

# Research Office Credentialing of Researchers Procedure

## Purpose:

To describe the procedures for The Royal Victorian Eye and Ear Hospital ('Eye and Ear') credentialing of researchers and Honorary Researcher appointments.

## Scope:

This procedure applies to all researchers (both employees and honoraries) who conduct research at the Eye and Ear, to ensure they are credentialed and are acting within an agreed scope of practice.

All researchers who do not have a current appointment as an Eye and Ear employee and are part of a research team on an authorised research project require an honorary researcher appointment if they require:

- On site access to non-public areas of Eye and Ear premises for research purposes
- Role on the research project requires contact with Eye and Ear patients
- Access to Eye and Ear medical records
- Other research-related responsibilities involving Eye and Ear patients, staff, resources, facilities

## Risks/Precautions:

None have been identified at the time of this review.

## Procedure/Method:

### 1. Good Clinical Practice (GCP)

All researchers involved in a clinical trial (including Eye and Ear employees and honorary researchers) must have current certification of GCP training. Unless otherwise agreed by the Research Office the training must be delivered by a TransCelerate listed provider and is valid for three years from the date of issue. Evidence of current GCP training is to be provided to the Research Office.

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## 2. Eye and Ear employees

All researchers working within the Eye and Ear environment require credentialing for their research role. If the researcher is a current Eye and Ear employee and the role to be performed in the research project is NOT within his or her current scope of practice, or determined by the Research Office to lack appropriate experience for the role, approval will NOT be granted.

## 3. Honorary Researchers

### 3.1 The following individuals may apply for an Eye and Ear Honorary Researcher Appointment (HRA):

- An Eye and Ear employee leaves the employ of the Eye and Ear, but continues to be involved in the research project
- Staff employed by a research partner
- Staff employed by a third party
- Students undertaking a research project as part of their course of study
- Volunteers

### 3.2 Requirement for an Honorary Researcher Appointment

3.2.1 An Honorary Researcher Appointment is required for the following purposes:

- Access to Eye and Ear medical records (hard copy and electronic)
- The researcher's role on the research project requires contact with Eye and Ear patients, as follows
  - i Patient recruitment and obtaining consent
  - ii Conducting interviews and questionnaires
- A research related activity requires the researcher to be physically located in non-public areas of Eye and Ear premises
- Other research related responsibilities involving Eye and Ear patients, staff, resources, facilities

3.2.2 An Honorary Researcher Appointment is not required for

- Members of a research team, including Principal Investigators, on a research project that has been submitted for Eye and Ear HREC review and the project does not involve Eye and Ear patients, staff, resources or facilities.

### 3.3 Honorary Researcher Appointments will not be granted for

- Any clinical treatment involving Eye and Ear patients
  - Any clinical procedure involving Eye and Ear patients must be performed by an Eye and Ear employee according to any Eye and Ear credentialing procedures.
  - Employees of external organisations who require an Honorary Researcher Appointment in a clinical capacity should apply according to the Procedure for Recruitment, Credentialing, Scope of Practice and Appointment of Senior Medical Staff
- Any research procedure as per the Protocol
  - Any individual conducting a research procedure must be credentialed by the organisation employing the individual.

### 3.4 Medical Students

- Medical students are able to be granted an Honorary Researcher Appointment subject to the following
  - Medical Students must be supervised by a specific Eye and Ear employee at all times
  - Supervisors are responsible for ensuring medical students have appropriate supervision for the role they are undertaking
- Medical Students can only have a Scope of Practice for access to medical records, conducting interviews/questionnaires and physically located in non-public areas of Eye and Ear premises under supervision of their supervisor.
- Medical Students are not permitted to independently recruit and consent Eye and Ear patients into research projects.

### 3.5 Authorisation and accountability

The Honorary Researcher Application must be supported and authorised by an Eye and Ear Head of Clinic/Unit/Department or Executive Director.

That Head of Clinic/Unit/Department and/or Executive Director is responsible for the Honorary Researcher during the period of the appointment.

### 3.6. Application Procedure

#### 3.6.1 Application Form

Applicants must complete an Honorary Researcher Application Form.

The Honorary Researcher Application form is available for download from the Eye and Ear Research website.

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All information related to applications for Honorary Researcher appointments are available on the Research website.

