Co-enrolment of participants

The Alfred Hospital Ethics Committee guideline on ‘Participant enrolment in concurrent research projects’ has been developed to provide researchers with guidance on the issue of enrolling a person in more than one study at the same time.

As a general rule, participants should not take part in more than one interventional study at any one time.

There are several reasons for this approach:

• Being enrolled in more than one interventional research project may put participants at risk, when e.g. two interventional drugs influence each other’s metabolism and result in an accumulation of one of the drugs.

• Apart from physical risks, co-enrolment may lead to participants and their families being unduly burdened (section 1.4 of the National Statement).

• The scientific validity of data may be compromised, and

• Contractual arrangements may actually stipulate concurrent enrolment as an exclusion criterion.

In cases where researchers believe that participation in more than one interventional study does not involve additional risk or burden to participants, the guideline outlines steps that should be taken.

For applications to be submitted, the Alfred Specific Form and Module I have been revised to capture whether co-enrolment of participants in other interventional studies is intended.

For non-interventional studies, such as observational studies, surveys, interviews, etc., a common sense approach should be used when considering enrolment of a participant already taking part in other study. Patients should not be overburdened by such requests and should be reminded that their participation is voluntary. Consultation with the relevant heads of departments and/or the Ethics Committee may be useful when these issues arise or become contentious.

Please note that the Ethics Committee does not need to be notified in cases where a participant is enrolled in an additional non-interventional study.

The established methods of ‘flagging’ research participation in the patient’s medical record should be used to alert researchers and medical staff to a patient’s current research participation. These methods include listing the study on the alert sheet at the front of the medical record and inserting a copy of the Participant Information and Consent Form (PICF) and/or other relevant information in the research section of the medical record.

Please refer to the guideline for more information.

Change in complaints contact details in PICFs

Please note that we have changed the way the contact details for the person dealing with complaints are to be listed in the PICF. While the phone number and email are the same, we no longer list Emily’s name.

For studies conducted at Alfred Health:

For any complaints about any aspect of the project, the way it is being conducted or any questions about being a research participant in general, please advise participants to contact the Complaints Officer; Telephone: (03) 9076 3619; Email: research@alfred.org.au

Underneath these details, for single site submissions, please include the following sentence after the complaints contact details:

“You will need to tell the person the following Alfred Health project number: (insert project number)”
We have moved!

The Office of Ethics & Research Governance has moved. You can find us on level 1 of the Old Baker Building (see map below). Enter from Alfred Lane, take the lift up to level 1, coming out of the lift turn right and then left – we are at the end of the hallway.

In-trays for document drop-off and collection can be found at the entrance to the office.

If you wish to meet with a staff member, just give us a call or send an email.

Possible delays in completion of Medical Physicist reports

As previously advised via email, Alfred Health’s Medical Physicist/Radiation Safety Officer will be on leave from 14 Oct to 14 Nov. While the completion of reports will be contracted out, there may be some delays in Medical Physicist reports being completed.

We do not envisage that this will constitute an issue for the next round of ethics applications, as the November meeting takes place on 24 Nov only. Approval of amendments requiring a Medical Physicist report may be delayed slightly.

Thank you for your understanding.

Welcome Baby Marcus!

Congratulations to Kevin and his wife Min on the arrival of their first child!

After spending some time with Marcus and supporting Min, we are happy to have Kevin back in the office and look forward to status reports on little Markus.

Another Arrival

As part of the upgrades to Alfred Health’s internet presence, a new website has been created for the Office of Ethics & Governance. Please note that the site is still under construction – upgrades are made on a daily basis. Thank you for your patience.

Our old website will still be available until the end of November.
Updates to…

a) GUIDELINES/POLICIES

- **Publication of Case Study Reports**

  The guideline applies to the publication/dissemination of case study reports about Alfred Health patients (individual cases and case series) in medical journals, theses or presentations.

  A PDF of the ‘Consent for Publication of Case Study Report’ to be used to record the patient’s consent is attached to the guideline. For a Word version, please email the office. Written consent should be obtained, wherever possible — please refer to the guideline for exceptions. Ethics approval is required for certain scenarios.

- **Health Information Privacy guideline and policy**

  All staff and people engaged or doing work for Alfred Health who collect, access, use or disclose health information should familiarise themselves with these documents. In this context also note the Clinical Photography guideline (see right).

- **Clinical Photography**

  The document describes the principles in relation to collection, use, disclosure, and management of clinical photographs at Alfred Health, in particular regarding patient consent. The guideline has been updated to bring it in line with current clinical practice with clinical photography. Before taking a clinical photograph, staff must obtain consent using Alfred Health’s [Consent to Photography form](#).

- **Alfred Health Support for Clinical Registries**

  Researchers wishing to establish a clinical registry to collect data on Alfred Health patients’ (for example those undergoing a specific procedure) should familiarise themselves with this policy and liaise with the organisational data steward to discuss the nature and purpose of the proposed registry.

  Ethics approval is also required. To discuss an ethics application for a clinical registry, please contact [Kevin](mailto:kevin@alfred.org) or [Kordula](mailto:kordula@alfred.org).

- **Appointment of Medical Observers**

  The guideline details the requirements for the appointment of medical observers (including medical student observers). Note that the definition of a medical observer does NOT include: a medical visitor, medical honorary appointee and medical student electives.

b) WEBSITE

- **Resource Centre Declarations**

  The RCDs for the following services have been updated:
  - Medical records (Health Information Services)
  - Radiology
  - Nursing (for research involving nurses or nursing resources)

  Please note the following, new RCD for ‘Application & Knowledge Management’, to be included in ethics applications for registries, using REDCap or data from the REASON Discovery Platform.

- **Research Collaboration Agreement template**

  Please use the [Research Collaboration Agreement template - Alfred Health](#) for investigator-initiated research projects not testing a drug or device. Use of the template is preferred over non-template agreements, since the latter will require review by Alfred Health’s legal counsel.

- **Module 1/Alfred-Specific Form**

  Module 1 and the ASF have been updated to capture enrolment of participants into more than one research project at a time. Please see page 1 for more information.

---

Happy Friday!