Ritesh Chimoriya

Subject:

FW: 2020/ETH03128: ETHICS APPROVAL ONLY **SITE SPECIFIC AUTHORISATION REQUIRED**

From: no_reply@regis.health.nsw.gov.au Date: 16 February 2021 at 08:21:13 AEDT To: Milan Piya <<u>M.Piya@westernsydney.edu.au</u>> Cc: Milan Piya <<u>M.Piya@westernsydney.edu.au</u>>, <u>SWSLHD-ethics@health.nsw.gov.au</u> Subject: 2020/ETH03128: ETHICS APPROVAL ONLY **SITE SPECIFIC AUTHORISATION REQUIRED** Reply-To: no_reply@regis.health.nsw.gov.au

Date of Decision Notification: 16 Feb 2021

Dear Dr Milan Piya,

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

2020/ETH03128: Feasibility of partial meal replacements to reduce weight in people awaiting knee or hip arthroplasty

This Application was reviewed as a Greater than low risk review pathway and was initially considered by the South Western Sydney Local Health District Human Research Ethics Committee.

The project was determined to meet the requirements of the National Statement on Ethical Conduct in Human Research (2007) and was <u>APPROVED</u>.

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:

- Fairfield Hospital
- Camden Hospital

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

Human Research Ethics Application , Version 2.0 , 18.12.2020 Protocol , Version 1.1 , 03.02.2021 MASTER Participant Information Sheet , Version 1.1 , 03.02.2021 MASTER Consent Form , Version 1.0 , 19.11.2020 Telephone Consent Script for Verbal Consent , Version 1.0 , 19.11.2020 GP Letter , Version 1.0 , 19.11.2020 Patient Questionnaire , Version 1.0 , 19.11.2020

THIS EMAIL CONSTITUTES ETHICAL APPROVAL ONLY – SITE SPECIFIC APPLICATION IS REQUIRED BEFORE ANY RESEARCH CAN COMMENCE AT ANY NSW PUBLIC HEALTH SITE

Please note the following conditions of approval: <u>**Condition of approval: Please ensure that the restrictions and social distancing for COVID-19 are</u> <u>followed until the restrictions have been lifted**</u>

- 1. The Principal Investigator will immediately report anything which might warrant review of ethical approval of the project in the specified format, including: any serious or unexpected adverse events; and unforeseen events that might affect continued ethical acceptability of the project.
- 1. The Principal Investigator will report proposed changes to the research protocol, conduct of the research, or length of HREC approval to the HREC in the specified format, for review. For multi-centre studies, the Chief Investigator should submit to the Lead HREC and then send the amendment approval letter to the investigators at each sites so that they can notify their Research Governance Officer.
- 1. The Principal Investigator will inform the HREC, giving reasons, if the project is discontinued before the expected date of completion.
- 1. The Principal Investigator will provide an annual report to the HREC and at completion of the study in the specified format.
- 1. The Principal Investigator must reassure participants about confidentiality of the data.
- 1. Proposed changes to the personnel involved in the study are submitted to the HREC accompanied by a CV where applicable.
- 1. The Principal Investigator is responsible for ensuring the research project is conducted in line with relevant NSW Health, South Western Sydney Local Health District and Hospital policies available from: <u>https://www.swslhd.health.nsw.gov.au/ethics/policies.html</u>

Should you have any queries about your project please contact **Jessica Grundy** on the telephone number 8738 8304. The HREC Terms of Reference, Standard Operating Procedures, membership and standard forms are available from the SWSLHD website: <u>https://www.swslhd.health.nsw.gov.au/ethics/</u>

Please quote the Local HREC reference **2020/ETH03128** in all correspondence. The HREC wishes you every success in your research.

Yours faithfully Mrs Jessica Grundy on behalf of A/Professor Murray Killingsworth Chairperson, SWSLHD Human Research Ethics Committee This HREC is constituted and operates in accordance with the National Health and Medical Research Council's (NHMRC) *National Statement on Ethical Conduct in Human Research (2007)*. The processes used by this HREC to review multi-centre research proposals have been certified by the National Health and Medical Research Council.