

Guidelines to Assist in the Preparation of Information Sheet and Consent Form

1. A separate titled Information Sheet and Consent Form printed on departmental letterhead with the name and telephone number of the Chief Investigator must be submitted with your Application to Undertake Research Involving Human Subjects. Students should be introduced in the Information Sheet. (Please note that only staff members may sign letters sent out on University letterhead.)

2. The free consent of participants must be obtained before research is undertaken. The investigator is responsible for providing the participant at his or her level of comprehension with an information sheet outlining the purpose, methods, demands, risks, inconveniences, time requirements and discomforts associated with the study. If necessary, the services of an interpreter or other third party should be used. A description of the potential benefits for the individual and society should also be included.

3. Consent should be obtained in writing unless there is a good reason to the contrary. If consent is not obtained in writing, the reason for not so doing and the circumstances under which it will be obtained should be explained on the application form. Completion of an anonymous questionnaire may in certain circumstances be taken as evidence of consent to participate. In such cases, the Information Sheet should contain a statement that completion of the questionnaire is considered evidence of consent to participate in the study.

4. The Information Sheet and Consent Form must make it clear that the participant is free at any time to withdraw consent to further participation without prejudice in any way. The participant need give no reason nor justification for such a decision. In such cases, the record of that participant is to be destroyed, unless otherwise agreed by the participant.

5. The Information Sheet should contain a statement explaining how and why participants have been recruited for the project. Participants must be advised as to what data is being collected, what the purpose is, and what will be done with the data upon completion of the research.

6. The Information Sheet must offer to answer any questions the participant has concerning the research.

7. The Information Sheet where appropriate should contain a compensation clause indicating that the participant's participation in the study does not prejudice any right to compensation which they may have under statute or common law. An appropriate form of the following wording could be used as a standard clause: "Your participation in this study does not prejudice any right to compensation, which you may have under statute or common law."

8. The Consent form should make provision for signed agreement and the following terms are suggested:

I (the participant) have read the information provided and any questions I have asked have been answered to my satisfaction. I agree to participate in this activity, realising that I may withdraw at any time without reason and without prejudice. (Or where applicable - without prejudice to my future medical treatment).

I understand that all information provided is treated as strictly confidential and will not be released by the investigator unless required to by law. I have been advised as to what data is being collected, what the purpose is, and what will be done with the data upon completion of the research.

I agree that research data gathered for the study may be published provided my name or other identifying information is not used.

Participant

Date

(Please note that as this document is not a contract between parties, it is not necessary that the researcher sign it. Nor is it necessary to have a witness.)

9. It should be noted that where dependent adults or children are involved, the Consent Form must be amended to provide for parent/legal guardian to sign. A greater duty of care exists in the case of minors and parental consent is generally required for participants under eighteen years of age. See Item 11 below.

10. Copies of the Information Sheet and Consent Form must be provided for the subject to take home. The following paragraph must be included at the bottom of all Consent Forms (or if there is no Consent Form, the Information Sheet):

The Human Research Ethics Committee at the University of Western Australia requires that all participants are informed that, if they have any complaint regarding the manner, in which a research project is conducted, it may be given to the researcher or, alternatively to the Secretary, Human Research Ethics Committee, Registrar's Office, University of Western Australia, 35 Stirling Highway, Crawley, WA 6009 (telephone number 6488-3703). All study participants will be provided with a copy of the Information Sheet and Consent Form for their personal records.

Note for Investigators -Your attention is drawn to the following extracts from the Declaration of Helsinki:

(10) When obtaining informed consent for the research project the physician should be particularly cautious if the subject is in a dependent relationship to him or her or may consent under duress. In that case the informed consent should be obtained by a physician who is not engaged in the investigation and who is completely independent of this official relationship.

(11) In case of legal incompetence, informed consent should be obtained from the legal guardian in accordance with national legislation. Where physical or mental incapacity makes it impossible to obtain informed consent, or when the subject is a minor, permission from the responsible relative replaces that of the subject in accordance with national legislation.

Whenever the minor child is in fact able to give a consent, the minor's consent must be obtained in addition to the consent of the minor's legal guardian.

Human Research Ethics Committee Eligibility Criteria

Background

According to the NHMRC National Statement on Ethical Conduct in Research Involving Humans all research involving human participants must be reviewed and approved by a Human Research Ethics Committee (HREC). The University of Western Australia's HREC is the Human Research Ethics Committee, a committee of Senate established to perform this function and so protect the University, its staff and the participants of research projects. In March 1998, the Senate delegated authority to Sir Charles Gairdner Hospital (SCGH) HREC to review and approve research proposed by UWA staff based at SCGH. In order to clarify this issue, UWA has proposed the following eligibility criteria for UWA staff.

Eligibility Criteria

* The Human Research Ethics Committee at the University of Western Australia requires ethical approval to be obtained by all researchers employed by the University.

* The following personnel are required to submit protocols to the UWA Human Research Ethics Committee:

- o all UWA staff members, ie those persons currently on the UWA payroll;
- o all adjunct and clinical staff who use their UWA titles in support of their research.

* Where investigators are carrying out research projects at organisations remote from the central campus of the University of Western Australia, they may alternatively seek ethical approval from that organisation provided that the organisation's HREC is registered with the NHMRC. Under these circumstances applications and approval by the Human Research Ethics Committee is not required. The responsibility for ethical clearance and confirming that the approving HREC is registered with NHMRC lies with the researcher.

* Where a study involves subjects recruited from an external organisation, ethical approval from that organisation's HREC (if it has one) will be required if the majority of the subjects recruited to the project are from that organisation. Specifically, with regard to patient studies, patients are to be defined as patients of that organisation if they have a head sheet and medical record number raised within the hospital and have continuation notes entered in that record as part of the ongoing nature of the trial.

* Where the subjects are not recruited from an organisation but the project does impact upon human and/or consumable resources of the organisation, the Human Research Ethics Committee will also expect to see clearance or approval from that organisation as a pre-requisite to consideration of the application for ethical approval.

* Where patients involved do not have a medical record at the organisation and there is no impact on the facilities or premises of the organisation where the research is being performed, the Human Research Ethics Committee will assess the research protocol. In this case the University expects that any relevant supporting grant etc will be administered through the University