

4.2 Self assessment form

Self assessment tool for certification of ethical review processes

Section 1 Introduction

The self assessment tool is intended for use by an institution and its Human Research Ethics Committee (HREC) as part of the nomination for certification of institutional processes for ethical review of multi-centre research.

The self assessment tool provides the institution with an opportunity to review and confirm their readiness for assessment by the certifying body. The self assessment is intended to support institutional achievement of certification through enabling an efficient desktop audit and on-site assessment visit.

Section 2 Instructions

Most questions of self assessment can be answered with a response such as 'yes' or 'no'. The tool will also identify areas where greater depth of information is required. In these cases, a 'describe' field is provided for free text comment. Free text comment may not be required where a document title, number and/or filename is cited.

If additional space is needed to answer any question, please note the relevant question number and attach it as an appendix to the completed form.

Once completed, this form and supporting documents should be sent electronically to homer@nhmrc.gov.au with the words DOCUMENTATION FOR CERTIFICATION (INSTITUTION NAME) in the subject field.

Section 3 Definitions

Assessor – An assessor is a qualified individual who considers information provided by the institution and/or observations of institutional practice to make a recommendation to the certifying body on conformance to an agreed standard. An assessor may also gather information through interviews with key personnel and stakeholders.

Certification – The process of ensuring that a process conforms to an agreed standard or criteria determined by the certifying body.

Certifying body – The entity undertaking the assessment of institutional claims and issuing a certificate of conformance to the agreed standard or criteria (where appropriate).

Desktop audit – An off-site audit conducted by the certifying body that verifies information provided by an institution satisfies the requirements of the nomination process.

Institution – The entity that nominates its processes for ethical review for assessment and certification by a certifying body, with the intent that the outcome of an ethical review of multi-centre research is utilised by institutions collaborating in a given health and medical research project.

Monitoring – Monitoring of research is ‘the process of verifying that the conduct of research conforms to the approved proposal’¹. For multi-centre projects where there has been a single ethical review adopted by all participating institutions, monitoring is a shared responsibility between participating institutions (through their research governance and administrative functions), the researcher at each centre and/or site and the relevant study team and the Human Research Ethics Committee (HREC) that reviewed the research protocol. A study sponsor may also undertake monitoring.

On-site – The physical location of the institution seeking certification.

Self Assessment – The first step towards certification. In self assessment, the institution reviews and confirms its readiness for assessment by a certifying body through a structured consideration of its policies and practices supporting its processes for ethical review of multi-centre research. The process serves to clarify and enhance the success of the application and allows for remedial action prior to audit by the certifying body.

Section 4 Documents supporting claims

Institutions will need to provide electronic copies (.PDF format) of documents that support their claims of conformance to the assessment criteria. Supporting documents listed within this form are optional unless otherwise stated.

In some cases, these documents are ‘mandatory’ inclusions and where this is so, the word MANDATORY appears in the text.

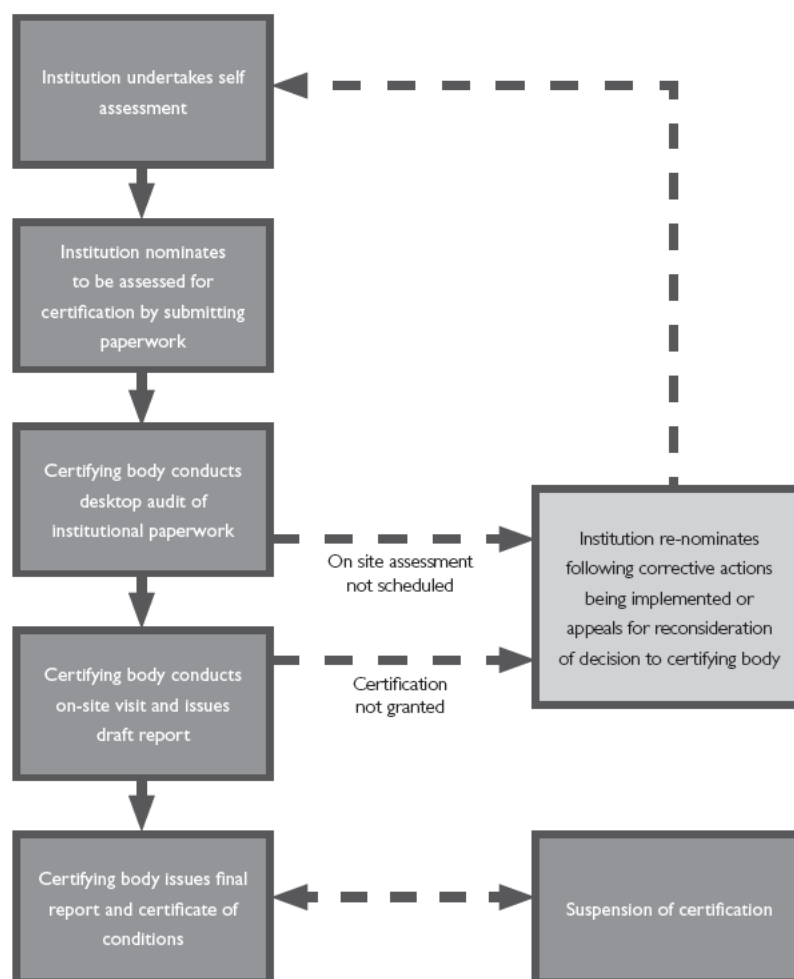
Examples of supporting documents include:

- Copy of duty statement or position description form for administrative officer(s) supporting ethical review process
- Terms of reference for the HREC
- Copy of template letter of appointment for HREC members
- Standard operating procedures related to ethical review process
- Templates of documents used by the HREC to communicate with researchers
- Institutional policies related to ethical review
- Annual report(s) on ethical review processes

Institutions should provide blank template documents where a standard form is used for letters, statements and declarations. Where it is not possible to provide a blank template, the institution should appropriately manage any sensitive and/or identifiable information contained in the proffered documents.

