EXHIBIT A

MPI # _____

REPRODUCTIVE ENDOCRINE ASSOCIATES OF CHARLOTTE, P.C.

In Vitro Fertilization/Gestational Carrier
Consent Form For Biological Parents

INFORMED CONSENT

We, _____ (hereinafter "First Partner"), and
_____ (hereinafter "Second Partner"),
desire for a compassionate gestational surrogate, _____
(hereinafter "Gestational Surrogate"),

(Print all names as appears on driver's license)

to carry and deliver a child for us, the First Partner and the Second Partner (hereinafter referred to collectively as "Parents"), for the sole purpose of allowing us to experience parenthood of a child who may be biologically related to or both of us. We intend to regard any child born of the procedure described herein to be our child.

We understand that ovulation induction drugs, including clomiphene citrate, human menopausal gonadotropin, and follicle stimulation hormone, will be prescribed to the First Partner (or a female donor) to stimulate multiple egg production. In addition, GNRH agonist may be used in conjunction with the aforementioned drugs to regulate ovarian function. Human chorionic gonadotropin (hCG) may be used to trigger ovulation and to assist in the maturation of the eggs prior to their retrieval. The First Partner (or a Female Donor) will have blood samples collected and ovarian ultrasound examinations, a standard technique in which high frequency sound waves are used to form an image. The purpose of these tests will be to identify the time at which the egg(s) is/are suitable for recovery. Surgery will be scheduled near the time that the First Partner (or the female donor) is expected to ovulate in order to collect her eggs. Eggs are collected by means of vaginal ultrasound guided aspiration of the ovarian follicles using a specially designed needle introduced through the vaginal wall under local anesthesia and/or intravenous sedation. After collection, all of the eggs will be inseminated with the sperm from the Second Partner (or a male donor). After a period of about three (3) to six (6) days, if fertilization takes place as planned, the resulting early embryo(s) will be placed into the uterus of the Gestational Carrier or cryopreserved for further attempts at pregnancy or both.

A. <u>Ovulation Induction</u>.

(The following processes and procedures and the risks associated therewith apply to the female partner unless eggs are to be provided by an egg donor, in which case said processes and procedures and the risk associated therewith apply to the egg donor:) We understand that a variety of medications are available for the induction of ovulation

including clomiphene citrate, human menopausal gonadotropins, pure follicle stimulating hormone, human chorionic gonadotripon, recombinant FSH, and GnRHanalogues or antagonists. We understand that some of these medications must be given by intra-muscular injection, which may cause bruising or discomfort at the injection site. Rarely, these medications may cause the ovaries to become over stimulated, leading to a condition called ovarian hyper stimulation syndrome (OHSS). We understand that in its most severe form, this condition might require hospitalization for intravenous fluids and monitoring until the syndrome resolves. Worldwide there have been rare reports of blood clots, stroke, paralysis, and death following severe OHSS. We therefore understand the importance of maintaining close contact with the IVF team during the time that these medications are being used and for two (2) weeks afterwards.

B. **Sperm Retrieval**.

(The following processes and procedures and risks associated therewith apply to the male partner unless sperm source is indicated by a sperm donor, in which case the processes and procedures and the risks associated therewith apply to the sperm donor) We understand that before the start of a cycle, the male partner will be asked to supply a semen sample for analysis by the andrology laboratory. He may be asked to take a specific antibiotic during the first part of the stimulation cycle to treat bacteria that may be present in order to increase chances for a successful fertilization. In certain cases, semen may also be frozen in advance to be certain of its availability at the time of egg retrieval. The semen sample may require testing for bacterial contamination depending on specific nature of treatment intended.

C. **Monitoring Protocol**.

(The following processes and procedures and the risks associated therewith apply to the female partner, unless the eggs are to be provided by an egg donor, in which case the processes and procedures and the risks associated therewith apply to the egg donor) We understand that while receiving the medications listed above, the female partner will be closely monitored. We understand that this monitoring will include daily blood drawing, which can cause mild discomfort and bruising at the puncture site. We understand that ultrasound examination of the ovarian follicles and the uterus will be performed frequently. These examinations may at times be uncomfortable, but have no known risks of any kind. We understand that if monitoring suggests a low probability for successful egg retrieval, that the stimulation cycle will be stopped and no egg retrieval will occur. We also understand that we may be given the option of starting the ovarian stimulation procedure again in a subsequent cycle.

