User guide
National 7T facility

Lund University BioImaging Center (LBIC),
Lund University
and
Department of Medical Imaging and Physiology (BoF),
Skåne University Hospital (SUS); Region Skåne

National 7T facility

Table of contents

1. How to apply for scanner access and scanning requirements

The application for scanner access is a step-by-step procedure, outlined below.

First, a project application is made to the Research Board (RB).

The research agreement (in form of an IIS; Investigator Initiated Study) between the vendor (Philips) and Institution (LBIC/LU) requires that each project and researcher signs it.

Furthermore, if applicable, applications to ethics boards (human and animal studies) or the medical products agency (Läkemedelsverket) need to be filed.

Those involved in the process are the principal investigator (PI), co-investigators assigned by PI, the 7T staff and the 7T research board. For definitions and contact information, see below.

Running a project, step by step

1. Apply for scanner access (PI and 7T staff)
    a. PI gets acquainted with the requirements for use of the national 7T facility (this user guide with appendices, 7T LBIC homepage, discussions with 7T staff).
    b. PI files an electronic project application (PA), available at the LBIC homepage.
    c. For human studies, PI applies for EPM.
2. 7T Research Board approval (RB)
    a. The 7T research board reviews and decides on the submitted project application. The 7T RB meets once per month.
    b. The PI is notified about RB's decision via email.

   c. The PI gets templates to Annex A and Annex B of the IIS, and is responsible for completing these and return two signed copies to the Philips Clinical Science representative (see further below).
   d. The PI gets a template to a "book of methods".

3. Complete project checklist (PI and 7T staff)
   Before a project can start, a checklist has to be completed to insure that all aspects of conducting the project are considered. The checklist includes RB approval, EPN approval, signed Annex A and Annex B's of IIS, training of staff, and a "book of methods" which outlines workflow, responsibilities and scan protocol.
   a. Set a meeting between PI and 7T staff where all these items are discussed, the book of methods is filled out, and time slots are determined.
   b. Arrange for training of project participants. To use the 7T facility, a certificate of authorization is needed, and to perform scanning a certificate of competence is required.
   c. The project is registered in the booking system. User fees will be calculated based on information registered.

4. Project phase (PI)
   a. The project is conducted according to the agreed plans.

5. Annual project reports
   a. The PI is required to send annual project reports to the 7T RB until the project is finished, including publications and conference contributions.
   b. The RB will send out a progress report forms to the PI in Q1 every year.

6. Finalizing a project
   a. Upon completion, the PI will be asked to fill out a survey or be interviewed on the experience of the project and facility.
   b. All publications from the project have to be reviewed by a Philips Clinical Scientist before submission
   c. All publications should acknowledge the support from the 7T facility; *"The National 7T facility at Lund University Bioimaging Center is gratefully acknowledged for providing experimental resources."*

PI = Principal investigator
PA = Project application (electronic form on LBIC homepage)
LBIC homepage: https://www.lbic.lu.se/platforms/the-swedish-7t-facility
RB = Research board

2. The research agreement (Investigator Initiated Study, IIS) with the vendor (Philips)

The 7T scanner is a research equipment and all scientific studies are performed under a research agreement between LBIC (LU) and the vendor (Philips Medical Systems, Best, The Nederlands). The general research agreement is an Investigator Initiated Study agreement (IIS). IIS documentation is obtained from the facility on request. A brief summary of is found in Appendix 4.

Each project has to consist of one Annex A and several Annex B, appended to the general IIS. Templates for the Annexes is provided after project acceptance in the research board.

Unless the project requires equipment from Philips (hard- or software) beyond what is already delivered, the project will be "standard clinical research", otherwise it will be "expanded clinical research".

Annex A: The study-specific Clinical Research Plan, which needs to be signed by the PI, Institution (LBIC director) and Philips.

Annex B: Each study participant (Investigator) has to sign his/her own Annex B, in which the individual Investigator acknowledges to have read the IIS agreement, and agree to be bound to the terms and conditions of the Agreement, including the Clinical Research Plan in Annex A. The Annex B is to be signed by 1) any investigator related to a study performed under the IIS, 2) the investigators employer, 3) Institution (LBIC director), 4) Philips.

Practical details: Sign Annex A and all Annex B's. Send them by email or mail to Pia Sundgren, who after signing them will hand them to the Philips Clinical Scientist at the 7T, who collects the Philips signatures.

