

Human Research Ethics Application (HREA) Checklist

- Mater Misericordiae Ltd Human Research Ethics Committee (MML HREC)

The following checklist/guidance information is provided to assist with your HREA application; it is not to be included with your submission.

All research projects	
Signed HREA form	
- To be submitted via ERM (Ethical Review Manager)	
Protocol	
- Footer should include: Version number, date and page numbering in the format 'Page XX of XX'.	
- A Protocol template is available in the Resource Library (Mater Research website or SharePoint)	
cv	
- A brief bio-sketch only (2 pages)	
- Only the Principle Investigator's CV is required	
Other – submit if applicable to your project	
Participant Information Sheet and Consent Form (PICF)	
- Footer should include: Version number, date and page numbering in the format 'Page XX of XX'.	
- For multi-site projects, only the Master PICF is required with your submission. Site-specific PICFs should be submitted to the relevant site with your SSA submission.	
- PICF templates are available in the Resource Library (Mater Research website or SharePoint)	
Waiver of Consent (WoC) justification	
- Waiver of consent justification template is available in the Resource Library (Mater Research website or SharePoint)	
HREC-only indemnity*	
- For multi-site studies, the sponsor is required to provide indemnity to the HREC for its review	
- Please use the Medicines Australia HREC Indemnity form*	
Data collection tools	
- Eg. Case Report Form / Spreadsheet	
Questionnaires, surveys, interview and focus group questions, other instruments, tools and measures	
Advertising materials and communications	
- Including flyers, letters of invitation, letters to GP, transcripts of advertisements or phone calls.	
Participant diaries and wallet cards	
Other correspondence	
- Eg. FDA reviews, correspondence or approval from other HRECs, expert independent reviews or peer reviews.	
Drug/Device Information / Investigator's Brochure	