

Human Research Ethics Committee

Web: http://www.usyd.edu.au/ethics/

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Ref: IM/PR

7 April 2010

Dr Nathan Johnson Faculty of Health Sciences Cumberland Campus - C42 The University of Sydney Email: n.johnson@usyd.edu.au

Dear Dr Johnson

Thank you for your correspondence dated 9 March 2010 addressing comments made to you by the Human Research Ethics Committee (HREC). After considering the additional information, the Executive Committee at its meeting held on 16 March 2010 approved your protocol entitled "A novel exercise regime to reduce cardiometabolic risk in overweight sedentary individuals".

Details of the approval are as follows:

Ref No.: 12539

Approval Period: March 2010 to March 2011

Authorised Personnel: Dr Nathan Johnson

Dr Helen O'Connor Ms Elizabeth Machan

Approved Documents: Participant Information Statement, updated

Informed Consent Recruitment Flyer

The HREC is a fully constituted Ethics Committee in accordance with the *National Statement on Ethical Conduct in Research Involving Humans-March 2007* under *Section 5.1.29*.

The approval of this project is **conditional** upon your continuing compliance with the *National Statement on Ethical Conduct in Research Involving Humans*. We draw to your attention the requirement that a report on this research must be submitted every 12 months from the date of the approval or on completion of the project, whichever occurs first. Failure to submit reports will result in withdrawal of consent for the project to proceed.

Chief Investigator / Supervisor's responsibilities to ensure that:

- (1) All serious and unexpected adverse events should be reported to the HREC as soon as possible.
- (2) All unforeseen events that might affect continued ethical acceptability of the project should be reported to the HREC as soon as possible.
- (3) The HREC must be notified as soon as possible of any changes to the protocol. All changes must be approved by the HREC before continuation of the research project. These include:-
 - If any of the investigators change or leave the University.
 - Any changes to the Participant Information Statement and/or Consent Form.
- (4) All research participants are to be provided with a Participant Information Statement and Consent Form, unless otherwise agreed by the Committee. The Participant Information Statement and Consent Form are to be on University of Sydney letterhead and include the full title of the research project and telephone contacts for the researchers, unless otherwise agreed by the Committee and the following statement must appear on the bottom of the Participant Information Statement. Any person with concerns or complaints about the conduct of a research study can contact the Manager, Ethics Administration, University of Sydney, on +612 8627 8176 (Telephone); +612 8627 8177 (Facsimile) or ro.humanethics@sydney.edu.au (Email).
- (5) Copies of all signed Consent Forms must be retained and made available to the HREC on request.
- (6) It is your responsibility to provide a copy of this letter to any internal/external granting agencies if requested.
- (7) The HREC approval is valid for four (4) years from the Approval Period stated in this letter. Investigators are requested to submit a progress report annually.
- (8) A report and a copy of any published material should be provided at the completion of the Project.

Yours sincerely

Associate Professor Ian Maxwell

Chair

Human Research Ethics Committee

cc: Elizabeth Machan, email: Emac5251@usyd.edu.au