I. What does it consist of?

Egg donation is an altruistic, confidential act, economically compensated under the terms set by law, by which a woman gives her eggs to another woman or couple so they can be used for assisted reproduction treatments in women for whom they are scientifically and clinically indicated.

II. When is it indicated?

It allows treatment in cases where women have a very low ovarian reserve, failure of assisted reproduction with her own eggs or risk of transmitting a genetic defect.

III. Procedure

Egg donation usually begins with stimulating the ovaries using drugs, whose action is similar to that of certain hormones produced by women. The purpose of this treatment is to obtain the development of several follicles, inside which are the eggs. In order to prevent spontaneous ovulation, other treatments with hormonal action are associated.

The process of ovarian stimulation is usually controlled by analysis of blood levels of certain ovarian hormones and/or vaginal ultrasound that reveals the number and size of the developing follicles. Once proper development is achieved, other drugs are administered to achieve the final maturation of the eggs.

Many of the drugs used are injectable and presentation allows self-administration by the patient. Dosages and dosing schedules are tailored to each patient's clinical features and response to treatment may vary. Occasionally they are used in association with other types of drugs.

The eggs (oocytes) are extracted by ultrasound-guided ovarian puncture and aspiration of follicles, through the vagina. This procedure is usually performed on an outpatient basis and requires anaesthesia and subsequent observation for a variable period.

The eggs obtained are prepared and classified in the laboratory. The number of eggs that are removed during puncture, their maturity and quality cannot be predicted with accuracy. If a large number of eggs is recovered as a result of high response to ovarian stimulation, some centres may allocate those eggs to more than one recipient.

In any case, the Centre shall inform the donor of the number of offspring produced, as the legally authorized maximum number of children born in Spain, generated with the same donor gametes, shall not exceed six.

IV. General requirements to be an egg donor

Donors must be over 18 and under 35, in good psychophysical health, and with full capacity to act and sign the corresponding informed consent document.

V. Admission of donor by the Centre. Submission to prior studies.

The physical and psychological state of the candidate to donate oocytes will be evaluated by a study protocol including physical and psychological characteristics, as well as clinical conditions and laboratory tests necessary to demonstrate, to the extent possible, that the donor is not suffering from genetic, hereditary or infectious diseases that can be transmitted to the offspring.
For this reason the woman who wants to donate oocytes must provide with absolute accuracy the data that are requested on her personal and family history. She must also authorize supplementary examinations or tests designed to rule out the existence of transmissible diseases.

The tests that the donor will undergo are:
- Personalized and confidential interview
- Gynaecological check-up with cytology and ultrasound
- Complete general analysis:
  - Blood type and RH
  - CBC
  - Blood chemistry panels
  - Hormone analysis
  - Serology for hepatitis, syphilis and HIV
  - Genetic rating
  - Psychological assessment

VI. Risks
The main risks of this therapeutic procedure are:

1) **Ovarian hyperstimulation syndrome:** This is an exaggerated response to ovarian stimulation treatment or hormonal changes arising from pregnancy. Sometimes ovarian response is excessive and development of many follicles occurs with ovarian enlargement and considerable increase in the amount of estradiol in the blood.

   It is classified as mild, moderate and severe, the latter being rare (less than 2%); it is characterized by accumulation of fluid in the abdomen and even in the chest, as well as impaired renal and/or liver function. In critical cases it may be associated with respiratory failure or coagulation disorders.

   It may require hospitalization and medical-surgical treatment.

2) **Smoking and significant body weight changes** increase the risk of complications during treatment. These conditions require adaptations in the treatment necessary for ovarian stimulation and reduce the quality of response.

3) **Psychological risks.** Symptoms of psychological disorders such as anxiety and depressive symptoms may occur.

4) **Risks of anaesthesia** are detailed in the specific informed consent on this subject.

