

PATIENT INFORMED CONSENT
completed by
Österreichischen Gesellschaft für Reproduktionsmedizin und Endokrinologie
and the
Österreichischen IVF-Gesellschaft

Dear Couple,

<u>Female (patient):</u>	<u>Husband/partner/legal partner (patient):</u>
Family name:	Family name:
Maiden name:	Maiden name:
First name:	First name:
Date of birth/- town of birth:	Date of birth/ -town of birth:
Social security number:	Social security number:
Nationality:	Nationality:
Street:	Street:
Postcode/town:	Postcode /town:
State:	State:
Telephone/Fax:	Telephone/Fax:
Mobile phone:	Mobile phone:
Email-Address:	Email-Address:

Before initiating treatment, your doctor will inform you about the treatment options, the interventions planned and he or she may also perform some preparatory examinations.

Each patient receives an individualized IVF treatment plan according to her particular situation and needs. For this reason, it is necessary for our team to take the time to analyse your problems and compile an optimal therapy plan according to your needs.

We ask you to thoroughly review the **informational brochure „Infertility: The unfulfilled desire for pregnancy for a child“**. Before you will sign the contract and informed consent for treatment, you will receive additional Information regarding the potential side effects and risks of IVF. You are welcome to ask your treating doctor(s) whatever questions you may have.

I. MEDICAL INFORMATION ABOUT IVF TREATMENT

1. When does IVF make sense? What are the reasons for undergoing IVF?

The In-vitro Fertilisation (“test tube baby”) was initially used for women with tubal factor infertility but has with time shown to be a highly successful treatment for couple with many different etiologies of infertility, both primary and secondary, as well as those with unexplained infertility. Although the procedure is safe and generally well tolerated, it is nonetheless entirely free from risks and may lead to physical and psychological stress. Moments of stress can be perceived quite differently. IVF, in any case, should only be attempted, after all other treatment options (e.g. pharmaceuticals, small surgical interventions or insemination) have first been excluded or already been performed. Some common indication for IVF include:

Female:

- **Tubal factor Infertility:** Both fallopian tubes are blocked or have had to be removed.
- **Endometriosis:** An often painful, chronic disease in women defined by endometrial tissue found outside the uterus, e.g. on the fallopian tubes, ovaries, bowel or bladder, and peritoneum.
- **PCOS – Polycystic Ovary Syndrome: A condition marked by lack of ovulation,** Multiple small cysts in the ovaries and often signs of elevated androgen (male) hormones in women.

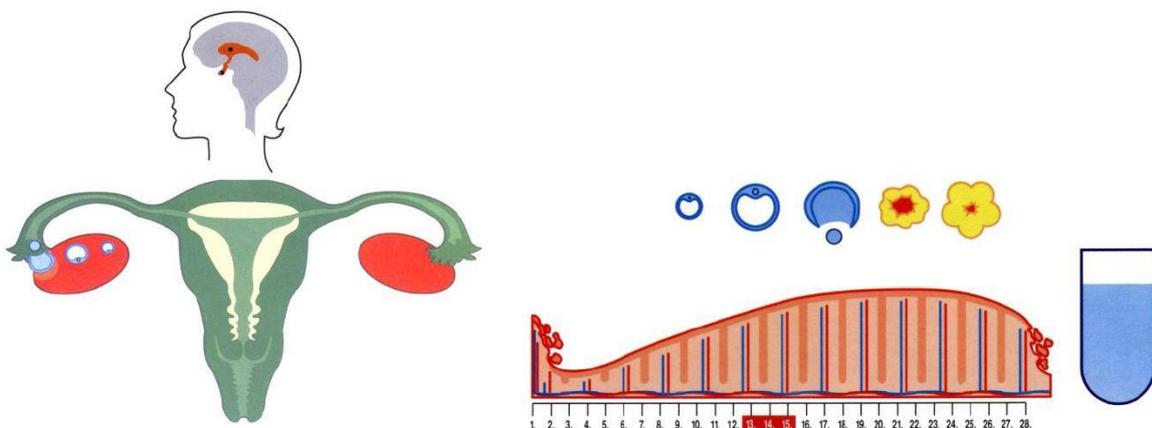
Male:

- The fertility of the male partner can be significantly reduced when the concentration, the number or the appearance of normal spermatozoa is reduced (**male Subfertility**); in this case ICSI or the the injection of a single sperm into a single oocyte using micro-manipulation may increase the chances of fertilization
- **Immunological Sterility:** Antibodies against oocytes or sperm cells were found.

