Guide for adding GE UHP scanner to IRB protocol

Start amendment

1.1 Title - something like “MRI Scanner information”

1.2 Keywords
GE UHP MRI scanner
Non-significant risk investigational devices
3T 32-channel receive coil

1.3 Changes:
Changes to or addition of study devices/Section 16 Devices

1.3.1
N/A

1.4 Description and Justification

Three changes are described below:

1. One of the GE 3T MR750 MRI scanners in the Functional MRI Laboratory on North Campus was upgraded to the GE 3T Ultra-High Performance (UHP3T) system in May 2021. Here we add the information on this scanner to the present study, and maintain a risk level of ‘No more than minimal risk’. New device has been added to Section 16.2.1.

DESCRIPTION AND BENEFITS OF THE UHP3T SCANNER

The UHP3T system will provide several important benefits to the present study:
* Reduced mechanical vibration and more stable gradients, which will help reduce the ‘background noise’ (temporal fluctuations unrelated to brain function) in all fMRI studies.
* Increased peak magnetic field gradient strength (100 mT/m compared to 50 mT/m for the current system), which will improve all existing and future diffusion MRI protocols (improved signal-to-noise-ratio, SNR; improved ability to resolve crossing white matter fibers).
* The UHP3T system will be compatible with head coil receive arrays with a larger number of channels (>32), that may help reduce scan times for all protocols.

Importantly, none of the scheduled hardware upgrades impact subject safety:
* The main field strength is at 3T, significantly below the 8T significant risk limit.
* The radiofrequency (RF) sub-system has the same specifications as an FDA approved 3T system (GE Signa Premier). This includes the RF specific absorption rate (SAR) watchdog software and hardware monitor which will be fully engaged at all times. The risk of RF heating (e.g., skin burns) will therefore not increase.

* The maximum gradient slew rate (dB/dt) will remain limited to 200 T/m/s, and the gradient hardware is the same as an FDA approved system (GE Signa 7T) and will use the PNS calculations and limits for that system. Thus, the risk of peripheral nerve stimulation (PNS) will not increase.
* Scanner noise will remain similar or better due to prior 3T system due to the improved design of the gradient sub-system.

Although the various sub-components (RF chain, gradients, main magnet) have been used in other GE MRI systems that are FDA cleared/approved, the UHP3T system is at an investigational system. For example, the UHP3T gradient sub-system is also used in the GE 7T Signa system which received FDA clearance in Nov 2020. The UHP3T system has undergone safety testing by the manufacturer, and has been installed at other US academic sites (including Stanford University, Duke University). We therefore consider the UHP3T system to be a nonsignificant risk device

and will work with the MICHR IND/IDE Investigator Assistance Program (MIAP) to seek 'abbreviated IDE' status which is subject to regulatory requirements set forth in 21 CFR 812.2(b) and does not require FDA approval.

2. Use of 32-channel receiver array.

The 32-channel receiver array used is a passive unit to receive signals emitted by the body as part of the MRI operation and has been constructed for brain imaging. It does not impact safety. While GE provides several receive coils as part of their FDA approved products, this 32-channel array (Nova Medical 3T 32 Channel Head Coil) has been optimized for certain neuroimaging applications, such as simultaneous multislice imaging and these are very useful for our research studies. The device has received FDA 510(k) clearance for use with GE MRI systems. This coil has been added to Section 16.2.28.

1.5.
No previously enrolled subjects will be re-consented

1.6
Initiated by PI

1.7
Most studies: No

Edit the Study, Go to: Section 16.

16.2.1 Add device

16.2.2
3T MRI Scanner, GE 3T Ultra-High Performance (UHP3T)

16.2.3
GE Precision Healthcare LLC
3200 North Grandview Boulevard
Waukesha, WI 53188

16.2.4
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Post manufacturing modifications include custom scanning software (known as pulse sequences). These changes all adhere to safety checks built into the system.

Include a brief explanation of the purpose of the study. Be sure to clarify if the purpose or aim of the study is related to testing safety and efficacy of the fMRI scanner or not.

16.2.5
It will be used similarly to all MRI scanners, with intervals of roughly 30s to 10 minutes for a 1-2 hour period.

16.2.6
No

16.2.7
Most studies will respond "No" here unless you are conducting a study to evaluate the MRI scanner performance. If you answer "Yes" here; contact us for further needed items.

16.2.28 (add device)

16.2.29
3T 32 Channel Head Coil

16.2.30
K182737

16.2.31

Nova Medical, Inc.
150 West Street, Suite 201
Wilmington, MA 01887

16.2.32
This is used in conjunction with GE MRI 3T scanners to receive signals used to generate MRI images. It is a passive (receive only) device and does therefore not impact any of the FDA non-significant risk criteria. It is preferred over similar devices included with the MRI scanner due to higher performance (improved noise properties and improved parallel imaging capabilities).

16.2.33
It is used in intervals of 30 seconds to 10 minutes, over the entire duration of the MRI session, which could be up to 2 hours in length.

16.2.34
No