Eligibility and Expectations for Real-Time IRB Review

Eligibility – In order to qualify for Real-Time review, a project/ Project Team must meet the following Requirements:

- The project must be a departmental priority.
- The project must require full committee review, projects eligible for expedited or exempt review typically would not need to undergo Real-Time review.
- The PI or member of the study team must have adequate experience conducting research at MCW, Froedtert, Versiti, or Children's Wisconsin.

Expectations

- The PI and relevant members of the project team must be available to attend the assigned IRB Committee meeting and arrive at the designated arrival time.
- The project team must be able to communicate efficiently with the assigned IRB Coordinator and address modifications leading up to and during the assigned IRB Committee Meeting.
- If applicable, for-profit sponsor must be aware of the Real-Time IRB Review and be able to address project team questions in 24 hours or less leading up to the assigned IRB Committee meeting and a representative from the sponsor should be available for the study team to contact during the Real-Time review.

Recommendations for Successful Review

- We highly recommend that project teams have an experienced Research Coordinator to manage modifications before and during the IRB committee meeting.
- We recommend that project teams are aware of the required ancillary reviews and submit with adequate time for ancillary reviews to take place, final IRB approval cannot be granted until completion of all required ancillary reviews.
- Please review all instructions provided by the IRB Office regarding the Real-Time review.
- If applicable, we recommend having a well-informed representative from the sponsor attend the assigned IRB Committee meeting, who has the authority to approve changes requested by the IRB Committee.