

AMENDMENT TO APPROVED PROJECT HEALTH AND MEDICAL HREC

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

Ethics Reference Number	H0014568	Date:	27/04/2015
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TITLE of Approved Project (*Title used on the NEAF*)

Supporting Expectant Mothers to Quit Smoking

INVESTIGATOR NAMES

Chief Investigator	Dr Mai Frandsen
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Other Investigator	Dr Mona Thorpe
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Data Manager:	Dr Mai Frandsen
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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.)

1. Including assessment of perceived partner support (**PIQ-20**; Cohen & Lichtenstein, 1990) [this is assessed during Baseline and End-of-Study visits only in the current study protocol] at all participant study visits (including Enrolment, End-of-Pregnancy, and End-of-Study/Postpartum visits, as well as additional monthly assessments, if participant self-reports as quit during monthly telephone calls and attends a study visit [maximum 10]).
2. Including assessment of motivation (internal/external motivation for quitting as measured by the Reasons for Quitting questionnaire; **RFQ** [Curry et al., 1990]; and includes additional pregnancy questions [Curry et al., 2001]) [this is an additional assessment not included in the current study protocol] at all participant study (including Enrolment, End-of-Pregnancy, and End-of-Study/Postpartum visits, as well as additional monthly assessments, if participant self-reports as quit during monthly telephone calls and attends a study visit [maximum 10]).
3. Include PhD candidate Dr Mona Thorpe as a study investigator

JUSTIFICATION/REASON FOR THE CHANGES

1. Including assessment of perceived partner support (as measured by PIQ-20; Cohen & Lichtenstein, 1990) at all study visits will allow us to determine change in partner support over time and determine if this is related to/effects motivation to quit/actual quitting behaviour. This 20 item questionnaire should only add an additional 10 minutes to study visits.
2. Including a measure of motivation for quitting (as measured by the Reasons for Quitting questionnaire; **RFQ** [Curry et al., 1990]; and includes additional pregnancy questions [Curry et al., 2001]) will allow us to determine if the underlying mechanism of providing quit contingent monetary/voucher incentives acts initially as an external motivator but fosters a transition to internal motivation over time. This 24 item questionnaire should only add an additional 10 minutes to study visits.
3. Dr Mona Thorpe has recently commenced a PhD and is supervised by Dr Mai Frandsen and A/Prof Stuart Ferguson. Her PhD studies will focus on promoting smoking cessation in pregnancy.

Do the changes raise any ethical issues?	<input checked="" type="checkbox"/> No
	<input type="checkbox"/> Yes

If you answered yes please identify these issues below:

Do the information sheet and/or consent form need to be changed?	<input checked="" type="checkbox"/> No
	<input type="checkbox"/> Yes

If you answered yes please attach new information sheets and consent forms.

Has this amendment been approved by another Australian HREC?	<input checked="" type="checkbox"/> No
	<input type="checkbox"/> Yes

If you answered yes please attach a copy of the approval letter.

Has this amendment been approved for another Tasmanian site or study?	<input checked="" type="checkbox"/> No
	<input type="checkbox"/> 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: 27/04/2015

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.