From: Astrid Nordmann
To: Won Sun Chen

Cc: RES Ethics; Denny Meyer; Matthew Pase; Wil I@hotmail.com

Subject: SHR Project 2019/035 - Ethics clearance
Date: Friday, 3 May 2019 9:52:34 AM

Attachments: <u>image001.png</u>

To: Dr Sharon Chen, FHAD

Dear Sharon,

SHR Project 2019/035 – The Virgin Pulse Global Challenge Study (VEGAS): a single-blind, randomised controlled trial to evaluate the health outcomes of the Virgin Pulse Global Challenge (VPGC) programme

Dr Won Sun (Sharon) Chen, Prof. Denny Meyer, Mr Wilson Hong H Low (Student), Dr Matthew Pase - FHAD

Approved duration: 03-05-2019 to 02-05-2022 [adjusted]

I refer to the ethical review of the above project protocol by Swinburne's Human Research Ethics Committee (SUHREC). Your response to the review, as emailed on 30 April 2019, accords with the Committee review.

I am pleased to advise that, as submitted to date, the project may proceed in line with standard on-going ethics clearance conditions outlined below.

The approved duration is **03 May 2019** to **02 May 2022** unless an extension request is subsequently approved.

All human research activity undertaken under Swinburne auspices must conform to Swinburne and external regulatory standards, including the *National Statement on Ethical Conduct in Human Research (2007 – updated 2018)* and with respect to secure data use, retention and disposal.

The named Swinburne Chief Investigator/Supervisor remains responsible for any personnel appointed to or associated with the project being made aware of ethics clearance conditions, including research and consent procedures or instruments approved. Any change in chief investigator/supervisor, and addition or removal of other personnel/students from the project, requires timely notification and SUHREC endorsement.

The above project has been approved as submitted for ethical review by or on behalf of SUHREC. Amendments to approved procedures or instruments ordinarily require prior ethical appraisal/clearance. SUHREC must be notified immediately or as soon as possible thereafter of (a) any serious or unexpected adverse effects on participants and any redress measures; (b) proposed changes in protocols; and (c) unforeseen events which might affect continued ethical acceptability of the project.

At a minimum, an annual report on the progress of the project is required as well as at the conclusion (or abandonment) of the project. Information on project monitoring and variations/additions, self-audits and progress reports can be found on the Research Ethics

Internet pages.

A duly authorised external or internal audit of the project may be undertaken at any time.

Please contact the Research Ethics Office if you have any queries about on-going ethics clearance, citing the Swinburne project number. A copy of this email should be retained as part of project record-keeping.

Best wishes for the project.

Yours sincerely

Astrid Nordmann Secretary, SUHREC



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