



Below is a list of forms/documents required for SERP/NMA research applications. This guidance does not apply to more than low risk research applications being reviewed by PH HREC.

New Applications

	Form/Document Name	Mandatory/Project Dependent	Guidance
Research Governance Application	Site Specific Assessment (SSA) Form	Mandatory for all applications	Create SSA form as a sub-form of the HREA form using ERM. The SSA is created as a sub-form of the HREA and is usually transferred to you from the lead site via ERM. You will need to have an ERM account already set up in order to have the SSA transferred to you.
	Governance Payment Form	Mandatory for all applications	Refer to the payment form and complete relevant section.
	Reviewing HREC documents	Mandatory for all applications	If the reviewing HREC is within Vic or Qld the reviewing HREC documents will be viewable to the Office for Research and do not need to be uploaded within the SSA. If the reviewing HREC is within ACT, NSW, SA or WA the reviewing HREC documents will not be viewable to the Office for Research and need to be uploaded within the SSA.
Research Governance Supporting Documents	Reviewing HREC Approval Letter	Mandatory for all applications	Must list Peninsula Health as an approved site.
	Investigator CV for each researcher	Mandatory when a CV has not been submitted in the previous 3 years	Investigator CV Template available Full CV is not required
	Site Specific Participant Information and Consent Forms (PICFs)	Mandatory for all applications that require participant consent	Based on the HREC approved Master PICFs. The Master PICF version approved by the reviewing HREC is to be modified to create the Peninsula Health site specific PICF. PICFs which are not compliant with the templates available from DHHS will not be accepted. Templates for Clinical Trials Templates for Health and Medical Research For projects approved through an interstate reviewing HREC, ensure all Victorian specific privacy wording is included prior to submitting to the Office for Research. The Peninsula Health logo and site specific contact information will be supplied by contacting the Office for Research
	Site Specific Data Collection Tools	Project dependent	This includes site specific questionnaires, surveys, focus group questions/themes, telephone questionnaires that are based on the HREC approved master version.



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	Site Specific Advertising / Recruitment material	Project dependent	This includes site specific letter or email invitations, posters, brochures or leaflets, content for media (including radio, print and digital/social media) that are based on the HREC approved master version. See Advertising Guidelines
	Research Agreement	Project dependent	Refer to Monash Partners Legal Document Repository Contact the Manager Office for Research if you are unsure if this is required for your project.
	Clinical Trial Notification (CTN)	Project dependent	For projects involving the use of unapproved therapeutic goods. See TGA guidelines . Contact Manager Office for Research.
	Indemnity	Project dependent	Refer to Monash Partners Legal Document Repository Contact the Manager Office for Research if you are unsure if this is required for your project.
	Certificate of Currency (Insurance)	Project dependent	Must provide sufficient evidence that the commercial sponsor or CRO meets minimum insurance requirements. Contact the Manager Office for Research if you are unsure if this is required for your project.

Post Approval

Below is a list of the post-approval sub-forms which can be created in ERM from the **SSA form**. Please refer to the guidance below:

Form Type	Guidance from form	Use for
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).	<ul style="list-style-type: none"> See guidance Applicable for multi-site and single-site projects
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 <i>Serious Breach Report</i> . 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</i>	<ul style="list-style-type: none"> Site related deviations for multi-site and single-site projects



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	<p><i>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>	
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 <i>Site Audit Report</i> .	<ul style="list-style-type: none"> 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.	<ul style="list-style-type: none"> 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.	<ul style="list-style-type: none"> 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 set you up 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:



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Form Type	Guidance from form	Use for
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>This amendment request must be completed and submitted to the reviewing HREC or ethical 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"> • 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	<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"> • Significant Safety Issue (SSI) • Suspected Unexpected Serious Adverse Reaction (SUSAR) • Unanticipated Serious Adverse Device Effect (USADE) <p>* NOTE: Use for clinical trials only. For investigator-initiated clinical trials the form is to be completed by the PI.</p>
Annual Safety Report	<p>This <i>Annual Safety Report</i> is required for an interventional clinical trial only.</p> <p>Information on safety reporting is available in Safety Monitoring and Reporting in Clinical Trials Involving Therapeutic Goods (NHMRC, 2016).</p>	<ul style="list-style-type: none"> • No site related submission required
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"> • No site related submission required
Suspected Breach Report	<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>	<ul style="list-style-type: none"> • A site related suspected breach of GCP or protocol



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	<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>	
Project Progress Report	<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"> No site related report required as report is submitted as an SSA sub-form (see under SSA sub-form).
Site Closure Report	<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"> 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	<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"> 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	<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"> Use the SSA sub-form Site Notification Report