



## Ethics Committee

### Certificate of Approval of Amendments

This is to certify that amendments to

Project: **545/14 Treating metastatic melanoma with Stereotactic ABLative Radiotherapy and IMMune Pathway ACTivation: A phase I dose-escalation trial**

Principal Researcher: **Dr Sashendra Senth**

Amendment: **In addition to using Nivolumab, Pembrolizumab and Ipilimumab alone, the PBS now funds combination treatment with Nivolumab and Ipilimumab at the same time. The protocol has been amended to reflect this line of immunotherapy being available to patients.**

**Protocol SABR IMPACT I, Version 6.0, dated: 09/Dec/2016;**  
**Participant Information & Consent Form, Version 6.0, dated: 09/Dec/2016**

have been approved in accordance with your amendment application dated **22-Nov-2016** 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.

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

**Date: 13-Jan-2017**

*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).*