

# WA Health Central Human Research Ethics Committee Authorised prescriber application

The WA Health Central Human Research Ethics Committee (Central HREC) undertakes the review and approval of applications from medical practitioners seeking to become an authorised prescriber of an unapproved product with the Therapeutic Goods Administration (TGA) under the *Therapeutic Goods Act (1989*). The requirements set out in this application form reflect the requirements of the TGA.

Please submit the completed application form to HREC@health.wa.gov.au with the following supporting documentation:

* Cover letter.
* CV and GCP certificate of each medical practitioner.
* Patient informed consent form.

The Central HREC meets to review authorised prescriber applications up to six times each month, except January. Please refer to the meeting calendar for dates of meetings.

*Text in red is instructional only. Please delete before submission to the Central HREC*

## The prescriber

### Legal name(s) of each medical practitioner for whom approval is sought:

|  |  |
| --- | --- |
| **Practitioner 1** |  |
| **Practitioner 2** |  |
| **Practitioner 3** | *Add or remove rows as required* |

### Reasons why the Central HREC should consider that the practitioner(s) have the training and expertise appropriate to the use of the product (do not duplicate information already contained in the practitioner(s) attached CV):

|  |  |
| --- | --- |
| **Practitioner 1** |  |
| **Practitioner 2** |  |
| **Practitioner 3** | *Add or remove rows as required* |

### Signature(s) of medical practitioner(s) making the application:

|  |  |
| --- | --- |
| **Practitioner 1** |  |
| **Practitioner 2** |  |
| **Practitioner 3** | *Add or remove rows as required.* |

## The product

### The product for use of which approval is being sought:

|  |
| --- |
| **For unapproved medicines** |
| **Active ingredient** |  |
| **Trade name** |  |
| **Strength/concentration** |  |
| **Dose form** |  |
| **Supplier** |  |
| **Sponsor/supplier** |  |
| **For unapproved biologicals** |
| **Name of biological** |  |
| **Sponsor/supplier** |  |
| **For unapproved medical devices** |
| **Name of device** |  |
| **Sponsor/supplier** |  |

### Administration and monitoring regime:

|  |  |
| --- | --- |
| **Dosage range**  | *If a single dose will be used for all patients, please list that here* |
| **Route of Administration or type of sample for In Vitro Diagnostic (IVD) medical devices** |  |
| **Duration of treatment** |  |
| **Determination of efficacy** | *criteria for how the applying medical practitioners will determine treatment efficacy* |
| **Determination of adverse events** | *criteria for how the applying medical practitioners will determine adverse events* |
| **Details of proposed monitoring** | *how it will be done, and the interval and duration of monitoring* |
| **Location (e.g. clinic) where treatment will be given**  | *if the product is to be self-administered at the patients’ home, please detail why this is the requested location as opposed to a medical setting.* |
| **Relevant safety features available at location** |  |

### Efficacy and safety data:

|  |
| --- |
| *Include information on the unapproved product’s efficacy and expected benefits; any known/expected adverse effects, risks, and safety issues; related toxicology.*  |

### Evidence:

|  |
| --- |
| *Include appropriate sources of evidence to support the use of the ‘unapproved’ product. The sources of evidence for data, with the highest level of significance first, in decreasing order are:** *product information documents (or equivalent) (if the good is approved by an overseas regulator).*
* *randomised controlled trials.*
* *non-randomised controlled trials.*
* *individual case studies.*
* *consensus opinion of specialist colleges and societies.*
 |

### Regulatory status of the product for this indication:

|  |  |
| --- | --- |
| Has the ‘unapproved’ product been withdrawn from the Australian market or refused registration because of safety concerns?*(If yes, please elaborate in the box below)* | [ ]  Yes [ ]  No |
| *Describe the regulatory status of the product in Australian and in overseas countries with regulatory standards comparable to those in Australia (USA, UK, The Netherlands, Canada, and Sweden).*  |
| Has the product been approved for the indication by an overseas regulatory body?*(Please elaborate in the box below)* | [ ]  Yes [ ]  No  |
| *If the product is not approved in any of these countries, please detail whether the product has been the subject of clinical trials either in Australia or overseas.* |

### I/we confirm that:

|  |  |
| --- | --- |
| The unregistered product is not for use in a clinical trial | [ ]  Yes [ ]  No |

## The recipients

|  |  |
| --- | --- |
| **The indication for which the product will be supplied** |  |
| **Clinical justification** | *Include an outline of the seriousness of the condition, the expected benefits of the proposed treatment vs the potential risks, approved treatments for the same indication, and how the risks associated with the unapproved good will be managed. Refer to the* [*authorised prescriber scheme guidelines*](https://www.tga.gov.au/resources/resource/guidance/authorised-prescriber-scheme) *for more detail on completing this section.* |
| **Information to be provided to the patient about the product** | *You may use the WA Health template Patient Information and Consent Form on the* [*RGS website*](https://rgs.health.wa.gov.au/Pages/Document-Templates.aspx) *or you may use an alternative format as long as all the information in the template is included in the form you create.*Is the patient information and consent form attached to this application form?[ ]  Yes [ ]  No  |

### Contact details for this application:

|  |  |
| --- | --- |
| **Name** |  |
| **Position** |  |
| **Email** |  |
| **Phone** |  |
| **Date of submission** |  |

**For further information please contact:**

The Central Office for Research Ethics | *Phone*: (08) 9222 4214 | *Email*: HREC@health.wa.gov.au

**This document can be made available in alternative formats
on request for a person with disability.**

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