Post Approval

Below is a list of the **post-approval sub-forms** which can be created from the **LNR VIC application in ERM**. Not all available forms are applicable. Please refer to the guidance below:

Form Type	Guidance from form	Use
Amendment Request	Once a research project has been ethically approved, any change to its design or conduct must be approved by the reviewing HREC or ethics review body. An amendment must not be implemented at a site until the HREC or ethics review body has granted approval of the amendment **and** (if applicable) the site RGO has granted authorisation of research governance/SSA amendment.	• Add or amend documents • Change investigator or personnel • Request extension of HREC approval • Other (must specify) *NOTE: Must tick 'Add or amend documents' when adding a new investigator so CV and Change to research personnel form can be uploaded to form.
Project Progress Report	Information on the progress of an approved research project must be provided to the reviewing the Human Research Ethics Committee (HREC) or ethics review body, in accordance with the National Statement on Ethical Conduct in Human Research (NHMRC, 2007).	• See form guidance • Submit annually by 1 September • Report should cover the reporting period 1 July – 30 June each year • The Self Audit Tool (LNR VIC SSA sub-form – see below) must be submitted at the same time as the progress report.
Suspected Breach Report	A suspected breach is a report that is judged by the reporter as a possible serious breach but has yet to be formally confirmed as a serious breach by the sponsor. This form must be completed when a third party (e.g. individual or institution) wishes to report a suspected breach of Good Clinical Practice (GCP) or the protocol. This should be reported directly to the reviewing HREC without reporting through the sponsor.	• See form guidance

	Information on reporting breaches is available in Reporting of Serious Breaches of Good Clinical Practice (GCP) or the Protocol for Trials Involving Therapeutic Goods (NHMRC, 2018). A serious breach must be notified to the reviewing Human Research Ethics Committee (HREC) using the Serious Breach Report.	
Project Final Report	When a research project is completed at all approved sites, the reviewing HREC or ethics review body must be notified. This *Project Final Report* must be used when the research project is completed at **all** sites approved by the reviewing HREC.	• See form guidance • For single-site studies that are either abandoned or completed
Project Notification Form	This notification form should be used to inform the reviewing Human Research Ethics Committee (HREC) or ethics review body of pertinent matters for which there is **not** a dedicated reporting form available.	• See form guidance • Report an adverse event/incident occurring to a participant (incidence resulting in harm must be notified to the Office for Research within 24 hours). Reporting in VHIMS may be required

Below is a list of the **post-approval sub-forms** which can be created from the **LNR VIC SSA application** in ERM. Not all available forms are applicable. Please refer to the guidance below:

Form Type	Guidance from form	Use
Complaint Report	If a complaint is made about a research project, the site Principal Investigator must report it to the site Research Governance Officer (RGO). The site RGO will advise whether the complaint should also be sent to the reviewing Human Research Ethics Committee (HREC).	• Contact the Manager Office for Research to report complaint and to determine if form is required to be completed
Site Audit Report	If the site Research Governance Officer (RGO) requests a self-audit report for a research project, the site Principal Investigator should complete this *Site Audit Report*.	• This should be submitted annually at the same time as the annual progress report