

ROYAL ADELAIDE HOSPITAL

North Terrace Adelaide SA 5000 Tel: +61 8 8222 4000

Tel: +61 8 8222 4000 Fax: +61 8 8222 5939 ABN 80 230 154 545

Research Ethics Committee

Tel: (08) 8222 4139 Fax: (08) 8222 3035

Email:

Health.CALHNResearchEthics
@sa.gov.au

PROCEDURE: HREC MEETING PROCEDURES

- 1. The composition of the Research Ethics Committee (REC) membership may vary from time to time, but the minimum composition will always comply with that indicated in the National Health and Medical Research Council (NHMRC) National Statement on Ethical Conduct in Research Involving Humans, 2007 (The NHMRC Statement). This requires that there shall be:
 - equal numbers of men and women
 - at least one third of the members from outside the institution for which the HREC is reviewing research.
 - a chairperson, with suitable experience, whose other responsibilities will not impair the HREC's capacity to carry out its obligations under this National Statement:
 - at least two lay people, one man and one woman, who have no affiliation with the institution and do not currently engage in medical, scientific, legal or academic work;
 - at least one person with knowledge of, and current experience in, the professional care, counselling or treatment of people; for example, a nurse or allied health professional;
 - at least one person who performs a pastoral care role in a community, for example, an Aboriginal elder, a minister of religion;
 - at least one lawyer, where possible one who is not engaged to advise the institution:
 - at least two people with current research experience that is relevant to research proposals to be considered at the meetings they attend. These two members may be selected, according to need, from an established pool of inducted members with relevant expertise.
- 2. The REC will meet on the third Thursday of each month, excepting for January when no meeting will be held.
- 3. The meeting agenda, including copies of protocols, will be distributed to all members on the Friday preceding each meeting.
- 4. If notification is received that a member will not attend the following meeting, the agenda, including copies of the protocols, will be sent to a proxy member.
- 5. If a member is unable to attend but is able to provide written feedback about proposals before the meeting they are encouraged to do this and such information will be tabled in discussions of the relevant protocol.
- 6. Attendance of members, apologies and proxy members are recorded in the mi8nutes of the meeting.
- 7. When there is less than full attendance, the Chairperson must be satisfied, before a decision is reached, that the minimum membership listed in paragraph 1 have received all documents and have had the opportunity to comment. This procedure is in compliance with The NHMRC Statement.
- 8. At each REC meeting, the Minutes of each preceding meeting will be ratified.
- 9. Decisions will be reached by consensus. Only members who participate in the review and discussion process will be allowed to vote to approve or reject a protocol.

- 10. Decisions to approve a protocol will be recorded in the minutes and the investigator will be promptly notified in writing of the decision.
- 11. Decisions to reject a protocol will be recorded in the minutes and the investigator will be promptly supplied in writing with the reasons for the decision and actions that can be taken to discuss the situation further (where applicable).
- 12. When a decision is delayed:
 - the reasons will be recorded in the minutes and the investigator will be supplied in writing with the reasons / queries.
 - responses from the investigator to REC queries must be in writing (responses may take the form of clarifications, agreement to protocol modifications, appeal against protocol modifications)
 - the REC will decide whether the investigator's response should be considered
 at the following meeting or whether authority will be delegated to the
 Chairperson to consider the response. This decision will be recorded in the
 Minutes.
 - if authority is delegated to the Chairperson, the Chairperson may approve the protocol or may decide the response will be considered at the next REC meeting.
 - approval will be recorded and tabled in the Agenda at the following REC meeting.
- 13. When a decision is made to terminate or suspend a previously approved protocol, the reasons will be recorded in the minutes and the investigator will be supplied in writing with the reasons for the decision and actions that can be taken to discuss the situation further (where applicable).
- 14. Any REC member who is an investigator on a protocol under consideration, must leave the meeting room during Committee discussion and decision making on that protocol.
- 15. At all times, the Chairperson has the delegated authority to consider and to approve protocols in which there is little or no intervention and little or no risk to subjects. The written criteria for consideration for this accelerated review have been approved by the REC. The principal details of any protocol (Title, Investigators) which is approved by this process of accelerated review will be listed on the agenda for the following REC meeting. The REC may ask the Chairperson for details of aspects of the protocol and reasons for approval at the following meeting.
- 16. The Chairperson has the delegated authority to consider and approve all amendments to approved protocols. The written criteria for consideration for this accelerated review have been approved by the REC. The principal details of any protocol (Title, Investigator) which is approved by this process of accelerated approval will be listed on the agenda for the following REC meeting. The REC may ask the Chairperson for details of aspects of the protocol amendment at the following meeting.
- 17. The Chairperson may co-opt individuals for expert opinion at any time.
- 18. The Chairperson may invite a researcher to attend the committee meeting to support their proposal.
- Complaints from researchers about REC decisions will be tabled at REC meetings.
 Complaints that cannot be resolved by discussions between the REC and the complainant will be referred to the Director, Medical Administration.
- 20. Relevant records, including written procedures, membership lists, lists of occupations/affiliations of members, submitted documents, minutes of meetings and correspondence, will be retained for at least 15 years.

- 21. Information submitted to the REC will be treated as confidential by all members of the REC and its subcommittee(s).
- 22. A Committee audit of Expedited Approvals will be conducted at the March and September meetings. Prior to these meetings, the REC Secretary will distribute to each Committee member 1 to 2 protocols which have received Chairperson's Approvals in the preceding six month period. During the meeting, Committee members will provide comments to the Deputy Chairperson, in the absence of the Chairperson from the meeting room. These will be discussed with the Chairperson at the same meeting.
- 23. The Radiation Protection Branch of the Department of Health, will be notified each month of protocols involving radiation for research which have been approved.

Revision history

Version 6.0 M James 19 July 2007 Version 7.0 A Thornton 6 February 2010