New Applications

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

	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 Clinical Trials Research website will not be accepted. https://www.clinicaltrialsandresearch.vic.gov.au/ethics-application

			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.
	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 Clinical trials | Therapeutic Goods Administration (TGA). 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.