Southern Cross University

Office of Research

Guidelines for Writing an Information Sheet and Consent Form 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.

Information Sheet: The information sheet should be polite and 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 and in a font size that is easily read by the majority of people in the community (i.e. equal to Times New Roman 12). The information sheet is kept by the participant.

Consent Form: Where there will be direct contact with participants, consent should be provided in the standard written format (Consent Form) but in some cases it can be implied or verbal. For example, if participation involves completion of an anonymous on-line or hard-copy survey, then submitting or returning the survey is implied consent. For some participant groups, e.g., those with low literacy levels or where cultural issues mean that potential participants are not able or willing to read and sign the consent form, it may be appropriate for the researcher to read the consent form to the participant and for them to give verbal consent. 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. All research would normally require consent in some form. As long as your method of seeking consent is validated, the 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 non-specific (use in any future research). The necessarily limited information and understanding about research for which extended or non-specific 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. 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 at the end of it).

Ensure that 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.

Upload all additional documentation (e.g., research invitation, Information Sheet, Consent Form, questionnaire, project design/protocol) as separate files with your Expedited Ethics Application Form under the Documents tab in Irma.scu.edu.au.