D. **Egg Retrieval**.

(The following processes and procedures and the risks associated therewith apply to the female partner, unless the eggs are to be provided by an egg donor, in which case the processes and procedures and the risks associated therewith apply to the egg donor) We understand that at a time determined by the IVF team, the First Partner (or a Female

Donor) will be admitted to the Procedure Room at REACH for egg retrieval. We understand that in the vast majority of cases, ultrasound directed needle puncture of the follicles will be done. Rarely, the retrieval may be done by laparoscopy under general anesthesia. We understand that the procedure involves the small risk of general anesthesia as well as injury to bowel, bladder, or blood vessels, which might require a large incision (laparotomy) to repair. A separate informed consent will be obtained for a laparoscopic retrieval if it becomes necessary. With either type of egg retrieval, there could be bleeding from the site where the ovaries were punctured. This may require laparotomy (an incision in the abdomen) if the bleeding cannot be controlled through the laparoscope. The risks of the procedure are similar to the risks of laparoscopy, including general anesthesia.

We understand that we cannot be guaranteed that the number of eggs predicted prior to retrieval will indeed be recovered, or that any of the eggs will be normal or capable of fertilization. Some follicles may not yield eggs and rarely none of the follicles will yield eggs. The egg retrieval involves equipment such as incubators, suction apparatuses and ultrasound machines that may fail because of technical malfunction. We also understand that once the eggs are isolated in the laboratory that blood and abnormal nursing cells are removed from around the egg using dissection needles and that although unlikely, some or all of the eggs may be damaged in the process. In addition, once removed from the body, eggs may undergo spontaneous, degenerative changes due to their new environment

E. **<u>Insemination, Fertilization and Embryo Growth</u>**.

Once retrieved, the eggs will be incubated in the laboratory in a special solution (culture medium) and evaluated for timing of insemination by the embryology team of the IVF program. We understand that a sample of semen from the Second Partner, obtained by masturbation in a private collection room near the laboratory (or otherwise from a sperm donor), will be evaluated, prepared, and used for insemination. Semen by masturbation is rarely unsuccessful and, if there are any doubts, a sample from the Second Partner can be prepared and frozen in advance for thawing at this time (unless sperm is to be provided by a donor). However, in cases of unexpected failure when sperm is to be provided by the Second Partner, it may be possible to obtain spermatozoa from the Second Partner's testicle using a minor operative procedure (testicular sperm retrieval). Separate consent is needed for this procedure.

The seminal fluid that surrounds the spermatozoa must be removed prior to insemination. Sperm processing involves high centrifugal force, washing with an artificial colloidal suspension called *Puresperm*^{TM} or by 'swim-up' technique. We understand that the consistency of highly viscous semen will be reduced by an enzyme. The prepared semen may be exposed to substances intended to promote sperm movement or materials intended to remove toxic substances. The zygotes are changed into a culture solution. This solution may be changed every forty-eight (48) hours, or more frequently. Solutions may be specially tailored to the embryonic stage. The embryos are checked at least once daily and their development is determined. Embryos will remain in the solution(s) for

forty-eight (48) to one hundred twenty (120) hours and then transferred.
Should a pregnancy occur, we understand that no risk to the fetus is presently known to medical science arising from the materials and methods used in the preparation and handling of eggs, semen and embryos. We understand that not all eggs recovered can be fertilized, and that it is possible that none of the eggs may fertilize. Further, some eggs may be fertilized multiple times by sperm or even self-fertilize without the sperm participating. Zygotes and later stage embryos may develop abnormally at any time.

