Ethics Checklist

To assist with preparing an ethics application

* Use the **Ethical Review Manager (ERM) website** <https://au.forms.ethicalreviewmanager.com> to create, complete and submit an ethics application
* The Human Research Ethics Application (HREA) or Victorian Low Negligible Risk (LNR VIC) form can be used
* The LNR VIC is for selected organisations only: ***always*** consult your research office before creating a LNR VIC.
* If the HREA is used, the Victorian Specific Module (VSM) is also created and submitted in ERM

**ERM Project ID**  Enter Project ID

**Project Title** Enter Project Title

Preparation

Research team members:  have their own ERM accounts  have set up ERM collaborators

are familiar with the [Applicant user guide to ERM](https://au.forms.ethicalreviewmanager.com/Personalisation/DisplayPage/50)

can refer to [ERM guidance documents](https://au.forms.ethicalreviewmanager.com/Personalisation/DisplayPage/50)

can refer to Victorian [Clinical trial and research](http://clinicaltrialsandresearch.vic.gov.au) website

Application form signatories:  have their own ERM accounts

can refer to [ERM guidance documents](https://au.forms.ethicalreviewmanager.com/Personalisation/DisplayPage/50)

Supporting documents

The application requires supporting documents to be uploaded in ERM, as applicable to the project.

|  |  |  |  |
| --- | --- | --- | --- |
| Supporting document | | Required | Office use only |
| Protocol or Project description | |  |  |
| Participant information and consent form(s) | |  |  |
| For project taking place in Vic: Victorian Specific Module *(not required if LNR VIC is used)* | |  |  |
| For project taking place in WA: Western Australian Specific Module | |  |  |
| Investigator CV *(if not submitted to research office in last two years)* | |  |  |
| Copy of the Form of Indemnity ([Medicines Australia](https://www.medicinesaustralia.com.au/policy/clinical-trials/indemnity-compensation-guidelines/) or [MTAA](https://www.mtaa.org.au/sites/default/files/uploaded-content/website-content/mtaa-standard-form-of-indemnity-for-a-clinical-investigation-%28version-1---8-april-2010%29.pdf) standard form) for each site | |  |  |
| Correspondence e.g. peer review, communication with other HREC | |  |  |
| Letter of Invitation/letter to GP etc | |  |  |
| Advertising material e.g. email, flyer, website; transcript for phone call | |  |  |
| Data management plan | |  |  |
| Data collection tools e.g. case report form, questionnaire | |  |  |
| Participant documentation e.g. diary, wallet card | |  |  |
| Supporting document | | Required | Office use only |
| Clinical trial | Evidence of [CTN](https://www.tga.gov.au/clinical-trials) or [CTA](https://www.tga.gov.au/clinical-trials) |  |  |
| Investigator Brochure or reference safety information |  |  |
| Form of Indemnity ([Medicines Australia](https://www.medicinesaustralia.com.au/policy/clinical-trials/indemnity-compensation-guidelines/) / MTAA HREC Review only form) for each site |  |  |
| IBC & GMO | Institutional biosafety committee (IBC) approval |  |  |
| License for dealing with a genetically modified organism (GMO) |  |  |
| Radiological | For each site, **either:**  Letter form Principal Investigator stating that radiation exposure is part of normal clinical management/care *(letter should be based on template)*  **or:**  If radiation exposure is additional to that received as normal clinical management/care: an independent assessment report by a Medical Physicist of the total effective dose and relevant organ doses including risk assessment |  |  |

List of supporting documents to be uploaded in ERM, as applicable to the research project.

|  |  |
| --- | --- |
| Supporting document | Office use only |
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Help

ERM Guidance: <https://au.forms.ethicalreviewmanager.com> go to Help → Templates

Coordinating Office for Clinical Trial Research Receiver 0408 274 054 Envelope [multisite.ethics@ecodev.vic.gov.au](mailto:multisite.ethics@ecodev.vic.gov.au)

Infonetica Helpdesk (ERM technical issues) Receiver 02 9037 8404 Envelope [helpdesk@infonetica.net](mailto:helpdesk@infonetica.net)

ERM, select Create Project and choose 0408 Main Form = HREA.

Authorised by the Coordinating Office for Clinical Trial Research

Department of Jobs, Precincts and Regions

121 Exhibition Street Melbourne Victoria 3000

Telephone 0408 274 054

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This document is also available in an accessible format at [multisite.ethics@ecodev.vic.gov.au](mailto:multisite.ethics@ecodev.vic.gov.au)