Health and Disability Ethics Committees
Ministry of Health
Freyberg Building
20 Aitken Street
PO Box 5013
Wellington
6011

0800 4 ETHICS
hdecs@moh.govt.nz

15 September 2016

Dr Sunita Azariah
Auckland Sexual Health Service
Greenlane Clinical centre
Private Bag 92189
Auckland mail Centre
Auckland 1142

Dear Dr Azariah

Re:	**Ethics ref:**	**16/NTA/112**
	Study title:	The NZPrEP study: a demonstration project of HIV pre-exposure prophylkaxis in Aotearoa, New Zealand

I am pleased to advise that this application has been *approved* by the Northern A Health and Disability Ethics Committee. This decision was made through the HDEC-Full Review pathway.

Conditions of HDEC approval

HDEC approval for this study is subject to the following conditions being met prior to the commencement of the study in New Zealand. It is your responsibility, and that of the study's sponsor, to ensure that these conditions are met. No further review by the Northern A Health and Disability Ethics Committee is required.

Standard conditions:

1. Before the study commences at *any* locality in New Zealand, all relevant regulatory approvals must be obtained.

2. Before the study commences at *any* locality in New Zealand, it must be registered in a clinical trials registry. This should be a WHO-approved (such as the Australia New Zealand Clinical Trials Registry, www.anzctr.org.au). However https://clinicaltrials.gov/ is acceptable provided registration occurs prior to the study commencing at *any* locality in New Zealand.

3. Before the study commences at *a given* locality in New Zealand, it must be authorised by that locality in Online Forms. Locality authorisation confirms that the locality is suitable for the safe and effective conduct of the study, and that local research governance issues have been addressed.

After HDEC review

Please refer to the *Standard Operating Procedures for Health and Disability Ethics Committees* (available on www.ethics.health.govt.nz) for HDEC requirements relating to amendments and other post-approval processes.

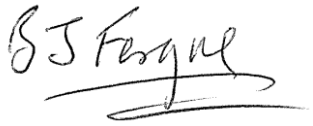
Your **next progress report** is due by **14 September 2017**.

Participant access to ACC

The Northern A Health and Disability Ethics Committee is satisfied that your study is not a clinical trial that is to be conducted principally for the benefit of the manufacturer or distributor of the medicine or item being trialled. Participants injured as a result of treatment received as part of your study may therefore be eligible for publicly-funded compensation through the Accident Compensation Corporation (ACC).

Please don't hesitate to contact the HDEC secretariat for further information. We wish you all the best for your study.

Yours sincerely,



Dr Brian Fergus
Chairperson
Northern A Health and Disability Ethics Committee

Encl: appendix A: documents submitted
appendix B: statement of compliance and list of members

Appendix A
Documents submitted

Document	*Version*	*Date*
Covering Letter: covering letter re-submission	1	05 September 2016
CV for CI: CV	1	14 March 2016
Evidence of scientific review: Scientific review	1	14 July 2016
PIS/CF: consent form	2	31 August 2016
PIS/CF: consnet for storage of blood samples	1	25 July 2016
PIS/CF: participant information sheet	3	31 August 2016
Survey/questionnaire: behavioural survey	2	07 July 2016
Survey/questionnaire: behavioural survey study entry	2	07 July 2016
Protocol: protocol	3	31 August 2016
CVs for other Investigators: CV	1	25 July 2016
Application		
letter defining roles and responsibilities of Gilead Sciences in funding the study	1	29 July 2016
Response to Request for Further Information		

Appendix B
Statement of compliance and list of members

Statement of compliance

The Northern A Health and Disability Ethics Committee:

- is constituted in accordance with its Terms of Reference
- operates in accordance with the *Standard Operating Procedures for Health and Disability Ethics Committees*, and with the principles of international good clinical practice (GCP)
- is approved by the Health Research Council of New Zealand's Ethics Committee for the purposes of section 25(1)(c) of the Health Research Council Act 1990
- is registered (number 00008714) with the US Department of Health and Human Services' Office for Human Research Protection (OHRP).

List of members

Name	*Category*	*Appointed*	*Term Expires*
Dr Brian Fergus	Lay (consumer/community perspectives)	11/11/2015	11/11/2018
Ms Rosemary Abbott	Lay (the law)	15/03/2016	15/03/2019
Dr Karen Bartholomew	Non-lay (intervention studies)	13/05/2016	13/05/2019
Dr Charis Brown	Non-lay (intervention studies)	11/11/2015	11/11/2018
Ms Susan Buckland	Lay (consumer/community perspectives)	11/11/2015	11/11/2016
Ms Shamim Chagani	Non-lay (health/disability service provision)	11/11/2015	11/11/2016
Dr Christine Crooks	Non-lay (intervention studies)	11/11/2015	11/11/2018
Dr Kate Parker	Non-lay (observational studies)	11/11/2015	11/11/2018

Unless members resign, vacate or are removed from their office, every member of HDEC shall continue in office until their successor comes into office (HDEC Terms of Reference)

http://www.ethics.health.govt.nz