Fred Hutch Cancer Center

Institutional Review Board

IRB Turnaround Times

NOTE: The turnaround times below represent the schedule for complete submissions. Incomplete submissions or submissions requiring follow-up are not scheduled for review until the study team resolves the issues identified by staff. IRB staff will contact the PI and/or study team within the screening window so issues may be addressed and corrected.

All turnaround times are counted in **business days**.

	ACTIVITY / DOCUMENT TYPE	SCREENING TIME TO CHAIR OR IRB MEETING	REVIEW TIME ONCE ITEM IS REVIEW READY[1]	PROCESSING TIME
Full Committee Review	New Study, New Participating Site, Modification, PI Response to IRB[1]	Screened by staff within 7 days of receipt	To next available IRB meeting	Approval letter distributed within 2 days following the IRB meeting[3]
	Continuing Review	Will be reviewed by two weeks before expiration		Approval letter distributed within 2 days following the IRB meeting[3]
	Continuing Review + Modification	Screened by staff within 7 days of receipt	To next available IRB meeting	Approval letter distributed within 2 days following the IRB meeting[3]
Expedited Review	New Application (New Participating Site, Minimal Risk, Exempt, Not Human Research Determination)	Screened by staff within 7 days of receipt	2 days	Approval letter distributed 2 days following Designated Review[5]
	Modifications involving "Other parts of the study"	Screened by staff within 5 days of receipt[4]	2 days	Approval letter distributed 2 days following Designated Review[5]
	Modifications involving "Study team member information"	Administratively approved by staff within 5 days		
	Continuing Review	Will be reviewed by two weeks before expiration		Approval letter distributed 2 days following Designated Review[5]
	Reportable New Information (RNI)	Screened by staff within 2 days of receipt	2 days	Final documents distributed 3 days following Designated Review[6]
	Closure	Screened by staff within 7 days of receipt	2 days	Final documents distributed 3 days following Designated Review

[1] "Review ready" means the submission is complete and all issues identified by IRB staff have been resolved.

	ACTIVITY / DOCUMENT TYPE	PROCESSING TIME	NOTES
Other Activities	Result letter for items approved with contingencies	Letter distributed within 5 days following IRB review	If a submission is disapproved, the PI will first be notified by email within 1 day of meeting.
	Result letter for RNIs with further information required	Letter distributed within 5 days following IRB review	If a study is suspended or terminated, the PI will be notified immediately by email.
	Letter to OHRP / FDA / Institutional Official	Letter distributed (a) 30 calendar days after the RNI is reported to the IRB or (b) 10 business days following the IRB meeting, whichever is later.	If the IRB determines an event is Serious and/or Continuing Noncompliance or an Unanticipated Problem, external organizations will be notified as required
	External IRB Supplement	5 days	Permission from the IRO is required before applying to an external IRB. This approval is documented on the "IRO Endorsement of External IRB Application" form.
	Certification Letter	3 days to IRO Director for signature	Certification of IRB Approval, generally provided to funding agencies upon request

Footnotes

1 - Submissions that are Disapproved will return to the same Full IRB Committee that Disapproved the submission.
2 - New Applications that require Scientific Review Committee (SRC) must obtain SRC approval before submission to the IRB. New Applications that require entry into CTMS/OnCore must be entered before IRO will screen the item.
4 - If a Modification meets the criteria for rush review, IRB staff will screen the item within 1 day of receipt.
5 - If the Expedited Reviewer determines a submission requires Full Committee Review, it will be assigned to the next available IRB meeting
6 - If the Designated Reviewer refers an RNI to the Full Committee, IRB staff will notify the PI and Primary Contact of its agenda assignment. The PI will then be given an opportunity to provide further information for Committee consideration.
7 - Third-Party Safety Reports that do not meet reporting criteria will undergo administrative review by IRB staff only and will be acknowledged and returned to the PI within 7 days.