Authorised Prescriber Application Form

This is the authorised prescriber application form to be submitted to the Southern Adelaide Clinical Human Research Ethics Committee (SAC HREC)

Before completing this document please read [TGA’s Authorised Prescriber Scheme Guidance for Medical Practitioners, Specialist Colleges and Sponsors v3.0 July 2017](https://www.tga.gov.au/sites/default/files/authorised-prescriber-scheme.pdf). Please email the completed authorised prescriber application form and supporting documentation to the Office for Research: [Health.SALHNOfficeforResearch@sa.gov.au](mailto:Health.SALHNOfficeforResearch@sa.gov.au)

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| **Section A. Prescriber** |  |
| Name: |  |
| Qualifications: |  |
| Hospital / Department: |  |
| Contact details: | Phone: Email:  Fax:  Postal address: |
| Please confirm submission of a current CV detailing qualifications, specialty, training and experience | CV attached |
| **Contact Person** | If other than the proposed prescriber |
| Name: |  |
| Position: |  |
| Contact details: | Phone:  Email: |

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| * **Section B. Please provide details about the product or drug to be prescribed** | | | |
| For unapproved medicines:   * trade name * active ingredient * strength / concentration * dosage form * sponsor |  | | |
| For unapproved medical devices:   * name of device * sponsor |  | | |
| For unapproved biologicals:   * name of the biological * sponsor |  | | |
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| **Section C. Please provide regulatory status in overseas countries:**  Indicate whether this product has been registered in other jurisdictions and any associated conditions or constraints. | | | |
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| **Section D. Please specify the indication for which the product will be prescribed:** | | | |
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| **Section E. Please provide the clinical justification for the use of the product:**   * This should include an appraisal of the nature of alternative treatments (i.e. marketed products) available for the indication and the circumstances under which the unregistered product could be used in preference to marketed product. | | | |
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| **Section F. Please provide efficacy and safety data:**   * This information should be sufficient to support the proposed use of the product. Copies of the relevant literature should be included. | | | |
| Please list documents: | | | |
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| **Section G. Use and monitoring**  Please detail: | | | |
| How the applicant will determine if the use is effective? |  | | |
| How the applicant will determine whether an adverse event has occurred? |  | | |
| What monitoring is required, how it will be done, and the interval and duration of monitoring? |  | | |
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| **Section H. Please provide a letter from the Head of Department supporting this application. This letter should confirm:**   * The applicant is seeking to treat a condition in their area of specialty or training and expertise. * The applicant has the training and expertise appropriate for the proposed use of the product | | | |
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| **Section I. Please provide the information to be given to the patient about the product.**  Please list these documents: | | | |
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| **Section J.** **Please provide details of the consent process:** | | | |
| Name of person(s) who will be obtaining consent | |  | |
| Please describe how consent will be obtained.This will include the provision of the provided Patient Information and Written Consent: | |  | |
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| **Section K. Conflicts of Interest:** | | |  |
| Financial or other interests resulting from contact with related companies, which may have a bearing on this submission | | | Yes or  No |
| Share holdings (does not include mutual fund ownership) and/or board membership | | | Yes or  No |
| Paid employment, including consultancy, commissioned fee-paid work, paid speaker, paid expert advisor | | | Yes or  No |
| Fellowship, research grant, education grant | | | Yes or  No |
| Travel grant or conference fees or other hospitality or gift | | | Yes or  No |
| Any other direct or indirect pecuniary interest for example equipment, staff or funding | | | Yes or  No |
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| **Section L. Statement of Compliance:** | | | |
| **I confirm that:** | | | |
| • The condition outlined above is within my area of speciality or training and expertise.  • I have the training and expertise appropriate for the proposed use of the product. | | | |
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| **I agree to:** | | | |
| • Obtain from each patient (or guardian) informed consent in relation to the proposed use of the unapproved product, and in this context, inform the patient that the product is not approved in Australia;  • Report any suspected adverse reactions to the TGA, the sponsor and the endorsing Ethics Committee;  • Submit a review every 6 months;  • Comply with all relevant State/Territory legislation; and  • Comply with any other conditions imposed by the SAC HREC | | | |
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| **Signed:**\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  **Print name:**\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  **Dated:**\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | | | |

**Consent to treatment continues next page**

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| **SA Health 2008(3)** | **fido_fmclogo** |
| **Consent to Treatment:** | |
| I, First name | Last name |
| consent to treatment with the following medication(s) or product(s):  •  • | |
| I acknowledge that I have had the following explained to me by the following medical practitioner: | |
| First name | Last name |
| I have considered the alternative treatments or courses of action that might be reasonably considered in the circumstances. | Yes or  No |
| I acknowledge that the detail(s) of the following has been explained to me: | |
| • The Therapeutic Goods Administration has not evaluated the medication(s) / product(s) safety, quality and efficacy;  • Potential benefits of treatment;  • Potential harms of treatment (including risks specific to me);  • Possibility that there may be unknown side effects  • Method and frequency of treatment;  • Likely duration of treatment;  • Any additional tests or other procedures that may be required.  Yes or  No | |
| I also acknowledge and agree to the following conditions regarding my treatment with this medication(s) (insert as applicable). | |
| •  •  •  • | Yes or  No  Yes or  No  Yes or  No  Yes or  No |
| I have received written information about the above treatment  Yes or  No | |
| I have understood and I am satisfied with the explanations given  Yes or  No | |
| **Signature of Patient: Date:** | |
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| I, \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  (insert the name of medical practitioner) (insert the name of patient)  the above details of the treatment involved. In my opinion he/she understands the explanation and has freely given his/her consent. | |
| **Signature of medical practitioner: Date:** | |
| **Position:** | |