Reporting timeframes for events (local principal investigators)

Timeframes required by the Research, Ethics and Governance Unit for reporting of events (from date of knowledge of event) are outlined in the table below.

Type of event	Timeframe for reporting	Format required	# of copies required	Submit to Ethics or Governance
Commencement of project	Within 7 days	Commencement Form	1	Ethics (if reviewed at that site) Governance (if reviewed elsewhere)
Serious adverse events and adverse events (SAEs and AEs) that materially impact on the continued ethical acceptability of the project.	ASAP but not later than 7 days of first knowledge of the event	SAE template (Principal Investigator to sign)	1	Governance
All other serious adverse events and adverse events	6 monthly line listing of events	Any concise line listing format accompanied by a covering letter.	1	Governance
Other Events e.g. Annual reports from sponsor / DSMB	Within 30 days of receipt.	Notification from the sponsor to be accompanied by a comment from the local investigator on the implications for ongoing conduct of the study. Research status report	1	Governance
Significant Safety Issues (Any significant safety issue which has been identified through analysis of results at any site, or action taken with respect to safety at any site)	Within 7 days	The report should include the basis for any action.	1	Ethics
Major Deviations from Informed Consent Process or Inclusion/Exclusion Criteria & other major Protocol Deviations. (Minor deviations need to be documented in the site file. It is not a requirement to report these events to the Research, Ethics and Governance Unit.)	Within 7 days	Letter to HREC along with revised Patient Information Sheet and Consent Form / Protocol if applicable. **Protocol Deviation Report** to be completed.	1	Governance

Change in Investigators	Within 7 days	Letter to HREC along with revised Patient Information Sheet and Consent Form to reflect changes 2 page CV for researchers who have NO**T** previously submitted (**signed and dated**)	1	Governance
Amendments to Protocol	Within 30 days and prior to enactment of amendments	Letter to HREC outlining amendments along with revised Protocol	Major 1 + 16 copies of tracked changes Minor 1 + 1 tracked change	Ethics
Amendments to Participant Information Sheet	Within 30 days and prior to enactment of amendments	Letter to HREC outlining amendments along with revised Participant Information Sheet (don't forget to update footer details with correct Versions & dates), along with copies of track changes	Major 16 + 16 copies Tracked Changes Minor 1 + 1 tracked changes	Ethics
Progress Reports	Annually (from the anniversary of the approval date) or more frequently if directed, and at study close	Progress Report Template	1	Ethics
Publications or oral presentations	Include in next Progress Report	Progress Report Template (Manuscripts must be sent before publication)	1	Ethics
Investigator Brochure Updates	Within 30 days	Letter to HREC outlining version & date changes	1 + 16 copies summary of tracked changes	Ethics
Updates to Insurance Cover, or Clinical Trial Agreements.	Within 30 days	Letter to Governance office outlining the changes.	1	Governance