG FREEZING PROGRAMME

**I.** We have been informed of the opportunity to freeze our eggs. We have been explained that this method has led to very different results in the various Centres for assisted reproduction and the ASRM (American Society for Reproductive Medicine) has lifted its experimental designation of egg freezing only since January 2013.

**II.** We are aware that oocyte cryopreservation is an option for us to keep seeking a pregnancy:

1. without having to undergo another stimulation therapy and egg retrieval;
2. in the event of failure to obtain sperm on the day of egg retrieval.

**III.** As a result of the information received we have understood that:

1. egg survival rates after freezing cannot be predicted and may vary from 0 to 100%;
2. only some oocytes (metaphase II) can be cryopreserved and a micro-sperm injection (ICSI) will be needed to achieve fertilisation;
3. at the current state of knowledge, the chances of egg fertilisation, division and implantation may change depending on the chosen protocol, and the results obtained in the centres that offer this option are less uniform than those observed with other methods;
4. no increase in birth defects or development abnormalities has been reported in pregnancies achieved with frozen eggs, although the number of babies born through this method is still lower than that observed with other methods, (over 1000 children born as at September 2009 according to the international literature and more than 290 pregnancies in our experience as at June 2013).

**IV.** We are aware that:

1. the request for gamete cryopreservation is a free choice of the female partner.
2. an annual contribution to cryopreservation service costs will be required at the time of storage (date of cryopreservation or transfer from another centre), The Centre will not store frozen embryos indefinitely, except under specific conditions to be individually agreed upon, and may at any time decide to give the frozen embryos back to the couple/patient, who shall bear the cost of their transfer to another Tissue Bank, in compliance with the relevant Italian Law, or request our Centre to destroy them or donate them for research purposes.
3. eggs will be stored for twelve months (**from the time of freezing or transfer from another centre**) at the end of which this agreement shall be renewed. If patients fail to apply for renewal and to pay storage costs, the Centre will be allowed to discard their cryopreserved oocytes.
4. at our Centres, cryopreserved gametes can be used in patients aged up to 50 years (based on the code of ethics of the Medical Association);
5. the request for transfer of cryopreserved gametes to another Centre can only be done by the undersigned, who will bear the costs of the procedure and the transfer itself in accordance with the provisions of the law.
6. The patient has been informed that she will not be entitled to any compensation in case of loss or deterioration of the stored material, for any reason and/or despite the care taken by the Centre. The patient authorises the Centre to destroy her gametes in the event of her death.

We have read and understood the above and:

\***YES** I agree to have my eggs frozen, if more eggs than can be used are retrieved, and I know that this condition does not exclude the possibility of freezing any non-transferred embryos, if agreed upon.

\***NO** I do not agree to freeze my eggs and I desire that any surplus eggs are:

- \* Destroyed
- \* Used for research purposes only (they cannot be used for procreation)

## Section D

### CONSENT TO SURPLUS GAMETE DONATION FOR RESEARCH (NON-VIABLE EGGS AND SPERM USED FOR NON-REPRODUCTIVE PURPOSES)

**YES** I AGREE TO DONATE

**NO** I DO NOT AGREE TO DONATE

## Section E

### DECLARATION PURSUANT to Article 14 of Italian Law 40/2004

The Director della Centre, or his representative, has informed us of the possibility that our embryo(s) may be affected severe and irreversible developmental abnormalities (abnormal pronuclear number).

We have been informed that in these cases embryo transfer may be refused.

If the embryological staff finds embryos with severe and irreversible developmental abnormalities, we request that:

- \* **NO abnormal embryos be transferred to the uterus**
- \* **Abnormal embryos be in any case transferred to the uterus**

## Section F

### CONSENT TO ASSISTED REPRODUCTION FOR PATIENTS WITH EXISTING OR POTENTIAL DISEASES AND INCREASED RISK CONDITIONS

(Warning: THIS SECTION IS TO BE COMPLETED WITH THE SUPPORT OF A SPECIALIST OF OUR FERTILITY CENTRE)

As we applied to be part of the Assisted Reproduction programme of the Gynecology and Reproductive Medicine Unit of Istituto Clinico Humanitas, we hereby declare that we are aware of and have received all the information available about our condition of increased risk for:

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\*The tests performed have not revealed an increased risk of the diseases screened for and the couple's family history did not suggest a greater risk than in the general population.

## Section G

### Information pursuant to art. 13 of the Italian Personal Data Protection Code (Italian Legislative Decree no. 196 of 30 June 2003,)

The personal information provided by you or retrieved from third parties (such as, for example, your general practitioner) will be used by the medical staff of Istituto Clinico Humanitas – in both paper and electronic format - solely for the purposes of **treatment, diagnosis, prevention, care and rehabilitation** and for all other related medical or administrative services. **With your consent, Humanitas will be able to use your personal data to carry out these activities.** Once you give your consent, your personal data may also be used:

- to remind you about your **appointment dates** via e-mail or text message, and to send you, via fax or e-mail, the preparation instructions for the tests that will be performed;
- **scientific research** related to the disease for which you contacted Humanitas;
- to send you, via SMS, e-mail or mail, **information material** relating to prevention, cultural and charitable initiatives promoted by Humanitas and the associated Foundations.

To receive these notices, you need to provide a private fax number, mobile phone number, and/or email address, to ensure the required level of confidentiality. You are free to give or withhold consent to this without any repercussions on the level of care you will receive. Please note that you may revoke your consent at any time and that it may take a maximum of two to three weeks for your request to become effective.

Information about your state of health, the likelihood of your admission, inpatient or outpatient treatments at the Centre, may be disclosed (unless you specifically request to remain anonymous) to your close relatives or other authorised persons. Your data will not be disclosed to third parties, except as may be necessary to provide you with health services or as required by law.

