

## Far North Queensland HREC (EC00157)

### Research Study Checklist for Principal Investigators

Full submission requirements can be found online at the [CHHHS QHEPS intranet](#) or the [CHHHS public website](#).

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 checklist is to be completed and included with every application.**
- Please submit the research application as a collated set. Please ensure each document is stapled/clipped together.
- 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.	<b>Cover letter</b>	One (1) hard copy of each document.
2.	<b>Research Study Checklist for Principal Investigators</b> ( <i>this document</i> ).	
3.	<b>Human Research Ethics Application (HREA) Form</b> submitted via ERM. Please ensure that the HREA form has reference # in the footer.	
4.	<b>Study Protocol / Plan</b>	
5.	<b>CV for each investigator / student supervisor</b> (maximum of 2 pages).	

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