

# Review Process Summary for Research Involving Greater than Low Risk



The following table summarises Barwon Health’s review processes for single and multi-site research applications which involve greater than low risk.

Type of Research	Application Requirements	Process/Forms
Single site	<ul style="list-style-type: none"> <li>Where Barwon Health (BH) is the only site; or</li> <li>Where BH is reviewing for another single site (e.g. SJOG)</li> </ul>	<ol style="list-style-type: none"> <li><b>1. Review by BH Research Review Committee (RRC)</b> <ul style="list-style-type: none"> <li>Pre-review for scientific validity and merit</li> <li>BH researcher completes HREA via <a href="#">Ethical Review Manager (ERM)</a></li> </ul> </li> <li><b>2. Review by BH Human Research Ethics Committee (HREC)</b> <ul style="list-style-type: none"> <li>Review of HREA and RRC comments and recommendations</li> </ul> </li> <li><b>3. Research governance review</b> <ul style="list-style-type: none"> <li>BH researcher completes SSA via <a href="#">ERM</a></li> </ul> </li> </ol>
Multi-site – Streamlined Ethics Review Process (SERP)	<ul style="list-style-type: none"> <li>For participating organisations, multi-site research projects can be reviewed under the SERP</li> <li>SERP projects are allocated to a single accredited HREC via the Central Allocation System (CAS) – <i>for more information, call (03) 9096 7395</i></li> <li>All sites involved accept one HREC review</li> <li>All sites conduct separate research governance</li> </ul>	<ol style="list-style-type: none"> <li><b>1. HREC approval</b> <ul style="list-style-type: none"> <li>Multi-site projects reviewed under the SERP have ethical review completed by one of the reviewing HRECs (<i>Note: BH is an accepting site, not a reviewing site</i>)</li> <li>Lead site completes HREA via <a href="#">ERM</a></li> <li>Lead site submits via ERM to the reviewing HREC (<i>not BH</i>)</li> </ul> </li> <li><b>2. Research governance approval</b> <ul style="list-style-type: none"> <li>BH researcher completes SSA via <a href="#">ERM</a></li> <li>BH researcher submits SSA to BH RGO</li> </ul> </li> </ol>

Type of Research	Application Requirements	Process/Forms
Multi-site – Non-SERP ( <b>where BH is <u>not</u> the lead site</b> )	<ul style="list-style-type: none"> <li>• For multi-site research outside the scope of SERP, researchers must seek independent review through the lead site’s HREC</li> <li>• Application is reviewed by the HREC of the lead institution – According to 5.3.1 NS “...each institution has the further responsibility to adopt a review process that eliminates any unnecessary duplication of ethical review”</li> <li>• Many HRECs will accept the prior review of accredited HRECs</li> <li>• At BH, projects may be eligible for an exemption from BH HREC review on the basis of prior HREC approval from another accredited HREC</li> </ul>	<ol style="list-style-type: none"> <li><b>1. HREC approval</b> <ul style="list-style-type: none"> <li>• Lead site submits HREA via <a href="#">ERM</a></li> <li>• Review is conducted by lead HREC</li> </ul> </li> </ol>
Multi-site – Non-SERP ( <b>where BH is the lead site</b> )	<ul style="list-style-type: none"> <li>• Multi-site research is reviewed by the HREC of the lead institution</li> <li>• Where BH is lead site, submit to BH HREC for review</li> <li>• Other sites may choose to accept BH review and BH HREC approval</li> </ul>	<ol style="list-style-type: none"> <li><b>1. Review by BH RRC</b> <ul style="list-style-type: none"> <li>• Pre-review for scientific validity and merit</li> <li>• BH researcher to complete HREA via <a href="#">ERM</a></li> </ul> </li> <li><b>2. Review by BH HREC</b> <ul style="list-style-type: none"> <li>• Review of HREA and RRC comments and recommendations</li> </ul> </li> <li><b>3. Research governance review</b> <ul style="list-style-type: none"> <li>• Complete SSA via <a href="#">ERM</a></li> <li>• Submit SSA to BH RGO</li> </ul> </li> </ol>