



1 February 2018

Conjoint A/Professor Lisa Lincz
Hunter Haematology Research Group
Calvary Mater Newcastle

Dear A/Professor Lincz,

**Re: HaemFit: Exercise and Wellness Program for Haematology Cancer Patients
(17/12/13/5.15)**

HNEHREC Reference No: 17/12/13/5.15
NSW HREC Reference No: LNR/17/HNE/616
NSW SSA Reference No: LNRSSA/17/HNE/617

Thank you for submitting the above study for single ethical review. This project was considered to be eligible to be reviewed as Low and Negligible risk research, and so was reviewed at an Executive Meeting of the Hunter New England Human Research Ethics Committee on **30 January 2018**. This Human Research Ethics Committee is constituted and operates in accordance with the National Health and Medical Research Council's *National Statement on Ethical Conduct in Human Research (2007)* (National Statement) and the *CPMP/ICH Note for Guidance on Good Clinical Practice*. Further, this Committee has been accredited by the NSW Department of Health as a lead HREC under the model for single ethical and scientific review. The Committee's Terms of Reference are available from the Hunter New England Local Health District website.

I am pleased to advise, the Hunter New England Human Research Ethics Committee has determined that the above protocol meets the requirements of the *National Statement on Ethical Conduct in Human Research* and, following acceptance of the requested clarifications and revised Information Sheets and Consent Form, Survey, Nutrition Resource; Exercise Program Booklet and Follow-up phone survey by Dr Nicole Gerrand Manager, Research Ethics & Governance, under delegated authority from the Committee, grants ethical approval of the above project.

The *National Statement on Ethical Conduct in Human Research (2007)*, to which the Committee is obliged to adhere, include the requirement that the Committee monitors the research protocols it has approved. **Ethics Approval will be ongoing subject to the following conditions:**

- A report on the progress of the above protocol is to be submitted at 12 monthly intervals, or, 2 months after the proposed closure date of the project, if this date is less than 12 months. A proforma for the annual report will be sent. Your review date is **December 2018** as per your anticipated closure date.
- All variations or amendments to this protocol must be forwarded to, and approved by, the Hunter New England Human Research Ethics Committee prior to their implementation.
- A final report must be submitted at the completion of the above protocol, that is, after data analysis has been completed and a final report compiled.
- Adherence to the safety reporting requirements of the with the NHMRC Safety Monitoring and Reporting Guidance for Therapeutic Goods Trials (November 2016) available at

Hunter New England Research Ethics & Governance Office

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<http://www.hnehealth.nsw.gov.au/ethics/Pages/Research-Ethics-and-Governance-Unit.aspx>

https://www.nhmrc.gov.au/files_nhmrc/file/publications/16469_nhmrc_-_ahec_position_statement-web.pdf

- If for some reason the above protocol does not commence (for example it does not receive funding); is suspended or discontinued, please inform Dr Nicole Gerrand as soon as possible.

The following documentation has been reviewed and approved by the Hunter New England Human Research Ethics Committee:

Document	Version	Date
LNR [Submission Code: AU/6/D77236]		
Protocol	Version 1	30 November 2017
Participant Information Statement and Consent Form	Version 2	24 January 2018
Nutrition Resource	Version 2	24 January 2018
Exercise Program Booklet	Version 2	24 January 2018
Log for Admission and Discharge Documents	no version	undated
Patient Mobility Survey 1	Version 1	30 November 2017
Follow-up Phone Survey	Version 2	24 January 2018
Staff Satisfaction Survey	Version 2	24 January 2018
Hospital Anxiety Depression Scale		1983
EORTC QLQ-C30	Version 3.0	1995

Approval has been granted for this study to take place at the following sites:

- **Calvary Mater Newcastle**

You are reminded that this letter constitutes ethical approval only. You must not commence this research project at a site until separate authorisation from the Chief Executive or delegate of that site has been obtained.

A copy of this letter must be forwarded to all site investigators for submission to the relevant Research Governance Officer.

Should you have any concerns or questions about your research, please contact Dr Gerrand as per the details at the bottom of the page. The Hunter New England Human Research Ethics Committee wishes you every success in your research.

Please quote **17/12/13/5.15** in all correspondence.

The Hunter New England Human Research Ethics Committee wishes you every success in your research.

Yours faithfully

For: Ms M Hunter
Chair
Hunter New England Human Research Ethics Committee

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