**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

<table>
<thead>
<tr>
<th></th>
<th>Mandatory component</th>
<th>Yes</th>
<th>No of copies</th>
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</thead>
<tbody>
<tr>
<td>1</td>
<td>Cover letter* signed by Coordinating Principal Investigator</td>
<td></td>
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<tr>
<td>2</td>
<td>NEAF with a Submission Code (MUST be accessed from Online Forms website <a href="http://www.ethicsform.org/au">www.ethicsform.org/au</a>)</td>
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<tr>
<td>3</td>
<td>Study protocol†</td>
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<td>4</td>
<td>CV for researchers who have not submitted a CV to the reviewing HREC within the last 2 years</td>
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</tbody>
</table>

*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

<table>
<thead>
<tr>
<th></th>
<th>Other item</th>
<th>Yes</th>
<th>No</th>
<th>N/A</th>
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<tbody>
<tr>
<td>7</td>
<td>Master Participant Information Sheet and Consent Form</td>
<td></td>
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<tr>
<td>8</td>
<td>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)</td>
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<tr>
<td>9</td>
<td>CTN form(s) – include original CTN forms with details for each site</td>
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<tr>
<td>10</td>
<td>CTX Form</td>
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<td>11</td>
<td>Investigator’s Brochure</td>
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<td>12</td>
<td>Questionnaires/other instruments</td>
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<td>13</td>
<td>Data collection tool(s) e.g. Case Report Form</td>
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<tr>
<td>14</td>
<td>Form of Indemnity (Medicines Australia HREC Review Only form) for each participating site</td>
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<tr>
<td>15</td>
<td>Copy of the Form of Indemnity (Standard form) for each participating site</td>
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<tr>
<td>16</td>
<td>Advertising materials (including transcript for advertisement, e-mail, website, letter, telephone call etc.)</td>
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<td>17</td>
<td>Letter of invitation/Letter to GP, etc.</td>
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<td>18</td>
<td>Participant diaries</td>
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<tr>
<td>19</td>
<td>Participant wallet card</td>
<td></td>
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<tr>
<td>20</td>
<td>Other correspondence e.g. FDA reviews, correspondence from other HRECs, expert independent reviews, peer review etc.</td>
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#### Research using gene technology

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<thead>
<tr>
<th></th>
<th>Research using gene technology</th>
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<th>N/A</th>
<th>No of copies</th>
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</thead>
<tbody>
<tr>
<td>21</td>
<td>Institutional Biosafety Committee (IBC) approval</td>
<td></td>
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<tr>
<td>22</td>
<td>Licence for dealings with a Genetically Modified Organism (GMO)</td>
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#### Research using radiological procedures that are performed for research

<table>
<thead>
<tr>
<th></th>
<th>Research using radiological procedures that are performed for research</th>
<th>Yes</th>
<th>No</th>
<th>N/A</th>
<th>No of copies</th>
</tr>
</thead>
<tbody>
<tr>
<td>23</td>
<td>For each site in NSW or QLD, either</td>
<td></td>
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<td></td>
<td>OR</td>
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<td></td>
<td>- 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</td>
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<tr>
<td>24</td>
<td>For Victorian sites: Complete Section 4 – “Use of Ionising Radiation” for each Victorian site (provided by site’s Principal Investigator to Coordinating Principal Investigator)</td>
<td></td>
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Checklist for HREC Submission  
Version: November 2012
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.

### Items that may be required depending on the particular research project application

<table>
<thead>
<tr>
<th></th>
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<tbody>
<tr>
<td>1</td>
<td>Site-Master (if applicable) Participant Information Sheet and Consent Form with site-specific wording</td>
<td>□ □</td>
</tr>
</tbody>
</table>
| 2 | For each site in NSW or QLD, either  
  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 | □ □  |

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### INFORMATION

**Online Forms Website**  
Online Forms allows access to NEAF and SSA forms. If investigators or applicants have not previously registered an account, please create one at [www.ethicsform.org/au](http://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

The Office for Medical Research acts as a resource centre and source of advice to clinicians, researchers and Human Research Ethics Committees.

<table>
<thead>
<tr>
<th></th>
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<tbody>
<tr>
<td>Email</td>
<td><a href="mailto:healthethics@doh.health.nsw.gov.au">healthethics@doh.health.nsw.gov.au</a></td>
</tr>
<tr>
<td>Telephone</td>
<td>02 9391 9785</td>
</tr>
</tbody>
</table>

#### Queensland

The Research Ethics and Governance Unit (REGU) is responsible for consultation, development and review of State-wide research ethics and research governance policies.

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<tbody>
<tr>
<td>Email</td>
<td><a href="mailto:regu@health.qld.gov.au">regu@health.qld.gov.au</a></td>
</tr>
<tr>
<td>Telephone</td>
<td>07 3234 0034</td>
</tr>
</tbody>
</table>

**Central Coordinating Service (CCS) line**  
For allocating a HREC application to a reviewing HREC in Queensland  
1300 QLD CCS (1300 753 227) or 07 3234 0654

#### Victoria

Governance of the streamlined ethical review for multi-site clinical trials is provided by the Consultative Council for Human Research Ethics. Support for users of the system is provided by the Coordinating Office for Human Research Ethics.

<table>
<thead>
<tr>
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<tbody>
<tr>
<td>Email</td>
<td><a href="mailto:multisite.ethics@health.vic.gov.au">multisite.ethics@health.vic.gov.au</a></td>
</tr>
<tr>
<td>General enquiries line</td>
<td>03 9092 1981</td>
</tr>
<tr>
<td>Information line</td>
<td>03 9092 1987</td>
</tr>
<tr>
<td>Central Allocation System (CAS) line</td>
<td>03 9092 1983</td>
</tr>
</tbody>
</table>