3. Ethics approval

If the project includes scanning of research persons or animal experiments, ethical permission has be obtained from Etikprövningsmyndigheten. Contact the facility for specific questions.

For more information, please see: https://etikprovningsmyndigheten.se/ for studies with human subjects.

4. Other applications

It is the responsibility of the PI to apply any further approvals required for the conduct of an individual study according to Swedish and/or local regulations. Please note that if other BoF equipment will be used, a separate application to the BoF forskningsråd is needed.

Forskningsrådet BoF, SUS: https://vard.skane.se/skanes-universitetssjukhus-sus/om-oss/specialistomraden/bild-och-funktion/forskningssamarbete-med-bild-och-funktion/

Läkemedelsverket: http://www.lakemedelsverket.se/

Strålskyddsmyndigheten: http://www.stralsakerhetsmyndigheten.se/start/

Strålskyddskommittén Skånes Universitetssjukvård: http://intra.skane.se/Organisation--Ledning/Natverk-och-arbetsgrupper/Sakerhet-och-miljo/Stralsakerhet/Stralskyddskommitten-Skanes-Universitetssjukvard/

5. Other requirements for users of VR funded national infrastructures

The requirements stated by the Swedish research council are summarized below.

A. The equipment is open and equally available for Swedish researchers. Projects will be prioritized according to scientific merit in case of limited access time.
B. For this purpose, a nationally composed research board is established. See Appendix 1.
C. User support is available: See Appendix 3 below.
D. Publications: Research at the 7T facility is expected to result in scientific publications in journals with international coverage.
E. The equipment grant should be acknowledged by mentioning the grant, *VR-RFI 829-2010-5928.*
F. Open access: The VR policy for Open access must be followed, see www.vr.se
G. Co-authorship: VR recommendations and policies are to be followed, see www.vr.se
H. In addition, the following policies are adapted by the National 7T facility:

a. We ask authors to acknowledge LBIC using the following sentence: *The National 7T facility at Lund University Bioimaging Center is gratefully acknowledged for providing experimental resources.*
b. The National 7T facility strongly encourages sharing of for example pulse sequences, patches and other methodology between groups.

6. Scanner fees

Information about 2019 scanner fees and comments/explanations can be found on the LBIC homepage https://www.lbic.lu.se/platforms/the-swedish-7t-facility

7. Contact information

7T STAFF

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8. Appendix 1: 7T research board

The national 7T facility is open and equally available for all Swedish researchers and projects will be prioritized according to scientific merit in case of limited access time and availability of other resources. For this purpose, a nationally composed research board (RB) has been established and assembles monthly.

Present members

Isabella Björkman-Burtscher	*University of Gothenburg*
Boel Hansson	*Lund University*
Gunther Helms	*Lund University*
Peter Lundberg	*Linköping University*
Pia Maly Sundgren, ***chair***	*Lund University*
Karin Markenroth Bloch	*Lund University*
Greger Orädd	*Umeå University*
Cecilia Petersen	*Skåne University hospital*

Örjan Smedby	*KTH*
Göran Starck	*University of Gothenburg*
Johan Wikström	*Uppsala University*

The tasks of the RB:

- Approve or reject projects and if applicable define conditions for approval.
- Prioritize projects according to scientific merit in case of limited access time or limited availability of necessary support.
- Give guidance and support to PI´s applying for research time, for example by giving constructive comments on applications.
- Define adequate user fees for accepted projects.

9. Appendix 2: Which support can be provided?

A group that helps the user with his/her project is available on-site. This "7T staff" (see "contact information" in the main document) acts as contact persons to all researchers interested in applying for scanner time.
As for all scanners and systems provided by LBIC, we would like to draw the user´s attention to the following:
The national 7T staff is limited and not all contact persons work with the 7T full time, but the staff is committed to helping researchers with their projects.
As a general rule, the staff will as far as possible help with:

- Initial discussions and design of experimental layout.
- Advice regarding filing project applications.
- Assist in performing pilot studies and methodology development for the project.
- Initial pilot studies/technical development of general interest can in certain cases be performed by the facility.
- Giving 7T specific education which is required to handle the equipment. The training is scheduled with the research technologist and contains handling of the equipment and information of routines according to local regulations (Verksamhetsområde Bild och Funktion VO BoF, Skåne University Hospital, Lund and LBIC, LU). There are two levels of licenses, certificate of authorization ("assistant license") and certificate of competence ("scanning license").
- Limited assistance with platforms for data storage, data transfer and image analysis tools.
- The clinical department VO BoF at SUS Lund can together with LBIC provide radiograhers to assist in equipment handling and scanning, but these resources are limited and the support has to be agreed on during the project application process.
- A newsletter is distributed to keep the users updated on local regulations, system state and practical things regarding the use of the system. Normally, a PI with an accepted RB decision will be automatically included in the newsletter email list, but researchers without an accepted project are welcome to contact Karin.markenroth@med.lu.se to be included in the list.

Unless they are participants in the project, the staff does not have resources to develop methodology "from start to goal" for a project, to perform large investigational experiment series, to recruit subjects for scanning, or to perform image analysis or statistical data analysis for the research group.

10. Appendix 3: Brief summary of the Research agreement (IIS) Lund-Philips

The following is an unofficial summary of some contract items relevant for investigators. For the legally binding text, the reader is referred to the full IIS, which can be obtained by from the 7T facility staff.

- **Obligations of the PI**: The PI is responsible for the scientific conduct of the research, for the Clinical Research plan, and for ensuring that informed consent is obtained from all humans subjects. The PI shall obtain ethics approval prior to start of project and before enrolling subjects. If the PI can't pursue the Clinical Research, Philips and LBIC can consent to a substitute PI. The PI is responsible for all investigators in the project.
- **Obligations of the institution**: As the institution. LBIC is responsible for the technical conduct of the research. LBIC is responsible towards Philips for the PI and all investigators have signing all documents needed, including Annex A and Annex B, ethical permissions, and so forth. LBIC must ensure that only qualified personnel operate the 7T MR and other equipment. LBIC must report incidents (adverse events or situations that could have resulted in an event) to Philips within two days.
- **Standard clinical research**: Using the system as delivered by Philips without additional support from Philips. Pulse-programming tools and support from the Clinical Scientist on site is considered a part of the delivery.
- **Expanded clinical research**: Projects where hardware, software or other support not included in the system delivery is supplied by Philips. (Example: a patch provided by Philips). For such projects, more extensive reporting to Philips is required (i.e. PIs CV, periodic progress reports).
- **Publications**: The IIS requires all publications to be made available to Philips before submission; for conference abstracts 5 days before submissions and for papers 30 days before. In practice, the manuscript should be sent to the Philips clinical scientist affiliated to the 7T (see staff overview).
- **Confidentiality**: Items and information that Philips provides are presumed to be confidential until Philips in writing advises to the contrary. Confidential information must be kept confidential and may only be used for the research carried out under this agreement. It is not allowed to copy or transfer any part of the Philips software.
- **Intellectual property rights**: All rights to an invention made solely by LBIC, PI or investigators resides with the inventor, who must have signed Annex B. Philips and its affiliates are granted a worldwide license to Inventions made by Philips personnel resides with Philips. Any joint invention, meaning that both Institution and Philips personnel are involved, will be jointly owned and each party will have equal and unrestricted ownership.

11. Appendix 4: What can be expected from 7T MRI

The 7T MRI scanner is not a routine scanner for clinical use, although it utilizes the same software platform as the vendor´s clinical products. The 7T scanner is not labeled as a medical device, and all experiments on human subjects must be performed under adequate ethical permission[1]. Details on the scanner HW and SW specifications, available equipment and basic protocols will be found at the facilitys home page.

[1] BoF/SUS has completed an inhouse manufacturing process for the 7T scanner in Lund, so that it is legally allowed to refer clinical patients to 7T MRI for diagnostic purposes. This was the first 7T in the world to be approved for clinical use. However, there is as of yet little clinical evidence for using 7T MRI, and referrals are restricted.

The 7T site strives to offer a basic set of protocols for morphological and functional scanning. However, be aware that the optimal protocols for each specific project are reached by running pilot scans at the site, in collaboration between the site staff and the project participants.

