RESEARCH GOVERNANCE CHECKLIST

FOR ALL PRINCIPAL INVESTIGATORS

A copy of this Research Governance Checklist must be included with every new research governance application submitted to the site's research governance office.

HREC Reference Number		Local Reference Number	
Principal Investigator		Trial Coordinator	
Telephone		Email	

A Early Action

Submit these items **as early as possible**, before or at the same time as the HREC submission

		Yes	N/A	Office Use Only
1	Explanatory Cover Letter	☐		
2	Detailed Budget (draft is acceptable)	☐		
3	Research Governance Review Fee	☐		
4	Study Protocol	☐		
5	Investigator Brochure	☐	☐	
6	Standard Form of Indemnity (Medicines Australia or MTAA *Standard Form of Indemnity*) for the site	☐	☐	
7	Insurance Certificate	☐	☐	
8	CTN Form (COPY only; original must be submitted with ethics submission to the reviewing HREC)	☐	☐	
9	Standard CTRA/CIRA or other collaborative agreement	☐	☐	
10	Site-specific Forms and Statements of Approval (access these from your research governance office)	☐	☐	
11	Section 4 - 'Use of Ionising Radiation' for the site, accompanied by Medical Physicist's report	☐	☐	

This Checklist must be submitted to the site's research governance office with completion of Part A.

B After the HREC submission has been made

Submit these items when they have been finalised for submission to the reviewing HREC

		Office Use Only
12	**Site Specific Assessment (SSA) Form** (Victorian version) with original signatures	
13	Full copy of the ethics submission with all supporting documents, including Victorian Specific Module	
14	Detailed site budget (final version signed by the site Principal Investigator)	

C After HREC approval

Submit these items after approval has been given by the reviewing HREC; all must be approved versions

		Office Use Only
15	Copy of the HREC approval letter/certificate	
16	Original CTN form for the site, signed by the reviewing HREC	
17	Complete copy of **all** HREC-approved documents including correspondence between the CPI and the reviewing HREC, and appropriately edited site-specific version of HREC-approved documents	
18	Copy of the TGA acknowledgement letter	

State Government Victoria

RESEARCH GOVERNANCE CHECKLIST - INFORMATION

FOR ALL PRINCIPAL INVESTIGATORS

- Site-specific research governance authorisation is required for each site participating in a research project.
- A copy of this Research Governance Checklist must be included with every new research governance application submitted to the site's research governance office. It should be submitted **once**, with completion of Part A.
- A research governance application is the responsibility of the Principal Investigator at each site participating in a research project. Research governance documents should be submitted to the site's research governance office as early as possible and before the ethics application submission.
- Research governance documents can be submitted as available and in parts (i.e. a complete application in one submission is not required). Consult with the site's research governance office regarding submission.
- All research projects require authorisation of research governance before the project can commence at the site.
- Early submission of a research governance documents allows for timely commencement of research governance, which should be conducted in parallel with HREC review. This permits research governance authorisation to be given shortly after HREC approval is given, which will lead to timely commencement of the research project at the site.

Online Forms - www.ethicsform.org/au

A separate **Site Specific Assessment** (SSA) Form is required for each site participating in a research project. All SSA Forms must be completed using the Online Forms website.

The Coordinating Principal Investigator (or delegate) **must** create all SSA Forms from the NEAF submitted to the HREC. They must then transfer each site's SSA Form to the site Principal Investigator (or delegate) for completion.

The Principal Investigator (or delegate) is responsible for generating a Submission Code on Online Forms before submitting their SSA to the site's research governance office.

All Online Forms users must create an account on the website.

For technical issues with Online Forms, contact the IT Helpdesk. Available Monday - Friday, 10am - 4pm EST
Tel: 02 9037 8404 Email: helpdesk@infonetica.net

Further Information

For further information on research governance and streamlining ethical review of clinical trials in Victoria and as part of Interstate Mutual Acceptance, visit www.health.vic.gov.au/clinicaltrials.

For queries, contact the Coordinating Office.
General Enquiries line: 03 9096 7394 Information line: 03 9096 7398
Email: multisite.ethics@health.vic.gov.au

State Government Victoria