Male and Female:

Idiopathic Sterility: When, even after extensive examinations, no reason for the absence of pregnancy can be found, the condition is called idiopathic or unexplained infertility.

2. Description of In vitro Fertilisation:



In Vitro fertilization involves the fertilization of the egg or oocyte obtained from the female partner with the sperm obtained from the male in the laboratory or outside the body. The sperm may be left to fertilize the egg in the dish or a micro injection of a sperm cell into the oocyte (Intra Cytoplasmic

Sperm Injection) may be undertaken, especially in cases of very poor sperm quantity or quality or limited egg number. This procedure gives very good results. Prior to harvesting the eggs, hormonal stimulation of the female partner must be carried out in order to maximize the number of eggs. The pick up of the mature oocytes is done by ultrasound guided vaginal puncture of the follicles seen in the ovary. Thereafter comes the fertilisation of the oocytes with the husband's/partner's sperm cells outside the female patient's body (in vitro). After several days of culture during which the embryos (fertilised oocytes) grow and divide, a predetermined number of embryos will be transferred back into the uterus. In this manner, a pregnancy can result without the need to transport oocytes through the fallopian tubes.

In order for us to take the best care of you, we ask that you to bring to the first appointment all existing information about previous surgeries, hormone analyses, ovulation tests and/or basal body temperature curves, sperm analysis of your husband/partner for to discuss your and optimize your further diagnosis and therapy.

The treatment consists of the following steps (listed as examples only, because **every** treatment is planned individually):

- First appointment for consultation and examination after arrangement via telephone.
- Discussion of details of therapy and therapy schedule
- Prescription of stimulation medication

3. Treatment schedule:

- 3.1 The stimulation will be done with various combinations of hormonal treatment with or without pretreatment called ultrashort-, short- long-protocol or antagonist-protocol. Your doctor will precisely explain the very protocol chosen for you. He or she will precisely demonstrate how you will have to take your medication and give you the protocol together with a detailed instruction for follow-up visits
- 3.2 Ultrasound examinations will be done regularly, beginning approximately on Day 6 of treatment and continuing until day 10-14. We will let you know about the exact dates and times of these appointments. The final oocyte maturation will be induced once specific criteria are met, for example several follicles have reached a size of 18mm and other laboratory parameters suggest sufficient oocyte maturation. The final oocyte maturation is accomplished by an i.m. (intra muscular) or s.c. (subcutan) injection (hCG - **Pregnyl, Ovitrelle, Pregnesin, Profasi, Choragon, oder Decapeptyl**) which will be administered in the evening. 34 -36 hours prior to the ovum pick up.
- 3.3 The puncture of the follicle for oocyte pick-up is done transvaginally using ultrasound guidance under sedation (mild anesthesia) with a combination of an anesthetic agent and a sedation drug. In some cases, a short general anesthesia is necessary or desired. You must not eat or drink within the last 6 hours before the procedure.
- 3.4 On the day of the ovum pick up it is necessary that your partner come to the institute at a predetermined time to provide his sperm (by masturbation). In case he would bring the sperm sample from home, he has to provide a signed declaration that it originates from him. In select cases, sperm is retrieved directly from the testes [Testicular Sperm Extraction (TESE)] or from the epididymis [Microsurgical Epididymidal Sperm Aspiration (MESA)]. In those cases, you will be given instructions about the precise day and time of the procedure (usually performed by a urologist).

In most cases, oocytes will be fertilized on the same day they are retrieved either via in-vitro fertilization or intracytoplasmic sperm injection (ICSI), the latter performed always after TESE or MESA.

- 3.5 If the fertilization of the oocytes has been successful, then the resulting embryo(s) will be cultivated in the laboratory for the subsequent 2-6 days until the transfer of ONE Embryo into the uterus (also called embryo transfer or blastocyst transfer). Only in exceptional cases (older age of the female partner, previous unsuccessful IVF attempts, poor embryo quality, etc.) can a total of one or two embryos be transferred. In all cases, both partners of the couple need to sign an informed consent

that that they are aware and accept the potential risk of multiple gestation. (See the Home Page of the Austrian Society for Endocrinology and Reproductive Medicine and the Home Page of the Austrian IVF-Society).

- 3.6 Problems during the treatment period: If unexpected problems such as heavy cramping, vaginal bleeding, or pain arise during your treatment, we advise you to get in touch with our institute and ask for professional help. In case of emergency (please only then!) you can contact us via the following phone numbers or seek immediate medical attention at a emergency room:

EMERGENCY TELEPHONE NUMBER:.....

