

# ETHICS COMMITTEE CERTIFICATE OF APPROVAL



<b>Barwon Health Reference</b>	<b>19/118</b>
<b>Project Title</b>	<b>Botulinum toxin for the treatment of anal fistulae - a double blinded randomized trial</b>
<b>Protocol Reference</b>	<b>V4</b>
<b>Principal Researcher</b>	<b>A/Prof Douglas Stupart</b>
<b>Research Team</b>	<b>Prof David Watters, Dr Eileen Moore</b>

The above project was considered by the Human Research Ethics Committee at the meeting of 11 September 2019 and having fulfilled the requirements of the National Statement on Ethical Conduct in Human Research (2007), was approved on 6 December 2019.

The documents reviewed and approved are:

HREA
SSA
PICF V4 dated 04/12/2019
Protocol V4 dated 04/12/2019
Appendix 1 – Pilot Study Paper dated 15/08/2019
BH Authorship dated Aug 2019
Drug Data Sheet dated June 2019
Prescription Form dated 19/08/2019
VSM V1 dated 19/08/2019

It is the Principal Researcher's responsibility to ensure that all researchers associated with this project are aware of the conditions of approval and which documents have been approved.

The Principal Researcher is required to notify the Research Ethics, Governance & Integrity (REGI) Unit, via amendment or report, of:

- Any significant change to the project and the reason for that change, including an indication of ethical implications (if any);
- Any serious adverse effects on participants and the action taken to address those effects;
- Any other unforeseen events or unexpected developments that merit notification;
- The inability of the Principal Researcher to continue in their role, or any other change in research personnel involved in the project;



- A delay of more than 12 months in the commencement of the project;
- Annual progress reports on the progress of the project and at the conclusion of the project. Failure to report as required may result in suspension of your approval to proceed with the project, and;
- If applicable, please provide the clinical trial registration number.

This approval covers the project as described in the application (including any modifications made prior to approval).

***Please quote the Barwon Health reference number and title in all future correspondence.***

### **Special Conditions**

The site/s to which this approval pertains includes:

- *Barwon Health*

Templates for reporting changes to the project and annual/final reports may be obtained from the Department of Health website - <http://www.health.vic.gov.au/clinicaltrials/application-instructions.htm>

All research subject to the Barwon Health HREC review must be conducted in accordance with the National Statement on Ethical Conduct in Human Research (2007). Barwon Health may conduct an audit at any time.

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

On behalf of the Committee, best wishes for your project.

Yours sincerely



**Mr Richard Larsen**  
**Research Ethics Officer**  
**Research Ethics, Governance & Integrity (REGI) Unit**  
**Barwon Health**

**on behalf of**

**Mr Mike Feehan**  
**Chair**  
**Human Research Ethics Committee**



## **Site Specific Assessment (SSA)**

SSA authorisation is required at all sites participating in this study. This letter also indicates that site specific assessment has been authorised at Barwon Health.

Yours sincerely



**Ms Lisa Fry**  
**Research Governance Officer**  
**Research Ethics, Governance & Integrity (REGI) Unit**  
**Barwon Health**

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