MPI #

STATE OF NORTH CAROLINA

Form 3 Revision 3-28-14

KNOWN DONOR, OOCYTE RECIPIENT and IVE ACREEMENT

COUNTY OF MECKLENBURG RECIPIENT and IVF AGREEMENT
THIS AGREEMENT is made this, the day of, 20, for good and valuable consideration, by and between REPRODUCTIVE ENDOCRINE ASSOCIATES OF CHARLOTTE, P.C. (hereinafter referred to as "REACH");
(hereinafter referred to as "Female Partner"); and
(hereafter referred to as "Male Partner"). At all times
herein shall be referred to as "Donor."
(Print names as appears on driver's license)
RECITALS
WHEREAS, REACH is a Professional Corporation organized, existing, and doing business within the State of North Carolina; and
WHEREAS , REACH operates a clinic in Charlotte, Mecklenburg County, North Carolina, in which its physicians, in pertinent part, provide reproductive assistance to its patients; and
WHEREAS, among the techniques employed by the physicians of REACH to assist couples in becoming pregnant is a procedure known as Donor Oocyte Transfer and In Vitro Fertilization (IVF); and
WHEREAS, Female Partner and Male Partner (hereafter referred to collectively as "Parents") are each adults who are mutually monogamous and desire to give birth to, and parent a child who is the result of the union of the Male Partner's sperm (or anonymous donor's sperm) and Donor's egg, and which embryo shall be implanted in the uterus of the Female Partner. Following the time of gestation, the child shall be born of the Female Partner and the Parents shall have full care and legal custody and control of this child until this child reaches his or her age of majority; and
WHEREAS, Parents desire to take part in the assisted reproduction procedure offered by REACH in an attempt to become pregnant with a child; and

WHEREAS, Parents have had the opportunity to be fully advised and counseled by persons of trust and confidence, including, but not limited to, attorneys licensed to practice law with respect to the obligations assumed under this Agreement, and have considered the ramifications, consequences, obligations, and effects of this Agreement.

NOW, THEREFORE, in consideration of the mutual promises contained herein, and with the intention of being fully bound, the Parties agree as follows:

- 1. <u>Consent By Female Partner To The Procedure</u>. Female Partner stipulates, agrees to, and understands the purpose of this Agreement, has read each and every provision of it and chooses and agrees to go forward as a recipient of the Oocyte Donation Procedure and IVF Procedure contemplated by this Agreement.
- 2. <u>Consent By Male Partner To The Procedure</u>. Male Partner stipulates, agrees to, and understands the purpose of this Agreement, has read each and every provision of it, and chooses and agrees to go forward as a recipient of the Oocyte Donation Procedure and IVF Procedure contemplated by this Agreement.
- 3. General Description Of The Contemplated IVF Procedure. The Parents agree that the following description set forth below is a simple outline of the Oocyte Donation and IVF Procedure contemplated by the Parties. The Parties agree and stipulate that the procedure shall be tailored specifically to the Parents in order to create the greatest likelihood for a safe and healthy pregnancy and delivery of a healthy child. However, Parents understand that REACH gives no assurance of a successful completion of the Oocyte Donation and IVF Procedure, that a pregnancy will be achieved by the procedure, or that a healthy child will be delivered. It is further agreed that any party hereto may, without the prior consent or approval of any other party, discontinue the procedure contemplated herein.

It is anticipated that the Female Partner will receive medication to prepare her uterus to receive the embryos which result from the Oocyte Donation Procedure. The eggs will be obtained from the Donor who knowingly relinquishes all control of the eggs for use by the Parents. This Donor has been selected by the Parents. Once the eggs are donated, they will then be prepared and in marked dishes inseminated with a sample of Male Partner's sperm which has been prepared by a procedure which removes the sperm from the seminal fluid. At the discretion of REACH, in consultation with the Parents, some or all of the embryos which may result from fertilization may be placed in Female Partner's uterus by means of a small catheter which passes through her cervix under ultrasound guidance.

