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Consent to Purchase Frozen Donor Eggs

Patient name: _____ DOB: _____

Partner name: _____ DOB: _____

Referring Physician/Affiliate Clinic: _____

Tennessee Reproductive Medicine (TRM) is an in vitro fertilization practice that acquires eggs from anonymous egg donors for use with recipient patients both at TRM and with affiliate clinics. In order to expand the availability of donated eggs to other clinics, TRM has an egg donor bank, in which previously donated eggs are stored for later use.

I/we desire the purchase of donated eggs for Patient to use. TRM will provide vitrified, mature, oocytes to Affiliate Clinic. TRM will abide by FDA regulations in egg donor screening for infectious diseases. TRM also performs limited recessive carrier genetic testing on donors, and will provide those results to Patient and Partner. TRM will have no role in the care of Patient or Partner; all consultations, pre-cycle screening, medical clearance determination, cycle monitoring, egg fertilization, embryo culture, embryo transfer, and early pregnancy care will be administered by Affiliate Clinic. The Affiliate Clinic will also be responsible for obtaining all medical treatment consent forms from Patient and Partner. Because TRM will have no role in the care of Patient or Partner, TRM is not responsible and will not be held liable for any adverse outcomes with Patient or Partner.

I/we understand that as with any conception, adverse outcomes in offspring can occur in pregnancies conceived with the use of donated frozen eggs. To date, medical studies have not shown a difference in risks to offspring conceived by way of frozen eggs; however, future studies may show other results. I/we understand and agree that we will not hold TRM liable for adverse health conditions in any pregnancy or child conceived with the use of donor eggs purchased from TRM, including but not limited to miscarriage, ectopic pregnancy, chromosome disorders such as Down syndrome, genetic diseases, congenital malformations, developmental disorders including autism and attention deficit disorder, and cancers. I/we understand that TRM has performed genetic screening in the donors, which is above and beyond the minimum recommendation for genetic carrier screening in reproductive aged women. While the purpose of this added screening is to further decrease the risk of recessive genetic conditions in children conceived from the use of donor eggs, I/we understand that no test can completely eliminate the risk of recessive conditions. I /we understand that TRM has not screened for any dominant genetic conditions in donors, as this is not recommended by expert physician panels in the absence of family history suggestive of a dominant genetic disease.

TRM will ship the purchased eggs to Affiliate Clinic, insured for the amount paid by the patient. I/we understand that TRM cannot control the shipment process once the eggs leave TRM. I/we agree not to hold TRM liable for shipment problems; if it appears upon arrival to Affiliate Clinic that the cryostorage tank has been damaged, I/we agree that Affiliate Clinic will alert TRM and the insurance will be utilized to pay for a new batch of eggs. TRM will make every effort to provide a new batch of eggs from the same donor; however, if no additional eggs exist from the initial donor, TRM will rematch Patient with a new donor and obtain Patient approval before shipping the new batch of eggs.

The majority of patients who thaw and fertilize one batch of eggs (5-6 eggs) will have at least 1 blastocyst grow and be suitable for transfer 5-6 days after the eggs are thawed. However, unforeseen variables may occasionally affect the success of the egg thaw and/or the embryo growth in culture and result in no suitable blastocysts being available for transfer. If desired, patients may elect to enroll in one of two blastocyst guarantee options, which guarantees that after thawing and fertilizing one batch of eggs, at least one blastocyst will be available for transfer.

There are two options to purchase donor eggs, a basic program and a euploid blastocyst guarantee programs (46 chromosomes detected by preimplantation genetic testing (PGT)).

Option 1: Basic program: The base price for the cost of a batch of eggs is \$17,500, which includes:

- Review of donor database and assistance with donor selection
- All donor screening and treatment
 - Diagnostic testing
 - FDA lab tests
 - Recessive panel genetic test
 - Donor medications and stimulation cycle
 - Donor compensation
- Egg freezing (vitrification)
- Shipping eggs to your practice and return shipment for the storage tank to be shipped back to TRM

All fees related to your consultations, medical testing, treatment and embryology laboratory services for fertilization and culture of the eggs once received by your primary clinic will be handled by your primary clinic.

With the basic program, for patients who meet eligibility criteria we guarantee that at least one blastocyst will develop after thawing and fertilizing the eggs.

In order to be eligible for the *Blastocyst Guarantee*, patients and partners must meet medical criteria as follows.

- 1) If the partner's sperm has been used previously in IVF, that normal fertilization (at least 50%) and blastocyst development (at least 50% of fertilized eggs) occurred.
- 2) Partner has a normal semen analysis, or donor sperm are being used for fertilization.
- 3) Affiliate clinic agrees to thaw the oocytes using the protocol and thaw media recommended by TRM.
- 4) If a partner has an abnormal semen analysis, the couple may be deemed eligible for the guarantee if there are isolated abnormalities (low count, or low motility, or low morphology). If there is a combination of severely low concentration < 5 million/ml and a high percent of abnormal morphology, the couple would not be eligible for the guarantee due to these sperm abnormalities being risk factors for impaired fertilization and embryo growth.
- 5) Sperm may not be derived from testicular extraction procedures.

For patients who are eligible for the blastocyst guarantee and choose to enroll in the *BGP*:

- 1) If no blastocyst is available for transfer, but the Patient has a clinical pregnancy after the transfer of any embryo resulting from the initial egg thaw cycle, or from the transfer of a frozen embryo derived from the initial egg thaw cycle, then no additional eggs will be provided (clinical pregnancy is defined as ultrasound documentation of a fetus with cardiac activity by 7 weeks gestation).

