

# Australian & New Zealand Ophthalmic Surveillance Unit (ANZOSU)

## Guidelines on Applications for the Inclusion of Studies

### 1 INTRODUCTION

- 1.1 Applications for the inclusion of a study in the Australian & New Zealand Ophthalmological Surveillance Unit (ANZOSU) reporting scheme are considered by peer review through The Ophthalmic Research Institute of Australia (ORIA). This document gives detailed guidance on making an initial application, completion of a full application, the requirements which must be met and the considerations which are most likely to influence the ANZOSU's decision. It is assumed that the reader will be familiar with the general nature and operation of the scheme.
- 1.2 The ANZOSU is not the appropriate method of case ascertainment for all study applications. Sometimes this may not become apparent until considerable time and effort has gone into the preparation of a full application. A two-stage application has therefore been initiated. Potential investigators (applicants) are therefore invited to submit an initial outline proposal including a short questionnaire (Phase One Application). If this is supported by the ANZOSU a full application (Phase Two) will be requested.
- 1.3 The ANZOSU will give fair and impartial consideration to all applications (both Phase One and Phase Two) with, where appropriate, the advice of independent referees. The committee may also make enquires to help avoid duplication or possible conflict with the work of other investigators in the same field. **[Principal research workers may be invited to discuss their proposal].**
- 1.4 Research workers who are interested in applying for inclusion of their study in the ANZOSU scheme should first make informal enquiries to the Scientific Coordinator, who will be pleased to discuss protocols at the design stage.
- 1.5 Formal Phase One applications should be made with a short (two pages of A4) schematic proposal. These should be returned to the ANZOSU office. If this is accepted by the ANZOSU then Phase Two application forms will be sent to the applicants.
- 1.6 Investigators are advised to submit their application at least six months before the proposed starting date, although a proposal can be considered within one month if there is genuine urgency.
- 1.7 The support of ophthalmologists in Australia and New Zealand is vital in order to make the ANZOSU a successful and fruitful research facility. However, the number of conditions included on the reporting card at any one time must be limited so as not to overburden reporting doctors. It is anticipated that competition for a box on the report card will become intense. Research workers are therefore advised to take note of the following guidelines when submitting a Phase One application.

### 2 IMPORTANT CONSIDERATIONS IN DETERMINING THE ACCEPTANCE OF AN APPLICATION

#### Main Considerations

- 2.1 **Rarity.** A study is eligible for participation in the scheme if the condition of interest is a relatively rare ophthalmological disorder (or a rare complication of a more common disease or procedure) of such low incidence or prevalence as to require ascertainment of cases on a national

scale in order to generate sufficient numbers of study. The ANZOSU may also consider inclusion of short-term or geographically limited studies of comparatively more common disorders.

- 2.2 Public Health Importance.** Proposals with outcomes of clear public health importance are particular priority.
- 2.3 Scientific Importance.** The ANZOSU prioritises with scientific interest and importance.
- 2.4 Uniqueness.** A proposed study that has already been undertaken recently, or is in progress elsewhere, is less likely to be prioritised. If other data sources are more readily available for achieving the goals then a proposal is likely to be given a lower priority (see also 2.9)
- 2.5 Quality of Proposal.** It is expected that all studies will, on initiation, be of high quality in terms of clear and achievable objectives, practicability, confidentiality of patient details, adequate resources, having well prepared questionnaire, etc. However, the ANZOSU is also committed to assisting potential investigators, especially those less experienced in research methodology, in improving potentially good studies.
- 2.6 Workload on Ophthalmologists.** An important aim of the ANZOSU is to lessen the burden on reporting doctors of requests for reporting cases. Accordingly, the ANZOSU must be certain that the work entailed in reporting cases will be worthwhile contribution to well-designed studies, and will not make excessive demands on the time and goodwill of its respondents. To this end, some guidelines on follow-up questionnaires are given below (Section 5).