¹ NHMRC/ARC/AVVC *National Statement on Ethical Conduct in Human Research* (2007) Chapter 5.5 *Monitoring Approved Research*

Section 5 Steps in Certification



* The institution will be given the opportunity through open and active dialogue with the certifying body to respond to any deficiencies or discrepancies found in the desktop audit.

Section 6 Institution and HREC Contacts and Profile²

Name of institution	Alfred Health									
Address of institution	55 Commercial Road, Prahran, VIC, 3181									
Address of HREC (if different from institution)										
Address where HREC meetings are held (if different from institutional address)										
Name of Head of institution (or delegate) supporting certification	s 47F									
Name of institutional contact for questions on nomination (if different from above)	s 47F									
Telephone number for institutional contact	s 47F									
Fax number for institutional contact	s 47F									
Email address for institutional contact	research@alfred.org.au									
Name and telephone number for institutional contact during on-site visit (if different from above)										
HREC year of establishment	1975									
Name of HREC Chair and year of initial appointment	s 47F 1989									
Frequency of HREC meetings (e.g. monthly, etc.)	Monthly									
Day and time of HREC meetings (e.g. third Thursday for full day, as needed for ½ day, etc.)	Third Thursday of the month, 4pm to around 6.30pm									
Number of protocols reviewed by the HREC in the previous calendar year (whether or not research commenced)	247 (plus 189 Low Risk)									
Number of protocols reviewed by the HREC in the previous calendar year that were multi-centre (whether or not research commenced)	192									
Categories of research where HREC has significant experience ³ Please tick all that apply: <table border="0" style="width: 100%;"> <tr> <td>☒ Clinical trials of drugs and devices</td> <td>☒ Justice health</td> <td>☒ Qualitative health research</td> </tr> <tr> <td>☒ Population health and/or public health</td> <td>☒ Clinical interventional research other than clinical trials</td> <td>☒ Mental health</td> </tr> <tr> <td>☐ Other</td> <td>☐ Aboriginal Torres Strait Islander Peoples health</td> <td>☐ Paediatric</td> </tr> </table>		☒ Clinical trials of drugs and devices	☒ Justice health	☒ Qualitative health research	☒ Population health and/or public health	☒ Clinical interventional research other than clinical trials	☒ Mental health	☐ Other	☐ Aboriginal Torres Strait Islander Peoples health	☐ Paediatric
☒ Clinical trials of drugs and devices	☒ Justice health	☒ Qualitative health research								
☒ Population health and/or public health	☒ Clinical interventional research other than clinical trials	☒ Mental health								
☐ Other	☐ Aboriginal Torres Strait Islander Peoples health	☐ Paediatric								
Institutional format requirement for receipt of application for ethical review (e.g. hardcopy or electronic, if electronic, .PDF or other)	Electronic									
Institutional requirement to export data from application into other format ⁴	No									

² This is the first page of the self assessment tool to be provided with nomination package

³ If it is intended that multi-centre clinical trials of unapproved therapeutics or multi-centre clinical interventional research will be reviewed by the institutional HREC, then these must be listed

⁴ The National Ethics Application Form may be configured and shared in .xml, .mdb or .csv format if raw data fields from NEAF need to be imported into an institutional database

Section 7 Self Assessment Audit Tool

Group I Assessment criteria based on the NHMRC/ARC/AVCC *National Statement on Ethical Conduct in Human Research* (2007) (the National Statement)

1.1. How the establishment of the committee reflects the requirements of the National Statement Sections 5.1.26 – 5.1.28

Section 5.1.26 Resources supporting ethical review

1.1.1. How many administrative staff members support the ethical review process?

Seven

1.1.2. How many administrative staff members support communication with researchers on the ethical review process?

Six

1.1.3. Are the administrative staff members employed full-time or part-time?

Both

1.1.4. Does the administrative support for the HREC have a dedicated office space?

Yes ☒ No ☐

Describe location within site:

Located in the centre of the Alfred Health campus

1.1.5. Does the HREC have a meeting space?

Yes ☒ No ☐

Describe location/capacity:

The HREC has access to a variety of meeting spaces at Alfred Health, easily accessible and capable of providing space for all members. Four meetings rooms are used monthly for the various meetings.

1.1.6. Does the institution charge fees for ethical review?

Yes ☒ No ☐

Supporting documents that may be attached as evidence of claims:

- copy of organisational structure for administrative area supporting ethical review and researcher communication
- copy of duty statement of relevant administrative officer(s)
- copy of institutional policy on charging fees for ethical review

Supporting documents:

1.1.6 Organisational structure
1.1.6 Ethics Officer Duty Statement A
1.1.6 Ethics Officer Duty Statement B
1.1.6 Fees for HREC Review

Section 5.1.27 HREC terms of reference

1.1.7. Does the HREC have terms of reference which defines its scope, relationships to relevant groups, accountability mechanisms, categories of membership and remuneration (if any)?

Yes ☒ No ☐

Supporting document to be attached (MANDATORY)

- copy of HREC terms of reference

1.1.7 HREC Terms of Reference

- 1.1.8. Is the terms of reference for the HREC and the membership made public?
Yes ☒ No ☐

Describe (cite document title, number and/or filename as applicable):

Available on the Alfred Research & Ethics website at:
<http://www.alfredresearch.org/ethics/Terms%20of%20Reference%20EC%202011.pdf>

- 1.1.9. Do the HREC members complete a conflicts of interest declaration?
Yes ☒ No ☐

Supporting documents to be attached (MANDATORY)

- copy of declaration of conflicts of interest form

1.1.9 Statement and Declaration of Interests
1.1.9 Confidentiality Statement Observer
1.1.9 Alfred Ethics Committee Guidelines: Conflicts of interests available at:
<http://www.alfredresearch.org/ethics/policies/COI-policy.pdf>

Section 5.1.28 Institution responsibilities

- 1.1.10. Does the institution ensure HREC members receive appropriate induction?
Yes ☒ No ☐

Describe (cite document title, number and/or file location as applicable):

New members are invited to attend the Ethics Office for a face-to-face induction session and are provided with copies of the following documents:
National Statement on Ethical Conduct in Human Research 2007
Australian Code for the Responsible Conduct of Research
1.1.10 Ethics Committee Induction Information

- 1.1.11. Does the institution ensure that the HREC operates in accordance with the National Statement?
Yes ☒ No ☐

Describe (cite document title, number and/or filename as applicable):

1.1.11 Alfred Health Policy: Responsible Conduct of Research (requires researchers to comply with the Australian Code, which in turn refers to the National Statement.) Non-compliance with an Alfred Health policy is a potentially sackable offence.
<http://www.alfredresearch.org/policies/ResponsibleConductofResearchPolicyRev1.pdf>
See also:
1.3.2 Appointment new members template
1.4.1 Obligations of Ethics Committee Members

1.2. Does the composition of the committee reflect the requirements of the National Statement Sections 5.1.29 – 5.1.33

Section 5.1.29 Membership composition of HREC

- 1.2.1. Does the institution have a list of all HREC members together with their current CVs?

