



## Ethics Committee

### Certificate of Authorisation of Amendments

This is to certify that amendments to

Project: **HREC/16/Alfred/16 (Local reference: 100/16)  
The PrEPX Study - Pre-exposure Prophylaxis  
Expanded**

Principal Researcher: **A/Professor Edwina Wright**

Amendment: **Revised PICF: Truvada now TGA-approved for use as  
PrEP; collection and storage of UR number in PrEP  
database; changes regarding ACCESS; revised  
wording to be more inclusive of transgender  
participants**

**FAQ, version 1, dated: 25/Jul/2016;  
Participant Information & Consent Form: Version 4 dated 6/27/2016**

have been authorised under the Consultative Council for Clinical Trial Research (CCCTR) Streamlined Ethics Review Program (SERP) in accordance with your amendment application dated **07/Jul/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: **25/Jul/2016**

*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).*