

Part 8: When a Participant is Unable to Make an Informed Choice

To be completed when one or more participants in a project will likely not be able to make an informed choice about whether to take part. **Do not complete this section if all participants in the study are competent to make an informed choice and give informed consent themselves.** Refer to the Guidelines for information about children in research.

1. Will any of the participants have a person with them who is available and entitled to make an informed choice on their behalf if they themselves are unable to do so? Yes No

If yes, that person can make a proxy informed choice for the potential participant. Include an appropriate consent form for that person legally entitled. (Note: Where possible the incompetent person should also orally consent to the level of his or her understanding.)

If no, complete sections 1.1 and 1.2.

- 1.1 Is there any person interested in the potential participant's welfare who knows the participant (eg, family member/friend/whānau) and is willing and available to express a view as to what the potential participant would choose were he or she competent and fully informed about the study. Yes No

If yes, include an information sheet for the family member/friend/whānau statement as per page 24.

Please note: if it is appropriate that there be wider consultation with family, then this should be encouraged.

- 1.2 Explain why it is not possible for a potential participant to make an informed choice and why it is not possible for a proxy choice to be made or for a person interested in the potential participant's welfare to state what the participant would choose if he or she was competent and fully informed.

2. What would be the risks to the participants of taking part in this study?

3. Could the research be carried out on people who are able to consent? Yes No

4. Explain why approval is being sought to use this participant/population/patient group.

5. What is the potential health interest for the group of patients/population of which the participant would be a member?

(To be on letterhead)
 (Include the lay title at the top of each page)

STATEMENT BY RELATIVE/FRIEND/WHANAU

Lay title:

Principal investigator:

Participant's name:

I have read and I understand the information sheet dated _____ for people taking part in the study designed to _____. I have had the opportunity to discuss this study. I am satisfied with the answers I have been given.

I believe that _____ (participant's name) would have chosen and consented to participate in this study if he/she had been able to understand the information that I have received and understood.

I understand that taking part in this study is voluntary and that my relative/friend may withdraw from the study at any time if he/she wishes. This will not affect his/her continuing health care.

I understand that his/her participation in this study is confidential and that no material which could identify him/her will be used in any reports on this study.

I understand that the treatment will be stopped if it should appear to be harmful **(if applicable)**.

I understand the compensation provisions for this study **(if applicable)**.

I know whom to contact if my relative/friend has any side effects to the study or if anything occurs which I think he/she would consider a reason to withdraw from the study.

I know whom to contact if I have any questions about the medication of the study.

This study has been given ethical approval by the _____ Ethics Committee. This means that the Committee may check at any time that the study is following appropriate ethical procedures.

I believe my relative/friend would agree to an auditor appointed by the sponsoring pharmaceutical company and approved by the _____ Ethics Committee reviewing my relative's/friend's relevant medical records for the sole purpose of checking the accuracy of the information recorded for the study **(if applicable)**.

I/my relative/friend would like a copy of the results of the study. Yes No

I believe my relative/friend would agree to his/her GP being informed of his/her participation in this study. Yes No

Signed: Date:

Printed name:

Relationship to participant:

Address for results:

STATEMENT BY PRINCIPAL INVESTIGATOR

I *(name of investigator)* declare that this study is in the potential health interest of the group of patients of which *(name of participant)* is a member and that participation in this study is not adverse to *(name of participant)*'s interests.

(If applicable)

I confirm that if the participant becomes competent to make an informed choice and give an informed consent, full information will be given to him/her as soon as possible, and his/her participation will be explained. If the participant makes an informed choice to continue in the study, written consent will be requested and if the participant does not wish to continue in the study, he/she will be withdrawn.

Signed:

Date:

(Principal Investigator)

(If applicable at a later stage)

I *(participant)* having been fully informed about this study agree to continue taking part in it.

Signed:

Date:

(Participant)

STATEMENT BY INDEPENDENT CLINICIAN

I confirm that participation in the study is not adverse to *(participant)*'s interests.

Signed:

Date:

(Clinician)

Printed name: