



s 47F

Chief Executive Officer
Alfred Health
55 Commercial Road
Prahran VIC 3181

s 47F

Certification of institutional processes relating to the ethical review of multi-centre human research

I refer to your institution's nomination for certification of processes relating to the ethical review of multi-centre research, and the subsequent on-site assessment conducted on 4 May 2011. A draft assessment report was submitted to your institution on 23 May 2011.

As the person with delegated responsibility for the National Certification Scheme within the NHMRC I have now been given a final report with recommendations. The report advises that Alfred Health's processes relating to the ethical review of multi-centre research are not quite to the stage of conformance with the National Certification Scheme that would allow certification to be recommended. A copy of that report is enclosed for your information and relevant action.

In accepting the recommendations of the final assessment report, I would like to encourage you to continue to pursue your nomination for certification. In order for me to reconsider my decision not to certify your institution's ethical review processes at this time, I would be pleased to receive evidence that the recommendations in Attachment B of the final assessment report have been addressed, implemented and documented at a minimum of three meetings of the Human Research Ethics Committee.

I would also like to draw your attention to the recommendations in Attachment C of the final assessment report. At the very latest, these recommendations would need to be considered and acted upon during the initial period of certification, when granted, in order for your institution to be eligible for recertification.

I look forward to hearing from you at an appropriate time in the future should you choose to continue to seek certification of your institution's processes relating to the ethical review of multi-centre research. If you have any queries about this matter, please do not hesitate to contact s 47F Director, Research Integrity Section on s 47F

Yours sincerely

s 47F

Mrs Cathy Clutton
Executive Director
Research Quality Branch

21 June 2011

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Mrs Cathy Clutton
Executive Director, Research Quality Branch
National Health and Medical Research Council

Dear Mrs Clutton

RE: Assessment outcome of the ethical review processes of multi-centre human research

We provide to you the outcome of our assessment of the nomination for certification received from the Alfred Health (the institution).

Following a desktop assessment of nomination documentation, an on-site assessment visit was conducted on 4 May 2011. The on-site assessment visit consisted of review of documentation and discussion with institutional representatives. Attachment A lists attendance during the on-site assessment visit.

The assessment team make the following recommendations:

- I. We recommend that NHMRC consider not granting certification of ethical review processes for multi-centre research until demonstration that the institution has implemented changes identified in Attachment B.
- II. We recommend, as a first step, that NHMRC request the institution to provide and outline their intended approach to implementing the changes identified in Attachment B, as well as their estimate of the time required to do so and that this outline be reviewed and agreed by the assessment team.
- III. When the changes identified in Attachment B have been implemented, we recommend that NHMRC consider granting certification of ethical review processes for multi-centre research in the following research categories:
 1. Clinical trials of drugs and devices – Phase 0
 2. Clinical trials of drugs and devices – Phase I
 3. Clinical trials of drugs and devices – Phase II
 4. Clinical trials of drugs and devices – Phase III
 5. Clinical trials of drugs and devices – Phase IV
 6. Justice health
 7. Clinical interventional research other than clinical trials
 8. Qualitative health research
 9. Mental health

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NHMRC should ask the institution to provide any subcategories to the above research categories that reflect an institutional focus.

- IV. In the event that NHMRC grants certification, we recommend that NHMRC grant certification of institutional ethical review processes of multi-centre research for a period of three years.
- V. In the event that NHMRC grants certification, we recommend that NHMRC inform the institution that the improvements identified in Attachment C will need to be implemented during the initial certification period and demonstration of that implementation will be a condition of continuation of certification.
- VI. We recommend NHMRC inform the institution that details of institutional reporting requirements related to the certification of ethical review processes for multi-centre research will follow.

Attachment D summarises the evidence and findings of the assessment team against the certification assessment criteria of the National Certification Scheme of Institutional Processes related to Ethical Review of Multi-centre Research¹.

In the assessors' view, stakeholders using a single review of multi-centre research system must have confidence that there are clear and robust institutional processes that ensure the Alfred Hospital Human Research Ethics Committee (HREC) functions in conformity with the *National Statement on Ethical Conduct in Human Research (2007)*. Such processes will typically include clear accountability obligations for a HREC and equally clear obligations for institutions to receive, to actively consider and, where necessary, to act on the outcome of the reports provided to them by the HREC.

Sincerely,

s 47F

A large black rectangular box redacting the signature of the Lead Assessor.

