



TheAlfred

Ethics Committee

Certificate of Approval of Amendments

This is to certify that amendments to

Project: **325/15 A Randomized, Double-Blind, Placebo-Controlled, Single and Multiple Ascending Dose Study to Assess the Safety, Tolerability and Pharmacokinetics of DUR 928 Administered Intramuscularly (IM) in Healthy Volunteers**

Principal Researcher: **Dr Jason Licklitter**

Amendment: **Revised protocol and PICF (SAD component): Addition of cohort 4 for SAF at 300 mg (2x150 mg injections)**

**Protocol C928003, Amendment 2, dated: 04/11/2015;
Participant Information & Consent Form – part A: SAD, Version 3, dated:
12/Nov/2015**

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

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.

Date: **16/Nov/2015**

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

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).