



Post Approval

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

Form Type	Guidance from form	Use
Amendment Request	<p>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.</p> <p>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.</p> <p>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.</p>	<ul style="list-style-type: none"> • Add or amend documents • Change investigator or personnel • Request extension of HREC approval • Reactivate approval • Other (must specify) • Add site <p>*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.</p> <p>*NOTE: Complete and attach the Ethics 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</p>
Safety Report	<p>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).</p>	<ul style="list-style-type: none"> • See form guidance
Serious Breach Report	<p>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).</p>	<ul style="list-style-type: none"> • See form guidance



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<p>Suspected Breach Report</p>	<p>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.</p> <p>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.</p> <p>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).</p> <p>A serious breach must be notified to the reviewing Human Research Ethics Committee (HREC) using the <i>Serious Breach Report</i>.</p>	<ul style="list-style-type: none"> • See form guidance
<p>Project Progress Report</p>	<p>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).</p>	<ul style="list-style-type: none"> • See form guidance • Submit annually by 1 September • Report should cover the reporting period 1 July – 30 June each year • The Self Audit Tool (SSA sub-form – see below) must be submitted at the same time as the progress report.
<p>Site Closure Report</p>	<p>If an individual site closes from within an ongoing multi-site research project, the reviewing HREC or ethics review body must be notified.</p> <p>This <i>Site Closure Report</i> 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 <i>Project Final Report</i> instead.</p>	<ul style="list-style-type: none"> • See form guidance • Not required for single-site projects
<p>Project Final Report</p>	<p>When a research project is completed at all approved sites, the reviewing HREC or ethics review body must be notified.</p> <p>This <i>Project Final Report</i> must be used when the research project is completed at all sites approved by the reviewing HREC.</p>	<ul style="list-style-type: none"> • See form guidance • For single-site studies that are either abandoned or completed
<p>Project Notification Form</p>	<p>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.</p>	<ul style="list-style-type: none"> • See form guidance • For updated insurance certificates that require submission prior to the progress report submission.



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Form Type	Guidance from form	Use
Complaint Report	<p>If a complaint is made about a research project, the site Principal Investigator must report it to the site Research Governance Officer (RGO).</p> <p>The site RGO will advise whether the complaint should also be sent to the reviewing Human Research Ethics Committee (HREC).</p>	<ul style="list-style-type: none"> Contact the Manager Office for Research to report complaint and to determine if form is required to be completed
Non-Serious Breach/Deviation Report	<p>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 <i>Serious Breach Report</i>.</p> <p>To fulfil GCP requirements, any deviation must be reported to the sponsor. The sponsor, in collaboration with the site Principal Investigator, should complete this <i>Non-serious Breach/Deviation Report</i> form to inform the site Research Governance Officer (RGO) of a non-serious breach/deviation.</p> <p>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.</p>	<ul style="list-style-type: none"> Site related deviations for multi-site and single-site projects
Site Audit Report	<p>If the site Research Governance Officer (RGO) requests a self-audit report for a research project, the site Principal Investigator should complete this <i>Site Audit Report</i>.</p>	<ul style="list-style-type: none"> This should be submitted annually at the same time as the annual progress report.
Site Notification Report	<p>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.</p>	<ul style="list-style-type: none"> Not required for single-site projects.
Site Progress Report	<p>The site Principal Investigator should report to the site Research Governance Officer (RGO) according to site policy.</p>	<ul style="list-style-type: none"> Not required for single-site projects.