Lead Assessor on behalf of Assessment Team Members

Attachment A – Attendees present during on-site assessment visit

Attachment B – Changes to be implemented before certification recommended

Attachment C – Improvements to be implemented before certification renewal

Attachment D – Summary of evidence, observations and findings

¹ Certification handbook November 2009

Alfred Health

4 May 2011

Assessment Team

s 47F

Lead Assessor*
Co-Assessor
Trainee Assessor

Opening meeting

Attendees

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Director of Research, The Alfred; Head, Central
Clinical School, Monash University
Chair, Alfred Hospital Ethics Committee; Head, School
of Public Health & Preventive Medicine, Monash
University
Chair, Research Review Sub-Committee; Professor of
Medicine, Baker IDI Heart and Diabetes Institute
Ethics Manager, Research & Ethics Unit, Alfred Health
Ethics Officer, Research & Ethics Unit, Alfred Health

Morning session

Attendees

s 47F

Ethics Manager, Research & Ethics Unit, Alfred Health
Ethics Officer, Research & Ethics Unit, Alfred Health

Afternoon session

Attendees

s 47F

Ethics Manager, Research & Ethics Unit, Alfred Health
Ethics Officer, Research & Ethics Unit, Alfred Health
Director of Research, The Alfred; Head, Central
Clinical School, Monash University
Chair, Research Review Sub-Committee; Professor of
Medicine, Baker IDI Heart and Diabetes Institute

Closing meeting

Attendees

s 47F

Chair, Alfred Hospital Ethics Committee; Head, School
of Public Health & Preventive Medicine, Monash
University
Ethics Manager, Research & Ethics Unit, Alfred Health
Ethics Officer, Research & Ethics Unit, Alfred Health

s 47F

Changes to be implemented before certification recommendation

Assessment Criterion	Evidence and findings	Source	Time for implementation	Suggestions and comments
6. Making and communicating decisions 5.2.22	Decisions are generally reached by consensus however there have been occasions where a vote on the tabled research proposal was required. Formal documentation that supports this process was not evident (<i>National Statement 5.1.37(k)</i>). There was no evidence that communication with researchers explicitly links the reasons for the decision/s to the <i>National Statement</i>. <i>Non-conformance.</i>	Documentation provided in support of nomination and examined during the on-site visit. Interview with institutional staff and HREC Chair.	To be determined by institution-prior to consideration for certification	It is recommended that the institution consider documenting processes that reflect methods of decision making by the HREC. Correspondence templates should be revised to incorporate references to the <i>National Statement</i>. The recent practice of referring to relevant paragraphs of the <i>National Statement</i> in correspondence with researchers should be reinforced and maintained.

Assessment Criterion	Evidence and findings	Source	Time for implementation	Suggestions and comments
7. Documents and records 5.2.23 – 5.2.27	Members are provided with all documentation to be considered in research proposals prior to the meeting, including recommendations from consulted subcommittees and experts. Records of proposals are currently kept in electronic and paper based copies, with a gradual transition being made to a paperless process. HREC meeting minutes document how decisions were made however decisions do not link back relevant parts of the <i>National Statement</i> (NS 5.2.26). <i>Non-conformance.</i>	Documentation provided in support of nomination and examined during the on-site visit. Interview with institutional staff and HREC Chair.	To be determined by institution-prior to consideration for certification	It is recommended that HREC meeting minutes refer back to the relevant parts of the <i>National Statement</i> when documenting the decision making process. These references are paramount when requesting amendments (e.g. pointing out the NS section on consent processes there are changes required to consent processes in a protocol) or when denying ethical approval.
25. Institutional governance for ethical review process including appointment of HREC members	Upon review of the tabled documentation a number of the documents appeared disjointed and did not have a	Documentation provided in support of nomination and	To be determined by institution-prior to consideration for	It is recommended that the institution consider formalising delegation authorities for the day to day functions of the HREC. It is also recommended that the institution

Assessment Criterion	Evidence and findings	Source	Time for implementation	Suggestions and comments
<i>Members of the HREC have been appointed in accordance with institutional protocols and provided with statements of role and responsibilities.</i> <i>Institution has policies and procedures in place that describe its governance arrangements for multi-centre ethical review process.</i> <i>Institution has policy in place that describes approach to monitoring the ethical conduct of multi-centre research conducted on site.</i>	consistent flow to them. Approval processes, authorities and delegations were unclear. The HREC currently issues certificates of ethical approval for research proposals that are approved by the committee however this could be confused with an institution giving authorisation for a research proposal to commence at individual sites. <i>Non-conformance.</i>	examined during the on-site visit. Interview with institutional staff and HREC Chair.	certification	consider reviewing the certificates of ethical approval to minimise confusion between ethical review approval and site approval.

