From: donotreply@infonetica.net

Sent: Wednesday, 29 August 2018 4:34 PM

To: Angie.Fearon; Jaquelin.Bousie; Bhavleen Kaur.Smoot

Cc: Human Ethics Committee

Subject: 20180227 - Approved

Dear Angie

The Human Research Ethics Committee has considered your application to conduct a clinical

trial with human subjects for the project 20180227 - The GTPS shoe insert study

The Committee made the following evaluation: Approved

The approval is valid until: 01/05/2019

The following general conditions apply to your approval. These requirements are determined by

University policy and the National Statement on Ethical Conduct in Human Research

(National Health and Medical Research Council, 2007).

Monitoring

You must assist the Committee to monitor the conduct of approved clinical trials by completing

and promptly returning project review forms, and, in the case of extended research, reporting at

least once a year during the approval period. Audits of projects may occur at any time during the

project.

Reporting Adverse Events

You must report any unexpected adverse events or complications that occur anytime during the

conduct of the clinical trial or during the follow up period after the trial. Please refer these

matters promptly to the HREC. Failure to do so may result in the withdrawal of the Ethics

approval.

Discontinuation of Research

You must inform the Committee, giving reasons, if the clinical trial is not conducted or is

discontinued before the expected date of completion.

Extension of Approval

If the clinical trial will not be complete by the expiry date stated above, you must apply in writing

for extension of approval. Application should be made before current approval expires; should

specify a new completion date; should include reasons for your request.

Retention and Storage of Data

You must ensure that all records are transferred to the University when the project is complete.

For most clinical trials, data should be retained for a minimum of 15 years and longer if

necessary. For areas such as Gene Therapy, research data must be retained permanently.

Insurance Coverage

Appropriate University insurance must be arranged for researchers, external co-investigators

and research participants. Non-UC personnel involved in conducting the trial should also have

adequate insurance cover.

If the trial is being conducted at multiple sites or overseas, it is recommended that you provide a

list of sites to Insurance and request confirmation of coverage for those sites.

Good Clinical Practice

Clinical trials must be conducted in accordance with the Note for Guidance on Good Clinical

Practice (CPMP?ICH135/95 - Annotated with TGA Comments) and the Good Clinical Practice

(GCP) guidelines adopted in Australia. GCP is an international ethical and scientific quality

standard for designing, conducting, recording and reporting trials that involve human

participants.

Contact Details and Notification of Changes

All email contact should use the UC email address. You should advise the Committee of any

change of address during or soon after the approval period including, if appropriate, email

address(es).

Please do not hesitate to contact us via email humanethicscommittee@canberra.edu.au if you

require any further information.

All the best,

Hendryk Flaegel

Research Ethics & Integrity

Research Services

University of Canberra

29/08/2018