- 2) If a blastocyst does not develop AND no embryo is transferred, the patient will be provided one additional batch of eggs at no additional cost. If a second batch of eggs is provided, TRM will make every effort to use the same donor's eggs or one of the original chosen donors; if none of those donor's eggs are available, TRM will help Patient rematch with another donor. **No more than two batches of eggs will be provided, and if another thaw cycle still does not result in an embryo to transfer, no monies will be refunded.**

Euploid Blastocyst Guarantee Program (EBGP): The cost of a batch of eggs with the euploid blastocyst guarantee (guarantee that a minimum of 1 euploid embryo results from the fertilization of the eggs) includes all of the items above in the *Basic Program* and includes the guarantee that at least one euploid blastocyst will develop after thawing and fertilizing the eggs (euploid means 46 chromosomes are detected by preimplantation genetic testing (PGT)). The *EBGP* costs \$29,000. This includes the costs to ship the sperm from your primary clinic to TRM, cost of the eggs (as summarized in the *Basic Program*), costs to thaw/fertilize with ICSI/culture the blastocysts/embryo biopsy for PGT and the genetic testing costs of PGT and the shipment of the embryo(s) back to your primary clinic. All fees related to your consultations, medical testing, sperm freezing (more than 1 sample may be required) treatment and embryology laboratory services for embryo thawing and embryo transfer once received by your primary clinic will be handled by your primary clinic.

In order to be eligible for the *EBGP*, patients and partners must meet medical criteria as follows.

- 1) If the partner's sperm has been used previously in IVF, that normal fertilization (at least 50%) and blastocyst development (at least 50% of fertilized eggs) occurred.
- 2) Partner has a normal semen analysis, or donor sperm are being used for fertilization.
- 3) If a partner has an abnormal semen analysis, the couple may be deemed eligible for the guarantee if there are isolated abnormalities (low count, or low motility, or low morphology). If there is a combination of severely low concentration < 5 million/ml and a high percent of abnormal morphology, the couple would not be eligible for the guarantee due to these sperm abnormalities being risk factors for impaired fertilization and embryo growth.
- 4) Sperm may not be derived from testicular extraction procedures.

For patients who are eligible for the euploid blastocyst guarantee and choose to enroll in the *EBGP*:

TRM guarantees that after thawing frozen eggs and fertilizing all eggs that survive the thaw process, blastocysts will be grown and preimplantation genetic testing (PGT) will be performed and at least one euploid embryo will result. If no euploid embryo results, TRM will thaw additional eggs (number to be determined at the discretion of TRM) and repeat the fertilization, blastocyst growth and PGT processes until a euploid embryo results. TRM may not be able to use the same donor if additional eggs must be thawed. If the same donor is not available and a new donor is required, TRM will work with the patient to find another suitable match and will confirm the match is approved by your donor coordinator at your primary clinic before new donor eggs are thawed.

The euploid blastocyst guarantee option requires sperm to be shipped from the patient's primary clinic to TRM and all embryology work will occur at TRM. Once the PGT report is complete and TRM confirms we have a euploid embryo, we will ship the euploid embryo(s) to your primary clinic. While we only guarantee one euploid embryo, we will ship all euploid embryos to you if you have more than one. If you want the aneuploid (abnormal) embryos shipped to you, we will ship those if your primary clinic agrees to receive them. If they do not agree to receive them, but you want to store them, we can help you set up long term storage at an embryo storage center.

I/we understand that using frozen donor eggs to conceive does not guarantee a pregnancy or live birth. I/we understand that laboratory conditions outside of TRM are not within TRM’s control, and we agree not to hold TRM liable for any laboratory problems or adverse laboratory outcomes in the Affiliate Clinic laboratory.

I/we understand that if we choose to utilize PGT on our blastocysts that PGT is a screening test and not a definitive diagnostic test and that additional prenatal genetic testing is recommended to confirm the PGT results. I/we understand that transferring a euploid embryo does not guarantee a livebirth and does not guarantee the birth of a healthy child (additional PGT consent must be signed for PGT cases)

I/we understand and agree that the identity of the donors is confidential and will never be shared with us, so long as legal guidelines do not change and mandate the release of such information. I/we give permission for TRM to contact Affiliate Clinic to inquire about my reproductive outcome with the frozen eggs, so as to collect ongoing data about our donors. TRM agrees to comply with all material aspects of applicable laws and regulations governing the licensing and conduct of its profession, including, without limitation, maintenance of all licenses, registrations, certificates and qualifications necessary. I/we understand that TRM is not responsible for the compliance of Affiliate Clinic with laws, regulations, licenses, registrations, certificates and necessary qualifications and agree to not hold TRM liable for any lack of compliance or acts of omission on behalf of Affiliate Clinic.

My/our signature below affirms that I/we have read the above information, understand the information, and have had an opportunity to have my/our questions answered to my/our satisfaction, and hereby desire the purchase of frozen donor eggs for attempting pregnancy. I/we desire to purchase:

_____ **Basic program, batch of 6 eggs, \$17,500**

_____ **Euploid blastocyst guarantee program (EBGP), if eligible, \$29,000**

Patient Signature

Date

Partner Signature

Date

TRM Representative

Date