Yes ☒ No ☐

Supporting documents that may be attached as evidence of claims

- Copies of CVs of current HREC members

1.2.1 Membership of Alfred Ethics Committees 2010

There are over 40 members of the various committees. CVs can be supplied on request.

- 1.2.2. Has the institution appointed a HREC with 8 or more members, with equal gender distribution and with one-third of members being independent from the institution (as far as possible)?

Yes ☒ No ☐

Section 5.1.30 Experience and background of HREC members

- 1.2.3. Does the HREC have at least two lay members who do not engage in medical, scientific, legal or academic work?

Yes ☒ No ☐

- 1.2.4. Does the HREC have at least one member who performs a pastoral care role in a community?

Yes ☒ No ☐

- 1.2.5. Does the HREC have at least one member who is a lawyer?

Yes ☒ No ☐

Is this member also a legal advisor to the institution?

Yes ☐ No ☒

- 1.2.6. Does the HREC have at least two members with current research experience that is relevant to the research proposals considered by the HREC?

Yes ☒ No ☐

Section 5.1.31 Pool of inducted members

- 1.2.7. Does the institution maintain a pool of inducted HREC members in each category listed above?

Yes ☒ No ☐

Section 5.1.32 Experience in ethical decision making

- 1.2.8. How many of the HREC members (included inducted members) have experience in reflecting and analysing ethical decision-making?

Main Ethics Committee 24/30

Research Review Sub-Committee 13/13

General Ethical Issues Sub-Committee 15/17

Section 5.1.33 Access to expertise

- 1.2.9. Does the institution utilise specialists or persons with expertise in an advisory capacity to the HREC to assist with ethical considerations of the categories of research that it considers?

Yes ☒ No ☐

Supporting documents that may be attached as evidence of claims

- copy of institutional policy for co-opting or accessing expertise
- copy of list of specialists or technical experts assisting ethical decision-making who are not members of HREC (if any)

We follow the VMIA's guidelines regarding use of external experts:
<http://www.vmia.vic.gov.au/display.asp?entityid=3023#M5>
 1.2.9 Sample letter to external expert reviewer

- 1.3. Does the appointment of HREC members reflect the requirements of the National Statement Sections 5.1.34 & 5.1.36

Section 5.1.34 Appointment process

- 1.3.1. Are HREC members appointed in an open and transparent process?

Yes ☒ No ☐

Describe (cite document title, number and/or filename as applicable):

New members are recruited via advertisements in local and state-wide media.
 A selection of applicants are invited to present for interview.
 New members serve a probationary period of three months before full membership is granted.
 1.3.1 Position description Lawyer
 1.3.1 Lay person ad newspaper Dec 09

Section 5.1.36 Notice of appointment

- 1.3.2. Do members receive a formal notice of appointment?

Yes ☒ No ☐

Supporting documents that may be attached as evidence of claims

- copy of template letter of appointment of HREC members or other formal notice

1.3.2 Appointment new members template

1.4. Do the responsibilities assigned to the HREC by the institution reflect the requirements of the National Statement Sections 5.2.3 – 5.2.4

Section 5.2.3 Individual member responsibility

1.4.1. Does the institution have a mechanism to assure itself that HREC members are meeting their responsibilities as described in the National Statement?

Yes ☒ No ☐

Describe (cite document title, number and/or filename as applicable):

1.4.1 Obligations of Ethics Committee Members

1.4.2. How many days prior to a scheduled meeting are the meeting papers distributed to HREC members?

21

1.4.3. Do HREC members attend continuing education or training programs in research ethics?

Yes ☒ No ☐

Supporting documents that may be attached as evidence of claims

- copy of training records for HREC members

The HREC advertises relevant programs to members and encourages interested members to also identify relevant courses. The HREC provides financial support any course or conference attended.

Section 5.2.4 Disclosure of conflicts of interest

- 1.4.4. Does the institution have policies and procedures for disclosure and management of potential conflicts of interest of HREC members including financial or other interest or affiliation that bears on any research coming before the review body?

Yes ☒ No ☐

Describe (cite document title, number and/or filename as applicable):

1.1.9 Alfred Ethics Committee Guidelines: Conflicts of interests available at:
<http://www.alfredresearch.org/ethics/policies/COI-policy.pdf>
 1.4.4 Code of Conduct for Alfred Health
 1.4.4 Financial Code of Practice for Alfred Health

Supporting documents to be attached (MANDATORY)

- copy of institutional policy on disclosure of conflicts of interest (HREC specific or generic as applicable)

- 1.5. Do the institutional procedures for ethical review reflect the requirements of the National Statement Sections 5.1.37, 5.2.13 – 5.2.15, 5.2.18 – 5.2.20, 5.2.28 – 5.2.31, *Section 5.1.37 HREC procedures*

- 1.5.1. Does the institution have standard operating procedures (SOPs) that cover the ethical review of multi-centre research?

Yes ☒ No ☐

- 1.5.2. When were the SOPs last updated?

