RANZCO HUMAN RESEARCH ETHICS COMMITTEE

GUIDELINES FOR SUBMISSIONS

COMMITTEE STANDARDS

1. The Royal Australian and New Zealand College of Ophthalmologists (RANZCO) Human Research Ethics Committee (HREC) follows the guidelines developed by the National Health and Medical Research Council (NHMRC).

SUBMISSIONS

2. There are two applications which can be completed depending on the project. The Low and/or Negligible Risk Research (LNR) form should be completed for research where:
   - The only foreseeable risk is one of discomfort
   - There is no foreseeable risk of harm or discomfort
   - Any foreseeable risk is no more than an inconvenience

   If a study is not classified as an LNR, researchers will be required to complete the Human Research Ethics Application (HREA).

3. Projects may be submitted at any time to the HREC, however researchers are encouraged to submit their proposals one month before the next scheduled meeting. The Committee will meet quarterly or whenever there are sufficient studies for review.

4. Applicants are to allow for up to four weeks between a submission and an initial decision if proposals were not submitted one month prior to a scheduled meeting. Decisions will be advised as soon as practicable after meetings.

5. It should be noted that the time frame for a decision may be longer if it is necessary to consult wider on the submission. Wider consultation will occur only with the concurrence of the researchers and any costs incurred will be borne by the researcher. In the case of a new class of molecule being tested sufficient pre-clinical and/or early phase clinical data must be included and/or a report from an independent Australian toxicologist must be provided to justify the study.

6. All correspondence including submissions are to be electronic. No paper copies will be accepted.

LAY STATEMENT

7. A brief one-page outline, in lay language, of the plan and its benefits and costs must be included. Perceived ethical implications and their management should be discussed. What participants will be required to do is also required.

PATIENT INFORMATION SHEET AND CONSENT FORM

8. A requirement of the NHMRC is that trial participants in a study receive full information about the research in language that they can understand. A facility

should be available to produce information sheets in the native language of non-English speaking participants, if required.

9. The Patient Information Sheet and Patient Consent Form need to address the following:
   - The freedom for all parties to participate or withdraw without compromise
   - Full disclosure of possible side effects of medications
   - Methods of ensuring confidentiality for all parties involved in the study
   - Full details of potential inducements to participants or to doctors
   - Independent monitoring of data
   - Safety measures and personal costs to the participants

10. The Patient Information Sheet and Consent Form should also contain the following elements:
   - Study title
   - Introduction
   - Investigators' names and contact details
   - Purpose of study
   - Eligibility to participate
   - Study procedures and what participants will be required to do
   - Risks
   - Other treatments
   - Clause re voluntary participation
   - Clause re stopping the study if events indicate
   - Treatment and compensation for injury
   - Possible benefits of participation including reimbursement of costs
   - Disclosure of payments to investigators
   - Details of data collection, storage, use and disposal
   - Printing/publishing of findings

The language of the form should be specific and understandable to persons of about a Year 8 reading level.

PROTOCOL

11. The protocol should include a description of the following:
   - The research question or hypotheses
   - Literature review, including the estimated effect of this research on current knowledge
   - Research plan, time frame and expected benefits
   - Method of data collection and analysis and who has the final decision to publish results
   - All researchers involved, their qualifications and experiences
   - Full details of any financial and legal agreements involving investigators and participants
   - Detailed expansion of information given in the lay statement including details of and method of obtaining consent

REQUIREMENTS FOR CLINICAL TRIALS

12.

a. **Prerequisite**
All clinical trial proposals are to be registered with the Australian New Zealand Clinical Trials Registry (ANZCTR) – http://www.anzctr.org.au/

b. **Summary of all available scientific data**
When therapeutic agents are being investigated the full investigational drug, brochures are required for ethics review according to the guidelines developed by the Therapeutic Goods Administration (TGA).

A subcommittee of the HREC will assess this information. Comments from independent experts such as clinical pharmacologists and toxicologists may be requested. In such cases, applicants are required to meet the costs, if any, of obtaining the same.

Clinical trials' protocols will be assessed according to the December 1991 TGA document "Guidelines for Good Clinical Research Practice in Australia" as well as the previously mentioned NHMRC guidelines.

c. **Clinical Trials Notification (CTN) Forms**
If CTN forms are required for the TGA, they are to be completed by the applicant for each participating centre, and included with the submission for the Chair of the HREC to sign on approval of the project.

d. **Legal Indemnity**
These trials have specific legal as well as ethical implications. The RANZCO, in consultation with its legal advisers, deems that the Australian Pharmaceutical Manufacturers' Association (APMA) Form of Indemnity for Clinical Trials is the only form of indemnity accepted by the College in respect of clinical trials conducted within the framework. This document provides indemnity for the RANZCO and its agents. A signed copy of the Indemnity Form should be included with the submission for clinical trials.

Organisations not working within the RANZCO framework but requiring ethical review by RANZCO will be requested to provide indemnity to RANZCO and will be provided with the appropriate forms, based on the APMA format, on receipt of their submission by the committee manager. It is important to note that this indemnity does not cover the ophthalmologists who may be acting as agents for these organizations.

FEE STRUCTURE

13. The routine ex GST fees are:

- $1,950 for applications from commercial organizations or industry sponsored trials

- $400 for other groups or individual researchers

14. These fees are charged to cover the administration costs for ethics review. Full payment must be made prior ethical review. If a submission is withdrawn or not approved, after being reviewed by the HREC, the review fee will still apply.

15. Researchers applying for research grants should include the fee for ethics review as a specific budget item when submitting their grant application. For these researchers, the fee may be paid to the RANZCO once the research funds have been received.

16. It is acknowledged that practitioners conducting individual research may not always be able to obtain funds for ethics review. It is not the intention of RANZCO that this will be a barrier to them seeking or obtaining ethics approval. In such instances, that fee may be waived or deferred at the discretion of the Chair of the HREC.

DECLARATION OF PRIOR REVIEW

17. It is a requirement of the HREC that the Declaration of Prior Review regarding previous consideration of the submission by other committees, be signed and returned with the submission.

MONITORING OF PROJECTS

18. Researchers are required to inform the HREC of the progress of their projects. In addition to immediate notification of any serious adverse events, an annual progress report and a final report are requested.

CONTACT PERSON

HREC Manager
RANZCO
94-98 Chalmers Street
Surry Hills NSW 2010
Phone: 02 9690 1001
Fax: 02 9690 1321
Email: ranzco@ranzco.edu