

**HUMAN RESEARCH ETHICS COMMITTEE**

**(TASMANIA) NETWORK**

**AMENDMENT TO APPROVED PROJECT**

**HEALTH AND MEDICAL HREC**

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| 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. |

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| Ethics Reference Number | H0014568 | Date: | **05/08/2015** |

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

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| INVESTIGATOR NAMES |
| **Chief Investigator** | Dr Mai Frandsen |
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| **Data Manager:** | Dr Mai Frandsen |
| Phone: | 03 6348 8167 |
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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. Amend the inclusion criteria which is currently ‘pregnant women in their first half of pregnancy (<21 weeks gestation)’, to include any woman who is pregnant (and has smoked, even a puff, in the last 7 days).
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| **JUSTIFICATION/REASON FOR THE CHANGES** |
| 1. To facilitate recruitment of study participants. To increase recruitment to the study, we wish to include all women who are pregnant and smoking, regardless of gestational stage. Conversations with midwives indicate that there are many more interested participants, but due to the current inclusion/exclusion criteria (must be <21 weeks gestation), they are not eligible to participate. Changing the inclusion criteria to include all pregnant women who smoke will not affect research protocol or aims, since secondary analysis comparing participants who were enrolled during their first or second half of pregnancy can still be conducted.
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| Do the changes raise any ethical issues? [x]  No [ ]  Yes  |
| If you answered yes please identify these issues below: |

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

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

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

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| **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: **05/08/15** |

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| **Submission Details** |
| **Requirements for submission:****All documentation** to be emailed to human.ethics@utas.edu.auAll 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.  |