4. Risks and side effects of IVF treatment

4.1 Could side effects result from an IVF treatment?

- The treatment with **hormonal tablets** (Antiestrogen such as Clomiphene) may sometimes result in uncomfortable yet transient and relatively harmless side effects such as hot flushes, headache, visual field defects, bloating, pain in the lower abdomen or ovarian cysts. Nevertheless hyperstimulation and multiple pregnancies may occur in a few cases.
- During the treatment with hormonal injections – depending on dosage and disposition – a transitory enlargement of the ovaries is expected from the multi-follicular growth. Rarely, the Ovarian Hyperstimulation Syndrome may occur, with varying degrees of severity. This can lead to mild to moderate abdominal pain. Rarely, and mostly in more severe cases, free fluid or ascites may accumulate in the abdomen and lungs, leading to shortness of breath and nausea. In connection with this condition, liquid may leak from the blood vessel, aggregate in the abdomen, lungs and peripheral tissues and result in leg and arm oedema. The risk of developing a blood clot is increased, as is the risk of an embolic event (blood vessel blocking by clot)
- Usually these side effects (**OHSS = Ovarian Hyper Stimulation Syndrome**) can be well managed with appropriate medical care. In rare cases a stay in hospital will be needed. In extremely rare cases life threatening conditions and even death may result.

4.2 Which problems may arise during oocyte pick up?

Usually oocyte pick up will be a short procedure without complications. In some cases, problems may arise, despite the utmost of care. Potential risks include:

- Injury of inner organs (e.g. bowels, blood vessels, nerves, bladder) The risk of needle injuries during the ultrasound guided ovarian puncture is increased in unfavourable anatomical conditions, especially in cases of previous surgery with subsequent development of adhesions.
- Heavy bleeding: Potential injury to vessels may cause moderate to heavy bleeding which is usually detected and treated immediately. Blood transfusions are nearly never required
- Light bleeding and haematoma formation: usually there is no treatment needed
- Perfusion problems: This extremely rare complication may result from occlusion of blood vessels, leading to tissue or organ necrosis can happen by occlusion of blood vessels and may lead to tissue necrosis (e.g. skin) or organs (e.g. bowels). This only happens very rarely;
- Infections: An intraabdominal infection of the ovary, tube or uterus may rarely occur as a complication of egg retrieval. Usually this mild infections can be successfully treated with antibiotics. Very rarely, an abscess may develop that requires drainage or surgical removal. In isolated cases of severe infection, the removal of the uterus and ovaries has been reported. Such severe infections are extremely rare.
- Therapy failure: In some rare cases no oocytes suitable for fertilisation can be retrieved, or no fertilization occurs, resulting in cancellation of the planned embryo transfer

4.3 Special problems during embryo transfer (embryo- or blastocyst-transfer)?

Usually the transfer of embryos or blastocysts into the uterus is not problematic. Nonetheless, complications may rarely occur:

- Uterine infection following transfer
- Very rarely severe cramping or abdominal pain may occur during embryo transfer.
- There may be difficulty placing the embryos in the uterus, especially in cases of previous cervical surgery or infection
- The embryo transfer does not always result in implantation (pregnancy) and implantation in the fallopian tube or ectopic pregnancy cannot be totally excluded.

4.4 Success rate:

On average a clinical pregnancy rate (positive heartbeat) of 29% - 34% per cycle. is expected. (source IVF Fonds data) Regarding your individual case a success rate of around.....% can be expected in our institute.

4.5 IVF/ICSI and risks of multiple pregnancy?

With the transfer of two and three embryos the probability that a multiple pregnancy will occur, increases. All multiple pregnancies (twins, triplets, rarely even quadruplets) are high risk pregnancies that should be avoided if possible. There is a significant increase in miscarriage rates and premature birth rates in multiple pregnancies. Also, several development disorders are at an increased risk in children resulting from multiple pregnancies, e.g, mental retardation (development deficiencies, retardation of physical and/or mental development). According to the Austrian IVF Register 2018 the rate of twin pregnancies is approximately 7,7 %, 0,1% for triplets, and only a single case of quadruplets. In comparison with the German Register DIR the 2016 figures for twins were 21% and 0,6% for triplets. There were 2 quadruplets in 2016. In comparison with previous years the multiple pregnancy rate is continuously falling. The miscarriage rates for multiple pregnancies are between 18,9 and 20,3%.

In rare cases (<1%) the transfer of two embryos can lead to higher grade multiples (triplets very rarely also quadruplets) by formation of identical, monozygotic twins. This is a high risk situation because these cases are associated with premature birth, possible deficiencies and increased mortality in these children.