1.5.1 SOP ethical review and administration
 In addition, for studies conducted at Victorian sites, the SOPs of the CCHRE have been adopted. The Alfred also reviews (and accepts reviews of) studies submitted under the Cancer Trials Australia MAP program. The Alfred has also initiated an arrangement with Monash University for mutual acceptance of ethical review between the two institutions. The Alfred also considers requests from other HRECs to accept reviews.
 The Alfred Ethics Office updates standard operating procedures, instructions and guidelines for

- 1.5.3. Who reviews and endorses the HREC SOPs? Provide name and title of relevant party(ies)

s 47F

1.5.4. Does the institution make the SOPs publicly available?

Yes ☒ No ☐

Describe (cite document title, number and/or filename as applicable):

The submission instructions on the Alfred Ethics website describe the SOPs for review of multi-centre research:

http://www.alfredresearch.org/ethics/applicat/NEAF_National.htm

http://www.alfredresearch.org/ethics/applicat/NEAF_Streamlined.htm

<http://www.alfredresearch.org/ethics/applicat/CAF.htm>

1.5.4 Instructions for submitting research applications

1.5.1 SOP ethical review and administration

Supporting documents to be attached (MANDATORY)

- copy of standard operating procedures for ethical review
- copy of standard operating procedures for administering paperwork for ethical review

Section 5.2.13 Open communication

1.5.5. Does the institution or the HREC promote the National Statement to researchers?

Yes ☒ No ☐

Describe:

There are numerous links to the National Statement from the Alfred Ethics website, and within Alfred Ethics Committee Guidelines, all publicly available:

<http://www.alfredresearch.org/links.htm>

<http://www.alfredresearch.org/ethics/ecguidelines.htm>

Section 5.2.14 Face-to-face meetings with researchers

1.5.6. Does the HREC hold face to face meetings with researchers when written and telephone communication does not resolve issues about the research proposals?

Yes ☒ No ☐

Describe:

Research and/or Ethics Committee members may request meetings to resolve issues regarding a particular project. Some projects may require a series of meetings before the issue is resolved. Researchers also request to present cases for ethical consideration at meetings such as those of the the General Ethical Issues Sub-committee.

Approximately two projects each month are selected for interview. The Principal Researcher is invited to attend the ethics committee meeting to discuss his/her project application.

Section 5.2.15 Resourcing open communication

1.5.7. This question has been removed intentionally

Section 5.2.18 Invited Researchers

1.5.8. Does the HREC operate under a formal institutional process for inviting researchers to elaborate on specific issues related to their application or responding to requests from researchers to attend meetings?

Yes ☒ No ☐

Describe (cite document title, number and/or filename as applicable):

Principal researchers responsible for all Phase I studies are required to present for interview at the ethics committee meeting.

1.5.9. Are confidentiality agreements signed by invited researchers and experts prior to the HREC seeking advice on specific issues?

Yes ☒ No ☐

Describe (cite document title, number and/or filename as applicable):

Researchers are not required to sign confidentiality agreements.
Experts, observers or other persons who are not ethics committee members or researchers are asked to sign confidentiality agreements before receiving any information pertaining to the ethics committee or its deliberations.
1.1.9 Confidentiality Statement Observer
1.5.9 Agreement for the conduct of Expert Review of a clinical trial

Section 5.2.19 Advice from experts

- 1.5.10. Do experts complete a declaration on potential conflicts of interest and confidentiality prior to attending a HREC meeting?

Yes ☒ No ☐

Describe (cite document title, number and/or filename as applicable):

1.1.9 Confidentiality Statement Observer
1.5.9 Agreement for the conduct of Expert Review of a clinical trial

Supporting documents that may be attached as evidence of claims

- copy of confidentiality agreement and/or conflicts of interest statements

Section 5.2.20 Communication between a research sponsor and HREC

- 1.5.11. Does the HREC operate under an established institutional policy on communicating with research sponsors?

Yes ☐ No ☒

Describe (cite document title, number and/or filename as applicable):

The HREC prefers to correspond with researchers who in turn correspond with sponsors.

- 1.6. Does the institutional process for communicating a decision from an ethical review process reflect the requirements of the National Statement Section 5.2.22

Section 5.2.22 Communicating the outcome of an ethical review

- 1.6.1. Are HREC decisions communicated in writing to applicants?

Yes ☒ No ☐

- 1.6.2. Does the HREC offer partial or provisional approval of proposals?

Yes ☐ No ☒

Describe (cite document title, number and/or filename as applicable):

- 1.6.3. Are the reasons for amendments to the protocol being requested routinely provided?

Yes ☒ No ☐

- 1.6.4. Are the reasons for rejecting a research proposal on ethical grounds routinely linked to the National Statement?
Yes ☒ No ☐
- 1.6.5. Does the final approval letter routinely include information on how the HREC will monitor the ethical conduct of the research including any reporting requirements?
Yes ☒ No ☐

Supporting documents that may be attached as evidence of claims

- copies of templates for letter for approval, letter for requesting amendment and letter for rejecting a proposal on ethical grounds

1.6.4 There have not been any recent projects that have been rejected on ethical grounds. Most are rejected on scientific grounds before reaching the Ethics Committee.
1.6.5 Approval Certificate
1.6.5 Requesting changes to project

- 1.7. Do institutional processes for documentation and record keeping related to ethical review reflect the requirements of the National Statement Sections 5.2.23 – 5.2.27
- 1.7.1. Does the HREC operate under an institutional standard operating procedure for record keeping and archiving of all records and documents related to ethical review?
Yes ☒ No ☐

Describe (cite document title, number and/or filename as applicable):

1.7.1 SOP record keeping and archiving of ethics office files

Section 5.2.23 Approval of documents used for participant recruitment

- 1.7.2. Is there an institutional mechanism to ensure materials used to recruit participants for multi-centre research are considered by the HREC?
Yes ☒ No ☐

Section 5.2.24 Records of received and reviewed research proposals

- 1.7.3. Is all information listed in Section 5.2.24 kept in an accessible record?
Yes ☒ No ☐

1.7.4. In what form is the record kept?

Describe (cite document title, number and/or filename as applicable):

One paper copy of the research application and subsequent correspondence and other documentation is filed in the Ethics Office.
Electronic copies are also filed securely by the Ethics Office.

How long is the record kept before archiving?

Who can access the record and what is the protocol for access?

