

## Laboratory rules for the use of the 7 Tesla MRI at the Leibniz Institute for Neurobiology

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### § 1 Scope of application

These laboratory rules apply to all scans carried out using the 7 Tesla MRI at the Leibniz Institute for Neurobiology ("LIN"). In particular, they apply irrespective of the institutional affiliation of the users, the funding body, financing and management of the respective study, and the type of use (application or service operation; phantom or study participant scanning).

### § 2 General requirements of users; safety instructions; training and user categories

- (1) 7 Tesla MRI scans may only be carried out by users with the necessary training, knowledge and experience. A scan in the aforementioned sense includes all activities before, during or after scanning using the 7 Tesla MRI that facilitate the preparation or implementation of the scanning process and the briefing or preparation of study participants (hereafter referred to under the umbrella term of "use" of the 7 Tesla MRI).
- (2) Any person who wishes to take part in training in accordance with para. (3) or who wishes to use the 7 Tesla MRI, must, within the current or preceding calendar year, have undergone safety training. Their participation must be evidenced in writing. The safety training consists of a presentation in which the participants are familiarised with general rules of conduct and safety-relevant principles regarding the MRI plus an explanation of safety-related occurrences involving the 7 Tesla MRI.
- (3) Using the 7 Tesla MRI requires training. Training courses are exclusively carried out by the persons appointed for this purpose by the LIN and registered in the 7 Tesla MRI medical device log. Training courses must be evidenced by a corresponding entry in the 7 Tesla MRI medical device log, which contains the date of training, the name of the person trained and the signatures of those involved. Trained users receive password-protected access to the LIN e-groupware server.
- (4) Trained users are grouped into user categories by the LIN. The categorisation determines the scope of authorisation to use the 7 Tesla MRI. The LIN checks the categorisation of users as part of the allocation of scanning time slots via the e-groupware server as well as through random checks of the respective scans. Users are categorised at the discretion of the LIN based, in particular, on
  - their general level of training, knowledge and experience,
  - their experience in the use of the 7 Tesla MRI and
  - their confidence in dealing with the 7 Tesla MRI and test participants.

Users who have been trained in accordance with paragraph 3 of these rules will initially be allocated to category 1. It is only possible to move into a higher user category from the preceding user category. It is also possible for a user's categorisation level to be reduced, for example if the user has not carried out any scans using the 7 Tesla MRI during the previous 6 months, or if they infringe the laboratory rules. There is not entitlement for a user to be assigned to a specific category.

- (5) **Category 1:** Category 1 users may carry out scans on phantoms independently.
- (6) **Category 2:** In addition, category 2 users may carry out scans on study participants under the supervision of category 3 users. Reaching category 2 requires substantial experience in the use of the 7 Tesla MRI and practised, confident and responsible handling of the machine.
- (7) **Category 3:** Category 3 users may carry out scans on study participants independently. Reaching category 3 requires extensive experience and a practised and confident handling of feedback from the 7 Tesla MRI (for example in the event of abortive adjustments, SAR or stimulation warnings) and when dealing with study participants (especially with regard to their briefing, preparation and positioning, actions when the alarm ball is used, and conducting reviews).

### § 3 General rules of conduct

- (1) Within the context of the use of the 7 Tesla MRI the rules of conduct apply that were defined in the safety briefing and the training in accordance with § 2. In addition, the following general rules of conduct apply:
- (2) The 7 Tesla MRI must only be used in compliance with its designated purpose of non-invasive imaging of the human body for research. It may only be used within the context of a research project that has been approved by the LIN in accordance with the criteria set out in § 7 of the Rules of Use.
- (3) The 7 Tesla MRI may only be used once the user, within the context of the possibilities available to him or her, and, as set out in the training, is satisfied that the 7 Tesla MRI is capable of functioning and is in a proper condition.
- (4) The 7 Tesla MRI must be used taking into consideration the operating instructions and other applicable safety-related information including these laboratory rules. The relevant information is available in paper form in the control room. It is also available to trained users in electronic format via e-groupware.
- (5) Users may only remain in the magnet or control room of the 7 Tesla MRI for as long as is needed for its use.
- (6) Users may only enter the magnet room if it has been ensured that another person is within earshot and sight for the duration of their presence there.

- (7) The introduction of ferromagnetic objects of any kind into the magnet room is forbidden; exceptions must be agreed with the operator.

#### **§ 4 Special rules of conduct for study participant scans**

- (1) Study participant scans may only be carried out using the scanning protocols and sequences that are set out in the "List of Permitted Scanning Protocols and Sequences" available in paper form at the operating station of the 7 Tesla MRI ("**permitted sequences and protocols**"). The use of sequences and protocols other than those permitted must be agreed with the operator.
- (2) When carrying out scans on study participants, two users must be present in the 7 Tesla building, of whom at least one must be a category 3 user. The people responsible for carrying out the scans must be able to enter the magnet room at any time. In particular, they must not be wearing any ferromagnetic clothing or items. At least one of these people must, in addition, be in a position to verbally communicate fluently with the study participant.
- (3) When conducting scans on study participants, there must always be a German-speaking person on direct standby to contact the emergency doctor if necessary.
- (4) Before conducting a scan on a study participant, the study leader must check on the need for doctor to be present and ensure their presence if required.
- (5) Before conducting a scan on a study participant, the participant must take part in an information briefing. During the information briefing, the study participant must be asked if they have had any operations or if they wear dental braces / false teeth in order to exclude the possibility of any ferromagnetic objects in or on their body. In case of doubt (e.g. gall bladder / appendix / knee operation), the corresponding operation report must be requested before the scanning process takes place and submitted to the study contact person nominated by the LIN in accordance with § 7 of the rules of use. This person shall then make a decision about whether to approve the scanning of the study participant depending on the description of the implant / material. The user may only conduct the scan on the study participant if they are able to exclude the risk of metallic objects in the body of the participant without any residual doubt.
- (6) Every study participant must complete and sign an up-to-date copy of the MRI consent form provided by the LIN prior to the scan. This is also required if a study-specific consent form has already been signed in advance.
- (7) All study participants must put on ear defenders and metal-free clothing before any scan.
- (8) Immediately before entering the magnet room, each study participant must be asked once again whether they have removed all objects about their person (for example jewellery, watches, glasses, mobile phone, braces, false teeth).
- (9) As a general rule, entering the magnet room during a scan, which begins with the positioning of the study participant, is only permitted for the users responsible for carrying out the scan, or must be agreed with them.