It is always possible that during the follicle puncture not all oocytes can be retrieved and some ovulate spontaneously. Therefore, to avoid a concomitant spontaneous conception (and multiple-pregnancy), we strongly advise patients to use non-hormonal for contraception (condom) during intercourse from the start of the stimulation until at least 3 days after the oocyte pick up.

Regarding the risk of congenital malformations: there is no clear consensus from the available research whether there is a higher risk of malformations following assisted reproductive techniques. The data appears reassuring, however, that children born following in vitro fertilization do not have a higher risk of malformations. For pregnancies following ICSI, there is some evidence that the rate of malformation is slightly higher compared to natural conceptions. A likely explanation for this is the poorer sperm quality of men requiring ICSI, as this slightly higher malformation rate has also been reported following intrauterine insemination.

The birth of a healthy child can certainly never be guaranteed.

II. Questionnaire for patients with infertility.

Please, answer the following questions carefully, so that we will be able to assess the feasibility of an IVF treatment and discuss your individual case with you and also minimize potential risks. Please mark what is applicable. If need be, we will help you to complete the form.

1. How long was the interval between you monthly bleeds (periods) without taking medication? Between _____ and _____ days. <u>1.a. How many days did you bleed on average?</u> _____ days <u>1.b. Amount of bleeding?</u> <input type="radio"/> heavy <input type="radio"/> medium <input type="radio"/> light <input type="radio"/> MODERATE			
2. Hight: _____ Weight: _____			
3. Do you smoke? If yes, how many cigarettes /cigars per week? _____		<input type="radio"/> yes	<input type="radio"/> no
4. Do you drink alcohol? If yes, how many alcohol drinks do you consume per week? _____		<input type="radio"/> yes	<input type="radio"/> no
5. First day of your last menstrual bleeding? _____ If you do not know this exactly please, state month or year.			
6. Have you ever been pregnant? a) Births: 1. (year) _____ 2. (year) _____ 3. (year) _____ . b) Miscarriages: 1. (year) _____ in which month? _____ . 2. (year) _____ in which month? _____ . 3. (year) _____ in which month? _____ . c) Terminations of Pregnancy (elective abortions): 1. (year) _____ 2.(year) _____ 3. (year) _____ .		<input type="radio"/> yes	<input type="radio"/> no
7. Have you ever undergone abdominal- oder gynaecological surgery? If yes, what kind of operation? _____ . When? 1. (year) _____ . 2. (year) _____ . Has the patency of your fallopian tubes been tested?		<input type="radio"/> yes	<input type="radio"/> no
8. Did increased bleeding/blood loss occur during former operations or injuries (e.g. teeth extractions)? Was a transfusion of blood or cells necessary?		<input type="radio"/> yes	<input type="radio"/> no
9. Do you take blood coagulation inhibitors (clotting inhibitors) (like e.g.. Marcoumar, Sintrom, Aspirin or low molecular heparin, Heparin)? If yes, - which dosage?		<input type="radio"/> yes	<input type="radio"/> no
10. Did you have German measles (rubella)? 10.a) Have you been vaccinated against German measles? 10.b) If yes, has the vaccine protection been checked?		<input type="radio"/> uncertain <input type="radio"/> uncertain <input type="radio"/> uncertain	<input type="radio"/> yes <input type="radio"/> yes <input type="radio"/> yes
How long have you been attempting pregnancy?			

<p>12. Regarding your desire for pregnancy, - have you already consulted other doctors?</p> <p>If yes, which diagnostic procedures have already been done?</p> <p>Which treatments have already been performed?</p> <p>How long? _____ years. <input type="radio"/> at the general practitioner <input type="radio"/> at the gynaecologist</p>	<input type="radio"/> yes	<input type="radio"/> no
<p>13. Do you have psychological problems? Do you feel stressed?</p> <p>If yes, what do think the main reason may be?</p> <p>a) because of your infertility? b) in connection with your relationship? c) because of your job? d) due to other reasons?</p>	<input type="radio"/> yes	<input type="radio"/> no
<p>14. Do you have problems with your metabolism (e.g. diabetes) or important organs (circulation, heart, kidneys, liver, lungs, thyroid gland, nervous system)?</p> <p>If yes, what kind of problem?</p>	<input type="radio"/> yes	<input type="radio"/> no
<p>15. Do you suffer from an infectious disease (e.g. Hepatitis A, B or C, or HIV/AIDS)?</p> <p>If yes, which ones?</p>	<input type="radio"/> yes	<input type="radio"/> no
<p>16. Did suffer from allergies (e.g. band-aid or medical tape, , latex, medication, food?)</p> <p>If yes, which ones?</p>	<input type="radio"/> yes	<input type="radio"/> no
<p>17. Did you have problems with woundhealing, abscesses, fistulas, kelloid formation?</p>	<input type="radio"/> yes	<input type="radio"/> no
<p>18. Have you ever had a thrombosis (blood clotting) or embolism?</p>	<input type="radio"/> yes	<input type="radio"/> no
<p>19. Do you regularly take medication (analgesics/pain killers, blood pressure medications, anti-coagulants, thyroid medications or diabetes medication)?</p> <p>If yes which ones? _____</p>	<input type="radio"/> yes	<input type="radio"/> no
<p>20. Which questions related to your planned IVF treatment are on your mind?</p>		
<p>21. Did you ever receive local anesthesia (e.g. at the dentist) or sedation (semi conscious state)?</p>	<input type="radio"/> yes	<input type="radio"/> no

