ALFRED HOSPITAL ETHICS COMMITTEE GUIDELINE:
REQUIREMENTS FOR A WITNESS TO PARTICIPANT CONSENT

PURPOSE AND SCOPE

This document aims to provide a clear statement of when and why The Alfred Hospital Ethics Committee requires a witness signature on the Participant Information and Consent Form (PICF).

It is important to note the difference between a 'signature witness' and a 'witness to the consent process'. A 'signature witness' merely sees the participant sign consent, whereas a 'witness to the consent process' is present for the whole consent discussion.

A. 'SIGNATURE WITNESS'

What is a 'signature witness' witnessing?

The Participant Information and Consent Form templates for *clinical research*[1] include a place in the consent section for a "witness to participant's signature".

This merely documents that the participant was seen by the witness to sign the consent form/section.

The 'signature witness' ***is not*** verifying the identity of the participant, that the participant was competent, understood the consent discussion or the PICF, nor that sufficient information was provided.

When is it necessary to have a 'signature witness'?

- The Alfred Hospital Ethics Committee does not require someone to witness the signing of the consent form (i.e. a 'signature witness') as part of the written consent process.
- The Alfred Hospital Ethics Committee has no objection to the inclusion of a "witness to participant's signature" on the consent form if this is required by others.

Adapting the PICF if a 'signature witness' is not required

- For non clinical trials: When developing a new PICF for a research project, the "witness to participant's signature" section (from the template) does not need to be included.
- For clinical trials: When developing a new PICF for a clinical trial project, the words "to participant's signature" should be removed from the 'witness' section on the Consent Form page. [i.e. it should simply read: "Name of Witness"] This only needs to be signed when a witness to the **full consent process** is required, in cases where the participant or proxy can't read. (*see Section B below*)
- For existing/already approved PICFs, when a witness to the **full consent process** is not required the 'signature witness' section may be struck out and marked "not required".

[1] Interventional, Genetic, & Non-interventional templates (for Self, Parent & Guardian, Person Responsible) http://www.health.vic.gov.au/clinicaltrials/application-instructions.htm

Monitors who query the annotated form can be directed to these Guidelines for confirmation of the Ethics Committee's stance.

B. WITNESS TO THE CONSENT PROCESS

In some situations, there are regulatory requirements for a witness with broader responsibilities in the informed consent process. Depending on the types of research participants likely to be recruited, researchers may need to factor the following requirements into the consent process as a whole, and the consent section of the PICF may need to be adapted or annotated to capture the witness's role.

When the consent giver can't read

The *ICH Guideline for Good Clinical Practice* requires an impartial witness* if the consent giver (i.e. the participant or their legal representative) can't read [GCP 4.8.9][1].

In such cases the witness must:

- be present for the whole informed consent discussion; and
- sign and date the consent form after the consent giver has done so.

What is this person witnessing?

In signing the consent form, the witness is attesting to the fact that (a) all written information was accurately explained to, and apparently understood by, the consent giver, and (b) informed consent was freely given by the consent giver.

When the participant sometimes has impaired capacity to consent

The *National Statement on Ethical Conduct in Human Research* [4.5.8][2] requires a witness to the consent process if the potential research participant has a temporary or episodic cognitive impairment, intellectual disability or injury, or a mental illness, and consent is being obtained at a time when their condition does not interfere with their capacity to consent.

In such cases the witness must:

- be someone who has the capacity to understand the merits, risks and procedures of the research
- be independent of the research team
- where possible, know the participant and be familiar with his/her condition.

There is no explicit requirement in the National Statement for the witness to sign the consent form. However, the presence of a witness should be documented in the research records.

C. WHEN THE CONSENT PROCESS IS 'SPLIT'

In some circumstances, a person providing clinical care to the participant may also need to provide the explanation of the research and answer questions (e.g. they may be the only one with the necessary expertise). To mitigate the impact of this unequal relationship, another person (e.g. the research coordinator) should complete the consent process and obtain the written consent of the participant.

Both the person who provided the explanation and the person who obtained the written consent should sign the consent form.

- For existing/already approved PICFs, the person who obtained the written consent may sign the section "witness to participant's signature".

- When developing a new PICF for a research project that involves a 'split' consent process, a suitably worded section should be included for the person obtaining the signed consent. [See example below*]

- Documentation associated with this 'split role', such as delegation sheets, should be kept with source documents.

***Sample section for person obtaining signed consent**

Name of Person obtaining signed consent (please print) _____
Signature _____ Date _____

Notes

[1] From ICH-GCP (International Conference on Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH) 'Good Clinical Practice: Consolidated Guideline', published by the Food and Drug Administration, USA). *Note that the National Statement on Ethical Conduct in Human Research (2007) specifies that research involving randomization or blinding (usually clinical research) meets GCP requirements [NS 3.3.3d]*

> 4.8.8 Prior to a subject's participation in the trial, the written informed consent form should be signed and personally dated by the subject or by the subject's legally acceptable representative, and by the person who conducted the informed consent discussion.
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> 4.8.9 If a subject is unable to read or if a legally acceptable representative is unable to read, an impartial witness* should be present during the entire informed consent discussion. After the written informed consent form and any other written information to be provided to subjects is read and explained to the subject or the subject's legally acceptable representative, and after the subject or the subject's legally acceptable representative has orally consented to the subject's participation in the trial, and, if capable of doing so, has signed and personally dated the informed consent form, the witness should sign and personally date the consent form. By signing the consent form, the witness attests that the information in the consent form and any other written information was accurately explained to, and apparently understood by, the subject or the subject's legally acceptable representative, and that informed consent was freely given by the subject or the subject's legally acceptable representative.
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> *** Definition of "impartial witness" (GCP 1.26)**
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> **1.26 Impartial witness**
> A person, who is independent of the trial, who cannot be unfairly influenced by people involved with the trial, who attends the informed consent process if the subject or the subject's legally acceptable representative cannot read, and who reads the informed consent form and any other written information supplied to the subject.

[2] From the NHMRC's National Statement on Ethical Conduct in Human Research (2007): Chapter 4.5: People with a cognitive impairment, an intellectual disability, or a mental illness

> 4.5.5 Consent to participation in research by someone with a cognitive impairment, an intellectual disability, or a mental illness should be sought either from that person if he or she has the capacity to consent, or from the person's guardian or any person or organisation authorised by law.

4.5.6 Where the impairment, disability or illness is temporary or episodic, an attempt should be made to seek consent at a time when the condition does not interfere with the person's capacity to give consent.

4.5.7 The process of seeking the person's consent should include discussion of any possibility that his or her capacity to consent or to participate in the research may vary or be lost altogether. The participant's wishes about what should happen in that circumstance should be followed unless changed circumstances mean that acting in accordance with those wishes would be contrary to the participant's best interests.

4.5.8 Consent under paragraph 4.5.6 should be witnessed by a person who has the capacity to understand the merits, risks and procedures of the research, is independent of the research team and, where possible, knows the participant and is familiar with his or her condition.

Approved by: Alfred Hospital Ethics Committee
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