Project Title: ……

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Project Number: ……..(office use)

The Royal Australian and New Zealand College of Ophthalmologists
ACN 000 644 404

94 - 98 Chalmers Street, Surry Hills NSW 2010 Australia
T 61 2 9690 1001 **F** 61 2 9690 132 **E** ranzco@ranzco.edu

www.ranzco.edu

APPLICATION FORM FOR LOW AND/OR NEGLIGIBLE RISK RESEARCH

Purpose of this form

All research involving human participants requires an application to be made to a certified human research ethics committee (HREC). The type and level of risk to human participants, determines the type of HREC application required.

The purpose of Part A of this form is to determine the type and level of risks associated with your project. If the type and level of risk is determined to be of "low" or "negligible" risk, then you may proceed to complete Parts B and C and submit this application to RANZCO HREC.

If your project does not qualify as "low" and/or "negligible" risk, you will be required to complete the Human Research Ethics Application (HREA) online via https://hrea.gov.au/ . The online application can be completed and submitted to RANZCO HREC for the committee's consideration.

To assist us in the process of determining whether your application will be considered for review as a low and/or negligible risk research project, please complete the relevant pages of this document.

According to the National Statement on Ethical Conduct in Human Research 2007 (Updated 2018)

2.1.6 Research is 'low risk' where the only foreseeable risk is one of discomfort. Where the risk, even if unlikely, is more serious than discomfort, the research is not low risk.

2.1.7 Research is 'negligible risk' where there is no foreseeable risk of harm or discomfort; and any foreseeable risk is no more than inconvenience. Where the risk, even if unlikely, is more than inconvenience, the research is not negligible risk.

Examples of research with low and negligible risk include, but are not limited to, the following:

- Research involving only questionnaires and general surveys on non-controversial, non-personal issues that also include only basic demographic data and where, in all instances, respondents are not identified;
- Research involving only the use and/or disclosure of information from existing data collections, where the identity of the person cannot reasonably be ascertained from the information to be disclosed to researchers;
- Research involving human tissue where participant consent is not required because broad consent has been provided for use of the tissue in research and specific individuals cannot be identified from specimens used e.g. where specimens have never been labelled with individual identifiers or individual identifiers have been permanently removed; and
- Research requiring access to individual medical records or to information stored electronically, through the site's medical records department or other department/specialty, but where participant consent is not required or where a waiver of consent requirement is being requested because, in all instances, individuals cannot be identified from data extracted or provided.

Use of this form

Please *read the* ***"Guidelines for Submissions***" which can be found on the RANZCO Website after logging in. You may want to discuss the project with RANZCO before completing this form. If you believe that the research project involves only low or negligible risk to participants, then this form is to be completed by the Principal Investigator responsible for the conduct of the research project and emailed to hrec@ranzco.edu. Alternatively, the form can be posted to RANZCO.

Standard College approved audits do not necessarily require ethics approval, however if you intend to publish in peer-reviewed journals that are affiliated with, and follow the publication guidelines of the International Committee of Medical Journal Editors, then you will need ethics approval and it is suggested that you submit an application on this Low and/or Negligible Risk form.

If the RANZCO HREC informs you that that the project is not eligible for low or negligible risk research, you will be required to complete an application for full HREC review by completing the Human Research Ethics Application (HREA) Form https://hrea.gov.au/

Contact Person: Monica Nation hrec@ranzco.edu RANZCO 94-98 Chalmers St Surry Hills NSW 2010 Ph: (02) 9690 1001 Fax: (02) 9690 1321

Checklist for Low and/or Negligible Risk Research

PART A

The National Statement describes Low to Negligible Risk as an inconvenience and as the least form of harm that is possible for human participants in research. The most common examples of inconvenience in human research are:

- Filling in a form;
- Participating in a survey that cannot be linked back to an individual;
- Giving up time to participate in a research activity.

With these characteristics in mind please complete the following questionnaire:

1. This research presents no foreseeable risk of harm or discomfort and any foreseeable risk is no more than an inconvenience to the participants.