Describe (cite document title, number and/or filename as applicable):

Paper copies of files are archived after a final report has been submitted and the study has been archived by the researchers, indicating that the study has closed at this site. HREC members can access the file. Researchers can access the file after confidential information (such as reviews) have been removed.

Section 5.2.25 Copies of approved research proposals and associated materials

1.7.5. Does the institution retain a copy of each application and associated materials in the form it was approved?

Yes ☒ No ☐

1.7.6. Is the above copy accessible to the HREC?

Yes ☒ No ☐*Section 5.2.26 Record of decisions*

1.7.7. Is a record of all decisions related to an application for ethical review maintained?

Yes ☒ No ☐

Describe (cite document title, number and/or filename as applicable):

Minutes of Ethics Committee meetings record decisions. All additional correspondence, or decisions conducted out-of-session, is also documented and filed.

1.7.8. Does the record link the outcome of the ethical review to relevant parts of the National Statement?

Yes ☐ No ☒

1.7.9. Who can access the record and what is the protocol for access?

See 1.7.4 above

Section 5.2.27 Records of multi-centre research

1.7.10. Is all information listed in Section 5.2.27 kept in an accessible record?

Yes ☒ No ☐

Section 5.2.28 HREC meetings

1.7.11. Does the HREC meet on a date that is publically known and announced in advance?

Yes ☒ No ☐

Describe (cite document title, number and/or filename as applicable):

<http://www.alfredresearch.org/ethics/submisdate.htm>

Supporting documents that may be attached as evidence of claims

- copy of schedule of meetings

Section 5.2.29 Attendance at meetings

1.7.12. Are attendance records kept of HREC meetings?

Yes ☒ No ☐

1.7.13. Does the institution have a policy regarding a quorum or minimal representation needed for a meeting to proceed?

Yes ☐ No ☒

Describe (cite document title, number and/or filename as applicable):

There is no institutional policy, though the HREC follows the guidelines set out in the National Statement regarding HREC membership (5.1.29-30). The minimum membership is considered a quorum.

1.7.14. Are decisions made by members about whether a research proposal meets the requirements of the National Statement minuted?

Yes ☐ No ☒

Describe (cite document title, number and/or filename as applicable):

Section 5.2.30 Consideration of viewpoints of absent members

- 1.7.15. Is there an institutional process to obtain the input from HREC members unable to attend a meeting?

Yes ☒ No ☐

Describe (cite document title, number and/or filename as applicable):

All members are sent a CD containing all project submissions, an agenda, review template and instructions. All members are required to submit reviews prior to the meeting, regardless of whether or not they are able to attend.

1.7.15 Reviewing Instructions CD1

A second CD is sent to all members, prior to the meeting, containing members' reviews and researchers' amendments to projects in response to those reviews.

Members are paid a lesser rate if they submit their reviews but are unable to attend a meeting.

Section 5.2.31 Arriving at a decision

- 1.7.16. Does the HREC have a consistent methodology for arriving at a decision (e.g. by consensus, majority vote or other)?

Yes ☒ No ☐

Describe (cite document title, number and/or filename as applicable):

A consensus model is usually adopted, though on occasion a vote is taken if the consensus process fails to lead to a clear decision.

- 1.8. Does the institutional process for minimising the duplication of ethical review reflect the National Statement Sections 5.3.2 & 5.3.3?

Section 5.3.2 Single ethical review experience

- 1.8.1. Has the institution previously participated in collaborative research which received only a single ethical review?

Yes ☒ No ☐

Describe (cite document title, number and/or filename as applicable):

See 1.5.1 above

Section 5.3.3 Management of institutional input into a single ethical review

- 1.8.2. Does the institution have a written procedure for engaging with a HREC outside the institution that is carrying out a single ethical review for a collaborative project?

Yes ☒ No ☐

- 1.8.3. What role, if any, does the institutional HREC play in the governance of research that has been reviewed by another HREC?

Describe (cite document title, number and/or filename as applicable):

The HREC has adopted the CCHRE SOPs.
The HREC does carry out occasional inspections of other sites, checking insurance, SAEs, progress reports, credentials of research personnel etc. to ensure that the study under review can be competently carried out. For example, a recent inspection was carried out at Emeritus Research.

- 1.9. Does the institutional process for managing conflicts of interest related to ethical review processes reflect the requirements of the National Statement Sections 5.4.1 – 5.4.6

Section 5.4.1 Transparency of processes managing conflicts of interest

- 1.9.1. Does the institution have established policies and procedures for disclosure and management of potential conflicts of interest involving the institution itself and researchers?

Yes ☒ No ☐

Describe (cite document title, number and/or filename as applicable):

1.1.9 COI Guidelines <http://www.alfredresearch.org/ethics/policies/COI-policy.pdf>
1.9.5 SOP: conflicts of interest

Section 5.4.2 Informing relevant bodies about conflicts of interest

- 1.9.2. How does the HREC inform relevant ethical bodies about conflicts of interest it receives from institutions involved in multi-centre research?

Via email

Section 5.4.3 and Section 5.4.6 Measures to manage conflicts of interest

- 1.9.3. How does the HREC manage declarations of conflicts of interest it receives from researchers involved in multi-centre research?

1.9.5 SOP: conflicts of interest
From the guidelines:
"The Committee will generally not approve studies in which those with financial or other personal interests in the outcome are involved in selection of study participants or in the evaluation of outcomes of the investigation."
Researchers with competing interests may be asked to remove themselves from the research team.

Section 5.4.4 Notification of the institution

1.9.4. Does the HREC inform institution(s) of a potential conflict of interest for that institution(s)?

Yes ☒ No ☐

Describe (cite document title, number and/or filename as applicable):

Via email

Section 5.4.5 Disclosure of conflicts of interest

1.9.5. Does the institution have a policy for managing conflicts of interest of HREC members and advisors to the HREC that arise in a consideration of a particular proposal?

