



**Accreditation Standards for lead HRECs operating under the
NSW Health model for single ethical and scientific review of
multi-centre research**

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Background

These accreditation standards are based upon the legislation and guidelines surrounding the ethical review of research, including the requirements of the NHMRC *National Statement on Ethical Conduct in Human Research* and the HREC Operations Manual for NSW Health. The standards are designed to be implemented in two stages: the initial accreditation application and the accreditation review.

The initial accreditation application stage is when an HREC first applies for accreditation as a lead committee. At this stage, accreditation relies largely upon the provision of written information by the HREC itself. Within 6 to 12 months after initial accreditation, an accreditation review will be undertaken. At this stage, continuance of accreditation relies both on written material supplied by the HREC and the report of an independent peer review process. The independent peer review process is yet to be finalised, however Health Research and Ethics Branch will undertake consultation on this process at a later stage. Subsequent accreditation reviews will take place at specified periods.

Once accredited, a lead HREC remains accredited until its accreditation is revoked following an accreditation review. Generally, accreditation will only be revoked if there is a substantial and continuing failure to meet the accreditation standards. The particular process to be followed for the revocation of accreditation is yet to be finalised and will be included in the independent peer review process for consultation. However, the Health Research and Ethics Branch will endeavour to work with all accredited committees so that, as far as possible, lead HRECs can make any changes necessary to retain accreditation. All reasonable efforts will be made to facilitate continued accreditation before any lead HREC has its accreditation status revoked.

The accreditation standards are qualitative and quantitative in nature and relate to both the scientific and technical review mechanisms relied upon by the HREC, and the ethical review process.

Committees may be accredited in either or both of the following two categories:

- Clinical trials/interventional clinical research;
- General research (which includes epidemiological research, population health research, health services research, qualitative research, clinical research of a non-interventional nature and other general categories of research).

Further information on how to submit an application for accreditation is available from the document "Guidance for institutions and organisations nominating an HREC for accreditation under the NSW Health model for single scientific and ethical review", which can be located from the Health Research and Ethics Branch website: www.health.nsw.gov.au/healthethics. Enquiries may also be directed to Health Research and Ethics Branch on 9391 9427.

Lead HREC Accreditation Standards

1. Registration

- 1.1 The HREC is registered with the NHMRC and meets their annual reporting obligations.

Evidence

- *At initial accreditation application: copy of most recent NHMRC annual report acknowledgement letter.*
- *At accreditation review: copies of most recent reports.*

2. Timeliness

- 2.1 The HREC is able to review and provide a final ethical opinion on research proposals in a timely manner. That is, the time from the submission closing date to notification of the final ethical opinion on a multi-centre research proposal must be no more than 60 calendar days (excluding any time during which the HREC is awaiting a response from the investigator).

Evidence

- *At initial accreditation application: statement by the HREC Chair that, based on past experience of the HREC, the HREC is likely to be able to achieve a 60-day turnaround for most projects within the next 12 months.*
- *At accreditation review: report from the Research Ethics Database will indicate percentage of projects for which this was achieved.*

3. Executive support

- 3.1 The HREC has sufficient executive support to enable it to administer the number and type of applications that it is expected to receive, and to do so in a timely manner. This includes the provision of detailed and accurate advice to potential applicants.
- 3.2 A suitable percentage of the support officer's employment is dedicated to HREC work and is included in that officer's position description.

Evidence

- *At initial accreditation application: copy of position description of support officer(s) including estimate of the number of hours of administrative support provided to the HREC per week, record of number of applications received in the preceding calendar year and an estimate of the number of applications to be received in the coming year. Written confirmation by HREC Chair and Chief Executive that the executive support is sufficient for the effective operation of the committee.*

- *At accreditation review: report from peer-reviewer on level of executive support. Opinions from support officer(s) and HREC Chair.*

4. Resources

- 4.1 The HREC has sufficient resources to enable it to carry out its functions in an efficient and effective manner.

