

Report to HREC and RGO post approval

Frequency	Report	Responsible
Ongoing	Amendments, protocol, Master PICF, Investigator, IB updates	Site PI
	Site specific PICF amendment	Site PI
	Complaints by participants - Research conduct	Per reviewing HREC/org/site policy
	Complaints by researchers – HREC or RGO decision	Per reviewing HREC/org/site policy
	HREC/RGO Decision complaints	Per reviewing HREC/org/site policy
	Site progress report (ACT, NSW, QLD)	Site PI (completes and submits)
Every 12 months	HREC annual report	Site PI (submits copy)
	Annual safety report	Site PI (submits copy)
As they occur	Serious breach	Site PI (submits copy)
	Suspected breach*	Site PI (submits copy)
	Significant Safety Issue (SSI)	Site PI (submits copy)
	Urgent Safety Measure (USM)	Site PI (submits copy)
End of study	Site close-out report (submit original in ACT, SA, WA)	Site PI
	Site close-out report (submit copy NSW, QLD, VIC)	Site PI
	HREC final report	Site PI

* Sites can report serious breaches if: 1) the Sponsor-Investigator disagrees with their assessment; or 2) the site believes the Sponsor-Investigator has committed a serious breach