## INFORMATION AND CONSENT

**SURNAME**_____**NAME**_____

**PLACE OF BIRTH**_____ **DATE OF BIRTH**_____

**WEIGHT**_____**HEIGHT**_____

**DOCTOR RECOMMENING THE EXAM**_____

***Dear Patient,***

***The procedure we recommend you to do requires your consent so that, through this information sheet and a conversation with the doctor, you can make an informed decision. You will receive detailed information about possible complications associated with the diagnostic procedure recommended. We kindly ask that you carefully review the following details before the procedure and address any questions, doubts, or requests for clarification with us, so you can make a well-informed, responsible, and calm decision.***

**READ CAREFULLY AND DISCUSS WITH YOUR PRIMARY CARE PHYSICIAN FOR A CLEARER COMPREHENSION OF THIS FORM.**

**WHAT IS IT**: Magnetic Resonance Imaging (MRI) is a diagnostic technique that does not use ionizing radiation or radioactive substances. MRI diagnostic utilizes strong static magnetic fields and radiofrequency electromagnetic waves. According to the current knowledge, MRI examinations do not entail significant biological effects on patients without contraindications and are conducted in respect of safety regulations and standards. Although there is no evidence proving the embryo's sensitivity to the static magnetic fields and RF electromagnetic waves used for MRI diagnostics, it is prudent not to perform MRI during the first trimester of pregnancy.

**WHAT IT IS USED FOR**: MRI is used for diagnosing pathological diseases affecting the brain and the spinal column, the abdomen, the pelvis, the major blood vessels, and the musculoskeletal system.

**HOW IT IS PERFORMED**: Upon arrival, the patient will be introduced by the service staff who will verify his identity and check the presence of documentation (medical referral, information, completed and signed questionnaire, previous clinical and instrumental documentation). To perform the MRI exam, the following objects must be removed: contact lenses, hearing aids, dentures, temporary mobile crowns, hernia belts, hair clips, pins, glasses, jewellery, watches, credit cards or other magnetic cards, pocket knives, money clips, coins,

keys, hooks, automatic items, metallic buttons, pins, clothing with zippers, nylon stockings, acrylic clothing, metal tweezers, staples, nail files, scissors and any other metallic objects.

There are lockers available in the MRI area where it is advisable to store personal effects.The average duration of the MRI exam is approximately 45 minutes, but it may vary according to the clinical needs and the number of anatomical areas to be examined. During the MRI exam data acquisition phase, rhythmic noises of varying intensity may be heard, due to the normal operation of the procedure equipment. The conditions of ventilation, lighting, and temperature ensure maximum comfort and reduce possible claustrophobic effects. During the examination, it is necessary to remain calm and maintain total immobility, in order to avoid compromising the diagnostic quality of the images. Regular breathing and swallowing do not disturb the exam. In some types of examinations, the patient may be asked to cooperate through breathing actions and brief periods of apnoea, to improve the diagnostic quality of the images.

In the control room, the staff is always present and intervenes in case of any necessity. The patient is always in vocal, acoustic and visual contact with the operators, who maintain constant monitoring throughout the examination. If symptoms like feelings of claustrophobia, heat, itching, shortness of breath, palpitations, or fainting appear, the patient should promptly inform the Responsible Physician for the MRI exam using the appropriate warning devices.

**WHAT COULD HAPPEN - POTENTIAL COMPLICATIONS**: Rarely, mild disturbances such as feelings of claustrophobia, heat, itching, shortness of breath, palpitations, or malaise may occur. In these cases, it is possible to alert the operators using a designated warning device that will be at your fingertip during the exam. During the MRI exam, the occurrence of adverse reactions is very rare. The most likely occurrence is a transient episode of claustrophobia.

**IMPORTANT INFORMATION FOR THE EXAM PERFORMANCE:** Patients who have undergone surgical procedures must present documentation attesting the type of the implanted device.

