



APPLICATION TO HUMAN RESEARCH ETHICS COMMITTEE

RESEARCH PROTOCOL PROFORMA

Please address the points listed below. Some questions might not be relevant to your study; for any that are not, simply write N/A.

Please keep your responses as brief as possible, while providing enough information for members of the ethics committee to gain a good understanding of what your research will involve. Your responses should be written in plain English for a non-expert audience. The suggested length of responses is shown in brackets for each section, but this is a guide only. Simple, uncontentious research might be adequately explained more briefly, while research projects with a number of components or which involve possible risks to the research participants will require more detailed explanation.

Please attach appendices as requested in each section, and label as specified. Please place a footer on each page of your proposal indicating the date of submission and the version number of your submission. (If it is a first submission, write 'version 1', but if it is a second submission for the same project, write 'version 2', etc.)

A covering letter is to be provided with your submission and needs to be signed off by all co-investigators and/or supervisors.

If applicable, copies of any other HREC approvals granted are to be provided with the submission. If approvals are still being sought, meeting dates are to be advised and a copy of their approvals provided to the Executive Officer prior to commencement of the project.

Submit a hardcopy of your protocol to:

Ms Katrina Stamp
Executive Officer
Human Research Ethics Committee
The Cancer Council South Australia
202 Greenhill Rd
EASTWOOD
SA 5063

Ph: 08 8291 4276
Fax: 08 8291 4268
Email: kstamp@cancersa.org.au

1. TITLE

2. INVESTIGATORS AND QUALIFICATIONS

Please include contact details for the researcher submitting the protocol.

3. RESEARCH AIMS

3.1 **State the aims of your research.** (50-100 words)

3.2 **Explain the need for, and value of, your research.** (100-300 words)

Place the aims in the context of existing research or practice.

Include a list of not more than 10 key references at **appendix 1**.

4. RESEARCH METHODOLOGY

4.1 **List your research questions or hypotheses.** (50-100 words)

Your protocol should clearly identify the questions which you want your research to answer. Depending on your methodology, these questions may be refined as your study progresses.

4.2 **Outline your research design and methodology.** (250-300 words)

The ethics committee must be convinced that your research methods can be expected to produce valid results.

Include a copy of your research tools (e.g. questionnaires, data collection sheets, etc.) as **appendix 2**.

4.3 **Explain the expected outcomes of your study and how they will be evaluated.** (100-200 words)

Can the aims be realised given your study design, sample sizes etc.?

4.4 **Indicate whether your research is the first stage of a larger project.** (50-100 words)

If it is, briefly explain your intentions for the development of your study to facilitate further ethics approval if you do extend your research project.

5. RESEARCH PARTICIPANTS

5.1 **Who will be approached or recruited to be research participants?** (50-100 words)

How many participants will be involved in your study?

5.2 **List the selection and, if appropriate to your study, the exclusion criteria for participants.** (50-100 words)

5.3 **How will you recruit participants for your research?** (200-300 words)

If you will use advertisements, flyers or other recruitment material please provide a copy of these materials in **appendix 3**.

- 5.4 **How will you provide detailed information about your study to potential applicants?** (50-100 words)
 Include as **appendix 4** the information sheet/s* that you will use.
- *Please note that all information sheets for participants must include the following information:
"This project has the approval of The Cancer Council South Australia Human Research Ethics Committee. Should you have any queries or complaints regarding the ethical conduct of this study, please contact Ms Katrina Stamp, ph. 08 8291 4113"
- 5.5 **Describe how you will obtain consent to participate from those volunteering as participants for your research.** (100-200 words)
 Include as **appendix 5** the consent form or forms that you will use.
 Please note that consent is not required for anonymous questionnaires.
 Return of the completed questionnaire indicates consent.
- 5.6 **If your research participants will be drawn from any dependent group (people who have an unequal power relationship with you or with an organisation which is cooperating in the research) please detail how you will ensure that participants do not feel under any obligation to assist you with your research as participants.** (100-200 words)
- 5.7 **Describe how you will preserve participants' confidentiality as you collect and analyse the data and when you report the results.** (50-100 words)
- 5.8 **If there are any potential risks (physical, emotional, social or legal) to individual subjects' well being (beyond those normally encountered in everyday life) as a result of their involvement in the research, detail the steps that will be taken to address these risks including any support facilities such as counselling, debriefings or referrals.** (100-200 words)
- 5.9 **If there are any potential risks for yourself as the researcher (beyond those normally encountered in everyday life) please indicate how these will be addressed.** (50-100 words)
- 5.10 **If the research participants will receive any payment, reimbursement or other benefit from participation in the research, please detail this and provide a justification for the level of compensation.** (50-100 words)

6 RECORDING, REPORTING, STORAGE AND ACCESS TO THE RESEARCH DATA AND RESULTS

- 6.1 **Describe briefly how the research data will be recorded, for example, audiotape, videotape, or written notes.** (50-100 words)
 Please note that explicit consent must be obtained from participants if material is to be audio or videotaped or photographed. Provision for this should be included in the consent form.
- 6.2 **Describe what you will do with the recorded data once it has been analysed. Describe how and where the data will be stored.** Please be aware of your obligations under federal Privacy Legislation, as well as any other legislation that may apply to the agencies involved in the research eg. Freedom of Information legislation. (50-100 words)

- 6.3 **Specify who apart from yourself (and your supervisors if applicable) will have access to the research data and results, and any conditions to be placed on that access.** *(25-50 words)*

7 OWNERSHIP OF THE RESEARCH

- 7.1 **Detail who will own the data and the results of your research.** *(25-50 words)*
Please consult The Cancer Council South Australia policy on Intellectual Property.

8 OTHER INFORMATION

- 8.1 **If the protocol has been submitted to any other ethics committees, please specify which, as well as the status of that/those application/s.**
- 8.2 **Proposed date of commencement and expected duration of the study.**
- 8.3 **Any other information relevant to the ethical conduct of your study.**

9 APPENDICES

- Appendix 1: Reference list
- Appendix 2: Research tools
- Appendix 3: Recruitment material
- Appendix 4: Information sheet
- Appendix 5: Consent form