Health and Disability Ethics Committees
Ministry of Health
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0800 4 ETHICS
hdecs@moh.govt.nz

17 May 2016

Dr Christian Schwabe
PO Box 8963
Symonds St
Grafton
Auckland 1150

Dear Dr Schwabe

Re:	**Ethics ref:**	**16/NTA/42**
	Study title:	A randomized, double-blind, single-dose, 3-way, parallel group, comparator-controlled, adaptive design, pharmacokinetic, safety, and tolerability study in healthy male volunteers to evaluate bioequivalence of CIPLA bevacizumab (CBT-124) to Avastin ® (EU and US)

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.

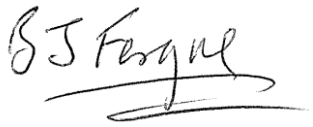
Your **next progress report** is due by **16 May 2017.**

Participant access to ACC

This clinical trial is to be conducted principally for the benefit of the manufacturer or distributor of the medicine or item being trialled. Section 32 of the Accident Compensation Act 2001 provides that participants injured as a result of treatment received as part of this trial will **not** 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*
CV for CI: Christian Schwabe 16 December 2015	n/a
Evidence of CI indemnity	n/a
Participant card	2
Evidence of scientific review: Evidence of SCOTT review in parallel	1
Investigator's Brochure: IB	1
Protocol: CT2-CBT124 Protocol Final 20160329_Clean	1
Radio ad text	1
Print ad text	1
Evidence of sponsor insurance	1
PIS/CF: PICF v2 05 May 16	2
PIS/CF: PICF PP v1 30 Mar 16	1
Application	
Response to questions raised by committee	1

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	Lay (consumer/community perspectives)	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