



2024/ETH00751: Notification of an amendment to a research study - General Amendment (185160) - Approved

Date of Decision Notification: **19 Dec 2024**
Greater than low risk review pathway

Dear Dr Sonali Gnanenthiran,

Thank you for submitting an Amendment for the following study;
2024/ETH00751: Low dose combinations To improve stroke outcomes: The LOTUS randomised trial

The Amendment has been reviewed on 19 Dec 2024, by the Executive Officer as delegated by the HREC Chair and has been approved.

Notification of an amendment to a research study - General Amendment with form ID 185160

The following documentation is included in this approval:

- LOTUS Protocol (Version 5.0, 17 Dec 2024)
- LOTUS Master PISCF (Version 5.0, 17 Dec 2024)
- LOTUS Easy Read Participant Information Sheet (Version 3.0, 17 Dec 2024)
- LOTUS Health Practitioner Advertisement (Version 3.0, 17 Oct 2024)
- LOTUS Participant Diary Intervention Group (Version 2.0, 17 Oct 2024)
- LOTUS Participant Diary Usual Care Group (Version 2.0, 17 Oct 2024)
- LOTUS Letter to GP trial entry (Version 3.0, 17 Oct 2024)
- LOTUS Letter to GP trial completion (Version 2.0, 17 Oct 2024)
- LOTUS Master Electronic PISCF (Version 1.0, 17 Oct 2024)
- LOTUS A4 Poster (Version 1.0, 17 Oct 2024)
- LOTUS Participant Information Video Script (Version 1.0, 17 Oct 2024)
- LOTUS Participant Instructional Video Script – Measuring your BP at home (Version 1.0, 17 Oct 2024)
- LOTUS Services Australia Participant Consent Form (Version 1.0, 17 Dec 2024)
- LOTUS Services Australia Participant Information Document (Version 1.0, 17 Oct 2024)
- LOTUS Services Australia Participant Withdrawal of Consent Form (Version 1.0, 17 Oct 2024)

It is noted that the Sydney Local Health District Ethics Review Committee (RPAH Zone) is constituted in accordance with the National Statement on Ethical Conduct in Human Research, 2023 (NHMRC).

This email constitutes ethical and scientific approval only.

For NSW authorised sites (listed in REGIS): A Site General Amendment form will need to be submitted to each affected site. You are not required to upload this form or the ethics approved documents into the site form but you will need to identify this approved amendment form ID (185160).

Please contact us if you would like to discuss any aspects of this process further, as per the contact details below.

Yours Sincerely,

Sanaa Thomas

Executive Officer - Clinical Trials Sub-committee

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