☐ Yes ☐ No

2. The project involves the analysis of existing collections of data or records that contain only nonidentifiable data about human beings. (Survey based studies would be included if data is non-identifiable and existing)

☐ Yes ☐ No ☐ NA

If you have ticked 'Yes' to both questions, complete PART B. If you have ticked 'No' or 'NA' for one or more questions, your study will require a full HREC application through HREA.

In addition, if the research project targets any of the following groups or categories it will require a full HREC application on the HREA and may not be eligible for low and / or negligible risk review.

- Interventions and/or therapies, including clinical and non-clinical trials, and innovations using new treatment modalities.
- Human genetics.
- Human stem cells.
- Women who are pregnant and the human foetus in utero, and human foetal tissue after the separation of the foetus from the woman.

- Any person who may be unable to consent to participate freely and accurately (such as those highly dependent on medical care, or people with cognitive impairment or intellectual disability).
- Aboriginal and Torres Strait Islander Peoples.
- People who may be involved in illegal activities.
- Children and young people.
- People in dependent or unequal relationships, such as people who are patients of, and will be consented by, the researcher, or people who are employed by the researcher.

PART B

Section 1: ISSUES THAT MAY REQUIRE CONSENT

	Yes	No
1. The project involves direct contact with patients, consumers, or members of the public.	☐	☐
2. The project poses additional risks or burdens to the patient beyond their routine care.	☐	☐
3. The data to be collected is of a sensitive nature or application.	☐	☐
4. The purpose of the activity is not directly related to the patients' disease, illness or its management.	☐	☐

Section 2: PRIVACY AND CONFIDENTIALITY

5. The final dataset will contain information that may lead to identification of participants, such as nature of the condition, very rare conditions or very small communities.	☐	☐
6. Is the proposed activity to be conducted by a person who does not normally have access to the participants' health or other records for care or a directly related secondary purpose (to normal clinical care)?	☐	☐
7. Data will be selected or identified by: a) Aboriginal and/or Torres Strait Islander Peoples; or b) Ethnic, religious or minority groups.	☐	☐
8. Data will be collected beyond that which is normally collected in routine care.	☐	☐

Section 3: OTHER IMPLICATIONS

9. The project uses 'new' interventions, protocols, drugs or equipment.	☐	☐
10. The project will involve allocation of patients to groups to enable comparisons.	☐	☐
11. The project will involve genetic tests/testing.	☐	☐
12. The project may potentially infringe the rights, privacy or professional reputation of carers, health professionals or institutions.	☐	☐

13. The project involves use of a placebo.	☐	☐
14. The project requires access to medical records for a secondary purpose where a request to the Institution's Privacy Office will be required	☐	☐
15. Do you plan to publish this work?	☐	☐

If you have answered "**Yes"** to any of the above a Low and/or Negligible Risk application is required. Please fill in Part C. If you have answered **"No"** to **all** of the above, then no ethical issue arises and no ethical review is required.

Part C: Application Form for Low and/or Negligible Risk Research

1. Research reference

1.1 Project type

☐ Single Centre ☐ Multi-centre ☐ Multi-National

☐ Low risk ☐ Negligible risk

1.2 Project title

1.3 Protocol name and number

1.4 Has this project been evaluated and approved by a funding agency?

2. Research personnel

1.1 Principal Investigator

Title: ……..

First Name: ……..

Surname: ……

Position: ……..

Department: ……

Organisation: ……..

Mailing Address: ……

Suburb/Town: ……

State: ……..Postcode: ……..

Phone (business): …… Phone (mobile): ……

Fax: ……..

Email: ……

1.2 Other Investigator(s)

Title: ……..

First Name: ……..

Surname: ……

Position: ……..

Department: ……

Organisation: ……..

Mailing Address: …….

Suburb/Town: …….

State: ……...Postcode: ……..

Phone (business): …… Phone (mobile): ……

Fax: ……...

Email: ……
If you are not the contact person for this project, please provide relevant contact details

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1.3 Other personnel relevant to the research project

Please provide details (for example study nurses, research assistants or other personnel) who will be involved in this project.

