

This 16-page **Informed Consent Form** is used by **Synphaet Hospital SMART Center** for all female infertility and male infertility couples seeking treatment. Page 5 has been edited to include 5-Color Preimplantation Genetic Diagnosis (PGD) which is conspicuously missing from their standard document. The six sections, which each require signatures, are:

1. Consent for Assisted Reproductive Technology Treatment (IVF)
2. Consent for Embryo Cryopreservation (Embryo Freezing)
3. Consent for Microassisted Fertilization (ICSI Treatment)
4. Consent for Microassisted Hatching (Laser Assisted Hatching)
5. Consent for Use of Donor Oocyte/Embryo (Donor Egg used)
6. Consent for Use of Donor Sperm (Sperm Donor used)

This is **Section One**. We provide each section separately but the actual document is a single 16-page document.



The Royal Thai College of Obstetricians and Gynecologists

Consent Form for Assisted Reproductive Technology Treatment

Article No. 1/1997 by the Thai Medical Council, regarding the standard of care for assisted reproductive technology treatment, requires an institute to provide a consent form and relevant information to both client and spouse.

The signed informed consent will be provided in two copies. One copy is retained by the infertile couple, who wish to receive assisted reproduction technology treatment. The other copy is kept at the treatment center as a part of the medical record.

Patient's Name:

Spouse's Name:

Hospital: Synphaet Hospital SMART Center

Hospital Number:

Date:

Doctor (s): Dr Napadon Yaibuates, MD

.....

.....

.....

Consent for Assisted Reproductive Technology Treatment

Explanation

There are several causes of infertility. Some are common among women, such as damaged fallopian tubes (which prevents the establishment of a normal pregnancy), endometriosis (abnormal growth of the uterine lining), abnormality of the uterus and fallopian tubes, pelvic adhesion and immune reaction to sperm; while others are found in men, such as very low sperm count, inability to have vaginal ejaculation, abnormal position of the urethra, and retrograde ejaculation. For some couples, the causes of infertility may remain unknown even after a complete workup for their infertility.

Treatment Procedure

To treat your infertility, the attending physician will systematically perform one or more of the following procedures:

1. Diagnose the cause of your infertility through a standard procedure and determine your suitability for assisted reproductive technology treatment.
2. Monitor hormone levels in the blood and administer suitable drug(s) to induce ovulation.
3. Predict the expected time of ovulation in order to schedule oocyte (egg) retrieval under transvaginal ultrasound guidance.
4. Retrieve oocyte(s) under the guidance of transvaginal ultrasound or laparoscopic visualization.
5. A semen sample provided by the husband is collected and processed in the laboratory.
6. The retrieved oocyte(s) will be inseminated with the husband's processed sperm in the laboratory and left in an incubator for fertilization. In gamete intrafallopian transfer (GIFT), the gametes (oocytes and sperm) will be transferred into the uterine tube(s).
7. The fertilized embryos will be cultured in the laboratory until they reach a stage that is suitable for transfer into the uterus.
8. Transfer of the embryo(s) into the uterus and cryopreserve the remaining viable embryo(s)

Success Rate

We realize that a considerable amount of time is required to perform the aforementioned procedures. We also understand that a pregnancy may not be established even after all standard medical principles and protocols have been strictly followed. Many factors influence the success of assisted reproductive treatment, such as:

1. Oocyte (egg) retrieval schedule may be inaccurate or oocyte(s) may not be mature as anticipated.
2. No oocyte(s) can be retrieved due to technical failures.
3. Retrieved oocyte(s) may be abnormal.
4. Male partner may not be able to produce a semen sample on demand.
5. Fertilization may not take place as planned.
6. Abnormal fertilization may occur and abnormal embryo(s) may be produced. In such cases, the resulting embryo(s) will not be transferred in the uterus.
7. The transferred embryos(s) may fail to implant into the lining of the uterus or they may cease development. This is the most common cause of *in vitro fertilization* (IVF) failure.

After a pregnancy is established, complications such as a miscarriage, tubal (ectopic) pregnancy, stillbirth, and congenital abnormality (birth defects) may develop at the same rate as would have been found in a natural pregnancy. Up to now, there have been over one million births worldwide through assisted reproductive technology. Available data indicates that these children have the same risk of birth defects as children conceived naturally. However, they may have a little higher risk of certain pregnancy complications, such as premature delivery and lower birth weight, than children of natural conception.

