Human Research Ethics Committee

Modification Form for Research Project

Please complete, "sign", date and email this form to Res.Ethics@acu.edu.au.
For additional information visit the ACU Research Ethics website or
contact the Ethics Officers on Res.Ethics@acu.edu.au or +61(02) 9739 2646.
Your request will be processed in approximately 20 working days
Answer all questions. If a question does not apply, indicate N/A.
This form is available from the ACU Ethics web pages ACU Research Ethics Homepage .

Modifications to the project may NOT be introduced prior to written approval of the ACU HREC

1. PROJECT DETAILS

1.1 HREC Register No.

1.2 Approval End Date

1.3 Principal Investigator/Supervisor

Project Manager/Assistant (on behalf of PI - if applicable)

1.4 Student Researcher (if applicable)

1.5 Project Title

2. PROPOSED MODIFICATIONS TO THE PROJECT

Modifications may include changes to procedures, duration, personnel, recruitment methods, number and type of participants as well as alterations to supporting documents (i.e. questionnaires). The ACU HREC will review the proposed modifications and determine if a new application is required.

2.1 PROPOSED CHANGES TO THE PROJECT (*NOT INCLUDING PARTICIPANT GROUPS OR RESEARCH PERSONNEL)

Please outline the proposed changes to the project in the table below. *(*Changes to personnel and new participant groups are to be outlined in Section 2.2 AND 2.3.)*

What is the proposed modification? If no changes other than change to personnel please indicate 'NIL".	**Explain how this differs from what was originally approved and justify the reason for the change.**	**Describe the impact on participants and any ethical issues arising from these changes and how they will be managed.**
SAMPLE - Addition of blood samples to the study protocol.	Saliva swabs were included in original protocol and now blood samples are being added. Blood samples will provide more information as to the effectiveness of the treatment being tested.	It will require an additional 5 mins and slight pain for participants. We will ensure that the researchers are qualified to take blood and that safety protocols are adhered to in the handling of blood products and a blood collection protocol is attached.

2.2 RESEARCH PARTICIPANTS

Does the modification involve changes to participants eg: changes to the numbers, recruitment methods, or type of participant?

YES ☐ **NO** ☐

If yes, provide full details of the following – questions below are to guide your answer:

Explain the changes to participants.	Explain the changes to recruitment.	What are the ethical / practical considerations that may arise with the inclusion of this new participant group (eg. Identification of any risks)
SAMPLE: We are increasing the number and range of school children and teachers that we are recruiting.	SAMPLE: Independent schools and public schools will be included in addition to Catholic schools. We will follow the same recruitment methods with the addition of a meeting with the community.	SAMPLE: There are no additional ethical issues involved with the inclusion of the new participant groups. We will need to provide evidence of approval from the Independent schools and public schools.

You should attach any additional relevant documents such as a revised information letter/consent form, recruitment advertisement, letter of support etc. Revised documentation must have changes highlighted and be identified with a version # and date.

2.3 RESEARCH PERSONNEL

2.3.1 Does the modification involve changes to research personnel working on the project?

YES ☐ **NO** ☐

If yes, please explain via the tables below the changes to personnel.

2.3.2 ADDITION of research personnel (including students).

For each new investigator, provide the following information:

NEW INVESTIGATOR			
Name		Phone	
		Email	
School/Institute Position		Staff/ Student No. (if known)	
Academic Title / Qualification relevant to the project			
Role in the project			
Other information eg Copies of Working with Children Checks. See information ACU HR Webpage			

2.3.3 REMOVAL of research personnel

For each person who is leaving the research team, provide the following information:

Name	Contact details – Phone/email address	Reason for Leaving the Project	Other information

2.4. Certification by Principal Investigator/ Supervisor (or Project Manager)

Modifications must be emailed by either the Principal Investigator / Supervisor (or Project Manager). Forms will not be accepted directly from Co-Investigators or students.

☐ I certify that the information provided above is an accurate and full account of the modification proposed to the protocols for this research project.

☐ I understand that the proposed modification is not to be implemented until written approval has been received from the Human Research Ethics Committee.

Name *(block letters)*

Date

Principal Investigator/Supervisor/Project Manager

Privacy Statement

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