Post Approval

Below is a list of the **post-approval sub-forms** which can be created from the **SSA Application** in ERM. 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
Non-Serious Breach/Deviation Report	A **deviation** is any breach, divergence or departure from the requirements of Good Clinical Practice (GCP) or the protocol that **does not** have a significant impact on the continued safety or rights of participants or the reliability and robustness of the data generated in the research project. If a deviation is considered to be a **serious breach** it should be reported using the *Serious Breach Report*. To fulfil GCP requirements, any deviation must be reported to the **sponsor**. The sponsor, in collaboration with the site Principal Investigator, should complete this *Non-serious Breach/Deviation Report* form to inform the site Research Governance Officer (RGO) of a non-serious breach/deviation. Some deviations may require reporting to the reviewing Human Research Ethics Committee (HREC). The RGO will advise whether this is required and, if so, the form should be forwarded to the reviewing HREC. For a multi-site project, the Coordinating Principal Investigator should be informed if HREC reporting is required.	• Site related deviations for multi-site and single-site projects
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
Site Notification Report	This notification form should be used to inform the site Research Governance Officer (RGO) of site matters for which there is **not** a dedicated reporting form available.	• **Multi-site SSA amendments** Must include sufficient detail about the amendment at Peninsula Health to assess the impact and suitability of the

		amendment at this site. Attach the amendment submitted to the reviewing HREC as supporting documentation. ***NOTE:** Complete and attach the Governance Payment Form as part of your submission if the project is commercially sponsored and the amendment relates to a revised protocol or new/amended Investigator's Brochure. • **Site changes to Principal Investigator** See under HREA sub-form for guidance. • **Site related SUSAR reports in clinical trials** Attach a copy of the Safety Report submitted to the reviewing HREC. Only submit site related SUSAR reports as the Office for Research may need to notify VMIA. • **Site Closure Report/Project Final Report** Attach the Site Closure Report/Project Final Report submitted to the reviewing HREC. See under HREA sub-forms for guidance.
Site Progress Report	The site Principal Investigator should report to the site Research Governance Officer (RGO) according to site policy.	• Annual site progress reports for multi-site studies. • Attach the HREC progress report and HREC approval as the insurance certificate (as this is the only way to upload a document). If you also have an insurance certificate to upload, please scan all documents as one document and upload as one file).

Depending on the nature of the study, there may be post-approval sub-forms which are created in ERM from the HREA form that may need to be completed at this site.

*NOTE: You will need to contact the lead site so that the HREA form owner can create the HREA sub-form required and add you as a collaborator so you can complete the form.

Below is a list of the **post-approval sub-forms** which can be created in ERM from the **HREA form**. 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. This amendment request must be completed and submitted to the reviewing HREC or ethical review body. An amendment to a research project may also impact research governance/site specific assessment (SSA). The Research Governance Officer (RGO) at each affected site must be notified of the amendment by the site Principal Investigator (PI), in order to determine if research governance/SSA amendment is required. 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.	• Site Change to Principal Investigator • A copy of this request and the HREC acknowledgement to be submitted as an attachment to a Site Notification Report (see under SSA sub-form).
Safety Report	The sponsor is responsible for reporting a safety event to the reviewing HREC, in accordance with Safety Monitoring and Reporting in Clinical Trials Involving Therapeutic Goods (NHMRC, 2016).	• Significant Safety Issue (SSI) • Suspected Unexpected Serious Adverse Reaction (SUSAR) • Unanticipated Serious Adverse Device Effect (USADE) * NOTE: Use for clinical trials only. For investigator-initiated clinical trials the form is to be completed by the PI.
Annual Safety Report	This *Annual Safety Report* is required for an **interventional clinical trial** only.	• No site related submission required

	Information on safety reporting is available in Safety Monitoring and Reporting in Clinical Trials Involving Therapeutic Goods (NHMRC, 2016).	
Serious Breach Report	A serious breach is a breach of GCP or the protocol that is likely to affect to a significant degree the safety or rights of a research participant of the reliability and robustness of the data generated in the research project. A serious breach must be notified to the reviewing HREC. The form must be completed by the **sponsor**. It may be used for reporting a serious breach to the HREC or for providing additional/follow-up information following notification by an individual/institution of a confirmed serious breach. Information on reporting breaches is available in Reporting Serious Breaches of GCP or the Protocol for Trials Involving Therapeutic Goods (NHMRC, 2018).	• No site related submission required
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. 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*.	• A site related suspected breach of GCP or protocol
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).	• No site related report required as report is submitted as an SSA sub-form (see under SSA sub-form).

Site Closure Report	If an individual site closes from within an ongoing multi-site research project, the reviewing HREC or ethics review body must be notified. This *Site Closure Report* must be used for an **individual site closure in a multi-site research project**. If the research project is completed at all sites approved by the reviewing HREC, use the *Project Final Report* instead.	• For our site if we close prior to lead site • A copy of this report and the HREC acknowledgement to be submitted as an attachment to a Site Notification Report (see under SSA sub-form).
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.	• For our site if we close at the same time as all other sites • A copy of this report and the HREC acknowledgement to be submitted as an attachment to a Site Notification Report (see under SSA sub-form).
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.	• Use the SSA sub-form Site Notification Report