In accordance with Italian Legislative Decree 196/03, Regional Executive Decision 5198L/2007 “CRS-SISS Health Care Information System”, the associated regional provision “Processing of personal data within the CRS-SISS system – Information according to Art. 76 of Legislative Decree 196/2003” issued and distributed by the Lombardy Region and the “Guidelines on the Electronic Health Record and the health profile”, Humanitas will allow access to your health information only if you have expressly agreed to that, as required and specified by law and by the above mentioned provision. We therefore ask for your consent to include your data in the following electronic systems:

**Electronic Health Record** (FSE – Fascicolo Sanitario Elettronico ): an electronic tool that provides the patient's medical history to health and social workers, even of different healthcare facilities, or to your general practitioner. Please note that you can always refuse the inclusion of individual test results in your Electronic Health Record, if you believe that they require more privacy.

**Health Profile:** an electronic tool that allows Humanitas physicians to know which health services have been provided to the patient, including inpatient and outpatient treatments, through a comprehensive and complete view of the patient’s problems. A health profile can be created only with your consent, which you may give by checking the appropriate box at the bottom of this form. If you do not agree, you will still be guaranteed the medical services requested.

You can learn at any time about the data that concern you, get to know how they were acquired, check if they are correct, complete, updated and well kept, and assert your rights in this regard, including the right to revoke your consent to the inclusion of these data in your health profile by contacting the Medical Director at the following numbers: tel. 02/8224.2301 - fax 02/8224.2299.

We agree to the processing of my personal data, including sensitive data and health information, for purposes of <b>treatment, diagnosis, rehabilitation and prevention.</b>	YES <input type="checkbox"/>	NO <input type="checkbox"/>
We agree to the inclusion of our data in the so-called <b>health profile</b> , which allows Humanitas physicians to know which health services have been provided to the patient, through a comprehensive and complete view of the patient/couple’s problems.	YES <input type="checkbox"/>	NO <input type="checkbox"/>
We agree to the possibility of being contacted via text message, e-mail or voice messages to remind me the <b>date of my appointments</b> at Humanitas and via text messages, fax or e-mail, to send me the <b>preparation instructions</b> for the tests that will be performed (these communications will be sent within the limits of the data provided in the consent).	YES <input type="checkbox"/>	NO <input type="checkbox"/>
We agree to the processing of my/our personal data for <b>scientific research</b> activities related to the disease for which I/we contacted Humanitas, according to the rules laid down by the Humanitas Scientific and Ethics Committee. We are aware that the study and research programmes are submitted to the Scientific Committee of Istituto Clinico Humanitas and, where required, to the approval of the Ethics Committee of Istituto Clinico Humanitas and we are aware that, if required, we will be asked to sign a specific consent form for each individual research programme.	YES <input type="checkbox"/>	NO <input type="checkbox"/>
We agree to receive text messages, e-mail and mail communications with <b>information material</b> relating to prevention, cultural and charitable initiatives promoted by Humanitas and the associated Foundations.	YES <input type="checkbox"/>	NO <input type="checkbox"/>

In the light of all the above (Sections A, B, C, D, E, F, G) we declare that:

- a. we have decided to undergo this assisted reproductive procedure following the information supplemented during our consultation with the the medical staff
- b. the medical staff answered our questions and clarified our doubts about the procedure we are about to undergo, including its success rate;
- c. we have understood all of the indications of the procedure suggested for our specific case;
- d. we have obtained adequate information about alternatives to the treatment and the possibility to apply for adoption;

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- e. we are aware of the risks, including psychological, involved in participating in an assisted reproduction programme and the possible alternatives, including giving up the idea of getting pregnant;
- f. we are aware that we may ask for further advice in order to support our decisions and for this purpose the hospital unit and can provide dedicated support and psychological counseling as required by regulations (Italian ministerial decree 11.04.2008 "Guidelines on assisted reproduction technologies");
- g. we are aware that during treatment the medical team will be available to answer our questions and consider our problems.

We further declare that we have completed all the preliminary tests required and we have provided the medical team with all the information that may suggest an increase of risk.

We therefore agree to participate in this therapeutic assisted reproduction programme, and in addition to the explanations provided by the medical team, we have received and evaluated all the clauses in this agreement.

We also confirm that we are both irrevocably committed to recognising our future child as our legitimate or natural offspring, waiving any future denial of paternity/maternity.

Fully aware of the legal consequences a false statement, we hereby declare that we are an adult heterosexual couple, married and/or living together, both alive at the beginning of the procedure (article 76, paragraphs 1 and 2 of the Consolidated laws and regulations for administrative documentation, referred to in Italian Presidential Decree no. 445 dated 28 December 2000).

We have read, fully understood and agree to all the clauses in this consent form, which consists of 8 pages.

- consent to the procedure;
- consent to embryo cryopreservation;
- consent to oocyte cryopreservation;
- consent to treatment for patients with specific ongoing or potential diseases;
- consent to donation;
- arrangements on the transfer of abnormal embryos;
- consent to anaesthesia;
- consent to the processing of personal data and for research purposes.

Date \_\_\_\_\_

Patient's signature \_\_\_\_\_

Partner's signature \_\_\_\_\_

NB: At least 7 days should elapse between the signing of the consent and treatment (Italian Law no. 40/2004, art. 6 paragraph 3). We also invite the couple to read the full text of Law no. 40/2004 published in the Official Gazette of 24 February 2004, Italian Ministerial Decree no. 40/2004 dated 11.04.2008 "Guidelines on Law no. 40/2004", as well as the text of Constitutional Court decision dated 8 May 2009.

The Physician of the Humanitas Fertility Centre \_\_\_\_\_