

Submitting a new project that involves scanning on the GE 7T requires responses to FDA approval and Device Exemption Information (DEI) within the Project Details section (VII.B.). Below you will find the appropriate responses to fields VII.B.18 through VII.B.36. The provided FDA Statement will need to be uploaded in the Attachments section under category IDE: Sponsor Justification for NSR.

VII.B.18 Does this project involve testing the safety and/or efficacy of a medical device?

Yes

VII.B.19 Describe in detail procedures in place for maintaining device shipment and receipt records:

This procedure does not require device shipment.

VII.B.20 Who will be responsible for maintaining these shipment and receipt records?

N/A

VII.B.21 Describe in detail procedures in place for tracking use and disposition of devices described in this study:

N/A

VII.B.22 Who will be responsible for maintaining these use and disposition tracking records?

N/A

VII.B.23 Describe in detail procedures in place to limit access to authorized study personnel for the storage, control, and dispensing of the investigational devices. (For example, investigational devices are kept in a locked area away from approved devices or have a keyed interlock, and only study personnel authorized to dispense the device have the keys)

The MR scanner is located in the scan room. The scan room is only accessible if the scan room door key is turned to the on position and the actuator-run button is pushed. Every night the MR technologist is responsible for turning the door to the locked position, removing the access key for the door and putting the key in a push-button combination lock box which is bolted to the equipment room wall. Only limited personnel will have access to the lock box that houses the MR scan door key.

VII.B.24 Is the device FDA-approved for the way it will be used in this study?

No

VII.B.25 Is there an IDE (Investigational Device Exemption) for this device in this research project?

No

VII.B.29 Indicate the appropriate FDA status you and/or the sponsor are requesting for the use of this device in this study.

Non-Significant Risk (NSR) device/software

VII.B.31 Provide a detailed rationale for why this device meets the FDA definition of a Non-Significant Risk Device (NSR)

The 7 Tesla MRI scanner is labeled as a class II device, 892.100 by the FDA. The studies proposed in this study will operate the 7T scanner below the limits set forth in the "Criteria for Significant Risk Investigations of Magnetic Resonance Diagnostic Devices." The FDA currently considers the operating of the MRI scanner as significant risk based on the following criteria.

1. Main static magnetic field greater than 8.0T for subjects older than 1 month and 4.0T for subjects less or equal to 1 month of age.
2. Specific absorption rate (SAR) greater than 4W/kg over the whole body and 3.2 W/kg in the head.
3. Gradient fields rate of change sufficient to produce discomfort or painful nerve stimulation
4. Sound pressure level greater than 140dB

Below these conditions, the FDA has determined that the higher magnetic field of the 7 Tesla is without significant risk while having a considerable beneficial impact on the quality of imaging and spectroscopy.

The scanner sequences are monitored to stay within the FDA limits for the four criteria listed above.

VII.B.32 Provide a summary of prior investigations with this device.

We have scanned on the 7T scanner for the past five years without any significant adverse events.

VII.B.33 Have there been any prior IRB reviews (at UI or elsewhere) and/or determinations made regarding this device?

Yes

VII.B.34 Provide a discussion of these reviews/determinations.

Prior reviews by the IRB board at the University of Iowa have deemed the 7T scanner Non-Significant Risk if the four criteria listed above are maintained.

VII.B.35 Has the FDA made an assessment of risk regarding this device?

No

VII.B.36 Has this device/software been approved by the FDA for another indication or in another form from its use in this project?

The FDA has approved 7T scanners from GE for clinical imaging in the summer of 2020. This model however predates the FDA approval and was not included in its approval.