
Application for Renewal of Certification of the Ethical Review Process for Multi-centre Research

Renewal requirement

The Renewal form leads the Institution through the requirements for certification renewal and provides a valuable opportunity for the Institution to review its ethical review processes and determine whether they continue to meet the requirements of the *National Statement on Ethical Conduct in Human Research (2007, updated March 2014)* and the National Certification Scheme.

The Renewal Form will be reviewed by the assessment team in order to inform their decision on whether renewal of certification can be granted.

Have you completed your certification requirements in order to proceed to certification renewal?
Certification requirements include:

- Annual reporting compliance.
- Implementation of assessment team recommendations/requirements identified at original certification.

Yes Please proceed with renewal request application.

If applicable, please ensure you provide evidence (refer to the Renewal of Certification Section) demonstrating that your Institution has considered and/or implemented the recommendations of the assessment team.

No Your Institution may not be eligible to apply for certification renewal. Please contact the Director, Health and Research Ethics Section via email HREP@nhmrc.gov.au and you will be advised on your eligibility to continue with renewal of certification.

Institution and HREC details	
Institution	
Name:	
Primary affiliation:	<input type="checkbox"/> Public Hospital <input type="checkbox"/> Private Hospital <input type="checkbox"/> University <input type="checkbox"/> Government Department (hospital/local health district or equivalent) <input type="checkbox"/> Government Department (other) <input type="checkbox"/> Medical Research Institution <input type="checkbox"/> Other (<i>please specify</i>) <div style="border: 1px solid black; height: 40px; margin-top: 5px;"></div>
Address:	
Postal address:	
City/Town:	
State:	
Postcode:	
Switchboard number:	
Head of Institution	
Name:	
Title:	
Phone:	
Email address:	
Institution contact officer for certification process	
Name:	
Title:	
Phone:	
Email address:	
HREC name	
Name:	
NHMRC registration code:	EC

HREC Chair (Chair will be contacted only with knowledge of Institution)	
Name:	
Title:	
Phone:	
Email address:	

HREC administrative support officer	
Name:	
Title:	
Phone:	
Email address:	

Research	
Please indicate the category(ies) in which your Institution is currently certified:	
<input type="checkbox"/> Justice health	<input type="checkbox"/> Mental health
<input type="checkbox"/> Population health and/or public health	<input type="checkbox"/> Qualitative research
<input type="checkbox"/> Children and young people	
<input type="checkbox"/> Clinical trials <input type="checkbox"/> Devices <input type="checkbox"/> Drugs <input type="checkbox"/> Surgery <input type="checkbox"/> Other <input type="checkbox"/> Phase 0 <input type="checkbox"/> Phase I <input type="checkbox"/> Phase II <input type="checkbox"/> Phase III <input type="checkbox"/> Phase IV	<input type="checkbox"/> Clinical interventional research other than clinical trials
<input type="checkbox"/> Other health and medical research <i>Please specify</i> <div style="border: 1px solid black; height: 100px; width: 100%; margin-top: 5px;"></div>	<input type="checkbox"/> Other human research (not health and medical) <i>Please specify</i> <div style="border: 1px solid black; height: 100px; width: 100%; margin-top: 5px;"></div>

Please indicate if you wish to add or delete a category of certification as part of the renewal process.

Yes No

If Yes, please indicate in the table below which category(ies) you wish to add or delete.

Delete	Add	Delete	Add
<input type="checkbox"/>	<p>Justice health</p> <p><input type="checkbox"/> Number of reviews in last two calendar years <input type="text"/></p> <p>Percentage of total reviews in the last two calendar years <input type="text"/> %</p>	<input type="checkbox"/>	<p>Mental health</p> <p><input type="checkbox"/> Number of reviews in last two calendar years <input type="text"/></p> <p>Percentage of total reviews in the last two calendar years <input type="text"/> %</p>
<input type="checkbox"/>	<p>Population health and/or public health</p> <p><input type="checkbox"/> Number of reviews in last two calendar years <input type="text"/></p> <p>Percentage of total reviews in the last two calendar years <input type="text"/> %</p>	<input type="checkbox"/>	<p>Qualitative research</p> <p><input type="checkbox"/> Number of reviews in last two calendar years (<i>specify sub category where relevant</i>) <input type="text"/></p> <p>Percentage of total reviews in the last two calendar years <input type="text"/> %</p>

