

AUTHORISED PRESCRIBER APPLICATION GUIDE

1. GENERATE A BARWON HEALTH REFERENCE NUMBER

Please contact the Research Ethics, Governance & Integrity (REGI) Unit to request a Barwon Health Reference Number for your Authorised Prescriber Application by emailing regi@barwonhealth.org.au.

2. DOCUMENTS TO BE SUBMITTED AS PART OF YOUR APPLICATION

- Cover Letter (required to be signed by the applicant and department head) outlining the following:
 - The condition to be treated
 - Other approved treatments available for the condition
 - Justification for use of the product in preference to those approved treatments
 - Active ingredient, trade name, dose form, supplier (only applicable if you are applying to be an authorised prescriber of an unapproved **medicine**)
 - Name of device, supplier (only applicable if you are applying to be an authorised prescriber of an unapproved **medical device**)
 - Dosage, route of administration, duration of treatment, details of proposed monitoring
- Curriculum Vitae of each person applying for authorised prescriber status
- [TGA's Agreement to Treatment](#)
- Consent Form
- Supporting Documents (literature, documentation and efficacy/safety data which supports and/or justifies the proposed use of the product)

3. SUBMITTING YOUR APPLICATION

- Please refer to our [document naming guidelines](#) before submitting your application
- Send your complete application electronically to regi@barwonhealth.org.au – *Please notify the REGI Unit if your application is under/intended for review by the Barwon Health Innovations Committee (Technology/Clinical Practice Committee)*

4. REVIEW OF YOUR APPLICATION

Once your application has been received, the REGI Unit will arrange:

- Review of your application by the Drugs and Therapeutics Committee
- Endorsement by the Barwon Health Human Research Ethics Committee Chair
- Approval by the relevant executive

If you have any queries or require some assistance, please contact the Research Ethics, Governance & Integrity (REGI) Unit by emailing regi@barwonhealth.org.au