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

- Submissions must have all required ancillary reviews **complete** prior to the deadline provided to the project team at the time of scheduling.
- 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.
- 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.