Yes ☒ No ☐

Describe (cite document title, number and/or filename as applicable):

1.9.5 SOP: conflicts of interest
See also 1.4.4 Code of Conduct for Alfred Health

Supporting documents to be attached (MANDATORY)

- copy of institutional policy on management of conflicts of interest
- copy of standard operating procedures for managing conflicts of interest relative to ethical review

1.10. Do the institutional processes for monitoring the ethical conduct of research reflect the requirements of the National Statement Sections 5.5.1 – 5.5.10 and 3.3.19 – 3.3.22

Section 5.5.1 Institutional responsibility for monitoring approved research

1.10.1. Does the institution have governance arrangements in place for monitoring approved research?

Yes ☒ No ☐

Describe (cite document title, number and/or filename as applicable):

Ethics approval is conditional upon provision by researchers of an annual progress report by the anniversary of approval. Approval will lapse if a progress report is not submitted.
Email reminders are sent to researchers.
Random audits are conducted using a three-tiered audit system (self audit, short audit, in-depth audit), or as requested by the Ethics Committee.
1.10.1 Ethics Progress Report Form
1.10.16 Monitoring research

Section 5.5.2 Frequency and type of monitoring

1.10.2. Is the frequency and type of monitoring of approved research based on the degree of risk to the participant?

Yes ☒ No ☐

Describe (cite document title, number and/or filename as applicable):

For low risk projects, a final report is sufficient.
1.10.2 Low Risk Final Report Mar 2010
1.10.16 Monitoring research

Supporting documents that may be attached as evidence of claims

- copy of institutional policy on monitoring of approved research
- schedule of monitoring of approved research showing role and responsibility within governance arrangements

Section 5.5.4 Notification of mechanisms for monitoring

1.10.3. Does the HREC require researchers to provide notice of their proposed mechanisms for monitoring research as part of the proposal or following approval?

Yes ☒ No ☐

Describe (cite document title, number and/or filename as applicable):

Section 5.5.5 Reporting of approved research

1.10.4. Does the HREC require researchers to provide, at a minimum annual reports of research progress for all approved research?

Yes ☒ No ☐

Describe (cite document title, number and/or filename as applicable):

1.10.1 Ethics Progress Report Form

- 1.10.5. Does the HREC require researchers to provide final reports of completion for all approved research?

Yes ☒ No ☐

Describe (cite document title, number and/or filename as applicable):

1.10.1 Ethics Progress Report Form
1.10.2 Low Risk Final Report Mar 2010

- 1.10.6. Does the HREC review the manner in which the results of the research will be reported and published?

Yes ☒ No ☐

Section 5.5.6 Discontinuation of research

- 1.10.7. Does the HREC require researchers to provide notice of the discontinuation of a research project including reasons for its discontinuation?

Yes ☒ No ☐

Describe (cite document title, number and/or filename as applicable):

1.10.1 Ethics Progress Report Form

- 1.10.8. Do approval letters for multi-centre research include requirements for how the discontinuation of research will be communicated to all participating institutions?

Yes ☒ No ☐

Section 5.5.7 Withdrawal of ethical approval where participant welfare is compromised

- 1.10.9. Does the institution have a policy and processes supporting the withdrawal of ethical approval in cases where participants' welfare may be compromised?

Yes ☒ No ☐

Sections 5.5.8, 5.5.9 and 5.5.10 Process for the withdrawal of ethical approval

1.10.10. Are all steps listed in Section 5.5.8 carried out under institutional policy on the withdrawal of ethical approval?

Yes ☒ No ☐

Supporting documents to be attached(MANDATORY)

- copy of institutional policy on withdrawal of ethical approval
- copy of letter template notifying withdrawal of ethical approval
- copy of letter template providing approval of modified research proposal after ethical approval was withdrawn
- copy of letter template from institution ordering the urgent suspension of research

1.10.10 DRAFT POLICY Withdrawal of ethical approval

1.10.10 suspension of project letter

1.10.10 lifting of suspension

These letters can be adapted to advise researchers of withdrawal of ethical approval instead of suspension when required.

Section 5.5.3 and 3.3.19 – 3.3.22 Monitoring of approved clinical research

1.10.11. Does the institution require researchers to promptly report to the institution and the HREC events or unexpected outcomes that affect the conduct of the approved research?

Yes ☒ No ☐

Describe (cite document title, number and/or filename as applicable):

1.10.11 Ethics Comm Update Adverse Events February 2008

1.10.11 SAE report form

Guidelines for reporting: <http://www.alfredresearch.org/ethics/adverse.htm>

1.10.16 Protocol deviations violations guidelines

1.10.12. Does the institution have arrangements in place to be notified of the outcome of monitoring activities being undertaken by sponsors of clinical trials?

Yes ☒ No ☐

Describe (cite document title, number and/or filename as applicable):

Researchers are requested to attach monitoring/audit reports from sponsors to the annual progress report: 1.10.1 Ethics Progress Report Form

- 1.10.13. Are all mechanisms for monitoring clinical research listed in Section 3.3.20 carried out under institutional policy?

Yes ☒ No ☐

Describe (cite document title, number and/or filename as applicable):

1.10.11 Ethics Comm Update Adverse Events February 2008
 1.10.11 SAE report form
 Guidelines for reporting: <http://www.alfredresearch.org/ethics/adverse.htm>
 DSMB reports are requested with the annual progress report:
 1.10.1 Ethics Progress Report Form
 1.10.16 Protocol deviations violations guidelines

- 1.10.14. Does the institution have a policy and process for HREC review of serious adverse events, serious adverse drug reactions, serious unexpected suspected adverse reactions and serious adverse device events for approved research at all sites for which the institution is responsible?

Yes ☒ No ☐

Describe (cite document title, number and/or filename as applicable):

1.10.11 Ethics Comm Update Adverse Events February 2008
 1.10.11 SAE report form
 Guidelines for reporting: <http://www.alfredresearch.org/ethics/adverse.htm>

- 1.10.15. Does the HREC have a process of monitoring approved clinical research that ensures conditions listed in Section 3.3.22 are met?

Yes ☒ No ☐

Describe (cite document title, number and/or filename as applicable):

1.10.11 Ethics Comm Update Adverse Events February 2008
 1.10.11 SAE report form
 Guidelines for reporting: <http://www.alfredresearch.org/ethics/adverse.htm>
 1.10.1 Ethics Progress Report Form
 Three-tiered audit system

- 1.10.16. Does the HREC review the adequacy of provisions made for monitoring the conduct of the research, including the constitution of a data safety and monitoring board where needed?

