MEDICAL HISTORY FORM AND INFORMED CONSENT FOR MAGNETIC RESONANCE EXAMINATION WITH CONTRAST MEDIUM

Survey administered by _____

(Indicate the name, surname and professional qualification of the member of the MRI TEAM)

The patient:

Surname _____ Name _____

Place and date of birth _____ body weight (kg) _____

Registered residence_____ Phone _____

Examination required _____ Department /Doctor requesting the MRI exam _____

Preliminary Survey

The medical history survey has the purpose of ascertaining the absence of contraindications to the MRI examination or the irrelevance of specific preventive investigations. This questionnaire must be carefully filled out by the MRI Team and signed by the Doctor Responsible for Diagnostic Services, who, in relation to the answers provided by the patient, can conclude that there are no contraindications to the MRI examination. The patient's countersignature at the end of the same page, at the bottom of the consent formula, guarantees - among other things – his/her full awareness of the serious consequences that any false or mendacious answers to the questions put to him/her may have.

- HAVE YOU PREVIOUSLY HAD ANY MRI? ..... YES NO
- HAVE YOU HAD ALLERGIC REACTION AFTER ADMINISTRATION OF THE CONTRAST MEDIUM? ..... YES NO
- DO YOU SUFFER FROM CLAUSTROPHOBIA? ..... YES NO
- HAVE YOU EVER WORKED (OR ARE YOU WORKING) AS A WELDER, A TURNER OR A COACHBUILDER? ..... YES NO
- HAVE YOU EVER HAD ANY ROAD ACCIDENT OR ANY HUNTING ACCIDENT? ..... YES NO
- HAVE YOU BEEN A VICTIM OF A BLAST INJURY? ..... YES NO
- ARE YOU PREGNANT OR PRESUMED TO BE PREGNANT? ..... YES NO
- LAST MENSES OCCURRED: .....
- DID YOU UNDERGO ANY SURGERY ON YOUR:
  HEAD, NECK, ABDOMEN, UPPER OR LOWER EXTREMITIES, CHEST OR ANY OTHER PART OF YOUR BODY ..... YES NO
  DESCRIPTION _____
- ARE YOU AWARE YOU HAVE ANY MEDICAL DEVICE OR METALLIC BODY INSIDE YOUR BODY? ..... YES NO
- ARE YOU A PACEMAKER OR DEFIBRILLATOR OR ANY OTHER CARDIAC DEVICE (LOOP-RECODER) WEARER? ..... YES NO
- ARE YOU A WEARER OF ANY METAL SPLINTERS OR FRAGMENTS? ..... YES NO
- ARE YOU A WEARER OF CLIPS ON ANEURYSMS (BLOOD VESSELS), AORTA, BRAIN? ..... YES NO
- ANY OTHER TYPE OF METAL CLIPS? ..... YES NO
- HEART VALVES? ..... YES NO
- STENTS? ..... YES NO
- IMPLANTED DEFIBRILLATORS? ..... YES NO
- SPINAL COLUMN DISTRACTORS? ..... YES NO
- INFUSION PUMP FOR INSULIN OR OTHER DRUGS? ..... YES NO
- METALLIC BODIES IN THE EARS OR HEARING IMPLANTS? ..... YES NO
- NEUROSTIMULATORS, ELECTRODES IMPLANTED IN THE BRAIN OR SUBDURAL? ..... YES NO
- OTHER TYPES OF STIMULATORS? ..... YES NO
- INTRAUTERINE DEVICES (IUD)? ..... YES NO
- SPINAL OR VENTRICULAR OR VENTRICULUM-PERITONEAL SHUNT (VP) SHUNT)? ..... YES NO
- FIXED OR REMOVABLE DENTAL PROSTHESES? ..... YES NO
- METALLIC PROSTHESES (FOR PREVIOUS FRACTURES, CORRECTIVE JOINT INTERVENTIONS, ETC.), SCREWS, NAILS, WIRE, ETC? ..... YES NO
  OTHER PROSTHESES (MAMMARY, BREAST TISSUE EXPANDER, PENILE PROSTHESIS ETC.)? ..... YES NO
- DO YOU THINK YOU HAVE PROSTHESES/DEVICES OR METALLIC BODIES IN YOUR BODY THAT YOU MAY NOT BE AWARE OF? ..... YES NO
- ADDITIONAL INFORMATION _____
- DO YOU SUFFER FROM SICKLE CELL ANEMIA? ..... YES NO
- DO YOU HAVE AN INTRAOCULAR LENS IMPLANT? ..... YES NO
- DO YOU HAVE A PIERCING? LOCATION: ..... YES NO
- DO YOU HAVE A TATTOO? LOCATION: ..... YES NO
- ARE YOU USING ANY MEDICAL PLASTERS? ..... YES NO
- VIDEO CAPSULE FOR INTESTINE TESTS (PILLCAM®)? ..... YES NO
- DO YOU WEAR MAGNETIC FALSE EYELASH EXTENSIONS? ..... YES NO

