

Guidelines to apply when researchers leave The Alfred

Introduction

When researchers leave The Alfred to take up positions in other institutions, a variety of legal, financial, ethical and contractual issues may arise. The likelihood of disputes is relatively high and, therefore, explicit procedures are necessary to provide advance guidance as to what is likely to be acceptable.

There is less likelihood of disputes taking place on the departure of an investigator if appropriate procedures have been established well in advance of this eventuality. In particular, disputes are likely to be reduced by a high degree of financial transparency in the handling of study budgets, particularly amongst the study investigators.

Disputes may also arise about the ownership of biological specimens and source data obtained as part of a research project. As a general principle, access to these must be available to all investigators on a project to allow for completion in accordance with the Ethics Committee approval. Specimens and other research material (including original copies of data gathered as part of a research program) should only be removed from The Alfred under appropriate circumstances (see General Principles).

The following principles provide guidance for an orderly handover of responsibilities when a researcher leaves The Alfred; they apply principally to clinical research projects. In the case of laboratory studies not involving human subjects, or other AMREP based collaborators, the removal of data and records will generally be determined in discussion with the department, laboratory or institution head.

Relevant parties

The likelihood of serious disputes will be reduced if the particular role and responsibility of each relevant party is understood.

Those with particular decision making responsibilities are:

- 1. Responsible investigator:** This is usually the first named of the investigators and is typically the person who initiated the project and sought the funding. He/she bears primary responsibility for the conduct of the study, for its adherence to good research practice guidelines and ethical requirements, and for management of the study budget.
- 2. Other investigators:** These are the other individuals named as 'chief investigators' or 'co-investigators' on the research grant or proposal. They are typically enlisted because of particular skills that they bring to the project or because of their access to resources. In general, they have only a secondary level of responsibility for the conduct of the study or for the management of the study budget.
- 3. Head of Department:** He/she is responsible for establishing mechanisms to ensure that all studies undertaken within his/her department are conducted to appropriate scientific and ethical standards. He/she is also responsible for ensuring that the budget is expended appropriately and in accordance with the study budget and the policies of the institution. He/she is not necessarily the 'Responsible investigator for a research study'.
- 4. Executive Director of Medical Services:** has ultimate decision-making capacity for issues related to the research activities of medical staff. These include matters related to departmental budgets.
- 5. Director of Nursing:** has ultimate decision making capacity for issues related to the research activities of nursing staff, including budgets.
- 6. Director, Support Services:** has ultimate decision making capacity for issues related to the research activities of allied health staff, including budgets.
- 7. Monash University Head, Central and Eastern Clinical School:** has ultimate responsibility for research activities carried out under the name of Monash University. He/she also has ultimate control over study budgets managed via the university.

General principles applying when investigators leave The Alfred

- 1. New responsible investigator:** An early decision must be made as to future supervision of the study. This should be determined principally by the responsible investigator who will determine whether he/she is able to retain supervision of the study from his/her new position. 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 responsible investigator should be sought by discussion between the responsible investigator, the other investigators and the head of department.

All changes in study personnel must be reported in writing to the Ethics Committee and the Research & Ethics Unit at the earliest opportunity.

- 2. Study records:** When a study involves patients of The Alfred or volunteers studied on site, the original copies of all study documentation must be retained at The Alfred. On completion of the study it is the responsibility of the responsible investigator and the head of department to ensure that all documentation is archived in keeping with hospital policy. Only copies of documentation may be removed by departing investigators.

When copies of records are removed by departing investigators, 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 Ethics Committee and the Research & Ethics Unit.

- 3. Equipment:** All equipment purchased using funds administered by the hospital is the property of the hospital. A departing responsible investigator may request permission in writing to take with him/her items of equipment purchased with funds gained from outside granting bodies. The head of department and/or the Executive Director of Medical Services should generally approve such requests where the departing responsible investigator bore the sole or major responsibility for securing the funds to purchase the equipment and if the equipment is not needed for the continuation of this project.

- 4. Biological specimens:** These may include various tissue or blood samples collected as part of a research program. When a departing chief investigator 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 Ethics Committee which will include details of the proposed new site where the specimens will be housed;
 - If the Ethics Committee approves the request there should be a formal written handover from one Ethics Committee 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.

- 5. Legal and contractual responsibilities:** A proportion of the research undertaken at The Alfred 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. When an investigator 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, a meeting involving the outgoing responsible investigator, the other investigators and the head of department must be held to clarify the nature of the continuing responsibility and to select a new responsible investigator 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. These should also be communicated to the Executive Director of Medical Services / University head of school / appropriate hospital director, the Ethics Committee and the Research & Ethics Unit.

- 6. Research grants (including budgets):** When a responsible investigator 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 more senior officer must review the budget and provide a written endorsement indicating that all outstanding financial responsibilities have been met.

Special circumstances

When the departing 'responsible 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 of Medical Services / University Head of School / appropriate hospital director, 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 & Ethics Unit and/or the university will be sought paying particular attention to incomplete commercial contracts.

Resolution of disputes

When a senior investigator leaves an institution, potential disputes are most likely to arise over:

- whether all costs within the institution have been met before funds are transferred to another institution
- the handling of outstanding commercial obligations
- whether it is appropriate to remove records or specimens from the hospital.

In some instances these will be complex issues which will require a detailed review by a third party. Where 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.

A dispute procedure will be available to deal with disputes in relation to any of the above matters. Appointees will include two or more of the Executive Director of Medical Services, University Head of School, Chair of Ethics Committee, Chair of Senior Medical Staff, Director Research Strategy, Director of Nursing, Director Support Services, as applicable.