The applicant should complete and submit the most current version of the application form to the Research Office as instructed:

- Handwritten applications are not accepted
- The application form must be complete, including signature from an Eye and Ear Head of Clinic and all supporting documentation, to be accepted for review

3.6.2 The application must include the following:

3.6.2.1 Evidence of current role

The applicant must provide evidence of current appointment

| Current role                     | Evidence required                          | Examples                     |
|----------------------------------|--|------------------------------|
| Employee of research partner     | Evidence of employment                     | Letter of appointment        |
| Employee of another organisation | Evidence of employment                     | Letter of appointment        |
| Student at a University          | Evidence of enrolment in the research unit | Course enrolment certificate |
| Volunteer                        | Curriculum Vitae with 3 references         |                              |

3.6.3 Scope of Practice and credentialing

3.6.3.1 Appropriate role in research activity and risk assessment

All applicants are required to submit

- A current resume/curriculum vitae (CV)
  - The Eye and Ear will assess the applicant has an appropriate reason to be involved in the research activity by reviewing the applicants CV and in some cases contacting referees
- A National Police Check
  - The Eye and Ear will assess the risk associated with the applicant by reviewing a National Police Check
  - The National Police Check must be dated within the past 3 months

3.6.3.2 Applicants involved in a research related activity which usually involves direct contact with children are required to submit

- Working with Children Check
  - The Eye and Ear will assess the risk associated with the applicant by reviewing a Working with Children Check (WWCC)
  - The Working with Children Check must be current and not expired

### 3.6.4 English language requirements

For researchers who have received their education in non-English speaking countries, evidence of proficiency of the English language is required. The minimum requirement for the English language (IELTS) is as per AHPRA requirements (a minimum of 7 in each section).

### 3.6.5 Health check requirements

As an honorary researcher working within a health care facility, there are mandatory vaccination requirements. Based on the requested scope of practice, an occupational risk category is considered. Refer to table below:

| <b>Category</b> | <b>Risk Category Descriptor</b>  | <b>Summary of the risk category</b>  |
|-----------------|--|--|
| A               | <i>Healthcare workers at risk of acquisition and/or transmission of blood borne viruses and infectious spread via respiratory or enteric routes.</i> | <i>Healthcare workers with direct physical contact with patients, clients, deceased persons or body parts, blood, body substances, infectious material or surfaces or equipment that might contain these. For example, workers with prolonged face-to-face contact with patients or clients or where their normal work is in a clinical area</i> |
| B               | <i>Healthcare workers at risk of acquisition and/or transmission of infections via respiratory or enteric routes.</i>                                | <i>Healthcare workers who rarely have direct physical contact with patients, clients, deceased persons or body parts, blood, body substances, infectious material or surfaces or equipment that might contain these.</i>   |
| C               | <i>Healthcare workers at risk of acquisition and/or transmission of infectious spread via respiratory routes.</i>                                    | <i>Healthcare worker with no direct physical contact with patients, clients, deceased persons or body parts, blood, body substances, infectious material or surfaces or equipment that might contain these.</i>  |

All Researchers are required to provide evidence of their health status based on their occupational risk category. The Honorary Researcher Health Survey must be completed and submitted along with the relevant evidence. This documentation

will be provided to the Eye and Ear Infection Prevention and Control team for review and approval prior to commencing. Suitable proof will include an Australian Immunisation certificate (or equivalent) and blood tests (serology) must be provided with suitable identifiers. Researchers who fall under Occupational Risk Category A or B must provide evidence of receiving a seasonal influenza vaccination on an annual basis.

### 3.6.6 Credentialing for specific scope of practice

#### 3.6.6.1 Access to medical records

For access to medical records the applicant must demonstrate

- Evidence of current AHPRA registration; or
- evidence of Health Records Act training

#### 3.6.6.2 Recruitment and/or obtaining consent for a research related activity of Eye and Ear patients

For this Scope of Practice the applicant must demonstrate

- Evidence of current AHPRA registration; or evidence of Health Records Act training;
- Evidence of hand hygiene training;
- English Language proficiency (if education not from a recognised country as per AHPRA registration);
- evidence of Good Clinical Practice training (if the research project is a clinical trial).

#### 3.6.6.3 Interviews/survey for a research related activity of Eye and Ear patients

For this Scope of Practice the applicant must demonstrate

- Evidence of current AHPRA registration; or evidence of Health Records Act training;
- Evidence of hand hygiene training;
- English Language proficiency (if education not from a recognised country as per AHPRA registration); and
- If the research project is a clinical trial, evidence of Good Clinical Practice training;

## 3.7 Salary / payment

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Honorary Researcher appointments do not have a salary or any other financial benefit associated with the appointment.

