

Radiation and Imaging in Research at Children's Wisconsin

Visual Flowchart

→ *When all imaging services/radiation is being done at CW on CW equipment:*

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, consider whether the imaging department has the appropriate resources to accommodate the research, 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 CW imaging services for a proposed research project, including:

- Access to, and possibly de-identification of CW imaging records
- MRI/imaging/radiation in a research project as part of routine care
- MRI/imaging/radiation as a research intervention

CW imaging requires review of any imaging services being used as part of research, even when standard of care, to review for logistics and the impact on the department. The CW imaging manager (Linda Strain) is the point person at CW for all studies that will utilize imaging services at CW.

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.

Note: echocardiograms are done through cardiology rather than the imaging department. If cardiology services for echocardiograms is needed, please contact Alex Bruss at abruss@childrenswi.org

Note: CW and MCW/Froedtert are separate, independent institutions. Each institution has their own processes and requirements for review of imaging and radiation being done in their space with their equipment. As such, each institution will review the use of imaging in research from the standpoint of their process and requirements.

→ *Process: (this should be started PRIOR to submission in eBridge)*

1. Determine whether any imaging or radiation is being done as part of research participation.
2. Determine what services are being done for research purposes only, and which are being done as part of routine care (would occur as part of the patient's care regardless of participation in the research)
 - The Director of Clinical Research Operations (Theresa Kump) and Corporate Compliance (Maria Vallejo) can assist in determining this if needed.
3. **Determine WHERE imaging, radiation, or MRI services will be taking place.**
 - If MRI services are being done outside of any CW hospital space, the [MRI Safety Plan](#) must be completed and included in Section 52 of the submission.
 - If any imaging/MRI/Radiation services are taking place in CW space with CW equipment
 - Complete the [Imaging Research Intake Form](#) and send this to the CW Imaging Services manager
 - If any changes are needed in order for imaging to accommodate, this will be communicated by the imaging manager to the study team.
 - The imaging manager will email the study team that she has reviewed the protocol and the intake form, and whether the study activities can be accommodated by imaging along with instructions to upload that email into section 52 of the eBridge submission.
 - [CW Safety Committee Review](#)
 - Please see this [guidance](#) for additional details
 - Radiation Safety Research Subcommittee review is required when imaging studies utilizing radiation will be performed for research purposes only, outside of routine care.
 - The CW Radiation Safety Research Subcommittee 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. Linda Strain and the CW HRPP office can assist if needed.
 - CW Radiation Safety Committee approval/documentation must be uploaded into section 52 of the eBridge PRO Smart Form
 - When study team receives documentation from the state, this must be uploaded into section 52 of the eBridge PRO Smart Form
 - 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.

- CW MRI Safety Committee approval/documentation must be uploaded into section 52 of the eBridge PRO Smart Form
- The CW Imaging Services manager will work with the study team and will refer to the appropriate CW safety committee for review (CW Radiation Committee/CW MRI Safety Committee)
- CW Imaging Manager will email documentation of review (from a logistics standpoint) as well as the safety committee approval letter, to study teams with instructions to upload 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.

→ *If any Imaging/MRI/Radiation services are taking place in MCW/FH space with MCW/FH equipment*

- Review by the MCW radiation safety office, and if applicable the MCW Radiation Safety Committee, and/or the MCW MRI Safety Committee will be required. (This is a separate review from the CW safety committees).
- Their process is different (for example, the radiation safety staff will submit the Appendix M variance to the state if needed for imaging being done on MCW equipment). For questions about this, contact the MCW HRPP office.
- The MCW Radiation Safety Office will be automatically notified when the PRO Smart Form indicates use of imaging/radiation/MRI for the study.
 - If all of this activity is being done at CW on CW equipment, the MCW Radiation Safety Office will pass the project through with a note in the history that their review is not required.
 - If formal review is conducted
 - changes or clarification required by the MCW Radiation Safety Office will be requested in eBridge.
 - If State approval is needed the MCW Radiation Safety Office will complete and submit the Appendix M variance
 - Any approvals (by the MCW Radiation Safety Office, MCW Radiation or MRI safety Committees, and state approval for activities at MCW/FH on MCW/FH equipment) will be uploaded into eBridge by the MCW Radiation Safety Office and will show up in the history of the project.

[Guidance - Process of Review for Radiation and Imaging in Research at CW](#)