Yes ☒ No ☐

Describe (cite document title, number and/or filename as applicable):

Supporting documents to be attached when institution has nominated the ethical review process of proposals involving clinical trials and/or clinical interventional research for assessment (MANDATORY)

- copy of institutional policy on managing serious adverse events, serious adverse drug reactions, serious unexpected suspected adverse reactions and serious adverse device events
- copy of HREC procedure for ensuring appropriate monitoring of clinical research
- copy of example letter from researchers informing the HREC about serious adverse events, serious adverse drug reactions, serious unexpected suspected adverse reactions and serious adverse device events
- copy of template for letter informing researchers about necessary actions related to serious adverse events, serious adverse drug reactions, serious unexpected suspected adverse reactions and serious adverse device events
- copy of descriptor of system for tracking participants in trials of implantable medical devices
- copy of template for letter to Therapeutic Goods Administration (TGA) from institution informing them of device incidents

1.10.16 Monitoring research

1.10.11 Ethics Comm Update Adverse Events February 2008

1.10.11 SAE report form

Guidelines for reporting: <http://www.alfredresearch.org/ethics/adverse.htm>

DSMB reports are requested with the annual progress report:

1.10.1 Ethics Progress Report Form

1.10.16 Protocol deviations violations guidelines

Group 2 Assessment criteria linked to arrangements for the conduct of ethical review by the institutional HREC

2.1. Length of HREC service

- 2.1.1. Do at least half the members appointed in the minimum membership categories listed under the National Statement (5.1.30) have two or more years experience on a HREC?

Yes ☒ No ☐

- 2.1.2. Do the HREC Chair and Deputy Chair (if one is appointed) have suitable experience to perform their roles?

Yes ☒ No ☐

Describe (cite document title, number and/or filename as applicable):

2.2. Consideration of statutory and administrative frameworks related to the ethical conduct of research in jurisdictions where research is conducted

- 2.2.1. Does the institution have a process in place to consider legislative and administrative requirements that relate to the ethical conduct of research?

Yes ☒ No ☐

Describe (cite document title, number and/or filename as applicable):

Changes to legislative requirements are often discussed at the General Ethical Issues Sub-committee meetings. Submissions are made to the Victorian Law Reform Commission etc. Lawyer members provide advice regarding legislative matters, especially relating to other states.

- 2.2.2. If not, how does the institution propose to ensure appropriate consideration of jurisdictional legislative and administrative requirements in the ethical review processes?

Describe (cite document title, number and/or filename as applicable):

2.3. Induction of new HREC members

2.3.1. Do new HREC members receive induction materials when they begin their service?

Yes ☒ No ☐

Describe (cite document title, number and/or filename as applicable):

New members are invited to attend the Ethics Office for a face-to-face induction session and are provided with copies of the following documents:
National Statement on Ethical Conduct in Human Research 2007
Australian Code for the Responsible Conduct of Research
1.1.10 Ethics Committee Induction Information

2.3.2. Do new HREC members receive training relevant to the institution's ethical review process when they begin their service?

Yes ☒ No ☐

Describe (cite document title, number and/or filename as applicable):

The HREC advertises relevant programs to members and encourages interested members to also identify relevant courses. The HREC provides financial support any course or conference attended.

Group 3 Assessment criteria linked to training of HREC members and institutional administrative HREC support staff

3.1. Training

3.1.1. Provide the following information regarding training and education for each person or group of persons listed below:

	Training received before assuming position? (Yes/No)	Training received after assuming position? (Yes/No)	Frequency of training? (e.g. annually, bi-annually, etc.)
HREC support staff	No	Yes	Ongoing
HREC Chair	No	Yes	Bi-annually
HREC Deputy Chair	No	No	NA
HREC members	No	Yes	Ongoing
HREC advisors	No	No	NA

3.1.2. Briefly describe the training provided to the following groups in the past twelve months:

HREC support staff	Attendance at VMIA seminars, CCHRE workshops, other workshops, seminars and conferences, study leave for completion of Masters degrees.
HREC Chair	Attends relevant seminars, workshops, conferences and national HREC Chair meetings.
HREC Deputy Chair	Courses have been offered but am not aware of any attended.
HREC members	Attendance at Monash Research Ethics or Bioethics Intensive Courses, attendance at workshops and seminars
HREC advisors	The HREC coopts recognised experts in their respective fields to provide reviews. The HREC doesn't provide any training.

- 3.1.3. Does the institution have a policy on training for HREC members, HREC advisors and relevant administrative staff?

Yes ☒ No ☐

Describe (cite document title, number and/or filename as applicable):

The HREC advertises relevant programs to members and staff and encourages interested members and staff to also identify relevant courses. The HREC provides financial support any course or conference attended.

Supporting documents that may be attached as evidence of claims

- copy of institutional policy on training relevant to persons involved with ethical review processes

- 3.1.4. Does the institution document the training received by HREC members, HREC advisors and staff?

Yes ☐ No ☒

Describe (cite document title, number and/or filename as applicable):

The Ethics Office retains copies of emails detailing training and also requests report from members/staff following training.

Supporting documents that may be attached as evidence of claims

- copy of evidence of completion of training delivered in past 12 months

Group 4 Assessment criteria related to institutional ethical review processes of multi-centre research

4.1. Access to relevant expertise

- 4.1.1. Does the institution have a mechanism that ensures the HREC has access to relevant technical/scientific expertise needed to conduct the ethical review of multi-centre research proposals that fall within the categories of research where it has expertise?

Yes ☒ No ☐

Describe (cite document title, number and/or filename as applicable):

The membership of the Research Review Scientific Sub-committee comprises people with scientific/technical expertise in areas of research reviewed by the Committee. On occasion, when such expertise is lacking an external expert review is sought. External expert review is also sought for the review of all Phase 0 and Phase I trials.

4.2. Timelines of ethical review

- 4.2.1. Does the institution have protocols that establish the timelines related to the scheduling of an application for review, and to the communication of the outcome of the review to the applicant?

