

Hudson Valley Fertility  
Informed Consent for IUI/ICI procedure

Female Name: \_\_\_\_\_

Partner Name: \_\_\_\_\_

We (I), the undersigned, request, authorize and consent to the performance of the procedure of artificial insemination, including either intrauterine or cervical insemination, by Hudson Valley Fertility, Dr Daniel Levine, and as appropriate, his employees, contractors, consultants and authorized agents.

Treatment with artificial insemination, including either intrauterine insemination (IUI) or, in some cases, intracervical insemination (ICI) may help a couple (or woman) achieve a pregnancy. The treatment involves three main steps: 1) obtaining a semen sample; 2) for IUI, preparation of the semen sample to isolate motile sperm; and 3) depositing the isolated motile sperm into the woman's uterine cavity or cervix around the time of ovulation.

IUI and ICI treatments involve several steps as outlined below. We (I) acknowledge and agree that we (I) cannot be guaranteed success at any or all of these steps and that if optimal results are not achieved at any step, it may be recommended that the treatment is stopped and the cycle canceled.

- A. **Follicular Development:** During a woman's menstrual cycle, usually one mature follicle develops within the ovary, resulting in the ovulation of a single egg. The growth of the ovarian follicle during the first half of a woman's cycle is influenced by several hormones, including follicle stimulating hormone (FSH) and luteinizing hormone (LH) which are produced in the pituitary gland at the base of the brain. FSH is the main hormone that stimulates the growth of the follicle, which produces an estrogen hormone called estradiol. When the follicle is mature, a large amount of LH is released by the pituitary gland. This "LH surge" helps to mature the egg and leads to ovulation 36-40 hours after the initiation of the surge. The insemination is performed the day prior to ovulation, the day of ovulation, or soon after ovulation. This process may be monitored using home or office testing of the woman's blood or urine or through the use of ultrasound or other methods determined by our (my) physician. We (I) acknowledge that in some cases this treatment may involve the use of superovulation therapy and that if this treatment is used that a separate consent form will be executed.
- B. **Preparation of the semen sample:** On the day of the insemination, the male partner provides a semen sample. This sample may be brought to the office, collected on site or may have been in storage in a frozen state and thawed for use in this treatment cycle. We (I) understand and agree that a picture ID is required for the patient or partner who brings the sample to the office or produces the sample on site. If donor samples are used they will be thawed on the day of insemination. The semen sample is then processed in the laboratory in preparation for the insemination process. This preparation may involve removal of seminal plasma (the liquid portion of the semen) and poorly motile sperm, concentration of the motile sperm or other evaluation of the sample. We (I) acknowledge that in some cases this treatment may involve the use of donor sperm and that if this treatment is used that a separate consent form will be executed.
- C. **Artificial Insemination--Intrauterine insemination (IUI) or Intracervical Insemination (ICI):** The woman will return to the office at the specified time, after the semen sample is dropped off. To perform the IUI, the woman is placed in the same position as if she were having a pelvic exam. A speculum is placed in the vagina to visualize the cervix. The sperm are loaded into a catheter, which is inserted through the cervical canal and into the uterine cavity. In cases where intracervical insemination is performed (ICI), the sample is placed in the cervix. The woman will lie down for a short time before leaving. Following the insemination normal activity can be resumed.
- D. **Treatment outcomes:** The success rate (the delivery of a live born infant) of IUI/ICI varies and depends on many factors. Some of the factors are: the age of the woman, the type of fertility medication used (if any); the diagnosis, the number of previous cycles of treatment and the quality of the semen sample. We (I) have discussed the success rates that my doctor. We (I) acknowledge and agree that the use of IUI versus ICI depends on individual circumstances that may only become apparent on the day of insemination and that that decision will be made by medical staff in consultation with us (me).
- E. **Risks**
1. **Miscarriage:** The risk of miscarriage in the general population is approximately 10-20%, but varies with age. Studies have not shown a significant increase in the risk of miscarriage in women who conceive with IUI or ICI treatment. Most miscarriages are associated with lower abdominal cramping and bleeding, but do not necessarily require treatment. In some cases, however, complete removal of the pregnancy tissue must be accomplished by a surgical procedure. This procedure is usually performed under anesthesia in the operating room.