Delete	Add	Delete	Add
<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>	<p>Clinical trials</p> <p><input type="checkbox"/> Devices</p> <p><input type="checkbox"/> Drugs</p> <p><input type="checkbox"/> Surgery</p> <p><input type="checkbox"/> Other</p> <p><input type="checkbox"/> Phase 0</p> <p><input type="checkbox"/> Phase I</p> <p><input type="checkbox"/> Phase II</p> <p><input type="checkbox"/> Phase III</p> <p><input type="checkbox"/> Phase IV</p> <p>Number of review in last two calendar years for each clinical trials sub category (eg. Clinical trials Surgery = 2 Clinical trials Phase 0 = 5)</p> <div style="border: 1px solid black; height: 40px; width: 100%;"></div> <p>Percentage of total reviews in the last two calendar years for each clinical trials sub category (eg. Clinical trials Surgery = 10% Clinical trials Phase 0 = 25%)</p> <div style="border: 1px solid black; height: 40px; width: 100%; text-align: right;">%</div>	<input type="checkbox"/>	<p>Clinical interventional research other than clinical trials</p> <p><input type="checkbox"/> Number of reviews in last two calendar years</p> <div style="border: 1px solid black; height: 25px; width: 100%;"></div> <p>Percentage of total reviews in the last two calendar years</p> <div style="border: 1px solid black; height: 25px; width: 100%; text-align: right;">%</div>

Delete	Add	Delete	Add
<input type="checkbox"/>	<p>Other health and medical research*</p> <p><input type="checkbox"/> Number of reviews in last two calendar years</p> <div style="border: 1px solid black; height: 25px; width: 100%;"></div> <p>Percentage of total reviews in the last two calendar years</p> <div style="border: 1px solid black; padding: 2px; text-align: right;">%</div> <p><i>Please specify</i></p> <div style="border: 1px solid black; height: 150px; width: 100%;"></div>	<input type="checkbox"/>	<p>Other human research (not health and medical)*</p> <p><input type="checkbox"/> Number of reviews in last two calendar years <i>(please list by phase)</i></p> <div style="border: 1px solid black; height: 25px; width: 100%;"></div> <p>Percentage of total reviews in the last two calendar years <i>(please list by phase)</i></p> <div style="border: 1px solid black; padding: 2px; text-align: right;">%</div> <p><i>Please specify</i></p> <div style="border: 1px solid black; height: 150px; width: 100%;"></div>
<input type="checkbox"/>	<p>Children and young people*</p> <p>A specialist assessor may be required to review processes relating to research involving children and young people.</p> <p><input type="checkbox"/> Number of reviews in last two calendar years</p> <div style="border: 1px solid black; height: 25px; width: 100%;"></div> <p>Percentage of total reviews in the last two calendar years</p> <div style="border: 1px solid black; padding: 2px; text-align: right;">%</div>		

An explanation of the categories of research can be found on pages 8–11 of the Certification Handbook.

***If your Institution nominates this category, the certifying body may contact you upon receipt of your nomination to discuss the categories nominated.**

Renewal of Certification

Identified improvements

Has the Institution addressed any recommended improvements identified in the assessment report on which current certification is based? Please refer to the attachment to view your Institution's required improvements, if any.

Yes N/A

If **Yes**, please attach evidence.

Please note that it is mandatory for institutions to supply evidence that addresses identified areas of improvement prior to renewal of certification.

Current HREC or Sub-Committee Member Composition and HREC Administrative Staff Profile

Has the member profile for either the HREC or any sub-committee listed in the original certification changed?

Yes No

If **Yes**, please complete the table titled 'Current HREC Member Profile' and/or 'Current Sub-committee Member Profile'.

Does the composition of the Committee continue to reflect the requirements of 5.1.29 – 5.1.33 of the National Statement?

Yes No

Does the Institution utilise specialists or persons with expertise in an advisory capacity to the HREC to assist with the research that it considers?

Yes No

If **Yes**, for which categories of research are expert advisors used?

Is the membership of the HREC made public?

Yes No

If **Yes**, please provide web link.

Has the HREC administrative staff profile listed in the original certification changed?

Yes No

If **Yes**, please complete the table titled 'Current HREC Administrative Staff Profile'.

Current HREC Member Profile									
Name	Gender	Category they represent (see N.S. 5.1.30)	Institutional or non Institutional (see N.S. 5.1.29)	Term of appointment	Induction training completed (Y/N)	Two or more years accumulated HREC experience (Y/N)	Signed letter of appointment on personnel file (Y/N)	Current Conflict of Interest Declaration on file (Y/N)	Training record attached* Y/N
<i>e.g. Prof J. Doe</i>	<i>M/F</i>	<i>e.g. A (Chair) B (Lay person)</i>	<i>e.g. Institutional</i>	<i>e.g. 1 Jan 09 – 30 Jun 11</i>					

*Please attach training records for all HREC Members who have undergone training since the certification commencement date.

