
ALFRED HOSPITAL ETHICS COMMITTEE GUIDELINES: PARTICIPANT ENROLMENT IN CONCURRENT RESEARCH PROJECTS

PURPOSE AND SCOPE

This document aims to provide a clear statement of the approach adopted by the Alfred Hospital Ethics Committee regarding the enrolment of participants in concurrent research projects (i.e. the involvement of patients in more than one research project at any one time).

GUIDELINES

Unit/departmental heads are responsible for ensuring that the level of research taking place within a department does not overburden patients.

Flagging research participation

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*.

Interventional Studies

1. As a general rule, patients should not be enrolled in more than one **interventional** study at any one time. There are several reasons for this, including:
 - a) the possibility that patients could face an increased risk and/or be unduly burdened by participating in more than one trial;
 - b) a detrimental impact on the scientific validity of data for either trial;
 - c) legal contracts for a trial (such as the Clinical Trial Agreement) that specifically exclude participation in another trial.
2. No patient currently involved in an intervention study should be approached to take part in a second interventional study without formal approval as outlined below.
3. If there is a legal agreement disallowing simultaneous/concurrent participation in other studies, the Participant Information and Consent Form must make this clear to participants and it should also be flagged in the trial alert at the front of the medical record. Clinical Trial Agreements should generally not exclude participation in non-interventional studies, such as questionnaire-based research.
4. In cases where researchers believe that participation in more than one *interventional* study does not involve additional risk or burden to participants, the following steps should be taken:
 - a) The matter should be discussed between the principal researchers of both studies, and the head/s of the clinical units concerned, taking into account the burden and risks to participants and any threats to the validity of either study if both are undertaken concurrently.
 - b) If it is agreed that concurrent participation is appropriate, **and one or both studies are yet to be submitted for ethical review**, approval from the Ethics Committee should be sought as part of the ethics application process. A written comment about issues raised in section (a) above should be provided, endorsed by the principal investigators and/or clinicians involved.

c) If it is agreed that concurrent participation is appropriate, **and both studies are already running**, a written request for approval should be made to the Ethics Committee. This should include a comment about issues raised in section (a) above, endorsed by the principal researchers and/or clinicians involved.

d) Where a HOD is also a researcher, this should be stated. The Ethics Committee will make a note of the potential conflict of interest and reserves the right to seek additional opinions in such cases. The final decision lies with the Ethics Committee

e) When concurrent enrolment is not approved by the Ethics Committee, heads of clinical units (or their delegates) may be required to adjudicate on the priority amongst different studies being undertaken involving patients from their units.

5. The Ethics Committee does not need to be advised when discussion between principal researchers results in one study taking precedence over another unless there is disagreement and an arbiter is needed.
6. Researchers may also approach the Ethics Committee to act as arbiter if they have issues about unfair recruitment practices.

Non-Interventional Studies

1. 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.
2. The Ethics Committee does not need to be notified in cases where a patient is enrolled in an additional non-interventional study.

**Note: Researchers are asked to confirm that they are fulfilling these requirements in the annual Progress Report. The Research Governance Officer also checks that trial alerts and PICFs are included in the medical record when auditing projects.*

Pale blue Research dividers for the medical record are available from supply and in small quantities from Health Information Services.

FURTHER INFORMATION

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