

**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: | **27/02/2015** |

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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 | |
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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.) |
| The purpose of this pilot study is to determine if providing quit incentives ('paying' [with vouchers'] for abstinence) to pregnant smokers will motivate them to quit during their pregnancy and stay quit once the baby is born. The study will determine if such an incentives intervention is more effective than the current 'usual care' adopted in a regional Australian antenatal unit. Furthermore, the proposed research will determine if incentivising partner support, that is paying the partner of the pregnant smoker to be a more effective and active 'quit buddy', is more effective than providing incentives to the expectant mother alone.  In the original application monthly incentives vouchers to the value of $25 were approved to be used making the maximum total incentives amount $295 for the pregnant participants, and $275 for treatment group partners.  We wish to increase the monthly incentive voucher value to $50. This would mean all participants (pregnant smokers) would be eligible to receive (if verified as quit) a monthly $50 kmart shopping voucher, making the maximum total incentives amount $570. For partners of participants in the control group, whose partners verify monthly as being quit, the maximum incentive amount they would receive, at the completion of the study, would be $550. |

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| **JUSTIFICATION/REASON FOR THE CHANGES** |
| Providing incentives for pregnant smokers to quit has been shown to be the most effective (and cost effective) cessation treatment, increasing abstinence rates several-fold compared to any other type of treatment (Lumley et al., 2009). Incentives programmes and studies conducted to promote smoking cessation in pregnant women have found a direct correlation between the amount paid/voucher incentive value, and smoking cessation success (Donatelle et al., 2004).  Indeed, the originally incentive voucher amount proposed for the present study ($25/month) would have represented one of the smallest amounts ever tested. In a review of seven incentives programs for pregnant smokers in the UK, maximum incentives amounts ranged from £100 – £650 (approx. AU$200 – $1300) (Marteau et al., 213). A number of US studies have similarly used monthly incentives vouchers of US$50 (Higgins et al., 2012) to motivate their pregnant participants to quit.  As such, we believe that for the study to be feasible in terms of recruiting the required number of participants (n=200) and effective in motivating pregnant women to quit, a larger incentive/motivator is necessary. Furthermore, an incentive value of $50/month is in line with other research and thus allows more effective program/study comparison and critique.  Donatelle, R., Hudson, D., Dobie, S., Goodall, A., Hunsberger, M., & Oswald, K. (2004). Incentives in smoking cessation: status of the field and implications for research and practice with pregnant smokers. *Nicotine Tob Res, 6 Suppl 2*, S163-179. doi: 10.1080/14622200410001669196  Higgins, S. T., Washio, Y., Heil, S. H., Solomon, L. J., Gaalema, D. E., Higgins, T. M., & Bernstein, I. M. (2012). Financial incentives for smoking cessation among pregnant and newly postpartum women. *Prev Med, 55 Suppl*, S33-40. doi: 10.1016/j.ypmed.2011.12.016  Lumley, J., Chamberlain, C., Dowswell, T., Oliver, S., Oakley, L., & Watson, L. (2009). Interventions for promoting smoking cessation during pregnancy. *Cochrane Database Syst Rev*(3), Cd001055. doi: 10.1002/14651858.CD001055.pub3  Marteau, T. M., Thorne, J., Aveyard, P., Hirst, J., & Sokal, R. (2013). Financial incentives for smoking cessation in pregnancy: protocol for a single arm intervention study. *BMC Pregnancy Childbirth, 13*, 66. doi: 10.1186/1471-2393-13-66 |

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| Do the changes raise any ethical issues?  No  Yes |
| If you answered yes please identify these issues below:  As identified in our earlier application, paying (or rather not paying, if do not verify as quit) both pregnant women and their partners (in the treatment group) if the participant is quit, may increase the likelihood of domestic violence. Arguably, doubling the incentive amount to $50 (from $25) may further increase this risk (although the actual risk is unknown).  In response to the Committee’s earlier concerns and recommendations, stringent screening and monitoring of participants (inc. changes in their relationship with their partner, participation-induced strain/pressures) will be conducted at screening, enrolment and throughout the study. A detailed protocol has been established, in consultation with the Department of Health and Human Services social work team (letter of support attached), to ensure participants who do identify experiencing stress/abuse as a result of participating in the study are supported and referred to appropriate support channels (this protocol was approved by the HREC in the original application).  Furthermore, as per HREC guidelines, in the event of a serious adverse event (e.g., participant reporting relationship strains with their partner as a result of study involvement), researchers will report to the HREC, via the reporting protocol, within 24 hours of occurrence. The researchers have ensured that they are familiar with the reporting process.  We believe that our existing protocol (which includes strict screening, enrolment and monitoring procedures to reduce the risk/capture participation-induced stress/abuse) is as thorough as it can be and is sufficient to support the potential increased risk of participation-induced stress/relationship tension of increasing the incentives value from $25 to $50. |

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| 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. |

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| Has this amendment been approved by another Australian HREC?  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?  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: **27/2/15** |

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| **Submission Details** |
| **Requirements for submission:**  **All documentation** to be emailed to [human.ethics@utas.edu.au](mailto: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. |