Research Governance Submission Checklist

(Site Specific Assessment)

A. Mandatory items	Yes	N/A
Cover letter (address to Research Governance Officer, brief description of study, study sites and list of attachments)	☐	
Site Specific Assessment (SSA) Application – completed online at http://au.forms.ethicalreviewmanager.com (Create a Sub-form of the HREA)	☐	
Budget information – Details of revenue, study costs and in-kind costs If costs are $10,000 or greater a separate budget spreadsheet and Finance approval is required. Evidence of external funding (if applicable) must also be uploaded.	☐	
Head of Department support/signature – Must be sought from Executive General Managers for TCHHS sector (North and/or South). Contact RGO for advice or email a PDF of your SSA Form and Protocol to tchhs-edms@health.qld.gov.au for signatures.	☐	
Protocol	☐	
Study Documents (copy of final documents approved by HREC as per section B – relevant to study conduct at TCHHS)	☐	☐
HREA Form (final copy from HREC submission)	☐	☐
HREC Approval letter	☐	☐

B. Study specific documentation	Yes	No	N/A
Studies involving a non-QH Collaborator or Sponsor (includes Student or university projects and other collaborative projects)			
Study Agreement – Contact RGO for advice or use Medicines Australia templates: https://medicinesaustralia.com.au/policy/clinical-trials/clinical-trials-research-agreements	☐	☐	☐
Studies prospectively recruiting participants (including opt out consent)			
Participant Information and Consent Form/s (PICF) (For multi-centre studies only - submit both the clean Master PICF and a tracked and clean site specific PICF)	☐	☐	☐
Any other Site-Specific Recruitment Documentation (multi-centre studies only)	☐	☐	☐
Clinical Trial			
Indemnity Form	☐	☐	☐
Notification of submission of eCTN/CTX from (TGA Clinical Trial Notification or Clinical Trial Exemption)	☐	☐	☐
Certificate of Insurance	☐	☐	☐
Evidence of Good Clinical Practice (GCP) Training for site investigator/s	☐	☐	☐
QCAT approval for adults with impaired capacity to consent (For advice see QCAT)	☐	☐	☐
Tests / Data / Samples outside standard practice that are performed specifically for research			
Quote and/or approval from relevant department (Clinical Information, Pathology Queensland, Pharmacy, Radiation Services, Forensic and Scientific Services etc.)	☐	☐	☐
Waiver of consent (including opt out consent)			
Public Health Act approval: https://www.health.qld.gov.au/hiiro/html/regu/aces_conf_hth_info *(or for QH staff seeking permission under section 150 Hospital and Health Boards Act 2011, evidence of support from Digital Health Services/Clinical Information and cover letter must state how study meets section 150 requirements)*	☐	☐	☐
When and where to submit: All documents must be uploaded in ERM *(hard copy not required)*			
Applications can be submitted anytime – concurrent submission of HREC and RGO applications is encouraged			

Questions? Contact 07 4226 5966 or Torres-Cape-Research-Governance@health.qld.gov.au