Yes ☒ No ☐

Describe (cite document title, number and/or filename as applicable):

Submission dates are advertised on the HREC website at:
<http://www.alfredresearch.org/ethics/submisdate.htm>
 4.2.1 Initial instructions to researcher provides dates of when the researchers will next hear from the Ethics Office
 1.5.1 SOP ethical review and administration

Supporting documents that may be attached as evidence of claims

- copy of institutional protocol for timeliness of administrative processes supporting ethical review of multi-centre research

- 4.2.2. Does the HREC support staff record the time of receipt and the progress of each application received, as well as dates of key communication?

Yes ☒ No ☐

- 4.2.3. Is the decision letter communicated in writing to the applicant within a certain timeframe?

Yes ☒ No ☐

Describe (cite document title, number and/or filename as applicable):

Letters are usually sent to researchers the same day or day after reviewers are received or decisions made at the meeting.

- 4.3. Experience and knowledge of the ethical review of specialist areas of research

- 4.3.1. Does the institution record the number and types of multi-centre research proposals reviewed by the institutional HREC?

Yes ☒ No ☐

Describe (cite document title, number and/or filename as applicable):

A custom database is used to record the progress of all project submissions.

Group 5 Assessment criteria related to ethical review of multi-centre clinical trial proposals or multi-centre clinical interventional research proposals

5.1. Experience and knowledge informing ethical review of clinical trial proposals and clinical interventional research proposals

- 5.1.1. Does the HREC membership include at least two members, or expert advisors, with at least two years experience in undertaking ethical review in clinical trials and interventional clinical research of the nominated categories of research considered by the HREC?

Yes ☒ No ☐

Describe (cite document title, number and/or filename as applicable):

1.2.1 Membership of Alfred Ethics Committees 2011

Supporting documents that may be attached as evidence of claims

- copies of attendance records of relevant HREC members or advisors where specific types of clinical trials or clinical interventional research has been considered

5.2. Relevant legislative frameworks related to unapproved therapeutic goods

- 5.2.1. Does the HREC consider the relevant legislative frameworks related to unapproved therapeutic goods when reviewing clinical trial proposals or clinical interventional research proposals?

Yes ☒ No ☐

Group 6 Assessment criteria linked to institutional policy and administrative processes supporting ethical review

6.1. Adequacy of support relative to HREC workload

- 6.1.1. Does the institution have sufficient administrative support (full-time or part-time) to administer in a timely manner the number and type of multi-centre applications received?

Yes ☒ No ☐

Describe (cite document title, number and/or filename as applicable):

- 6.1.2. Will a change in the workload of the HREC impact on the workload of the Chair such that, combined with his or her other responsibilities, he or she may impair the capacity of the HREC to carry out its obligations under the National Statement?

Yes ☒ No ☐

- 6.1.3. Does the institution have a plan for responding to a higher than expected number of applications for ethical review or increased HREC workload?

Yes ☒ No ☐

Describe (cite document title, number and/or filename as applicable):

There is provision for an extra meeting to be convened if required.
The staff of the Ethics Office has been increased over time to respond to increasing workload.

Supporting documents that may be attached as evidence of claims

- copy of institutional plan for responsiveness to increased HREC workload

6.2. Transparency and clarity of administrative roles and responsibilities and relevant institutional policy and procedures

6.2.1. Does the institution have documentation explaining the duties, obligations and responsibilities of the administrative support?

Yes ☒ No ☐

Describe (cite document title, number and/or filename as applicable):

Administrative staff roles are published on the website:
<http://www.alfredresearch.org/contact.htm>
 See also 1.1.6 Position descriptions Officer A and B

Supporting documents that may be attached as evidence of claims

- copy of position description(s) of relevant staff involved in the ethical review process

6.3. Utilisation of national processes and procedures

6.3.1. Will the institution adopt and implement national processes and procedures for the processing, documentation and recording of ethical reviews?

Yes ☒ No ☐

6.3.2. Does the institution accept the National Ethics Application Form for multi-centre research projects?

Yes ☒ No ☐

6.3.3. Where the institution maintains an IT system or IT tool to capture, share and report on ethical review processes, does this system use information or raw data imported from NEAF?

Yes ☒ No ☐

Describe (cite document title, number and/or filename as applicable):

Information is pasted into an Access database. AURED is used for CCHRE projects.

6.4. Timeliness of administrative processes supporting ethical review of multi-centre research

6.4.1. Does the institution have protocols that establish the timelines related to the administrative processes supporting the ethical review of multi-centre research?

Yes ☒ No ☐

Describe (cite document title, number and/or filename as applicable):

Group 7 Assessment criteria linked to institutional commitment

7.1. Institutional commitment

- 7.1.1. Does the senior management of the institution and relevant institutional governance bodies endorse the institutional HREC undertaking ethical review of multi-centre research proposals that will be used across and/or within jurisdictions?

Yes ☒ No ☐

- 7.1.2. Has the institution documented criteria for the acceptance of applications for ethical review of multi-centre research including circumstances where it may not accept the ethical review of multi-centre research?

Yes ☐ No ☒

Describe (cite document title, number and/or filename as applicable):

The HREC accepts many multi-centre projects every month.

- 7.1.3. Is legal protection provided to HREC members and advisors that covers their consideration of ethical review of multi-centre research?

Yes ☒ No ☐

Describe (cite document title, number and/or filename as applicable):

7.1.3 Information regarding legal protection for Ethics Committee members

7.2. Institutional governance for ethical review process

- 7.2.1. Does the institution have policies and procedures in place that describe how its processes of ethical review of multi-centre research are governed?

Yes ☐ No ☒

Describe (cite document title, number and/or filename as applicable):

Alfred Health is in the process of developing a Research Governance Framework which is due to be completed by mid 2011.

7.3. Institutional policy and resourcing of ethical review processes

- 7.3.1. Has the institution provided funding and structural support sufficient to enable the ethical review process for multi-centre research?

Yes ☒ No ☐

Describe (cite document title, number and/or filename as applicable):

Supporting documents that may be attached as evidence of claims

- copy of institutional policy showing scope of ethical review capacity and delineating those circumstances (if any) where ethical review applications would not be accepted