Darling Downs Health

Darling Downs Health

Human Research Ethics Committee (EC00182)

HREC Application Closing Dates (greater than low risk only) and HREC Meeting Dates 2021

Closing Date – 2021 **Applications to be submitted by 12 midday**	**Meeting Date - 2021** **2nd Wednesday of the month**
27 January	10 February
24 February	10 March
31 March	14 April
28 April	12 May
26 May	9 June
30 June	14 July
28 July	11 August
25 August	8 September
29 September	13 October
27 October	10 November
24 November	8 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) applications are to be completed using the LNR (Low/Negligible Risk) form on ERM.
- Both 'low risk' and 'greater than low risk' 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.***

Queensland Government

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)*	☐
Ethics Application (HREA) – completed online at http://au.forms.ethicalreviewmanager.com	☐
Protocol *(This is the specific plan for the research. Must have a version number and date)* Template and Guide available at https://qheps.health.qld.gov.au/darlingdowns/html/research	☐
CV's of all investigators who have not submitted a CV to the HREC within the last 2 years	☐

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

C Study specific documentation	YES	NO	N/A
Clinical Trial			
Certificate of Insurance	☐	☐	☐
Investigator's Brochure	☐	☐	☐
Radiological procedures outside standard practice that are performed specifically for research			
Independent assessment report by a Medical Physicist or District Radiation Safety Officer	☐	☐	☐
Study taking place in Victoria			
Victorian Specific Module https://www2.health.vic.gov.au/about/publications/FormsAndTemplates/Victorian%20Specific%20Module%20Guidelines	☐	☐	☐

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

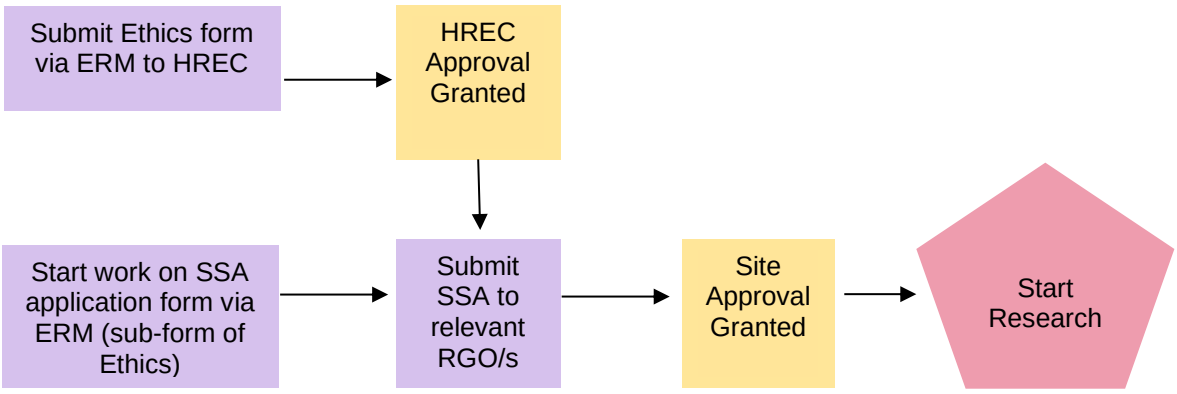
D Governance submissions – mandatory items	YES	N/A
Cover letter *(address to Research Governance Officer, brief description of study, study sites and list of attachments)*	☐	
Site Specific Assessment (SSA) Application – completed online at http://au.forms.ethicalreviewmanager.com *(A Sub-form of the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

E Study specific documentation – for Governance	YES	NO	N/A
Study agreement (if applicable) *Please contact the RGO for advice*	☐	☐	☐
Clinical Trial			
Clinical Trials Research Agreement	☐	☐	☐
Indemnity	☐	☐	☐
Notification of submission of CTN/CTX from (TGA Clinical Trial Notification or Clinical Trial Exemption)	☐	☐	☐
Certificate of Insurance	☐	☐	☐
Investigator's Brochure	☐	☐	☐
QCAT approval for adults with impaired capacity to consent	☐	☐	☐
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)	☐	☐	☐
Radiological procedures outside standard practice that are performed specifically for research			
Independent assessment report by a Medical Physicist or District Radiation Safety Officer	☐	☐	☐
Confirmation that study has been added to Radiation Risk License	☐	☐	☐
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.*	☐	☐	☐
When and Where to submit: All documents must be uploaded in ERM			
Ethics and Research Governance Office DDHHS-Governance@health.qld.gov.au			

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

Frequently Asked Questions

1. What is the process for a research project from application to commencement



2. How long will it take to get ethical approval?

   All Queensland Health HRECs work on a 60 day clock i.e. the time it takes us to approve your research from closing date until the HREC meeting and contact with you after the meeting with the HREC decision and recommendations. The clock stops until your response to recommendation has been received and starts again on receipt. This does not include the Site Specific Assessment authorisation.

3. What is Site Specific Assessment (SSA)?

   The Site Specific Assessment form and supporting documentation is submitted to the local Research Governance Officer (RGO) for research governance review and recommendation to the HSCE or delegate for study authorisation. A separate SSA form is required for each proposed site, eg. proposed sites are Darling Downs HHS and West Moreton HHS – two SSA forms are submitted to the two relevant RGOs for review. Contact information for RGO's in Queensland Health is available at https://www.health.qld.gov.au/hiiro/html/regu/for_researcher

4. What is the difference between Quality Activity, low/negligible risk or greater than low risk projects?

   QA – An activity where the primary purpose is to monitor or improve the current quality of service delivered by an individual, group or an organisation. They seek to measure the quality or efficacy of a service provided by the HHS and may be a clinical audit, service evaluation or service development.

   Low/negligible risk – Section 2.1.6 of the National Statement on Ethical Conduct in Human Research describes research as "Low Risk" where the only foreseeable risk is one of discomfort. Negligible risk research is where there is no foreseeable risk of harm or discomfort and any foreseeable risk is no more than inconvenience.

   Greater than low risk – All other research where the risk is considered more serious than Low or Negligible risk, as outlined above.

5. What if my project is a Quality Activity only?

   The DDHHS has a process in place for Quality Activities where the researchers wish to present or publish their research outside of the DDHHS. Please refer to the Quality Activity Decision Tool Work Instruction and the NRER (Not requiring ethical review) Application Process Work Instruction both published on QHEPS.

6. Waiving consent and the Public Health Act (PHA):

   The requirement for consent may sometimes be justifiably waived and an HREC can grant this waiver. If consent is not being obtained and the researcher wants to access confidential identifiable health information, they must find a permission to allow that. One permission that allows this is PHA approval in accordance with the *Public Health Act 2005*. However, other permissions may be available to enable a researcher to access information without consent including permissions in the Hospital and Health Boards Act 2011 so please speak with the Research Governance Officer for further information.

7. Reporting

   Annual reports to the HREC on the progress of your study are due by the 30th April each year.

   A project is considered completed when the data has been analysed and the outcome of the study has been written up in the form of a report or published study. A Final report and copy of any publications / abstracts / posters etc. is required by the HREC at the end of the project.

   Annual and Final reports (post approvals) are to be submitted on the ERM website. Complete and submit as post approval forms on your project tree.