

## Site authorisation submission checklist

### Who should use this form?

Anybody seeking site authorisation – either Site Specific Assessment (SSA) form or Access Review Request (ARR) from the Chief Executive of the Justice Health & Forensic Mental Health Network (JH&FMHN or the Network).

### Purpose

The purpose of this form is to help you check that your site authorisation application is complete and error-free. There is no need to submit this form.

Requirements	Yes or No
<p><b>Cover letter</b></p> <ul style="list-style-type: none"> <li>• Addressed to the Network’s Chief Executive</li> <li>• List all Network sites and facilities involved</li> <li>• List all documents submitted with the application</li> <li>• Provide details of the nominated research contact person</li> <li>• Signed by the co-ordinating investigator</li> <li>• Submitted online via the Research Ethics Governance and Information System (REGIS), with the documents described below uploaded.</li> </ul>	
<p><b>Curriculum vitae</b></p> <p>Provide short (1-2 page) CVs for all investigators and research staff, unless already submitted to the Network’s Chief Executive in the past two years. If this is the case, please note in your cover letter.</p>	
<p><b>Site Specific Assessment (SSA) form or Access Review Request (ARR) form</b></p> <p>Complete electronically through REGIS and seek Head of Department sign-off from the relevant Network Executive Director. For further instructions, use the <a href="https://regis.health.nsw.gov.au/how-to/">Quick reference guides (https://regis.health.nsw.gov.au/how-to/)</a>.</p>	
<p><b>Letter of Support from Head of supporting Department/s</b></p> <p>Endorsement from the Head of the supporting Department/s is required to ensure the relevant staff are familiar with the project.</p>	

Requirements	Yes or No
<p><b>JH&amp;FMHN HREC approval letter</b></p>	
<p><b>JH&amp;FMHN HREC approved documents</b></p> <p>Provide all documents that were approved by the HREC for use at Network sites</p>	
<p><b>Research budget</b></p> <p>Provide a budget for research studies that have allocated funding. If funds will be used or received in a Network cost centre, provide details and evidence of support by the cost centre authority. A template is available upon request.</p> <p>For any studies involving the use of drugs, whether they are already approved for the intended indication or not, a pharmacy budget should be specified, given the pharmacy will be dispensing the drug regardless of the regulatory status of the drug.</p>	
<p><b>Documents for clinical trials supported by a commercial sponsor</b></p> <ul style="list-style-type: none"> <li>• Clinical Trial Research Agreement (CTRA) – Medicines Australia Standard Form/Contract Research Organisation acting as the Sponsor/Phase 4. Please note any schedule 7 conditions should be approved by the Eastern Border States, alternatively these can be sent for external legal review at the sponsor’s expense. Please find the CTRA templates at <a href="https://medicinesaustralia.com.au/policy/clinical-trials/clinical-trials-research-agreements/">https://medicinesaustralia.com.au/policy/clinical-trials/clinical-trials-research-agreements/</a></li> <li>• Medicines Australia Form of Indemnity (standard) between the sponsor and the NSW Public Health Organisation, please see the template at <a href="https://medicinesaustralia.com.au/policy/clinical-trials/indemity-and-compensation-guidelines/">https://medicinesaustralia.com.au/policy/clinical-trials/indemity-and-compensation-guidelines/</a></li> <li>• Certificate of Currency/ Insurance – covering a minimum of \$20 million (AUS) per occurrence and in the aggregate with an Australian named sponsor and excess/deductible or self-insured retention amount not greater than \$25,000 for each and every claim or series of claims. The policy must meet the requirements of Section 2.2.2 of the <a href="https://www1.health.nsw.gov.au/pds/ActivePDSDocuments/PD2011_006.pdf">https://www1.health.nsw.gov.au/pds/ActivePDSDocuments/PD2011_006.pdf</a></li> <li>• Clinical Trial Notification (CTN) Form/Clinical Trial Exemption (CTX) Form. For clinical trials that involve the use of a drug or device not yet approved by the TGA or not yet approved for its proposed indication, it is necessary to submit a CTN or CTX form signed by the HREC. Further information on these schemes can be accessed via <a href="https://www.tga.gov.au/clinical-trials">https://www.tga.gov.au/clinical-trials</a></li> </ul>	

Requirements	Yes or No
<p><b>Documents for investigator-initiated clinical trials</b></p> <ul style="list-style-type: none"> <li>• Indemnity assessment – the process of indemnity assessment varies between public health organisations. Consultation is recommended with the Research Governance and Ethics Officer prior to submission. Investigators who are conducting investigator-initiated clinical trials (no sponsor) must make an application to the Chief Executive of the relevant NSW Public Health Organisation for consideration to assess whether the organisation will accept the indemnity for the trial under Treasury Managed Funds (TMF). The Chief Executive is the only one who can bind the use of TMF in this circumstance. Individual requirements should be discussed with the relevant Public Health Organisation.</li> <li>• Clinical Trial Notification (CTN) Form/Clinical Trial Exemption (CTX) Form. For clinical trials that involve the use of a drug or device not yet approved by the TGA or not yet approved for its proposed indication, it is necessary to submit a CTN or CTX form signed by the HREC. Further information on these schemes can be accessed via <a href="https://www.tga.gov.au/clinical-trials">https://www.tga.gov.au/clinical-trials</a></li> </ul>	
<p><b>Aboriginal Health &amp; Medical Research Council (AH&amp;MRC) HREC approval letter</b></p> <p><b>Aboriginal Reference Group endorsement letter</b></p>	
<p><b>Approval from other relevant HREC/s or research committees</b></p>	
<p><b>For ARR applications – letter of in-principle support from data custodian/s</b></p>	

Contact: [JHFMHN-Ethics@health.nsw.gov.au](mailto:JHFMHN-Ethics@health.nsw.gov.au)