Southern Cross University

Office of Research

Guidelines for Writing an Information Sheet/Letter for participants in Research

National Statement on Ethical Conduct in Human Research (NS) Chapter 2.2

2.2.1 The guiding principle for researchers is that a person's decision to participate in research is to be voluntary, and based on sufficient information and adequate understanding of both the proposed research and the implications of participation in the research.

2.2.2 Participation that is voluntary and based on sufficient information requires an adequate understanding of the purpose, methods, demands, risks and potential benefits of the research.

Therefore, potential participants must be presented with an information sheet about the research and a consent form, unless written consent is waived for the specific research project.

Information sheets and consent forms **MUST** be separate documents.

The information sheet should be polite, fully informative, while also being as concise and brief as possible. To be both comprehensible and consistent with the principle of respect, the information sheet must be written in language that is appropriate to the potential participant. The information sheet is kept by the participant.

Consent can be written and can also be implied or verbal. When consent is implied (e.g. by return of a completed questionnaire) or verbal, then a written consent form is unnecessary. Consent may also be inappropriate, depending on the participant group and circumstances. For example, if the research involves observation of random passers-by to a homeless person, it would be inappropriate to ask for the consent of such passers-by. Research that is not low-risk would normally involve consent. As long as your method of seeking consent is validated, HREC will consider its appropriateness accordingly.

If it is intended to use the data or tissue in future research, consent for future use of data or tissue may be specific (limited to the specific project under consideration), extended (closely related to original project or in same area of research), or unspecific (use in any future research). The necessarily limited information and understanding about research for which extended or unspecific consent is given, can still be sufficient and adequate for the purpose of consent (see 2.2.2).

The consent form is returned to the researcher. It is recommended that a copy of the consent form, signed by both parties, be given to the participant. Also ensure that consent is not bundled, but that each box is ticked individually (i.e each option or request has an individual Yes / No tick box).

Ensure the Information Sheet and Consent Forms are designed to suit **your** individual research. Do **not** just copy everything on the sample forms as some sections may not apply to your research.

All additional documentation **MUST** be attached to the Expedited Ethics Application Form. Do **NOT** send separate documents.

The following samples give an idea of how researchers can structure their information sheets and consent forms.