Government of **Western Australia**
South Metropolitan Health Service

National Mutual Acceptance projects with an external lead Health Research Ethics Committee

Submission of HREC approved documents	
Activity	**Explanation**
Workspace creation	CPI has overall responsibility for the project so needs to be signed up to RGS and create the workspace. If the delegate creates the workspace the CPI needs to be invited to the project team. **Ensure** that when the workspace is created the project is categorised as '**interjurisdictional'** using 'national mutual acceptance' and that the lead HREC is outside WA.
WA Specific Module (WASM) - PI/PI delegate to complete and authorise	1. Ensure project details are authorised 2. Complete and authorise governance section in project details. 3. Complete WASM and authorise
Submit WASM to lead HREC	Save the WASM as a pdf and send to external lead HREC. The WASM contains all WA legislation that the HREC must consider when approving the project for the WA site. WASM must be noted on the HREC approval letter
Upload HREC approved documents	So that all participating sites in WA can see your approved documents Upload documents to Ethics section of applications tab in RGS Submit HREC approved documents for use at the site e.g. Protocol , IB, Master PICF, Questionnaires and Diaries, Card and Poster to Governance by clicking the 'Submit Ethics to

	Governance button’
Lead HREC approval letter (original)	Ethics approval letter should list the documents reviewed and all sites involved (if a WA Health site is listed, ensure WASM is listed)
Lead HREC amendment letter	If a WA Health/SMHS site is added after initial HREC approval please ensure that you upload the amendment approval letter. (Ensure WASM is noted on letter).

Site Authorisation Application (Governance)

Activity	Instruction
Site PICF	Footer to state site, version, date and master document details FHHS PICF Version 2 dated 1/03/2018 based on Master PICF Version 3 dated 1 /12/2017) Add Research Governance (RG) contact details; SMHS.RGO@health.wa.gov.au Ph 6152 2646 or 6152 2253 under Complaints section.
Clinical Trial Research Agreement	Draft Word version of the Medicines Australia (MA) 8 March 2017 template including WA Health Schedule 7 (or Schedule 4) clauses
Name of Institution	**South Metropolitan Health Service trading as ----------** Site address: ---------- ABN: 92 264 056 442
Indemnity	Need MA **Standard Form** of Indemnity Not HREC-only form of Indemnity
Insurance	For Phase 1 or 2 trial or new Pharma sponsor request the Certificate of Currency and Insurance Policy wording
Clinical Trial Notification	For a drug or device not registered with the TGA for use in Australia or if the drug/device is being used for a new indication. Or provide the ARTG number / certificate if TGA registered

This document can be made available in alternative formats on request.

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	Upload a copy of the CTN acknowledgement form to RGS
Declaration of Confidentiality	If identified data is being shared with non-WA Health employees they need to be project member in RGS.
Service Agreement	Needed if there is a 3rd party contractor e.g. SKG Radiology
Dosimetry Assessment	If the project involves administration of ionising radiation above standard of care, upload the dosimetry assessment to RGS or copy of an email from a Physicist approving the dose. Radiological Council approval letter should be uploaded into RGS, if applicable.
Site Specific Assessment Form	Add funders and obtain approval of form from Business Manager and Co-Director of the Service
Budget Form	Indicate Research Department and obtain approval by Head of Dept. and Heads of Supporting Departments as required. Add costs for SMHS Executive- HREC and RG review at $3,500 each. Substantial amendment review (for commercially sponsored trials) at $600 for HREC and $600 for RG. For investigator initiated and collaborative projects add RG costs under 'in-kind' column. Ensure that budget for project has been costed properly (template in RGS) using the Independent Hospital Pricing Authority (IHPA) clinical trial cost guide. There should not be a surplus or a deficit.

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