Evidence

- *At initial accreditation application: copy of HREC budget or statement by Director of Finance or equivalent as to the resources available for HREC operations. Written confirmation by the Chief Executive that fees received for ethical review remain in the HREC budget, in accordance with the Department's PD 2007_046 HREC and Research Governance: Fee Policy for Review of Commercially Sponsored Research*
- *At accreditation review: report from peer-reviewer on level of resources. Opinions from support officer(s) and HREC Chair.*

5. Membership

- 5.1 The HREC is able to meet the minimum membership requirements under the NHMRC *National Statement*. The HREC does not have any one member appointed to fill more than one category of membership.
- 5.2 The HREC members have sufficient experience in serving on an HREC (at least half of the members appointed in the minimum membership categories listed under the NHMRC *National Statement*, have two or more years of HREC membership experience).
- 5.3 Relevant details regarding HREC membership is made publicly available on request and on the HREC's website.
- 5.4 The HREC has a deputy chair who has the authority to carry out chair duties when the chair is unavailable.

Evidence

- *At initial accreditation application and accreditation review: record of membership composition of HREC, including dates of appointment and brief description of qualifications and experience of members (including that of scientific sub-committees where applicable). Relevant details from the HREC's website and other publications.*
- 5.5 There exist written methods of appointment of new members, and HREC members are appointed by the Chief Executive.

Evidence

- *At initial accreditation application and accreditation review: standard letters of appointment signed by Chief Executive (documenting the*

date of appointment, length of tenure, 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). If such appointment letters have not been provided to HREC members or are unavailable, the HREC will be requested to provide reasons why and how this will be rectified in the future.

- 5.6 The members of the HREC understand their responsibilities under the *NHMRC's National Statement on Ethical Conduct in Research Involving Humans* and the *NSW Health Records Information Privacy Act 2002* (including the statutory guidelines under this legislation) and apply the principles set out in these documents.

Evidence

- *At initial accreditation application: written confirmation by the HREC Chair that, based on experience, members are reasonably aware of the National Statement and the Health Records and Information Privacy Act and that copies of these documents are provided to new members.*
- *At accreditation review: peer-review of HREC meeting(s) to determine whether the relevant principles were applied to research projects.*

- 5.7 New members appointed to the HREC are provided with appropriate induction and receive copies of legislation and guidelines surrounding the ethical review of research including the *NHMRC National Statement* and *Health Records and Information Privacy Act 2002*.

Evidence

- *At initial accreditation application and accreditation review: written statement by HREC Chair as to the material supplied to new members.*

6. Meetings

- 6.1 The HREC must convene a sufficient number of meetings (not less than eight) per year at appropriate intervals. Such meetings should, where possible, not be cancelled or deferred in order to maintain capacity.

Evidence

- *At initial accreditation application and accreditation review: copy of proposed meeting schedule for the coming year and contingency arrangements should a core category member be unavailable to attend a meeting. Record of meetings held during the previous 12 months.*

- 6.2 Opportunity is given for investigators to meet with the HREC face-to-face if matters regarding their projects are questioned by the HREC.

Evidence

- *At initial accreditation application: written statement by the HREC Chair that the HREC considers holding face-to-face meetings with investigators to resolve issues which have been unresolved by written or telephone communication.*
- *At accreditation review: review of minutes of past meetings and discussions with the Chair to determine whether investigators have been given the opportunity to meet with the HREC where appropriate.*

6.3 Each member of the HREC has appropriate input into the deliberations of the committee.

Evidence

- *At initial accreditation application: written statement by the HREC Chair as to participation of members.*
- *At accreditation review: peer-review of HREC meeting(s) to assess member input.*

6.4 The HREC accepts applications for review submitted on the National Ethics Application Form (NEAF).

Evidence

- *At initial accreditation application and accreditation review: written statement by the HREC Chair that NEAF is accepted.*

6.5 The HREC considers characteristics of the local setting, both at which the research will be conducted and from which participants will be recruited, relevant to the ethical conduct of the research and seeks advice where appropriate.

Evidence

- *At initial accreditation application: written statement by the HREC Chair as to the operations of HREC in this regard.*
- *At accreditation review: peer-review of HREC meeting(s) and previous minutes.*

7. Expedited review of minimal risk research

7.1 The HREC has and implements a documented standard procedure for expedited review of minimal risk research proposals.

Evidence

- *At initial accreditation application and accreditation review: copy of documented procedure.*
- *At accreditation review: peer review of HREC minutes and documents to determine whether expedited review is undertaken in appropriate circumstances.*

- 7.2 For research proposals that have undergone expedited review, the HREC documents the determination made that the proposal involved minimal risk, the matters considered during the review, the decision taken by the HREC, the reasons for that decision and the ratification of the decision by the full committee.

