Research Office
Procedure for Credentialing of Researchers

Purpose:

To describe the procedure for credentialing researchers employed by the Royal Victorian Eye and Ear Hospital (Eye and Ear) and Honorary Researchers working within the Eye and Ear environment.

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.

Procedure / Method:

All researchers working within the Eye and Ear environment require credentialing for their research role. Refer to Appendix 1 – Researcher Credentialing - Matrix of Requirements.

1. For each Principal Investigator (PI), Researcher and Trial Co-ordinator listed on a research ethics application, a fully completed Researcher's Declaration must be signed and submitted to the Research Office (RO). This form constitutes an application to be credentialed and to obtain a scope of practice either with the application or as part of an amendment or reapplication. An up to date curriculum vitae should also be provided, if not provided in the previous two years.

2. The Researcher Credentialing Committee will review the credentials for each researcher based, in the first instance on the information supplied in the Researcher Declaration form. This form is available on the Research area of the Eye and Ear internet site and once completed, should be submitted to the Research Office (RO).

   - In addition to the Researcher Declaration Form, the Credentialing Committee's review will considers the adequacy, recency and evidence of sufficient training in: Good Clinical Practice (GCP) training;*
   - fire and hospital emergency code training;
   - hand hygiene;
   - patient identification; and
   - aseptic technique, if invasive treatment given, e.g. venepuncture

   All potential Eye and Ear clinical and research staff must also supply a:

   - Police check
   - Working with Children check (if working with children in project scope and contact with a child is unsupervised, direct and a part of the person's duties)
   - Health Record Act training (if not AHPRA registered)

   *From 1 March 2016, GCP training is required for Principal Investigators (PI) of interventional trials or drug/device trials requiring a CTN notification. GCP training is required every three years. It is likely that the mandate for GCP training will be extended over time to include all clinical researchers. All other PIs and clinical research staff are strongly encouraged to complete GCP training and keep it up to date.

   The training should be TransCelerate approved.

3. Honorary researcher appointments will be granted for a period of five years, and will not be project specific. If the researcher wishes to extend his/her honorary appointment beyond five years, a request to the Research Office for an extension is required.

4. If the researcher is a current employee of the Eye and Ear, and the role to be performed in the research project is within his or her current scope of practice, approval will be granted by the Researcher Credentialing and Implementation Committee.

5. If the researcher is a current employee of the Eye and Ear, and the role to be performed in the research project is not within her or his current scope of practice, with supporting information, the Committee will consider amending the scope of practice.

6. If the researcher has a current Eye and Ear honorary appointment and the role to be performed in the research project is not within his or her current scope, with supporting information, the Researcher Credentialing Committee will consider whether a change to the scope of practice is required and whether to approve such a change.

7. If the researcher does not have any Eye and Ear appointment but will be directly involved in patient care, or require access to the health medical record (including Electronic Medical Record (EMR), the Researcher Credentialing Committee will consider whether an Eye and Ear honorary appointment and a defined scope of practice are required.

8. 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).

9. An Eye and Ear ID badge will be allocated to researchers with an approved honorary appointment. This badge is to be worn at all times within the Hospital.

10. The Research Office keeps a list of all current hospital employed and honorary researchers, and their defined scope of practice. A list will be available to Clinic Managers.

11. 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.

12. If a researcher leaves the employ of the Eye and Ear, but continues to be involved in the research project in another capacity, the Researcher Credentialing Committee will consider whether an Eye and Ear honorary appointment and a defined scope of practice are required.

    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 researchers are credentialed to undertake the role specified for their research projects and are acting within an approved scope of practice.

Definitions:

RO Research Office
PI Principal Investigator

Standard:

National Standard 1 Governance References:

National Statement on Ethical Conduct in Human Research (2007 and as amended)

Australian Code for the Responsible Conduct of Research (2007 and as amended)

Note for Guidance on Good Clinical Practice (CPMP/ICH/135/95) annotated with TGA comments

Linked Policy & Procedure:

Research Policy

Approval / Committees:

This procedure was approved by the Researcher Credentialing Committee.

Evaluation:

This procedure will be reviewed every three years, or earlier if credentialing arrangements change, by the Researcher Credentialing Committee and the Executive Director Medical Services/Chief Medical Officer.

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Policy / Procedure Details:

Details		
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Attachment 1 Researcher Credentialing Matrix of Requirements

Credentialing Requirement / Project Type	Researcher Declaration Form	Curriculum Vitae (if not provided in past year)	Police Check	Working With Children Check	Health Record Act (if not AHPRA registered)	Hand Hygiene	Researcher Handbook Compliance Sign Off	Good Clinical Practice
Eye and Ear employed researcher	√	√	In place as employee	In place as employee, if working with children in scope of role	In place as employee	In place as employee	In place as employee	Reqd if PI on interventional trial Others - not at this point but is highly recommended
Principal Investigator on interventional drug/device trial	√	√	√	If working with children in project scope and contact with a child is unsupervised, direct and a part of the person's duties	√	√	√	√
Principal Investigator on non-interventional clinical research project with patient contact and medical record access	√	√	√	If working with children in project scope and contact with a child is unsupervised, direct and a part of the person's duties	√	√	√	Not at this point but is highly recommended
Principal Investigator with oversight of research project with no Eye and Ear patient contact	√	√	√	-	√	-	-	Not at this point but is highly recommended
Researcher on project with patient contact and medical record access	√	√	√	If working with children in project scope and contact with a child is unsupervised, direct and a part of the person's duties	√	√	√	Not at this point but is highly recommended
Researcher on project involving medical record access only	√	√	√	-	√	-	-	Not at this point but is highly recommended