MPI # _____

REPRODUCTIVE ENDOCRINE ASSOCIATES OF CHARLOTTE, P.C.

Consent Form for Assisted Hatching and Fragment Removal

INFORMED CONSENT

We, _____ and _____
(Print names as appear on driver's license)

understand that this Consent gives REPRODUCTIVE ENDOCRINE ASSOCIATES OF CHARLOTTE, P.C. ("REACH"), and the embryology team associated therewith, permission to assess our embryos microscopically and determine whether assisted hatching with or without fragment removal will be performed on any of our embryos.

A. Initial Studies and Inclusion Criteria

We understand that embryologists have performed assisted hatching and fragment removal in scientific studies involving hundreds of infertile couples and have found this micromanipulation technique to be advantageous for some of the embryos by promoting attachment to the uterus. It was found that certain patients and embryos benefited from the procedure, whereas others did not. We agree that the embryologists will study the embryos and determine the speed of their development. Based on this study, some embryos may be selected for the procedure, whereas others will be left as is. We agree that the embryologists may remove debris and/or fragments (blebs released from the embryonic cells) from underneath the zona pellucida (clear layer of membrane surrounding the egg), which may otherwise interfere with the development of the embryo. We understand that this procedure is only performed when there are many fragments present or when the appearance of the fragments suggests that they could interfere with normal growth of the embryo. We understand that there are embryonic characteristics which are used to determine whether assisted hatching can be safely applied to those embryos which have been elected for transfer. We also understand that certain aspects of the Female Partner's history, such as age, basal FSH levels, previous IVF history and prior medical history may also be used to determine whether the embryos should undergo selective assisted hatching. Further experiences in over five thousand (5,000) patients beyond those initial studies have confirmed the results of the published studies, which indicate enhanced pregnancy rates with the use of the aforementioned procedures. We understand that the magnitude of the anticipated result varies from patient to patient and will depend on our specific circumstances.

B. Description of Procedure

We understand that the actual procedure contemplated herein involves the use of the micromanipulator to pick up the embryo and another micromanipulator to deposit minute amounts of acidic solution on a small area of the zona pellucida to create an opening. The use of laser may alternatively be used to accomplish this task. We also understand that by consenting to have selected assisted hatching performed, our physicians will prescribe antibiotics for the Female Partner and corticosteroids, both beginning on the day of retrieval. These drugs are administered to protect the embryos from bacterial contamination and attack by immune cells. The IVF procedure will otherwise not deviate from the standard protocol. Embryo transfer may occur anywhere between three (3) to five (6) days after retrieval. If for any reason our embryos need to be replaced prior to day three (3), the selective assisted hatching procedure cannot be performed.

C. Potential Drawbacks and Risks

We understand that while the IVF team believes that there are clear benefits to having our embryos undergo "Selective Assisted Hatching," the procedure may also involve the following risks and/or disadvantages:

(1) There is potential for harm to occur to our embryos during the hatching process. Although damage to the embryos is exceedingly rare, single cells within the embryo may be damaged in less than one percent (1%) of cases. Information available at this time indicates that this does not appear to affect the overall developmental potential of the embryo.

(2) The exact likelihood of success for a given embryo or patient cannot be predicted. However, "selected assisted hatching" causes the implantation rate per embryo to rise. This rise in implantation rate raises the risk for multiple gestation.

(3) Although unlikely, this technique may yield unknown risks to the baby or mother. The holes in the zona may decrease its protective effect for the embryo. The higher implantation rates found in appropriately selected embryos, which undergo selective assisted hatching indicate that the net effect is likely to be beneficial.

(4) The micromanipulation itself may harm embryos or, rarely, may cause immediate degeneration of the embryos. The high experience level of our staff should minimize the possibility of harm to an embryo, nevertheless technical difficulties may make successful micromanipulation impossible.

(5) The corticosteroids given to the Female Partner is considered a small dose. Over five thousand patients have now been treated with this regimen in cycles where there was some zona manipulation. The only notable side effect has been the occurrence of vaginal yeast infection. Though none of the following effects have been reported to date in the aforementioned cases, we nevertheless understand that these drugs may: Mask signs of infection and new infections may occur during

use; Increase blood pressure, salt and water retention, and excretion of potassium and calcium; Cause mood swings, insomnia, depression, psychotic manifestations, and muscle weakness; Impair wound healing; Increase sweating, headaches, vertigo, allergic reaction, loss of muscle mass, osteoporosis and abdominal distention; Cause nausea, vomiting, diarrhea, loss of appetite, rashes, and cause increased sensitivity to the sun, hypersensitivity reactions resulting in shock, blood disease, including reduced platelets or fractured red cells which occur with anemia or bleeding.

(6) The chances of having identical twins may be increased. Identical twins carry all the risks of any multiple pregnancies, but may also have special risks. These include an increased risk for preterm labor and umbilical cord accident, and the babies may be small compared to their gestation-age. In addition, so-called conjoined twins, also known as Siamese, are abnormal identical fetuses and can occur rarely after IVF and assisted hatching. In such cases, fetal reduction may be considered. This associated procedure can produce increased financial and emotional burdens.

(7) Small a-cellular fragment material within the embryos' cells may need to be removed for the benefit of the embryos. Fragment removal may cause damage to cells in less than five percent (5%) of cases.

We understand that our decision to have selective assisted hatching may be beneficial to us as the chance of pregnancy may increase. In our particular case, however, we understand that there is no guarantee that our embryos will receive any benefits from the procedure, or even that the procedure will be performed on any of our embryos.

D. General Policies

We recognize that our decision whether or not to participate in the assisted hatching and fragment removal procedure contemplated herein will not prejudice our future relations with REACH, and the treatment we are now undergoing. If we decide to participate in the assisted hatching and fragment removal procedure, we are free to discontinue participation at any time. Our participation is voluntary and our refusal to participate will involve no penalty or loss of benefits to which we are otherwise entitled. We have been encouraged to ask questions and any questions that we have asked have been answered to our satisfaction. A member of the IVF team will answer questions in the future.

E. Execution of Consent

By signing this form below you 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 over the age of twenty-one (21).

Female Partner's Signature	Date
Male Partner's Signature	Date
REACH representative verifying completion of consent	Date
Witness – if signed outside of REACH	Date