5) **Other risks and complications** that may occur:
   a) Intolerance to or side effects of medication.
   b) Abdominoperineal infection.
      The risk of inoculation of germs into the abdominal cavity through the vagina is rare (0.3-0.5%) thanks to the use of a sterile technique.
   c) Bleeding from accidental puncture of blood vessels:
      Bleeding is the most common complication that can occur in the transvaginal puncture. Only 0.5% of these bleeds are of relevant nature. Most bleeding secondary to ovarian puncture is usually caused by the existence of possible bleeding points in the vagina and are usually solved by compression on the area for a few minutes. Very rarely it can cause a laceration of the ovarian capsule with intraperitoneal bleeding or retroperitoneal haematoma formation due to accidental puncture of pelvic vessels that may require strict control and even surgical evaluation.
   d) Abdominal pain is avoided with the use of sedation during transvaginal ovarian puncture and analgesics in the immediate postoperative period.
e) Puncture of an intestinal loop or another part of the anatomy. Visceral lesions: they are exceptional; an intestinal loop can be perforated. Normally, perforation with the puncture needle, given its small size, resolves spontaneously with absolute diet and prophylactic broad-spectrum antibiotic coverage.

f) Ovarian torsion.

g) Functional impotence and incapacity.

h) Cancellation of ovarian stimulation due to absence of or inadequate follicular development or excessive response to treatments.

i) Eggs not obtained in the puncture.

Donating eggs does not affect the donor woman’s future fertility.

VI. Personalized risks:
Medical, social and occupational characteristics of each patient may lead to a modification of the general risks or appearance of specific risks. In this case they would be:

VII. Financial compensation for costs and inconvenience (if applicable)
Notwithstanding the altruistic and non-profit status of oocyte donation, donors will be compensated for the physical discomfort and travel expenses and lost wages, if any that may result from the donation, without such compensation being considered a financial incentive.

VIII.- Legal aspects to consider in donating oocytes
The legal framework governing assisted human reproduction is constituted mainly by Law 14/2006 of 26 May, on assisted human reproductive technologies. This regulation states that the techniques are aimed at solving the problems of human infertility, to facilitate procreation when other treatments have been ruled out as inadequate or ineffective.

Gamete donation is a free, formal, confidential contract between the donor and the authorized centre. The gamete bank as well as the donor and centre activity registries must ensure the confidentiality of donors’ identity data. Notwithstanding the foregoing, the recipient and the children born are entitled to obtain general information about the donors, which does not include their identity. Also in extraordinary circumstances involving a certain danger to the life or health of the child, or where appropriate in accordance with criminal procedural law, the identity of the donor may be revealed, in restriction and without ever modifying the previously established paternity.

The choice of donors can only be made by the medical team applying the technique, and in no case at the request of the recipient or partner. In any case the medical team should seek the greatest possible phenotypic and immunological similarity with the recipient woman. The maximum permissible number of children born in Spain generated from gametes from the same donor should never be more than six. For effective maintenance of this limit, donors must declare during each donation if they have made one previously, and the conditions thereof, and indicate the time and the centre in which they made such donations.

The donation will only be revocable when the donor specifies it for the donated gametes, provided that on the date of revocation they are available. Revocation would involve the refund by the donor of all expenses incurred by recipient centre for cryopreservation and maintenance of the samples revoked.

In any case, approved centres may reject the donation when the donor’s psychophysical conditions are not suitable. In the event that a donor was not accepted as such, she is entitled to know the reasons for her exclusion, ensuring the confidentiality and privacy of information.

Neither the recipient woman nor her spouse, if they have given their formal, express prior consent to insemination with donor contribution, may challenge the paternity of the child born as a result of such fertilization. This same limitation applies to unmarried heterosexual couples when the man had previously signed informed consent for the use of the techniques.
The identity data of the donors should be held in the strictest confidence and secured in the database of the centre and, as provided by law, the National Registry of Gamete and Pre-embryo Donors for Human Reproduction Purposes.

The contents of this document reflect the current state of knowledge, and therefore are subject to change if new findings or scientific advances so warrant.

In __________________ on the ______ day of __________________ year ______

Signature
National I.D. no.:    Physician Signature
National I.D. no.: