

Risk Based Quality Monitoring

As part of the CW HRPP's evolving quality program, the CW HRPP conducts post approval risk-based quality monitoring (RBQM) of research happening at CW.

All human subject research being conducted at Children's Wisconsin, with Children's Wisconsin patients, using Children's Wisconsin data or otherwise engaging Children's Wisconsin in human subject research, will be subject to quality monitoring by the CW HRPP office. The purpose of these reviews is to monitor for compliance and provide feedback and guidance to investigators to improve the quality of how research is conducted at Children's Wisconsin.

Research projects approved at a fully convened IRB meeting, or by expedited review, that are being conducted in CW space, with CW data or with CW patients, are eligible for Quality Monitoring. Once research has undergone local context review and been approved by an Institutional Review Board, it may be selected for quality monitoring by the CW HRPP office.

This monitoring will allow the CW HRPP office to provide feedback to investigators and study teams regarding the conduct of their research in accordance with:

- The approved protocol
- Federal regulations and local laws
- Children's Wisconsin policies, SOPs, guidance documents and local context considerations
- General good clinical practice

This review also provides an opportunity for investigators and study teams to ask questions, bring up concerns about the research, and provide additional learning opportunities for investigators and research staff. The feedback from the review can be used by investigators to prepare for monitoring by other entities such as sponsors or the FDA as well as plan for modifications or continuation of the research. It will also help provide information from another source to the IRB of record about the conduct of the research which can be considered in the continued oversight by the IRB of record. This monitoring will allow the CW HRPP office to fulfill its mission to protect the rights, welfare and privacy of individuals participating in IRB approved research conducted at CW by helping to ensure compliance with a variety of standards (regulatory, ethical, local context, scientific quality) and help improve the quality of human subject research conducted at CW. Additionally, evaluation of aggregate information collected from this monitoring can direct where education efforts should be targeted.

See the full outline of the [HRPP quality program](#) at Children's Wisconsin for more details about this monitoring as well as more information about our quality program.