

Clinical Trial Contracts, Indemnities and CTN Process Map

<p style="writing-mode: vertical-rl; transform: rotate(180deg);">Industry Sponsored Trial - contracts with MCRI</p>	<p>Medicines Australia CTRA – Standard Form OR Medicines Australia CTRA CRO acting as the local sponsor Both are available on Medicines Australia website</p> <p>A Standard Form of Indemnity is also required (include MCRI/RCH Standard Wording) available on RCH REG website Clinical Trial Notification (CTN) - will be required (the Sponsor company will handle this)</p> <p>Sponsoring company is sponsor (CTRA, Indemnity & CTN); MCRI is institution (CTRA & Indemnity); RCH is site (CTRA Schedule 1 & CTN)</p>
<p style="writing-mode: vertical-rl; transform: rotate(180deg);">Investigator Initiated Trial Single Site MCRI/RCH</p>	<p>MCRI/RCH Single Site</p> <p>External funder (non-commercial)</p> <p>External funder (commercial) providing limited support (e.g. drugs)</p> <p>Funding Agreement (e.g. NHMRC-MCRI agreement)</p> <p>Use the company's template (or CRG CTRA* if none available)</p> <p>A separate indemnity is not applicable. Clinical Trial Notification (CTN) – required where the study involves a drug or device intervention. Contact MCTC at mctc@mcri.edu.au to request.</p> <p>* CRG CTRA = Collaborative or Cooperative Research Group (CRG) Clinical Trial Research Agreement For CTRA: MCRI is institution, MCRI or RCH is site. For CTN: MCRI is sponsor; MCRI or RCH is site.</p>
<p style="writing-mode: vertical-rl; transform: rotate(180deg);">Investigator Initiated Multicentre Trial MCRI/RCH is leading the trial</p>	<p>MCRI/RCH responsible for protocol design</p> <p>MCRI first contracts with the external funder</p> <p>MCRI then contracts with the Participating Sites</p> <p>Funding Agreement (e.g. with NHMRC)</p> <p>CRG CTRA template</p> <p>Indemnity – MCRI does not provide indemnity to participating sites but liability & insurance clauses are included in CRG CTRA. Clinical Trial Notification (CTN) – required where the study involves a drug or device intervention. Contact MCTC at mctc@mcri.edu.au to request.</p> <p>For CTRA: Where MCRI/RCH responsible for protocol design: MCRI is Organisation & enters into CTRAs with each site as Institution Where CRG (Collaborative/Cooperative Research Group) responsible for protocol design: CRG enters into CTRAs with each site/Institution</p> <p>For RCH/MCRI CTN: MCRI or RCH is the site; MCRI or CRG is sponsor. For Participating site CTN: Other sites will either be added to MCRI CTN or alternatively act as their own sponsor and submit their own CTN.</p>
<p style="writing-mode: vertical-rl; transform: rotate(180deg);">Investigator Initiated Multicentre Trial MCRI/RCH is Participating Site</p>	<p>The Lead Site is responsible for protocol design - MCRI/RCH is just the Accepting Site</p> <p>Collaborative Group Protocol Design</p> <p>CRG CTRA template</p> <p>Indemnity not applicable. Liability & insurance clauses are included in CRG CTRA. Clinical Trial Notification (CTN) – required where the study involves a drug or device intervention. MCRI/RCH may be added to the CTN of the site leading the trial or be required to submit own CTN (for this contact MCTC at mctc@mcri.edu.au to request).</p> <p>For CTRA: Lead site or CRG is Organisation; MCRI is Institution; MCRI or RCH is site (CTRA Schedule 1). For CTN: MCRI or RCH may be added as a site to the CTN of the Site/Institution or CRG leading the research – alternatively MCRI will submit own CTN listing MCRI as sponsor and MCRI or RCH as site.</p>