Improvements to be implemented before certification renewal

Assessment Criterion	Evidence and findings	Time for implementation	Suggestions and comments
1. Establishment of HRECs <i>5.1.26 – 5.1.28</i>	The current Terms of Reference outline a number of functions of the HREC however further clarity is required to ensure that the requirements under <i>5.1.27 National Statement</i> are met. <i>Partial conformance</i>	Before renewal of certification.	It is recommended that the institution consider revising the Terms of Reference to clarify the relationship to non-affiliated researchers, composition and membership of the HREC, what constitutes quorum at meetings, remuneration, resignation of members and to update the relationship to other processes of research review (to reflect current processes). Additionally, consideration should be given to how the HREC will function when reviewing multi-centre processes on a national level.
3. Appointment of HREC Members <i>5.1.34 & 5.1.36</i>	Members are appointed by the Chief Executive Officer annually. Where members commence part way through the year, the membership term is for the remainder of the calendar year. Expressions of interest are sent to staff in late November/early December for the following calendar year. The Chief Executive Officer, Ethics Manager and the HREC Chair review EOIs and members are sent a letter of offer. <i>Partial conformance</i>	Before renewal of certification.	It is recommended that the institution should consider implementation of a formal appointment process of members that could incorporate declarations of conflict of interest and confidentiality agreements.

Assessment Criterion	Evidence and findings	Time for implementation	Suggestions and comments
4. Review body member responsibilities 5.2.3 – 5.2.4	Members are directed to the <i>National Statement</i> and the Australian Code of Conduct for Responsible Conduct of Research upon commencement along with a list of obligations of committee members. Members are required to declare conflicts of interest at each meeting when signing in. There was also evidence in meeting minutes that members removed themselves from meetings when a conflict of interest arose. <i>Partial conformance</i>	Before renewal of certification.	It is recommended that the institution consider referencing the <i>National Statement</i> in the review of research proposals to encourage new members to increase their knowledge of the <i>National Statement</i>. The institution should also consider including conflicts of interest as a standing item at committee meetings.
5. HREC procedures 5.1.37 Good communication between review bodies and investigators 5.2.13 – 5.2.15 Investigators or experts at review body meetings 5.2.18 – 5.2.20 HREC meetings 5.2.28 – 5.2.31	The institution demonstrated well developed processes that support the requirement of the <i>National Statement</i> (5.1.37) however there was an absence of documentation that supported these processes. The Alfred Research and Ethics Unit website contains a significant amount of information that is readily available to the public. Additionally, administrative staff within the Ethics Office are readily available to discuss research proposal processes with researchers. The Ethics Office contact details are contained on the website and details what the responsibilities are for each of the administrative staff. Researchers are occasionally invited to attend meetings, to discuss research proposals that are before the HREC. This is beneficial for both the researcher and the reviewing body.	Before renewal of certification.	It is recommended that the institution consider documenting working processes that promote good ethical review is accordance with the <i>National Statement</i> (5.1.37).

Assessment Criterion	Evidence and findings	Time for implementation	Suggestions and comments
	Two primary reviewers are assigned for each research proposal and they are required to provide a summary of the proposal to members at the HREC meeting. Papers for the meeting are distributed to all members prior to the meeting for their consideration and feedback approximately one week prior to the meeting. <i>Partial conformance</i>		
9. Conflicts of interest guidelines 5.4.1 – 5.4.6	Members are required to declare conflicts of interest at the time of initial appointment and recent practice includes signing a form that declares if you have a conflict of interest at the beginning of each meeting for any research proposals that are before the committee. If a member does have a CoI they are required to leave the meeting for the duration of the discussion relating to that proposal. Formal annual declarations of conflicts of interest for each member are currently not in place. The tabled Conflicts of Interest Policy and Conflicts of Interest Standard Operating Procedure contained some minor inconsistencies. <i>Partial conformance</i>	Before renewal of certification.	It is recommended that the institution review the Conflicts of Interest Policy and Conflicts of Interest Standard Operating Procedure to ensure consistency between the documents and to outline processes on how declarations of conflicts of interest are done. This should include a formalised process for members to provide their annual conflicts of interest.

