Metro North Health Human Research Ethics

Human Research Ethics Application (HREA) Checklist

- All applications must be submitted via the Ethical Review Manager (ERM) https://au.forms.ethicalreviewmanager.com/Account/Login
- The Human Research Ethics Application (HREA) is used for full HREA applications and Low/Negligible Risk projects.
- Upload all supporting documents to via the ERM HREA form under the "Documents" tab.
- 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 finalised on ERM, please sign the application and press 'Submit'. Check that the application states that it has been submitted.

Application checklist

No	Description	Yes or N/A
1.	**Cover Letter** (signed by the Principal Investigator (PI) or Coordinating Investigator (CI) for multi-centre projects) including: • Sponsor of the study (this is the institution who has overall responsibility for the project[1]) • List of all sites and Principal Investigators requiring approval • List of all documents submitted including versions and dates	
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. 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.	
3.	**CV / Resume** – for the CPI and/or PI for each site	
	Other items which may be required, depending on the research type	
4.	**(Master) Participant Information Sheet & Consent Form (PICF)**	
5.	Data collection tool(s)	
6.	**All other documents -** Examples include questionnaires (if not validated), advertisements, participant cards, letters of invitation, diaries, interview questions, telephone scripts all must have versions and dates	
7.	**Radiation Safety Officer report** - radiation exposure that is in addition to routine care	
8.	**Multisite research that includes a Victorian site** - Victorian specific module	

9.	**CTN / CTX Form** - Copy of eCTN Registration to be submitted with application	
10.	**Investigator's Brochure/s** The Investigator's Brochure or IB, is a compilation of the clinical and nonclinical data on the investigational product(s) relevant to the study. It provides the investigators and others involved in the trial with the information to facilitate their understanding of the rationale for, and their compliance with, many key features of the protocol, such as the dose, dose frequency/interval, methods of administration: and safety monitoring procedures. The information should be presented in a concise, simple, objective, balanced, and non-promotional form that enables an investigator to understand and make an unbiased risk-benefit assessment of the proposed trial.	
11.	**For industry sponsored research –** Medicines Australia Form of Indemnity for Clinical Trials (Standard form for HREC Review Only) - if HREC is not located at a participating site and for the review of private sites. **Legal entity name:** Metro North Hospital and Health Service (ABN 18 496 277 942), Block 7 Level 7, Butterfield Street, Herston, Qld 4029, Australia	
12.	**Fee template** signed by the sponsor if applicable	
13.	**Teletrials –** please refer to HREC Notification of **teletrials checklist**	

[1]The sponsor is the individual, company, institution or organisation that takes on legal responsibility for the initiation, management of the research.

[2]If you intend to conduct a clinical trial and are seeking Metro North sponsorship; you are required to request sponsorship approval prior to a HREC submission. Please contact MetroNorthResearch-ClinicalTrials@health.qld.gov.au for more information.