

KUTTEH KE FERTILITY ASSOCIATES OF MEMPHIS, PLLC

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Affiliated With the University of Tennessee, Memphis
Department of Obstetrics and Gynecology
Division of Reproductive Endocrinology and Infertility

AND

MEMPHIS FERTILITY LABORATORY, INC.

**IN VITRO FERTILIZATION/EMBRYO TRANSFER (IVF/ET) WITH DONOR OOCYTES
CONSENT FORM for the RECIPIENT COUPLE**

1. We (*name of Patient*), _____ and (*name of Partner*), _____, the undersigned, are committed and intimate partners. We request, authorize, and consent to the performance of in vitro fertilization and embryo transfer with donor oocytes (donor IVF/ET). Oocyte (egg) donation will provide an opportunity for pregnancy for patients who could not otherwise conceive or, because of the risks of transmitting a genetic disorder, wishes not to conceive her own genetic child. This will be accomplished by a procedure in which a fertile woman (referred to in this Consent Form as "the Donor") donates her oocytes for fertilization and transfer to Patient.
2. We understand and acknowledge that Kutteh Ke Fertility Associates of Memphis, PLLC (FAM) is a medical practice in reproductive endocrinology and will be managing our IVF/ET care and performing our procedures. Memphis Fertility Laboratory, Inc. (MFL) is an independent laboratory responsible for our IVF/ET laboratory testing and services including blood hormone assays, semen analysis, sperm preparation, oocyte identification and preparation, embryo culture, embryo micromanipulation and cryopreservation.
3. We understand the following to be a general outline of the steps that may be required in this procedure. We consent to the performance of these steps.
 - a. Determination by certain tests that we are suitable candidates for the procedure. The evaluations will include detailed medical histories, physical examinations, and laboratory tests including (but not limited to) tests for general health, HIV infection, and psychosocial assessment. The evaluation will minimize, though it cannot eliminate, the possibility of passing on a genetic or infectious disease. We represent and warrant that, to the best of our knowledge and belief, all medical and genetic information we provide to FAM and MFL will be true, correct, and complete.
 - b. A suitable donor has to be matched with us. With the assistance of FAM and/or a third party donor recruitment agency, we may select an anonymous donor, whose identity will not be revealed to us and who will not be aware of our identity. A separate agreement with the Donor to donate her eggs will be exercised. Alternatively, we may select a known donor of our acquaintance as long as she meets all medical, psychological and social criteria of FAM.
 - c. Preliminary screening of a donor by FAM is based upon medical and historical information provided by the Donor. FAM makes no representation or warranty, express or implied, as to the accuracy or authenticity of information furnished by the donor.

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- d. After a suitable donor is matched to us in a mutually agreeable manner, Patient will be given a trial cycle (one month) of hormone (estrogen and progesterone) replacement to assess the uterine lining needed for embryo implantation. Some of these hormone therapies will require us to perform self-injection on Patient on a daily basis. If the lining is inadequately prepared, this trial cycle will allow adjustments to be made prior to actual embryo transfer.
 - e. For our actual treatment cycle, Patient's cycle will need to be synchronized with that of the Donor. This is accomplished by charting menstrual calendars and by adjusting the duration and dose of hormone replacement therapy given to Patient.
 - f. Oocyte retrieval will be performed on the Donor's ovaries. This involves the insertion of a needle into the Donor's ovaries through which the oocyte(s) are removed. We agree to accept any oocytes recovered through this retrieval process and determined by MFL to be suitable for fertilization and transfer.
 - g. If applicable, Partner will provide a sperm specimen on the day of the oocyte retrieval to be used for fertilization of the Donor oocytes. If we have previously agreed that donor sperm will be used for fertilization, then this procedure will have been separately explained and a separate consent will be obtained as is routine.
 - g. Fertilizing the Donor's oocytes(s) with sperm under controlled environmental conditions to allow conception to occur. In the opinion of our Physician and the Laboratory Director, our egg(s) will be fertilized by either:
 - i. placing each egg within several thousand sperm so they may fertilize through conventional cellular process, or
 - ii. intracytoplasmic sperm injection (ICSI) where a single sperm cell is microscopically placed in each egg, or
 - iii. both.
 - h. After fertilization, transferring the oocyte(s) into a controlled culture environment to optimize for growth. A successfully fertilized egg is referred to as an embryo.
 - i. After several days of growth, Patient will undergo an embryo transfer where our best embryo(s) will be placed into Patient's uterus by means of a small catheter inserted through the cervix. Patient will continue her scheduled hormone replacement treatment to assist in implantation.
 - j. Pregnancy can be determined by a blood test within 14 days of embryo transfer.
4. We recognize and understand that a child conceived after ovum donation and embryo transfer will not have Patient's genetic make-up, but will have that of the Donor and Partner's (or sperm donor, if applicable).
 5. We understand that up to two (2) of our developing embryos may be transferred to the uterus. We have been told that this could result in multiple gestation (twins, triplets, etc.), with an increased risk of premature delivery, and an increased financial and emotional burden.
 6. We understand that the procedure of IVF/ET may result in viable embryo(s) beyond those selected for transfer to my uterus. Alternatively, there may be circumstances in which embryo transfer is not recommended. In such circumstance and in the discretion of the Laboratory Director, viable embryos (s) can be cryopreserved (frozen) and stored for possible use at a later time. The cryopreservation, storage and disposition of our embryos will require a separate consent.
 7. We understand that ICSI, if used, may expose a risk to our embryo(s) conceived by this technique. ICSI may result in conception of an embryo from abnormal sperm. This may result in a pregnancy with unknown genetic or birth defects. We understand that studies have revealed a small but significant risk of both minor and major birth defects after conception through ICSI, especially if the Partner's semen analysis is abnormal.
 8. We acknowledge that a successful pregnancy after donor oocyte IVF/ET cannot be assured and that neither FAM or MFL has made no such representation or guarantee. We understand that a number of occurrences may prevent the establishment of a successful pregnancy, including:
 - a. Through unforeseen circumstances, the matched Donor cannot perform her procedures.
 - b. The Donor may not respond to her medications, reducing the probability of a successful oocyte retrieval.

