Research Office Procedure
When a Principal Investigator Leaves the Eye and Ear Precinct

Purpose

To ensure the transparent transfer of arrangement for continuation, transfer or cessation of research projects when a Principal Investigator, on projects approved by the Royal Victorian Eye and Ear (Eye and Ear) Human Research Ethics Committee (HREC) departs the Eye and Ear research precinct.

Scope

This procedure applies to all Eye and Ear Staff and Honorary Researchers who are Principal Investigators (PI) and departing the Eye and Ear.

Background

When principal researchers leave the Eye and Ear, a variety of legal, financial, ethical and contractual issues may arise.

The following principles are most applicable to clinical research projects and provide guidance for an orderly handover of responsibilities when a key researcher leaves the Eye and Ear.

In the case of laboratory studies not involving human subjects, the removal of data and records will generally be determined in discussion with the department, laboratory or institution Head.

Procedure

General principles applying when Principal Investigators leave the Eye and Ear

1. **Sponsored Trial**:

   Where the research trial is governed by a Clinical Trial Research Agreement (CTRA) which has been executed by the Eye and Ear, the processes to occur on departure of the PI shall be as detailed in that agreement and shall take precedence over any provisions detailed below should there be a conflict between that agreement and these guidelines.

2. **Viability of the Study**:

   A decision between the PI and his or her research Department Head must be first made as to whether it is viable to continue the study.

   If the project is to relocate, the impact of this decision on research participants must be taken into consideration.

   If it is judged to not be possible to continue the study, the project should be wound up. It remains the PI's responsibility to submit the relevant final reports to the HREC and to ensure that records relating to the study are preserved in accordance with International Committee on Harmonisation Code of Good Clinical Practice.

3. **Principal Investigator leaving the Eye and Ear**:

   When a PI leaves, early consideration must be given to on-going project arrangements. If the departing PI no longer holds appointments at the Eye and Ear and/or its partner research organisations, the responsibility for the trial must be transferred to another suitably experienced researcher, be transferred with the PI if appropriate or the study closed. In cases where most of the data has already been collected, this may be appropriate. When the study is at an earlier stage, and particularly when the study requires the enlistment of hospital patients or studies conducted on-site at the hospital, a replacement PI should be sought by discussion between the PI, the other investigators and the Head of Department.

   All proposed changes in study personnel must be submitted for approval in writing to the HREC at the earliest opportunity and to ensure the new personnel has/seeks an Honorary Researcher appointment.

4. **Study records**:

When a study involves patients of the Eye and Ear or volunteers studied on site, the original copies of all study documentation must be retained at the Eye and Ear or at an approved collaborator's facilities (eg: CERA, Dept of Otolaryngology). The Eye and Ear, Research Office must have unrestricted access to the documents during the study and for the required period after the completion of the study. On completion of the study, it is the responsibility of the PI and the Head of Department to ensure that all documentation is archived in keeping with Hospital and Research Office policies and procedures.

Only copies of documentation may be removed by departing investigators and subject to permission from the Eye and Ear's Research Manager. A record of exactly what has been copied, by whom, for what reason and where it will subsequently be stored must be kept, especially if the data copied includes patient identification. When such copies of records include identifiable patient information, approval must be requested from the HREC.

5**.** **Equipment**:

Except where specified by an explicit agreement with a donor or sponsor, all equipment purchased using funds administered by the Eye and Ear is the property of the Hospital. A departing PI may request permission in writing, to the Research Manager, to take with him/her items of equipment purchased with funds gained from external granting bodies.

6. **Drug stocks**

If the research is a drug trial, there must be full accountability for the study drug including counting of stock, ownership and return of stock.

7. **Biological specimens**:

These may include various biospecimens collected as part of a research program.

A departing PI must ensure there is good governance in place and approved for any samples remaining including leaving full details of sample locations within freezers, sample integrity requirements such as optimal storage temperatures, periods of storage and any other information that is key to maintain sample integrity.

When a departing PI has particular expertise in the analysis and/or processing of such specimens it may be appropriate for them to be taken by this individual. However, such removal must be undertaken in a systematic and ordered fashion. This will involve:

- documenting the exact nature and origin of the specimens and whether the specimens are marked with identifiable patient information;
- securing approval in writing from co-investigators and the head of department;
- providing such documentation to the HREC which will include details of the proposed new site where the specimens will be housed;
- if the HREC approves the request there should be a formal written handover from one HREC to the other, noting that the specimens can only be used for the purpose for which the patient has given informed consent and not for other future unspecified studies unless further ethics approval is obtained from the new institution; and
- a completed material transfer agreement reflecting the transfer must be completed.

