

Far North Queensland HREC (EC00157)

Research Study Checklist for Principal Investigators

Please note the following:

- All study documentation must have a version number, document date and page numbers in the footer of each document. The relevant logo/s must be included in the header of each study document.
- This check list is to be completed and included with every application.
- Please submit the research application as a collated set.
- Please do not submit the application as a rolling document. Each document can be printed double sided however each document must be separate.
- Please do not bind the application.

A) Mandatory documents for all submissions

1.	Cover letter	One (1) hard copy of each document.
2.	Research Study Checklist for Principal Investigators (this document).	
3.	Human Research Ethics Application (HREA) Form submitted via ERM. Please ensure that the HREA form has reference # in the footer. (The FNQ HREC no longer accepts applications presented on the LNR form. All ethics applications for HREC review are to be submitted on a HREA form in ERM.)	
4.	Study Protocol / Plan	
5.	CV for each investigator / student supervisor (maximum of 2 pages).	

B) Additional documents

		Yes	No	N/A		
6.	Data collection tool (eg. CRF) if applicable				One (1) hard copy of each document.	
7.	Participant Information Sheet and Consent Form (PISCF) if applicable					
8.	Investigator Brochure if applicable					
9.	Questionnaires / other instruments					
10.	Advertising materials (including a copy of transcript for advertisement, e-mail, website, letter or telephone call).					
11.	Letter of invitation / Letter to GP etc					
12.	Participant diaries and/or wallet card					
13.	Letter of Support from the relevant Indigenous Health Group. (Only required for Aboriginal and Torres Strait Islander targeted research in remote communities.)					
14.	Form of Indemnity for HREC Review Only. Only required if the study site/s are not Queensland Health site/s. The template can be sourced from the Medicines Australia website.					One (1) hard copy of each document.
Research which is using radiological procedures that are performed specifically for research:						
15.	Independent assessment report or verification by a Medical Physicist (or District Radiation Safety Officer) detailing the total effective dose and relevant organ doses for those radiological procedures that are performed specifically for the research protocol.				One (1) hard copy of each document.	