



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 template [here](#)
- 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](#)
- Fee Template (Research Ethics and Governance Office)** (required for all submissions except those sponsored or led by a QH HHS) [Template](#). Please refer to the [Schedule of Fees](#) for further information

Y	N	N/A	Study specific documentation
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|--------------------------|--------------------------|--------------------------|---|
| <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | Study Agreement (if applicable) Please contact the RGO for advice |
| <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | GCP Certificates (all team) if study involves prospective recruitment and clinical sampling / tests |
| <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | QCAT approval for adults with impaired capacity to consent |

Clinical Trial

- | | | | |
|--------------------------|--------------------------|--------------------------|--|
| <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | Indemnity |
| <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | Certificate of Insurance |
| <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | Notification of submission of CTN/CTX from (TGA Clinical Trial Notification or Clinical Trial Exemption) |
| <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | Investigator's Brochure |

Tests / Data / Samples outside standard practice that are performed specifically for research

- | | | | |
|--------------------------|--------------------------|--------------------------|---|
| <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | Quote and approval from relevant department (e.g. Pathology Queensland, DDHHS Pharmacy etc) |
|--------------------------|--------------------------|--------------------------|---|

Radiological procedures outside standard practice that are performed specifically for research

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|--------------------------|--------------------------|--------------------------|---|
| <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | Independent assessment report by a Medical Physicist or District Radiation Safety Officer |
|--------------------------|--------------------------|--------------------------|---|

Waiver of consent

- | | | | |
|--------------------------|--------------------------|--------------------------|---|
| <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | 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. |
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Contact Us

Research Ethics & Governance Officer, RDEU

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