ACT Government
Health

ACT Health
Human Research Ethics Committee

Dr Samuel Bennett
Department of Haematology
Building 10, Level 3
Canberra Hospital
Garran ACT 2605

Dear Dr Bennett

ETH.7.14.166

The ACT Health Human Research Ethics Committee considered the proposed:

DCA in Myeloma (DICAM): Phase 2 clinical trial of Dichloroacetate in Plasma Cell Myeloma patients in plateau phase at its meeting of 4 August 2014.

I am pleased to inform you that, following further correspondence, your application has been approved.

Approval includes:

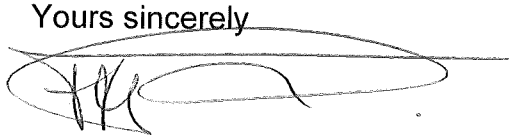
- HREC Application
- Protocol version 1.0 dated August 2014
- DICAM Participant Information Sheet, version 2.0, dated 1 September 2014
- DICAM-SS Consent Form, version 2.0, dated 1 September 2014
- PPF Funding Approval
- Study Procedures
- DICAM Blood Sampling Schedule

I confirm that the ACT Health Human Research Ethics Committee is constituted according to the National Statement on Ethical Conduct in Human Research 2007 and is certified for single review of multi-centre clinical trials. ACT Health HREC operates in compliance with applicable regulatory requirements and the International Conference on Harmonization Guidelines on Good Clinical Practice.

I attach for your records an Outcome of Consideration of Protocol form.

You are reminded that this letter grants ethical approval only. The research project must not commence at any non-ACT Health site until site-specific governance approval has been granted.

Yours sincerely



A/Professor Frank van Haren
Acting Chair
ACT Health Human Research Ethics Committee

17 September 2014

ACT HEALTH HUMAN RESEARCH ETHICS COMMITTEE

Outcome of Consideration of Protocol

Submission No: **ETH.7.14.166** **Date of Approval:** **17 September 2014**

Project Title: DCA in Myeloma (DICAM): Phase 2 clinical trial of Dichloroacetate in Plasma Cell Myeloma patients in plateau phase

Submitted by: Dr Samuel Bennett

Your project was considered by the ACT Health Human Research Ethics Committee and Approved for a period of 5 years from September 2014 to September 2019

First Annual Review due: September 2015

Conditions of Approval:

- At regular periods, and not less than annually, Principal Investigators are to provide reports on matters including:
  - adverse affects on participants
    - Serious Adverse Events as they occur on site
    - SUSAR/Line Listing reports
  - unforeseen events that could affect the continued ethical acceptability of the project
  - proposed changes in the protocol
  - updates of the investigator brochures
  - continued compliance with approved consent procedures and updates of consent documentation
  - Data Safety Monitoring Board Reports (where applicable)
  - security of records
  - updated insurance coverage
  - compliance with other approved procedures.
- All published reports are to carry an acknowledgement stating:
  - Approved by ACT Health Human Research Ethics Committee on 17 September 2014

A/Professor Frank van Haren
Acting Chair
ACT Health Human Research Ethics Committee

17 September 2014