

Patient informed consent to examination

MAGNETIC RESONANCE IMAGING

Patient's last and first name:			
Personal number:			
Body weight:		Insurance company:	

For minor persons, for person not capable of giving their consent or persons with limited legal capacity or persons deprived of legal capacity , to be filled by legal representative of the patient or a witness who was present to the manifestation of consent (where the patient cannot sign):

<p>First name and last name of the legal representative (guardian):</p> <p>Date of birth of the representative:</p> <p>Reasons due to which the patient could not sign the consent:</p>
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Dear Madam, Dear Sir, Dear Parents,

Based on clinical examination of your/your child's health condition, the attending physician recommended an examination with magnetic resonance imaging (MRI examination). It is one of the most state-of-the art examination methods, which can currently examine most of the human body organs including brain, spine, vessels, joints, pelvis as well as abdominal organs. **Examination is not based on the x-ray principle.** No harmful biological effects have been proved so far in the electromagnetic energy used for MR imaging. Still, we have chosen to avoid this examination in pregnant women during the first three months of pregnancy. Beginning of the examination may be delayed in the event that an acute examination needs to take priority. Your consent is necessary to perform the suggested healthcare procedure. To make your decision easier, we would like to provide you with the following information.

Reasons for procedure

To detect and evaluate potential diseases in the examined area or to check and evaluate already known changes in order to consider potential additional examination or therapeutic procedures.

Alternatives (other options) to the procedure / treatment

Computed tomography (CT) examination, which is loaded with ionisation radiation and increased incidence of allergic reaction to administration of contrast or, where appropriate and possible, an ultrasound examination. Information as to whether the suggested medical procedure has any alternative (other option) and whether you have the option to choose from several alternatives, was provided to you by your attending physician who recommended this medical procedure.

Procedure risks and potential complications

A "panic" reaction may occur during the examination, i.e. fear of closed space, anxiety, unease, restlessness. You can notify the examination staff of this trouble to by pressing the **signal button**, which you are holding in your hand during the examination. The staff will deal with your acute problem immediately and they can remove you from the tunnel within a few seconds. The examination is accompanied by **big noise**, which is caused by machine parts. This noise is a normal phenomenon and should not disturb you. We are ready to provide you with **hearing protectors**, of course. **Contrasts need to be applied in some cases** (these are gadolinium chelates, not iodine preparations), and it is therefore good to know if the patient has experienced any allergic reaction in the past. Headache, nausea, short-term dizziness, pain in the injection site may occur after administration of the contrast. Very rarely there can be reactions of allergic type, skin rash, vomiting, breathing difficulties, oedema, heart rhythm disorders, renal damage. It is therefore necessary to report whether the patient suffers from any long-term renal dysfunction. Incidence of allergic reactions to contrasts used in magnetic resonance examinations is very rare. Our staff is made familiar with the methodology of handling allergic reactions. Application of contrast, if any, is decided by the examining doctor (radiologist). If you have an **allergy to the contrast**, MRI examination can be performed natively, i.e. without administering the contrast. **Breastfeeding mother will discontinue breastfeeding for 24 hours after application of MRI contrast**; it is appropriate to collect milk for this period ahead.

MRI examination is safe. However, it may become dangerous if there are any metal instruments or object in or on the patient's body; it is therefore necessary to put off everything before the examination (dentures, hearing aids, prosthetic aids, bra, belt, wig, hair pins, hair needles, pins, etc.), metal coins, keys, watches, credit cards, wallets, glasses, mobile phone, piercing, rings and jewels; otherwise they may get damaged or the patient or staff injured.

Preparation for procedure

The examination is performed in a strong magnetic field; it is painless and requires almost no special preparation (except for examination of abdomen and pelvis). You need to come to brain and face examinations without contact lens and make-up, without mascara, make-up, powders, hair gels, sprays, etc. If you appear with a make-up, you will be asked to remove it.

