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	IRB # M2012-024 MOU	

September 27, 2016

Dr. Jodi Roberts
Office of Regulatory Compliance & Safety
Post Office Box 6223
Mississippi State, MS 39762

RE: Modifications to I²AT MR Safety Procedures & Confidentiality Clause

Dr. Roberts,

We are requesting a modification to IRB# M2012-024MOU to reflect a change in screening form handling.

In order to insure the safety of all researchers and participants that engage in research activities involving the magnetic resonance imaging (MRI) system; each individual must complete the I²AT Safety Training. This training includes watching a 90-min video and passing a quiz. All are required to watch a 30 minute video on an annual basis to maintain access to the MR (follow scheduling link below).

Screening forms are also required to be completed prior to entering the MR area. The MRI system has a very strong magnetic field that may be hazardous to individuals entering the MR environment or MR system room if they have certain metallic, electronic, magnetic, or mechanical implants, devices, or objects. Therefore, we have set up policies and procedures for the protection of all individuals who will be entering the MR environment or system room. This form is for safety purposes only and is not used for any other purpose.

The I²AT's current process for handling of screening form as outlined in our previous MOU:

1. Office Associate receives screening forms (electronic or hard copy from any individual prior to entering the MR).
2. MR Technologist receives screenings forms from Office (electronic or hard copy).
3. MR Tech reviews documents to ensure safety of the participant, staff and machine.
4. For Participants, MR Tech destroys hard/electronic copies of screening forms.
5. For active PIs and any person involved in running the experiments, the MR Tech stores screening forms in locked cabinet.
6. Any stored screening forms will be destroyed if inactive for one year and thereafter, the PI/researcher will be required to complete a new screening form



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The recommended modifications of the process are as follows:

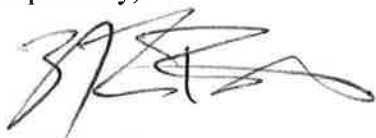
1. PI or researcher conducting the experiments requests and receives screening forms (electronic or hard copy) from either I2AT Office Associate or the MR technician. Prior to entering the MR room, all individuals participating in the research must complete and submit screening forms to the MR technician.
2. MR Technologist receives screenings forms from PI or researcher conducting experiment for review.
3. MR Tech reviews documents to ensure eligibility and safety of the participants, research staff, animal subject and the MR machine.
4. Once the MR Tech reviews and ascertains that the participant is in no danger according to the submitted form, the MR Tech destroys all screening forms. No copies of screening form are maintained by the MR tech or researchers.
5. For PIs and other persons involved in reoccurring exposure to the MR system during specific projects, the MR Tech reviews screening form for those individuals prior to experiment starting, then the MR Tech stores screening forms for those individuals in a locked cabinet.
6. Upon completion or termination of the project or if it has been longer than one year since the form was completed, the MR Tech will destroy the form.
7. The PI/researcher will be required to complete a new screening form yearly, when a new project starts or when there is a change in medical history.

This change in screening form handling ensures proper disposition of forms throughout the research activity.

The screening form also includes a confidentiality section (see links below). This clause is required due to the nature of our partnership with a private clinic, Premier Radiology (Premier). We are obligated through the Business Associate Agreement with Premier to ensure that steps have been taken to protect patient health information.

For more information, I have provided links which provide details as well as the forms required by I2AT. Any changes/updates to the submitted documents will be forwarded to your office for your records. If you have any questions or concerns, please let me know.

Respectfully,



Zach L Rowland
Director

Links:

- A. Scheduling - <http://www.i2at.msstate.edu/scheduling/>
- B. Screening - http://www.i2at.msstate.edu/pdf/MRI_Screening_form_participant_and_personnel.pdf
- C. MRI Checklist - http://www.i2at.msstate.edu/pdf/SchedulingChecklist_1.pdf

