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| REQUEST FOR ENDORSEMENT OF INDIVIDUAL’S APPLICATION FOR TGA AUTHORISED PRESCRIBER OF UNAPPROVED DRUGS AND DEVICES  *Complete the form below and submit to the Office of Research Ethics and Governance, The Royal Children’s Hospital Melbourne with signatures of relevant RCH Committee and administration fee (where applicable).* | | |
| **Section 1: Application & Applicant’s Details** | | |
| **1.1 Applicant’s name** | | Click here to enter text |
| **1.2 Title** | | Click here to enter text |
| **1.3 Position** | | Click here to enter text |
| **1.4 Name of Department (within RCH)** | | Click here to enter text |
| **1.5 Telephone number** | | Click here to enter text |
| **1.6 Email address** | | Click here to enter text |
| **1.7 Name of product** | | Click here to enter text |
| **1.8 Reviewing Committee other than HREC (RCH employees only)- DUC or NTCPC** | | Click here to enter text |
| **1.9 Date of DUC or NTCPC approval** | |  |
| **1.10 Initial application or renewal** | | Click here to enter text |
| **Section 2: Description of unapproved therapeutic good** | | |
| **2.1 Description**  *Provide a brief plain language statement describing the unapproved therapeutic good*  *(if drug) dosage, route of administration, duration of treatment, active ingredient, trade name, supplier, manufacturer*  *(if device)manufacturer, supplier, mode of operation* | | Click here to enter text |
| **2.2 Use of product elsewhere**  *Describe any known use of unapproved therapeutic good nationally or internationally* | | Click here to enter text |
| **2.3 Approvals/registrations**  *List any current or pending international approvals/ registrations for the therapeutic good* | | Click here to enter text |
| **2.4 Availability and cost**  *Provide, comments on availability*  *(if drug) Active ingredient, trade name, dose form, supplier*  *Provide comments on costs including cost of existing treatment compared to cost for use of unapproved therapeutic* | | Click here to enter text |
| **Section 3: Clinical need** | | |
| **3.1 Clinical condition**  *Specify the clinical indication/disease/condition that the unapproved therapeutic good will be used for including an outline of its seriousness* | | Click here to enter text |
| **3.2 Current therapeutic approach**  *What existing and approved therapeutic good(s) is/are used for the clinical condition?* | | Click here to enter text |
| **3.3 Comparison to current therapeutic approach**  *Describe how the proposed use of the therapeutic good differs from each of these:*   * *Significant clinical advantages over existing treatment- for example-* * *No worse than existing treatment in terms of effectiveness/toxicity or* * *Less effective than existing treatment, but less complication* | | Click here to enter text |
| **3.3 Patient population**  *What are the subgroups of the patient population that will benefit from the use of this therapeutic good?* | | Click here to enter text |
| **3.4 Number of patients to receive the therapeutic good**  *If this number is expected to increase over time, please specify the predicted number of patients per year for 5 years* | | Click here to enter text |
| **Section 4: Evidence of safety, efficacy and clinical effectiveness** | | |
| **4.1 Safety evidence**  *Comment on safety evidence base* | | Click here to enter text |
| **4.2 Side effects**  *List nature and incidents of side effects, contraindications, cautions, warnings and adverse effects for the therapeutic good and the source of this information* | | Click here to enter text |
| **4.3 Comparison to current therapeutic approach**  *What are the main differences between the side effects, contra indications, cautions warnings and adverse effects between the unapproved therapeutic good and existing treatments and the source of this information* | | Click here to enter text |
| **4.4 Efficacy and clinical effectiveness**  *Summarise the best available evidence, outlining key aspects, for clinical effectiveness of the therapeutic good for defines clinical problems including*   * *Supporting references* * *Level and source of evidence* | Click here to enter text | |
| **Section 5: Clinical feasibility** | | |
| **5.1 Operator competency**  *Describe what, if any, credentialing and competency assurance is needed to ensure safe implantation of the unapproved therapeutic.* | | Click here to enter text |
| **5.2 Team environment**  *Are all others involved (e.g. allied health/research assistants) familiar with the requirements of dealing with this unapproved therapeutic good?* | | Click here to enter text |
| **5.3 Associated service utilisation**  *Specify all services, such as intensive care, operating theatre, imaging, pathology, outpatients and others that will be involved in the implementation of the unapproved therapeutic.*  *Are these available within existing capacity and, if not, why not?* | | Click here to enter text |
| **5.4 Future service impacts**  *If additional services are required to implement the unapproved therapeutic good, specify what these are and how they will be sourced (including any maintenance/ service requirements).*  *Are there any emerging trends in the use of this therapeutic good that may have future substantive impacts on services? If so, specify and briefly describe.* | | Click here to enter text |
| **5.5 Future Australian approval**  *What is the projected timeframe for this unapproved therapeutic good to receive approval from the TGA?* | | Click here to enter text |
| **Section 6: Governance** | | |
| **6.1 Clinical governance**  *Describe the arrangements and processes for clinical governance and management of the therapeutic good, including arrangements for patient informed consent.* | | Click here to enter text |
| **6.2 Monitoring**  *Specify how the unapproved therapeutic good will be monitored once it is introduced into the clinical setting.* | | Click here to enter text |
| **6.3 Evaluation**  *Specify an evaluation protocol, including performance indicators and defined time points, for the therapeutic good.* | | Click here to enter text |
| **6.4 Reporting**  *Describe the reporting schedule for TGA and other relevant bodies.* | | Click here to enter text |
| **Section 7: Signatures** | | |
| **Medical practitioner: I certify that the information contained in this application form is true. I certify that I have no real or perceived conflict of interests or relationships with supplier or manufacturers of this unapproved therapeutic good.** | | |
| **Name:**  *Printed name in full.* | **Click here to enter text** | |
| **Signature** | **X\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**  **­­­­­­­­­­­­­­­­­­­­­­­­­­­­­­­­­Medical practitioner**  **\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**  **Date** | |
| **Chair of the RCH NTCPC or DUC: I certify that I have read this application, discussed the application at Committee and, on behalf of the Committee, endorse this application for the above medical practitioner to become an Authorised Prescriber.** | | |
| **Name:**  *Printed name in full.* | **Click here to enter text** | |
| **Signature** | **X\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**  **Chair of RCH NTCPC or RCH DUC** *(circle one)*  **\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**  **Date** | |
| **Chair of the HREC: I certify that I have read this application, noted the signature of the Chair of the RCH Novel Technology and Clinical Practices Committee or the Chair of the RCH Drug Usage Committee (where relevant), and endorse this application for the above medical practitioner to become an Authorised Prescriber.** | | |
| **Name:**  *Printed name in full.* | **Click here to enter text** | |
| **Signature** | **X\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**  **Chair of RCH HREC**  **\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**  **Date** | |