#### Subsidiary Considerations

- 2.7 Assessing Service Needs.** For example, measuring the numbers of patients with particular conditions requiring care.
- 2.8 Gathering Cases.** It can be valuable to gather together cases of rare conditions so as to better describe their natural history and outcome, or to apply a new treatment or care regimen. However, studies depending on retrospective case ascertainment over a number of years, or on immediate reporting and/or sample collection, or requiring the participation of other specialities, are less likely to be suitable, but the Unit may be able to address means of overcoming some of these difficulties in the future. Investigators are strongly advised to discuss such studies informally in advance with the Scientific Coordinator.
- 2.9 Estimating Completeness of Reporting.** The ANZOSU places particular emphasis on proposals using readily available alternative sources to estimate the completeness of reporting.
- 2.10 Duration of a study.** The ANZOSU recognises that two or more years surveillance of a very rare condition may be required to provide adequate cases for study. However, a study will not normally be accepted for inclusion on the scheme for an initial period of more than a one year. Continuation thereafter is subject to annual review by the peer review committee from ORIA, bearing in mind that the progress of the study, the number of new proposals received, and the importance of ascertainment through the ANZOSU as opposed to any other means available to the investigators.

### 3 PHASE ONE APPLICATION- SUBMISSION OF AN OUTLINE PROPOSAL

- 3.1** Applicants are invited to submit an outline proposal; this should take the form of a summary of the study (two sides of A4).
- 3.2** To aid in presentation of the outline proposal to the peer review committee from ORIA the Scientific Coordinator may seek clarification from the

applicants.

#### 4 PHASE TWO APPLICATION - COMPLETING THE FULL APPLICATION FORM

- 4.1 Once a study has been accepted into Phase Two applicants are immediately sent a Full Application form for completion. **When completed this is in effect the full study protocol and is accordingly detailed with its questionnaire, covering letter(s), etc.** To maintain feasibility and high quality of ANZOSU studies this is developed in consultation with the Scientific Coordinator and is then considered by the peer review committee from ORIA for Phase Two approval. The criteria used by reviewers for assessing the application are enclosed.
- 4.2 If a study is approved a summary protocol, which will be sent to all ANZOSU respondents (all ophthalmologists in Australia and New Zealand), will be prepared by the ANZOSU office from the full application form. This will be sent to the investigators in draft but it is essential to facilitate its preparation by completing all sections of the form in accordance with the instructions below.
- 4.3 **Condition to be studied.** Give the accepted name of the condition followed by the recognised abbreviation, if any.
- 4.4 **Investigators.** Give the names, appointments and institutions of the research workers. Indicate clearly (a) the principal contact for correspondence on this application, (b) the contact for reporting cases if different; for both give full postal address, telephone and fax numbers.
- 4.5 **Abstract of Proposal.** Give here a brief statement of the general aim of the project.
- 4.6 **Proposed Starting Date.** Remember that the report card is sent to respondents at the end of each month, for cases seen in that month.
- 4.7 **Proposed Duration of Study.** Justification of the proposed duration should be included in the supporting statement.
- 4.8 **Proposed Territorial Coverage.** Studies cover across Australia and New Zealand.
- 4.9 **Statement of Research Questions.** Give a clear statement of the specific research questions(s) which will be answered by this study.
- 4.10 **General Supporting Statement.** The statement should explain the need to study this condition, give a brief review of the background to the proposal, draw attention to the state of current knowledge including incidence and prevalence, indication of public health and scientific importance, and show why the use of the ANZOSU is appropriate. References should be given at the end of this section.
- 4.11 **Study Methods.** Give an outline of the proposed study methods, drawing particular attention to the consequences of reporting for (a) the ophthalmologist, (b) the GP, (c) the patient, in terms of request for information or specimens, and questionnaires which will be sent out. This section should include arrangement for protecting confidentiality and justification of collection of patient identities. **Copies of questionnaires and covering letters to respondents must be attached even if they are only in draft form.** On acceptance the ANZOSU will request final versions of these for its files.
- 4.12 **Case Definition.** Give a clear case definition for the condition of interest, preferably one that is internationally accepted. State the desired age limit. Any specialist terms or abbreviations which will not be familiar to ophthalmologists should be explained in full.

- 4.13 Reporting Instructions.** You may give different reporting instructions for (a) the first mailing in which the condition is included, and (b) subsequent months. A sample set of reporting instructions can be found at the end of these guidelines.
- 4.14 Ethical Approval.** Give the name of the research ethics committee to which the proposal has been submitted and the date on which the approval was given. If approval has not yet been given, state when the decision will be known.
- 4.15 Funding Arrangements.** Outline the funding arrangements for the project, naming the body or bodies to which grant application(s) have been submitted, unless this is confidential, and give the date by which arrangements are expected to be agreed. A detailed budget is not required. Investigators are expected to include in their grant application(s) a sum to cover the contribution requested by the ANZOSU.
- 4.16 Organisational Arrangements.** Give a brief outline of the other arrangements (eg/location, resources) for managing the project, such as administrative, scientific and computing support.
- 4.17 Draft questionnaires and letters.** The covering letter should include a reference to the ANZOSU as well as to items 5.2 b), g) and 1) below. It should state why (if it is) the patient's name and/or address including post code is required and what the arrangements are to preserve medical confidentiality.

