

Authorised Prescriber Application Guidelines

These guidelines are designed to give applicants the current documents, templates and information to assist in authorised prescriber applications being submitted to the Southern Adelaide Clinical Human Research Ethics Committee (SAC HREC)

How to use this document:

Listed below is a link to the SAC HREC Authorised Prescriber application form. Download, complete and submit this form to the SAC HREC for approval. Once approved by the SAC HREC notify the Therapeutic Goods Administration (TGA).

Background:

There are circumstances where patients may require access to medicines or medical devices that have not been approved for supply by the TGA. In these circumstances a medical practitioner may be granted authority to become an authorised prescriber of a specified unapproved therapeutic good (or class of unapproved therapeutic goods) to specific patients (or classes of recipients) with a particular medical condition. The medical practitioner becomes an 'Authorised Prescriber' and can prescribe that product for that condition (also known as the 'indication') to individual patients in their immediate care without further TGA approval. An Authorised Prescriber is only allowed to supply the product directly to specified patients under their immediate care and not to other practitioners who prescribe/administer the product.

- > [SAC HREC Authorised Prescriber application form](#). This document is used by committee members to assess the application.
- > Email the completed form, ensuring it is not password protected, to the Office for Research: Health.SALHNOfficeforResearch@sa.gov.au
- > Once your application has been approved by the SAC HREC, email the Therapeutic Goods Administration (TGA) at eps@tga.gov.au
- > Information regarding [authorised prescribers from the TGA](#)

Research governance is not required for authorised prescriber applications

For more information

Office for Research
SAHLN
Telephone: (08) 8204 6453
www.sahealth.sa.gov.au/SALHNresearch

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