### 3.8 Length of appointment

The maximum length of a term of appointment will be 5 years.

The term of the appointment will be determined by the purpose of the Honorary Researcher Appointment and the length of the activity

### 3.9 Title of appointment

A successful applicant will be able to use the title Eye and Ear Hospital Honorary Researcher.

### 3.10 Conduct

Honorary Researchers are required to comply with

- Eye and Ear policies and procedures
- All research related codes

### 3.11 Application Review procedure

- Research Office staff are responsible for reviewing and approving Honorary Researcher Appointments
- Applications will be reviewed with the Director Medical Services and/or Executive Director Medical Services if there are any concerns or queries.
- Applications may be
  - Approved
  - Approved with amendment

The applicant will be notified by email and once the response has been received the application will be reconsidered by the Research Office staff

- Not approved

The applicant will be notified by email

The applicant can appeal the decision as per the Eye and Ear Research Office Complaints Procedure

### 3.12 Approved appointments

- The applicant will receive a letter of appointment
- An Eye and Ear identification badge will be allocated to researchers with an approved Honorary Researcher Appointment if they need to be physically located on site within the hospital. The ID badge is available from the Research Office. This badge is to be worn at all times within the Hospital.
- Access to the Eye and Ear Hospital's ICT systems will be organised through the Research Office, in alignment with the approved scope of practice.

### 3.13 Duration of appointment

- The applicant is required to advise the Eye and Ear Research Office if any aspect of their situation changes i.e., no longer involved in research at the hospital
- The Research Office keeps a list of all current HRA and their defined scope of practice.
- Spot audits may be undertaken to ensure all researchers who are interacting with Eye and Ear patients or accessing records have appropriate identification and are working within their defined scope of practice.

### 3.14 Amendment of HRA

- Requests for amendments to an HRA should be submitted to the Research Office by completing the Honorary Researcher Application and providing relevant evidence.
- From time to time, the Eye and Ear may make changes to Honorary Researcher appointment policies and procedures. The Eye and Ear may contact an HR to make changes to the appointment.

### 3.15 Renewal of appointments

If required, prior to the end of the appointment, the Honorary Researcher should apply for an extension to the term of the appointment by completing the Honorary Researcher Application.

- The renewal does not require resubmission of a new Police Check or additional evidence.
- The request will be reviewed by the Research Office.

#### Approved requests

- The applicant will receive a letter of renewal of Honorary Researcher Appointment

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### 3.16 Termination of appointment

- Termination of the HRA will be immediate if the Honorary Researcher leaves the employment of the research partner or third party organisation.
- If an Honorary Researcher is no longer involved in research at the Eye and Ear, the RO must be notified and any permission(s)/access granted to the Honorary Researcher will be withdrawn.

#### Outcome:

To ensure that all individuals involved in research related activity involving the Eye and Ear are credentialed to undertake the role specified for their research projects and are acting within an approved scope of practice.

#### Definitions:

**HR** : Honorary Researcher

**HRA** : Honorary Researcher Appointment

**PI** : Principal Investigator

**RO** : Research Office

#### Standard:



NSQHS Standard 1: Clinical Governance

#### Legislation:

Current Legislation may be sourced at: <http://www.austlii.edu.au/> or Victorian legislation at: <https://www.legislation.vic.gov.au/>

#### References:

- [National Statement on Ethical Conduct in Human Research](#) (2025 and as amended)
- [Australian Code for the Responsible Conduct of Research](#) (2018 and as amended)
- [Guidelines for Good Clinical Practice](#)
- [National Clinical Trials Governance Framework](#)

## Linked Policy & Procedure:

- Research Policy
- Procedure for Recruitment, Credentialing, Scope of Practice, Appointment and Reappointment of Senior Medical Staff

## Approval/Committees:

Research Committee

## Responsible Executive:

Executive Director Medical Services

## Document Author:

Research Manager

## Evaluation:

Processes and procedures are evaluated within the context of organisation risk management accreditation and legislative standards.

## Procedure Review:

This procedure will be reviewed - in 3 years to assess effectiveness and fit for purpose.

## Author/ Co-Authors:

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|-----------------|--|-----------------------|
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## Version Details:

| Details              |                                      |
|----------------------|--------------------------------------|
| Procedure No:        | RVEE0195709                          |
| Parent Policy:       | Research Policy                      |
| National Standard:   | Clinical Governance                  |
| Legislation Section: | E - Patient's Rights<br>F - Privacy  |
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