F. **<u>Embryo Transfer</u>**.

(The following processes and procedures and risks associated therewith apply to the Gestational Carrier.) Prior to transfer, the Gestational Carrier will undergo a prescription drug regime and monitoring of hormone levels and other tests to fix the timing of the transfer. Thereafter, between three (3) to four (4) days after egg retrieval the embryos will be placed into the uterine cavity of the Gestational Carrier. Alternatively, the embryos may be transferred at the blastocyst stage five (5) or six (6) days after transfer, using culture solutions that support growth for a longer period. For the embryo transfer, a thin catheter will be passed through the Gestational Carrier's cervix and into her uterus so the embryo may be deposited there. We understand that this procedure may cause some cramping and discomfort, and possibly a small amount of bleeding. Rarely, infection could be introduced at the time the catheter is inserted into the uterus, requiring antibiotic therapy. We understand there is no guarantee that any of the embryos thus transferred will result in a pregnancy.

We understand that the success of IVF can often relate directly with the number of embryos transferred to the uterus. We also understand that IVF significantly increases the risk for multiple gestation (more than one baby), and that this risk also correlates directly with the number of embryos transferred, their development, the age of the First Partner (or the egg donor), the number of prior attempts and other unknown factors. We also understand that in rare cases, embryos may split in two (2) or three (3), resulting in multiple fetuses. (On occasion, this can mean that there are more fetuses than embryos transferred.) There are distinct obstetric risks to multiple gestations, the most serious of which are pre-term labor and the delivery of premature infants who require intensive care. It is the policy of this program to replace the number of embryos deemed medically necessary in a given cycle which determination is based in part, but not limited to, on availability and factors such as age, cycle attempts and embryonic parameters. Any additional viable embryos may be cryopreserved (frozen) for possible replacement in a subsequent cycle. We understand that a separate consent must be completed if the embryos are to be cryopreserved.

G. **<u>Post-Transfer Management</u>**.

(The following processes and procedures and the risks associated therewith apply to the Gestational Carrier.) We understand that in conjunction with the transfer of embryos, the Gestational Carrier may be given natural progesterone by intramuscular injection, vaginal suppository, vaginal gel, or oral capsule in an attempt to increase the chances of

successful implantation. Further, natural estrogen by skin patch or oral tablet may be given. Should a pregnancy result, we understand that no harmful effects to the mother of the fetus are presently known to medical science from the use of this natural progesterone and/or estrogen supplementation. During this period, we understand that various blood hormone levels may be evaluated.

H. <u>Disposition Of Unwanted or Unsuitable Cells, Fluids, Spermatozoa, Eggs and Embryos</u>.

Blood, blood products and cells, as well as follicular and seminal fluids and cells contained therein obtained during follicular monitoring, egg or sperm retrieval, may be used for scientific observations. In the event that we have unused spermatozoa, these may be subjected to scientific observations or discarded without any further observations. Under no circumstances will these spermatozoa be used for fertilization purposes or donation to other individuals, couples, corporations or institutions. In the event that we have immature, unfertilized or abnormally fertilized eggs, these may be subjected to scientific observations or discarded without further studies. We also understand that these eggs are unwanted and considered abnormal. Embryos that arrest after one (1) to six (6) days after egg retrieval, that are partially degenerate, or for any other reasons considered unsuitable for embryo transfer or cryopreservation may be observed to determine cellular inclusions, genes, gene mutations, proteins and chromosomes. The studies use protocols that will cease the immediate growth of individual cells. We also understand that these embryos or their cells are unwanted and considered abnormal.

I. <u>Use Of Blood Products</u>.

Human serum albumin, a commercially prepared blood product for clinical laboratory use, is added to the egg collection fluid, micromanipulation, and semen preparation fluids. Careful screening is done by the manufacturers to reduce the likelihood of transmission of infectious diseases such as HIV, Hepatitis B and C. To date there have been no documented cases of disease transmission linked to human serum albumin usage at REACH. We understand and accept the remote risk that use of these blood products could result in the transmission of HIV and Hepatitis and/or other viral or possibly as yet unknown non-viral diseases.

