AMENDMENT TO APPROVED PROJECT
HEALTH AND MEDICAL HREC

This form should be completed for all types of Health and Medical amendment applications and sen to the administrative officer along with the attachments indicated below.

Ethics Reference Number	H0014568	Date:	19/5/2015

TITLE of Approved Project *(Title used on the NEAF)*
Supporting Expectant Mothers to Quit Smoking

INVESTIGATOR NAMES	
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REQUESTED CHANGES TO PROJECT

(These may include, for example, changes in procedure or direction of the project, changes to research personnel, changes in the source or manner of recruitment, or changes in the number of subjects.)

Changes to recruitment protocol:

1. Allow antenatal ***staff to record the contact details*** of consenting interested participants.
2. Antenatal staff/midwives to conduct a ***one-off review of patient database and inform, via telephone call***, eligible patients (currently receiving care from/in antenatal system, indicated smoking, < 21 weeks pregnant) of the opportunity to participate in the study.
3. ***Advertise and recruit for study at GP clinics*** around Launceston and surrounding suburbs.

Study flyers and posters will be updated to include (in **bold**) the statement "For more information please contact Dr Mai Frandsen (6348 8168 or email Mai.Frandsen@utas.edu.au) **or leave your contact details with your midwife/doctor and the researcher will contact you**."

JUSTIFICATION/REASON FOR THE CHANGES

To boost recruitment to the study (since launch, 3 weeks ago, approximately 10 people have [anecdotally] been interested in the study and taken a brochure from antenatal staff to contact the researcher, but as yet, no-one has contacted the researchers to participate), we wish to implement the three following recruitment strategies:

1. Pregnant women attending antenatal appointments, who self-report as smoking and are interested in participating in the study, may leave their contact details with antenatal staff if they would prefer for the researcher to contact them (e.g., for financial reasons, no phone credit etc.), rather than them have to make contact with the researcher (via contact details on provided study brochure). ***Antenatal staff will be instructed only to take the contact details of those women who wish to participate in the study, and who would prefer for the researcher to contact them.*** Antenatal staff will offer interested participants both a study brochure (so that *they* may contact the researcher) and to record their contact details so that *the researcher* can contact them. Midwives will email (secure UTAS email address) the researcher the contact details of these interested women. The researcher will screen and explain the study as per usual protocol via the telephone screening call.
2. As a one off, antenatal staff/midwives will conduct a review of the patient database and inform, via telephone call, eligible patients (currently receiving care from/in antenatal system, indicated smoking, and < 21 weeks pregnant: estimated ~n=50) of the opportunity to participate in the study. This one-off participant recruitment strategy will be especially useful for recruiting eligible women (first 20 weeks of pregnancy, smoked in last 7 days) who have not recently attended a scheduled antenatal appointment (and thus have not seen the study advertised), and do not have an appointment scheduled in the near future (due to early stages of pregnancy). This strategy will thus allow us to recruit eligible women before they potentially become ineligible (later than 20 weeks gestation).
3. To capture women who may just have found out they are pregnant, and are still smoking, the study will be advertised at collaborative GP clinics. GPs will inform eligible patients (< 21 weeks pregnant, > 15 years, smoked in the last 7 days) of the study, provide a study brochure to interested patients, and ***offer to take their details and forward them to the researcher if the patient would prefer the researcher to contact them.***

Do the changes raise any ethical issues?	☒ No ☐ Yes
If you answered yes please identify these issues below:	

Do the information sheet and/or consent form need to be changed?	☒ No ☐ Yes
If you answered yes please attach new information sheets and consent forms.	

Has this amendment been approved by another Australian HREC?	☒ No ☐ Yes
If you answered yes please attach a copy of the approval letter.	

Has this amendment been approved for another Tasmanian site or study?	☒ No ☐ Yes
If you answered yes provide the ethics reference number for the project for which this amendment has been approved.	

Signatures:

Please note: The signed version of this form must accompany the initial submission. Unsigned forms will not be accepted

Chief Investigator Name: Dr Mai Frandsen

Chief Investigator Signature:

Date: **19/05/2015**

Submission Details

Requirements for submission:

All documentation to be emailed to human.ethics@utas.edu.au

All updates to documents are to be clearly identified with the changes tracked and updated document version numbers.

Where possible, amended Protocols are to be accompanied by summary of changes. Where a summary of changes is not available the changes to the document must be visible by using tracked changes.

Submission of substantial amendments

As of 1 July 2013 a submission fee will be charged for all substantial amendments. Please see the Health and Medical Human Research Ethics Committee Finance and Administration Form for the schedule of fees.

Following receipt of the submission, the Ethics Officer will inform the Chief Investigator (and if applicable the research administrators) of the decision that the submission is deemed substantial. The researchers will then be required to submit invoice details which are to be received prior to the amendment being submitted to the committee for review.

Please contact Lauren Black, Ethics Officer, Health and Medical Human Research Ethics Committee, 03 6226 2764 if further information is required.