Cherise Jaye Fletcher

From: no_reply@gems.sahealth.sa.gov.au
Sent: Thursday, 22 April 2021 10:28 AM
To: Lisa Smithers
Cc: Cherise Jaye Fletcher; Lisa Smithers
Subject: 2021/HRE00038: Application HREA - Approved

Date of Decision Notification: 21 Apr 2021
Dear Lisa Smithers,

Thank you for submitting the following Human Research Ethics Application (HREA) for HREC review;

2021/HRE00038: Smoking Cessation in Pregnancy: Investigating the Feasibility and Acceptability of Carbon Monoxide (CO) monitoring and Financial Incentives to Encourage Smoking Cessation.

This project was considered by the Central Adelaide Local Health Network HREC (CALHN HREC) at its meeting held on 08 April 2021 and was determined to meet the requirements of the National Statement on Ethical Conduct in Human Research (2007).

This project has been approved to be conducted at the following sites:

- Lyell McEwin Hospital, SA, PI: A/Prof Lisa Smithers
- Modbury Hospital, SA, PI:A/Prof Lisa Smithers

The following documentation was reviewed and is included in this approval:

Application Documents - (Please note : Due to security reasons, this link will only be active for 14 days.)

The Human Research Ethics Application reviewed by the HREC was:
Version: 1.01
Date:

The approval is for a period of 3 years from the date of this e-mail (21 April 2021) on condition of the submission of annual reports for both ethics and governance applications.

The CALHN HREC is constituted and operates in accordance with the National Statement on Human Conduct in Research, 2007 (Updated 2018) (NHMRC). The processes used by this HREC to review multi-centre research proposals have been certified by the National Health and Medical Research Council.

All clinical trials approved by the CALHN HREC must comply with the *NHMRC Guidance on Safety Monitoring and Reporting in Clinical Trials Involving Therapeutic Goods* (November 2016). The CALHN HREC must be notified within 72 hours of any Urgent Safety Measures (USMs) occurring at any approved sites.

Confidentiality of the research participants must be maintained at all times as required by law.

A report and a copy of any published material should be forwarded to the HREC at the completion of the project. If the project is discontinued before its completion, the HREC must be advised immediately and provided with reasons for discontinuing the project.

We wish you all the best with the project and remind you that any changes to the application and safety reports will need to be submitted and reviewed by the approving HREC prior to implementation. You must immediately report to the HREC anything that may change the ethics or scientific integrity of the project.

This email constitutes ethical and scientific approval only. This project cannot proceed at any site until separate research governance authorisation has been obtained from the institution under whose auspices the research will be conducted at that site.

If your study involves a tertiary institution, contact the University to ensure compliance with University requirements prior to commencement of this study. This includes any insurance and indemnification.

Please contact us if you would like to discuss any aspects of this process further, as per the contact details below. We look forward to managing this application with you throughout the project lifecycle.

Regards,

CALHN Research Ethics

for
Mr Ian Tindall
Chair, Human Research Ethics Committee
Central Adelaide Local Health Network
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