Clinical Trial Contracts, Indemnities and CTN Process Map

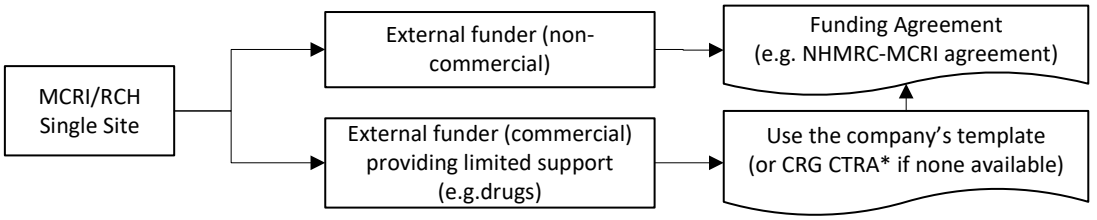
Industry Sponsored Trial - contracts with MCRI

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)

Sponsoring company is sponsor (CTRA, Indemnity & CTN); MCRI is institution (CTRA & Indemnity); RCH is site (CTRA Schedule 1 & CTN)

Investigator Initiated Trial Single Site MCRI/RCH

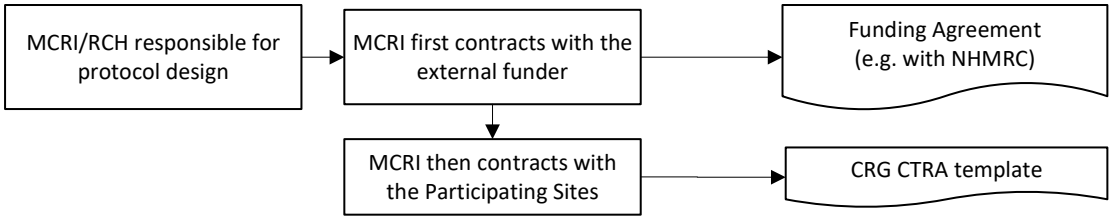


A separate indemnity is not applicable.

Clinical Trial Notification (CTN) – required where the study involves a drug or device intervention. Contact MCTC at mctc@mcri.edu.au to request.

*** 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.

Investigator Initiated Multicentre Trial MCRI/RCH is leading the trial



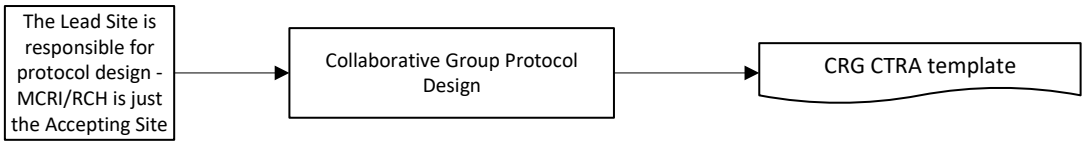
Indemnity – MCRI does not provide indemnity to participating sites but liability & insurance clauses are included in CRG CTRA.

Clinical Trial Notification (CTN) – required where the study involves a drug or device intervention. Contact MCTC at mctc@mcri.edu.au to request.

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

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.

Investigator Initiated Multicentre Trial MCRI/RCH is Participating Site



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).

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.