NSW GOVERNMENT Health

HR 02/19

Application for Authority to Prescribe and Supply a Substance for the Purpose of Human Research

Use this form to request for authority under the *Poisons and Therapeutic Goods Act 1966* to prescribe and supply any of the following for the purpose of research involving humans, including clinical trials:

- a substance in Schedule 8 (S8) of the Standard for the Uniform Scheduling of Medicines and Poisons (SUSMP), including a cannabis medicine, an unregistered medicine or an extemporaneously-compounded medicine
- a substance in Schedule 9 (S9) of the SUSMP
- a substance in Schedule 1 (S1) of the *Drug Misuse and Trafficking Act 1985 (DMTA)*

The form is available online in PDF format (http://www.health.nsw.gov.au/pharmaceutical) and should be completed electronically using a computer. If completing the form by hand, use BLOCK LETTERS and ensure that all details are clear.

Do not use this form to apply for authorisation to prescribe for the treatment of an individual patient. Use the appropriate form available at https://www.health.nsw.gov.au/pharmaceutical/doctors/Pages/default.aspx

For research involving multiple sites and/or investigators, the Supplementary Page at the end of this form must be completed and attached.

Eligible applications are generally processed within 30 business days of receiving all required information. Further information in support of the application may be requested.

Section A: Applicant (principal investigator) *Applicant must be a medical practitioner*		
Name of principal investigator: *(salutation)* *(first name)* *(family name)*		
AHPRA registration no:		
Name of practice/hospital/facility/research institution: **Address:** **Suburb/Town:** **Postcode:**		
Telephone:	**Fax:**	**Email:**

Section B: Substance *Attach additional page if more than one substance*	
Drug name/trade name	
ARTG registration	☐ **Y** ☐ **N** ⋯▶ *attach Certificate of Analysis and Product Information Brochure*
Active ingredient(s) *State the full name of each active ingredient as it appears in the DMTA or SUSMP.* *For analogues of S1 substances of the DMTA, and derivatives of S8 or S9 substances of the SUSMP, state the name of the substance as it appears in the relevant Schedule.*	
Manufacturer name	
Schedule	☐ **S1 DMTA** ☐ **S8 SUSMP** ☐ **S9 SUSMP**
Dosage form *(e.g. oil, spray, solution, capsule, tablet)*	
Strength *(e.g. 1mg/mL)*	
Route of administration *(e.g. oral, oromucosal, inhalation)*	

Maximum total quantity *State the maximum quantity to be possessed and used for the study/trial.* *For proprietary products, enter multiples of pack sizes available.*	
Maximum period of treatment per participant	

Section C: Approval of Human Research Ethics Committee

Name of Committee:

HREC Approval Number: **Expiry Date of Approval:** ___ ___ _____

Approved Protocol Version Number *(This must be the current protocol version in use)*:

Attach the approved study protocol

Provide a summary of the research project in non-technical language:

Section D: CTX and CTN Schemes *Clinical trials that involve 'unapproved' therapeutic goods are subject to requirements of the CTN Scheme or CTX Scheme administered by the Therapeutic Goods Administration (https://www.tga.gov.au/clinical-trials)*

Indicate below the CTN or CTX Scheme status of your study and provide requested clinical trial details

☐ **Not applicable – no CTN Scheme or CTX Scheme requirements**

☐ **CTN scheme**

☐ **CTX scheme** ☐ **Approval pending** ☐ **Approved**

Clinical Trial Number:

Clinical Trial Name (Short Name): .....

Clinical Trial Name (Long Name): .....

