**Authorised Prescriber Scheme – Site Specific Authorisation**

### Declaration by Authorised Prescriber Scheme Applicant

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| Department: |       | Allocated AP No. |       |
| Project Title: |       |
| Name of unapproved product: |       |
| Name of Applicant: |       |
| Position: |       |
| NOTE: Please provide details of exactly how the drug or device will be obtained and/or supplied. If an agreement between the Royal Melbourne Hospital and the provider is required, provide an electronic copy of the agreement from the supplier for review and execution by the Office for Research. I certify that:* The information contained in this application is accurate to the best of my knowledge and I take full responsibility.
* I will only action this Authorised Prescriber application following approval from the Melbourne Health Human Research Ethics Committee and the Therapeutic Goods Administration
* I undertake to administer the unapproved product in accordance with relevant legislation and regulations.
* I will adhere to the conditions of approval stipulated by the HREC and will report any adverse events and provide regular reports on the use of the unapproved product as required by the HREC and TGA.

A full copy of the Authorised Prescriber Scheme Application is attached. |
| Applicant Signature: |       |
| Date: |       | Cost centre: |       |  |  |

*An Authorised Prescriber applicant* ***must not approve their own authorised prescriber requests*** *on behalf of their department. Where an Authorise Prescriber applicant is also Head of Department, approval must be sought from the person to whom the Head of Department is responsible (e.g., Divisional Director).*

### Declaration by Head of Department/Divisional Director

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| I certify that:* I have read the attached Authorised Prescriber application as above.
* I have discussed this Authorised Prescriber application and the resource implications for this department with the applicant
* All prescribing doctors listed in the attached “Authorised Prescriber Scheme Application Form” have the skills, training, and experience necessary to undertake their role.
* There are suitable and adequate facilities and resources (including financial) for the unapproved therapeutic product to be prescribed at the Royal Melbourne Hospital.
* I support this Authorised Prescriber application
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| Signature (Head of Department/Divisional Director) |       | Date |       |
| Print Name of Signatory: |       |