

Darling Downs Health

Human Research Ethics Committee (EC00182)

HREC Application Closing Dates (greater than low risk only) and HREC Meeting Dates 2022

Closing Date – 2022 Applications to be submitted by 12 midday	Meeting Date - 2022 2 nd Wednesday of the month
27 th January	9 th February
24 th February	9 th March
31 st March	13 th April
28 th April	11 th May
26 th May	8 th June
30 th June	13 th July
28 th July	10 th August
1 st September	14 th September
29 th September	12 th October
27 th October	9 th November
24 th November	14 th December

SUBMISSION OF DOCUMENTS

Online via Ethical Review Manager (ERM)

- **For all applications, please access Ethical Review Manager (ERM) at <https://au.forms.ethicalreviewmanager.com>**
- Not Requiring Ethical Review (NRER) quality assurance applications are to be completed using the Ethics Exemption application option on ERM.
- All research projects are to be completed and submitted on the Human Research Ethics Application (HREA) form.
- Please upload all supporting documents against the ethics application form. **Please note a Protocol is required with every submission.** (Templates available on the Darling Downs Health Research page on QHEPS)
- All documents require a document identifier ie. version numbers, version dates and page numbers in the footer.
- There are no closing dates for Low Risk submissions – you may submit at any time.
- This document is for information only and is not required to be submitted with your application.

Please note: *Incomplete applications will not be placed before the HREC for consideration.*



Research Application Checklist

Ethics Submission

A HREC submissions – mandatory items	YES
Cover letter (addressed to HREC Chair, brief description of study, study sites and list of attachments)	<input type="checkbox"/>
Ethics Application (HREA) – completed online at http://au.forms.ethicalreviewmanager.com	<input type="checkbox"/>
Protocol (This is the specific plan for the research. Must have a version number and date) Template and Guide available at https://qhps.health.qld.gov.au/darlingdowns/html/research	<input type="checkbox"/>
CV's of all investigators who have not submitted a CV to the HREC within the last 2 years	<input type="checkbox"/>

B Study documents (possible appendices required for your study) <i>All documents must have a version number, date and page number in the footer</i>	YES	NO	N/A
Data collection tool(s)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Participant Information and Consent Form (PICF) (include researcher and HREC contact info) <i>NB: Multi centre studies must have MASTER version</i>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Questionnaire/Survey/Interview Guide or other instruments	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Advertising materials e.g. transcript for ad, e-mail, website, letter or phone call	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Letter of invitation/Letter to GP etc.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Other correspondence e.g. participant diary, peer review etc.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

C Study specific documentation	YES	NO	N/A
Clinical Trial			
Certificate of Insurance	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Investigator's Brochure	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Radiological procedures outside standard practice that are performed specifically for research			
Independent assessment report by a Medical Physicist or District Radiation Safety Officer	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Study taking place in Victoria			
Victorian Specific Module https://www2.health.vic.gov.au/about/publications/FormsAndTemplates/Victorian%20Specific%20Module%20Guidelines	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
When and Where to submit: All documents must be uploaded in ERM			
Submit anytime:	Low or Negligible Risk research		
Submit to HREC meeting:	All other research		
Ethics and Research Governance Office DDHHS-Research@health.qld.gov.au			

Questions? Contact (07) 4616 6696 or DDHHS-Research@health.qld.gov.au

Research Application Checklist

Governance (SSA) Submission

D Governance submissions – mandatory items	YES	N/A
Cover letter (address to Research Governance Officer, brief description of study, study sites and list of attachments)	<input type="checkbox"/>	
Site Specific Assessment (SSA) Application – completed online at http://au.forms.ethicalreviewmanager.com (A Sub-form of the HREA)	<input type="checkbox"/>	
Protocol	<input type="checkbox"/>	
CV of <u>Site</u> Principal Investigator	<input type="checkbox"/>	
Master/Site Participant Information and Consent Form (PICF)	<input type="checkbox"/>	<input type="checkbox"/>
Study Documents (copy of documents provided to HREC as per section B)	<input type="checkbox"/>	<input type="checkbox"/>
Copy of HREC Approval letter	<input type="checkbox"/>	<input type="checkbox"/>

E Study specific documentation – for Governance	YES	NO	N/A
Study agreement (if applicable) Please contact the RGO for advice	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Clinical Trial			
Clinical Trials Research Agreement	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Indemnity	<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"/>
Certificate of Insurance	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Investigator's Brochure	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
QCAT approval for adults with impaired capacity to consent	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
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)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Radiological procedures outside standard practice that are performed specifically for research			
Independent assessment report by a Medical Physicist or District Radiation Safety Officer	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Confirmation that study has been added to Radiation Risk License	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Waiver of consent			
Public Health Act approval: https://www.health.qld.gov.au/hiiro/html/regu/aces_conf_hth_info There are other permissions that can allow access to confidential data without consent that may be appropriate. Please contact the RGO for advice.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
When and Where to submit: All documents must be uploaded in ERM			
Ethics and Research Governance Office DDHHS-Governance@health.qld.gov.au			

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