**THHS Research Application Checklist – GOVERNANCE (SSA) SUBMISSIONS**

|  |  |  |
| --- | --- | --- |
| **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/> |
|  | | **Study Protocol** |
|  | | **CV for all investigators** (applicable to the THHS site) |
|  | | Copy of **all other Study Documents** provided to HREC (or post HREC approval – all final HREC approved documents) |
|  | | Copy of **HREC Approval Letter** (when obtained) |
|  | | Copy of approved **Human Research Ethics Application (HREA) form** or **LNR ethics form** |
| **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 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 a study is a LNR, low resource study and only between JCU and THHS an agreement will not be required. However, a declaration in the THHS RG cover letter from the PI which states: *“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*” is required ) |
| **Clinical Trial** (includes Collaborative Research Group, Investigator Initiated or Industry Sponsored Clinical Trials) | | |
|  | | Indemnity Form (in triplicate) |
|  | | Evidence of submission of eCTN/CTX form (TGA Clinical Trial Notification or Clinical Trial Exemption) |
|  | | Certificate of Insurance |
|  | | Investigator’s Brochure |
|  | | QCAT approvalfor 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: [www.adelaide.edu.au/ethics/genetech/working/committee.html](http://www.adelaide.edu.au/ethics/genetech/working/committee.html) |
|  | | 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 (eg. 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>  (Alternatively if QH investigators seeking permission under section 150 Hospital and Health Boards Act 2011, SSA form to be signed by Data Custodian and include in RGO cover letter how study meets section 150 requirements i.e. study is for the evaluating, managing, monitoring or planning of health services) |
| **When and Where to submit:**  Documents must be uploaded in <https://au.forms.ethicalreviewmanager.com/> (and provide 1 **Hard Copy** if greater than low risk) | | |
| Applications can be submitted **anytime** – concurrent submission of HREC and THHS RG applications is encouraged  **Deliver to:** Townsville Research Education Support and Administration, Office 9, Townsville Institute of Health Research & Innovation, Level 2, The Townsville Hospital, Douglas QLD 4814  **Post:** TRESA Unit - IMB 101, The Townsville Hospital, PO Box 670, Townsville QLD 4810 | | |

**Questions?** Contact 07 4433 1351 or [TSV-RGO@health.qld.gov.au](mailto:TSV-RGO@health.qld.gov.au)