OPTIMUM
CLINICAL RESEARCH INC.

July 23, 2014

Ethics Review Board General Approval Form

File No. 757

Principal Investigator:

Dr. Anatoly Langer
Canadian Heart Research Centre
259 Yorkland Road, Suite 200
North York, ON M2J 0B5

This is to notify you that following review of the documents detailed below, the status of approval has been allocated to the research project by the Ethics Review Board of Optimum Clinical Research Inc.

TITLE: **CHOLESTABETES (CHOLESTerol lowering in type 2 diABETES) Quality Enhancement Research Initiative (QuERI)**
SPONSOR: **VALEANT CANADA/CANADIAN HEART RESEARCH CENTRE**
DATE: **JUNE 5, 2014**
JULY 8, 2014

Status of Approval

At the meeting held on June 11, 2014, the Board reviewed and unconditionally approved the above protocol. The amended protocol dated July 8, 2014 was reviewed and approved at the meeting held on July 16, 2014.

At the meeting held on July 16, 2014, the Board reviewed and approved the revised Informed Consent Form dated July 8, 2014. The attached stamped Informed Consent Form received approval by the Board for your use. This is the version which must be used. If the consent form is required in any language other than English, a copy of the translated form, along with confirmation that translation of the approved version was made, must be forwarded to the Board. Any changes to the form must be submitted to Optimum for review.

The Board provided approval on behalf of Principal Investigator, Dr. A. Langer.

This approval is valid for one (1) year from the date of initial approval, **to expire June 18, 2015.**

Signature of Co-Chair

July 23, 2014
Date

PAUL MACNEIL
Name of Co-Chair

PM/pgh

Optimum Ethics Review Board is constituted and functions according to Division 5 of the Food and Drug Regulations, ICH/GCP Guidelines, FDA 21 CFR Parts 50 & 56, DHHS Section 45 CFR 46, the Declaration of Helsinki, FDA Information Sheets: Guidance for IRBs and Clinical Investigators and the Tri-Council Policy Statement for Ethical Conduct of Research Involving Humans.