

# MML HREC Application Checklist

* For all new research applications please log in to [ERM](https://au.forms.ethicalreviewmanager.com) and complete a HREA.
* Upload all supporting documents with the HREA.
* Each document requires a version number, date and page numbering in the footer.
* HREC meeting dates and corresponding [closing dates](https://www.materresearch.org.au/Researchers/For-researchers/Ethics-and-Governance/Ethics/Human-Research-Ethics-Committee) can be found on our website. Please note closing time for applications is 4pm on the closing date.

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| ***A) Required components for all submissions to the Mater Misericordiae Ltd HREC:*** |  |
| **1.** | Cover letter providing:1. A list of all supporting documentation submitted
2. A brief description of the project including whether it will be reviewed by multiple HRECs and why (including details such as whether the study is already running at other sites or if multiple HREC review is occurring simultaneously)
3. A list of all sites to be approved (if other sites are to be reviewed under a different HREC please briefly describe)
4. For commercially sponsored studies, billing information is required including company name, address, ABN, contact person, email address and telephone number for the sponsor organisation / CRA (must be an Australian address), and purchase order number (if required).
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| **2.** | Completed HREA. Signature is required from the Coordinating Principal Investigator. A Supervisor signature is also required if a member of the research team is involved in this research as part of a higher degree. |
| **3.** | Protocol. This is the working document for the study. It is the formal design or specific plan for the research and describes the conduct of the research in detail. The protocol must include a version number, date, and page numbering in the footer. Refer to our website for [guidance in writing a protocol](https://www.materresearch.org.au/Researchers/For-researchers/Ethics-and-Governance/Ethics/Preparing-and-submitting-your-application/All-Human-Research-Ethics-Applications-including-l). |
| **4.** | CV (brief bio-sketch – 2 pages) required for all researchers and clinical trial coordinators who are involved with the project |

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| ***B) Other research documentation that requires HREC approval:*** |  |
| **5.** | * Obtaining Participant Consent?

Participant Information Sheet and Consent Form (PICF). [Templates and guidance](https://www.materresearch.org.au/Researchers/For-researchers/Ethics-and-Governance/Ethics/Preparing-and-submitting-your-application/All-Human-Research-Ethics-Applications-including-l) can be found on our website. The PICF must include a version number, date, and page numbering in the footer. For multi-centre studies a Master PICF is required for HREC review. Site-specific PICFs can be subsequently created from the Master document and submitted to each of the site Research Governance Offices.* Not Obtaining Participant Consent? (i.e. retrospective data)

Waiver of Consent. A justification for the waiver of participant consent for the use of their data for the secondary purpose of research must be reviewed by the full Committee at an HREC meeting. The justification should refer to the value of the research, the risk and burden to participants in seeking their consent *and should be based on the information outlined in Chapter 2.3 of the National Statement* (page 21) *and Section 95A of the Privacy Act* (page 23-24, D.5). [Links to these documents](https://www.materresearch.org.au/Researchers/For-researchers/Ethics-and-Governance/Ethics/Method-and-timeline-for-review) (including a guide on how to word the waiver of consent justification) can be found on our website. This justification is best placed in your protocol. |  |
| **6.** | Data collection tools e.g. spreadsheet for collecting research data*.* |  |
| **7.** | Questionnaires, surveys, interview and focus group questions, other instruments, tools, and measures. |  |
| **8.** | Investigator’s Brochure (for drugs and devices*).* |  |
| **9.** | Advertising materials (including a copy of transcripts for advertisements, emails, websites, letters or telephone calls). |  |
| **10.** | Letters of invitation and letters to GP. |  |
| **11.** | Participant diaries and wallet cards. |  |
| **12.** | Other correspondence e.g. FDA reviews, correspondence or approval from other HRECs, expert independent reviews, peer reviews. |  |
| **13.** | Institutional Biosafety Committee (IBC) approval. |  |
| **14.** | Licence for dealings with a Genetically Modified Organism (GMO). |  |
| **15.** | 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. |  |
| **16.** | HREC-only indemnity: For sites outside of MML or QH a form of indemnity may be required (see Medicines Australia website - [HREC Review Only form](https://medicinesaustralia.com.au/policy/clinical-trials/indemity-and-compensation-guidelines/)). Contact the MML HREC Office for confirmation. |  |