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11 March 2020

Dr Amy Dennett
Allied Health Clinical Research Office
Level 2, 5 Arnold St
Box Hill VIC 3128

Dear Dr Amy Dennett,

Study Title: Prehabilitation to Improve outcomes after Autologous sTem cEll transplantation (PIRATE) – A randomised controlled trial

Principal Investigator: Dr Amy Dennett

Associate Investigators: Prof Nicholas Taylor, A/Prof Judi Porter, A/Prof Stephen Ting

ERM Project ID: 61055

Eastern Health Site Reference Number: E20/003/61055

Further to HREC correspondence sent 25 February 2020 and responses received 05 March 2020 including a final series of amendments and clarifications.

I am pleased to advise that the above study has received full ethical approval from the Eastern Health Human Research Ethics Committee (HREC). The study has received full governance authorisation also from the Office of the Chief Executive Officer or delegate at Eastern Health and may commence at the nominated site.

The HREC confirms that your proposal meets the requirements of the National Statement on Ethical Conduct in Human Research (2007 all updates inclusive) (**National Statement**). This HREC is organised and operates in accordance with the National Health and Medical Research Council's (**NHRMC**) National Statement and all subsequent updates, and in accordance with the Note for Guidance on Good Clinical Practice (CPMP/ICH/135/95), the Health Privacy Principles (HPP's) described in the Health Records Act 2001 (Vic).

HREC Final Approval Date: 11 March 2020

Research Governance Authorisation: 11 March 2020

Ethical approval for this project applies at the following site(s): Box Hill Hospital

Approved Documents:

The following documents have been reviewed and approved by the HREC:

Document	Version	Dated
Human Research Ethics Application (HREA)	HREC/61055/EH-2020-204216(v3)	26 February 2020
Protocol	2	25 February 2020
Participant Information Sheet and Consent Form (PICF)	2	25 February 2020
Victorian Specific Module (VSM)	N/A	06 March 2020

The following documents have been reviewed and authorised by the Office of Research and Ethics (Research Governance):

Document	Version	Dated
Site Specific Assessment (SSA)	SSA/61055/EH-2020-204212(v1)	26 February 2020

Approval is subject to:

1. The Principal Researcher is to ensure that all associate researchers are aware of the terms of approval and to ensure the project is conducted as specified in the application and in accordance with the National Statement.
2. Immediate notification to the Office of Research & Ethics of any serious adverse events on participants.
3. Immediate notification of any unforeseen events that may affect the continuing ethical acceptability of the project.
4. Notification of any changes to personnel on the study.
5. Notification and reasons for ceasing the project prior to its expected date of completion.
6. Notification of amendments to the study.
7. Submission of an annual report due in February each year for the duration of the study (report template is [here](#)).
8. Submission to the HREC of any proposed modifications to the project or documents as approved by the HREC and noted above.
9. Submission of a final report and papers published on completion of the project.
10. Projects may be subject to an audit or any other form of monitoring by the Eastern Health Office of Research & Ethics at any time.

Confidentiality, Privacy & Research:

Research data stored on personal computers, USBs and other portable electronic devices must not be identifiable. No patients' names or UR numbers must be stored on these devices. Electronic storage devices must be password protected or encrypted. The conduct of research must be compliant with the conditions of ethics approval and Eastern Health policies.

Publications:

It is very important that the role of Eastern Health is acknowledged in publications.

Composition of the HREC

We confirm at the meetings at which the above project was considered, the Committee fulfilled the requirements of the NHMRC National Statement in that it contained men and women encompassing different age groups and included people in the following categories:

HREC Members

Chairperson

Lay Man

Lay Woman

Lawyer

Person/s fulfilling a Pastoral Care Role

Person/s with Counselling Experience

Person/s with Current Research Experience

Please quote the reference number **E20/003/61055** in all future correspondence.

Yours sincerely

Ethics Governance and Project Officer
Eastern Health Office of Research and Ethics

On behalf of

1. Eastern Health Human Research Ethics Committee (Ethics Approval)
2. Executive Director Research (Site Research Governance Authorisation)