

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

Dear Patient Couple,

<u>Female (patient):</u>	<u>Husband/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 the treatment your doctor will inform you about the options of the interventions planned and perform some preparatory examinations. You must know the obvious, typical risks and consequences in order for you to make a decision.

The IVF treatment must be planned and performed in a very individual way. Due to this reason it is necessary that our team will take enough time to analyse your problems and compile an optimal therapy plan according to your needs.

We ask you to thoroughly read the **information brochure „The unfulfilled wish for a child“**. Before you will sign the contract, you will get some more Information for better understanding. You are welcome to ask your doctor(s), who will treat you, whatever questions you may have.

I. MEDICAL INFORMATION ABOUT IVF TREATMENT

1. When does IVF make sense?

The In-vitro Fertilisation (test tube baby) procedure is not 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 selection criteria are:

Female:

- **Tubeal factor Sterility:** Both fallopian tubes are blocked or have had to be removed.
- **Endometriosis:** Is an often painful, chronic disease in women, when endometrial tissue can be found beyond the uterus, e.g. at the fallopian tubes, the ovaries, at the bowels or bladder.
- **PCOS – Polycystic Ovary Syndrome:** Multiple small cysts in the ovaries.

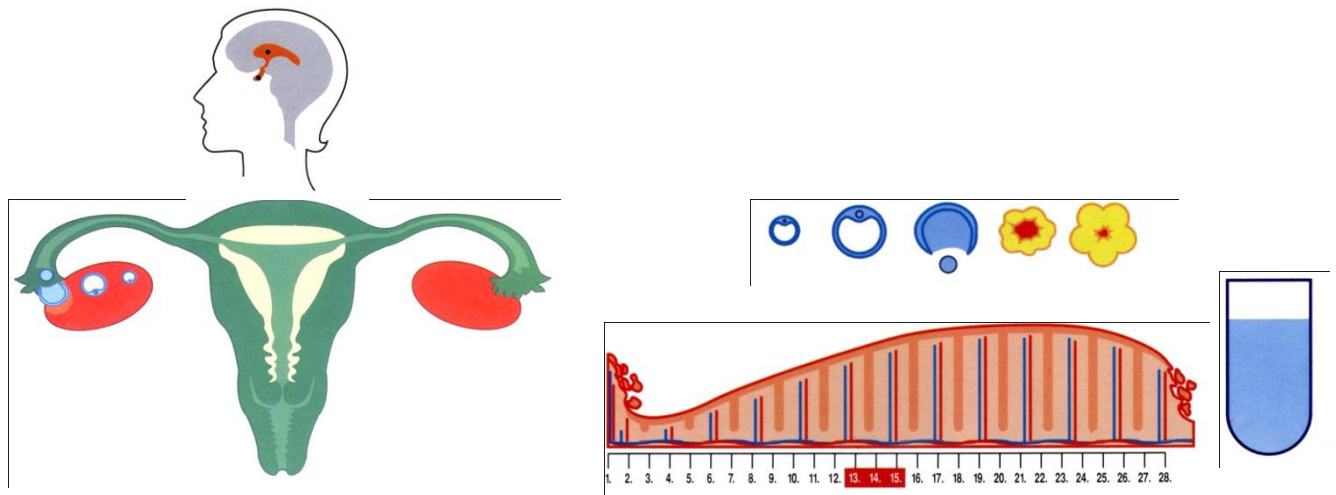
Male:

- The fertility of the male partner can be significantly reduced when the number or the number of normal spermatozoa is reduced (**male Subfertility**); in this case the importance of ICSI treatment increased.
- **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:



Patients, that cannot become pregnant in the natural way (compare point 1), will be cared for in our institute. Also regarding a disorder/malfunction from the husband/partners side extracorporal fertilisation (In-vitro Fertilisation and Embryo Transfer – IVF/ET) ev. together with a micro injection of a sperm cell into the oocyte (Intra Cytoplasmic Sperm Injection) very good results can be expected in many cases. The target of this hormonal stimulation treatment is to harvest several oocytes. The pick up of the mature oocytes is done by ultrasound guided vaginal puncture of the follicles. Thereafter comes the fertilisation of the oocytes with the husband's/partner's sperm cells outside the female patients body (in vitro). After several days a predetermined number of fertilised oocytes will be transferred back into the uterus. So a pregnancy can result without the need to transport oocytes through the fallopian tubes. A few points are important in case you decide to let us take care of you.

