

How to fill out an RSRB application for RCBI

The RSRB application is now done online at <http://www.urmc.rochester.edu/rsrb> For certain sections there is standard information that needs to be included, based on previous discussions RCBI 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 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 images).

The guidelines for enrolling children under 18yrs:

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

7-12 years [Parent/Guardian Consent form and verbal child assent script required]

3-17 years [Parent/Guardian Consent form and written child assent form required]

Consent templates—PLEASE READ!

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.

- 1.4 Note that the Principle Investigator(s) and other key personnel that interact with subjects and subject data need to take a written test and get a CITI number.
- 1.7 The study coordinator is generally the PI, unless someone else has been assigned as a liaison to the RSRB.
- 3.1 If you have gotten a pilot grant from RCBI or have a research agreement such that RCBI is not being reimbursed by some other funding source for your scanning time, indicated “Rochester Center for Brain Imaging” under Department Funding.
- 5.1 MRI studies do not involve procedures that are greater than minimal risk.
- 62.1 Be sure to select RCBI.
- 63.2 RCBI is a not a non-UR facility, so indicate “no” here.
- 64.1 “Direct contact” with subjects means being in their physical presence. If you are acquiring new data from subjects (and not just re-analyzing previously acquired data), then your study involves direct contact with study subjects.

- 64.3** If you don't know the racial, ethnic and gender breakdowns of your subject population, leave the entries in the table blank, but make sure to include the totals in the appropriate column.
- 67.1** Currently the standard rates of pay are \$20 per hour for MRI sessions and \$8 per hour for behavioral testing. This is a guideline, you do not need to adhere to these rates.
- 67.2** Generally, the subjects are paid in cash.
- 70.1** The RCBI is not part of the covered entity.
- 73.4** If you receive RCBI funding or support, your study is still independent and is not considered to be part of the study.
- 75.2** Since we do not scan women who are known to be pregnant, pregnancy is an enrollment restriction.
- 77.1** MRI scans can discover previously unknown conditions. Include the following text:

“Conditions that can be diagnosed from having access to research quality brain 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.”

Under “Other risks” answer yes and include the following text:

“Risk related to the use of a large magnetic field.”

- 77.2** Include the following text:

“There is no immediate risk from exposure to magnetic fields of 1.5 or 3 Tesla. Possible anxiety may result from claustrophobia or dizziness experienced by the subjects when placed in the magnet. During the brain imaging part of the experiment, subjects must remain in the bore of the magnet, which is approximately 2 feet in diameter. Also, the scanning coil closely encloses the subject's head. 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 this risk. 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 have the subject seek medical treatment.

Subjects will be screened for magnetic material before each study (see attached screening form). 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.

Functional 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.”

78 Generally there is no Data Safety Monitoring Board or independent monitor for fMRI studies.

81 fMRI studies generally do not have any associated research or care treatments.

83.1 Upload here your MRI consent form and the MRI image release form. For HIPAA entities add our HIPAA template to your consent form. The MRI consent form and the MRI image release form contain standard RCBI language. Templates for these forms are available on the RCBI 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.

Does your department conduct on-line review and approval of studies?

The department should be listed as the one in which the PI has a primary appointment. If the PI does not have a primary appointment at the University of Rochester, or has a primary appointment in RCBI, indicate Brain & Cognitive Sciences (BCS) as the department. BCS does conduct on-line review and approval. The department review primarily serves to ensure that the proposal has valid scientific content.