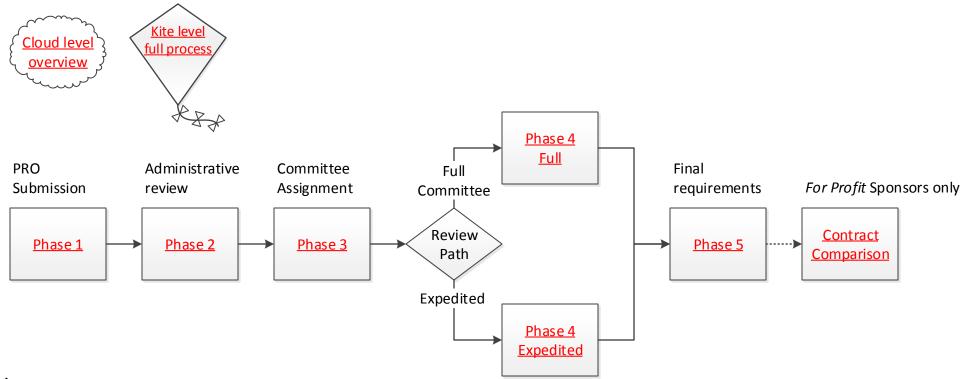
Revised 9 20 18

Important Notes

In order to conduct research with human subjects at MCW, including data and specimens, Principal Investigators (PIs) must obtain approval from the Institutional Review Board (IRB). For more information, visit Working with Human Subjects or email IRBOffice@mcw.edu

Median time from submission to approval for new protocols: Expedited Review = 28 days; Full Committee = 64 days

Index of Process Maps



Glossary

C2 - IRB Coordinator II

C3 - IRB Coordinator III

eBridge – online system for routing approvals

FP – Funding Proposal in eBridge

IRB - Institutional Review Board

PI - Principal Investigator

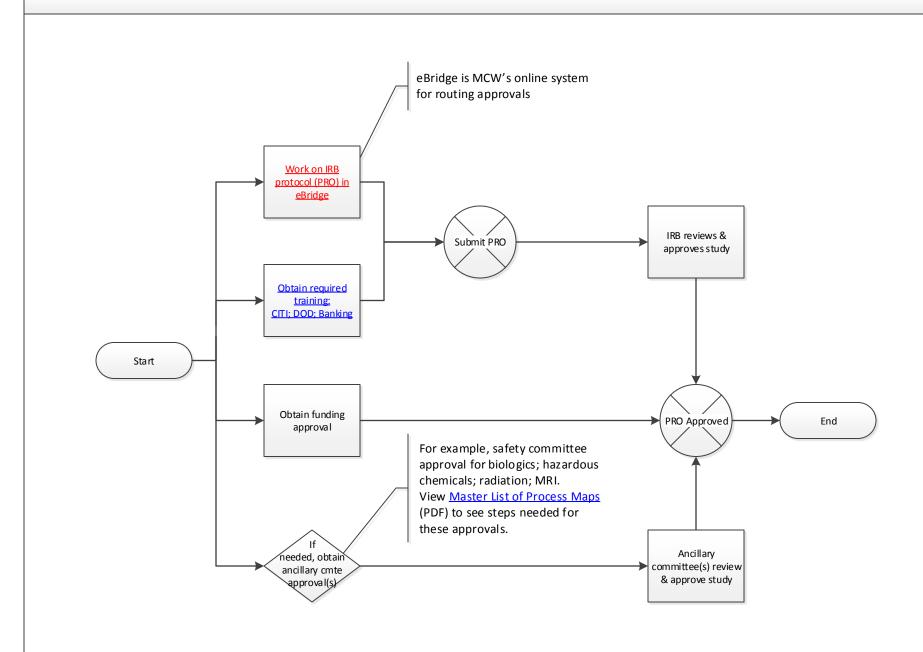
PRO – human research protocol in eBridge

