**NIIM HREC AUTHORISED PRESCRIBER SCHEME AMENDMENT FORM- PSYCHEDELIC MEDICINES-MDMA**

**CHECKLIST**

To assist with our processing of your application:

1. Please submit distinct documents as separate files, rather than merged into one file.
2. Please name each file clearly: include the applicant’s name in the file name

|  |  |
| --- | --- |
| 1. Amendment Form (form completed, signed, and dated)
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| 1. Resumes: any new staff members involved in psychedelic-assisted therapy (PAT)
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| 1. Evidence of staff professional education in MDMA
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\*if applicable

**NIIM HREC AUTHORISED PRESCRIBER SCHEME AMENDMENT FORM PSYCHEDELIC MEDICINES-MDMA**

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**THIS FORM**

This amendment form is to be used by registered psychiatrists who are already approved as Authorised Prescribers of MDMA for treatment-resistant depression to advise the NIIM HREC of changes in staff involved in psychedelic-assisted therapy (PAT) and/or a change in clinical site(s) where PAT will be conducted.

**SECTION 1: AUTHORISED PRESCRIBER DETAILS**

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| **A.** | **Authorised Prescriber Name:**  |  |
| **B.** | **AHPRA No.:** |  |
| **C.** | **RANZCP Fellowship No.:** |  |
| **D.** | **Date of Authorised Prescriber Approval by TGA to prescribe MDMA** |  |
| **E.** | **Practice Address:**  |  |
| **F.** | **Phone Number:**  |  |
| **G.** | **Email:**  |  |
| **H.** | **Third-Party Contact:***If the applicant is being supported by a third party, to be copied in on correspondence, please include contact information here including email.* |  |

**SECTION 2: ADDITION OF NEW STAFF MEMBER(S)**

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| --- | --- | --- |
|  | **ADDED STAFF MEMBERS** |  |
| **A.** | **Psychedelic Assisted Therapy/Therapies (PAT) Team/ Support Staff: Names, Roles, Qualifications, Training and Experience\*\***List the personnel (names), roles, minimum qualifications and relevant experience of other professionals who will be involved in the treatment of patients with MDMA. For each individual, provide details of:a) Role in PAT treatment protocol;b) Relevant minimum professional qualifications; c) Relevant clinical experience in treatment of the relevant condition (treatment-resistant depression) including, where relevant, experience in treatment using MDMA; and d) Training in the use of MDMA in the context of psychedelic-assisted therapy (PAT) *\*\*Note: Applicants must append the resumes of all support staff involved in the treatment of patients using psychedelic assisted therapy (PAT), plus evidence of the support staff training in PAT.* | **Name:****Role in PAT Team:**Minimum Qualifications:Relevant Clinical Experience:Training in use of MDMA in context of PAT:**Name:****Role in PAT Team:**Minimum Qualifications:Relevant Clinical Experience:Training in use of MDMA in context of PAT:**Name:****Role in PAT Team:**Minimum Qualifications:Relevant Clinical Experience:Training in use of MDMA in context of PAT:[Add more entries as required] |
|  | **REMOVAL OF STAFF MEMBERS** |  |
| **B.** | Please provide details of any support staff members listed in your original authorised prescriber application who will no longer be involved in your PAT treatment protocol.  |  |

**SECTION 3: ADDITION/REMOVAL OF NEW PAT TREATMENT SITES**

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| --- | --- | --- |
|  | **ADDED TREATMENT SITES** |  |
| **A.** | **Treatment Sites**For all sites at which the unapproved therapeutic good(s) will be prescribed and the treatment protocol conducted, provide the type of facility (eg. hospital inpatient dept, hospital outpatient dept, medical clinic) and full addresses. | **Site 1**Type of Facility:Address of Facility:**Site 2** Type of Facility:Address of Facility:**Site 3** Type of Facility:Address of Facility: |

|  |  |  |
| --- | --- | --- |
|  | **REMOVED TREATMENT SITES** |  |
| **B.** | **Treatment Sites**Please provide details of any previously approved treatment sites you are no longer providing psychedelic-assisted therapy at. | **Site 1**Type of Facility:Address of Facility:**Site 2** Type of Facility:Address of Facility:**Site 3** Type of Facility:Address of Facility: |

**SECTION 5: DISCLOSURES AND UNDERTAKINGS**

5.1 I certify that I

[ ]  have not [ ]  have (tick one)

applied for Authorised Prescriber approval of another Australian HREC *(not NIIM)* within the last 12 months.

*Evidence: If yes, please append a copy of the letter from the other HREC and/or TGA*

Where an applicant has been refused approval for Authorised Prescriber by an Australian HREC or the TGA within the last 12 months, please detail why approval was denied.

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5.2 I understand that completing this application form is part of a two-step process to become an Authorised Prescriber and that if I am approved by the NIIM HREC, the next and final step is to apply to the TGA for final approval.

[ ]  Yes [ ]  No

5.3 I certify that any Support Staff who will be involved in the treatment protocols detailed in this application are appropriately qualified, experienced and trained in relation to the unapproved therapeutic good(s) that are the subject of this application, as detailed in this application.

[ ]  Yes [ ]  No

5.4 I understand that if any of the support staff/PAT Team involved in the treatment of patients under my care using psychedelic-assisted therapy (PAT) change, I will notify the NIIM HREC and if required, the TGA, of any new support staff member’s name, qualifications, role in the PAT team, training in PAT and clinical experience. I also understand that the NIIM HREC may revoke my Authorised Provider approval if such individual(s) are deemed to not have the required qualifications, experience and training in PAT.

[ ]  Yes [ ]  No

5.5 I understand that my authorised prescriber approval is specific to the clinical sites listed in this application and that I am required to notify the HREC of any changes to sites from which psychedelic medicines/psychedelic-assisted therapies will be administered. I am aware that the HREC has the right to reject and/or cancel my authorised prescriber status if the facility in which I intend to practise psychedelic-assisted is not considered appropriate.

[ ]  Yes [ ]  No

5.6 I undertake to remain up to date in relation to knowledge about potential future approved goods that may be entered on the ARTG that could be used instead of the unapproved therapeutic good(s) to which this application relates, and where a suitable alternative good becomes available on the ARTG, I will stop using the unapproved therapeutic good, or where there is a good reason to continue using the unapproved therapeutic good, I will reapply for approval, submitting a clinical justification to the HREC on why I want to use the unapproved therapeutic good instead of the now-approved good.

[ ]  Yes [ ]  No

5.7 I understand that I am required to comply with all requirements of my state/territory in relation to the prescribing of MDMA.

[ ]  Yes [ ]  No

5.8 I undertake to submit the required six-monthly reports to the TGA and the NIIM HREC.

[ ]  Yes [ ]  No

5.9 I agree to abide by any conditions set by the HREC and/or TGA in relation to approval to use the unapproved therapeutic good(s).

[ ]  Yes [ ]  No

5.10 I certify that I

[ ]  do not have a commercial interest in any of the products which I may prescribe.

[ ]  do have a commercial interest in one or more of the products which I may prescribe.

Details of my commercial interests and their management are as follows:

5.11 I certify that I understand that HREC approval is for 12 months only and that I will need to apply for renewal of my Authorised Prescriber approval at least 30 days before the expiry date.

[ ]  Yes [ ]  No

5.12 I certify that the information I have provided in this application is true and accurate.

[ ]  Yes [ ]  No

|  |  |
| --- | --- |
| **Full Name** |  |
| **Signature** |  |
| **Date** |  |