

UR CABIN: How to fill out a CLICK IRB submission

The RSRB application is done online at <http://www.rochester.edu/ohsp/rsrb/>. For certain sections there is standard information that needs to be included, based on previous discussions UR CABIN staff have had with the RSRB, lawyers, etc. This document includes all the standard language for these sections. In addition, you will need to use the standard MRI safety screening form and fill in the standard templates for the consent form and the image release form (if subjects wish to obtain copies of their brain image).

Information helpful for your written protocol:

- MRI studies do not involve procedures that are greater than minimal risk.
- Any MRI scan involves “Direct Contact” with subjects.
- The UR CABIN is a part of the covered entity; all consent forms must be HIPAA compliant.
- It is UR CABIN’s policy that pregnant women not be scanned at this facility due to the unknown biological effects MRI has on fetuses. If the MRI is a requirement of your study, pregnancy is an enrollment restriction.

Text required in your written protocol:

- Add the following text about discovering previously unknown conditions:
“Conditions that can be diagnosed from having access to research quality MRI. Our scans are not read by a neuro-radiologist and the subjects are explicitly told that the experiment will not provide information as to their health status. However, if the researcher suspects something abnormal, he will seek advice from a qualified neuro-radiologist.”
- Add the following text to risks related to being in the study and undergoing an MRI:
“There is no immediate risk from exposure to magnetic fields of 3 Tesla. Possible anxiety may result from claustrophobia or dizziness experienced by the subjects when placed in the magnet. During the imaging portion of the experiment, subjects must remain in the bore of the magnet, which is approximately 3 feet in diameter. Also, the scanning coil closely encloses the subject's anatomy being imaged. These two factors may increase the likelihood of claustrophobia. Should the subject feel discomfort, the experiment will be terminated upon their request.

In rare cases, contact with the MRI transmitting and receiving coil or conductive materials such as wires, or skin-to-skin contact that forms conductive loops, may result in excessive heating and burns during the experiment. The operators of the MRI scanner will take steps, such as using foam pads when necessary, to minimize these risks. The subjects will be informed of the risk and instructed to immediately report any heating sensations. In the rare event that this would occur the experiment will be terminated and if necessary we will have the subject seek medical treatment.

Subjects will be screened for magnetic material before each study. Subjects with pacemakers, aneurysm clips (metal clips on the wall of large artery), metallic prostheses (including heart valves and cochlear implants) or shrapnel fragments are at risk in an MR environment. Welders and metal workers are also at risk for injury because of possible small metal fragments in their eyes. Those at risk will be excluded from the study.

The effect of exposure to MRI scanning on an unborn child is unknown. Exposure to

MRI scanning might be harmful to a pregnant female or an unborn child. There are no established risks at this time, but the subjects will be informed that there is a possibility of a yet undiscovered pregnancy related risk.

MRI scanning produces a loud tone that can cause damage to the inner ear if appropriate protection is not used. Adequate protections in the form of earplugs or close fitting silicon-padded headphones will be provided.”

Basic Information:

Note the Principle Investigator(s)

Funding Sources:

If you have received a UR CABIN pilot grant; please list UR CABIN (RCBI) as the funding source here.

Basic Team Members:

Please list all study personnel that will be involved in direct contact with study subjects themselves or any of the subjects’ data. Any study team member needing access to data or present during a subjects’ scan must be listed here for the protocol. All team members must also have a current CITI number.

Local Site Documents; Consent Form templates—PLEASE READ!

The guidelines for enrolling children under 18yrs:

0-6 years [Parent/Guardian Consent form required]

8-12 years [Parent/Guardian Consent form and verbal child assent script required]

13-17 years [Parent/Guardian Consent form and written child assent form required]

Upload here your MRI consent form/s and the MRI image release form (if you will be releasing an image to subjects). The MRI consent form and the MRI image release form contain standard UR CABIN language. Templates for these forms are available on the UR CABIN webpage. The MRI image release form is the form that subjects need to fill out before a copy of an image of their brain is given to them.

As indicated on the first page of the templates, **the blue text in the consent form templates should not be changed, and any additions should be made in black text.** This allows the RSRB officials to verify that the proper language is used regarding the MRI. Be sure to remove brackets. **Consent forms should use the correct RSRB Case Number on the first page and also in the footer of the documents.**

There are two paragraphs on the consent form regarding compensation for injury. You need to choose one and be sure to delete the other. Also, delete the black wording in the brackets.

You can add as much additional information concerning your study as you like to the existing consent form template.

Local Site Documents; Study Measurement Documents:

The MRI safety screening form (available on the UR CABIN webpage) should be uploaded here. The MRI safety screening form is a standard form that everyone using the MRI scanner at

UR CABIN must use.

Ancillary Committee Review:

Be sure to select University of Rochester Center for Advanced Brain Imaging and Neurophysiology (UR CABIN) here. If not selected our ancillary committee notification for us to review your protocol will not generate, and you will not be able to use our facilities.