8. **Legal and contractual responsibilities:**

A proportion of the research undertaken at the Eye and Ear is conducted under contractual agreements with industry. This often requires strict adherence to timelines and may place additional requirements (eg. attendance at meetings, financial reporting) on the responsible investigator. Where there is an agreement in place, clauses in the agreement must be adhered to.

When a PI departs from the hospital there must be a detailed review of relevant projects to determine the responsibility of the Institution in relation to the project. If this is substantial, the Research Manager will convene a meeting involving the outgoing responsible PI, the other investigators and the Head of Department to clarify the nature of the continuing responsibility and to select a new PI who can ensure that these responsibilities are met. Following this meeting the sponsoring company should be contacted and a meeting arranged to discuss proposals for the continuation of the study. The departing investigator must co-operate with the Eye and Ear to ensure any obligations to third parties are met. The Research Office is to be informed of all relevant details.

9. **Research grants (including budgets):**

When a PI moves from one institution to another, it is often appropriate for the administration of the grant to be transferred. This is most clear-cut when a responsible investigator will retain administrative responsibility for the project. In such cases approval must be sought from the granting body and the research head within the institution ie. the Department Head or the University Head of School. Before a budget is transferred, a senior Finance Department Officer from the relevant organisation(s) must review the budget and provide a written endorsement indicating that all outstanding financial responsibilities have been met.

10. **Intellectual Property:**

Where the PI is a hospital employee and is conducting the research in a hospital capacity, all intellectual property in relation to the project shall be owned by the Eye and Ear unless there is a specific written agreement stating otherwise. Refer to IM3.6 Intellectual Property Commercialisation Procedure.

Special circumstances

When the departing Principal Investigator is a Head of Department:

Under these circumstances the departing investigator must not remove any records or specimens, or arrange any transfers of funds, without permission of the Executive Director Medical Services / Chief Medical Officer and University Head of School /Head of Research Partner Organisation, as applicable. Before approving any new arrangements, they will arrange a review of all research projects being undertaken which involve the individual concerned. A report from the Research Office and/or the University will be sought paying particular attention to incomplete commercial contracts.

Dispute Resolution

When a PI leaves an institution, the following matters need to be considered and openly discussed to reduce the potential for disputes to arise:

- whether all costs within the institution have been met before funds are transferred to another institution;
- the handling of outstanding commercial obligations; and
- whether it is appropriate to transfer records or biospecimens from the Hospital.

In some instances these will be complex issues which will require a detailed review by a third party. If there is a dispute over whether all payments have been made, a formal audit may be required.

Under no circumstances will a former member of staff be permitted to remove funds before appropriate approval is obtained or operate a special purpose account once they have departed from the institution.

If any matters cannot be resolved, the advice of people in the following roles is key to seeking resolution; Executive Director Medical Services / Chief Medical Officer, University Head of Department, Chair of Senior Medical Staff, Clinical Directors or Chief Operations Officer/Chief Nursing Officer, as applicable to the area of research under scrutiny.

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Standards:

NHMRC Australian Code for the Responsible Conduct of Research (The Code) (2007)

Note for guidance on Good Clinical Practice (CPMP/ICH/135/96) annotated with TGA comments DSEB, July 2000

Linked Policy & Procedure:

Research Policy

IM3.6 Intellectual Property Commercialisation Procedure

Approval / Committees:

Executive Director Medical Services/Chief Medical Officer

Responsible Executive:

Executive Director Medical Services/Chief Medical Officer

Evaluation:

This procedure will be reviewed to comply with current legislation, regulations, industry standards, guidelines and codes of conduct.

Procedure Review:

This procedure will be reviewed every three years.

Key words for search

Research, Principal Investigator (PI), departing, HREC

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Policy / Procedure Details:

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Leaving Checklist

Matters to consider	Comments	Completed
Ongoing project arrangements		
HREC notified		
Study records		
Equipment		
Drug stocks		
Biospecimens		
Research Agreements		
Research Grants		