HREC Submission guidelines for projects

	QA/QI/Clinical Audit	Clinical Case Study	Low 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.	Through creation of new knowledge that is generalizable and addressing a gap in the literature, low risk research describes research, including some types of clinical trials, in which the only foreseeable risk is no greater than discomfort.	Through creation of new knowledge that is generalizable and addressing a gap in the literature, low risk research describes research, in which the risk to the participant is greater than discomfort.
Consent	Participant consent should be considered.	Participant consent required: • Case Study Participant Information Sheet • Case Study Consent Form • Consent to Clinical Digital Images Form (if applicable)	Participant consent must be obtained, or a waiver of consent can be requested for specific circumstances. **Waiver of Consent** Any requests for a waiver of consent must be included in the Protocol including appropriate justification in accordance with the a-j criteria as set out in National Statement Section 2.3.10	
Ethics review	Does not undergo HREC review. Register project with the relevant Quality Coordinator. Load into GCH Innovation Portal. If planning to use results for external publication or presentation: 1. Complete QLD exemption form in ERM 2. Upload letter of support from HoD in ERM	Does not undergo HREC review. If planning to use results for external publication or presentation: Complete QLD exemption form in ERM Upload Clinical Case Study and the HREC form and consent documents in ERM Acknowledged and registered as Clinical Case Study by HREC delegate.	Mandatory documentation **HREA** Please be reminded that the HREA is an application form. All information contained within the HREA must be sourced from the Protocol as the central study document and other documents as relevant. **Protocol** Please use the Research Protocol template to guide your protocol development. Please include your risk assessment, data management plan and statistical considerations in the initial submission. **PICF – Participant Information Sheet and Consent Form** All PICF need to be pitched at a Grade 6 – 8 reading level to enable understanding to all potential participants. Use of tables, pictures and diagrams are encouraged to facilitate understanding. A consumer summary is requested for studies that have significantly lengthy PICF's (i.e. commercially sponsored. It is recommended that researchers request a lay person to review the PICF for general understanding BEFORE submission to the HREC or to use readability software to assess the reading age of the PICF. Please use the PICF template.	

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

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<td></td>
<td>Acknowledged as Exempt not Research and registered as Quality Activity by HREC delegate.</td>
<td></td>
<td>Letter of support from HoD
Please use the HoD support letter template.

Other
Other documents may be required depending on the project design. All study documents must be submitted to facilitate review including Protocol PICF, Surveys, Questionnaires, Participant facing materials (i,e advertising) Telephone Scripts, Semi Structure Interview scripts.

N.B All documents must include version control and date.</td>
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<tr>
<td>Post Approval HREC Review</td>
<td>No submissions post initial submission required.</td>
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<td>For Post Approval

Change of Practice Annual Progress Reports
Annual progress reports are now due by 30 April each year as per below:
<table>
<tr><th>Annual progress report due date</th><th>Annual progress report submission date</th></tr>
<tr><td>Activity Prior to 31 December 2023</td><td>Submit by 30 April 2024</td></tr>
<tr><td>1 January 2024- 31 December 2024</td><td>Submit by 30 April 2025</td></tr>
<tr><td>1 January 2025 - 31 December 2025</td><td>Submit by 30 April 2026</td></tr>
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Submission of an annual progress report annually by 30 April each year will permit ongoing ethical clearance until such time as a Final Report is submitted.
Please complete details of research activity using the HREC/RGO Annual Progress Report/Final Report uploaded as a supporting document in ERM

Please note
Annual progress reports are not required for studies that were approved as exempt
Where the GCHREC is the approving HREC, there is no requirement to submit an annual progress report to the GCRGO (ie there is no need to submit an annual progress report under the SSA), however if the approving HREC is not the GCHREC then the report and confirmation of acceptance by the approving HREC will need to be submitted to the GC REGO.

Amendments

Please provide justification for seeking an amendment that includes why the change is being requested. Ensure any changes to documents are marked in track changes and version control and dates are updated in the footer of your submitted documents.
Summary of changes to the Protocol are to be included in the version summary on the front page</td>
</tr>
</table>

			Change of PI needs to have confirmation (letter or email) from outgoing PI with acceptance of overall oversight for incoming PI. IB updates must include summary of changes and confirmation from the CPI that any IB updates do not affect the ongoing acceptability of the study and don't require changes to the PICF or Protocol. If the IB updates do require changes to study documents, these must be supplied at the same time as the IB update Other • DSUR updates must include confirmation from the CPI that the update does not affect the ongoing acceptability of the study and doesn't require changes to the PICF or Protocol. If the DSUR does require changes to study documents, these must be supplied at the same time as the DSUR.