2. Tubal (ectopic) pregnancy: An ectopic pregnancy may result following this treatment. The majority of ectopic pregnancies are present in the fallopian tube. The chance of a tubal pregnancy is greater in women with damaged tubes. If a woman has a tubal pregnancy, she may need surgical treatment, on occasion, which may involve the removal of the involved tube. Medical treatment with Methotrexate may be an option in selected cases.
3. Infection with an IUI/ICI is rare, but possible. Symptoms of an infection may include but are not limited to persistent abdominal pain beginning within several days of insemination, fever and/or a vaginal discharge. This complication may be associated with, or cause, tubal disease and scarring. Antibiotic treatment may be required.
4. Other risks: Genetic abnormalities, structural abnormalities, mental retardation and other abnormalities may occur following this treatment or pregnancies conceived naturally. The rate of congenital abnormalities (birth defects) in the general population is 2-3% and is not different in babies conceived with IUI treatment. Most infants who have been born following IUI/ICI treatment are normal.

F. Many factors may prevent this treatment from being successful. Some factors are known and some are unknown. Examples of the known factors include but are not limited to, the following:

1. An ovarian follicle may not develop.
2. The male partner may be unable to produce a semen sample.
3. The passage of the catheter into the uterus or cervix may be technically difficult or impossible.
4. Even if the insemination is successfully performed, pregnancy may not result.
5. If a pregnancy is established, it may not develop normally or may miscarry.
6. Equipment failure, infection, technical problems, human errors and/or other unforeseen factors may result

in injury to the patient or to loss or damage of the semen sample

- G. We (I) acknowledge that we (I) the undersigned, are voluntarily participating, individually and as a couple, in Hudson Valley Fertility's artificial insemination program (intrauterine insemination (IUI) and intracervical insemination (ICI) in order to conceive a child through this treatment.
- H. We (I) understand and consent that if the individual providing the sperm sample for this procedure is not the sexually intimate partner of the recipient, that we (I) have executed appropriate consents (for use of anonymous or identified sperm donors) and all involved parties will undergo all relevant federally mandated testing, screening and quarantine.
- I. We (I) understand and consent that semen samples provided for this treatment are provided for the purpose of achieving a pregnancy. We (I) agree and consent that the samples provided for this purpose are provided by the individual who has signed this consent where partner sperm is used. We (I) agree and consent that the individual providing the semen sample (for partner sperm), and who has signed this consent (for partner or donor sperm)
- J. We (I) understand, agree and acknowledge that we (I) are (am) not married to individuals who are not parties to this informed consent.
- K. We (I) understand that should this cycle be unsuccessful, it may be determined that further treatment with IUI/ICI may not be indicated.
- L. We (I) also understand that we are financially responsible for any medical expenses that are not covered by our insurance policy.
- M. We (I) expect this procedure to be performed with not less than the customary standard of care. We (I) understand the risks and benefits as outlined, and further understand and agree that
- N. Dr Levine shall be responsible only for acts of negligence on his part and the part of his employees, contractors, and consultants.
- O. We (I) have had the opportunity to review with and ask questions of our physician concerning alternative options to Intrauterine Insemination, including adoption and no treatment in an effort to help us (me) overcome our (my) infertility.
- P. The nature of Artificial Insemination (including intrauterine insemination (IUI) and/or intracervical insemination (ICI)) has been explained to us (me), together with the known risks. We (I) understand the explanation that has been given to us (me). We (I) have had the opportunity to ask any questions we (I) might have and those questions have been answered to our (my) satisfaction. Any further questions we (I) might have may be addressed to The Hudson Valley Fertility staff. We (I) acknowledge that Artificial Insemination (including intrauterine insemination (IUI) and/or intracervical insemination (ICI)) is being performed at our (my) request and with our (my) consent.

Note: Each signature Must be witnessed separately

\_\_\_\_\_/\_\_\_\_\_/\_\_\_\_\_  
Date

\_\_\_\_\_  
Female Signature

\_\_\_\_\_  
Witnessed By

\_\_\_\_\_/\_\_\_\_\_/\_\_\_\_\_  
Date

\_\_\_\_\_  
Partner Signature \*If no partner write N/A

\_\_\_\_\_  
Witnessed By

\_\_\_\_\_/\_\_\_\_\_/\_\_\_\_\_  
Date

\_\_\_\_\_  
Physician Signature

\_\_\_\_\_  
Witnessed By