Doctors notes regarding educational patient information:

III. Informed Consent according to § 8 FMedG

You fulfill the criteria for In-vitro Fertilisation that will offer good chances for pregnancy.

1. Legal Information

The Austrian law, BGBl Nr. 275/1992, (Fortpflanzungsmedizingesetz – FMedG) that has been passed for regulation of assisted reproductive techniques requires this mandatory informed consent agreement from you for undergoing Assisted Reproductive Techniques to be signed by both partners.

Assisted Reproductive Techniques may be performed until revocation acc. to §8(4) of the FMedG for a duration of ten years starting with today. We have had an explicit educative information about the fact that this agreement acc. to FMedG with the doctor may be revoked by the female or male patient up to the insemination into the body of the female patient; concerning the fertilization of oocytes by the sperm cells outside of the female's body the female patient can revoke her agreement till the transfer of viable cells into her body. The male patient can only revoke his agreement till the fertilization of oocytes by sperm cells [§8(4)] This revocation needs no special form; The doctor must write a protocol and issue a letter of confirmation on demand.

2. Agreement and Informed Consent

- We give our explicit consent for the testing of HIV-, Hepatitis B and C and Syphilis in blood as well as Chlamydia testing from urine as a requirement prior to the initiation of treatment for infertility at this institute
- We have received explicit information about the reason for an HIV-test and the implications of a positive result. We have also been informed about the manner of HIV transmission and appropriate prevention practices.
- We explicitly agree (until revocation) on performing Assisted Reproductive Techniques
 - by insemination of sperm into the uterus of the female patient or
 - by fertilization of oocytes with sperm cell outside the body of the female
 - or by transfer of viable cells (embryo) into the uterus or fallopian tube of the female
 - or the transfer of oocytes with sperm into the uterus or fallopian tube of the female patient
- Both partners give our consent that oocytes, sperm cells as well as fertilized eggs (embryos) are allowed to be cryopreserved (frozen). We understand that such embryos may be cryopreserved for at most 10 years, as specified by law. We consent furthermore to the thawing of the frozen oocytes, sperm and/or embryos. We understand that the cryopreservation of embryos is for the purpose of attaining a future pregnancy. Each of the partners is allowed to rescind his or her consent for both the cryopreservation (freezing) or thawing of the embryos. In the case that one of the partners rescinds his or her consent, the death of one of the partners, or at the expiration of the maximum time of cryopreservation (10 years), the embryos will be disposed of. With the appropriate indication, oocytes or sperm cells are permitted to be cryopreserved for as long as the donor is alive.

We married partners/legal partners document our marriage/legal partnership through the presentation of a sworn copy of our marriage certificate or documentation of our legal partnership. In the case of a non-legally recognized partnership (common law partnership), we present a notarized document according to the requirement of FMedG. We understand that we are obligated to inform our treating medical doctor if there is a change in the status of our relationship (separation, divorce) during the duration of our treatment. We confirm that we have been informed of the option to have psychological counseling, as specified by law.

I confirm to have read and understood the text and that I have answered all questions concerning myself to my best knowledge. During a personal consultation all my question have been sufficiently answered.

Day/Month/Year from ^h to ^h (Doctor)

Wife/partner/legal partner Husband/partner/legal partner

With **foreign-speaking Patients** an interpreter was in attendance or patient proposed lay person provided translation(Name: _____), who knows and can translate the language of the patient.

(interpreter's signature)

Sperm Certificate

The husband/partner confirms, that the sperm sample delivered and given to the team of the IVF institute originates from himself.

He agrees, that his wife/partner may hand over his sperm sample.

The wife/partner confirms that the delivered sperm sample originates from her husband/partner.

Husband/Partner/legal partner -----

Wife/Partner/legal partner -----

Town, Date