



TheAlfred

Ethics Committee

Certificate of Approval of Amendments

This is to certify that amendments to

Project: **152/15 A randomized, double blind, 2-treatment, 2-period, single-dose, cross over, comparative study to evaluate pharmacokinetics, safety and tolerability of Stelis Teriparatide [rh-PTH (1-34)] [teriparatide, Stelis Biopharma Pvt. Ltd., India] with Forsteo® (teriparatide, Eli Lilly Nederland BV, Grootslag 1-5, NL-3991 RA Houten, The Netherlands) in healthy volunteers following subcutaneous administration of a single dose of 20 mcg Teriparatide**

Principal Researcher: **Dr Jason Licklitter**

Amendment: **Revised protocol and PICF;
Wallet Card, version 2, date: 11/Sep/2015**

**Protocol PTH/CT1-001/R0, version 01, dated: 25/Aug/2015
Participant Information & Consent Form, Version 5, dated: 10/Sep/2015**

have been approved in accordance with your amendment application dated **11/09/2015** on the understanding that you observe the National Statement on Ethical Conduct in Human Research.

Acknowledgement of the letter from the sponsor, dated 28/Aug/2015

It is now your responsibility to ensure that all people associated with this particular research project are made aware of what has actually been approved and any caveats specified in correspondence with the Ethics Committee. Any further change to the application which is likely to have a significant impact on the ethical considerations of this project will require approval from the Ethics Committee.

**Professor John J. McNeil
Chair, Ethics Committee**

Date: 24/Sep/2015

All research subject to Alfred Hospital Ethics Committee review must be conducted in accordance with the National Statement on Ethical Conduct in Human Research (2007).

The Alfred Ethics Committee is a properly constituted Human Research Ethics Committee operating in accordance with the National Statement on Ethical Conduct in Human Research (2007).