RSS – Research Support Specialist



Overview

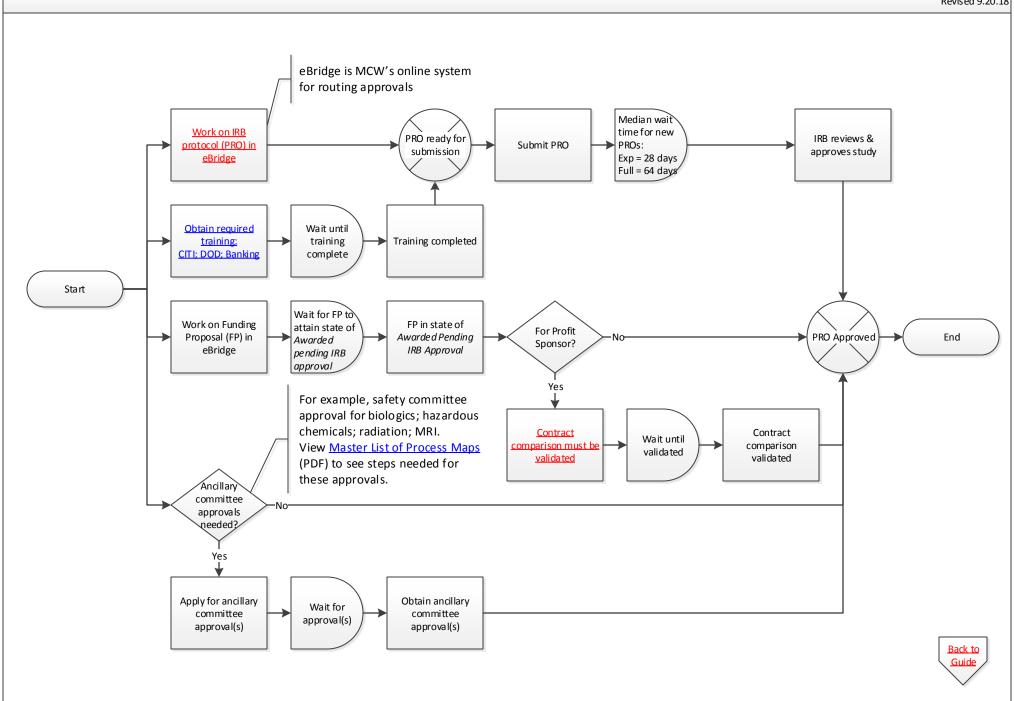
Revised 9.20.18





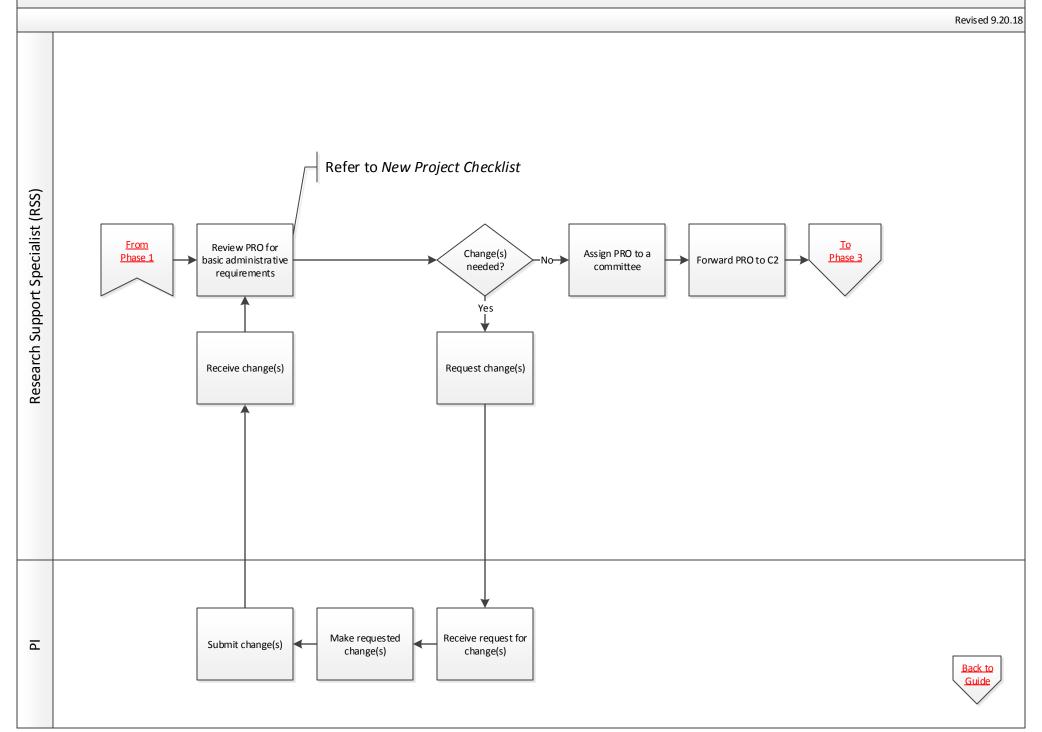
Full Process

Revised 9.20.18

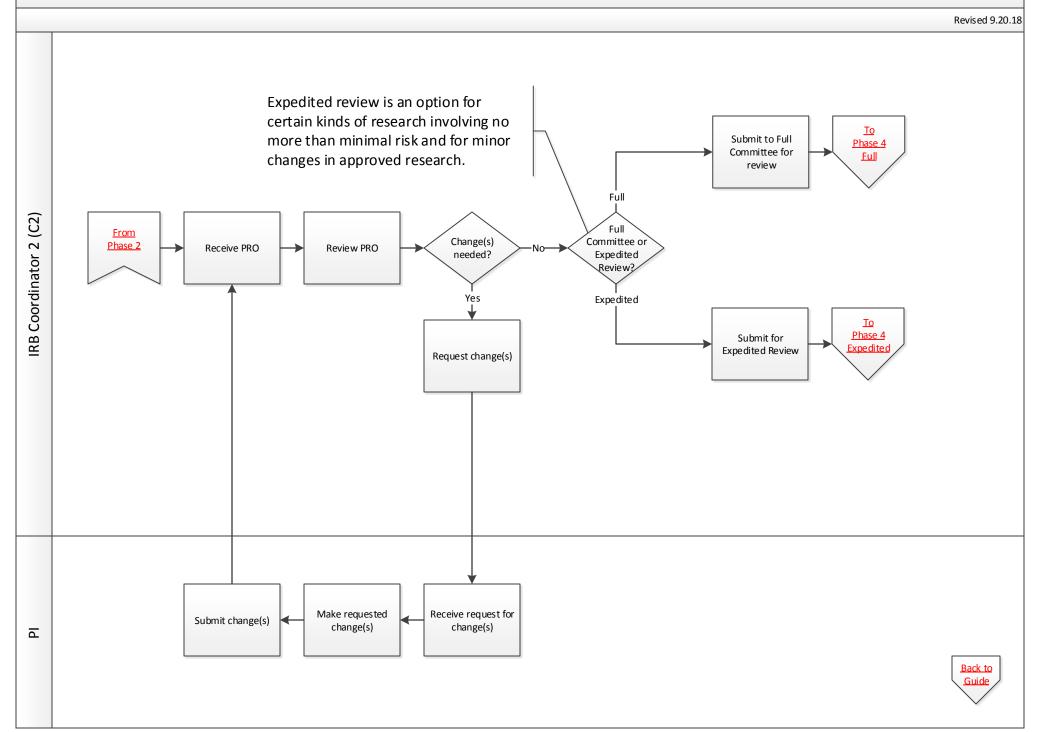


Phase 1 Human research approval process Revised 9.20.18 Research Support Specialist (RSS) <u>To</u> Notify PI of training Training Phase 2 Receive inquiry require ments Complete? Review PRO for Receive PRO training requirements Median wait submit to Complete required Receive notification Submit PRO approval: training Exp = 28 days Full = 64 days Yes Submit inquiry to Training Don't know Ы IRB Office needed? Work on PRO Submit inquiry to Start Need help? in eBridge eBridge Help Desk eBridge Help Assist PI Receive inquiry

