

**MASSACHUSETTS GENERAL HOSPITAL
VINCENT REPRODUCTIVE MEDICINE AND IVF**

INFORMED CONSENT FOR ASSISTED HATCHING

INTRODUCTION

The zona pellucida is a non-cellular layer of glycoprotein which forms a shell surrounding the embryo. In order to establish a successful pregnancy, a developing embryo must be able to break out of this shell (or "hatch") and attach to the lining of the uterus, where it can continue to grow. Assisted hatching is a laboratory procedure that is performed on the zona pellucida to assist the embryo to break out of its shell and attach to the uterine lining. Patients that may be best served by assisted hatching include older women, couples who have failed several cycles of IVF, patients with an elevated FSH level and couples whose embryos have a thick shell when evaluated under the microscope.

THE ASSISTED HATCHING PROCESS

During the process of assisted hatching, the embryo is inspected under the microscope and, with the aid of a microscope and fine instruments, an enzyme or acid solution is used to breach the zona pellucida in one area. Assisted hatching is performed on the day of the embryo transfer which, apart from the hatching procedure itself (and the addition of certain medications as described below) is undertaken in the manner described in the Informed Consent for In Vitro Fertilization.

RISK FACTORS AND TREATMENT OUTCOMES

We understand that assisted hatching involves a number of rare and/or theoretical risks and potential disadvantages, including:

1. During the assisted hatching procedure, the embryos may be destroyed or injured precluding their ability to implant.
2. This procedure may decrease the protective effect of the zona pellucida that surrounds the embryo and may result in bacterial contamination and infection to the embryo.
3. Assisted hatching may increase the chance of identical twinning whereby one embryo splits and leads to a set of twins.
4. The procedure may yield presently unknown risks to the baby and/or mother.

5. Assisted hatching may not improve your chances of establishing a pregnancy.
6. The use of antibiotics such as doxycycline may improve implantation of embryos. The use of antibiotics could result in side effects such as nausea, vomiting, diarrhea, loss of appetite, rashes, sensitivity to the sun, and rare hypersensitivity reactions which could cause shock, and/or blood diseases, including reduced platelets or fractured blood cells which could result in anemia and/or bleeding.
7. The patient must take a four-day regimen of methylprednisolone (a steroid). The use of steroids may improve implantation of micro-manipulated embryos. Methylprednisolone is a commonly known medication considered safe when properly used. Many people treated with this protocol have reported no adverse reactions. And we understand that the use of methylprednisolone could cause the following side effects, although they are more common when the drug is administered for a longer duration or at higher doses: mood swings, insomnia, depression, psychotic manifestations, muscle weakness, permanent hip damage requiring replacement, impaired wound healing, increased sweating, headaches, vertigo, allergic reaction, loss of muscle mass, osteoporosis, and abdominal distention. Other side effects of methylprednisolone may also mask signs of infection, make one susceptible to a new infection, and make it difficult to localize the source of an infection.

Although we have chosen to participate in the Assisted Hatching process because it may increase the chances of a successful pregnancy, we understand that assisted hatching may not improve the chances of establishing a pregnancy.

CONSENT

This consent will function as an addendum to the consent form entitled Informed Consent for In Vitro Fertilization which we executed previously. We, the undersigned, have read this document, understand the purposes, risks, and benefits of this procedure and have been given the opportunity to ask questions about it, which have been answered to our satisfaction. We consent to having our embryos treated with assisted hatching.

Female

Male/Partner

Print Name

Print Name

Date of Birth

Date of Birth

Date

Date