

Guidance

Process of Review by Imaging (Logistics, MRI Safety, Radiation Safety) for Studies Being Conducted at Children's Wisconsin

General

The use of radiation/imaging in a research project being conducted at Children's Wisconsin, and/or use of CW imaging records, needs to be reviewed as part of local context. The review will assess the logistics of the proposed use of CW imaging services and/or records (can the imaging department support the research project) as well as the need for radiation safety review - both locally and by the state of Wisconsin Department of Health and Human Services.

This review needs to occur for any use of imaging services for a proposed research project:

- Access to, and possibly de-identification of CW imaging records
- Imaging needed in the research project as part of standard of care
- Imaging needed for research only

The CW imaging manager (Linda Strain) is the gatekeeper/point person at CW for all studies that will utilize imaging services at CW.

Pre-Submission

When a proposed research project will need to enlist CW imaging services, for any reason, the imaging manager should be contacted prior to submission to discuss. There is a required [Imaging Intake form](#) that needs to be completed and provided to the CW imaging manager. The imaging manager will review this form and work with the study team to put any logistics in place and refer for any appropriate safety committee reviews. There is also a [Radiation Procedure Grid](#) that will need to be completed.

Note: echocardiograms are done through cardiology rather than the imaging department. If cardiology services for echocardiograms is needed, please complete the Herma Heart Intake Form for research projects that involve echocardiograms.

When review of use of imaging is more for logistics, and does not require safety committee or state review, there will not be a formal approval letter

- The imaging manager will email the study team that she has reviewed the protocol and the intake form, and the study activities can be accommodated by imaging along with instructions to upload that email into section 52 of the eBridge submission.
 - If any changes are needed in order for imaging to accommodate, this will be communicated by the imaging manager to the study team.
- Any documentation received from the imaging manager must be uploaded into section 52 in eBridge so the CW HRPP analysts can verify at the time of local context review.

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When use of imaging in a study requires formal review and approval by the local CW safety committees (MRI and Radiation) and, when applicable, State of Wisconsin Department of Health and Human Services Research Radiation Safety (see *Guidance - CHW Research Project Review by Safety Committees* for additional information)

- Radiation Safety Research Sub-committee review is required when imaging studies utilizing radiation will be performed for research purposes only, outside of standard of care.
 - If any Imaging for the research is being done with MCW equipment or in MCW space then review by the MCW MRI safety committee may also be required.
 - eBridge automatically routes projects that indicate imaging in the submission to the MCW radiation safety officer. However, if all imaging is being done on CW equipment in CW space, then the MCW radiation safety officer will move the project forward without formal review. The documentation provided regarding CW safety committee review will be uploaded to the history but the CW analyst during local context review so it is readily available for the MCW safety officer to see.
- CW MRI Safety Committee review is required for any study involving MRI. Meeting attendance is required for studies utilizing MRI for research purposes only and for studies with significant logistical needs.
 - If any MRIs for the research are being done with MCW equipment or in MCW space then review by the MCW MRI safety committee may also be required.
 - eBridge automatically routes projects that indicate MRIs in the submission to the MCW MRI safety officer. However, if all imaging is being done on CW equipment in CW space, then the MCW radiation safety officer will move the project forward without formal review. The documentation provided regarding CW safety committee review will be uploaded to the history but the CW analyst during local context review so it is readily available for the MCW safety officer to see.
- The imaging manager will assist in referring the project to the appropriate safety committee
- Linda will email documentation of her review (from a logistics standpoint) as well as the committee approval letter, to study teams with instructions to upload into section 52 of eBridge
- The CW Radiation Safety Research Sub-committee letter will indicate whether review by the State of Wisconsin Department of Health and Human Services is needed. In this case, the study team will need to submit an [Appendix M variance](#) to the state.
 - When study team receives documentation from the state, this must be uploaded into section 52 of eBridge
- This documentation will be verified by the CW HRPP staff during local context review. If this is missing, HRPP staff will contact the study team to ask for this to be uploaded.

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After Submission of the Research Project into eBridge

There will be sections in the eBridge PRO application that ask for indication about whether CW imaging services will be needed for the proposed research. If it is, there will also be instructional language indicating that the intake form needs to be completed and the study teams need to contact the imaging manager if this has not already been done. **Please note: that all of these approvals and review should be done prior to submitting the project into eBridge. If not, it will slow down the review and create delays in getting the proposal to the IRB committees for final approval.**

- If the CW HRPP staff notes, on local context review, that imaging services are needed they will be looking for this documentation (communication from the imaging manager, safety committee approval letters) of these approvals in section 52 of eBridge.
- If, on LC review, CW analysts see that imaging is being used, but do not see documentation in eBridge, they will reach out to the researchers with the instruction to contact the imaging manager.
- Researchers will be instructed by imaging manager/CW HRPP analysts to complete the Imaging Intake form Linda created, and send this and the protocol to Linda by email
- Review by the imaging manager and any necessary safety committee reviews must be complete and documentation provided before the proposed research will be moved forward to committee.