Section E: Sites and investigators

☐ **Multiple sites** ····▶ *use the Supplementary Page at the end of this form to list details of all sites and where the substance(s) will be stored and supplied from*

☐ **Single site** ····▶ *provide details below*

Site name:

Name of the place of supply (dispensing) to participants *(if different to site, e.g. pharmacy)*

Address (of place of supply):

Suburb/Town: **Postcode:**

☐ **Single investigator** ····▶ *go to Section F*

☐ **Multiple investigators** ····▶ *use the Supplementary Page at the end of this form to list all investigators*

Section F: Storage and access

Describe in detail how the substance(s) will be stored and who will have access, including what mechanisms are in place to restrict access to unauthorised persons

Section G: Substance Disposal

Describe the proposed disposal procedure for unused substance

Section H: Supply chain - Authorised supplier of the substance(s)

Name of wholesaler/importer/ supplier *If the substance is being imported, attach permit from the Office of Drug Control*	
Name of delivery/courier company:	

Section I: Attachments

Indicate the attachments provided with this application (tick all that apply):

- ☐ Additional page with list of substances (Section B)
- ☐ Certificate of Analysis (For a cannabis medicine, ensure the CoA completely identifies all cannabinoids present or certifies that no other cannabinoids were detected) (Section B)
- ☐ Product Information Brochure (Section B)
- ☐ Approval from Human Research Ethics Committee (Section C)
- ☐ Approved study protocol (Section C)
- ☐ CTN/CTX Scheme documentation (Section D)
- ☐ Supplementary Page listing all sites and/or investigators (Section E)
- ☐ Office of Drug Control import permit (Section H)

Section J: Declaration

I understand that the substances are to be stored apart from all other goods in a safe securely attached to a part of the premises, kept securely locked when not in immediate use, and accessed only by authorised persons. (Information is available online at https://www.health.nsw.gov.au/pharmaceutical/Pages/refrigeration-s8s.aspx)

☐ Yes

I understand that a record of the movement of the substances is to be kept in the form of a drug register that:

- contains consecutively numbered pages, and that is so bound that the pages cannot be removed or replaced without trace, and that contains provision on each page for the inclusion of the particulars required to be entered in the book. Separate pages of the register must be used for each drug of addiction, and for each form and strength of the drug, or
- if electronic, meets the criteria set out in the document 'Electronic Drug Register' (https://www.health.nsw.gov.au/pharmaceutical/Documents/electronic-drug-reg-phcy.pdf) and has been approved by the Secretary, Ministry of Health

☐ Yes

I understand that the substances may not be wilfully destroyed or allowed to be destroyed otherwise than by or under the direct personal supervision of a police officer or an inspector or by or under the direct personal supervision of a person authorised.

☐ Yes

Patients will be explained the following:

- **where the product is an unregistered medicine, it has not been assessed for safety or efficacy by the TGA**
- **the nature of treatment and potential harms**
- **why their personal health information is collected, how they can access their information, how it may be used, and who it may be disclosed to** *(see Privacy Statement below)*

I confirm that the information I have provided in this application is true, accurate and complete to the best of my knowledge.

Signed: ..... Date: __ __ __ __ __ __ __ __

Privacy Statement: The collection, use and disclosure of the information provided on this form will be in accordance with privacy laws. The information collected may be disclosed to other health practitioners when necessary to facilitate coordination of treatment and patient safety. In addition, personal and health record information may be disclosed where required by law or where otherwise lawfully authorised. NSW Health may provide any or all of the contents of this application and information provided with it to law enforcement agencies and regulatory agencies in the Commonwealth, States and Territories as necessary, in order to ensure laws and regulations are being complied with. For further information on privacy visit http://www.health.nsw.gov.au/patients/privacy. For further advice or clarification please email MOH-PharmaceuticalServices@health.nsw.gov.au

For assistance contact the Pharmaceutical Regulatory Unit during business hours on (02) 9391 9944
Email completed form and other required documents to: MOH-PharmaceuticalServices@health.nsw.gov.au

Supplementary Page

For studies and clinical trials involving multiple sites and/or investigators, list details of each site and each investigator.

Site details	
Name of site	**Name and address of place of supply to participants** *(if different to site)*

Investigator details		
First name	**Family name**	**AHPRA Registration No**