Fw: 2024/ETH00028: Application HREA - Approved

Yemima Berman (Northern Sydney LHD) <Yemima.Berman@health.nsw.gov.au>
Tue 2024-04-02 12:09
To:Nanette Dela Cruz Lacson (Northern Sydney LHD) <nanette.lacson@health.nsw.gov.au>

Best wishes

Mimi

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From: no_reply@regis.health.nsw.gov.au <no_reply@regis.health.nsw.gov.au>
Sent: Thursday, 28 March 2024 14:50
To: Yemima Berman (Northern Sydney LHD) <Yemima.Berman@health.nsw.gov.au>
Subject: 2024/ETH00028: Application HREA - Approved

Date of Decision Notification: **28 Mar 2024**

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

2024/ETH00028: A Randomized, Double-Blind, Placebo Controlled, Phase 3 Study Assessing the Efficacy and of L-carnitine Supplementation to Treat Muscle Fatigue and Weakness in children with Neurofibromatosis Type 1.

This Application was reviewed as a **Greater than low risk review pathway** and was initially considered by the **Northern Sydney Local Health District Human Research Ethics Committee** at its meeting held on 22 January 2024.
The project was determined to meet the requirements of the National Statement on Ethical Conduct in Human Research (2023) and was **APPROVED**.

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 at which the research will take place.

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

- **Royal North Shore Hospital**

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

- HREA - 1.04 - 25/3/24
- Protocol - V2.1 - 28/2/24
- L-carnitine _NSLHD-HREC Master Adult Main - 3.0 - 22/03/24
- L-carnitine_NSLHD HREC Master Adolescent PICF - 2.1 - 28/2/24
- Master Child Information and Assent Form - 1.0 - 28/2/24
- Master Parent Guardian ICF - 2.1 - 28/2/24
- Participant Flyer - 2.0 - 12/03/24
- ParticipantCard_RNSH-YB_L-carnitine - 2.0 - 12/3/24
- ParticipantFlyer_RNSH-YB_L-carnitine - 2.0 - 12/3/24
- ParticipantQuickReference_RNSH-YB_L-carnitine - 2.0 - 12/3/24
- ParticipantWelcomeLetter_RNSH-YB_L-carnitine - 2.0 - 12/3/24
- ThankYouCard_RNSH-YB_L-carnitine - 2.0 - 22/3/24
- Dear Colleague_RNSH-YB_L-carnitine - 2.0 - 11/03/24
- Dear Participant_RNSH-YB_L-carnitine - 2.0 - 11/03/24
- L-carnitine Study Facebook and social media post - 1.0 - 22/3/24
- NSLHD RNSH_EOI email to be contacted for relevant research - 1.0 - 10/2/24
- Participant Quick Reference Guide - 2.0 - 12/3/24
- StudyRecruitment_RNSH-YB_L-carnitine - 2.0 - 10/2/24
- Weekly Exercise Diary - 1.0 - 4/1/24
- Invitation_RNSH-YB_L-carnitine - 2 - 12/3/24
- Patient Dosing Diary - 1.0 - 8/12/23
- Brochure-Trifold_RNSH-YB_L-carnitine - 3 - 12/3/24
- PedsQL Multidimensional Fatigue Inventory
- PedsQL Neurofibromatosis Module
- PedsQL Quality of Life Inventory
- Hand Grip Record Sheet - 1.0 - 4/01/24
- Handgrip Strength Test Instructions - 1.0 - 04/01/24
- Handheld Dynamometry Instructions - 1.0 - 31/1/24
- Handheld Dynamometry Record Sheet - 1.0 - 31/1/24
- Invitation_RNSH-YB_L-carnitine - 2.0 - 12/03/24
- 6 Minute Walk Test Instructions - 1.0 - 4/1/24
- 6 MWT Record Sheet - 1.0 - 04/01/24
- Actigraphy Instructions - 1.0 - 04/01/24
- Quality Agreement with Syntro
- Service Agreement with Syntro
- Site Signature and Responsibility Log
- NSLHDSiteCPIPIList - 1.04 - 25/3/24

The following documentation is noted:

- CV_Jane Fleming
- CV_Nanette Lacson
- CV_Principal Investigator Y Berman

Application Documents - (link will only be active for 14 days from the decision date. The approved documents are also available to download from forms section of this project in REGIS)

The Human Research Ethics Application reviewed by the HREC was:
Version: 1.04
Date: 25 Mar 2024

The approval is for a period of 5 years from the date of this e-mail **(28 Mar 2024)**

The Coordinating Principal Investigator will:
• provide the HREC with an annual report and the final report when the project is completed at all sites. This will be through the submission of a milestone in REGIS.
• immediately report anything that might warrant review of ethical approval of the project.
• submit proposed amendments to the research protocol, including; the general conduct of the research, changes to CPI or site PI, an extension to HREC approval, or the addition of sites to the HREC before those changes can take effect. This will be through a notification of an amendment in REGIS
• will notify the HREC if the project is discontinued at a participating site before the expected completion date, with reasons provided.

• submit any necessary reports related to the safety of research participants in accordance with NHMRC Safety and Reporting Guidance. This will be through the Significant Safety Issue or Third Party Breach form in REGIS.
• Interventional trials must be registered on one of the clinical trial registeries e.g. https://secure-web.cisco.com/18DQ7I1IlAb6OlU7kZXBDhnDB_GrhSeIz8Dyje19yFdfpLufIyuG4AKbMEcEryBcFfYoZbXK4C0nh3jLWmcDpZbmsoWGqCEgBKuOkg6-dV-nf1UV64vgjlFXJ6lDa5mpN0SfKgQ5F9Hl8sVySL1GoDwwXzGsXUq9ykEE62jjoWjcqMH55yPebf0im2E_BshS7AzDietM4qhyL7X9iJ9-rSDTQRh-u3l6mt2vnMrlCSbNnu6lXwsGnyO1hOpOMHWyTrOd4PA3F-bOAHJRNMMRAK_5hK6hpdMnzLltJK-BlMR-U04V07NGnicpVCJNPwezlgfHCiWxX3VAb1sgirArqNvMRvK0CU2mMVAsRHGdWA53l1k_Ik8EbAQ037_zFycfRC6drp5lc0-EaurOqb3AkVWEBx5eO3kiLco5ZZ0ahnuRPJUEH576X93tuQQq6Aq0tujCFbn5lY6TYfTiJGWI_1u9gJ-bmDzoEqni7Q9ZQQeQ/https%3A%2F%2Fwww.anzctr.org.au.

Submission of annual progress/final reports (milestone), amendments and safety reports should be done through the forms provided in REGIS. Guidance on these processes can be found on the REGIS website.

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

The processes used by the HREC to review multi-centre research proposals have been certified by the National Health and Medical Research Council.

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 study with you throughout the project lifecycle.

Regards,

Björn Rostron (He/Him)
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