

Children's Wisconsin Institutional Review Board Human Research Protection Program

	PI/Study Team	IRB Analysts	Compliance	Expedited Reviewer	Convened Board
Pre-Submission Review and Approval	As applicable: →Department →Scientific Rev. Com. →Deferral Agreement →Safety Committees →FDA →Any affected dept. notified/agree				
IRB Pre-Review	Submit to IRB via IRBNet Modification made (Package relocked by study team)	Completeness Review * Det. If expedited or convened board review Modifications, if needed, communicated to study team (package unlocked by IRB) ** Forwarded to expedited reviewer OR to convened board and placed on a meeting agenda	Mods. needed; communicate to IRB/PI	OR	
Committee Review	Modifications made and submitted via "response/follow- up" package in IRBNet	(convened board only) *** Modifications, if needed, communicated to study team via decision letter published in IRBNet		Review and determination	Review and determination by committee vote Tabled
Final Processing	Modifications made and submitted via a new package in IRBNet. Process starts over	Approval letter and any stamped documents published in IRBNet Decision Letter Published in IRBNet		Approved	Disapproved



* If submission is incomplete or on initial review requires a lot of "clean up," submission will be withdrawn and require re-submission. New submission does **not** resume previous place in the queue but goes to the end of the queue.

** IRBNet will indicate package is "pending review," even though pre-review is in process.

*** IRBNet will indicate package as "forwarded." If expedited, agenda field will continue to show as "unassigned" until final approval. If convened board review, agenda field will show date of convened board review once package has been placed on an agenda.

! Expedited Reviewer cannot disapprove on their own. If this is the recommendation, package will go to full board for review.