German Ultrahigh Field Imaging

Recommendations regarding access procedures and user access rules at German ultra-high-field sites

An important goal of the GUFI project is the harmonization of access procedures and provision of recommendations to establish or develop user access rules in order to achieve a standard approach in the operation of ultra-high-field MRI.

These recommendations have been developed on the basis of a survey of all German ultra-high-field sites. The survey revealed a very similar approach at all sites for planning and conducting ultra-high-field MRI projects. The following common points can be summarized as a result of this survey. The procedure described is a consensus and is supported by all ultra-high-field sites involved in the DFG-funded GUFI project as a basis for future studies. Deviations in details are possible and can be sensible, and additional aspects can be considered locally.

Procedure for planning and realization of projects at ultra-high-field MRI

1. The Principle Investigator shall provide a written project description that describes preliminary work, hypotheses, required equipment, the required measurement methods (sequences), as well as the necessary number of subjects and/or measurement time. The description should clearly state why the question to be answered requires measurements at ultra-high-field MRI. In addition, it should be pointed out whether or how the study shall be financed.

2. A commission of representatives operating the ultra-high-field device shall decide whether the study is feasible with reasonable effort. The main criteria for the decision are scientific quality of the concept, the relationship between effort and likelihood of success, and the need or advantage of ultra-high-field MRI.
   It is possible to place conditions on the approval or request amendments to the project description. It must be clarified whether a separate vote of the ethics commission is required for the study and whether it is necessary to conclude a separate insurance policy for the subjects.
   If possible, an employee of the MRI laboratory should be named who shall act as the main contact person for the study.

3. The project can alternatively/additionally be presented as a talk.

4. The Principle Investigator is responsible for adherence to the following conditions:
   a. The measurements may only be performed by persons:
      - who have been instructed on the ultra-high-field MRI device where the study will be performed,
      - who are familiar with the use of the ultra-high-field measurement technology at the local site, and
      - who have attended the regular safety training course.
      - Physicians who accompany measurements must also have attended the regular safety training course.
   b. Informing of the subject and check for contraindications:
      - Before performing a measurement at ultra-high-field MRI, the Principle Investigator must check the subject for possible contraindications[1].
      - The subject shall receive an information sheet in which they are informed about the procedure of the investigation and the method of magnetic resonance imaging, the aim of the measurement, and possible side effects. In addition, the information sheet shall contain a questionnaire for evaluation of possible contraindications.
   c. Local user procedures and laboratory rules[2] must be observed.

5. Required additional examination devices (for example, RF coils or stimulation devices for fMRI etc.) must be tested and approved for use at ultra-high field.

6. If new hardware and sequences will be used for measurements with subjects for the first time, these measurement protocols and the hardware must be previously tested and approved in order to eliminate sources of error and to ensure proper operation. A pilot measurement is also recommended.

7. Data from devices without a CE label are generally not intended for medical diagnosis. Exceptions are possible in cases that are narrowly defined by law (for example, as part of clinical trials).

8. After completion and analysis of the measurements, the results should be presented.

[1] Refer to the GUFI document: *Approval of subjects for measurements at ultra-high-field MRI.*

[2] The user procedures and laboratory rules describe the code of behavior for persons conducting measurements and for persons being examined as well as rules of conduct for operating the available equipment.

List of GUFI Partners

Physikalisch-Technische Bundesanstalt, Berlin Ultrahigh Field Facility (B.U.F.F.)

Max-Delbrueck Center for Molecular Medicine, Berlin Ultrahigh Field Facility (B.U.F.F.)

German Center for Neurodegenerative Diseases (DZNE), Bonn

Universitätsklinikum Erlangen, Institute of Radiology

Erwin L. Hahn Institute for Magnetic Resonance Imaging, Essen

University Medical Center Freiburg, Department of Radiology, Medical Physics

German Cancer Research Center Heidelberg, Division of Medical Physics in Radiology

Forschungszentrum Jülich, Institute of Neuroscience and Medicine

Max Planck Institute for Human Cognitive and Brain Sciences, Leipzig

European Centre of Excellence in Ultra-High-Field Maastricht, scannexus

Leibniz Institute for Neurobiology Magdeburg, Non-Invasive Brain Imaging

Otto-von-Guericke-University of Magdeburg, Department of Biomedical Magnetic Resonance, Magdeburg

Max-Planck-Institute for Biological Cybernetics, Tübingen

High Field MR Centre, Medical University of Vienna, Department of Biomedical Imaging and Image-guided Therapy

Universitätsklinikum Würzburg, Comprehensive Heart Failure Center (CHFC)