To carry out the MRI exam, you need to remove:

contact lenses - hearing aids - dentures - removable temporary dental crowns - hernia belt - hair clips - hairpins - glasses - jewellery - watches - credit cards or other magnetic cards - pocket knives - money clips - coins - keys - hooks - metal buttons - pins - clothes with zippers - nylon stockings - acrylic clothing - metal tweezers - staples – nail files - scissors - any other metallic objects. Before undergoing the exam, please remove any cosmetic products from your face.

Santagostino
LA TUA SALUTE

MEDICAL HISTORY FORM AND INFORMED CONSENT FOR MAGNETIC RESONANCE EXAMINATION WITH CONTRAST MEDIUM

THE DOCTOR RESPONSIBLE FOR THE MRI DIAGNOSTIC SERVICE

Acknowledged the answers provided by the patient and completed any medical examination and / or further preliminary diagnostic investigations
AUTHORISES THE EXECUTION OF THE MRI INVESTIGATION WITH CONTRAST MEDIUM

Signature of the radiologist_____ Date_____

The patient:

LAST NAME		FIRST NAME	
Place and date of birth		TIN	

OR: For the patient indicated above, the undersigned:

LAST NAME		FIRST NAME	
Place and date of birth		TIN	

As:
☐ parent ☐ caregiver ☐ legal guardian ☐support administrator ☐ other figures _____

EXPRESSION OF INFORMED CONSENT TO THE MRI INVESTIGATION WITH CONTRAST MEDIUM

The patient believes he/she has been sufficiently informed about the risks and contraindications related to exposure to electromagnetic fields generated by the MRI equipment. Therefore, aware of the importance of the answers provided,

HE/SHE AGREES TO CARRY OUT THE EXAM and **DECLARES, if a woman, that she is NOT CERTAINLY OR PRESUMED PREGNANT**

Patient's signature _____ Date _____
In the case of a minor patient, the signature of a parent or guardian is required.

NOTICE OF ALLERGIES

1- to contrast medium: □ **YES** □ **NO**
2- allergies with previous episodes of respiratory failure, severe generalized urticarial manifestations, angioedema, bronchoconstriction, anaphylactic shock, loss of consciousness □ **YES** □ **NO**
3- drug allergies □ **YES** □ **NO**

Patient's signature _____ Date _____
In the case of a minor patient, the signature of a parent or guardian is required.

EXPRESSION OF INFORMED CONSENT TO THE CONTRAST MEDIUM SOMMINISTRATION

The patient considers himself sufficiently informed about the risks associated with the administration of the contrast medium. Therefore, informed by the Doctor Responsible for the diagnostic performance of the evaluation of the diagnostic benefits and related risks,

HE/SHE AUTHORIZES THE SOMMINISTRATION

Patient's signature _____ Date _____
In the case of a minor patient, the signature of a parent or guardian is required.

Information note related to the MRI examination

Magnetic Resonance Imaging (MRI) is a diagnostic technique that does not use ionising radiation or radioactive substances. MRI use static magnetic fields and radio frequency (RF) electromagnetic waves, similar to radio and television waves. In general, basal MRI is usually a non-invasive diagnostic test and, according to current knowledge, it does not involve any significant biological effects on patients without contraindications and it is carried out in accordance with safety regulations and standards. However, in some types of investigations, some substances with paramagnetic properties can also be administered to the patient intravenously as a contrast medium. On women in a confirmed or presumed state of pregnancy, particular attention is given to the justification of the examination, in particular in emergency, and to the optimisation of the MRI examination, in relation to and taking into consideration both the health of the patient that of the unborn child. **However, it is advisable not to perform MRI examination in female patients during the first trimester of pregnancy.**

Execution

Patients can undergo the MRI examination only after excluding any possible contraindication to the MRI examination, to be ascertained by the Doctor Responsible for the diagnostic service, after consulting the patient's medical history questionnaire and the informed consent form. To carry out the MRI examination it is necessary for the patient, supported where necessary by the service personnel to:

- remove any face make-up and hairspray;
- deposit any metallic, ferromagnetic or magnetic support objects (mobile phones, coins, watches, keys, earrings, pins, jewellery, hair clips, magnetic cards, credit cards, and so on) in the changing room or in the appropriate lockers;
- remove any dental appliance and hearing aid;
- remove contact lenses or glasses;
- undress, and then wear the specific single use gown provided by the service staff;
- use the headphones or earplugs provided.

