NANYANG TECHNOLOGICAL UNIVERSITY SINGAPORE

Reg. No. 200604393R

IRB-2020-03-040

06 August 2020

Assoc Prof Burns Stephen Francis
National Institute of Education

Dear Assoc Prof Burns Stephen Francis

NTU INSTITUTIONAL REVIEW BOARD (NTU-IRB) APPROVAL

Project Title: Low Energy Availability (LEA) Threshold in Male Athletes

We are pleased to inform you that the NTU-IRB has approved the application as titled above under **Full Board** review. This study has to be conducted in **National Institute of Education**.

The documents reviewed are:
a) NTU IRB application form dated 19 March 2020
b) BRUMS_Questionnaire.pdf
c) PAR-Q+_Physical Activity Readiness Questionnaire for Everyone.pdf
d) Burns_Sim_Informed Consent Form (HBR) v6.0_update_06082020.pdf
e)RecruitmentFlyer_25032020.pdf

The approval period is from **06 August 2020 to 05 July 2021**. The NTU-IRB reference number for this study is **IRB-2020-03-040**. Please use this reference number for all future correspondence.

Please note that this is a human biomedical research that is regulated by the Human Biomedical Research Act (HBRA). With the enactment of HBRA, PDPA and their subsidiary legislations, researchers are reminded to comply with all the relevant regulatory requirements stipulated in the applicable Acts. Contraventions under any of these Acts are criminal offences and would result in fines or imprisonment or both, subject to the nature of the offence.

The following protocol and compliances are to be observed upon NTU IRB approval

1. Any research involving subjects less than 21 years old would require IRB approved written Parental Consent and consent from the participant before any research protocols can be administered unless waiver of consent is given by IRB. Minimal risk refers to an anticipated level of harm and discomfort that is no greater than that ordinarily encountered in daily life, or during the performance of routine educational, physical, or psychological examination.

2. Only the approved Participants Information Sheet and Consent Form should be used. It must be signed by each subject prior to initiation of any protocol procedures. In addition, each subject should be given a copy of the signed consent form.

3. Consent forms are important documents therefore they should be stored in the strictest arrangement. Loss of consent form would result in disciplinary action.

4. No deviation from, or changes of, the protocol should be initiated without prior written NTU-IRB approval of an appropriate amendment.

5. The Principal Investigator should report promptly to NTU-IRB regarding:
    a. Deviation from, or changes to the protocol.
    b. Changes increasing the risk to the subjects and/or affecting significantly the conduct of the study
    c. All serious adverse events (SAEs) which are both expected and unexpected.
    d. New information that may affect adversely the safety of the subjects of the conduct of the trial.
    e. Completion of the study.

6. Continuing Review Request / Notice of Study Completion form should be submitted to NTU-IRB for the following:
    a. Annual review: Status of the study should be reported to the NTU-IRB at least annually using the Continuing Review Request/ Notice of Study Completion form.
    b. Study completion or termination: Continuing Review Request / Notice of Study Completion form is to be submitted within 4 to 6 weeks of study completion or termination.

7. All Principal Investigators should comply with existing legislation that would have an impact on the domain of their research.

8. Advertisements/ Notices for recruitment of subjects must meet the following requirements:
    a. Advertisements must clearly state that volunteers are being recruited to participate in an NTU research project with proper research title and NTU logo.
    b. Name and contact details of Principal Investigator (usually a faculty member), and NTU-IRB contact details (Tel: 6592 2495; Email: IRB@ntu.edu.sg) should be provided.
    c. The NTU-IRB project reference number should be stated.
    d. Advertisements should include eligibility criteria.
    e. Advertisements recruiting Minors must explicitly state that parental consent is required for participation (unless NTU-IRB has granted approval for a waiver of parental consent).

    Advertisements/ Notices should NOT contain the following:
    a. State or imply a certainty of favourable outcome or other benefits beyond what is outlined in the informed consent form and the application/protocol.
    b. Make claims, either explicitly or implicitly, that a procedure or intervention is safe or effective or superior to other standard procedures or interventions.
    c. Use catchy words like “free” or “exciting.”
    d. Advertisements may state that participants will be paid, but should not emphasize the payment or the amount to be paid (e.g. by such means of larger or bold type)

Dr Lim Jui
Chair, NTU Institutional Review Board
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