1.4 Other organisations involved in this research project.

2. Research summary

3.1 Site/s involved in this project
List number, names and addresses of sites involved in the project and indicate the site/s requiring ethical and scientific approval from this HREC.

3.2 Ethical Review

Please provide details of any submissions to other ethics committees

3.3 Guidelines

What is the source of funds available to conduct this project? ……..……

Provide details of the source of funds to be provided for this project, including the name of the funding organisation or source, and the amount.

3.4 Conflicts of interest

Please provide details of any conflict of interest or duality of interest issues that exist or are likely to arise.

3.5 Publications and Dissemination of results

How is it intended to disseminate the results of the research? For example, by a report, publication or thesis?

3. Anticipated start and finish dates

3.1 Anticipated start and finish dates

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4. Research Protocol

4.1 Research Protocol

Briefly state the aims, research objectives, key research questions and/or the hypothesis to be tested, where appropriate.

4.2 Methodology

Provide details of the proposed method to achieve the aims, including research design, data collection techniques, data to be collected, number of participants, tasks participants will be asked to complete, recruitment of participants and analysis of results. Provide a justification of the proposed sample size, including details of statistical power of the sample, where appropriate.

4.3 Known and/ or potential risks associated with the research and how these are balanced with respect to research objectives

4.4 **Lay Description**

Provide an overview of the project in plain language describing the aims, the research design, the methods used to achieve those aims and possible outcomes.

5. Consent

Will informed consent be obtained from potential participants or a parent / carer / guardian or Substitute Health Authority?

☐ Yes ☐ No

If yes, please provide a copy of the proposed consent form.

Will consent have already been given prior to this study being undertaken (as in an audit of clinical records, where patients consented to gathering of unidentified data)?

☐ Yes ☐ No

If you answered 'No' to both these questions, please explain how the issue of Consent is being managed ethically.

6. Data and privacy

Is there a requirement for the research project to collect, use, or disclose individually identifiable or re-identifiable data of a personal nature (including personal health information) about participants from:

Commonwealth departments or agencies?	☐ Yes	☐ No
State/Territory departments or agencies?	☐ Yes	☐ No
Private sector?	☐ Yes	☐ No

If 'Yes':

Provide details on the nature and source of the data.

7.1 Is there a requirement for the research project to collect, use, or disclose individually identifiable or re-identifiable data of a personal nature (including personal health information) about participants without their consent?

☐ Yes ☐ No

7.2 Please provide details on the storage (including length of storage) and security of data.

7.3 Will any surveys or questionnaires be used in this study?

☐ Yes ☐ No

If 'Yes' then please provide a blank copy

8. Fees

Amount to be invoiced: **$**.....

Commercial Organisations	**$1,950 plus $195 GST**
Groups or Individuals	**$800 plus $80 GST**

Declaration by the Principal /Investigator
Project title:

I certify that:

1. All information in this form is truthful and as complete as possible.

2. I have read the National Statement on Ethical Conduct in Human Research 2007 (Updated 2013) and the Australian Code for the Responsible Conduct of Research and will conduct the research so that it conforms with their requirements.

3. The research will be conducted in accordance with the ethical and research arrangements of the organisations involved.

4. I have consulted all relevant legislation and regulations, and the project will be conducted in accordance with these.

5. I will immediately report to the HREC anything which might warrant review of the ethical and scientific approval of the proposal, including:

   a) Serious or unexpected adverse effects on participants;

   b) Proposed changes in the protocol;

   c) Unforeseen events that might affect continued ethical and scientific acceptability of the project.

6. I will inform the HREC if the research project is discontinued before the expected date of completion.

7. I will not continue the research if ethical approval or authorisation is withdrawn and will comply with any special conditions required by the HREC.

8. I understand and agree that study files and documents and research records and data may be subject to inspection by the RANZCO HREC, the sponsor or an independent body for audit, inspection and monitoring purposes.

9. I will adhere to the conditions of approval stipulated by the HREC and will co-operate with HREC monitoring requirements. At a minimum, annual progress reports and a final report will be provided to the HREC.

10. I will only commence this research project after obtaining approval from the HREC.

Name: ……

Signature: ……

Title e.g. HOD: ……

Date: ……