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- c. The time of the Donor's ovulation may be misjudged, or may be unpredictable, thus preventing any attempt at obtaining any oocytes.
 - d. Through unforeseen circumstances, obtaining an oocyte from the Donor may be unsuccessful.
 - e. Donor's oocytes(s) may not be normal.
 - f. Partner (or the donor if applicable) may not be able to supply an adequate semen specimen.
 - g. Fertilization between donor oocytes and Partner's sperm may not occur.
 - h. Growth or cell division of any of our embryo(s) may not occur.
 - i. Our embryo(s) may not develop normally.
 - j. Implantation of the embryo(s) into the lining of Patient's uterus may not occur.
 - k. An unforeseen laboratory event may result in loss or damages of oocyte(s), sperm or embryo(s).
9. We understand that, if pregnancy is successfully established, there is a risk of miscarriage (approx 1 in 6 to 1 in 8), ectopic (tubal) pregnancy (1 in 30), stillbirth and/or birth defects. At present, available research does not indicate a greater risk of birth defects following donor oocyte IVF/ET as compared to equal-age women conceiving naturally. Nevertheless, we acknowledge that neither FAM or MFL cannot guarantee the genetic, physical, and mental characteristics of the child nor that the child will be born free of physical or mental abnormality, disease, or defect. We understand that pregnancy after donor oocyte IVF/ET may be at increased risk of premature labor and delivery. This may lead to complications of prematurity for our child and its associated financial and emotional costs.
10. We understand that a number of risks and discomforts may be associated with this procedure, including:
- a. From the blood tests: mild discomfort and bruising at the needle site.
 - b. From the medications:
 - (i) mild discomfort and bruising at the needle site of self-injected medications;
 - (ii) the possibility of an increased risk of developing ovarian tumors later in life has been proposed in women who have been exposed to long-term "fertility drugs.". Although recent studies do not demonstrate any association of tumors with fertility treatment, this risk has not been conclusively disproved,
 - (iii) estrogen therapy may cause nausea. Long-term administration of estrogen has been associated with gall bladder disease, blood clots, liver disease, and heart attacks. In post-menopausal women, long-term administration of estrogen has also been associated with breast cancer. Since the doses in this procedure are low and administration is short term, such side effects are unexpected, but cannot be ruled out. Natural estrogens given during pregnancy have not been associated with birth defects, however the potential for increased incidence of birth defects with artificial estrogen is unknown,
 - (iv) progesterone therapy may cause mood swings and water retention. Long-term administration is associated with elevation of cholesterol. Since the doses in this procedure are low and administration is short term, such side effects are unexpected, but cannot be ruled out. Recent studies do not demonstrate any association of natural progesterone given during pregnancy with birth defects, but this risk has not been conclusively disproved.
 - c. From the transfer of the embryo(s) into the uterus:
 - (i) the mild discomfort;
 - (ii) the small (1 in 400) risk of developing infection and possible bleeding,
 - (iii) if more than one embryo is transferred, that multiple pregnancy (twins, triplets, etc.) may occur;
 - (iv) that a pregnancy may occur in the tube (ectopic pregnancy), and require major surgery for treatment.