Multiple pregnancy is undesirable as it increases the risk of morbidity and mortality in both the mothers and the children than it would have been with a singleton pregnancy. With assisted reproductive technology treatment, it is sometimes necessary to transfer more than one (but no more than three) embryo in order to increase the chance of pregnancy at the cost of an increased risk of multiple pregnancy.

Data from the Royal Thai College of Obstetricians and Gynecologists reveal that in 2007, the average success rate of in vitro fertilization in Thailand was around 32.2% per embryo transfer, or 27.2% per oocyte retrieval cycle or 24.3% per initiated cycle.

Risks

In requesting assisted reproductive technology service, we have been informed and understand that there are possible, though minimal, risks and complications involved in all stages of the treatment. For example:

1. Pain, a bruise or a lump may develop at the needle site of blood drawing, but the symptoms will disappear within a few days.
2. Apart from mild discomfort, there is no evidence to suggest that ultrasound monitoring of oocyte development is harmful.
3. Some patients may be oversensitive to hormones used for ovulation induction. They may react by developing a large number of follicles. About 5% of these patients may develop a condition called ovarian hyperstimulation syndrome (OHSS), while only 1% may require hospitalization.
4. Case-controlled studies indicate that women with fertility problems tend to have 1.6 times higher risk of ovarian cancer rate than the general population. Available data reveal that ovarian cancer rate among patients undergoing ovulation induction is not higher than it would have been in infertile patients who do not received ovulation induction. However, more information from a long-term cohort study is still needed.
5. The use of laparoscopic technique to retrieve the oocyte(s) or to perform Gamete Intrafallopian Transfer (GIFT) may result in complications, such as abdominal bleeding, pelvic infection, pelvic adhesion, abdominal scar, and other surgery-related complications.
6. Oocyte retrieval under ultrasound guidance may cause infection of the bladder, ovary, uterus, and fallopian tubes. In very rare circumstances, aspiration needle may cause an injury to the intestine or blood vessel that requires an emergency operation.
7. There are possible complications from the anesthetics or sedation used during oocyte retrieval.

8. Embryo transfer may cause mild cramping discomfort or even infection of the female genital tracts in rare cases.
9. The use of hormone(s) to support pregnancy has not been found to cause any birth defect.
10. Risk of multiple pregnancies.

Consent Form

The physician has explained to us all the procedures and steps involved in assisted reproductive technology treatment. We understand the indications of the following procedures:

- In vitro fertilization (IVF)
- Intracytoplasmic Sperm Injection (ICSI)
- 5-Color Preimplantation Genetic Diagnosis (PGD)

In reading the explanations or having them read to us, we had an opportunity to ask questions and these questions have been answered to our satisfaction. By signing this document, we consent to the treatment of infertility by assisted reproductive technology. We realize that we have the right to withdraw from this treatment at any time, without jeopardizing our future medical care.

We have been assured that all our personal data obtained during the course of this assisted reproductive technology treatment will be confidential and will not be disclosed without our consent, unless required by law.

We, both husband and wife, wish to receive assisted reproductive technology treatment for infertility through the following procedure(s):

- In vitro fertilization (IVF)
- Intracytoplasmic Sperm Injection (ICSI)
- Preimplantation Genetic Diagnosis (PGD)

under the care of Dr Napadon Yaibuates MD and his/her staff.

In the event that the retrieved oocyte(s) fail to fertilize or fertilized abnormally, we consent to their utilization for research purposes or elimination according to guidelines and regulations of the Medical Council of Thailand.

In the event of problems or complications detrimental to our health, which are not due to acts of negligence on the part of the gynecologist, following assisted reproductive treatment under the established standard protocol, we, both husband and wife, will not claim any damages.

We, both husband and wife, fully understand and acknowledge that children born as a result of an assisted reproductive technology treatment may develop abnormalities at a similar rate as children born as a result of a natural reproductive process.

Signature
(.....) The Wife

Signature
(.....) The Husband

Signature
(.....) Witness

Signature
(Dr Napadon Yaibuates, MD)

Attending physician and provider of explanations

Date Month..... Year.....