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| Ethics Checklist |
| To assist with preparing an ethics application |
| OFFICIAL |

* 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

SSA 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  |  [x]  | [ ]  |
| 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 | [ ]  | [ ]  |
|  | Supervision Plan | [ ]  | [ ]  |
|  | Teletrial Supervision Plan (if required by HREC) |[ ] [ ]
|  | Teletrial Supervision Plan - HREC Information Sheet |[ ] [ ]
| 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 other supporting documents to be uploaded in ERM, as applicable to the research project:

| Supporting document | Required | Office use only |
| --- | --- | --- |
| Add item | [ ]  | [ ]  |
| Add item | [ ]  | [ ]  |
| Add item |[ ] [ ]
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### Help

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

Coordinating Office for Clinical Trial Research  0408 274 054  multisite.ethics@safercare.vic.gov.au

Infonetica Helpdesk (ERM technical issues)  02 9037 8404  helpdesk@infonetica.net

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| To receive this document in another format, phone 0408 274 054, using the National Relay Service 13 36 77 if required, or email Coordinating Office for Clinical Trial Research <multisite.ethics@safercare.vic.gov.au>Authorised and published by the Victorian Government, 1 Treasury Place, Melbourne.© State of Victoria, Australia, Department of Health, March 2024. |