Appendix 9.1 – Assessment Criteria

Assessment criteria for Certification of Ethical Review processes for multi-centre research

GROUP 1
Assessment criteria based on the NHMRC/ARC/AVCC *National Statement on Ethical Conduct in Human Research* (2007)

The institution and its HREC adhere to and demonstrate compliance with:

Assessment criterion	Possible sources of evidence
1. Establishment of HRECs *5.1.26 – 5.1.28*	Documentation of institutional and HREC policies, processes and procedures
2. Composition of HRECs *5.1.29 – 5.1.33*	Documentation of institutional and HREC policies, processes and procedures
3. Appointment of HREC Members *5.1.34 and 5.1.36*	Documentation of institutional and HREC policies, processes and procedures
4. Review body member responsibilities *5.2.3 – 5.2.4*	Documentation of institutional and HREC policies, processes and procedures
5. HREC procedures *5.1.37* **Good communication between review bodies and researchers** *5.2.13 – 5.2.15* **Researchers or experts at review body meetings** *5.2.18 – 5.2.20* **HREC meetings** *5.2.28 – 5.2.31*	Documentation of institutional and HREC policies, processes and procedures
6. Making and communicating decisions *5.2.22*	Documentation of institutional and HREC policies, processes and procedures
7. Documents and Records *5.2.23 – 5.2.27*	Documentation of institutional and HREC policies, processes and procedures
8. Minimising Duplication of Ethical Review *5.3.2 and 5.3.3*	Documentation of institutional and HREC policies, processes and procedures
9. Conflicts of Interest Guidelines *5.4.1 – 5.4.6*	Documentation of institutional and HREC policies, processes and procedures
10. Monitoring Approved Research *5.5.1 – 5.5.10* **Monitoring of approved clinical research** *3.3.19 – 3.3.22*	Documentation of institutional and HREC policies, processes and procedures

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

The arrangements for the institutional HREC adhere to and demonstrate compliance with:

Assessment criterion	Possible sources of evidence
11. Length of HREC service *At least half of the members appointed in the minimum membership categories listed under the NHMRC National Statement 5.1.30 have two or more years of HREC membership experience.* *Both the Chair and the Deputy Chair (if one is appointed) have suitable experience to perform their role.* *Where a member has been appointed for having specialist (technical) expertise, the member has at least two years recent experience in the area of specialist expertise.*	• Record of dates of appointment and terms served for all HREC members • HREC member bio's or cv's • Interviews with members
12. Institutional consideration of relevant statutory and administrative frameworks in jurisdictions where research is to be conducted *Consideration is given to the relevant statutory and administrative frameworks of the jurisdiction(s) where the multi- centre research will be conducted.*	• Documentation of relevant statutory and administrative frameworks related to the ethical conduct of research is available to all members • Documentation of process to ensure information on statutory and administrative frameworks is current • Observation that HREC utilises material on relevant statutory and administrative frameworks in its deliberations • Documentation that HREC decisions are consistent with the relevant administrative and statutory requirements of jurisdictions in which the research is proposed to be conducted
13. Induction of new HREC members *There is an institutional process for new members to gain an understanding of HREC responsibilities in the ethical review of multi-centre research proposals.*	• Standard Operating Procedures for HREC Administration • Induction process documentation • Record of member attendance at induction

GROUP 3
Assessment criteria related to training of HREC members and institutional administrative HREC support staff

The HREC members and administrative HREC support staff demonstrate compliance with:

Assessment criterion	Possible sources of evidence
14. Training *HREC members and institutional administrative support staff are provided and utilise opportunities to attend relevant in house and external training and continuing education opportunities.*	• Institutional provision of in-house training courses • Record of in-house and external training for HREC members from past two years • Record of in-house and external training for institutional administrative HREC support staff

GROUP 4
Assessment criteria related to process of ethical review of multi-centre research

The process of ethical review relevant to multi-centre research demonstrates compliance with:

Assessment criterion	Possible sources of evidence
15. Access to relevant expertise *There is an institutional mechanism that ensures the HREC has access to the relevant technical/scientific expertise needed to conduct the ethical review of a given multi-centre research proposal.* *There is an institutional mechanism that ensures the HREC has access to expertise with familiarity with specific ethical dimensions of an issue relevant to the ethical review of a given multi-centre research proposal.*	• Documentation of an institutional protocol for accessing technical and scientific expertise • Documentation of an institutional arrangements for accessing expertise for ethical deliberation • List of experts against categories of expertise utilised, as needed by the HREC • Attendance records at HREC meetings where research proposals requiring specialist expertise were discussed • Reports tabled at the HREC meeting from specialist experts
16. Timeliness of ethical review *There are timelines established by institutional protocols for conducting an ethical review of multi-centre research proposals related to the scheduling of an application for review and communicating the outcome of the review to the applicant.*	• Documentation of tracked timeline for ethical review processes • Trend data for timeliness of ethical review processes and corrective actions (if non compliance) • Documentation of 'stop the clock'[1] process relevant to timelines for multi-centre ethical review
17. Experience and knowledge of the ethical review of specialist areas of research *Each year, the HREC must review a sufficient number of the research projects in which the institution claims expertise. 'Sufficiency' will be determined having regard to the number and complexity of the reviews undertaken.*	• Documentation showing categories of multi-centre research proposals considered by HREC in the past twelve months

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

The process of ethical review of multi-centre clinical trial proposals or multi-centre clinical interventional research proposals undertaken by the HREC demonstrates compliance with:

Assessment criterion	Possible sources of evidence
18. Experience and knowledge informing ethical review of clinical trial proposals and clinical interventional research proposals *Where the institution claims the HREC is able to undertake ethical review of clinical trials and/or interventional clinical research, at least half of the members or advisors must have at least two years experience in undertaking such ethical reviews.*	• Documentation showing number of clinical trials and interventional clinical research proposals considered by HREC in the past twelve months • Membership information or attendance records of ethical review meetings • Reports tabled at the HREC meeting from advisors
19. Access to relevant legislative frameworks related to research using unapproved therapeutic goods *HREC members give consideration to therapeutic goods legislation and associated guidelines in their ethical review of multi-centre research of unapproved therapeutic goods.*	• Availability of relevant documents (the therapeutic goods legislation and the Note Guidance on Good Clinical Practice (CPMP/ICH/135/95) Annotated with TGA Comments) for HREC members' use • Documentation showing categories of multi-centre research proposals considered by HREC in the past twelve months • Standard Operating Procedures for monitoring clinical trials of unapproved therapeutics

Note: Group 5 assessment criteria only apply where the institution has nominated their expertise in the ethical review of clinical trials or clinical interventional research for certification.

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

The institutional policy and administrative processes supporting ethical review demonstrates compliance with:

Assessment criterion	Possible sources of evidence
20. Adequacy of support relative to HREC workload *Sufficient administrative support is provided to administer the number and type of multi-centre applications received in a timely manner. This includes institutional arrangements to provide detailed advice to researchers on the multi-centre ethical review application process.*	• Institutional position description form citing role of administrative officers supporting the ethical review process • Document of communication flows between HREC and Coordinating Investigator, Principal Investigators • Documentation of institutional mechanism(s) for ensuring support is maintained and responsive to fluctuating workload • Documentation of HREC workload (trend information) • Documentation of process for managing complaints related to multi-centre ethical review
21. Transparency and clarity of administrative roles and responsibilities and relevant institutional policy and procedures *Clearly defined role for officers providing administrative support to the ethical review process.* *Clearly defined policy in relation to cost recovery policy and/or the amount of fees charged for multi-centre ethical review.*	• Institutional position description form citing role of administrative officers supporting the ethical review process • Documentation of institutional mechanism(s) for ensuring support is maintained and responsive to fluctuating workload • Documentation of HREC workload (trend information) • Documentation of institutional policy for charging fees for multi-centre ethical review • Schedule of fees charged
22. Utilisation of national processes and procedures *The institution shall adopt, apply and maintain national processes and procedures for the processing, documentation and recording of multi-centre ethical review.*	• Documentation of institutional adoption and adherence to national processes and procedures (including use of standardised forms) for the ethical review of multi-centre research proposals
23. Timeliness of administrative processes supporting multi-centre ethical review *There are timelines established by institutional protocols for conducting an ethical review of multi-centre research proposals related to the scheduling of an application for review, communicating the outcome of the review to the applicant and other administrative processes associated with the multi-centre ethical review process.*	• Documentation of institutional protocols for ensuring timeliness of ethical review processes for multi-centre research • Documented measurement of time between receipt of applications, researcher informed of outcome of ethical review process and commencement date for research (including 'stop the clock') • Proportion of processes meeting agreed timelines

GROUP 7
Assessment criteria linked to institutional commitment

The institution hosting the HREC demonstrates compliance with:

Assessment criterion	Possible sources of evidence
24. Institutional commitment *The institution endorses its HREC undertaking multi-centre ethical review to be used across and/or within jurisdictions.*	• Nomination for certification form signed by Head of institution • Record of the number of applications for ethical review of multi-centre research received and reviewed • Documentation of reasons where applications of multi-centre research proposals received are not accepted for ethical review
25. Institutional governance for ethical review process including appointment of HREC members *Members of the HREC have been appointed in accordance with institutional protocols and provided with statements of roles and responsibilities.* *Institution has policies and procedures in place that describe its governance arrangements for multi-centre ethical review process.* *Institution has policy in place that describes approach to monitoring the ethical conduct of multi-centre research conducted on site.*	• Letters of appointment of HREC members and Chair signed by appropriate institutional authority setting out term of appointment, conditions of appointment, the circumstances whereby membership may be revoked and providing assurance that indemnity will be provided in respect of liabilities that may arise in the course of bona fide conduct of their duties as an HREC member • Documentation (or letter) informing HREC members of their roles and responsibilities • Deeds of confidentiality signed by HREC members • Disclosure of Interest documents signed by HREC members • Documentation of institutional governance arrangements for multi-centre ethical review process • Documentation of institutional policy and arrangements for governance of responsibilities related to multi-centre research reviewed by HREC • Documentation of process for monitoring ethical conduct of multi-centre research
26. Institutional policy and resourcing of ethical review processes *The institution provides sufficient funding and structural support to enable its HREC to conduct ethical review of multi-centre research proposals in an efficient and effective manner. Resources are provided to:* • *support members to prepare for and attend meetings* • *enable induction and mentoring of new members* • *enable participation in training and continuing education* • *ensure accessibility of institutional experts to support the ethical review process* • *alignment of institutional arrangements and structures to operate in accordance with the administrative and technological requirements of multi-centre ethical review.*	• Organisational chart showing placement of ethical review activities in structure and staff allocation • Evidence of recurrent funding for ethical review processes • Evidence of arrangements to respond to fluctuating HREC workload • Documentation of institutional commitment to multi-centre ethical review process • Documentation of financial support or resource support provided to HREC members • Financial records showing budget allocated to ethical review administration, HREC members support and HREC advisory support