Please, try to bring all existing information about former surgery, hormone analysis, temperature curves, sperm analysis of your husband/partner for the first appointment to discuss your situation.

- The treatment consists of the following steps (listed as examples only , because **every** treatment is planned individually):
- First appointment with examination after booking via telephone.
- The stimulation medication will be prescribed individually.
A therapy schedule will be issued at the first appointment and the details will be thoroughly explained.

3. Treatment schedule:

- 3.1 The stimulation will be done with various combinations of hormones 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 will exactly demonstrate how you will have to take your medication and give you the protocol together with a detailed instruction.
- 3.2 Ultrasound examinations will be done appr. from Day 6-10 of treatment. We will let you know about the exact date in time. If this examination will detect a follicle diameter from 18mm onwards and all parameter will hint a sufficient oocyte maturation, an i.m.(intra muscular) or s.c. (subcutan) injection (hCG - **Pregnyl, Ovitrelle, Pregnesin, Profasi, Choragon, oder Decapeptyl**) will be administered. So the last step of oocyte maturation will be induced. 34 -36 hours later the ovum pick up will be done.
- 3.3 The puncture of the follicle is done transvaginal (ultrasound guided) under sedation (mild anesthesia) with a combination of an anesthetic agent and a sedation drug in the institute. In some cases a short anesthesia is necessary or requested, You must not eat or drink within the last 6 hours before the intervention!
- 3.4 On the day of the ovum pick up also the partner has to 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 himself. In case an intracytoplasmic sperm injection (ICSI will be necessary after retrieval of sperm cells from the testicals [Testicular Sperm Extraktion (TESE)] or from the epididymides [Microsurgical Epididymidal Sperm Aspiration (MESA)] the exact time of this operation for the partner will be fixed. In general it will happen before the oocyte pick up.
- 3.5 If the fertilisation of the oocytes can be achieved , then usually max. 2 of them will be retransferred (so called embryo or blastocyst transfer)into the uterus 2-5 days after the puncture. Only in exceptional situations (Female>40, multiple failure, bad embryo quality, etc.) more embryos may be transferred. Subsequently further or additional hormonal treatment will be decided upon and clear advise given regarding dos and don'ts and some dates for eventual controle examinations issued. There may still remain surplus embryos. Depending on their quality, they can be stored frozen,
- 3.6 Problems during the treatment period: If problems (e.g. cramps, bleeding, pain) arise, 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:

EMERGENCY	TELEPHONE	NUMBER:
.....

4. Risks and side effects of an IVF treatment

4.1 Could side effects result from an IVF treatment?

- The treatment with **hormonal tablets** (Antiestrogens) leads sometimes to mostly harmless side effects like e.g. hot flushes, headache, eye defects, bloated feeling, 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 may happen. This can lead to severe abdominal pain. Additionally liquid may aggregate in abdomen and lungs, leading to shortness of breath and nausea. In connection with this liquid may leak from the blood vessel, aggregate in abdomen, lungs and peripheral tissues and lead to leg and arm oedema. The risk of blood clotting (thrombosis) may increase and embolic events (blood vessels blocking) could happen.

- Usually these side effects (**OHSS = Ovarian Hyper Stimulation Syndrom**) can be well controlled. In rare cases a stay in hospital will be needed. In extremely rare cases life threatening conditions and even death may occur.

4.2 Which problems may arise during oocyte pick up?

Usually oocyte pick up will be without complications. In some cases problems may arise, despite the utmost of care. e.g. this could be:

- Injury of inner organs (e.g. bowels, blood vessels, nerves, bladder) The risk of puncture needle injuries (ultra sound puncture) is increased in unfavourable anatomical conditions, especially when there were previous surgery with subsequent adhesions.
- Strong bleedings: mostly they will be detected immediately and treated.. blood transfusions are nearly never needed
- Light bleedings and haematoma: usually there is no treatment needed
- Circulation problems: can happen by occlusion of bloodvessels and may lead to tissue necrosis(e.g. skin) or organs (e.g. bowels). This only happens very rarely;
- Infections: depending on area and extent of the infection, different consecutive problems may occur. In the worst case large abdominal surgery together with removal of uterus and ovaries may be needed to keep the disease under control. This leads to terminal sterility and may also cause psycho-sexual disorders. These infections are extremely rare.
- Therapy failure: In some rare cases no oocytes suitable for fertilisation can be retrieved. So no extra corporal fertilisation (in vitro) or transfer (embryo transfer) of fertilised oocytes (embryos) can be performed.