Evidence

- *At initial accreditation application: written statement by the HREC Chair.*
- *At accreditation review: peer-review of HREC and Executive minutes.*

8. Recording of decisions

- 8.1 The HREC records the main ethical issues raised for each multi-centre research proposal and the decisions taken by the HREC.
- 8.2 The HREC records the manner in which scientific review was undertaken, by whom and the outcome of the scientific review, for each multi-centre research project.
- 8.3 The HREC records member's attendance and whether a quorum was achieved, including the minimum membership requirements under the *National Statement*.
- 8.4 The HREC records member's declaration of interests, including conflicts of interests, and the decision of the committee on the participation of the member concerned.
- 8.5 The HREC maintains records of all research proposals received and reviewed in an appropriate format and in accordance with the 'Joint NHMRC/AVCC Statement and Guidelines on Research Practice' and 'General Retention and Disposal Authority – Public Health Services: Administrative Records – GDA 21. IB2005_027'.
- 8.6 The HREC retains on file a complete copy of each research project and all associated documentation relating to its review by the HREC, including (where applicable) participant information sheets, consent forms and relevant correspondence, in the form in which they are approved.
- 8.7 The HREC notifies applicants promptly of the outcome of its review (no later than 10 working days from date of decision).
- 8.8 The HREC makes copies of its minutes available on request to peer-reviewers and the Chief Executive or delegate at sites at which the research is to be conducted (Chief Executives/delegates may only request sections of the minutes which are relevant to research projects being conducted within their site).

Evidence

- *At initial accreditation application: written statement by the HREC Chair as to these matters.*
- *At accreditation review: peer-review of HREC minutes and records.*

9. Handling of serious adverse events

- 9.1 The HREC has a documented and transparent procedure to manage notifications of serious adverse events, which is compliant with Departmental guidelines as may be issued from time to time¹.

Evidence

- *At initial accreditation application and accreditation review: copy of procedure.*

10. Terms of reference

- 10.1 The HREC terms of reference are made available upon request to the general public and posted on the HREC's website.
- 10.2 The terms of reference have been approved by the Chief Executive/delegate.

Evidence

- *At initial accreditation application and accreditation review: copy of dated HREC Terms of Reference including evidence of approval by Chief Executive or delegate.*

11. Standard operating procedures

- 11.1 The standard operating procedures of the HREC are commensurate with the Department's "HREC Operations Manual for NSW Health" (GL2005_059) and the "Research – Model for Single Ethical & Scientific Review of Multi-Centre Research: Standard Operating Procedures under the NSW Health model for single ethical and scientific review of multi-centre research" (PD2007_072).
- 11.2 The standard operating procedures are made available upon request to the general public and posted on the Area Health Service's website.

Evidence

- *At initial accreditation application and accreditation review: copy of dated Standard Operating Procedures..*

¹ The Department is currently developing a standard procedure for the handling of notifications of serious adverse events. In the interim, HRECs must demonstrate that they have a standard operating procedure with regards to serious adverse event reporting.

12. Complaints procedures

- 12.1 The HREC has written procedures for receiving and handling complaints from research participants about the conduct of an authorised research project which it has reviewed.
- 12.2 The HREC has nominated a person to whom complaints from research participants, researchers or other persons, may be made in the first instance.
- 12.3 The HREC has written procedures for receiving and handling appeals from researchers about the review process.

Evidence

- *At initial accreditation application: copy of written procedures.*
- *At accreditation review: peer review of complaints (if any) dealt with.*

13. Reporting

- 13.1 The HREC has a designated senior officer within the Public Health Organisation to whom it reports on decisions about ethical review of research proposals, on administrative and staffing matters, and on budgetary/resource matters.
- 13.2 The HREC must provide regular (at least annual) written reports to the Chief Executive on matters including membership, number of proposals reviewed, status of proposals, description of any complaints received and their outcome and other general issues (such as administrative, staffing matters and budgetary matters).

Evidence

- *At initial accreditation application and accreditation review: copy of most recent HREC report to Chief Executive or delegate.*

14. Training and education

- 14.1 The HREC members and support staff have attended relevant training and continuing education opportunities conducted by the NHMRC, NSW Health or other relevant body.
- 14.2 HREC members are given an equal opportunity to attend training and continuing education opportunities.

