This document has been written for the purpose of providing instruction to physicians wishing to obtain endorsement from the Tasmanian Health and Medical Human Research Ethics Committee (HREC) as an Authorised Prescriber in accordance with the Therapeutic Goods Act 1989 (Cth). Before submitting a request to the HREC for endorsement as an Authorised Prescriber, please ensure that you are familiar with the appropriate information contained in the Therapeutic Goods Administration (TGA) guidelines Human Research Ethics Committees and the Therapeutic Goods Legislation (June 2011) (available from http://www.tga.gov.au/hp/access-hrec.htm).

**Procedure**

Upon receipt of a request for endorsement, provided that all necessary supporting documentation has been provided, it shall be placed on the next available HREC agenda for review by the full committee. If deemed appropriate, the request may be considered out of session by the HREC Chair. This will be determined on a case to case basis. Following review of the request, if endorsed, the HREC Chair will provide a letter of HREC endorsement in the format suggested by the TGA. The HREC may impose conditions on the endorsement as is deemed appropriate and necessary.

**Information to be submitted**

Requests for endorsement as an Authorised Prescriber to the HREC must include:

1. A cover letter which details the submission.
2. A current CV of each person applying for Authorised Prescriber status.
3. A letter of endorsement from an appropriate expert body, such as the Clinical Ethics Committee at the Royal Hobart Hospital.
4. A report containing the following:
   - Information which supports/justifies the use of the product for the proposed indication;
   - Information about the class of recipients (identified by their medical condition);
   - Details about the product to be prescribed, including an assessment of the efficacy and safety of the product;
   - Information about the regulatory status of the product in overseas countries with regulatory standards comparable to those in Australia; and
   - Information as to whether similar requests have been made by other physicians to other HRECs in Australia.
5. A copy of the information sheet that will be provided to patients. This document must conform to the guidelines set out in Chapter 2.2 of the National Statement on Ethical Conduct in Human Research (NHMRC 2007).
6. A copy of the consent form that will be used to consent patients.

All requests are to be submitted electronically to Human.Ethics@utas.edu.au. Should further guidance be required, please contact the Health and Medical HREC Executive Officer via the above email.