

Research Governance Checklist

for all Principal Investigators

A copy of this checklist must be included with every new research governance application submitted to your research governance office. All research projects require authorisation of research governance before a project can commence.

Research governance applications are the responsibility of Principal Investigators at each site participating in a research project. It is strongly recommended that research governance applications are submitted to the office for research/ethics as early as possible and before the HREC submission. Research governance applications can be submitted at any time and in parts (i.e. a complete application in one submission is not essential).

This checklist is divided into three parts: **A)** Items which need to be submitted before or at the same time as the HREC submission to commence the assessment process; **B)** Items which can only be submitted after the HREC application has been submitted; **C)** All documents approved by the reviewing HREC.

This Research Governance checklist should be submitted **once**, with completion of **Part A**

| | |
|-----------------------------|--------------------|
| HREC Reference No. (AU RED) | Site Reference No. |
|-----------------------------|--------------------|

PART A) Early Action

Submit these items before or at the same time as the HREC submission

YES

Office
Use Only

Mandatory components of all research governance applications

- | | | |
|--|--------------------------|--------------------------|
| 1. Explanatory cover letter (signed by the Principal Investigator) | <input type="checkbox"/> | <input type="checkbox"/> |
| 2. Detailed budget (draft is acceptable) | <input type="checkbox"/> | <input type="checkbox"/> |
| 3. Research Governance Review Fee | <input type="checkbox"/> | <input type="checkbox"/> |
| 4. Study Protocol | <input type="checkbox"/> | <input type="checkbox"/> |

For all items marked "NA" please provide a brief explanation below the item

NA

YES

Office
Use Only

- | | | | |
|---|--------------------------|--------------------------|--------------------------|
| 5. Investigator Brochure | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| <input type="text"/> | | | |
| 6. Standard Form(s) of indemnity (Medicines Australia Standard Form of Indemnity for your site) | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| <input type="text"/> | | | |
| 7. Insurance Certificate | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| <input type="text"/> | | | |
| 8. CTN form (COPY for checking only - original CTN to be submitted with ethics submission to the reviewing HREC) | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| <input type="text"/> | | | |
| 9. Clinical Trial Research Agreement (CTRA) | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| <input type="text"/> | | | |
| 10. Site Specific Forms and Statements of Approval – access these from your office for research/ethics or institution website | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| <input type="text"/> | | | |
| 11. Section 4 – "Use of Ionising Radiation" for your site and a letter of risk assessment addressing the radiation dosage. | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| <input type="text"/> | | | |

Research governance applications can be submitted to the Research/Ethics Office in parts. Early submission will allow for timely commencement of research governance which should be conducted in parallel with HREC review. In this way, when HREC approval is issued, research governance authorisation can be completed and timely commencement of a study at your site can occur after these two endorsements.

Name _____ Contact Number _____ Date _____

Position _____

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Parts B and C are to be checked off by the Research Governance Officer as they are made available

PART B) Mandatory post- HREC submission components of all research governance applications

Office
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- 12. **Victorian Site Specific Assessment (SSA) Form** (with ORIGINAL SIGNATURES)
- 13. Full copy of the HREC submission with all supporting documents (including Victorian Specific Module) as submitted to the reviewing HREC
- 14. Detailed site budget (final, signed by the site Principal Investigator)

PART C) Post HREC Approval

Office
Use Only

- 15. Final HREC approval letter/certificate.
 - 16. Original CTN form for the site, signed by the reviewing HREC
 - 17. Full complete copy of the HREC submission as approved by the reviewing HREC and include copies of all approved PICFs. Include as applicable, advertisements, letters of invitation, questionnaires, letter from DLA Phillips Fox lawyers (for Victorian public hospitals only), etc. Include appropriately edited site-specific versions of these documents as well as copies of all correspondence between the CPI and the reviewing HREC.
- The Research Governance Officer can now take steps to finalise site SSA authorisation.**
- 18. Copy of the TGA acknowledgement letter (sponsor to send to Principal Investigators)

Information

Online Forms website: For access to NEAF and SSA forms. If investigators or applicants have not previously registered an account please create one at www.ethicsform.org/au

Consultative Council for Human Research Ethics (CCHRE) website:

For information on making an application to the streamlined system for ethical review of clinical trials in Victoria visit www.health.vic.gov.au/cchre

Information line: For general system and application form-related questions, call (03) 9092 1987

Central Allocation System (CAS) line: For allocating an HREC application to a reviewing HREC, call (03) 9092 1983 Monday to Friday 10am to 5pm EST

IT Help Desk: For technical questions regarding application forms, Investigators/Applicants can contact the IT Help Desk. For AU RED queries, reviewing HREC Coordinators and Research Governance Officers can also contact the IT Help Desk:

Phone: 02 9037 8404 Monday to Friday 10am to 4pm EST | Email: helpdesk@infonetica.net