Evidence

- *At initial accreditation application and accreditation review: record of number of attendances by HREC members and support staff at training and education sessions.*

15. Conflicts of interest

- 15.1 The HREC has a standard procedure for identifying and handling potential conflicts of interest for HREC members and experts, which is transparent.

Evidence

- *At initial accreditation application: copy of documented procedure..*
- *At accreditation review: peer-review of HREC minutes.*

16. Additional standards for HRECs accredited to review clinical trials and interventional clinical research

- 16.1 The HREC must have in place a means of obtaining a timely scientific review by relevant experts in a broad range of clinical areas without regular reliance on the NSW Health Shared Scientific Assessment Committee² and in accordance with “Human Research Ethics Committees: Standards for Scientific Review of Clinical Trials” (PD2007_035). That is, the scientific review relied upon by the HREC must be able to be completed within a sufficient timeframe so as to enable the HREC to provide a final ethical opinion on the proposal within a maximum of 60 calendar days.

Evidence

- *At initial accreditation application: written statement from HREC Chair setting out arrangements for scientific review and access to relevant expertise, including the areas of expertise available and the circumstances, if any, in which the HREC may need to rely on the Shared Scientific Assessment Committee. Copy of terms of reference of scientific/technical sub-committee if applicable.*
- *At accreditation review: peer-review of HREC minutes/scientific sub-committee minutes and/or expert reports.*

- 16.2 Understanding of Therapeutic Goods Legislation as it relates to clinical trials and the Note For Guidance on Good Clinical Practice (CPMP/ICH/135/95) Annotated with TGA Comments.

Evidence

- *At initial accreditation application: written statement by the HREC Chair that, based on experience, members are aware of the Therapeutic Goods Legislation and the Note for Guidance on Good Clinical Practice (CPMP/ICH/135/95) Annotated with TGA Comments and that copies of these documents are provided to new members.*
- *At accreditation review: peer-review of HREC minutes/scientific sub-committee minutes and/or expert reports.*

² This does not preclude use of the Shared Scientific Assessment Committee for unusually complex research, or occasional first-time-in-human and first-time-in patient clinical trials.

- 16.3 The HREC has demonstrated experience in reviewing clinical research, including clinical trials. In addition, the HREC must review a sufficient³ number of clinical research projects per year in order to maintain capacity.

Evidence

- *At initial accreditation application and accreditation review: number of clinical research projects (including clinical trials) reviewed in the previous 12 months.*

17. Additional Standards for HRECs accredited to review general research (including population health, health services and epidemiological research, non-interventional clinical research and other general research)

It is acknowledged that the degree to which these categories of general research require scientific or technical review is highly variable, depending on the nature and extent of the research project, the degree to which it has been previously reviewed and its risk profile. Generally, research projects in this category that have undergone peer review through an external funding process (for example, NHMRC review) do not require further scientific or technical review. However, scientific/technical review may be required for experimental studies involving interventions other than invasive clinical treatments (including randomised control trials of such interventions) as well as observational studies, including cohort studies, case-controlled studies, cross-sectional studies, large surveys and qualitative studies. Lead HRECs should be able to apply expertise to the review of these studies where required and this may include expertise or experience in general research techniques, epidemiology, public health research and health services research. Expertise in biostatistics, health economics and qualitative research may also be relevant. This expertise may not necessarily be vested in the HREC's membership, but may be available through obtaining external reviews where necessary.

- 17.1 The HREC must have in place a mechanism (either through its membership or through accessing relevant individuals with expertise/experience) that is sufficient to adequately review the scientific/technical aspects of general research, health services research, population health research and epidemiological studies, within a sufficient timeframe so as to ensure the HREC is able to provide a final ethical opinion on the proposal within a maximum of 60 calendar days.

Evidence

- *At initial accreditation application: written statement from HREC Chair setting out arrangements for scientific and technical review and access to relevant expertise, including the areas of expertise available.*

³ The Department has not set a threshold with regards to the number of research projects which must be reviewed in order to meet this standard. Rather, this standard will be reviewed as part of the overall assessment of the HREC's ability to meet the accreditation standards.

- *At accreditation review: peer-review of HREC minutes and other relevant documents.*

17.2 The HREC has demonstrated experience in reviewing population health, health services and epidemiological research. In addition, the HREC must review a sufficient number of these types of research per year in order to maintain capacity.

Evidence

- *At initial accreditation application and accreditation review: number non-clinical research reviewed in the previous 12 months.*
-