

20 October 2016

Dr Suresh Subramanian
30 Bairds Road
Otara
Auckland 1640

Dear Dr Subramanian

Re:	HDEC ref:	16/STH/125/AM01
	Study title:	d-mannose for prophylaxis against Urinary tract Infection in patients who sustained Spinal Cord Injury with neurogenic bladder dysfunction: Pilot Randomised control study

We have received this amendment for HDEC review that was submitted on 19 October 2016.

This amendment has not been validated for HDEC review as it relates to a non-standard condition that was set out in the HDEC approval letter of 05 October 2016.

It is the responsibility of the CI and study sponsor to ensure that applicants meet all standard and minor conditions of HDEC approval before the study commences (or commences at a given locality). Neither the HDEC nor the secretariat is required to undertake any further review to ensure that this is the case, or to confirm approval.

This letter confirms receipt of your non-standard conditions.

Because this amendment is not substantial it does not require HDEC approval. However, you should check that making this amendment would not affect any of the other approvals (such as regulatory approval or research governance approval) in place for this study.

If you consider that our decision not to validate this amendment is in error, please contact us as soon as possible giving reasons for this.

Yours sincerely,



Tania Siwatibau
Administrator
Health and Disability Ethics Committees
hdcs@moh.govt.nz

Encl: appendix A: documents submitted

Appendix A
Documents submitted

Document	Version	Date
Protocol: Protocol update	version 2	19 October 2016
Post Approval Form	01	-