J. <u>Use Of Chemical Substances, Disposable Items And Mechanical Devices During The Procedures</u>.

A large number of chemical substances (sugars, salts, enzymes, proteins), mechanical devices (incubator chambers, microscopes, air handling systems, filters, standard laboratory equipment) and disposable items (pipettes, Petri dishes, flasks, microtools) are used during the laboratory procedures. There may be unknown risks associated with the use of any of these items that cause the procedure to fail, even though checks and quality control measures are performed on a regular basis. Thus, there is no known association between the use of these materials and anomalies of pregnancy and fetal development.

K. **Possible Risks Associated With Procedures**.

Based on current medical knowledge, we understand there does not appear to be a higher incidence of birth defects associated with IVF procedures. However, there is not at present sufficient statistical data available to definitively conclude that this is the case. Therefore, we understand that IVF may impose risks to the fetus during development. We also understand that because more than one embryo or egg may be transferred, there may be a higher incidence of multiple births. Occasionally an embryo may split when inside the uterus, forming monozygotic twins and there may be other associated anomalies. In certain cases, fetal reduction may be considered if more embryos implant than can be medically (or personally) deemed advisable to carry through a pregnancy. We also understand that ectopic or tubal pregnancies may occur in the procedure. These associated procedures can also produce increased financial and emotional burdens.

We understand and accept that the use of ovarian fertility drugs may be associated with an increased risk of ovarian diseases in later life, including cancer. We recognize that the exact risk, if any, has yet to be established and may not be known for many years.

L. **Success Rate And Outcome**.

We understand that failure to obtain a pregnancy may result from many reasons, including the following:

(1) 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.

(2) Pelvic adhesions may prevent access to the ovary with the follicles, thus causing the procedure to obtain the egg from the ovary to fail.

(3) The egg(s) obtained may be abnormal.

(4) Normal spermatozoa may not be available.

(5) Normal fertilization of the egg(s) by the sperm may not occur.

(6) Cleavage or cell division of the embryo(s) may not occur or the embryo(s) may not develop normally.

(7) The embryo(s) may become infected in the laboratory or an unforeseen laboratory accident may result in loss or damage to the eggs, sperm, or embryo(s).

(8) The embryo(s) may become contaminated by infection in the semen or bacteria from the vagina.

(9) 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.

(10) Even if a pregnancy is established, we understand that delivery of a child may not occur due to miscarriage, ectopic pregnancy (outside the uterus), stillbirth, or other complications associated with pregnancy and delivery.

(11) There may be unknown side effects from any of the procedures used resulting in abnormal pregnancy or abnormal fetal development.

We understand that while the members of the IVF team hope that a pregnancy will result from this procedure, they cannot guarantee it. Even in normally fertile couples, the chance of pregnancy is approximately twenty-five percent (25%) in a natural menstrual cycle. If no pregnancy occurs, we may be offered participation in future cycles when assessment by the IVF team reveals no contraindications. We understand that the IVF team cannot guarantee the normality of any infant that results from this procedure.

We understand that we may at any time decide to withdraw from participation in this program without prejudice.

M. <u>Additional Risks</u>.

We acknowledge that the following are some of the additional risks and discomforts associated with the aforementioned various procedures. Some of the complications listed below may lead to injury, serious permanent disability, or death.

(1) <u>Blood Drawing</u>. We understand that blood drawing may result in mild discomfort and the possibility of developing a painful bruise or nerve injury at the needle site. A blood clot in the vein may also occur.

(2) <u>Ultrasound</u>. We understand that an ultrasound examination involves the use of a form of energy (sound waves) which at high energy levels may produce heat and tissue damage. At the extremely low energy levels utilized in diagnostic ultrasounds, no adverse effects have been observed.

(3) <u>Medications</u>. We understand the risks associated with taking hormones to stimulate multiple egg production are probably much less common than the known risks of pregnancy. Women may experience none to all of the following symptoms: nausea, vomiting, slight weight gain or loss, breast tenderness and enlargement, occasional vaginal bleeding, yeast infections of the vagina, vaginal discharge and wetness, hot flashes, night sweats, menstrual period cramping, headaches, fluid retention and mood swings. Much less common side effects include appetite changes, nervousness, fatigue and changes in sex drive. More serious, but rare, side effects include hypertension (high blood pressure), gallbladder disease, blood clots developing in the legs, lungs, eyes, brain, heart or elsewhere, heart attacks and strokes.

