Submission guidelines for projects

Project type	QA/QI project or clinical audit	Clinical Case Study	Low or negligible risk research	Greater than low risk research
Definition	To improve a practice or process within a particular unit or service. Often measures against pre-set standards or benchmarks.	Describes and interprets an individual case. May include up to three cases.	May involve treatments, samples, or investigations additional to routine care where the only foreseeable risk is discomfort.	Creates new knowledge and may involve treatments, samples or investigations additional to routine care.
Consent	Participant consent should be considered.	 Participant consent required: <u>Case Study Participant Information Sheet</u> <u>Case Study Consent Form</u> <u>Consent to Clinical Digital Images Form</u> (if applicable) 	Participant consent must be obtained, or a waiver of consent can be requested for specific circumstances.	
Ethics review	 Does not undergo ethics committee review. Register project with the relevant Quality Coordinator. Load into <u>GCH Innovation</u> <u>Portal.</u> If planning to use results for external publication or presentation: Complete QLD exemption form in ERM Upload letter of support from HoD in ERM Acknowledged and registered as Quality Activity by HREC delegate. 	 Does not undergo ethics committee review. If planning to use results for external publication or presentation: 1. Complete QLD exemption form in ERM 2. Upload <u>Clinical Case Study and the HREC</u> form and consent documents in ERM Acknowledged and registered as Clinical Case Study by HREC delegate. 	 Mandatory documentation HREA Protocol Letter of support from HoD Other documents may be required depending on the project design. 	
Governance review	Not required		 Mandatory documentation Site Specific Application (SSA) form in <u>ERM.</u> All supporting documents Authorisation: Commencement of the project granted after review and authorisation.	



Abbreviations: *ERM* Ethical Review Manager, *HoD* Head of Department, *HREA* Human Research Ethics Application, *HREC* Human Research Ethics Committee, *QA* Quality Assurance, *QI* Quality Improvement, *SSA* Site Specific Application

