Research Application Checklist – ETHICS (HREA) SUBMISSION

A	**HREC submissions - mandatory items**
☐	**Cover Letter** *(*Addressed to the HREC Chair, including a brief description of study, if the study is to be reviewed as Low or Negligible Risk (LNR) research or higher than low risk research, study sites and list of documents submitted for HREC review and approval)
☐	**Human Research Ethics Application (HREA) form** – completed online at https://au.forms.ethicalreviewmanager.com/ and signed by the Principal Investigator
☐	**Study Protocol** – This is the specific plan for the research. (Must have a version number and date in footer). Queensland Health staff can find the THHS template at https://healthqld.sharepoint.com/teams/THHS-TRESA/Shared%20Documents/Forms/AllItems.aspx
☐	**CV for all investigators** (signed/dated)
B	**Study specific documentation** (if applicable to your study)
☐	Data Collection Tool(s) e.g. case report forms, data spreadsheet
Studies prospectively recruiting participants (including opt out consent)	
☐	Participant Information and Consent Form (PICF) (Must have a version number and date in footer). Find NHMRC standardised PICF templates: https://www.nhmrc.gov.au/research-policy/ethics/ethical-issues-and-resources
☐	Questionnaire/Survey/Interview Guide or other instruments
☐	All Recruitment Documentation e.g. advertisement, poster, brochure, letter of invitation
☐	Other e.g. participant diary, letter to GP, identification card
Industry or privately sponsored studies	
☐	HREC only indemnity. See Medicines Australia Indemnity template: https://medicinesaustralia.com.au/policy/clinical-trials/indemity-and-compensation-guidelines/
Clinical Trial	
☐	Investigator's Brochure
Gene Technology	
☐	Institutional Biosafety Committee (IBC) approval For more info go to: http://www.ogtr.gov.au/internet/ogtr/publishing.nsf/Content/ibc-1
☐	Licence for dealings with a Genetically Modified Organism (GMO)
Radiological procedures outside standard practice that are performed specifically for research	
☐	Independent assessment report by a Medical Physicist or District Radiation Safety Officer
Study site in Victoria to be included under this HREC approval	
☐	Victorian Specific Module (sub form in https://au.forms.ethicalreviewmanager.com/)

When and Where to submit:

Documents must be uploaded in https://au.forms.ethicalreviewmanager.com/ and project submitted online for all studies

Low or Negligible Risk Research: **Submit online anytime** (No hard copies of documents required)

Greater than Low or Negligible Risk Research: **Submit online by meeting deadline** (No hard copies required)
Find the THHS HREC meeting submission dates here: https://www.townsville.health.qld.gov.au/research/for-researchers/research-ethics-and-governance/townsville-hhs-hrec-information/

Questions? Contact 07 4433 1440 or TSV-Ethics-Committee@health.qld.gov.au

Townsville Research Education Support and Administration, Office 10, Townsville Institute of Health Research & Innovation, Level 2, Townsville University Hospital, Douglas QLD 4814

Research Application Checklist – GOVERNANCE (SSA) SUBMISSION

A	**Governance Submissions - mandatory items**
☐	**Cover letter** (Addressed to THHS Research Governance (RG) Officer including a brief description of study, study sites and list of documents submitted for THHS RG review and authorisation)
☐	**Site Specific Assessment (SSA) Application** (with signatures) completed online at https://au.forms.ethicalreviewmanager.com/
☐	Copy of **all Study Documents,** relevant to this site, provided to HREC, including HREC application form and study protocol (or post HREC approval – all final HREC approved documents). Note: Researcher CVs no longer required for SSAs
☐	Copy of **HREC Approval Letter** (when obtained)
B	**Study specific documentation - Governance** (if applicable to your study)
Studies prospectively recruiting participants (including opt out consent)	
☐	**Participant Information and Consent Form/s** (PICF) (if applicable) (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** (For multi-centre studies only)
Studies involving a Non-QH Collaborator or Sponsor (includes Student or university projects and other collaborative projects)	
☐	Study Agreement – Contact RGO Administrator for advice or use Medicines Australia CTRA templates: https://medicinesaustralia.com.au/policy/clinical-trials/clinical-trials-research-agreements (If study is LNR, low resource study and only between JCU and THHS an agreement will not be required. Cover letter must state: *" I have discussed this study with the appropriate persons at JCU and have received confirmation from JCU that they are agreeable that this study fits the criteria to be covered by the overarching umbrella agreement between JCU and THHS".)* Check with study sponsor if hard copy documents are required
Clinical Trial (includes Collaborative Research Group, Investigator Initiated or Industry Sponsored Clinical Trials)	
☐	Indemnity Form (check with study sponsor if hard copy documents are required)
☐	Evidence of submission of eCTN/CTX form (TGA Clinical Trial Notification or Clinical Trial Exemption)
☐	Certificate of Insurance
☐	Investigator's Brochure
☐	Evidence of Good Clinical Practice (GCP) Training for each investigator
☐	QCAT approval for adults with impaired capacity to consent: For advice see: https://www.qcat.qld.gov.au/__data/assets/pdf_file/0015/100905/form-16-app-to-conduct-clinical-research.pdf
Gene Technology	
☐	Institutional Biosafety Committee (IBC) approval For info see: http://www.ogtr.gov.au/internet/ogtr/publishing.nsf/Content/ibc-1
☐	Licence for dealings with a Genetically Modified Organism (GMO)
Tests / Data / Samples outside standard practice that are performed specifically for research	
☐	Quote and approval from relevant department (e.g. Pathology Queensland, THHS Pharmacy, THHS Medical Imaging etc)
Radiological Procedures outside standard practice that are performed specifically for research	
☐	Independent assessment report by a Medical Physicist or District Radiation Safety Officer
☐	Confirmation that study has been added to Radiation Risk License
Waiver of Consent (including Opt Out Consent)	
☐	Public Health Act approval: http://www.health.qld.gov.au/ohmr/html/regu/aces_conf_hth_info.asp (or for QH staff seeking permission under section 150 Hospital and Health Boards Act 2011, SSA form signed by Data Custodian and RGO cover letter must state how study meets section 150 requirements)

When and Where to submit:

Documents must be uploaded in https://au.forms.ethicalreviewmanager.com/ (No hard copy required for THHS RG application)

Applications can be submitted **anytime** – concurrent submission of HREC and THHS RG applications is encouraged

Questions? Contact 07 4433 1351 or TSV-RGO@health.qld.gov.au