Assessment Criterion	Evidence and findings	Time for implementation	Suggestions and comments
13. Induction of new HREC members <i>There is an institutional process for new members to gain an understanding of HREC responsibilities in the ethical review of multi-centre research proposals.</i>	New members are provided with induction material upon commencement, are directed to the Alfred Health website for additional information and the administrative staff provide informal training to members as required. Additionally, new members are appointed for a 3 month probationary period upon commencement to ensure that they are happy to continue service on the committee and provide the institution assurance that they are suitable for the position. <i>Partial conformance</i>	Before renewal of certification.	It is recommended that the institution consider documenting processes for the induction of new members.
21. Transparency and clarity of administrative roles and responsibilities and relevant institutional policy and procedures <i>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.</i>	Committee correspondence is signed by the Executive Officer. Formal authorisation for the Executive Officer to enact this delegation was not sighted. <i>Partial conformance</i>	Before renewal of certification.	Alfred Health provide the Executive Officer with a written delegation to sign letters on behalf of the Committee.

Summary of evidence, observations and findings

Description of nature and scope of operation of the HREC

Alfred Health is one of the four founding partners of the Alfred Medical Research and Education Precinct (AMREP), established in 2002 on The Alfred campus.

Alfred Health has a strong commitment to research and undergraduate and postgraduate training for medical, nursing, allied health and other support staff through its major partnerships with Monash and LaTrobe Universities. It has research and development links with the Baker IDI, the Burnet Institute and Monash University as a partner in the Alfred Medical Research & Education Precinct (AMREP).

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

Assessment criterion	Evidence and findings
1. Establishment of HRECs 5.1.26 – 5.1.28	The current Terms of Reference outline a number of functions of the HREC however further clarity is required. <i>Partial conformance – see Attachment C.</i>
2. Composition of HRECs 5.1.29 – 5.1.33	The composition of the HREC is in accordance with the <i>National Statement</i>. Many of the HREC members are longstanding members and have the relevant experience in their fields of expertise. The HREC also has access to sufficient external reviewers for expert advice, when required. The HREC is supported by the Research Review Committee, Innovations Committee and the General Ethical Issues Subcommittee as well as numerous experts within Alfred Health. Conformance on the basis of the documents provided and evidence assessed during the on-site assessment visit.
3. Appointment of HREC Members 5.1.34 & 5.1.36	Members are appointed by the Chief Executive Officer annually. Where members commence part way through the year, the membership term is for the remainder of the calendar year. Expressions of interest are sent to staff in late November/early December for the following calendar year. The Chief Executive Officer, Ethics Manager and the HREC Chair review EOIs and members are sent a letter of offer. <i>Partial conformance – see Attachment C.</i>

Assessment criterion	Evidence and findings
4. Review body member responsibilities 5.2.3 – 5.2.4	Members are directed to the <i>National Statement</i> and the Australian Code of Conduct for Responsible Conduct of Research upon commencement along with a list of obligations of committee members. Members are required to declare conflicts of interest at each meeting when signing in. There was also evidence in meeting minutes that members removed themselves from meetings when a conflict of interest arose. <i>Partial conformance – see Attachment C.</i>
5. HREC procedures 5.1.37 Good communication between review bodies and investigators 5.2.13 – 5.2.15 Investigators or experts at review body meetings 5.2.18 – 5.2.20 HREC meetings 5.2.28 – 5.2.31	The institution demonstrated well developed processes that support the requirement of the <i>National Statement</i> (5.1.37) however there was an absence of documentation that supported these processes. The Alfred Research and Ethics Unit website contains a significant amount of information that is readily available to the public. Additionally, administrative staff within the Ethics Office are readily available to discuss research proposal processes with researchers. The Ethics Office contact details are contained on the website and details what the responsibilities are for each of the administrative staff. Researchers are occasionally invited to attend meetings, to discuss research proposals that are before the HREC. This is beneficial for both the researcher and the reviewing body. Two primary reviewers are assigned for each research proposal and they are required to provide a summary of the proposal to members at the HREC meeting. Papers for the meeting are distributed to all members one month prior to the meeting for their consideration and feedback. Members send in reviews two weeks before the meeting. Questions raised in reviews are forwarded to researchers and researchers' responses are distributed to members approximately one week prior to the meeting. <i>Partial conformance – see Attachment C.</i>
6. Making and communicating decisions 5.2.22	Decisions are generally reached by consensus however there have been occasions where a vote on the tabled research proposal was required. Formal documentation that supports this process was not evident (<i>National Statement</i> (5.1.37)). There was no evidence that communication with

