HUMANITAS
FERTILITY CENTER

TECHNICAL ANNEX TO THE INFORMED CONSENT

CONSENT FOR HOMOLOGOUS OOCYTE (EGG) RETRIEVAL AND CRYOPRESERVATION

I, the undersigned_____

FILE _____

born in _____ on _____

- Desire to undergo this oocyte cryopreservation (egg freezing) programme as a possible solution to any problems of infertility/sterility that may arise following the disease that affects me and/or the therapy I will undergo.
- Desire to undergo this oocyte cryopreservation (egg freezing) programme to postpone my reproductive choices and overcome at least in part the negative effects of aging on fecundity.

Following the medical examinations performed and evaluated by a physician at the_____ health centre, an indication for egg freezing has been found on the basis of the following diagnosis:

_____

_____

I AM AWARE THAT THIS METHOD INCLUDES THE FOLLOWING STEPS:

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 discontinued. 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 Combined administration - only in special cases, such as the presence of hormone-sensitive cancers – of a drug (aromatase inhibitors), the aim of which is to maintain a low level of hormones (namely estradiol).

3 Ovarian stimulation to grow multiple follicles through a daily intake of drugs (gonadotropins), 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 and **serial ultrasound examinations**.

4 Egg maturation will be induced by administering a drug (chorionic gonadotropins/GnRH agonist), and eggs will be retrieved within 34/36 hours after the administration of this substance.

5 Eggs are retrieved trans-vaginally under ultrasound guidance, under either local or general anaesthesia **(deep sedation**).

I am aware that this cryopreservation programme will require an estimated period of time of 15 to 20 days for tests and screenings, and that this may delay the proposed treatment. I shall take this into account when discussing this aspect with my physicians (start of chemo/radiation therapy, possible surgery, etc.).

I AM AWARE OF THE POSSIBLE COMPLICATIONS OF THIS METHOD, ALTHOUGH RARE:

1. Increased size of ovaries according to varying degrees of ovarian hyperstimulation, which may lead to swelling of the abdomen and abnormal blood values, requiring hospitalisation in the most severe cases (<1 % of cases in centres with greater experience in the field); in extreme cases, it can cause permanent damage (kidney failure, thrombosis or embolism), and death..
2. Complications associated with anaesthesia and surgical egg removal (< 0.2% of cases in centres with greater experience in the field).
3. Uterine/ovarian infections (< 0.1% of cases in centres with greater experience in the field).

I AM AWARE OF THE FOLLOWING ISSUES:

1. The induction therapy causes endogenous estrogen and progesterone levels to rise, for approximately 15 to 30 days, as in the early stages of pregnancy. Studies to date have not demonstrated increased risk of cancer associated with the use of these drugs. However, it is known that in the presence of hormone-sensitive cancer a slight increase in tumour growth potential may be reported during the period of intake. This condition should be carefully considered, especially when the indication for egg retrieval and freezing is the presence of breast cancer .
2. If response to ovarian stimulation is thought to be inadequate in some way, the cycle may be discontinued at any time.
3. Even when monitored parameters are normal, there is a possibility that no egg will be retrieved.
4. Maternal age affects the final outcome. The chances of pregnancy are closely related to the number of successfully preserved eggs and to the patient's age at the time of retrieval.
5. At the present state of knowledge, this method is still considered experimental in many countries (including the US).
6. Survival rates for frozen eggs cannot be predicted and may range from 0 to 100%. I have been informed that only some of the eggs may be used (metaphase II). I have also been made aware that an ICSI procedure will be required to fertilise the eggs that survived the thawing (a micro-injection of sperm in the egg cytoplasm), using the semen of my future partner.
7. At the current state of knowledge, chances of successful egg fertilisation, division and implantation have only been calculated on the basis of trials with small groups of patients, and the various Fertility Centres have obtained inconsistent results.
8. As of today, no increase has been reported in congenital and developmental defects in pregnancies induced with frozen eggs. We have however been informed that the number of babies born with this technique is still too small to draw any significant conclusion (a few thousand babies, according to data available as of September 2011).

I AM ALSO AWARE THAT:

1. Requests for cryopreservation of female gametes are strictly confidential.
2. Eggs will be preserved for 12 months, at the end of which this agreement will have to be renewed.
3. Requests to collect frozen gametes can be made exclusively by the person who signed this consent, who shall also collect them in person.
4. The patient must inform the Centre of any change of address or telephone number. Failure to comply with this requirement may make our Centre unable to contact you, while your gametes may be destroyed if you fail to renew the agreement in time.
5. The patient authorises the Centre to destroy her gametes in the event of death.
6. Eggs can be preserved and used for reproductive purposes until the patient turns 50.
7. The patient has the right to have her frozen eggs moved to another centre, after making an official request and notifying our Health Department. Transport will be organised and the relevant costs shall be borne by the patient.
8. I have received a detailed breakdown of all costs associated with the procedure and the continuation of cryopreservation, and I am also aware that there may be changes in the future as a result of amendments in the Regional and National legislation, which do not yet provide specific rules on the reimbursement of costs associated with egg retrieval, freezing, or prescribed medications.

9. The patient 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.

CONSENT TO THE PROCESSING OF PERSONAL DATA, PHOTOGRAPHS AND VIDEO FOOTAGE, AND PARTICIPATION IN STUDIES AND RESEARCH

After receiving information from the staff at the Gynaecology and Reproductive Medicine Unit about the rights and limitations as per Italian Privacy Law No. 675/96, "Protection of individuals and other subjects with regard to the processing of personal data", I hereby give my consent and authorise the team to the processing of my personal data solely for the purposes of diagnosis and treatment.
I give permissions for photographs/video footage to be taken during ultrasound monitoring and/or surgical procedures. These images may be used only by physicians and biologists of the Unit for educational or scientific purposes.
I understand the crucial role of research and analysis of clinical and scientific data in the improvement of techniques and procedures, and I give permission for my clinical data to be used for prospective and retrospective studies or for statistical purposes.
I also understand that medically assisted reproductive techniques are constantly evolving and improving and that ICH physicians and biologists are working on new treatment protocols, changes in existing laboratory procedures or the use of new ones, as well as the introduction of new materials, in order to increase the chances of success of these therapies.

I am aware that all studies and research programmes are submitted to the ICH Scientific Committee for approval, as well as to the Ethics Committee if required. I am also aware that, if necessary, I will be asked to sign a specific consent form for each research programme.

☐ **YES** I AGREE ☐ **NO** I DO NOT AGREE

CONSENT TO THE DONATION OF EXCESS GAMETES

FOR RESEARCH PURPOSES

(donation of EGGS that would otherwise be discarded and for non-procreative purposes)

☐ **YES** I AGREE TO DONATE

☐ **NO** I DO NOT AGREE TO DONATE

I acknowledge that we had a preliminary consultation with the medical team, during which health professionals answered my every questions and clarified my doubts concerning the procedure I am about to undergo, and I have understood all indications for the chosen technique.
I also know that during the procedure the medical team will be available to answer my questions and will take into account my personal situation.
I have been informed that I can withdraw from this programme at any time and for any reason, and I have read and understood all clauses in this consent form.

I agree to take part in this therapeutic programme.

Patient's signature[1] _____ Physician's signature _____

Interpreter's signature (if applicable)
_____

Signed on (date)
_____

[1] Legal Guardian if the patient is underage or legally incapacitated.