

Important Update from the TGA

A new online form is now available for the Clinical Trial Notification (CTN) scheme.

As of the 1st of July 2015, the Therapeutic Goods Administration (TGA) will no longer accept paper versions of the CTN forms. All applications to the TGA must now be submitted electronically. [Guidance material for the new online CTN form is available on the TGA website.](#)

This is a welcome initiative and will enhance the efficiency of governance aspects of clinical trials in Australia.

Please note that Barwon Health will take the following approach to the online system:

For commercially sponsored studies

- Upon receipt of confirmation of Site Specific Authorisation from Barwon Health, the commercial sponsor will be able to lodge the CTN directly to the TGA
- An email confirmation of CTN lodgement should be forwarded to the REGI Unit as per the Department of Health (DoH) guidelines by emailing REGI@barwonhealth.org.au

For collaborative group and investigator driven studies

- Upon receipt of confirmation of Site Specific Authorisation from Barwon Health, the researcher should make an appointment with the REGI Unit, by emailing REGI@barwonhealth.org.au, in order to enable completion of the CTN by the investigator with the support of the Research Governance Officer. This is to ensure correct details are provided and that applications comply with the TGA's requirements

Where Barwon Health is providing HREC review only

- The commercial sponsor, or the institution acting as the sponsor, may lodge the form directly to the TGA
- An email confirmation of CTN lodgement should be forwarded to the REGI Unit as per the DoH guidelines by emailing REGI@barwonhealth.org.au

If you have any further queries, please contact the REGI Unit by emailing regi@barwonhealth.org.au.