Assessment criterion	Evidence and findings
	researchers explicitly links the reasons for the decision/s to the <i>National Statement</i>. <i>Non-conformance— see Attachment B.</i>
7. Documents and records 5.2.23 – 5.2.27	Members are provided with all documentation to be considered in research proposals prior to the meeting, including recommendations from consulted subcommittees and experts. Records of proposals are currently kept in electronic and paper based copies, with a gradual transition being made to a paperless process. HREC meeting minutes document how decisions were made however decisions do not link back relevant parts of the <i>National Statement</i>. <i>Non-conformance— see Attachment B.</i>
8. Minimising duplication of ethical review 5.3.2 & 5.3.3	The institution is a participant in the SERP system within the Victorian public health system which supports multi-centre ethical review within the jurisdiction for clinical trial research. Conformance on the basis of the documents provided and evidence assessed during the on-site assessment visit.
9. Conflicts of interest guidelines 5.4.1 – 5.4.6	Members are required to declare conflicts of interest at the time of initial appointment and recent practice includes signing a form that declares if you have a conflict of interest at the beginning of each meeting for any research proposals that are before the committee. If a member does have a CoI they are required to leave the meeting for the duration of the discussion relating to that proposal. Formal annual declarations of conflicts of interest for each member are currently not in place. The tabled Conflicts of Interest Policy and Conflicts of Interest Standard Operating Procedure contained some minor inconsistencies. <i>Partial conformance – see Attachment C.</i>
10. Monitoring approved research 5.5.1 – 5.5.10 Monitoring of approved clinical research 3.3.19 – 3.3.22	Conformance on the basis of the documents provided and evidence assessed during the on-site assessment visit.

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

Assessment criterion	Evidence and findings
11. Length of HREC service <i>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.</i>	The majority of members have more than two years of experience in an HREC; with many of the members having been long serving members of the committee. The Chair and Deputy Chair of the HREC and associated subcommittees have significant levels of experience and members have relevant technical expertise. Conformance on the basis of the documents provided and evidence assessed during the on-site assessment visit.
12. Institutional consideration of relevant statutory and administrative frameworks in jurisdictions where research is to be conducted <i>Consideration is given to the relevant statutory and administrative frameworks of the jurisdiction(s) where the multi-centre research will be conducted.</i>	The Institution demonstrated an understanding of the relevant state laws. Evidence was sighted that indicated that where they were unsure of requirements within other states/territories that the HREC would liaise with researchers to ensure that consideration had been given to the relevant legislative requirements. Conformance on the basis of the documents provided and evidence assessed during the on-site assessment visit.
13. Induction of new HREC members <i>There is an institutional process for new members to gain an understanding of HREC responsibilities in the ethical review of multi-centre research proposals.</i>	New members are provided with induction material upon commencement, are directed to the Alfred Health website for additional information and the administrative staff provide informal training to members as required. New members generally attend the office for a 1-2 hour induction session prior to their first meeting. Additionally, new members are appointed for a 3 month probationary period upon commencement to ensure that they are happy to continue service on the committee and provide the institution assurance that they are suitable for the position. The institution should consider developing a document that details processes for induction of new members. <i>Partial conformance – see Attachment B.</i>

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

Assessment criterion	Evidence and findings
14. Training <i>HREC members and institutional administrative support staff are provided and utilise opportunities to attend relevant in house and external training and continuing education opportunities.</i>	Members receive an induction package upon commencement and receive informal training from administrative staff in the Ethics Office. Members are encouraged to participate in external ethics training eg. at least one member per year is sent to the annual Bioethics training conducted by Monash University. Informal training is also facilitated through the distribution of relevant “of interest/hot topics” materials being distributed to members and guests being invited to meetings to provide insight into relevant topics for the ethics committee. Administrative staff are also encouraged to identify and undertake relevant training and professional development opportunities during their annual review process. Conformance on the basis of the documents provided and evidence assessed during the on-site assessment visit.

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

Assessment criterion	Evidence and findings
15. Access to relevant expertise <i>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.</i> <i>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.</i>	The institution has established a multi-layered process for the review of research proposals. Administrative staff undertake an initial screening of proposals prior to them being tabled as agenda items and the relevant subcommittees and experts are requested to provide advice and/or recommendations on technical issues that the HREC may not have sufficient experience/knowledge in. Conformance on the basis of the documents provided and evidence assessed during the on-site assessment visit.
16. Timeliness of ethical review <i>The institution measures performance of established timelines for conducting an ethical review of multi-centre research proposals.</i> <i>In addition, there are institutional</i>	Whilst timelines for ethical review are tight, administrative staff ensures a high level of compliance to established timelines. Conformance on the basis of the documents provided and evidence assessed during the on-site assessment visit.