The average duration of the MRI examination is approximately 30 minutes, but it may vary depending on clinical needs and the number of anatomical districts to be examined. During the data acquisition phase of the MRI examination, rhythmic noises of variable intensity caused by the normal functioning of the MRI equipment can be heard. Ventilation, lighting and temperature conditions ensure maximum well-being and reduce any possible claustrophobic effect.

During the examination phase it is necessary to remain calm and maintain the maximum degree of immobility in order not to compromise the diagnostic result of the image. Regular breathing and swallowing saliva do not disturb the examination. In some types of investigations the patient may be asked to collaborate by breathing or by holding short periods of apnoea in order to improve the diagnostic quality of the images. Service personnel are always present in the control room ready to intervene in case of any need. The patient is always in vocal, acoustic and visual contact with the operators, who carry out constant monitoring throughout the entire examination phase. In case of disturbances, such as sensations of claustrophobia, heat, itching, breathlessness, palpitations or fainting, the patient should inform the Doctor responsible for carrying out the MRI examination as soon as possible, using the appropriate signaling devices.

Patients with intrauterine contraceptive devices (spirals or IUD) should check their correct positioning after the exam.

Patients must carry out a preliminary blood CREATININE measurement and glomerular filtration calculation (max 1 month) and present it to the medical staff of the MRI section in order to evaluate their renal function.

To carry out a **test using a contrast medium**, you must be fasting for **at least 6 hours** (with the exclusion of medications usually taken which can be ingested with a little water). When carrying out tests with contrast medium it is essential to warn in advance of important known **allergies and asthmatic conditions.**

It is not necessary to interrupt any ongoing drug therapies (e.g. for hypertension or diabetes).

Possible complications

During the MRI examination, adverse reactions are very rare. The most probable eventuality is represented by a temporary crisis of claustrophobia. The use of the contrast medium based on paramagnetic substances is generally well tolerated and does not cause any particular sensation. However, episodes of hypersensitivity such as urticaria or other allergic phenomena, heat, itching, breathlessness, palpitations or feeling of malaise may rarely occur. In very rare cases, episodes of anaphylactic shock have been reported. The MRI site always guarantees the presence of specialised medical personnel ready to intervene in the event of any medical emergency of this kind.

Information note relating to the contrast medium somministration in MRI

The administration of the contrast medium intravenously is an integral part of the MRI examination and, in some types of investigations, is essential for a correct diagnosis. The characteristics of these drugs ensure safe use, "while taking into account the generic risks of hypersensitivity, characteristic of every injectable formulation" (Circular of the Ministry of Health 900.VI/11.AG./642 of 17.9.97).

Patients with moderate and **severe renal insufficiency** who are administered a Gadolinium-based contrast medium intravenously are exposed to an increased risk of developing a rare disease known as *Nephrogenic Systemic Fibrosis* (NSF). NSF is a rare pathology characterized by thickening of the skin and connective tissues, which is debilitating and potentially fatal.

Based on recent evidence in literature, the use of Gadolinium-based contrast medium, in patients considered at high risk, in patients undergoing dialysis and/or kidney transplant recipients, is strictly linked to a conscious and shared choice between the requesting clinician and radiologist, in compliance with the lowest biological cost and best diagnostic response. The administration of the contrast medium can sometimes lead to some mild side effects (feeling of heat, redness, nausea, vomiting, headache, skin rashes, itching) which, with an unpredictable and quantifiable but still very low incidence, can also induce serious allergic reactions until anaphylactic shock**. It is therefore necessary to inform the Doctor in charge of the exam of any type of allergy before the exam itself**. The health personnel of the Operational Unit are always present inside the structure to guarantee prompt intervention in case of emergency.

Any pregnancy must be communicated in advance to the Doctor in charge of the MRI examination, as the use of Gadolinium in pregnant women requires an evaluation of the risk/benefit ratio. (Xagena2003) Source: UCSF (University of California San Francisco). In this regard, we inform you that low-dose Gd-chelated contrast agents do not create any issues.

It is also advisable to communicate the possible breastfeeding phase of your child to agree on any methods and times of interruption in relation to carrying out the MRI exam. Any clarification regarding the performance of the MRI exam with contrast medium can be requested from the Operating Unit staff.

Having taken note of the information provided in the consent form, the patient can request further explanations from the radiologist.

Source: *Società Italiana di Radiologia Medica e Interventistica (SIRM)*.