Parameter	Effect	Advantage	Disadvantage
Signal strength, M_0	Increases linearly with B_0	Increased SNR	-
Resonance frequency, f_0	Increases linearly with B_0, f_0(7T)=300 MHz	Better separation of peaks in MRS	SAR increases with f_0^2, chemical shift artefacts
T_1	In general increases, tissue specific	Better saturation, persisting tags (ToF angio, ASL)	Longer scan times in many cases
T_2, T_2^*	In general, decreases, tissue specific	Increased -effects and BOLD contrast	Faster T_2-decay requires short TE, increased linewidths

Among the main reasons to use 7T is high signal-to-noise (SNR), better separation of metabolite peaks in MR spectroscopy, increased susceptibility effects, enhanced fMRI contrast and increased T_1. However, several of the advantages mentioned above also create disadvantages, for example artifacts from susceptibility effects, increased linewidths due to shorter T_2-times and longer scanning time due to higher T_1 values.

An effect of the high RF frequency (approximately 300 MHz, giving wavelengths that are shorter than the scanned object) is that the user has to be prepared for inhomogeneous RF excitation patterns over the selected field-of-view. SAR values are reached faster at 7T compared to 3T and 1,5T. Practical consequences of elevated power deposition is that sequences needs to be modified and may not meet e.g. minimum TE/TR values at lower field strengths.

Furthermore, RF coil technology is still an active research field at 7T. It should be noted that all coils are transmit/receive coils as no body transmit coil is installed in the 7T system. As each coil is transmitting, the coils SAR simulations are body part specific and it is not allowed to scan body parts outside the coils intended use. For an overview of the currently available coils, refer to the homepage.

A 7T system differs from a clinical system only with respect to the main magnetic field, while gradient and RF fields follow the same regulations as clinical scanners and have similar specifications

The stray field from the scanner is compacted using active shielding technology, and the scanner room is designed to encompass the 0.5 mT (5G)–line within the scanner room. A consequence of the reduced stray field in combination with the high magnetic field in the center of the scanner is a large spatial field gradient when moving towards the scanner. Safety issues and regulations will be thoroughly discussed with the users of the system prior to the start of all projects.

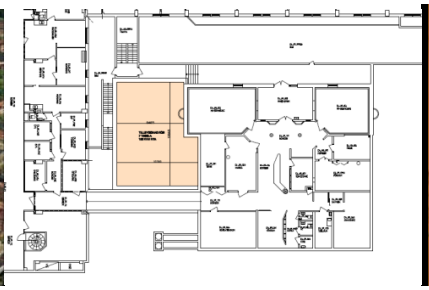
Further reading:

- https://www.lbic.lu.se/sites/lbic.lu.se/files/philips_e-learning_7t.ppsx
- 7-T MR - from research to clinical applications? Moser E, Stahlberg F, Ladd ME, Trattnig S., NMR Biomed. 2012 May;25(5):695-716
- MRI at 7 Tesla and above: demonstrated and potential capabilities. Kraff O et al, JMRI 2015; 41(1): 13-33
- www.revisemri.com/blog/2009/mri-field-strengths/

12. Appendix 5: Short overview - the Swedish National 7T facility

The application for the national7T facility was submitted to the Swedish research council (VR) in April 2010. Applicants were representing Lund University (LU), Umeå University, Uppsala University, the Karolinska

Institute, Linköping University and Gothenburg University. The application was granted in late 2011 by VR/RFI. In April 2011, after signing the funding contract between VR and LU in March 2011, a nationally composed purchase group was formed. In February 2012, the purchase contract was signed between Lund University (equipment), Region Skåne (building) and the vendor (Philips). The vendor provides equipment as well as the building for the scanner. The national 7T facility is owned by LU via Lund university bioimaging center (LBIC), it is placed centrally at Skåne University Hospital, Lund (SUS, Lund), and is operated within the Department of Medical Imaging and Physiology (Verksamhetsområde Bild och Funktion, VO BoF) at SUS. The 7T site falls within VO BoF under the section of Neuroradiology. In close proximity to the 7T facility another two scanners (Siemens 3T and 1.5T) are located and an additional 3 MR scanners (one 3T and two 1.5T) are located in house. The magnet arrived in December 2014 and the operative start time for the facility was October 1, 2015.


The system consists of a basic system package at delivery and an upgrade plan, in turn consisting of pre-defined upgrades and funds for future, not already defined upgrades. The contract also includes a 7-year combined warranty and full service undertaking from the vendor.