Examination of abdominal region and pelvis is the exception:

- **MRI enterography** (small intestine examination); perfect evacuation of the intestinal contents is necessary before MRI examination, and therefore a few days of diet are recommended
- **Liver, pancreas MRI** 3-hours fasting is recommended before the examination (i.e. no liquids or meal)
- **Pelvic MRI** it is recommended not to take any drink 2 hours before and use the toilet just before the procedure

Process before and during the procedure (examination):

All instructions of the examination staff need to be observed before and during the examination for the purpose of safety and health protection. After entering the preparation room, **put off** your clothes so that we can exclude the presence of any metal object in the magnetic field. Also **put off** any dentures, hearing aids, prosthetic aids, bra, belt, wig, hair pins, hair clips, hair needles, pins, etc., metal coins, keys, watches, credit cards, wallets, glasses, mobile phone, piercing, rings, and jewels). You can bring your own cotton T-shirt for the examination. The contrast will have to be applied; a cannula (plastic tube) will be introduced into your vein and the contrast will be applied into this cannula.

After completing the above-mentioned procedures you will be introduced to the examination room, where the magnetic field is effective already. A radiology assistant will lay you down on the examination table. A coil receiving response from the examined tissue will be placed around or under the examined part of your body. Then you will be taken into the tunnel on the table, which may make you feel uneasy. We assure you that the tunnel has fresh air delivery from the ventilator; the staff monitors during with a camera during the whole period of examination and you are connected with the staff by means of a microphone. You can notify the examination staff of any trouble to by **pressing the signal button**, which you are holding in your hand during the whole examination. You should **lie down peacefully without moving** during the whole period of examination, which takes approx. 15-45 minutes; do not blow your nose, do not scratch, and breath regularly. **Each move you make will impair the examination.** When examining the abdominal cavity organs, you will be asked repeatedly to hold your breath for a short period of time, approx. 15 to 20 seconds. The examination is accompanied by big noise, which is caused by the machine parts. This noise is a normal phenomenon and should not disturb you. We are ready to provide you with hearing protection aids, of course.

After the procedure (examination):

Immediately alert our staff in case of any difficulties. When the examination is finished, you will be taken back to the preparation room; check carefully all the things you have put off and then you will be able to leave and go home. **After the contrast examination, the patient will wait for additional 20 minutes in waiting room** due to potential late allergic reaction to the contrast. If any allergic manifestations occur after the examination with contrast (skin rash, nausea, dyspnoea) as late as after leaving the health institution, notify your attending physician or emergency medical service immediately. Breastfeeding mothers will discontinue breastfeeding for 24 hours after application of the contrast during which the contrast will be evacuated from the body. Sufficient hydration, i.e. at least 2 litres of liquids, is necessary after performed examination with contrast application. MRI examination will not restrict your or your child's normal way of life in any respect.

Information obtained will be processed after the examination; written results will be automatically submitted to the doctor who referred you to the examination. We can burn a copy of the acquired images from your MRI examination on your CD carrier, or **a copy of the finding (description) can be submitted to your private e-mail after completing a special consent.**

If you have a pacemaker, implanted permanent defibrillator, cochlear implant, or metal splinters from an injury anywhere in your body, you MUST NOT be MRI examined!!!

Please alert our staff of this fact!!!

MRI examination is safe. However, it may become dangerous if there are any metal instruments or object in or on the patient's body. Strong magnetic field may disturb function or change position of any metal object that have ever been placed into your body, mostly purposefully in terms of some surgery. It is therefore important to complete truthfully the following form.

The **“YES”** answer to any of the questions below **does not mean** that the examination cannot be performed. In the event of any uncertainty and additional question, contact the MRI staff, please.

Write YES or NO truthfully

Do not score out, please!

