
ALFRED HOSPITAL ETHICS COMMITTEE GUIDELINES: OBTAINING TELEPHONE CONSENT FROM THE PERSON RESPONSIBLE

PURPOSE AND SCOPE

Under the Guardianship and Administration Act (1986) (Part 4A, Div 6), medical research procedures involving adults who lack the capacity to consent may – *with Ethics Committee approval* – be undertaken with the consent of the person responsible (see definition below).

In some situations it may be difficult for researchers to approach, inform and obtain consent from the person responsible *in person*; eg. where there is limited time before the medical research procedures must commence, or where the person responsible is physically unable to attend the hospital.

The following guidelines outline the necessary requirements for the Alfred Hospital Ethics Committee to consider approval of telephone consent by the person responsible.

GUIDELINES

1. In all cases, providing information and obtaining consent from the Person Responsible by telephone (rather than face-to-face) has to be regarded as the exception rather than the rule and must be approved in advance by the Ethics Committee as part of the research protocol.
2. The type of research projects for which phone consent may be acceptable are typically 'lower risk' eg comparing routinely used approaches to care or alternatively where the research is of high significance and must commence immediately for it to be effective.
3. The person providing the explanation of the study by phone must be clearly and manifestly capable of conveying the risks and benefits of the research procedure/s involved. The task can not be delegated to junior staff with limited knowledge of the details of the research protocol.
4. Phone consent involves an additional onus on researchers to provide complete documentation of the consent process. The documentation should demonstrate that there has been a comprehensive telephone conversation and all significant questions raised have been addressed.
5. The submission to the Ethics Committee requesting approval for telephone consent (for new projects or post-approval amendments) should include a planned process for obtaining phone consent containing the following information:

a) Planned verbal approach:

A rough transcript of how the subject of consent would be broached, given that this may be the first instance in which the person responsible learns of the patient's admission.

b) Intention to document:

The researcher must document in the medical record

- why the patient was unable to provide consent
- why a telephone discussion was used
- who the discussion was with (i.e. names of researcher and person responsible)
- how the person responsible was identified (according to the hierarchy set out in the Act*), including any unsuccessful attempts to contact others in the hierarchy
- specific issues raised by the person responsible in the discussion
- arrangements for subsequently obtaining signed consent (see below)

c) Plan to provide written information:

The person responsible must be given the Information and Consent Form (ICF) to read as soon as is practicable. The researcher should transmit this by fax or email where possible, or, failing that, two copies* by Express Post or courier. The date on which the ICF was sent should be documented in the medical record.

**one to be returned and one for the person responsible to keep*

d) Plan for researcher to answer questions:

The researcher must provide contact details and be available to answer any additional questions that the person responsible may have.

e) Plan to obtain signed consent:

The person responsible must be asked to sign the consent section of the ICF.

- The consent section of the ICF should include the date of initial verbal/telephone consent (which may be completed by the researcher before it is posted out) and the date on which the Consent Form was signed.
- The ICF may be signed and posted back to the researchers if it is not possible for the person responsible to come in to the hospital.
- A photocopy of the signed ICF should be included in the medical record and the original kept with the research files.

f) When signed consent is not received:

Researchers should obtain the signed consent of the person responsible wherever possible because it provides additional evidence that consent was given. However, there may be instances when the signed consent is not returned and the medical research procedure has already commenced with phone consent. In such cases, properly documented phone consent (as set out above) would be considered as adequate evidence of person responsible consent. The researcher explaining the study should make clear to the person responsible that if the written consent form is not received and the person responsible does not actively revoke their consent, the original phone consent will stand.

DEFINITIONS

*** Person responsible**

is the first person listed below who is responsible for the patient and who, in the circumstances, is reasonably available and willing and able to make a decision —

- (a) a person appointed by the patient under section 5A of the Medical Treatment Act 1988;
- (b) a person appointed by VCAT to make decisions in relation to the proposed procedure;
- (c) a person appointed under a guardianship order with power to make decisions in relation to the proposed procedure;
- (d) a person appointed by the patient (before the patient became incapable of giving consent) as an enduring guardian with power to make decisions in relation to the proposed procedure;
- (e) a person appointed in writing by the patient (being the person appointed last in time before the patient became incapable of giving consent) to make decisions in relation to medical research procedures that includes the proposed procedure;
- (f) the patient's spouse or domestic partner;
- (g) the patient's primary carer;
- (h) the patient's nearest relative within the meaning of paragraphs (a) to (g) of the definition of "nearest relative".

Nearest relative

in relation to a person means the spouse or domestic partner of that person or, where that person does not have a spouse or domestic partner, the relative of that person first listed in the following paragraphs who has attained the age of 18 years, the elder or eldest of two or more relatives described in any paragraph being preferred to either or any of those relatives regardless of sex—

- (a) son or daughter;
- (b) father or mother;
- (c) brother or sister;
- (d) grandfather or grandmother;
- (e) grandson or granddaughter;
- (f) uncle or aunt;
- (g) nephew or niece.

Approved by The Alfred Hospital Ethics Committee: 23 October 2008
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