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

Usually the transfer of embryos or blastocysts into the uterus is not dangerous. But also here complications may rarely occur:

- Very rarely convulsive abdominal pain may occur during embryo transfer.
- Ectopic pregnancy or rising infection cannot be totally excluded.

4.4 Success rate:

On average a pregnancy rate (positive heartbeat) of 29% - 34% per cycle. (source IVF Fonds data) is possible. **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 possibly avoided. There is a significant increase in miscarriage rates and premature birth rates. Also several development disorders can occur in children resulting from multiple pregnancies, e.g. retardation (development deficiencies, retardation of physical and/or mental development). According to the Austrian IVF Register the rate of twin pregnancies was 21,8%, 1,2% for triplets, and only a single case of quadruplets. In comparison with the German Register DIR the 2008 figures for twins were 26% and 2,11% for triplets. There were no quadruplets in 2008. In comparison with previous years the multiple pregnancy rate is going down continuously. The miscarriage rates for multiple pregnancies are between 18,9 and 20,3%.

In rare cases (<1%) the transfer of two embryos can lead (by formation of identical, monozygotic twins) to higher grade multiples (triplets very rarely also quadruplets). This is a severe complication, 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. Therefore, to avoid a spontaneous conception (and multiplepregnancy), the advise for contraception(by a condom) during intercourse from the start of the stimulation till 3 days after the oocyte pick up, is given.

II. Questionnair for patients with the desire to have a child.

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

<p>1. How long was the interval between you monthly bleedings without taking medication?</p> <p>Between _____ and _____ days.</p> <p><u>1.a. How many days did you bleed on average?</u> _____ days</p> <p><u>1.b. Strength of bleeding ?</u> <input type="radio"/> strong <input type="radio"/> medium <input type="radio"/> weak</p>		
<p>2. Hight: _____ Weight: _____</p>		
<p>3. Do you smoke ? If yes, how many cigarettes /cigars per week ? _____</p>	<input type="radio"/> yes	<input type="radio"/> no
<p>4. Do you drink alkohol ? If yes, how much alcohol do you drink per week ? _____</p>	<input type="radio"/> yes	<input type="radio"/> no
<p>5. First day of your last menstrual bleeding? _____ If you do not know this exactly please, state month or year.</p>		
<p>6. Have you ever been pregnant?</p> <p>a) Births: 1. (year) _____ 2. (year) _____ 3. (year) _____ .</p> <p>b) Miscarriages: 1. (year) _____ . in which month? _____ . 2. (year) _____ . im which month? _____ . 3. (year) _____ . im which month? _____ .</p> <p>c) Interruptions: 1. (year) _____ 2.(year) _____ 3. (year) _____ .</p>	<input type="radio"/> yes	<input type="radio"/> no
<p>7. Have you ever had abdominal- oder gynaecological surgery performed?</p> <p>If yes, what kind of operation? _____ .</p> <p>When? 1. (year) _____, 2. (year) _____ .</p> <p>Have the fallopian tubes been tested?</p>	<input type="radio"/> yes	<input type="radio"/> no
<p>8. Did increased bleeding/blood loss occur during former operations or injuries (e.g. teeth extractions) ? Was a transfusion of blood or cells necessary?</p>	<input type="radio"/> yes	<input type="radio"/> no
<p>9. Do you take blood coagulation inhibitors (clotting inhibitors) (like e.g.. Marcoumar, Sintrom, Aspirin or low molecular heparins Heparin) ?</p>	<input type="radio"/> yes	<input type="radio"/> no

If yes, - which dosage?			
10. Did you have German measles (rubella)?	<input type="radio"/> uncertain	<input type="radio"/> yes	<input type="radio"/> no
10.a) Have you been vaccinated against German measles?	<input type="radio"/> uncertain	<input type="radio"/> yes	<input type="radio"/> no
10.b) If yes, has the vaccine protection been checked?	<input type="radio"/> uncertain	<input type="radio"/> yes	<input type="radio"/> no
11. Since how many years do you feel the desire to have a child? Since _____ years.			