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- d. From psychological stress. We understand there may be a greater psychological risk to us than in a naturally conceived pregnancy because of the manner in which our pregnancy was achieved and the fact that the oocyte was donated by another woman. In addition, information revealed during the psychological evaluation may cause stress for our relationship and to our mental well-being.
11. We agree to assume complete responsibility for any embryo, fetus, or child developing from the donated oocyte(s), from the time of retrieval and at all times thereafter. We agree to assume complete parental responsibility for any child born to Patient as a result of donor oocyte IVF/ET, regardless of the genetic make-up or physical or mental characteristics of the child at birth or at any time thereafter.
 12. We hereby release MFL, its' agents, servants, or employees from any injury or damage, known or unknown, that might result should our eggs, sperm or embryo(s) cease to be viable while in the custody of MFL, its agents, servants, or employees.
 13. We fully understand that insurance coverage for any or all of the above procedures may not be available and that we will be personally responsible for all the expenses of this treatment including those associated with the Donor. The expenses may consist of medication costs, hospital fees, laboratory fees and/or physician professional fees.
 14. In case of an unforeseen medical complication that may require medical care and/or hospitalization of the Donor, we agree to purchase adequate, third-party, medical insurance coverage for the Donor. The effective coverage date will begin with Donor treatment and last for a minimum of 90 days. We also agree that we will be financially responsible for any applicable insurance deductibles or co-payments as dictated by the terms of the policy. This policy is intended to cover unintended medical complications of oocyte donation and we understand that it will not be utilized for routine procedures or care related to the Donor's participation.
 15. I understand that FAM and MFL will NOT voluntarily disclose to us the identity of the donor. Conversely, I understand that FAM and MFL will NOT voluntarily disclose to the donor our identity or any child born to us as a result of egg donation. It is remotely possible, however, that FAM or MFL could be compelled, through legal process, to disclose identities and we understand and acknowledge that absolute anonymity cannot be guaranteed. If we are participating in egg donation with an anonymous donor, we agree that we will make no attempt to obtain the identity of the donor. We also understand that the donor will not be informed of pregnancy or childbirth as a result of her donated eggs, and has agreed to make no attempt to obtain the identity of any such child. The confidentiality of identities is not applicable to situations where the donor and we are already aware of each other's identities and our donor egg IVF/ET procedure is a result of direct prior arrangement with the donor.
 15. We consent to the photographing or televising of any laboratory procedure(s) to be performed for medical, scientific, or educational purposes, provided our identities are not revealed by the pictures or by descriptive text accompanying them.
 16. The Centers for Disease Control (CDC) is a "public health authority" and is authorized by law (PL 102-493 (H R 4773) to collect data on assisted reproductive technologies in the United States. In the interests of public health, we understand and acknowledge that both FAM and MFL are required, under the Fertility Clinic Success Rate and Certification Act of 1992, to submit information about our assisted reproductive treatment to the CDC. Furthermore, data collected by Society of Assisted Reproductive Technologies (SART) is used to generate statistics published annually in medical and scientific publications and for selected research projects. For such activities, our data is de-identified (stripped of information that could potentially lead to revealing the subject of the information).

We understand that all information about us obtained during the program will be handled confidentially and that neither our identities nor specific medical details will be revealed without our consent. Our medical details may be incorporated with other patients and analyzed as a group in professional publications as long as our identities are concealed.

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17. We each acknowledge that we have fully reviewed and comprehend the contents of this Consent Form. The nature of in vitro fertilization and embryo transfer (IVF/ET) with donor oocytes has been explained to us, together with the known risks. We understand the explanation that has been given us and that there may be unknown risks. We have had the opportunity to ask any questions we might have and those questions have been answered to our satisfaction. We acknowledge that IVF/ET is being performed at our request and with our consent. We understand that we may elect not to continue with the procedure at any time and that this decision would not affect any other present or future medical care and treatment from either FAM or MFL.
18. With full knowledge and understanding of the attendant risks and consequences of our participation, we each consent to the medical procedures described in this Consent Form and agree to participate in IVF/ET. We each acknowledge and affirm that we have given our consent and entered into this agreement without coercion or compulsion and of our own free will.

Signature of Patient

Signature of Partner

Print Patient's name

Print Partner's name

Date

Date

Physician
Kutteh Ke Fertility Associates of Memphis, PLLC

Date

Laboratory Director
Memphis Fertility Laboratory, Inc.

Date

Patient's Initials _____

Partner's Initials _____