#### **§ 5 Documentation requirements**

(1) The users must make the following entries in the laboratory log for every study participant scan:

1. date and time (of the start and finish of the scan)
2. study participant initials with consecutive number
3. the coil used,
4. the reference amplitude,
5. the name of the associated study,
6. the protocols measured and
7. the name and signature of the responsible user.

The laboratory log is completed in writing by the respective user and is kept at the 7 Tesla MRI operating station. A sample sheet for entering a scan in the laboratory log is included in the appendix to these laboratory rules.

(2) Users must immediately report any malfunction of the 7 Tesla MRI, or of the medical devices associated with it or its auxiliary equipment and any mistakes made during its operation, irrespective of their nature or effect on the scanning process, by telephone to the operator's personnel responsible for the MRI or, with a precise description by email to [7Tesla@lin-magdeburg.de](mailto:7Tesla@lin-magdeburg.de).

## **§ 6 Structural, technical and other changes; changes to programming; saving of data**

(1) Changes to

- the 7 Tesla MRI including its operating controls, controlling computer, stimulus computer and auxiliary equipment and
- the magnet room,

irrespective of whether the changes are

- structural or technical,
- to electrical installations,
- changes to hardware components,
- changes to or upgrades of software or
- other changes,

are not permitted. Exceptions must be agreed with the operator.

(2) Any manipulation of the programming of the controlling or stimulus computers is not permitted. The transferring of new scanning protocols, sequences or ICE programmes must be documented in the equipment log. Overwriting the permitted protocols and sequences in accordance with § 4 para. 1 is only permitted with the prior approval of the LIN. Approval by email must be applied for at least two weeks in advance of the notified scan by indicating the planned changes in an email to [7Tesla@lin-magdeburg.de](mailto:7Tesla@lin-magdeburg.de).

- (3) Using the 7 Tesla MRI with the parallel use of several transmitter coils (TX array) is subject to separate rules within the framework of Ethics Committee Approval 27/07 of the Ethics Committee of Otto von Guericke University Magdeburg and is only permissible in the cases stated and under the conditions set out therein.

## § 7 Saving, deleting and accessing scan results

- (1) Scan results and other data may only be stored on the controlling computer in the following files: "C:\temp\", "C:\User\", "C:\MedCom\Temp", "C:\MedCom\User" ("**Temporary storage**"). Users must externally back up any data saved by them immediately after the end of a scan and delete any data they have saved on the controlling computer as soon as possible. The users are personally responsible for the permanent external storage of their scan results and other data.
- (2) The temporary storage is emptied at regular intervals of approx. one week. This means that all scan data is irrevocably deleted from the temporary storage ("**regular emptying of the memory**").
- (3) Data from scans on study participants saved in the temporary storage will be saved as a tar file on a LIN server by LIN employees prior to the regular emptying of the memory. Only images of scans will be saved, but not spectra or other scan data. Images of phantom scans will only be saved at the express request of a user. If no storage request has been made, the results will be deleted from the temporary storage as part of the regular emptying of the memory.

## § 8 Relationship to other regulations

- (1) The LIN rules of use apply with regard to access to the 7 Tesla MRI, and in particular the registration and approval of studies, the registration and issuing of scanning time slots and the reimbursement of costs. These can be viewed on the LIN website ([www.lin-magdeburg.de/cni](http://www.lin-magdeburg.de/cni)) in the "Documents" section.
- (2) The applicability of the occupational safety and accident prevention regulations, the medical device operator ordinance (MPBetreibV) and the medical devices safety regulations (MSPV) as well as any other applicable statutory regulations remains unaffected. In case of doubt, they shall take precedence over the provisions set out in these laboratory rules.

**Attachment:** Example Page for Laboratory Note Book

<b>Datum/Date</b>	<b>Probandenkürzel_Fortlaufende Nummer/ Subject ID_Running Number</b>	<b>Spule/Coil</b>
		<b>Referenzamplitude (V)</b>
	<b>Studienname/Study name</b>	
<b>Startzeitpunkt/ Start time</b>	<ol style="list-style-type: none"><li>1. Localizer</li><li>2. ...</li><li>3. ...</li><li>4. ...</li><li>5. ...</li><li>6. ...</li><li>7. usw.</li></ol>	
<b>Endzeitpunkt/ End time</b>		
		<b>Platz für Bemerkungen/Störungen → Störungen unbedingt im „Gerätebuch 7Tesla – Störungen und Fehlermeldungen“ dokumentieren und eine Email an joerg.stadler@LIN-magdeburg.de</b>  Space for notes and errors → <i>IMPORTANT: Please document errors in the “Gerätebuch 7Tesla – Störungen und Fehlermeldungen” and send an email to joerg.stadler@LIN-magdeburg.de</i>
	<b>Name und Unterschrift des Operators/ Name and Signature of Operator</b>	