Parents agree and stipulate that each of the aforementioned steps carry known and unknown risks and theoretical concerns. The known risks and theoretical concerns are more

Verifier:	_	Date:
, 01111011		2

fully described in this Agreement and in the Informed Consent document(s) which are attached hereto and incorporated herein by reference. (See Exhibit A.)

4. <u>General Description Of Procedure For Male Partner</u>. Parents acknowledge, agree, and stipulate that Male Partner will be required to provide several semen samples. First, before the start of a cycle, Male Partner will be asked to supply a semen sample for laboratory analysis. Following the receipt of the results of the tests, Male Partner may be asked to take a specific antibiotic in order to treat bacteria that may be present within his semen.

Second, Male Partner may be asked to provide a semen sample to be cryopreserved in advance of the insemination in order to ensure its availability at the time of egg retrieval.

Finally, immediately prior to insemination, a third sample of semen will be obtained from the Male Partner. After evaluation and preparation, this sample will be used for insemination. Semen collected in this manner can generally be used to fertilize the egg. However, if there are any doubts concerning the viability of the collected sample, the frozen sample may be thawed or spermatozoa may be obtained from a testicle using a minor surgical procedure called Testicular Sperm Retrieval. A specific consent form will be required before Testicular Sperm Retrieval is employed.

- 5. **Egg Donation**. The parties agree, stipulate, and acknowledge that any and all children born from the process contemplated herein will be biologically related to the third-party Donor which has been selected by the Parents. Parents acknowledge that the Donor has undergone and satisfied a battery of psychological and physical tests in order to screen the Donor and reduce the likelihood of known risks. However, Parents acknowledge that unforeseen complications and risks may exist, and waive and release REACH from any and all unforeseen risks or complications related to the Donor.
- 6. **Donor Sperm**. On occasion, for one reason or another, it may be determined that a Male Partner's sperm cannot be used to fertilize Donor's egg(s). Should it be determined that Male Partner's sperm cannot be used to fertilize the Donor's egg(s), then under some circumstances, REACH and Parents may agree to accept the use of sperm from an anonymous donor. The Parents agree, stipulate, and acknowledge that the use of sperm from an anonymous donor is expressly contingent upon Parents and REACH agreeing to the process. If all parties agree, then Parents will obtain the necessary sperm from a donor. In all cases, donor sperm that has been frozen and quarantined will be used so that appropriate microbiologic screening can be done. However, even with appropriate screening of Donors for sexually transmitted diseases, the risk of infection cannot be eliminated. Further, Parents understand that there is no guarantee that these inseminations will result in a pregnancy. Parents understand that within the normal human population, approximately three percent (3%) of children are born with physical or mental handicaps or defects, and that the occurrence of such defects is beyond the control of REACH.

Form 3 Revision 3-28-14

Parents therefore understand and agree that neither REACH, its physicians, nor personnel, assume responsibility for the physical and mental characteristics of any child or children born as a result of artificial insemination. Parents agree to assume the risks which are present, in the absence of negligence by REACH, its physicians, nor personnel, of bearing a physically or mentally handicapped child.

Parents agree, stipulate, and acknowledge that the use of donor sperm will cause the child(ren) born to Female Partner not to be biologically, nor genetically, related to either Male Partner, nor Female Partner. The use of donor sperm shall not relieve Male Partner, nor Female Partner, of any obligation under this agreement.

Parents acknowledge that the anonymous sperm donor has undergone certain tests to reduce the likelihood of certain risks. However, parents acknowledge that unforeseen complications and risks may exist, and waive and release REACH from any and all unforeseen risks and complications related to the sperm donor.

Partners agree that a specific Consent Form will be required before Therapeutic Donor Insemination is employed.