**RECOMMENDATIONS FOR ESCORTS OR PARENTS ASSISTING THE PATIENT**: If there is the need to avoid or reduce sedation or other pre-examination procedures for the patient undergoing a MRI, a voluntary escort or parent may assist the patient during the execution in the examination room to calm and keep the patient still, in order to ensure the completion of the investigation. The escort may assist the patient only after:

• READING AND UNDERSTANDING THE INFORMATION regarding the risks associated with MRI (static, variable magnetic fields, and radiofrequency);

• COMPLETING THE QUESTIONNAIRE;

• POSITIVE OPINION of the Radiologist.

**CONTRAST AGENT**: If the requested examination requires the use of a contrast agent:

**A 6-hour fast for solid foods is required for all abdominal-pelvic and cardiac exams**; it is not required for other body areas.

• Continue taking any medications or drugs (unless otherwise indicated by the Primary care physician) and drink plenty of water orally (1.5 L the day before, the same day of the exam and the day after);

• Note that some blood tests values may be altered in the 24 hours following the exam.

During the intravenous infusion of the contrast agent, there is the possibility (due to anatomical reasons, fragility of the vein, etc.) that the vessel may rupture, provoking the leak of the contrast agent in the injection area; in this case, the swelling will be assessed and treated if necessary (following the guidelines provided for extravasation protocols). It is possible that during and after the administration of the contrast medium, undesirable effects related to allergic reactions may occur, which can be immediate or delayed. Depending on the severity, these reactions can be:

• **Mild**: nausea, vomiting, pain at the injection site, skin rash.

• **Moderate**: dyspnea, hypotension, tachycardia.

• **Severe** (life-threatening): severe arrhythmias, severe bronchospasm, cardiac arrest, acute renal failure. In these rare situations, our service has personnel, medications, and equipment suitable for patient care, and if necessary, the intensive care staff is readily available.

**Delayed** reactions (from 1 hour after injection up to 7 days) most frequently consist of skin rashes, flu-like syndromes, gastrointestinal diseases. In this case, it is recommended to consult the Primary care physician.

**TO BE COMPLETED IN CASE OF HOSPITALIZED/DAY HOSPITAL PATIENT, PRE AND POST HOSPITALIZATION**:

**The Ward Physician is required to provide all information related to the correct completion of the anamnesis questionnaire.**

Clinical information and reason for the exam

_____

_____

Operational Unit _____

Place, date _____ Signature of the Unit Physician_____

**QUESTIONNAIRE FOR EVALUATION OF RISK TO THE CONTRAST AGENT**

**Surname_____Name_____Date of birth____/____/____ Weight_____**

-Previous adverse reactions to gadolinium-based contrast agent ☐ YES ☐ NO

If the patient answered YES, describe the type of reaction and any therapy; if possible, attach any documentation:

□ anaphylaxis
□ mastocytosis
□ recurrent angioedema ongoing
□ chronic urticaria ongoing
□ uncontrolled bronchial asthma, or in the last 4 weeks has:

- Had symptoms more than 2 times a week? ☐ YES ☐ NO
- Had awakenings every night due to asthma? ☐ YES ☐ NO
- used salbutamol (Ventolin/Broncovaleas) more than 2 times a week? ☐ YES ☐ NO
- experienced activity limitations due to asthma? ☐ YES ☐ NO

**If the patient confirmed at least one of the mentioned conditions or answered YES** to one of the questions mentioned above, the possibility of performing the exam will be decided by the Radiology and may therefore be postponed, in order to have a prior consultation with an Allergist Specialist or an assessment by the primary care physician or specialist.
It is noted that according to the ESUR reference guidelines (10.0), **premedication is not recommended.**

IS THE PATIENT UNDERGOING HEMODIALYSIS: ☐ YES ☐ NO
If YES, specify which days:
…….
According to ESUR 10.0 guidelines, creatinine dosage is not required, except for pediatric patients (under 18 years) and for the study of liver and biliary tract diseases with a contrast agent that is partially excreted bilaterally. In this case, it is required to present the report of the creatinine dosage performed no earlier than 3 months from the day of radiological examination.

