Guidance
Research Project Review by Safety Committees

Notes and Reminders

Institutional Review Boards (IRBs) are charged with ensuring that risks to subjects are minimized and risks are reasonable in relation to anticipated benefits. When research involves certain hazards, the Children's Wisconsin IRB relies on supplemental information obtained from expert review (and approval) of proposed research by applicable safety committees.

If imaging is being done **solely for research purposes** the research must first be reviewed and approved by the appropriate safety committee. Research that involves the use of X-rays (including DEXA) or CT scans is reviewed by the Children's Radiation Safety Research Subcommittee and possibly the State of Wisconsin Department of Health and Human Services. Research involving MRI or PET/MRI is reviewed by the Children's MRI Safety Committee. This safety committee approval must be included in the submission to the IRB.

Even if all the imaging being done as part of the research study is considered **standard of care**, if the imaging will be done at Children's/with Children's equipment as part of a research study (where it is described in the protocol), the Children's Department of Imaging needs to be notified/consulted prior to submitting the study to the IRB. This is to review and plan for logistical considerations and is different than a safety review by the safety committee. Beyond any safety considerations, the Department of Imaging needs to be able to plan for staffing, scheduling, use of the equipment, and work out logistics in order to be able to support the study efficiently and without disruption to the department.

Appropriate safety committee approval should be sought out and obtained **before** submitting a project to the Children's Wisconsin IRB, and the approval letter must be included with the initial submission. If safety committee approval is pending, final IRB approval will not be issued until this is secured.

This should be obtained for any new projects, as applicable, or if a project is modified in a way that would make safety committee approval applicable.

	MCW Institutional Biosafety Committee	Children's Radiation Safety Committee	State of Wisconsin Radiation Safety Review	Children's MRI Safety Committee
How do I know if Safety Committee Review is needed?	When a research project involves use of any biologically hazardous or genetically engineered materials*. IBC approval is no longer required for IRB submissions that deal with only human source material unless the research involves the generation of cell lines, extensive processing of tissue, or work associated with animal studies. IBC review and approval is required for IRB submissions when deferred to non-MCW IRBs. Information on the IBC can be found here.	If the imaging is for **research only (beyond standard of care)**, then the radiation safety committee must review and approve before submitting to the IRB. There may be additional review by the State of Wisconsin required as well.	Children's Local Radiation Safety Committee will indicate in their approval letter if review by the state is also needed.	If your research project involves imaging on a **Children's MRI** scanner for **research** purposes only (beyond standard of care) the **Children's MRI Safety Committee** must review and approve before submitting to the IRB. If the project involves use of an MRI scanner at Froedtert or MCW this will need to go to **the MCW MRI Safety Committee.** If the MRI scanner is housed outside of a clinical area there may be additional considerations when used in a pediatric population. If this is the case, contact the Children's IRB Office early to discuss.
When should I request this?	Before submission to the IRB. Submissions are required at least two weeks prior to a meeting date in order to be scheduled on that meeting's agenda.	Before submission to the IRB. This should be submitted to the Children's Radiation Safety Committee as early in the process as possible for review of both safety and logistics.	Before submission to the IRB, if review is indicated by Radiation Safety Committee.	Before submission to the IRB. This should be submitted to the MRI safety committee as early in the process as possible for review of both safety and logistics.
How do I request this?	Applications are submitted through the MCW eBridge system. For	Send an email to Linda Strain at LStrain@chw.org requesting the review, with	Email William Balke at William.Balke@dhs.wisconsin.gov	Currently no specific application form. Email Linda Strain at

	direction/instructions on submitting an application through eBridge, please visit eBridge Support.	documents listed below attached.	Requesting the review with documents listed below attached.	LStrain@chw.org and she will get a review scheduled.
What documents are needed?	Follow eBridge study application directions and contact MCW Biosafety Officer at 414-955-8060 or IBCSafety@mcw.edu with submission questions.	• Radiation Procedure Grid • Research Protocol • Informed consent/assent	• Letter from Children's Radiation Safety • Appendix M Variance • Radiation Procedure Grid • Research Protocol • Informed Consent/Assent	• Study Protocol • Imaging Guide • Any documents that detail the MRI imaging needed (i.e. consent documents, etc.)
When are the meetings?	Meetings are held the second Tuesday of every month from 1:30-3:00pm in MFRC 3075, unless otherwise noted.	These reviews are done on an ad hoc basis as they are requested.	These reviews are done on an ad hoc basis as they are requested; response time is dependent on reviewer schedule.	The MRI Safety Committee meets once per month on the 4th Thursday of the month from 1:00 to 2:00 PM. The meetings are held in the Imaging Conference Room which is in the Imaging Department- first floor of the hospital.
Does the PI or a member of the study need to attend?	No, the PI and/or study team does not need to be present for the review of the submission.	No	N/A (No)	The committee would like to have the study coordinator and principal investigator attend the meeting if possible.
How is approval communicated?	Via letter in eBridge.	An approval letter will be sent/emailed to the PI/requestor of the review.	Typically, there will be an email response to the submitter followed by a mailing of the hard copy of the decision letter.	Email is utilized for requesting additional information or answering questions. An MRI Safety Review document is emailed to the study coordinator within a few days of the MRI Safety Committee meeting.
How long is the approval valid?	IBC approval is valid for 3 years. If the study changes the way they are using	Approval is valid for 3 years. If the study changes the use of	As long as the study is under IRB oversight and the subjects or parameters initially approved	Approval is valid for 3 years. If the study changes the use of MRI, or

	biologicals or adds new biologicals, an amendment to the submission must be submitted via eBridge. New work that is added to the amendment may not begin until the amendment has been approved by the IBC.	radiation, or adds new radiation exposure, this should be re-reviewed by this safety committee and their assessment submitted with the amendment to the IRB.	by DHSS remain unchanged there is no need for a re-review by the state for a new letter. An updated approval letter is only needed if something about the radiation use in the study changes.	adds additional MRI imaging, this should be re-reviewed by this safety committee and their assessment submitted with the amendment to the IRB.
How long does approval take?	IBC review times vary. If the submission is time sensitive, please contact the IBC Office at (414) 955-8060 or (IBCSafety@mcw.edu) so that appropriate arrangements can be made for submission.	Varies by study complexity and reviewer schedules – range is a couple of days to a couple of weeks.	Varies depending on study complexity and DHHS reviewer's schedule/availability. Typically this will take a few weeks.	The time needed is based on the time of request in relation to the next scheduled meeting date. Studies are generally reviewed at the next scheduled meeting unless the agenda is full (this would be unusual). The approval document can normally be provided within a few days of the meeting.

*Infectious agents; biological toxins; all recombinant DNA, both exempt and non-exempt; and all non-human primate derived materials including blood, tissue and bodily fluids.