RESEARCH PROJECT ETHICS CHECKLIST
FOR COORDINATING PRINCIPAL INVESTIGATORS

Name of HREC _____

A copy of this checklist must be included with every new research project application submitted to the reviewing HREC.

A	**Mandatory components for all submissions to a HREC**	**Yes**	**No. of copies**
1	Cover letter* signed by Coordinating Principal Investigator	☐	
2	NEAF with a *Submission Code* (MUST be accessed from Online Forms website www.ethicsform.org/au)	☐	
3	Study protocol†	☐	
4	CV for researchers who have not submitted a CV to the reviewing HREC within the last 2 years	☐	
5	For studies taking place in VIC: Victorian Specific Module (access from www.health.vic.gov.au/clinicaltrials)	☐	
6	For studies taking place in NSW: Privacy Form, if applicable (access from www.health.vic.gov.au/clinicaltrials)	☐	

***Cover letter must include:**

- A brief description of project including the Phase of the study if a clinical trial
- A list of all sites applicable to the HREC application for the study
- A list of supporting documentation submitted, including version dates/numbers
- For commercially sponsored studies: the name and address of the sponsor organisation/CRO/CRA for the HREC review invoice (Australian address)
- HREC Reference Number allocated by the Central Coordinating Service (QLD) or Central Allocation System (VIC) if submitted in those states

†The protocol may contain some of the information in the NEAF but the protocol is required because it is the working document for the study; the formal design or specific plan for the research. If revisions occur during the course of the research, a revised protocol must be submitted to the reviewing HREC as an amendment. The protocol must include a version date/number which is changed as the document is updated.

B	**Other items that may be required depending on the particular research project**	**Yes**	**No**	**N/A**	**No. of copies**
7	Master Participant Information Sheet and Consent Form	☐	☐	☐	
8	Site-Master (if applicable) Participant Information Sheet and Consent Form with site-specific wording added (provided by the site's Principal Investigator to the Coordinating Principal Investigator)	☐	☐	☐	
9	CTN form(s) – include original CTN forms with details for each site	☐	☐	☐	
10	CTX Form	☐	☐	☐	
11	Investigator's Brochure	☐	☐	☐	
12	Questionnaires/other instruments	☐	☐	☐	
13	Data collection tool(s) e.g. Case Report Form	☐	☐	☐	
14	Form of Indemnity (Medicines Australia HREC Review Only form) for each participating site	☐	☐	☐	
15	Copy of the Form of Indemnity (Standard form) for each participating site	☐	☐	☐	
16	Advertising materials (including transcript for advertisement, e-mail, website, letter, telephone call etc.)	☐	☐	☐	
17	Letter of invitation/Letter to GP, etc.	☐	☐	☐	
18	Participant diaries	☐	☐	☐	
19	Participant wallet card	☐	☐	☐	
20	Other correspondence e.g. FDA reviews, correspondence from other HRECs, expert independent reviews, peer review etc.	☐	☐	☐	
	Research using gene technology				
21	Institutional Biosafety Committee (IBC) approval	☐	☐	☐	
22	Licence for dealings with a Genetically Modified Organism (GMO)	☐	☐	☐	
	Research using radiological procedures that are performed for research				
23	For each site in NSW, QLD or SA, **either** • A letter from the PI stating that radiation exposure is part of normal clinical management/care (access template from www.health.vic.gov.au/clinicaltrials) **OR** • If radiation exposure is <u>additional</u> to that received as part of normal clinical management/care: an independent assessment report by a Medical Physicist of the total effective dose and relevant organ doses including risk assessment	☐	☐	☐	
24	For Victorian sites: Complete Section 4 – "Use of Ionising Radiation" for **each** Victorian site (provided by site's Principal Investigator to Coordinating Principal Investigator)	☐	☐	☐	

NSW GOVERNMENT · Queensland Government · Government of South Australia, SA Health · State Government Victoria

PRINCIPAL INVESTIGATORS' ETHICS CHECKLIST

The **Principal Investigator** at each site participating in a multi-site study is responsible for providing the Coordinating Principal Investigator with the following documents as part of the HREC submission.

A	Items that may be required depending on the particular research project application	Yes	N/A	No. of copies
1	Site-Master (if applicable) Participant Information Sheet and Consent Form with site-specific wording	☐	☐	
2	For each site in NSW, QLD or SA, **either** • A letter from the PI stating that radiation exposure is part of normal clinical management/care (access template from www.health.vic.gov.au/clinicaltrials)	☐	☐	
	OR • If radiation exposure is additional to that received as part of normal clinical management/care: an independent assessment report by a Medical Physicist of the total effective dose and relevant organ doses including risk assessment	☐	☐	
3	For Victorian sites: Complete Section 4 – "Use of Ionising Radiation" for **each** Victorian site	☐	☐	

INFORMATION

Online Forms Website

Online Forms allows access to NEAF and SSA forms. Investigators or applicants can register for an account at www.ethicsform.org/au.

IT Help Desk

For technical issues regarding the Online Forms website and application forms, investigators or applicants can contact the IT Help Desk. This facility can also be used for AU RED queries from reviewing HREC Coordinators and Research Governance Officers.
Available Monday - Friday, 10am - 4pm EST Phone 02 9037 8404; Email helpdesk@infonetica.net

State-Specific Contact Information

For information on the streamlined system for ethical review of clinical trials, please use the contact details below.

New South Wales Office for Medical Research	
Website	www.health.nsw.gov.au/ethics/research
Email	healthethics@doh.health.nsw.gov.au
Telephone	02 9391 9785

South Australia Office for Research Development	
Website	www.sahealth.sa.gov.au
Email	researchethics@health.sa.gov.au
Telephone	08 8226 6367

Queensland Health and Medical Research (HMR)	
The Central Coordinating Service (CCS) is for allocating a HREC application to a reviewing HREC in Queensland.	
Website	www.health.qld.gov.au/ohmr
Email	hmr_reg@health.qld.gov.au
Telephone	07 3328 9824
CCS	www.health.qld.gov.au/ohmr/html/regu/cen_coord_serv.asp

Victoria Coordinating Office for Clinical Trial Research		
Contact the Central Allocation System (CAS) for allocating a HREC application to a reviewing HREC in Victoria.		
Website	www.health.vic.gov.au/clinicaltrials	
Email	multisite.ethics@health.vic.gov.au	
Telephone	General Enquiries	03 9096 7394
	System Information	03 9096 7398
CAS	03 9096 7395	