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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

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. |