Darling Downs Health

Research Application Checklist

Governance (SSA) Submission

Governance submissions – mandatory items

- ☐ **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 Ethical Review Manager
  (To submit your SSA form, create it in ERM as a sub-form of the Human Research Ethics Application (HREA)
- ☐ **HREC Approval letter/s** *(incl. amendment approvals)*
- ☐ **Study Documents relevant to this site** *(as listed on HREC approval letter/s e.g. HREA Form, Protocol)*
- ☐ **Master Participant Information and Consent Form** (PICF) *(+ Site Specific PICFs if multi-site project)*
- ☐ **Budget** *(required for all projects + evidence of DDH Finance Manager review and approval if project involves any funding or is over$10,000 in-kind) Simple and Complex Budget templates*
- ☐ **Head of Department authorisation** *(Letter or Email support or via ERM if HOD has an ERM account – applicant should confirm with HOD prior to request)*
- ☐ **CV of Site Principal Investigator** *(one-page resume)*
- ☐ **Research Integrity Training Certificate** *(required for all research team members) DD-LOL or A-CTEC*

Y	N	N/A	Study specific documentation
☐	☐	☐	Study Agreement (if applicable) *Please contact the RGO for advice*
☐	☐	☐	GCP Certificates (all team) if study involves prospective recruitment and clinical sampling / tests
☐	☐	☐	QCAT approval for adults with impaired capacity to consent
			Clinical Trial
☐	☐	☐	Indemnity
☐	☐	☐	Certificate of Insurance
☐	☐	☐	Notification of submission of CTN/CTX from (TGA Clinical Trial Notification or Clinical Trial Exemption)
☐	☐	☐	Investigator's Brochure
			Tests / Data / Samples outside standard practice that are performed specifically for research
☐	☐	☐	Quote and approval from relevant department (e.g. Pathology Queensland, DDHHS Pharmacy etc)
			Radiological procedures outside standard practice that are performed specifically for research
☐	☐	☐	Independent assessment report by a Medical Physicist or District Radiation Safety Officer
			Waiver of consent
☐	☐	☐	Public Health Act approval *There are other permissions that can allow access to confidential data without consent that may be appropriate. Please contact the RGO for advice.*

Contact Us

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Queensland Government