Current HREC Member Profile Continued									
Name	Gender	Category they represent (see N.S. 5.1.30)	Institutional or non Institutional (see N.S. 5.1.29)	Term of appointment	Induction training completed (Y/N)	Two or more years accumulated HREC experience (Y/N)	Signed letter of appointment on personnel file (Y/N)	Current Conflict of Interest Declaration on file (Y/N)	Training record attached* Y/N
<i>e.g. Prof J. Doe</i>	<i>M/F</i>	<i>e.g. A (Chair) B (Lay person)</i>	<i>e.g. Institutional</i>	<i>e.g. 1 Jan 09 – 30 Jun 11</i>					

*Please attach training records for all HREC Members who have undergone training since the certification commencement date.

Current Sub-Committee Member Profile				
Name	Gender	Term of appointment	Signed letter of appointment on personnel file (Y/N)	Current Conflict of Interest Declaration on file (Y/N)
<i>e.g. Prof J. Doe</i>	<i>M/F</i>	<i>e.g. 1 Jan 09 – 30 Jun 11</i>		

Current HREC Administrative Staff Profile		
Name	Role	Length of service
<i>e.g. Jane Doe</i>	<i>e.g. Executive Officer</i>	<i>e.g. April 2013 – present</i>

HREC or Sub-Committee Terms of Reference

Has the Terms of Reference (ToR) for either Committee changed since providing your last Annual Report?

Yes No

If Yes*, do the ToR comply with 5.1.27 of the National Statement?

Yes No

**Please provide a copy of the new ToR.*

Are the ToRs made public?

Yes No

If Yes, please provide weblink.

HREC or Sub-Committee Standard Operating Procedures

Have the Standard Operating Procedures (SOPs) for either Committee changed since providing your last Annual Report?

Yes No

If Yes*, do the SOPs comply with 5.1.37 of the National Statement?

Yes No

**Please provide a copy of the new SOPs.*

Are the SOPs made public?

Yes No

If Yes, please provide weblink.

HREC Meetings

Since certification how many HREC meetings have been held?

Please provide endorsed HREC meeting minutes and associated correspondence for the previous three months (de-identified versions are acceptable). Only HREC meeting minutes are required, not minutes of Sub-committee or Executive Committee meetings. Examples of correspondence include an approval letter, a letter requesting further information, a rejection letter, a thank you letter for providing annual report updates and any other relevant letters.

Declaration Form

Please print this declaration form and obtain the required signatures. **If your HREC is affiliated with multiple institutions, please ensure that each Head of Institution signs the Declaration Form.** Once completed, this form should be scanned into an appropriate electronic format and sent to HREP@nhmrc.gov.au in conjunction with the application form.

Declaration

Head of Institution

I confirm that, to the best of my knowledge, all information contained in this form and the attached application form, is correct and accurate. I nominate the ethical review processes of this Institution for renewal of certification. I understand that the ethical review of multi-centre health and medical research carried out by this Institution's HREC may be used by other institutions to fulfil their obligations under the National Statement and inform their decision on the conduct of research at their institution. I authorise staff and members of the Human Research Ethics Committee to co-operate with the certifying body including sharing confidential Institutional information relevant to the ethical review process and Institutional support. I acknowledge a confidentiality and conflicts of interest declaration will be provided to the certifying body by assessors conducting on-site visits.

Printed name:

Signature:

Date:

Chair of Human Research Ethics Committee

I confirm that, to the best of my knowledge, all information contained in this Form, as it relates to the ethical review process of the Human Research Ethics Committee that I Chair is correct and accurate. I understand that the ethical review outcome of the Committee that I Chair may be used by other institutions to fulfil their obligations under the National Statement and inform their decision on the conduct of research at their institution. I attest that all members of the Committee have the same understanding.

Printed name:

Signature:

Date:

Checklist

Once completed, these forms should be sent electronically to HREP@nhmrc.gov.au with the words **APPLICATION FOR RENEWAL OF CERTIFICATION (INSTITUTION NAME)** in the subject field. Documents must be submitted as an attachment, web links to documents are not acceptable. Please ensure all items have been attached and are clearly labelled.

- Application for renewal form completed and Declaration Form signed
- Evidence to address changes to be implemented prior to certification renewal and evidence of identified areas of improvement
- HREC and or Sub-Committee membership and training records
- HREC Administrative Staff profile
- Terms of Reference *(if applicable)*
- Standard Operating Procedures *(if applicable)*
- Endorsed HREC meeting minutes and associated correspondence for the previous three months *(de-identified versions are acceptable)*

Please list below all documents provided with your Institution's application.

Attachment number	Name
01	
02	
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