Human Subject Scanning at 10.5T

Version: 4

Date: August 24, 2021

Current 10.5 Study Review Manager: Greg Metzger; gmetzger@umn.edu

Purpose: As the 10.5T MRI scanner safety study enters its second phase, a process to provide access to the system to more researchers is needed. As the system is still under an IDE with a single approved IRB, the process for running studies is necessarily different than our other human MRI systems. For those interested in running studies, we have drafted a process that we hope is the appropriate tradeoff between managing the requirements of the continued safety study as well as personnel, volunteer, scanner and hardware resources.

Scenario - researcher wants to run a 10.5T study with healthy control subjects.

1) Submit a brief project description to the 10.5T study review manager including the following information (Similar to a PARS applications):
    a. Study Goals/Purpose-
    b. Resources Needed
        i. RF coils
        ii. Sequences
    c. Number of sessions proposed.
    d. Personnel needed - (are the appropriate people included and have they achieved human operator certification at the 10.5T to ensure a successful study?)
    e. Any additional peripheral devices needed.
2) Discuss project proposal with the 10.5T study manager. The purpose of this step is to:
    a. Ensure efficient use of the researcher's time and CMRR resources
    b. Establish expectations
3) Project creation for your 10.5T studies
    a. Follow one of the two paths:
        i. Request to add 10.5T studies to an existing project. An example of a relevant project would be an existing technology development project.
        ii. Submit a new PARS application with the project details.
    b. Projects must provide a chart string for funding, or make a commitment pool request through PARS.
    c. Current rates for include:
        i. Magnet time: $500/hr.

ii. Subject Compensation: $30/hr covering from scheduled arrival time to departure (plan on at least 30 minutes before and after scanning for required safety testing procedures that will be conducted by trained personnel)

4) Operations Committee Review of modified project or new PARS application.
5) Upon project approval…
    a. Researcher/Team will be added to the IDE/IRB
    b. The 10.5T will be added to the appropriate Project or a new project would be created.
    c. The researcher commits to testing and demonstrating that all setup and methods required for in vivo studies are functioning as expected prior to scheduling a human subject.
6) Study planning/scheduling
    a. Studies will be scheduled through the CMRR Subject Recruiter (cmrrstudy@umn.edu) in coordination with Andrea Grant- Some study specific requirements to consider include:
        i. Volunteers are coming from a pre-screened 10.5T Volunteer Pool. The pool is limited in size so careful study planning is required to make the most of each study.
        ii. The time in the magnet bore is not to exceed 180 minutes.
        iii. Subjects will need at least 30 minutes before and after the requested scanner time and is time that will be compensated for by the researcher at standard rates. This time is needed to conduct the required pre and post field exposure studies including cognitive, vestibular, physiologic and sensorimotor.
        iv. RF Coil scheduling.
            1. Approved 10.5T coils will be listed under the resources pages and need to be scheduled along with the scanner time.
            2. While approved, 10.5T coils are still under continuous development and require scheduling with appropriate responsible researchers for use.

Additional points to consider:

- The current goal is to provide access while maintaining the integrity of the safety study required under the current IDE. Management of resources will be dynamic. Limitations on certain studies may occur given prioritization with the goal of maintaining transparency. Share data where appropriate under commitment pool studies (of course only with researchers on the IRB).
- Consider working together to efficiently use limited volunteer resources.
- Please provide feedback on the process. Critical comments to help improve clarity/functionality will be helpful and appreciated.