Appendix 9.2 – Self-Assessment Form

Section 1

Introduction

The self-assessment form 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 form provides the institution with an opportunity to review and confirm their readiness for assessment by the certifying body. The self-assessment supports the certifying body's desktop assessment of the institution 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 form will default to 'no' unless overwritten. The form 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 file name is cited.

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

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

Section 3

Definitions

Assessor – An individual who considers information provided by the institution and/or observations of institutional practice in order 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 the standard of 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 assessment – An off-site assessment 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 against criterion contained in the National Certification Scheme.

Monitoring – Monitoring of research is 'the process of verifying that the conduct of research conforms to the approved proposal.' 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), a researcher at each centre and/or site and the relevant study teams and the Human Research Ethics Committee (HREC) that reviewed the research protocol. A study sponsor may also undertake monitoring.

On-site assessment – An assessment occurring on the premises of the nominating institution.

Self-assessment – The first step towards certification (see Appendix 9.1) where the institution reviews and confirms its readiness for assessment.

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, documents are 'mandatory' inclusions and where this is so, the word MANDATORY appears in the following text.

Examples of supporting documents include:

- Copy of duty statement or position description for administrative officer(s) supporting ethical review process
- Terms of Reference (ToR) for the HREC and the associated subcommittees
- Standard Operating Procedures (SoP) related to ethical review process
- Templates of documents used by HREC to communicate with researchers
- Copy of template letter of appointment for HREC members
- 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 identifiable information contained in the proffered documents.

***Please note*: If you rely on Standard Operating Procedures issued by a central body (e.g. a State or Territory Health Department) please include a reference to the specific section and/or page when citing as evidence.**

Section 5

HREC Profile[2]	
HREC year of establishment	
Name of HREC Chair and year of initial appointment	
Frequency of HREC meetings (e.g. monthly)	
Number of protocols reviewed by the HREC in the previous calendar year (whether or ot research commenced)	
Number of protocols reviewed by the HREC in the previous calendar year that were multi-centre (whether or not research commenced)	
Institutional format requirement for receipt of application for ethical review (e.g. hardcopy or electronic, if electronic or both)	

2 This is the first page of the Self Assessment Form to be provided with nomination package.

HREC Member Profile								
Name	**Gender (M/F)**	**Category they represent** (see *N.S. 5.1.30*)	**Length of service**	**Term of current appointment**	**Induction training date (for new members)**	**Signed letter of appointment on personnel file (Y/N)**	**Current Conflict of Interest Declaration on file (Y/N)**	**Training record attached (Y/N)**
eg. Prof J. Dean	*F*	*A – Chair*	*Jan 2009 – present*	*1 Jan 2009 – 30 Jun 2011*	*9 Jan 2009*			

HREC Subcommittee Membership Profile			
Name	**Name of committee**	**Length of service**	**Term of current appointment**
e.g. Mr M. Jones	*Scientific Review Subcommittee*	*15 March 2007 – present*	*1 July 2011 – 30 June 2014*

HREC Administrative Staff Profile					
Name	**Role**	**Length of service**	**Appointment status**	**FTE**	**Induction training date**
e.g. Mr M. Jones	*HREC Co-ordinator*	*June 2011 – present*	*Temporary/permanent*	*0.9*	*15 June 2011*

Section 6

Self-Assessment Form

Group 1

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

1.1 Does the establishment of the committee reflect 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 (please include the allocated FTE)?

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

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

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

◯ Yes ◯ No

Describe location within site:

1.1.5 Does the HREC have a meeting space?

◯ Yes ◯ No

Describe location/capacity:

1.1.6 Does the institution charge fees for ethical review?

◯ Yes ◯ No

Supporting documents that should 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

▶ SECTION 5.1.27 *HREC Terms of Reference*

1.1.7 Does the HREC have Terms of Reference (ToR) which define 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 ToR

1.1.8 Are the ToR for the HREC and the membership made public?

◯ Yes ◯ No

Describe (include citation of document title, number and/or file name as applicable):

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

▶ 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):

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 file name as applicable):

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 CV?

◯Yes ◯No

Supporting documents that should be attached as evidence of claims

- copies of cv's of current HREC members

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

1.2.2 Has the institution appointed a HREC with 8 or more members, with equal gender distribution and with 1/3 of members being independent of 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?

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

▶ 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 should 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)

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

1.3 Does the appointment of HREC members reflect the requirements of the National Statement Sections 5.1.34 and 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 file name as applicable):

▶ SECTION 5.1.36 *Notice of appointment*

1.3.2 Do members receive a formal notice of appointment?

◯ Yes ◯ No

Supporting documents that should be attached as evidence of claims

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

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

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 file name as applicable):

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

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

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

◯ Yes ◯ No

Supporting documents that should be attached as evidence of claims

- copy of training records for HREC members

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

▶ 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

Supporting documents to be attached (MANDATORY)

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

Describe (cite document title, number and/or file name 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, and 5.2.28- 5.2.31?

