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| Research Governance Checklist |
| To assist with preparing a research governance / Site Specific Assessment (SSA) application |
| OFFICIAL |

* Use the **Ethical Review Manager (ERM) website** <https://au.forms.ethicalreviewmanager.com> to create, complete and submit a research governance / SSA application to the site’s Research Governance Officer (RGO).
* The research governance / SSA application can be submitted as soon as the ethics application is submitted

**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 |
| --- | --- | --- |
| Standard [CTRA](https://www.medicinesaustralia.com.au/policy/clinical-trials/clinical-trial-research-agreements/) / [MTAA](https://www.mtaa.org.au/clinical-investigation-research-agreements) research agreement or other research agreements |  |  |
| Participant information and consent form with site-specific details e.g. site contact details |  |  |
| Standard 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)) |  |  |
| Insurance Certificate |  |  |
| Copy of [CTN](https://www.tga.gov.au/clinical-trials) or [CTA](https://www.tga.gov.au/clinical-trials) |  |  |
| Copy of ethics approval letter / certificate |  |  |
| Supervision Plan |  |  |
| Drug committee approval |  |  |
| Biosafety approval |  |  |
| Gene related therapy assessment |  |  |
| Radiation safety approval |  |  |
| Embryo research licence |  |  |
| Approval of genetically modified organisms |  |  |
| Detailed site budget |  |  |
| Investigator CV |  |  |
| Evidence of Investigator’s professional registration |  |  |
| Evidence of Investigator’s Good Clinical Practice (GCP) training |  |  |
| Research governance review fee |  |  |

Teletrials – Additional documents:

| Supporting document | Required | Office use only |
| --- | --- | --- |
| Standard [CTRA](https://www.medicinesaustralia.com.au/policy/clinical-trials/clinical-trial-research-agreements/) Teletrial Subcontract (between Primary site and Satellite site) for each Satellite site |  |  |
| Teletrial Supervision Plan (between Primary site and Satellite site) |  |  |
| Delegation Log |  |  |
| Add item |  |  |
| Add item |  |  |
| Add item |  |  |
| Add item |  |  |

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 |  |  |

### 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](mailto:multisite.ethics@safercare.vic.gov.au)

Infonetica Helpdesk (ERM technical issues)  02 9037 8404  [helpdesk@infonetica.net](mailto: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](mailto:multisite.ethics@safercare.vic.gov.au) <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. |