We understand most patients will be given an antibiotic, usually Tetracycline. The use of Tetracycline may result in nausea, vomiting, diarrhea, loss of appetite,

rashes, sensitivity to the sun, or hypersensitivity reactions resulting in shock, or blood disease including reduced platelets or fractured red cells which occur with anemia or bleeding.

We understand the precautions regarding the potential risks of treatment with ovulatory agents must include uncertain risks of ovarian disease, including cancer. Even though these issues need to be addressed, available evidence still clearly supports the use of these drugs for fertility enhancement as an acceptable standard of practice.

We understand the overall risk of ovarian cancer for most women is approximately one percent (1%) in their lifetime. According to a few studies, the risk after the use of ovarian stimulating drugs may increase the background risk of ovarian cancer slightly. Ovarian cancer appears to have an inherited pattern, so that women with a maternal history of ovarian cancer will have a significantly greater risk for the disease. If the woman who provides the eggs has ovarian cancer in her family, a female embryo resulting from this procedure would also be expected to have this increased risk. Women who have a history of ovary stimulating drugs may wish to be screened for ovarian disease as they age. There are no highly reliable methods of screening available at this time. The aforementioned findings do not prove that fertility drugs cause ovarian cancer, but they support other data which suggest an association between lifetime nulliparity (never having delivered a baby) and ovarian disease. Currently, there are no specific guidelines which are available to guide women in terms of future surveillance for ovarian cancer.

(4) Ovarian Hyperstimulation. We understand that ovarian cysts may develop, causing pain, internal bleeding, and severe disturbances of fluid and chemistry balances. Hospitalization may be required. Blood clots are possible which could lead to strokes or other life threatening complications.

(5) Aspiration of Oocytes Under Ultrasonographic Guidance. We understand that aspiration of oocytes under ultrasonographic guidance may cause pain of short duration. There is a possibility of seeing blood in the urine for a day following the procedure. In addition, perforation of blood vessels, bladder, bowel, bleeding from the ovary, and pelvic infection are also possible.

(6) Anesthesia. We understand that local anesthesia or IV sedation, if used, may cause numerous possible reactions from various drugs and procedures.

(7) Controversial Ethics. Certain aspects of the ethics of this treatment are controversial. Some members of our community, including our own family or friends may not approve of this treatment. This disapproval may damage interpersonal relationships between us and our family and/or friends.

(8) Risk to Potential Children. We understand that there are theoretical risks of the procedure which potentially could damage the embryo and result later in defects in the child. Specifically, superovulation has been indicated by one laboratory

animal study and one human study as leading to an increased incidence of genetic defects. Other large studies have not confirmed these findings.

Although the early embryo is thought to be highly resistant to environmental damage, the laboratory culture conditions may induce previously unknown problems.

There is no apparent increase of developmental defects in the published worldwide experience with humans in IVF.

(9) Transmission of Infectious and/or Inheritable Diseases. We understand that despite strict adherence to the protocol, infectious and/or inheritable diseases may be transmitted. Specifically, infectious diseases may pass from the First Partner (or the female donor) through her egg(s), and/or the Second Partner (or the male donor) through his sperm to the Gestational Carrier, or from the Gestational Carrier to the resulting fetus(es). In addition, inheritable diseases may pass from the First Partner (or the female donor) and/or the Second Partner (or the female donor) to the fetus(es).

(10) Inability to Carry Fetus(es) to Term. We understand that following a successful establishment of pregnancy, there is a possibility that the Gestational Carrier will not carry the fetus(es) to full term as a result of abortion, miscarriage, ectopic (tubal) pregnancy or stillbirth.

(11) Ectopic (tubal) Pregnancy. We understand that there is a small, but significant, risk that an ectopic (tubal) pregnancy may occur as a result of the transfer of embryos to the Gestational Carrier's uterus. Ectopic pregnancy may be treated with medicine or surgery. There is up to a twenty-five percent (25%) chance of impaired tubal function and less than a one percent (1%) risk of death associated with an ectopic (tubal) pregnancy.

