RESEARCH STUDY INTO [TITLE OF PROTOCOL]

PARTICIPANT INFORMATION STATEMENT

You are invited to take part in a research study into [title of protocol]. The object is to discover/assess/investigate [where appropriate, also include up to three sentences of background information]. The study is being conducted by [name and position] and [if appropriate] will form the basis for the degree of [insert degree undertaken] at the [name of University] under the supervision of [name of supervisor and position].

If you agree to participate in this study, you will be asked/ requested to [description of procedures participant will undergo, plus information on inconvenience, risks, discomforts or side effects that may occur and an estimate of their severity and duration]. You will need to attend [insert location] for [insert time] hours on [insert number of sessions] occasions.

All aspects of the study, including results, will be strictly confidential and only the investigators named above [or others, as appropriate] will have access to information on participants, except as required by law [where appropriate]. [If appropriate] A report of the study may be submitted for publication, but individual participants will not be identifiable in such a report.

[If appropriate] It is important that participants in this study are not pregnant and do not become pregnant during the course of the study. If there is any possibility that you are pregnant, the researchers will perform a pregnancy (urine) test before you start in the study. If necessary, you should use oral contraception during the course of the study. If at any time you feel you may have become pregnant, it is important to let the researcher(s) know immediately.

[If appropriate] While we intend that this research study furthers medical knowledge and may improve treatment of this condition [or as appropriate] in the future, it may not be of direct benefit to you.
Participation in this study is entirely voluntary: you are not obliged to participate and can withdraw at any time. Whatever your decision, it will not affect your medical treatment or your relationship with medical staff. [INSERT, If necessary dialogue relating to your research].

You may stop the interview at any time if you do not wish to continue, the audio recording will be erased and the information provided will not be included in the study.

[Paragraph for the return of questionnaires/survey if not having a consent form] Being in this study is completely voluntary and you are not under any obligation to consent to complete the questionnaire/survey. Submitting a completed questionnaire/survey is an indication of your consent to participate in the study. You can withdraw any time prior to submitting your completed questionnaire/survey. Once you have submitted your questionnaire/survey anonymously, your responses cannot be withdrawn.”

When you have read this information, [name of investigator] will discuss it with you further and answer any questions you may have. If you would like to know more at any stage, please feel free to contact [names, positions and phone numbers].

[For Clinical Trials of new drugs or devices] In the event of loss or injury, the parties involved in this study agree to be bound by the Medicines Australia Guidelines for Injury Resulting from Participation in an Industry-Sponsored Clinical Trial. A copy of these guidelines is available from the website www.medicinesaustralia.com.au.

Any person with concerns or complaints about the conduct of a research study can contact the Deputy Manager, Human Ethics Administration, University of Sydney on (02) 8627 8176 (Telephone); (02) 8627 8177 (Facsimile) or human.ethics@usyd.edu.au (Email).

This information sheet is for you to keep.