RBWH HREC CHECKLIST

All applications:

- For all **research** applications, please complete the Human Research Ethics Application (HREA). For submission of requests for exemption for QA/Audit activities, please submit on the LNR Form. All applications should be submitted via Ethics Review Manager (ERM) - https://au.forms.ethicalreviewmanager.com/
- Upload all supporting documents to the Online HREA or Online LNR form. All documents require a document identifier: version numbers, dates (dd/mm/yyyy) and page numbers, which must be included in the footer.
- Once the ethics application is finalized on ERM, please sign the application and press 'Submit'. The application will then come into the HREC Work Area.
- No hard copies are required.
- The closing time for applications is 12 pm (midday) on the closing date. Please note there are no exceptions. Incomplete applications will not be accepted. It is encouraged that applications be submitted early. This allows for questions and responses to be actioned prior to the HREC meeting, thus reducing the number of days to approval.

Mandatory Components for all submissions to an HREC		Yes	Submission Requirements
			Greater than low risk studies & Low risk studies
1.	**Cover Letter** (signed by the Coordinating Principal Investigator) including: • Brief description of the project, including Phase of the study if a clinical trial • List of all sites and Principal Investigators requiring approval • List of supporting documents submitted and confirming they have been uploaded into ERM • Name, address, telephone number and email of the sponsor organisation/CRA for commercially sponsored research • If participants are not being consented for the use of their confidential health information in a research study, please justify a waiver of consent in accordance with the National Statement section 2.3.10		ERM submission

Mandatory Components for all submissions to an HREC		Yes	Submission Requirements
			Greater than low risk studies & Low risk studies
2.	**Study Protocol** The Protocol is a study's working document. It is the formal design or specific plan for the research. It should be robust, providing clear and detailed information on the research study. The Protocol should include a document identifier, version number and date.		ERM submission
3.	**Human Rights compliance** • All research studies need to consider compliance with the Human Rights Act 2019 (Qld) ['Human Rights Act'], i.e. how the application respects, protects and promotes human rights. Has this been considered? *(Please refer to the Human Rights Compliance template)*	**Yes** **No**	
4.	**CV** (for researchers and Clinical Trial Coordinators who have not submitted a CV within the last 2 years		"

Other items which may be required, depending on the research application being submitted		Yes	Submission Requirements
			Greater than low risk studies & Low risk studies
5.	**Data Collection Tool/s**		ERM submission
6.	**Master Participant Information Sheet & Consent Form (PICF)**		"
7.	**CTN / CTX Form** *(copy of eCTN Registration to be submitted with application)*		"
8.	**Investigator's Brochure**		"
9.	**Questionnaires / other instruments**		"
10.	**Medicines Australia Form of Indemnity (HREC Review Only)** *[Submitted for industry sponsored research where the HREC is not located at a participating site and for the review of private sites. The 'Indemnified Party' is:* ***Metro North Hospital and Health Service (ABN: 18 496 277 942), Butterfield Street, Herston, Qld 4029***		"

Other items which may be required, depending on the research application being submitted		Yes	Submission Requirements
			Greater than low risk studies & Low risk studies
11.	**Invoicing and Fee Form** *(to be completed for all commercially sponsored research)*		ERM submission
12.	**Advertising materials** *(including a copy of transcript for advertisement, email, website, letter or telephone call)*		"
13.	**Participant Letter of Invitation / Letter to GP, etc.**		"
14.	**Participant Diaries**		"
15.	**Participant Wallet Card**		"
16.	**Other correspondence**, e.g. FDA reviews, correspondence from other HRECs, expert independent reviews, peer reviews, etc.		"
17.	**Internal Risk Assessment Reports**		"
18.	**Privacy Impact Assessments** (e.g. if testing new digital technology)		"
19.	**Institutional Bio-Safety Committee (IBC) approval**		"
20.	**Licence for Dealings with a Genetically Modified Organism (GMO)**		"
21.	**Independent Assessment Report** or verification by a Medical Physicist (or District Radiation Safety Officer) of the total effective dose and relevant organ doses for those radiological procedures that are performed specifically for the research protocol		"