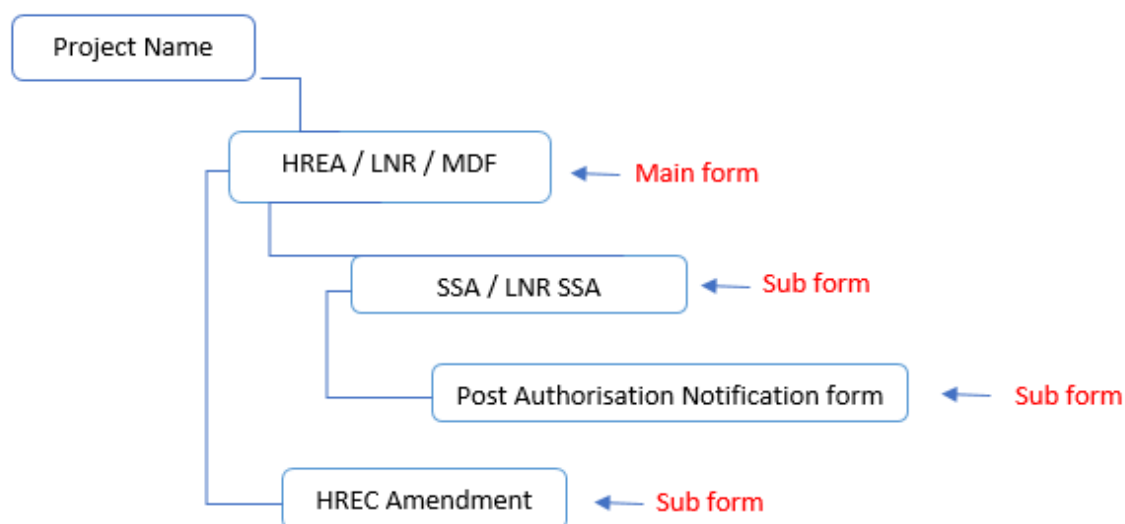# ERM Quick Guides

QLD Applicant ERM Form Architecture

ERM is based on **forms**. The project title layer is automatically created at the same time the applicant creates a **main form.**

From the **main form**, the applicant can create **sub-forms** e.g. SSA form, progress report.

From some sub-forms (SSA and LNR SSA) further sub-forms can be created
e.g. site progress report, complaints report and site notification form

Main Forms (There is only one main form for each project.)

Form	Description
Human Research Ethics Application **(HREA)**	Ethics application form
Low/Negligible Risk Application Form **(LNR)**	Ethics application form for low or negligible risk research
Minimal Dataset Form **(MDF)**	Proxy for an ethics application form; used when the ethics review was performed in a state/territory under NMA, and that jurisdiction does not use ERM; allows creation of SSA form(s) in ERM

Sub-forms for post-approval HREC

Form	Description
HREC Amendment QLD	Request ethical approval for a change to the design or conduct of a research project e.g. the protocol, PICF or change to personnel
Project Final Report QLD	Report to the reviewing ethics committee on the progress of a research project at the time of its completion
Safety Report QLD	Report a safety event to the reviewing ethics committee
Annual Safety Report QLD	Report to the reviewing ethics committee on the safety profile of an interventional clinical trial
Serious or Suspected Breach Report	Report a serious or suspected breach to the reviewing ethics committee
Site Closure Report Multi Centre Research QLD	For a multi-site project, report the closure of one participating site to the reviewing ethics committee

Sub-forms for initial application Main Form (site specific)

Form	Description
QLD Site Specific Assessment **(SSA)**	Research governance application form; one SSA is required for each site participating in a research project
Low/Negligible Risk Site Specific Assessment **(LNR SSA)**	Research governance application form; one LNR SSA is required for each site participating in a research project

Sub-forms for Post Authorisation (RGO)

Form	Description
SAE/SUSAR/SADE Reports	Report SAE/SUSAR/SADE to the site's research governance office
Post Authorisation Notification Form	Report a research project amendment to the site's research governance Office