Is there any pacemaker, defibrillator or any other instrument affecting the heart activity in your body?		
Did you have any pacemaker, defibrillator, or any other instrument in your body previously and electrodes have been left in your body?		
Is there any neurostimulator in your body? Any type of biostimulator or any other electronic instrument?		
Is there any metal in your body in consequence of a spinal surgery? <i>Specify the year of surgery, if appropriate:</i>		
Did you have artificial joint surgery? Is there any metal material or metal in your body in consequence of bone fracture surgery? <i>Specify the year and localisation, if appropriate</i>		
Have you ever been hit by a bullet, shrapnel, pellets, grenade splinters? Are there any foreign metal objects in your body (chip, needle, wire, splint, etc.)? <i>If so, specify details:</i>		
Do you have any stents (vascular braces) introduced? <i>Specify the year of insertion, if appropriate:</i>		
Do you have any vascular staples or any other objects in vessels (e.g. embolization material, spirals) after surgery? <i>If so, specify details:</i>		
Do you have any caval filter (inferior vena cava filter) introduced? <i>Specify the year of insertion, if appropriate:</i>		
Have you ever had intravenously applied) contrast during MRI examination before?		
Where contrast for MRI was applied, did you have any allergic reaction?		
Did you have any allergic reaction to any medication in the past? <i>If so, specify the name:</i>		
Are you claustrophobic (do you fear closed spaces)?		
Do you have a cochlear implant (<i>to aid your hearing</i>)?		Do you have a hearing aid?
Do you have a splinter in your eye or any other metal object?		Do you have an artificial eye?
Do you have an aneurysm vascular clip in your body?		Do you have a heart valve replacement?
Do you have any other instrument (e.g. insulin pump) in your body?		Have you been treated for asthma?
Did you have an organ (liver, kidney, ...) transplanted?		Do you have diabetes?
Do you have increased inclination to bleeding or, on the contrary, to increased blood clotting?		Do you have dental brace?
Do you suffer from any renal disease or reduced renal function?		Do you have any non-removable piercing?
Do you have a denture or non-removable prosthesis?		Do you have a tattoo?
		Do you have permanent make-up?

For women: Are you pregnant? If so, which week? Do you breastfeed?
Do you have an intrauterine device?

For men: Do you have a penile implant (prosthesis in penis)?

If any metal object with which MRI can be performed has been implanted in your body, this fact needs to be documented by a certified issued by the implanting site.

Statement of the patient (or the patient's legal representative)

I, the undersigned, declare that I have been comprehensibly and in detail made familiar with all above-mentioned facts including the warning about potential risks, complications, and their solutions. Alternative options and potential risks of refusal for undergo the procedure have been explained to me. I have understood them, I had the opportunity to ask additional questions that were answered to me, and I confirm that I have fully understood both the information and the instruction. I have not concealed any information known to me about my (my child's) health condition that might have adverse effect on my (my child's) treatment or endanger people around me, particularly by spreading an infectious disease. I declare that I have truthfully answered the questions asked in this document. Based on provided information and following my own consideration I hereby express my free and informed consent to performance of magnetic resonance examination with potential intravenous administration of the contrast. I accept, if it is necessary for the ensuing diagnostic or therapeutic procedure, transfer of findings and data to other doctors, healthcare institutions and health insurance companies within the scope permitted by the data protection law. I accept the use of anonymous data relating to my treatment for publication and education purposes.

Date: _____ **Patient's own signature:** _____

To be completed by legal representative for minor persons or persons with limited legal capacity or persons deprived of legal capacity

Complete provided that the patient cannot sign with regard to his/her health condition (e.g. due to upper limb injury):

The patient's present health condition does not allow him/her to sign this consent because:

Method of will (consent) manifestation: nodding: YES-NO gesture: YES-NO eyes: YES-NO

other: _____

Witness (first and last name signature): _____

Date, name, signature, and stamp of the referring physician who reviewed the answers to questions and instructed the patient:

Statement of the healthcare specialist who instructed the patient about the examination:

I declare that I duly informed the above-mentioned patient (legal representative) about the purpose, nature, consequences, risks, potential complications, and alternatives of the scheduled examination in a manner which was, in my opinion, comprehensible to them. I also informed the patient that an implanted pacemaker, defibrillator, cochlear implant, and a splinter anywhere in the patient's body is an absolute contraindication to the examination. I also declare that the patient was instructed that in the event of nausea or any other complications during the examination he/she may use the bell (ball) to call the staff.

Stamp and signature of the radiology assistant who reviewed the answers to the questions:
