

WOMEN'S & CHILDREN'S HEALTH NETWORK (WCHN) HUMAN RESEARCH ETHICS COMMITTEE (HREC)

GUIDELINES TO WRITING AND USE OF INFORMATION SHEETS

The WCHN HREC requires an Information Sheet to be given to potential research participants to assist them in their decision about involvement in the study. An Information Sheet must accompany each Consent Form.

As the content of an Information Sheet may subsequently be amended, the version and date should be included as a footer.

In order to assist researchers in preparing Information Sheets, the following guidelines on content and use are provided:

General:

1. The Information Sheet is one aspect of providing information so that people may come to informed decisions about their involvement in research. It must not replace personal communication between the investigator and the potential participant.
2. The investigator should ensure that the potential participant is given sufficient time to consider the verbal and written information provided, and to discuss it with family and/or friends, before being asked to give consent to involvement.
3. Whilst the HREC notes the problem faced by small units in recruiting participants, it would like to stress the need to separate the clinical and recruiting roles. The HREC therefore suggests that someone other than the treating clinician obtain final consent. Alternatively, where this is not possible, potential participants should be given time to consider participation after they have discussed the study with their treating clinician, and then submit the signed consent form with contact details to a third party.
4. In cases of research involving participants under the age of 18, researchers need to be mindful of changes in guardianship. In most cases, if guardianship changes during the course of a study the new guardians should be informed of the study and given the opportunity to continue/discontinue the involvement of the child/young person.
5. The Information Sheet is to remain the property of the participant and a copy of the signed Consent Form must be provided. In cases of ongoing studies involving children, consent should be updated in those cases where guardianship changes.

Style and Content:

1. Use simple language with minimal technical terminology or jargon.
2. The sheet must be translated if non-English speaking participants are to be recruited.
3. The use of headings is recommended.
4. Update the information sheet and re-consent participants if significant amendments are made or information has become available which may affect participants' decision to continue with the study.
5. The following items will be included (where appropriate):
 - a. Begin the information sheet with a prominent lay title (the scientific title should be included below this).
 - b. Introduce the researchers. If the study is being conducted as part of a student project state this at the outset.
 - c. Purpose of the study—why the study is being conducted.

- d. Relay all procedures that involve the participant. For example, the use of drugs or radioisotopes, questionnaires (indicating content), and so on. Information about where the procedures will be carried out and an estimate of the time involved should also be provided
- e. The possible benefits from the study to the participant and/or the community, indicating that these benefits are by no means assured.
- f. The possible risks of the study. Participants need to be informed of the risks involved in participating in the *particular* study. Risks include side effects, discomforts, inconveniences and restrictions, both immediate and in the future. Some examples are drug side effects, supply of a drug not being continued at conclusion of the study, travel, and absence from work. It is generally accepted that there are no studies involving human participants for which the risk is zero. However, sometimes it is acceptable to state that there are no *known* risks associated with the study.
- g. A comparison of the likelihood/probability of adverse effects from other procedures (or drugs) used for the same purpose should be included where relevant.
- h. If blood is to be taken from a child, the inclusion of the statement "Taking blood causes brief discomfort or pain, much like a pinprick. This can be minimised by using a simple anaesthetic cream and by comforting the child. Temporary bruising can occur and infection is possible but extremely rare.
- i. An explanation of the study design, e.g. randomisation and/or placebo use if relevant.
- j. A statement that the participant may withdraw from the study at any time without affecting his/her future treatment or relationship with the health service.
- k. If personal information pertaining to participants is to be obtained from a source other than participants, the information sheet and consent form should transparently state this. Some examples are patients'/clients' medical notes, GPs, records held by other services.
- l. If it is anticipated that information or samples from the current study will be used for future approved studies then this information should be included in the information sheet and consent form.
- m. Advice on sponsorship of any kind.
- n. Advice on any reimbursement or assistance with costs associated with the study that will be made to participants. It is generally expected that if participants are being asked to visit the WCHN over and above their normal clinical visits, then assistance with parking or travel costs will be provided. Please note, the HREC currently does not accept *payment* (as opposed to reimbursement) to participants.
- o. Assurances of confidentiality, except where there is a requirement by law for it to be divulged.

Suggestion: Your information will remain confidential except in the case of a legal requirement to pass on personal information to authorised third parties. This requirement is standard and applies to information collected both in research and non-research situations. Such requests to access information are rare; however we have an obligation to inform you of this possibility.
- p. Specification of measures that will be taken in the event of an adverse event or finding.
- q. The name, title and telephone numbers (work and after hours numbers) of all members of the research group who can be contacted if any problems arise. Please note, the HREC does not recommend researchers listing their private contact number.
- r. Confirmation that the study has been given approval by the Women's & Children's Health Network Human Research Ethics Committee. The name and contact details of the Executive Officer of the HREC (Mr Luke Fraser, Research Secretariat, ph 8161 6521) should be included as contact in case participants/potential participants wish to discuss the approval process, or have any concern or complaint.