

Usage Regulations of the Erwin L. Hahn Institute for MRI (ELH)

Following the board decision on 04.12.2024

1. General

These usage regulations apply to the MAGNETOM Terra 7 Tesla whole-body magnetic resonance imaging (MRI) system from Siemens Healthcare, located at the Erwin L. Hahn Institute for Magnetic Resonance Imaging (ELH). They establish fundamental rules for safe, efficient, and proper operation. The usage regulations are binding for all internal and external users of the ELH.

Users of the ELH have access to the 7T MRI system and the associated hardware and software. The available equipment and device specifications can be found on the ELH website.

2. Management and contacts

For administrative questions, contact the manager of the ELH. For technical and scientific inquiries, reach out to the ELH physicists. For questions regarding measurement time booking, contact the radiographer. The ELH is overseen by a board that makes decisions on fundamental matters of the institute. The contact information for all relevant personnel can be found on the ELH website.

3. Access and usage priorities

The MAGNETOM Terra 7 Tesla MRI system is accessible to all working groups of the ELH (internal users) after prior consultation and a mandatory briefing. All internal users have the same priority regarding the booking of the 7T MRI system. In the case of full utilisation, the allocation of usage priorities will be decided by the Measurement Time Committee, consisting of the ELH manager and the two ELH physicists in consultation with the radiographer. External users (academic and private sector) can only be granted access if sufficient capacity is available.

The ELH is equipped with an electronic locking system and an alarm system. Access is granted via transponders issued by the ELH office upon request. The sharing of issued transponders with third parties is not permitted. The loss of transponders must be reported to the ELH office immediately. Users may be held liable for lost transponders.

4. Project Application and MRI Booking

All users must discuss their planned projects with an ELH Principal Investigator (PI) and an ELH physicist before using the 7T MRI system. They must ensure that the project meets the necessary criteria to be initiated (in the case of a pilot project) or presented (in the case of a full project). Booking measurement time is only possible with a valid project number. Project numbers must be applied for by submitting a project proposal and completing the required documentation. Detailed information on how to submit a project can be found on the PANDA website (see point 14). A pilot project can be applied for with 6 hours of measurement time, or a full project with more measurement time. Full projects must be presented to the ELH members in project

proposal meetings (PPMs). For the project presentation, the ELH slide template should be used, and the presentation must be uploaded to Panda at least one week prior to the presentation. PPMs are typically held on the first Wednesday of the month at 10 am in the ELH conference room and online. The responsible ELH PI and the designated ELH physicist, along with the manager and the scientific director, will decide whether the presented project is approved and will determine the final extent of the measurement time. The originally requested scanning time for a project can be extended upon request. Furthermore, any changes to the details on the project application must be communicated to all signatories and confirmed by the manager before any further measurement times can be booked.

The 7T MRI can be reserved through the ELH online booking system, PANDA. Booking requests can be sent via email to scantime7T@uni-due.de or entered directly into the booking calendar and must include the following information: project number, desired booking date and time, whether in-vivo or phantom measurements will be conducted, and whether the radiographer is required. The booking is valid upon receipt of the confirmation email.

Bookings can only be made by ELH-certified MR operators who have been trained on the 7T MRI, have received the appropriate safety instruction, have an approved project, sufficient remaining measurement time within that project, and are listed as booking-eligible on the project proposal. Measurements can be booked up to three months in advance of the target date. The ELH reserves the right to reschedule or cancel individual appointments for urgent technical or organisational reasons after consultation with the users.

5. Cancellations

Reserved appointments that cannot be kept by users must be cancelled as early as possible and removed from the booking system. Only cancellations made up to three working days before the scheduled measurement date will not be deducted from the project's measurement time.

6. Services and Responsibilities of the ELH

The responsibilities of the ELH include:

- Briefing: All users receive appropriate technical instruction and safety training before they are allowed to independently use the 7T MRI system. These training sessions are the basis for authorisation in the online booking system.
- Project planning: Users are supported and advised by the ELH staff regarding technical and experimental questions and issues both in the preparation phase and during ongoing projects.
- Coordination and scheduling with users.
- Optimisation for the methodological development of the 7T MRI.
- System maintenance and upkeep.

7. Responsibilities and Obligations of Users

Users are obliged to:

- Implement the DFG guidelines for ensuring good scientific practice.
- Acknowledge and act in accordance with the present usage regulations and the data management instructions of the ELH.
- Comply with the general regulations for occupational safety and the operational instructions.
- Attend the annual safety briefings.
- Operate the 7T MRI based on the handling procedures learned during their briefing. Only methods that users have been trained in are to be applied.
- In the case of human in-vivo imaging, a second person, who can be called immediately in an emergency and is an ELH-certified MR operator, must always be informed and present in the ELH building.
- Document any usage that excludes others from using the 7T MRI in the designated logbook. This includes the actual start and end times of usage, including setup and post-processing; project number; and the names of all present individuals.
- Discuss any potential pathologies in the acquired images first with the responsible ELH PI and the designated ELH physicist to determine the next steps (e.g. transfer of scans to the hospital, who and how the participant should be informed).
- Report any hardware or software issues to the ELH physicists and the radiographer immediately during regular working hours (alternatively by email). Photographs and screenshots of error messages must be taken for error reconstruction and resolution and provided to the ELH physicists. If time permits, save a 7T Siemens SaveLog.
- Leave the workplace clean and tidy.
- Inform the manager if they cease to be users of the ELH and return any issued transponders as necessary.