12. Regarding your wish for a child, - did you already consult other doctors? If yes, which diagnostic procedures have already been done? Which treatments have been performed? How long? _____ years. <input type="radio"/> at the general practitioner <input type="radio"/> at the gynaekologist	<input type="radio"/> yes	<input type="radio"/> no
13. Do you have emotional problems? If yes, what is the reason ? a) because of your wish for a child ? b) in connection with your relationship? c) because of your job? d) due to other reasons?	<input type="radio"/> yes	<input type="radio"/> no
14. Do you have problems with metabolism (e.g. diabetes) or important organs (circulation, heart, kidneys, liver, lungs, thyroid gland , nervous system)? If yes, what kind of problem?	<input type="radio"/> yes	<input type="radio"/> no
15. Do you suffer from an infectious disease (e.g. Hepatitis A,B or C, or HIV/AIDS)? If yes, which ones?	<input type="radio"/> yes	<input type="radio"/> no
16. Did you observe allergic conditions (e.g. against patches, latex, medication, food?) If yes, which ones?	<input type="radio"/> yes	<input type="radio"/> no
17. Did you observe suppurative wounds , retarded healing, abscesses, fistulas, strong scaring?	<input type="radio"/> yes	<input type="radio"/> no
18. Did blood clotting/thrombosis/ embolism occur?	<input type="radio"/> yes	<input type="radio"/> no
<i>19. Do you regularly take medication (analgetics/pain killers, Heart tablets or coagulation inhibitors, anti hypertension tablets, diabetes medication)?</i> If yes , which ones?	<input type="radio"/> yes	<input type="radio"/> no
20. Which questions related to your planned IVF treatment, are on your mind?		
21. Did you ever receive a local anesthesia(e.g. at the dentist) of sedation (semi concious state)?	<input type="radio"/> yes	<input type="radio"/> no
22. How many embryos should be tranferred? <input type="radio"/> 1 <input type="radio"/> 2 <input type="radio"/> 3 <input type="radio"/> more than 3 _____		
<u>Please note point 4.5.</u>		

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 Informations

The Austrian law, BGBl Nr. 275/1992,(Fortpflanzungsmedizingesetz – FMedG) that has been installed for regulation of assisted reproductive techniques, demands this mandatory informed consent agreement from you. Therefore we kindly present you this informed consent agreement for Assisted Reproductive Techniques.

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 fertilisation 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 fertilisation 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 explicitly agree (until revocation) on HIV-, Hepatitis B- and C- tests to be performed within the treatment course for fertility in this institute of reproductive medicine and endocrinology.
- We have had an explicit educative information about the reason for an HIV-test and the implications of a positive result. Also about the ways of infection with HIV and the rules to avoid such an infection we have been informed...
- We explicitly agree (until revocation) on performing Assisted Reproductive Techniques
 - by insemination of sperm into the uterus of the female patient or
 - by fertilisation of oocytes with sperm cell outside the body of the female
 - or by transfer of viable cells 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
- We, as a couple agree on sperm cells, fertilised oocytes and embryos to be cryo preserved. We acknowledge that this is only possible for a period of ten years. This written consent (agreement) is also valid for eventual reactivation (thawing after freezing). We acknowledge that freezing (cryo preservation) of impregnated oocytes and embryos will be done for inducing a future pregnancy. Each of the two partners can revoke his consent anytime. In case of revocation of the consent or at the end of the storage period the impregnated oocytes and embryos are to be destroyed immediately.
- We married partners provide evidence of our marriage by the certified copy of our **marriage certificate** attached to this declaration. In case of a partnership we will provide a script attested by a notary, as demanded by FMedG. In case of an eventual termination of our marriage or partnership during the course of our treatment we are obliged to inform the treating doctor of the clinic immediately. We confirm that we have discussed the option of psychological advising as included in the FMedG.

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 -----

Wife/Partner -----

Town, Date