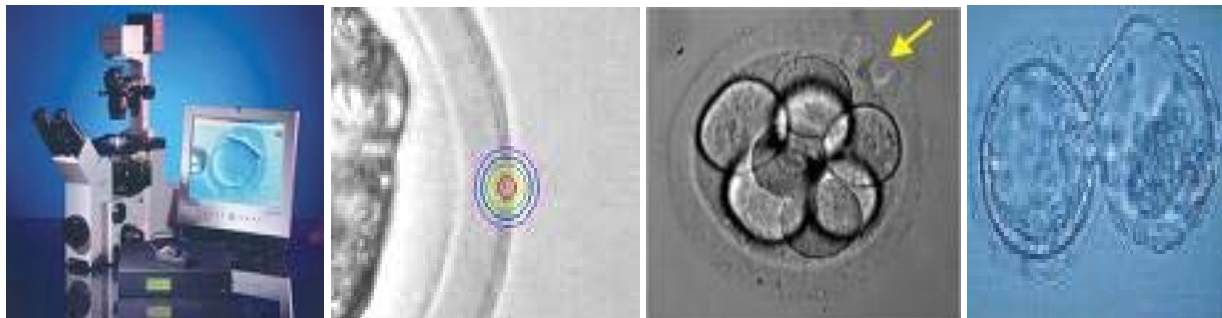


**THE FERTILITY CENTER, LLC
CONSENT FORM
ASSISTED HATCHING**

Introduction:

After fertilization, an egg begins to divide and becomes an embryo. These early cell divisions occur within the confines of the natural egg coating, the zona pellucida. After a few days, the dividing embryo outgrows its confines within the zona pellucida and must escape through the egg coating (embryo hatching). This process of hatching is critical to allow further embryo growth and then implantation in the uterus. In the IVF laboratory, it has been observed that embryos that have a thinner area in their zona pellucida prior to embryo transfer (or those that have had a small hole placed in the zona pellucida for the purpose of enhancing fertilization by sperm) had higher rates of implantation compared to embryos without the thin zona or hole in the zona. This led to the idea of Assisted Hatching.

The clinical use of Assisted Hatching is based on data showing that creating a small hole in the zona pellucida can make it easier for the embryo to hatch, and may improve implantation rates in selected situations. Assisted Hatching is performed by using a small laser under the microscope to make slight hole in the zona pellucida. Another form of Assisting Hatching is called zona thinning. This method uses the laser to thin the zona pellucida without making an actual hole.



Benefits:

A number of centers worldwide which employ Assisted Hatching have reported improvement in the rate of implantation of embryos among certain groups of patients who may be at risk for low rates of implantation. These groups include:

- 1) Older patients.
- 2) Patients with higher day 3 FSH or estradiol levels.
- 3) Patients with embryos with thickened or hardened zonae ($>15 \mu\text{m}$).
- 4) Patients who have had multiple embryo transfers without implantation.
- 5) Patients with embryos that are dividing slowly in the lab or demonstrate fragments within the embryo cells suggesting an embryo with lower likelihood of implantation.
- 6) Frozen and thawed embryo transfer cases.

Published studies report improved success rates in achieving pregnancy after embryo transfer in these groups with Assisted Hatching. However, using Assisted Hatching provides no guarantee of implantation, normal or otherwise and no guarantee of pregnancy.

Risks:

Assisted Hatching overrides some of the steps that are usually required for the embryo to escape the zona pellucid. This bypass may pose potential risks.

- I. The microscopic techniques themselves may injure the embryo.
- II. At this early stage of development in vivo, the zona may serve as a protective barrier against microorganisms, viruses and immune cells that theoretically could gain access to the embryo through the gap in the zona.
- III. Individual cells (blastomeres) may escape through the opening if they separate from the rest of the embryo. Alternately, some of the cells may be trapped within the zona as a result of incomplete escape through the small opening.
- IV. There is a risk of monozygotic twinning (identical twins).

Currently, experience with Assisted Hatching has shown a slight (<10%) increase in twinning.

Acknowledgements:

I _____ and _____
(Female Partner) (Male Partner)

Herein acknowledge that we have read this document on Assisted Hatching in detail. We acknowledge our desire to proceed with in vitro fertilization and Assisted Hatching and herein also acknowledge our understanding of:

1. The processes involved with Assisted Hatching
2. Its indications and why Assisted Hatching is being considered as part of our clinical care
3. The potential benefits and risks of Assisted Hatching (including the inability to currently assess the short term and long term risks of Assisted Hatching and that the risks beyond those risks discussed in this document may exist.)
4. Having had the opportunity to ask questions and have those questions adequately answered with available information.

With these acknowledgements, we wish The Fertility Center, LLC to proceed with Assisted Hatching as part of our in vitro fertilization process as they may deem clinically appropriate. We have read the document in detail and fully understand its contents. We have discussed this procedure with the IVF team members and all of our questions regarding this procedure have been answered to our satisfaction.

(Female Partner)

(Date)

(Male Partner)

(Date)

(Witness)

(Date)

Revised 2/18/2009