(12) Gestational Carrier's Participation in Sexual Activity. The Gestational Carrier shall be counseled and instructed to abstain from sexual activity during this procedure. Sexual activity at or about the time of embryo replacement may result in the Second Partner (or the male donor) and First Partner (or the female donor) not be being the biological/genetic parents of any or all child(ren) born.

(13) Prenatal Care. Should pregnancy occur, then Gestational Carrier shall be advised as to the appropriate prenatal care. Failure to follow the medical advice and instructions given may adversely effect the Gestational Carrier's health and the health of the fetus.

(14) Unpredictability of The Gestational Carrier's Future Behavior. Although a psychological evaluation was performed, we understand that the psychological evaluation will not necessarily predict future behavior of the Gestational Carrier. The effect of participation in the gestational carrier program differs for each person. We understand that REACH cannot predict, nor guarantee, the behavior of the Gestational Carrier in the future.

(15) Unpredictability of the Resulting Child's Behavior. In addition, we understand that the psychological evaluation performed cannot, and will not, predict future behavior of the resulting child. Further, REACH cannot predict, nor guarantee the behavior of the resulting child.

(16) Unknown Complications. We understand there may be other complications which have not been listed that my occur.

The major risk of the aforementioned procedure is that the treatment may not succeed and that you will be disappointed. Should the process not succeed, you should expect to feel frustration, anxiety, and depression, all of which may be severe. If the Gestational Carrier becomes pregnant you may experience greater psychological stress than in a normal pregnancy because of the manner in which the pregnancy was achieved and the fact that the Gestational Carrier is going to carry and deliver your child.

N. Alternate Treatment Available.

At this time, other treatment options may include adoption or to wait for the possibility of additional medical options in the future.

O. Dispute Between Parents and Gestational Carrier.

We have informed REACH that we have executed an Agreement with the Gestational Carrier setting forth the rights, responsibilities, and obligations between the Gestational Carrier and us. We agree and stipulate that REACH is not a party to the underlying agreement between Gestational Carrier and us, and that REACH was not in any way involved in the drafting, nor in specifying, the terms of that agreement. We agree that the execution of the underlying agreement with the Gestational Carrier was a free and voluntary act performed without duress and without coercion from any party. Further, we agree that we (each individually and/or collectively) shall not bring any action in any jurisdiction and waive any and all actions and rights, if any, against REACH for any issue with respect to our agreement with the Gestational Carrier including, but not limited to, issues concerning prenatal care of the child, birth of the child, custody or placement of the child, or any other direct or indirect aspect of the underlying agreement. We agree and stipulate that we shall indemnify and hold REACH harmless for any and all claims and disputes that arise by and between Gestational Carrier (and her Husband, if any), or their respective representatives, agents, or assigns, and us and which are in any way related to the prenatal care of the child, birth of the child, custody or placement of the child, or any other direct or indirect aspect of that aforementioned Agreement.

P. Confidentiality.

Any information obtained during this procedure and identified with us will remain confidential and will be disclosed only with our permission. Any publication resulting

from this procedure will not identify us individually. Representatives of The Food and Drug Administration (FDA), The Center for Disease Control (CDC), The Department of Health and Environmental Control of North Carolina, and the Society of Assisted Reproduction Technologies (SART) may inspect REACH's records.

Q. **Execution of Consent**.

By signing this form below we expressly indicate and certify the following:

(1) That we have read and understand each and every provision herein;

(2) That we have been given the opportunity to review this document with any and all third parties of our choosing;

(3) That we have been given an opportunity to ask any and all questions;

(4) That for each question we have asked, we have received a satisfactory answer;

(5) That we know that we may ask additional questions at any time in the future;

(6) That we may discontinue this program at any time in the future; and

(7) That we are each over the age of twenty-one (21).

First Partner's Signature _____ Date _____

Second Partner's Signature _____ Date _____

REACH representative verifying completion of consent _____ Date _____

Witness – if signed outside of REACH _____ Date _____