8. Safety Briefings

Annual safety briefings are conducted by the ELH physicists. All users must be able to provide proof of a valid safety briefing for work on the 7T MRI. The briefing must be repeated each year.

9. Data Storage

In accordance with the principles of Good Scientific Practice, research data should be archived for a minimum of 10 years. All users are personally responsible for data storage. Data should generally only be temporarily stored in the ELH Siemens control computers' database (sTx and pTx). The local hard drives of the control computers should not be used. Data should be transferred to other media (e.g. the servers of the respective research group) immediately after the MRI measurements. To avoid malware, external media used at the ELH (e.g. USB sticks, hard drives) should be regularly checked by the users. The available storage locations at the ELH that internal users can utilise (in the short and medium term) are the ELH PACS and the institute's internal network drive *userdata*. The data on the control computers are regularly reviewed by the ELH and may be deleted; therefore, the ELH is not responsible for any data saved locally.

When handling the acquired image and participant data, the SOP (Standard Operating Procedure) for data management and the associated data protection regulations must be observed.

10. Ethics Approval

A general ethics approval for 7T MRI examinations at the ELH is in place (No. 16 7214 BO). Before starting a study, it must be verified whether this is covered by the general ethics approval or if a study-specific approval from the local ethics committee (amendment) is required.

If participants are to be recruited through an official announcement, the study leader must inform the ethics committee in advance and obtain the necessary approval.

The corresponding screening form for participants, as per the existing ethics application (form for healthy participants or form for participants/patients with pathologies and/or administration of contrast agents), must be fully completed before participants are allowed to enter the safety area. A copy of the screening forms must remain at the ELH.

11. Publications

If recordings or datasets generated by the MAGNETOM Terra 7T MRI are used in publications, the DFG grant number (432657511) must be cited in accordance with the usage guidelines for large research facilities. In the case of substantial scientific contributions by ELH staff to a publication, they must be acknowledged as co-authors.

When using study protocols, WIP, or C2P, always contact the ELH physicists prior to publication.

12. Violations and Liability

Violations of the usage regulations or safety guidelines must be reported to the manager. Such violations may result in temporary or permanent exclusion from using the 7T MRI.

Users, or the respective organisational unit, are responsible for any damage to the 7T MRI that can be proven to have resulted from improper operation or gross negligence. In this case, the resulting repair and maintenance costs must be borne by the users or the respective organisational unit. The ELH is entitled to exclude users from further operation in justified cases.

For study participants at the ELH, there is a participant insurance as well as a journey and accident insurance.

Regarding participant insurance: Participants in a study are covered by insurance with a maximum coverage amount of 500,000 € per participant, which covers all damages that may arise from the measures conducted during the study. The insurance is currently provided by Zurich Insurance plc, Poppelsdorfer Allee 25-33, 53115 Bonn, Tel: 01802 02808080, Fax: 01802 025005059 (File reference 800.540.122.004).

Regarding journey accident insurance: The insurance coverage applies to accidents that participants may experience during their stay at the ELH, as well as on the direct routes to and from the ELH. Coverage is void if the journey is interrupted by private activities (e.g. shopping, visiting restaurants). The insurer covers up to a maximum of 50,000 € in the event of death and

100,000 € in the event of disability. The insurance is currently provided by SV Sparkassen Versicherung, Kölnische Straße 42-46, 34117 Kassel, Tel: 0561 78890, Fax: 0561 7889 6254 (File reference 50 036 909/880).

13. Usage Fees

Booking times are recorded through the online booking system Panda. The ELH distinguishes between academic research measurements and private/commercial measurements. The usage fees for academic research projects are based on the DFG usage flat rates for clinical and human MRIs at a field strength of 7 Tesla. Usage fees for measurements conducted for non-academic institutions are calculated according to the full-cost model of the University of Duisburg-Essen. The manager typically issues invoices based on the hours of usage on a semi-annual basis.

Usage fee for 7T MRI (valid from 01.01.2025)

- For academic research projects (DFG, MERCUR, NWO): 375 €
- For non-academic projects: 1.500 €

14. Links to Important Documents

- ELH Website: <https://hahn-institute.de/en>
- Online Booking System Panda
 - Scan time calendar:
<https://hahn-institute.de/projects/calendar>
 - Project setup:
<https://hahn-institute.de/projects>
 - Scan time extension:
<https://hahn-institute.de/projects/scantimeextension>
 - On this website, under section 7, are documents related to the project presentation (including the template), safety policy, SOP for data management, guideline and application for payment of expense allowances for volunteers, and the questionnaires for participants:
<https://hahn-institute.de/projects/help>