- 7. <u>Consideration</u>. In consideration for the medical procedure contemplated herein, the Parents, individually and jointly, agree to pay and guarantee payment in full of any and all charges for services rendered or to be rendered to the Parents by REACH.
- 8. Acknowledgment And Assumption Of Risks Created By The Procedure. Parents understand and agree to assume all risks to each of them and to the child, including the risk of death, which are incident to conception, pregnancy, childbirth, and postpartum complications. Parents assume and acknowledge that they have discussed the potential risk, adverse consequences, and complications which may relate, directly or indirectly, to the course of conduct described in this Agreement with their physicians, psychologists, attorneys and others. While many of the risks are listed and described below or in the separated Informed Consent forms attached hereto, incorporated herein by reference, and hereinafter referred to as Exhibit A, Parents understand, agree and acknowledge that some risks may not be known, nor contemplated, and the Parents accept those unanticipated risks and their consequences.
- 9. <u>Cryopreservation</u>. In the discretion of REACH, viable embryos which are not transferred may be cryopreserved for possible replacement in a subsequent cycle. Parents agree and stipulate that there are potential risks associated with cryopreservation. In part, for various reasons, some embryos may not grow in the laboratory and reach a stage where they can be cryopreserved. Other embryos which have been cryopreserved may not resume their normal growth when they are thawed, nor will they successfully implant when they are placed in the

Verifier:	Date:	

uterine cavity. Further, Parents agree and stipulate that the viability of the embryos may be compromised due to malfunction of equipment used in the cryopreservation laboratory. Storage and disposition of cryopreserved embryos is provided for in Paragraph 18 herein.

10. <u>Eggs Removed During Retrieval</u>. Parents agree, stipulate, and it is acknowledged that REACH cannot guarantee the number of eggs which will be removed from the Donor, whether the eggs will be normal, nor whether the eggs will be mature. In fact, some of the Donor's follicles may not yield eggs and, on some occasions, none of the follicles will yield eggs.

The egg retrieval process involves the use of equipment such as incubators, suction apparatuses, and ultrasound machines. These machines may fail due to technical malfunction.

Further, once the eggs are isolated in the laboratory, blood and abnormal nursing cells will be removed from around the egg using dissection needles. Although it is unlikely, some or all of the Donor's eggs may be damaged in this process.

Further, eggs may be damaged because of shock due to differences in their surrounding environment.

Initial egg yield numbers are counted once, and only once, immediately prior to the eggs being placed into the incubators so as to stabilize conditions. The eggs are not visualized during the egg retrieval. Instead, eggs are found by locating the nursing cells which surround the eggs. Whether an egg is normal cannot be determined at the time an egg is retrieved. The exact number of eggs is only determined at the time of insemination or at Intracytoplasmic Sperm Injection (ICSI).

- 11. <u>Success Rates</u>. Parents have been informed, acknowledge that they understand, agree, and stipulate that while REACH hopes that pregnancy will result from the Egg Donation/IVF Procedure, they cannot guarantee it. Even in normal fertile couples, the chance of pregnancy is approximately twenty-five percent (25%) in a given menstrual cycle. If no pregnancy occurs, then the Parents <u>may</u> be offered participation in future cycles when assessment by the physicians at REACH reveal no contraindications. As indicated above, failure to obtain pregnancy may result from many reasons, including, but not limited to, the following:
 - (a) Maturation of the egg(s) may not occur, or the time of the egg maturation may be misjudged, may not be predictable or may not take place in the monitored cycle.

			5		
Form 3	Revision 3-28-14	Verifier:		Date:	

- (b) Pelvic adhesion may prevent access to the Donor's ovary with the follicles, thus causing the procedure to obtain the eggs from the ovary to fail.
- (c) The egg(s) obtained from Donor may be abnormal.
- (d) Normal spermatozoa may not be available.
- (e) Normal fertilization of the egg(s) by the sperm may not occur.
- (f) Cleavage or cell division of the embryo(s) may not occur or the embryos(s) may not develop normally.
- (g) The embryo(s) may become contaminated by infection in the semen or bacteria from the vagina.
- (h) Implantation of the embryo(s) in the uterus after embryo transfer may not occur or an early pregnancy may be lost after an initial positive result.
- (i) Even if pregnancy is established, delivery of a child may not occur due to miscarriage, ectopic pregnancy (outside the uterus), stillbirth, or other complications associated with pregnancy and delivery.
- (j) There may be unknown side effects from any of the procedures resulting in abnormal pregnancy or abnormal fetal development.

<u>Under no circumstances can, nor does, REACH guarantee the normality of any infant</u> born as a result of the IVF procedure, nor success of the program.

- 12. <u>Withdrawal From The Program</u>. Parents, at any time, may decide to withdraw from participation from the program. However, Parents decision to withdraw from the program shall not relieve them of their obligation to compensate REACH for the fee that it has earned at the time of withdrawal.
- 13. <u>Confidentiality</u>. Any information obtained during the Oocyte Donor/IVF Procedure shall remain confidential and will be disclosed only with each of the Parents' express written permission. However, REACH reserves the right to publish results or information in a manner which protects the Parents' confidentiality. Specifically, any publication will not identify the Parents. In addition, from time to time, representatives of the Food and Drug Administration (FDA), The Center for Disease Control (CDC), and the Society of Assisted Reproduction Technologies (SART), and other agencies, may inspect REACH's records.

14.	Disposition (Of	Unwanted	Or	Unsuitable	Cells.	. Fluids. I	Eggs (& Embr	vos.
-----	---------------	----	----------	----	------------	--------	-------------	--------	--------	------

6

Verifier: Date:	_		
	Vanifian	Date:	

- (a) Parents agree, stipulate, and acknowledge that blood, blood products and cells as well as follicular and seminal fluids and cells and any other genetic or biological material which is obtained during follicular monitoring, egg or sperm retrieval, may be used for scientific observations and/or discarded at the discretion of REACH without any further observations.
- (b) Parents agree, stipulate and acknowledge that in the event immature, unfertilized or abnormally fertilized eggs result, these genetic materials may be subjected to scientific observations and/or discarded at the discretion of REACH without further studies. The Parents regard these eggs as unwanted and they should be disposed of or, in REACH's sole discretion, studied and then disposed of by REACH.
- (c) The Parents agree and stipulate that embryos which arrest after one (1) to six (6) days after egg retrieval, that partially degenerate, or for any other reasons are considered by the Embryologists at REACH to be unsuitable for embryo transfer or cryopreservation may be scientifically observed and studied and/or discarded at the discretion of REACH without further studies. These observations and studies use protocols that will cease the immediate growth of the individual cells. Parents agree and stipulate that these embryos or their cells will never be used for purposes other than scientific research. Parents further agree and stipulate that the embryos and their cells are unwanted and considered to be abnormal and should be disposed of or, in REACH's discretion, studied and then disposed of by REACH.
- 15. Release And Indemnification. Female Partner and Male Partner, on their own behalf, and on behalf of the child, hereby release REACH and its physicians, scientists, technicians, and personnel, from any liability for any physical or emotional health consequences or damages known or unknown, anticipated or unanticipated, which may result from participation in the medical procedure described herein.
- 16. <u>Waiver</u>. Parents acknowledge, agree and stipulate that the Oocyte Donor/IVF Procedure contemplated by this agreement and described above does not guarantee: (1) that REACH will complete the process; (2) that pregnancy will be achieved by the procedure; nor (3) that a healthy child will be delivered.
- 17. <u>Informed Consent</u>. Parents agree and stipulate that the medical procedures contemplated by this Agreement are invasive. In this regard, the Parents have signed a written document titled Informed Consent. A copy of this Informed Consent is attached hereto, incorporated herein by reference, and hereinafter referred to as Exhibit A. Parents agree and stipulate that Exhibit A describes, in part, the purpose of the treatment, the procedures to be followed, anticipated discomfort and risks of the procedure, financial responsibilities of the Parents, unknown complications, and some possible reasons for failure. Each party agrees and

stipulates that he/she has read Exhibit A in its entirety before signing his or her respective signature to the document.

- 18. <u>Disposition of Cryopreserved Genetic Material</u>. The medical procedure contemplated by the Parents herein may result in one (1) or more eggs of the Parents or the Parents' embryo, being cryopreserved (frozen) and maintained by REACH. Storage of such genetic material shall be covered by a separate document titled "Agreement For Determining The Disposition Of Embryos Not Transferred, Cryopreservation Of Embryos And Decisions For Future Disposition Of Cryopreserved Embryos."
- 19. <u>Acknowledgment Of Advice</u>. Each Party acknowledges that he or she fully understands this Agreement and its legal effect, having had the opportunity to review this Agreement with all persons of confidence, including an attorney, and having discussed each and every provision in detail with all the possible ramifications which may be associated with these provisions. Each Party acknowledges that he or she is signing this Agreement freely and voluntarily, being fully informed of its possible ramifications, and that no Party has reason to believe that the other did not freely and voluntarily execute this Agreement.
- 20. **Severability**. In the event any of the provisions of this Agreement are deemed to be invalid or unenforceable, such provisions shall be deemed severable from the remainder of this Agreement and shall not cause the invalidity or unenforceability of the remainder of this Agreement. If any provision of this Agreement is deemed invalid due to its scope or breadth, such provision will be deemed valid to the extent of the scope or breadth permitted by law.
- 21. <u>Integration</u>. This Agreement sets forth the entire Agreement between the Parties with regard to the subject matter hereof. All Agreements, covenants, representations, and warranties, expressed or implied, oral and written, of the Parties are contained herein. No other Agreements, covenants, representations, or warranties, expressed or implied, oral or written have been made by any Party to any of the others with respect to the subject matter of the Agreement. All prior and contemporaneous conversations, negotiations, possible and alleged Agreements and representations, covenants and warranties with respect to the subject matter hereof are waived, merged herein and superseded hereby. This is an integrated Agreement. However, from time to time, the Gestational Carrier may be asked to execute and shall execute additional consent documents which shall be binding and enforceable.
- Modifications, Revisions, Or Amendments. Any future revision, modification, amendment, or waiver of any of the provisions of this Agreement shall be effective only if made in writing, dated, signed, and executed with the same formality as this Agreement. Any such provision, modification, or amendment will specifically provide that it is intended to revise, modify, or amend this Agreement. No oral revisions, modifications, amendments, or waivers will be effective to revise, modify, amend or waive any terms or conditions of this Agreement. Failure of either Party to insist upon strict performance of any of the provisions of this Agreement shall not be construed as a waiver of any subsequent default of the same or similar nature.

8

Verifier: Date:	

23. **Alternate Dispute Resolution**. Any controversy or claim arising out of, or related to, this Agreement shall be submitted to mediation. A neutral shall be agreed upon by the Parties. Each party agrees to participate in good faith in mediation to reasonably, timely, and cost effectively resolve all disputes. If, after mediation, the Parties are unable to attain a resolution of all of the issues, they agree to have the unresolved issues determined in binding arbitration through the American Arbitration Association. The unsuccessful party shall pay the entire cost of the arbitration as well as the other party's attorney fees, unless the arbitrator should determine otherwise. 24. Jurisdiction and Controlling Law. This Agreement will be governed by, construed, and enforced with, the laws of the State of North Carolina. Female Partner signature Date Date Male Partner signature REACH Representative verifying completion of consent Date REPRODUCTIVE ENDOCRINE ASSOCIATES OF CHARLOTTE, P.C. If signed outside of REACH facility, then both partner signatures need notary attestation. STATE OF _____ COUNTY OF , a Notary Public of County and State of I. _____, certify that ______ And (if partner) ______ personally appeared before me this day and acknowledged the execution of the foregoing instrument consisting of _____ pages. Witness, my hand and official seal, this, the _____ day of _____, 20___. Notary Public My Commission Expires _____