Date_____/_____/_____

Signature of the proposing physician_____

Signature of the Radiologist_____

**The indications exposed in this form refer to international guidelines (ESUR 10.0 -2018).**

**ANAMNESIS QUESTIONNAIRE FOR MAGNETIC RESONANCE IMAGING**

The "anamnesis questionnaire" aims to verify the absence of contraindications for the examination performance. It must be read carefully and understood in all its parts. In case of doubts, refer to your Primary Care physician. The accuracy of the answers supplied to the MRI team during the questionnaire administration is essential for the assessment of suitability of the MRI examination by the Radiologist.

| | | |
|---|---|---|
| Have you previously undergone MRI examinations? | YES | NO |
| Have you had allergic reactions after the administration of the contrast agent? | YES | NO |
| Have you ever worked (or work) as a welder, lathe operator, car bodyworker? | YES | NO |
| Have you ever had road accidents, hunting accidents? | YES | NO |
| Have you been a victim of explosion trauma? | YES | NO |
| Last menstrual period occurred…… | YES | NO |
| Have you undergone surgical procedures on: head □ neck □ abdomen □ extremities □ chest □ other □ | YES | NO |
| Are you aware of having one or more medical devices or metallic bodies inside your body? | YES | NO |
| Are you a carrier of a cardiac pacemaker or other types of cardiac catheters? | YES | NO |
| Are you a carrier of shrapnel or metallic fragments? | YES | NO |
| Are you a carrier of clips on aneurysms (blood vessels), aorta, brain? | YES | NO |
| Cardiac valves? | YES | NO |
| Stents? | YES | NO |
| Implanted defibrillators? | YES | NO |
| Spinal distractors? | YES | NO |
| Insulin or other drug infusion pump? | YES | NO |
| Metallic bodies in the ears or hearing implants? | YES | NO |
| Neurostimulators, electrodes implanted in the brain or subdurally? | YES | NO |
| Other types of stimulators? | YES | NO |
| Intrauterine devices? | YES | NO |
| Spinal or ventricular shunt? | YES | NO |
| Fixed or removable dental prosthesis? | YES | NO |
| Metallic prosthesis (previous fractures, corrective joint surgeries, etc.), screws, nails, wire, etc.? | YES | NO |
| Other prosthesis? Location……. | YES | NO |
| Do you believe you may have prosthesis/appliances or other metallic bodies inside your body that you may NOT be aware of? | YES | NO |
| Additional information …….. | YES | NO |
| Do you suffer from sickle cell disease? | YES | NO |
| Are you a carrier of lens prosthesis? | YES | NO |
| Are you a carrier of piercings? Location …… | YES | NO |
| Do you have tattoos? Location …….. | YES | NO |
| Are you using medical patches? | YES | NO |

**Signature Patient/Parent/Legal representative**_____

In consideration of the answered written above, **the Responsible Physician for the MRI**

□ **AUTHORIZES** □ **DOES NOT AUTHORIZE** **The execution pf the MRI**

Place and date Signature of the Physician responsible for the MRI execution

_____ _____

PATIENT CONSENT for the execution of the MRI
□ **With Contrast Agent** □ **Without Contrast Agent**

I, the undersigned, _____,

In quality of □ patient □ parent □ authorized legal representative

**DECLARE THAT:**

I have received clear and complete information about the risks and contraindications due to the electromagnetic field's exposure generated by the MRI equipment and for eventual side effects provoked by the contrast agent. Aware of the information provided int his form, I
□ **ACCEPT** □ **DECLINE** **the execution of the MRI**

I confirm that I have informed the radiologist about any confirmed or suspected pregnancy:
□ NOT PREGNANT □ PREGNANT

Place and date **Signature Patient/Parent/Legal representative**

_____ _____

I, the undersigned _____declare to **REVOKE** the consent and do not want to proceed with the MRI examination.

Place and date Signature of the Physician responsible for the MRI execution

_____ _____