▶ SECTION 5.1.37 *HREC procedures*

1.5.1 Does the institution have Standard Operating Procedures (SOP) that cover the ethical review of multi-centre research?

◯ Yes ◯ No

Supporting documents to be attached (MANDATORY)

- copy of SOP for ethical review
- copy of SOP for administering paperwork for ethical review

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

1.5.2 When were the SOPs last updated?

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

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

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

1.5.4 Does the institution make the SOPs publicly available?

◯ Yes ◯ No

▶ SECTION 5.2.13 *Open communication*

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

◯ Yes ◯ No

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

▶ 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 (cite document title, number and/or file name as applicable):

SECTION 5.2.15 *Resourcing open communication*

1.5.7 Is there an institutional policy or SOP supporting HREC engagement with researchers?

◯ Yes ◯ No

Supporting documents that should be attached as evidence of claims

- copy of SOP on HREC or HREC administrative staff engagement with researchers

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

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 file name as applicable):

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 file name as applicable):

▶ 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

Supporting documents that may be attached as evidence of claims

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

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

▶ 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 file name as applicable):

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 file name 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 should 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

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

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 SOP for record keeping and archiving of all records and documents related to ethical review?

◯ Yes ◯ No

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

▶ SECTION 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 file name as applicable):

1.7.4.1 How long is the record kept before archiving?

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

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

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

▶ 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 file name as applicable):

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?

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

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 publicly known and announced in advance?

◯ Yes ◯ No

Supporting documents that may be attached as evidence of claims

- copy of schedule of meetings

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

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, that reflects National Statement Section 5.2.30?

◯ Yes ◯ No

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

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 file name 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 file name as applicable):

▶ SECTION 5.2.31 Arriving at a decision

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

◯ Yes ◯ No

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

1.8 Does the institutional process for minimising the duplication of ethical review reflect the National Statement Sections 5.3.2 and 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 file name as applicable):

▶ 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 the research that has been reviewed by another HREC?

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

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 file name as applicable):

▶ SECTION 5.4.2 Informing relevant bodies about conflicts of interest

1.9.2 How does the HREC manage declarations of conflicts of interest it receives of institutions involved in multi-centre research?

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

▶ SECTION 5.2.3 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 of researchers involved in multi-centre research?

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

▶ 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 file name as applicable):

▶ 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

Supporting documents to be attached (MANDATORY)

- copy of institutional policy on management of conflicts of interest
- copy of SOP for managing conflicts of interest relative to ethical review

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

1.10 Do the institutional processes for monitoring the ethical conduct of research reflect the requirements of the National Statement Sections 5.5. – 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 file name as applicable):

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

Supporting documents that should 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

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

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 file name as applicable):

SECTION 5.5.5 Reporting of approved research

1.10.4 Does the HREC require researchers to provide at least annual reports of research progress for all approved research?

◯ Yes ◯ No

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

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 file name as applicable):

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 file name as applicable):

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

▶ SECTION 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

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

▶ 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 file name as applicable)

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 file name as applicable):

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

◯ Yes ◯ No

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

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 file name as applicable):

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 file name as applicable):

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

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 TGA from institution informing them of device incidents

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

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 file name 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 file name as applicable):

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 file name 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 file name as applicable):

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 file name as applicable):

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. yearly, bi-annually, etc.)**
HREC Support Staff	◯ Yes ◯ No	◯ Yes ◯ No	
HREC Chair	◯ Yes ◯ No	◯ Yes ◯ No	
HREC Deputy Chair	◯ Yes ◯ No	◯ Yes ◯ No	
HREC members	◯ Yes ◯ No	◯ Yes ◯ No	
HREC advisors	◯ Yes ◯ No	◯ Yes ◯ No	

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

HREC Support Staff	
HREC Chair	
HREC Deputy Chair	
HREC Members	
HREC Advisors	

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

◯ Yes ◯ No

Supporting documents that may be attached as evidence of claims

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

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

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

◯ Yes ◯ No

Supporting documents that may be attached as evidence of claims

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

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

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 file name as applicable):

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

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

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

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 file name as applicable):

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 file name as applicable):

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

Supporting documents that should 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

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

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 related to ethical review of multi-centre clinical trial proposals or multi-centre clinical interventional research proposals

6.1 Adequacy of support relative to HREC workload

6.2.1 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 file name as applicable):

6.2.2 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

6.2.3 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

Supporting documents that may be attached as evidence of claims

- copy of institutional plan for responsiveness to increased HREC workload

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

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

Supporting documents that should be attached as evidence of claims

- copy of position description of relevant staff impacting ethical review process

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

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 (NEAF) 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 file name as applicable):

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 file name as applicable):

Group 7

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

7.1 Institutional commitment

7.1.1 Do the senior management of the institution and relevant institutional governance bodies support the institutional HREC undertaking ethical review of multi-centre research proposals to 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 file name as applicable):

7.1.3 Does legal protection provided to HREC members and advisors cover their consideration of ethical review of multi-centre research?

◯ Yes ◯ No

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

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 file name as applicable):

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

Supporting documents that should be attached as evidence of claims

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

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