

**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: | **02/07/2015** |

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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 |
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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. Extend participant advertising to additional public hospitals/health care services within the entire Tasmanian Health Service (THS) jurisdiction. Currently recruitment is restricted to Launceston General Hospital (LGH), however in the 2 months since recruitment commenced at LGH (1.5.15) only 2 participants have been enrolled in the study. Extension of recruitment to the North West Regional Hospital (NWRH), Mersey Community Hospital and the Royal Hobart Hospital (RHH) and satellite services would enable recruitment of greater numbers of participants. No changes in the current approved study protocol would be required by extension of the recruitment catchment area (e.g., advertising using posters, flyers and patient contact detail forms in antenatal units). In principle support has been obtained after consultation with the senior medical and nursing staff from Obstetrics and Gynaecology at the relevant hospitals (including Head of O&G, acting ADON/NUM Antenatal, Clinical Coordinator).
2. Use of the existing study recruitment poster (approved) to ‘advertise’ on social media platforms (e.g., Facebook, twitter), principally as a means to increase study participant recruitment by raising the level of awareness of the study amongst clinicians and researchers in this area. The specific Facebook pages would include those of the Behavioural and Situational Research Group (BSRG; School of Pharmacy, UTAS), and the personal Facebook and Twitter pages of individual research team members. This informal advertising/ ‘awareness raising’ **would not** include paid social media advertising (inc. Facebook). We have not included supplementary material for what these ‘adverts’ might look like since they will be direct replicas (inc. wording) of the study poster and brochures already approved.
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| **JUSTIFICATION/REASON FOR THE CHANGES** |
| To facilitate recruitment of study participants. Since study commencement on 1.5.15 at the LGH, only 2 participants have consented to participate in the study. Anecdotally, antenatal staff indicate that many patients indicate interest and take brochure, but these women then do not contact researchers. Further, many participants who are interested and are happy for antenatal staff to pass their details on to researchers (approved), many are not eligible as they are greater than 20 weeks gestation. We believe, a wider catchment area (state-wide), and raised clinician awareness of the study via social media platforms would yield more potential participants. |

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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: **02/07/2015** |

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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.  |