



## New Applications

Below is a list of forms/documents required for **more than low risk research applications reviewed by PH HREC**. This guidance does not apply to multi-site projects approved through SERP or NMA.

	Form/Document Name	Mandatory/Project Dependent	Guidance
<b>Register your project</b>	Protocol Template	Mandatory for all applications	<p>Submit your protocol for assessment by the Office for Research to determine application forms required to be completed and submitted.</p> <p>Submit your protocol to <a href="mailto:HREC@phcn.vic.gov.au">HREC@phcn.vic.gov.au</a></p> <p><a href="#">Protocol Template</a></p>
<b>Ethics Application Form Ethics Supporting Documents</b>	Human Research Ethics Application (HREA)	Mandatory for all applications	<p>Complete through ERM. <a href="#">Login - ERM Applications (ethicalreviewmanager.com)</a></p> <p>First time users will need to create an account.</p> <p><b>TIP: Don't press submit button until signature has been obtained.</b></p>
	Victorian Specific Module (VSM)	Mandatory for all applications	<p>Addresses Victorian specific legislative requirements not covered in the HREA.</p> <p>The VSM is created as a <b>sub-form of the HREA</b> in ERM. You must upload the VSM within the HREA form in order to submit your application.</p>
	Ethics Payment Form	Mandatory for all applications	Refer to the <a href="#">payment form</a> and complete relevant section.
	Protocol	Mandatory for all applications	<p>Must match the protocol submitted as part of project registration.</p> <p><a href="#">Protocol Template</a></p> <p>Attach as a supporting document to HREA Application Form.</p>



**GUIDANCE FOR HREA APPLICATIONS – FORMS AND DOCUMENTS**

	Participant Information and Consent Form (PICF)	Project dependent	<p>Templates available from Clinical Trials Research website. Other PICF formats are not accepted.</p> <p><a href="https://www.clinicaltrialsandresearch.vic.gov.au/ethics-application">https://www.clinicaltrialsandresearch.vic.gov.au/ethics-application</a></p>
	Data Collection Tools	Project dependent	<p>This includes questionnaires, surveys, focus group questions/themes, telephone questionnaires.</p> <p>For telephone questionnaires a <a href="#">Telephone Script Template</a> is available.</p>
	Advertising / Recruitment material	Project dependent	<p>This includes letter or email invitations, posters, brochures or leaflets, content for media (including radio, print and digital/social media).</p> <p>See <a href="#">Advertising Guidelines</a></p>
	Investigator CV for each researcher	Mandatory when a CV has not been submitted in the previous 3 years	<p>This includes letter or email invitations, posters, brochures or leaflets, content for media (including radio, print and digital/social media).</p> <p>See <a href="#">CV Template</a></p>
	Additional documents for clinical trials	Project dependent	<p>Investigator Brochure / Product Information Instructions for participants Any other documents required under GCP See <a href="#">Clinical trials   Therapeutic Goods Administration (TGA)</a></p>
	Projects involving ionising radiation	Project dependent	Contact the Manager Office for Research on 9784-2679
<b>Research Governance Application</b>	Site Specific Assessment (SSA) Form	Mandatory for all applications	<p>Create SSA form as a sub-form of the LNR VIC form using ERM</p> <p>Must be electronically signed by the Head of Department and all supporting departments</p> <p><b>TIP: Don't press submit button until all signatures have been obtained</b></p>



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<b>Research Governance Supporting Documents</b>	Research Agreement	Project dependent	Refer to <a href="#">Monash Partners Legal Document Repository</a> . Contact the <a href="#">Manager Office for Research</a> 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 <a href="#">Clinical trials   Therapeutic Goods Administration (TGA)</a> . Contact Manager Office for Research.
	Indemnity	Project dependent	Refer to <a href="#">Monash Partners Legal Document Repository</a> . 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 <a href="#">Manager Office for Research</a> if you are unsure if this is required for your project.