## **5 DESIGN OF QUESTIONNAIRES**

- 5.1** The ANZOSU is concerned that questionnaires should be as brief, simple, attractive and "user friendly" as possible, so as not to impose as excessively on the reporting ophthalmologist. Researchers are welcome to discuss questionnaire design with the Scientific Coordinator and copies of questionnaires used by other studies will be available on request. The ANZOSU office will have software and expertise which can be made available to investigators who require help. There may be a small charge for this service. For further details please contact the Coordinator.
- 5.2** Specific points which should be borne in mind are-

- (a) A description of the questionnaire development process and summary statistics on the performance of the questionnaire during pilot work will be required by the peer review committee prior to the approval of the project.
- (b) A length of two A4 sides is usually adequate for initial details, although there may be exceptions. Please do not ask the ophthalmologist detailed questions in the initial questionnaire which are more appropriate to a (potential) later stage of enquiry.
- (c) The ophthalmologist should at least be given the option of sending copies of discharge summaries and/or relevant correspondence instead of completing a questionnaire, although the latter is more desirable. If practical, a visit by one of the research workers to review case notes should be offered.
- (d) Words such as "In cooperation with the Australian and New Zealand Ophthalmological Surveillance Unit" should be included in the headings of the questionnaires and covering letters along with the name of the research base.
- (e) Where appropriate (see 4.17above), space should be left for the use of a hospital label for the patient's name and personal details.

- (f) Standard classification should be used where possible.
- (g) Specialist terms or abbreviations should be explained in full.
- (h) Respondents should be asked to return the questionnaire even if they are unable to complete all items.
- (i) A reply paid envelope for return of the questionnaire will enhance response rate.

## **6 ESSENTIAL FORMAL REQUIREMENTS**

- 6.1** Before final acceptance on to the report card the proposed study should have the approval of their own Clinical Research Committee, or Institution. Ethical approval before submission of the full (Phase Two) application to the ANZOSU is, however, not required although clearly it is desirable.
- 6.2** All the usual considerations of confidentiality in medical research apply to the information collected through the ANZOSU scheme.
- 6.3** Adequate funding must have been obtained for the completion of the research. The operation of the ANZOSU involves considerable expenses which would normally be incurred by the research worker, and to help with these costs the ANZOSU determines annual fee of \$5000 for a project which the investigators are asked to contribute. Acceptance of a project, however, is not conditional on receiving any contribution and all projects are considered on their scientific merits.

## **7 REPORTS AND ARTICLES**

- 7.1** The ANZOSU does not exercise any control whatsoever over when or where research workers publish their results, nor does it require being included in authorship. However, investigators are asked to acknowledge the assistance of the ANZOSU (including its funding from the Eye Foundation) in any manuscripts submitted for publication, and to provide for the information of the committee a copy of such articles as soon as they are published.
- 7.2** Regular feedback to reporting ophthalmologists is important to encourage their full cooperation with the scheme. Accordingly, participating investigators are asked to contribute short reports to form part of the ANZOSU Annual Report each year, on completion of their project, and occasionally for other periodic reports and articles as requested by the Scientific Coordinator. They are also reminded that the Annual General Meeting of the College of Ophthalmologists provides an ideal forum on such feedback - abstracts are usually required early June of each year for the RANZCO - Annual General Meeting & Scientific Congress held in November.
- 7.3** The ANZOSU would like to remind investigators who are not themselves ophthalmologists that the success of the scheme depends on the goodwill of the members of the Australian & New Zealand college of Ophthalmology.

## Appendix 1

### CONTRIBUTIONS FROM INVESTIGATORS

There will be a fee (of \$5000) contribution for all studies, irrespective of their total duration. The contribution, which is approved and revised annually by the ANZOSU, is based on the average cost incurred by the ANZOSU in the administration of a one-year study.

APPROVED and SIGNED by INVESTIGATORS:

_____	_____
Name	Signature
_____	_____
Name	Signature
_____	_____
Name	Signature

DATE: \_\_\_\_\_