CHQ HREC Standard Risk Submission Checklist Form

(to be submitted with application)

Study Title										
Type of Study *(Please tick)*	Clinical Trial Phase 0		Clinical Trial Phase 1		Clinical Trial Phase 2		Clinical Trial Phase 3		Clinical Trial Phase 4	
*See definitions below	Clinical Trial Device		Clinical Trial Drug		Clinical Trial Other*		Clinical Interventional Research Not a Clinical Trial*			
	Clinical Trial Surgery/Procedural Interventions*		Population Health*		Mental Health Research*		Qualitative Research*		Paediatric	
	Other Health and Medical Research*		Other *(please specify)*							
Department										
Is this a Student Project? (please circle)			Yes/No	Is this a University driven Project? (please circle)					Yes/No	
Mode of Approval	CHQ HREC and Research Governance			CHQ HREC Only			Research Governance Only			
Single Centre *(please list site)*		Multi Centre - More than one site external to CHQ HHS *(please list sites)*								

Definitions for Types of Studies

Clinical Trial Other* = Studies that do not fall under the broad definitions of drug, surgical or device trials. Examples include interventions such as exercise, physiotherapy, cognitive therapy, special diets, herbal medicines, web-based treatments, motivational classes, music therapy, and stem cell interventions

Clinical Interventional Research Not a Clinical Trial* = Interventional research involving human participants in health and illness done in response to a clinical research question. The aim of such research is to inform clinical practice through the application of patho-physiological, population-based, behavioural or qualitative research methods

Clinical Trial Surgery/Procedural Interventions* = Designed to assess the effect(s) of one or more manual or operative surgical techniques, whether it is in the field of cosmetic, elective, environmental, plastic or replacement surgery (which are performed to diagnose, treat or prevent disease or other abnormal conditions)

Population Health* = Research activities include the collection and analysis of qualitative and quantitative survey data, the analysis of administrative datasets, economic evaluation of health care interventions, healthcare financing priority, evaluation of health services and health policy, studies and knowledge translation. It includes population-level and health-system research but **NOT CLINICAL OR BIOMEDICAL RESEARCH**

Mental Health Research* = May involve research into the causes and treatment of mental illness or mental disorder. May include therapeutic and non-therapeutic interventions and also includes research involving the disciplined enquiry into mental health promotion including the evaluation of mental health policies or initiatives

Qualitative Research* = Involves disciplined enquiry that examines people's lives, experiences and behaviours and the stories and meanings individuals ascribe to them. It can also investigate organisational functioning, relationships between individuals and groups and social environments. This approach to research can involve the studied use and collection of a variety of empirical materials such as case studies, personal experience, life stories, interviews, observations and cultural texts

Other Health and Medical Research* = Examples may include Human movement and Sports Science; Nutrition and Dietetics; Genetics and Drug and Alcohol

CHQ HREC Full HREA Checklist

Please submit all documentation via ERM and EMAIL (1 zip file attachment) to:

CHQEthics@health.qld.gov.au

PLUS:

No.	Description	No. of Paper Copies	ERM/EMAIL
1.	Standard Risk Submission Checklist Form	3	1
2.	Cover letter signed by Principal Investigator including: • Brief description of project, including phase of study if a clinical trial • List all sites to be approved • List of supporting documents submitted and confirmation that they have been uploaded to ERM	3	1
3.	Human Research Ethics Application Form (HREA) completed through **ERM Website**	3	1
4.	Parent/Guardian Information Sheets and Consent Forms (from CHQ Templates)	3	1
5.	Child/Adolescent Information Sheet (from CHQ Templates)	3	1
6.	Protocol	3	1
7.	Questionnaires, advertisements, diaries, product information and other patient facing documentation to be used in the study	3	1
8.	Victorian Specific Module or Western Australia Module (for applications to be reviewed under MOU)	3	1
9.	Radiation Safety Report (if applicable)	3	1
10.	Investigator's Brochure (where applicable)	1	1
11.	Indemnity Form consistent with Medicines Australia guidelines where appropriate	1	1
12.	Letter of support from CHQ sponsor for external researchers wishing to conduct research within the hospital	1	1
13.	Letter of approval from Director of the Department in which the research will be conducted	1	1
14.	CV for CPI and Site PIs must be uploaded with the application	0	1
*	Do all documents contain version numbers, dates and page numbers?		
*	All documents MUST be uploaded to the ERM Website.		
*	Email all documents (as 1 zip file) to CHQEthics@health.qld.gov.au		

If any queries regarding submission requirements, please contact the HREC office CHQEthics@health.qld.gov.au or 3069 7002.

CHQ HREC LNR Checklist

Please submit all documentation via ERM

No.	Description	ERM
1.	Cover letter signed by Principal Investigator including: • Brief description of project, including phase of study if a clinical trial • List all sites to be approved • List of supporting documents submitted and confirmation that they have been uploaded to ERM	1
2.	HREA completed through **ERM Website** (NB: Ensure the Low Risk Pathway has been checked)	1
3.	Parent/Guardian Information Sheets and Consent Forms (from CHQ Templates)	1
4.	Child/Adolescent Information Sheet (from CHQ Templates)	1
5.	Protocol	1
6.	Questionnaires, advertisements, diaries, product information and other patient facing documentation to be used in the study	1
7.	Investigator's Brochure (where applicable)	1
8.	Indemnity Form consistent with Medicines Australia guidelines where appropriate	1
9.	Current insurance certificate where appropriate	1
10.	Letter of support from CHQ sponsor for external researchers wishing to conduct research within the hospital	1
11.	Letter of approval from Director of the Department in which the research will be conducted	1
12.	For student researchers working towards a higher degree, name, address and signature of supervisor must be supplied	1
13.	CV for CPI and Site PIs must be uploaded with the application	1
*	Do all documents contain version numbers, dates and page numbers?	
*	All documents MUST be uploaded to the ERM Website.	

If any queries regarding submission requirements, please contact the HREC office CHQEthics@health.qld.gov.au or 3069 7002.