



## Ethics Committee

### Certificate of Approval of Amendments

This is to certify that amendments to

Project: **HREC/91633/Alfred-2022 (Local Project No. 665/22)**

**A Randomized, Double-Blind, Parallel group, Comparative Phase I study for the assessment of Pharmacokinetics, Pharmacodynamics, Safety, Tolerability, and Immunogenicity of BP16 (Denosumab) versus US licensed - Prolia® and EU approved - Prolia® Following a Single dose (60mg/mL) Subcutaneous Administration in Healthy Male Volunteers**

Principal Researcher: **Dr Sam Francis**

Protocol: **BP16-101**

Amendment: **Protocol and PICFs**

<i>Document</i>	<i>Version</i>	<i>Date</i>
Protocol BP16-101	2.0	15-Mar-2023
Master Participant Information Sheet and Consent Form: Main	2	05-Apr-2023
Master Participant Information Sheet and Consent Form: Pregnancy	2	06-Apr-2023
Nucleus Network Procedure for Remote eConsent	-	-

have been approved under the National Mutual Acceptance (NMA) scheme in accordance with your amendment application dated **06-Apr-2023** on the understanding that you observe the National Statement on Ethical Conduct in Human Research.

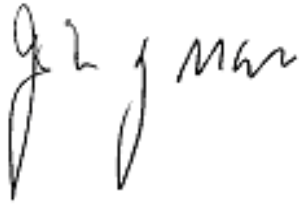
#### **Special Conditions:**

- 1. Continuous insurance coverage needs to be maintained throughout the period of the clinical trial (ie until the final report has been submitted to the Ethics Committee for acknowledgement). Therefore, once the policy expires it is expected that it will be renewed under the same terms.**
- 2. All research projects approved by the Alfred Hospital Ethics Committee are subject to, and must be carried out in compliance with, the most recent applicable COVID-19 government and relevant institution's restrictions.**

The Alfred Hospital Ethics Committee has approved the study but does not take responsibility for research governance processes at the participating sites. It is the responsibility of each participating site to create and implement research governance practices to adequately authorise, monitor and oversee the conduct of the study at their site.

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.

A handwritten signature in black ink, appearing to read 'J J McNeil', written in a cursive style.

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

**Date: 13-Apr-2023**

*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).*