Assessment criterion	Evidence and findings
<i>protocols for ensuring adherence to established timelines.</i>	
17. Experience and knowledge of the ethical review of specialist areas of research <i>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.</i>	Conformance on the basis of the documents provided and evidence assessed during the on-site assessment visit.

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

Assessment criterion	Evidence and findings
18. Experience and knowledge informing ethical review of clinical trial proposals and clinical interventional research proposals <i>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 considering the ethical aspects of such research.</i>	The experience and knowledge of HREC members supports the institutions nomination for certification in the categories identified on page 1 of this report. Conformance on the basis of the documents provided and evidence assessed during the on-site assessment visit.
19. Access to relevant legislative frameworks related to research using unapproved therapeutic goods <i>The HREC gives consideration to therapeutic goods legislation and associated guidelines in their ethical review of multi-centre research of unapproved therapeutic goods.</i>	Administrative staff were aware of a wide range of potentially relevant frameworks and had the knowledge of how to find, review and apply them. The review of meeting minutes reflects processes where researchers have been contacted to ensure relevant state legislative requirements have been considered in research proposals outside of the state of Victoria. Conformance on the basis of the documents provided and evidence assessed during the on-site assessment visit.

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

Assessment criterion	Evidence and findings
20. Adequacy of support relative to HREC workload <i>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 investigators on the multi-centre ethical review application process.</i>	The institution strongly supports the administrative side of ethical review. The institution indicated that should the workload increase under multi-centre review, additional staff and resources will be ensured. Conformance on the basis of the documents provided and evidence assessed during the on-site assessment visit.
21. Transparency and clarity of administrative roles and responsibilities and relevant institutional policy and procedures <i>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.</i>	Committee correspondence is signed by the Executive Officer. Formal authorisation for the Executive Officer to enact this delegation was not sighted. <i>Partial conformance – see <u>Attachment B</u>.</i>
22. Utilisation of national processes and procedures <i>The institution shall adopt, apply and maintain national processes and procedures for the processing, documentation and recording of multi-centre ethical review.</i>	Conformance on the basis of the documents provided and evidence assessed during the on-site assessment visit.
23. Timeliness of administrative processes supporting multi-centre ethical review <i>The institution measures performance of established timelines for conducting on ethical review of multi-centre research proposals related to:</i> <i>• the scheduling of an application for review</i> <i>• communicating the outcome of the review to the applicant</i> <i>• other administrative processes</i> <i>In addition, there are institutional protocols for ensuring adherence to established timelines.</i>	Conformance on the basis of the documents provided and evidence assessed during the on-site assessment visit.

GROUP 7: Assessment criteria linked to institutional commitment

Assessment criterion	Evidence and findings
24. Institutional commitment <i>The institution endorses its HREC undertaking multi-centre ethical review to be used across and/or within jurisdictions.</i>	Conformance on the basis of the documents provided and evidence assessed during the on-site assessment visit.
25. Institutional governance for ethical review process including appointment of HREC members <i>Members of the HREC have been appointed in accordance with institutional protocols and provided with statements of role and responsibilities.</i> <i>Institution has policies and procedures in place that describe its governance arrangements for multi-centre ethical review process.</i> <i>Institution has policy in place that describes approach to monitoring the ethical conduct of multi-centre research conducted on site.</i>	Upon review of the tabled documentation a number of the documents appeared disjointed and did not have a consistent flow to them. Approval processes, authorities and delegations were unclear. The HREC currently issues certificates of ethical approval for research proposals that are approved by the committee however this could be confused with an institution giving authorisation for a research proposal to commence at individual sites. <i>Non-conformance– see <u>Attachment B</u>.</i>
26. Institutional policy and resourcing of ethical review processes <i>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:</i> • <i>support members to prepare for and attend meetings</i> • <i>enable induction and mentoring of new members</i> • <i>enable participation in training and continuing education</i> • <i>ensure accessibility of experts to support the ethical review process</i> • <i>alignment of institutional arrangements and structures to operate in accordance with the administrative and technological requirements of multi-centre ethical review.</i>	Resourcing of the HREC is adequate and the Director of Research supports the provision of additional resources, if the need were to arise. Conformance on the basis of the documents provided and evidence assessed during the on-site assessment visit.