menzies school of health research

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A Participant Information Sheet is required for every research project.

The purpose of the Participant Information Sheet is to explain the project, what will be asked of research participants and subjects, and the safeguards in place for them. The form should be brief, written in plain language, and provide sufficient detail to allow an informed decision on whether to take part.

The material below is a guide. It outlines what is required, but researchers should tailor and add material to suit their project. If the research is being conducted in partnership with another agency, the guidelines of that agency relating to participant information should be melded with these guidelines.

For most projects a single Participant Information Sheet suffices. However, more complex projects can involve groups of participants (for example, adults and children; nurses and patients) with differing inputs. In these projects, separate Information Forms may be required for each group. Often in projects such as clinical trials a complex Participation Information Booklet is provided and in these cases a simplified 1–2 page Participant Information Sheet should be provided as well.

The Participant Information Sheet is to be on **LETTERHEAD** paper displaying full details of the organisation conducting the research.

PARTICIPANT INFORMATION SHEET

Advice Statement – "***THIS IS FOR YOU TO KEEP***" (**Mandatory statement at top of page just below the words "Participant Information Sheet")**

Project Title: Insert the title of the project (using bold type).

Researcher: Insert the personal title, name, academic qualification and section/branch/organisation of the principal researcher.

If you are a student insert your personal title, name, and your course of study. If there are assistant researchers, give the personal title, name, academic qualification, School and University, or parent agency, of the assistants.

Advise the personal title, name, academic qualification, position and School at the University of the supervisor of student undertaking the project.

Project Aim: Insert the aim/s of the research.

Benefits of the Project: Briefly describe the benefits of the research to the field of study. Be realistic. The benefits should reflect the level and complexity of the proposed research.

General Outline of the Project: Provide a brief overview of the project methodology. Indicate how and from whom the data will be collected, and how many

participants will be involved. Explain how the data will be collated, analyzed and presented including how the results will be shared with participants. If relevant, indicate that the project has received specific funding and name the funding body.

Participant Involvement: Describe what the participants will be asked to do: for example, complete a questionnaire, undertake an interview, participate in a focus group, and/or permit access to personal records. For interviews, focus groups and similar methodologies specify how the contribution of the participants will be captured. If information is to be recorded by the researcher or by video/tape recorder and then transcribed for analysis, indicate whether transcripts of their input will be provided to each participant for perusal before the analysis is finalised.

Indicate where the research will take place, the number of occasions on which the participants will be required, and the length of time on each occasion.

If relevant, indicate that an inducement to participation is to be offered (for example a payment or gift or academic credit), state its nature and how it will be provided.

Describe the **risks, discomforts**, hazards or side effects that might arise because of the subject of the research or the research method. If risks or hazards may arise, describe the emergency procedures, medical support or counselling that will be in place to support the participants, and the method by which the participants would access such support.

Exclusion criteria: If relevant, detail the reasons for which potential participants would be excluded from the project.

Inform the intended participants that the project is a **voluntary activity** and that they may, without any penalty, decline to take part or withdraw at any time without providing an explanation, or refuse to answer a question.

Depending on the research subject and the intended participants, it may be necessary to indicate exactly how the project relates to courses of medical treatment or courses of study or employment requirements or other activities. Potential participants need enough information to be confident that to decline the research will not have adverse personal effects.

Confidentiality: Indicate whether anyone but the nominated researchers will have access to the material provided by the participants.

Anonymity: Indicate whether the anonymity of the participants is to be preserved and, if so, how. Describe the process briefly but in sufficient detail for the participants to understand.

Data Storage: Indicate where the data will be stored and how security of personal information will be maintained during collection, analysis and preparation of results.

Inform the participants where the data will be stored once the project is complete. Normally this is at the organisation accepting responsibility for the research for a period of five years. Longer periods and different locations may apply if the research is conducted in conjunction with other agencies. Provide an explanation of what will happen to the data at the end of the storage period.

Ethics Committee Clearance: Include a statement that the project has been approved by the Human Research Ethics Committee of the NT Department of Health and Menzies School of Health Research. If the project has gained approval from other ethics committees or authorities, include a statement to the effect including the name of the relevant bodies.

Concerns and Complaints: Include information on the method by which participants can raise queries on the project. For further requests for information or queries regarding the study should be directed to the Principal Investigator. Provide name contact details (telephone, email)

Concerns regarding the ethical conduct must be directed to the ethics committee.

Please also include the MANDATORY statement: "If you have any concerns or complaints regarding the ethical conduct of the study, you are invited to contact Ethics Administration, Human Research Ethics Committee of the NT Department of Health and Menzies School of Health Research on 8946 8600 or email ethics@menzies.edu.au"