Quick Guide for RGS amendment forms

For Sites where the Lead HREC is a WA Health HREC.

Amendment form	Uses	Submit to
Amendment Form *Not to be used or projects approved under NMA – please see next table*	Changes and/or additions to project documentation: • Protocol amendments • Updated PICF's • Updated questionnaires, diaries, appointment cards • Changes in research staff/personnel • Addition of site • Extension of approval	Submitted to WA Health Lead HREC. Once approval granted from Lead HREC, submit to all active sites RGO's
Governance Only Amendment Form	Changes and/or additions to project documentation: • Site specific documents • Insurance certificates • Updated agreements • Changes to budget	Only to RGO. If changes are related to other document changes (i.e. protocol) please ensure these have been submitted with Lead HREC approval prior to submission
Safety Reports	• Annual safety report	Lead HREC, RGO
	• Serious breach occurred at site within 72hrs • Local SUSAR/USADE at site, report within 72hrs	RGO
Progress Reports	Annual progress report of project	Lead HREC, then RGO
Site Final Report	To close out site	Submit to each RGO separately (*not to be submitted to HREC*)
Project Final Report *Not to be used or projects approved under NMA – please see next table*	To close out project	Submitted to Lead HREC after all sites have been closed

For NMA projects where the Lead HREC is an interstate HREC.

Amendment form	Uses	Submit to
Amendment Form *Not to be used or projects approved under NMA*	N/A	N/A
Governance Only Amendment Form	Changes and/or additions to project documentation: • Protocol amendments • Updated PICF's • Updated questionnaires, diaries, appointment cards • Changes in research staff/personnel • Extension of approval	Submit to RGO after approval from Lead HREC has been granted.
	• Insurance certificates • Updated agreements • Changes to budget	Submit to RGO. If changes are related to other document changes (i.e. protocol) please ensure these have been submitted with Lead HREC approval prior to submission
Safety Reports	• Annual safety report	Lead HREC, RGO
	• Serious breach occurred at site within 72hrs • Local SUSAR/USADE at site, report within 72hrs	To RGO responsible for the site event occurred at.
Progress Reports	Annual progress report of project If the LEAD HREC approval has been provided by a HREC outside WA Health (under NMA) then only the sites within WA Health will be included in section 2 of the report.	Lead HREC, then WA Health RGO Please provide the progress report that has been submitted to the LEAD HREC together with the HREC's acknowledgment.
Site Final Report	To close out site	Submit to each RGO separately
Project Final Report *Not to be used or projects approved under NMA*	N/A	N/A