

This form is only for applications who have already received full ethics approval of the Protocol referred to below.

Formal notification of Ethics approval from UniSA HREC must be received in full, prior to administering any changes to your protocol. These changes include:

- Conducting additional or fewer interviews/focus groups/questionnaires than originally approved (eg if your approved protocol was to conduct 10 focus groups but it was decided that only 8 were needed then approval must be sought to alter the process)
- Altering the wording of any recruitment material. This includes recruitment flyers, information sheets, consent forms, letters sent to participants/potential participants and media advertisements/campaigns
- Including new survey tools/questions or removing or changing survey tools/questions
- Changing the inclusion/exclusion criteria for participants and/or participant groups
- Recruiting from a new organisation not previously approved/or deciding not to use a previously approved organisation
- Introducing, removing and/or altering the honorarium given to participants
- Changes to the research team (ie new researchers, researchers who are no longer involved in the project etc)
- Changes to the funding and/or contractual agreements.

SECTION 1: APPLICATION DETAILS

| | | | | | |
|------------------|--|-------------------------|--|----------------|--|
| Title: | | Surname: | | First Name(s): | |
| Project Title: | | | | | |
| Protocol Number: | | Original Approval Date: | | | |

SECTION 2: REQUESTED MODIFICATION TO PROTOCOL

Please indicate below what type of modification you are requesting:

| | |
|--------------------------|---|
| <input type="checkbox"/> | Addition of researcher(s) (<i>complete section A</i>) |
| <input type="checkbox"/> | Removal of researcher(s) (<i>complete section B</i>) |
| <input type="checkbox"/> | Other modifications (<i>complete section C</i>) |

SECTION A: ADDITION OF RESEARCHER(S)

Please supply the following details:

| | Researcher 1 | Researcher 2 | Researcher 3 |
|---|--------------|--------------|--------------|
| Title: | | | |
| Surname: | | | |
| First Name(s): | | | |
| Role within project (e.g. CI/Supervisor/Student): | | | |
| Reason for addition: | | | |

SECTION B: REMOVAL OF RESEARCHERS

Please supply the following details:

| | Researcher 1 | Researcher 2 | Researcher 3 |
|---|--------------|--------------|--------------|
| Title: | | | |
| Surname: | | | |
| First Name(s): | | | |
| Role within project (e.g. CI/Supervisor/Student): | | | |
| Reason for removal: | | | |

SECTION C: NATURE OF AND JUSTIFICATION FOR AMENDMENT(S)

Please provide details of the changes to the protocol, and a brief explanation for each change.

Amendments and changes to protocol may require recruitment material to be modified. Have any of the following recruitment materials been changed? *(please tick)*:

| | | | | | |
|--------------------------|------------------------------------|--------------------------|------------------|--------------------------|---------------------|
| <input type="checkbox"/> | surveys | <input type="checkbox"/> | advertisements | <input type="checkbox"/> | consent forms |
| <input type="checkbox"/> | questionnaires | <input type="checkbox"/> | safety protocols | <input type="checkbox"/> | interview questions |
| <input type="checkbox"/> | participant information statements | | | | |

NOTE: Please attach copies of these amendments with your Protocol Modification Request form

Will there be additional permissions or approvals required as a result of your proposed changes?

| | |
|--------------------------|---|
| <input type="checkbox"/> | No |
| <input type="checkbox"/> | Yes – <i>please provide details below</i> |
| | |

SECTION 3: CERTIFICATION

I confirm that the above information is accurate, and that the project will continue in accordance with the HREC approved protocol, and in compliance with the NHMRC National Statement on Ethical Conduct in Human Research (NHMRC, 2007).

| | | |
|---|---------------------|-------------|
| | | |
| <i>Researcher's Signature</i> | <i>Printed Name</i> | <i>Date</i> |
| | | |
| <i>Supervisor's Signature (If applicable)</i> | <i>Printed Name</i> | <i>Date</i> |

SUBMISSION DETAILS

Complete this form and email it to: ResearchCompliance@unisa.edu.au
Please also attach any relevant documents (i.e. recruitment material) affected by the amendment.