

**KUTTEH KE FERTILITY ASSOCIATES OF MEMPHIS, PLLC**

**AND**

**MEMPHIS FERTILITY LABORATORY, INC.**

80 Humphreys Center, Suite 307  
Memphis, Tennessee 38120  
(901) 747-2229

**CONSENT FOR EMBRYONIC BLASTOMERE BIOPSY DURING IN VITRO FERTILIZATION FOR PRE-IMPLANTATION GENETIC TESTING**

1. We (name of patient and partner), \_\_\_\_\_, the undersigned are the intended parents and have been counseled by Dr. \_\_\_\_\_. We request, authorize, and consent to the performance of embryonic blastomere biopsy and pre-implantation genetic testing (PGT) at time of in vitro fertilization and embryo transfer (IVF/ET).
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 (egg) identification and preparation, embryo culture, embryo biopsy and cryopreservation. FAM and MFL will be utilizing a third party genetics laboratory for PGT.
3. We understand that we will be undergoing IVF/ET and that the procedure of PGT has been developed to evaluate embryos before embryo transfer in an attempt to reduce the risk of an afflicted pregnancy and child. 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. We will undergo IVF/ET and will use intracytoplasmic sperm injection (ICSI) that has been explained and consented to separately. This results in the fertilization of egg(s) by sperm. If an egg successfully fertilizes, it is referred to as an embryo.
  - b. When our viable embryo(s) have reached an appropriate stage of development, an opening is created in the outer covering of the embryo (zona), under microscopic manipulation. One or more cells (blastomeres) are extracted (biopsied) while retaining the integrity of the embryo for further development and growth. This process will be repeated for each of our viable embryo(s).
  - c. The blastomeres will be prepared (fixation) and sent for appropriate genetic analysis. Results of the genetic analysis will be available within a few days of the biopsy.
  - d. Our embryo(s) will be cryopreserved (frozen) and temporarily stored while we await the results of the genetic analysis. This may result in the freezing and storage of embryo(s) that subsequently may be determined to have an abnormal or undesired genetic diagnosis.

Patient's Initials \_\_\_\_\_

Partner's Initials \_\_\_\_\_

- e. The results of these studies will determine which embryo(s) are selected for subsequent transfer procedure for pregnancy.
4. We understand that embryo biopsy can only be performed on viable embryos at appropriate stages of growth. We acknowledge that due to either an inadequate number of sperm or egg, and/or to poor fertilization or embryo development, embryonic blastomere biopsy may not be possible.
  5. We understand that embryonic blastomere biopsy and PGT are relatively new procedures with unknown risks. While current research demonstrates minimal risk to a developing embryo, there is the potential for embryo injury. This may result in our losing the opportunity to become pregnant in this IVF/ET cycle.
  6. We understand and acknowledge that according to current research there is a mis-diagnosis rate of approximately 10% for PGT. This may result in a pregnancy and child afflicted by genetic disorder.
  7. We acknowledge that blastomeres are extremely fragile and that events during biopsy, fixation or transport may make PGT impossible. In that case, we understand that we may not have genetic test results to guide our decision-making for embryo transfer.
  8. We understand that we should experience no additional discomfort by adding embryonic blastomere biopsy and PGT to "standard" IVF.
  9. We acknowledge that we have been strongly urged to have a thorough discussion of PGT with a qualified genetics counselor. Furthermore, we have been urged to have confirmation of the PGT results by amniocentesis or chorionic villus sampling (CVS) in the early stages of our pregnancy.
  10. We understand it is FAM's policy and agree that any of our embryo(s) that have undergone cryopreservation and subsequently found to have an abnormal genetic diagnosis may be destroyed, or in certain cases, the abnormal embryos may be used for quality control or research studies. We understand that these abnormal embryos are not suitable for embryo transfer.
  11. Since it is not possible to evaluate embryos for every possible disease state, we understand that if pregnancy is successfully established, miscarriage, ectopic pregnancy, stillbirth and/or abnormalities (birth defects) may occur.
  12. We hereby release MFL, its' agents, servants, or employees from any injury or damage, known or unknown, that might result should our embryo(s) cease to be viable while in the custody of MFL, its agents, servants, or employees.
  13. We do jointly and severally release and forever discharge both FAM and MFL, and each of its divisions, employees, officers, physicians, agents, successors, and assignees from any and all claims, demands, costs, expenses and loss of services incurred as a result of the physical or mental nature of any child or children produced using these procedures.
  14. 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 the expenses of this treatment. The expenses may consist of hospital charges, laboratory charges and/or physician professional fees.
  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 embryonic blastomere biopsy and PGT procedure 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).

Patient's Initials \_\_\_\_\_

Partner's Initials \_\_\_\_\_

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. Specific medical details may be revealed in professional publications as long as our identities are concealed.

- 17. We each acknowledge that we have fully reviewed and comprehend the contents of this Consent Form as well as the separate Consent for In Vitro Fertilization and Embryo Transfer. In addition, we each acknowledge that we have fully reviewed and comprehend the contents of the separate PGT consent form from the genetics laboratory. The nature of embryonic blastomere biopsy and PGT at time of IVF/ET 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 embryonic blastomere biopsy and PGT at time of 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 MFL or FAM.
- 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 embryonic blastomere biopsy and PGT at time of 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

\_\_\_\_\_  
PrintPartner's name

\_\_\_\_\_  
Date

\_\_\_\_\_  
Date

Patient's Initials \_\_\_\_\_

Partner's Initials \_\_\_\_\_