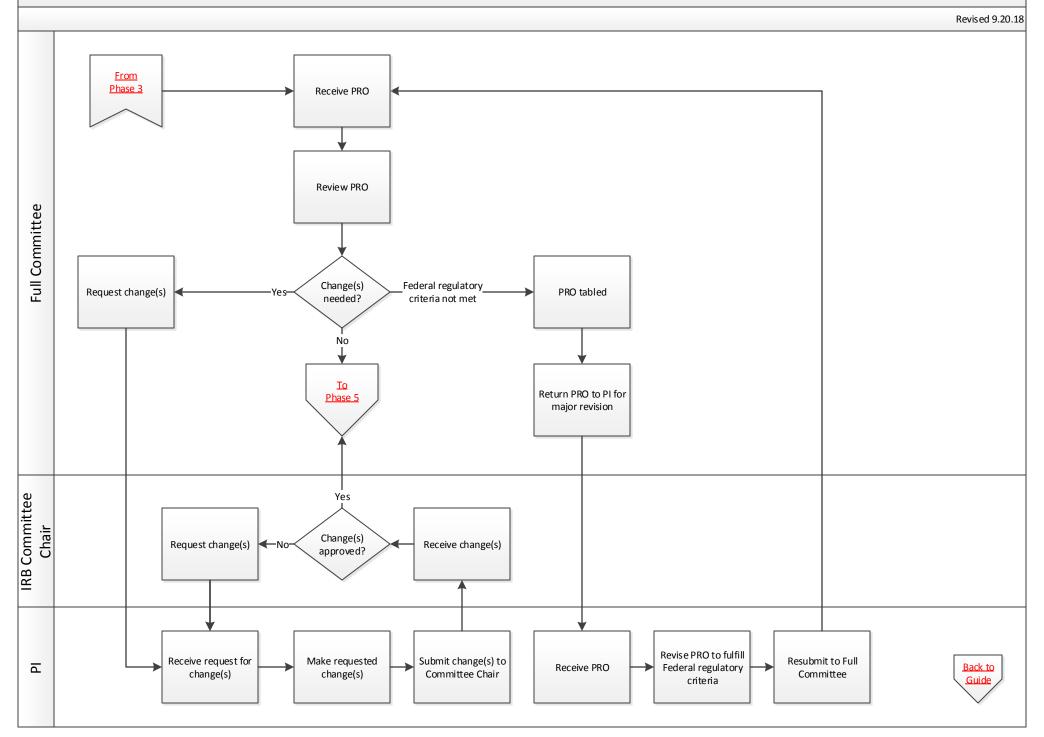
Phase 2



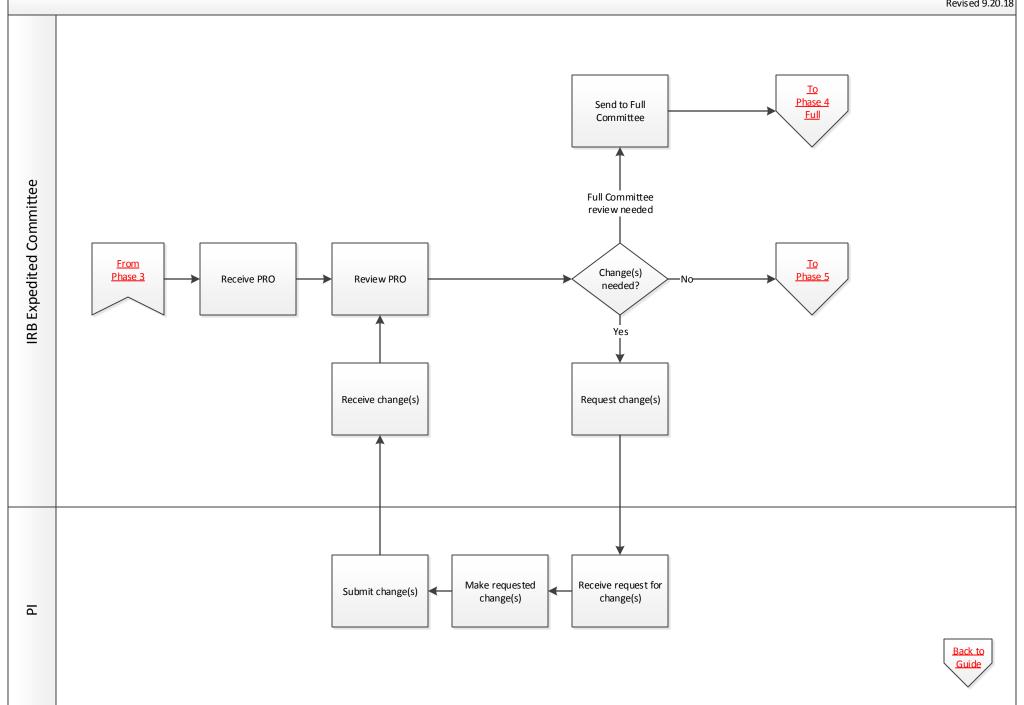
Phase 3



Phase 4 Full



Phase 4 Exp



Phase 5

Revised 9.20.18 Wait for Approved by ancillary ancillary committee committee(s) approval(s) Yes Ancillary PRO committee End approval Approved needed? **From** IRB Committee Phase 4 **Expedited** PRO approval pending <u>From</u> <u>Full</u> Wait for Funding Is FP Sponsor FP state is Awarded Proposal Pending IRB Review For Profit? (FP) to be awarded Forward to C2 to initiate contract comparison IRB Coordinator 2 Complete the subprocess for Receive PRO **Contract** Comparison

Contract Comparison Human research approval process Revised 9.20.18 2 (C2) Only for studies with For Profit Sponsors IRB Coordinator Notify C3 contract Send PRO to study Start Receive PRO comparison is Receive notification team to correct needed consent language Compare contract Comparison Notify C2 change(s) Receive notification with consent form valid? needed 3 IRB Coordinator PRO Approved End Receive request for Submit to C2 Make correction correction Ы