Application to change a Research/Education Permit

*Medicines and Poisons Act 2014*

Table of Contents

[INSTRUCTIONS and INFORMATION i](#_Toc98856327)

[PART 1: APPLICATION to change a RESEARCH/EDUCATION PERMIT 1](#_Toc98856328)

[1. General information 1](#_Toc98856329)

[Changes without a fee 2](#_Toc98856330)

[2. Change of postal address and other contact details 2](#_Toc98856331)

[3. Change the person responsible for a premises listed on the Permit 2](#_Toc98856332)

[4. Remove a premises from the Permit 2](#_Toc98856333)

[5. Remove certain medicines or poisons from the Permit 2](#_Toc98856334)

[6. Information about disposal of medicines or poisons 3](#_Toc98856335)

[7. Upgrading storage and security 4](#_Toc98856336)

[Changes with a fee 5](#_Toc98856337)

[8. Change of individual Permit holder 5](#_Toc98856338)

[9. Change of corporate officer or partner 5](#_Toc98856339)

[10. Increase quantity of medicines or poisons 5](#_Toc98856340)

[11. Addition of Schedule 2,3,4,8 medicines or Schedule 7 poisons to the Permit 6](#_Toc98856341)

[12. Relocation of an existing premises 7](#_Toc98856342)

[13. Addition of another new premises 7](#_Toc98856343)

[14. Information about the relocated or new added premises 8](#_Toc98856344)

[15. Schedule 2,3,4,8 medicines or Schedule 7 poisons at relocated or new added premises 9](#_Toc98856345)

[16. Schedule 8 medicines (Controlled Drug) 11](#_Toc98856346)

[17. Change of business or trading name 14](#_Toc98856347)

[18. Variation in the activities undertaken under the Permit 14](#_Toc98856348)

[19. Declaration by Permit holder 14](#_Toc98856349)

[PART 2: PERSONAL INFORMATION: new PERMIT HOLDER 15](#_Toc98856350)

[20. Identification of new Permit holder, corporate officer or partner 15](#_Toc98856351)

[21. Qualifications of new Permit holder 15](#_Toc98856352)

[22. Authority, access, standard operating procedures (SOPs) 16](#_Toc98856353)

[23. Prior permits/licences for medicines/poisons 16](#_Toc98856354)

[24. Criminal check for new Permit holder, corporate officer or partner 17](#_Toc98856355)

[25. Financial resources of new Permit holder, corporate officer or partner 17](#_Toc98856356)

[26. Declaration by new Permit holder, corporate officer or partner 17](#_Toc98856357)

[PART 3: PERSONAL INFORMATION: new RESPONSIBLE PERSON 18](#_Toc98856358)

[27. Identification of new responsible person 18](#_Toc98856359)

[28. Qualifications of new responsible person 18](#_Toc98856360)

[29. Prior permits/licences for medicines/poisons held by new responsible person 19](#_Toc98856361)

[30. Criminal check for new responsible person 19](#_Toc98856362)

[31. Declaration by new responsible person 19](#_Toc98856363)

[PART 4: PAYMENT and CHECKLIST 20](#_Toc98856364)

[32. Payment (where required) 20](#_Toc98856365)

[33. Checklist 21](#_Toc98856366)

[PART 5: APPENDICES 22](#_Toc98856367)

[Appendix A: Requirements for a small safe 22](#_Toc98856368)

[Appendix B: Requirements for a large safe 23](#_Toc98856369)

[Appendix C: Certifying true copies of photographic identification 24](#_Toc98856370)

|  |
| --- |
| INSTRUCTIONS and INFORMATION |
|  | This form is for requesting changesto an existing **Research/Education Permit** issued under the *Medicines and Poisons Act 2014.*This form MUST be completed by the current Permit holder or incoming Permit holder who is suitably qualified and understands the requirements and terminology contained in this application.If the Permit holder is a corporation or partnership, this form must be completed by the corporate officer or partner who originally applied for the Permit. **All communication will ONLY be with the Permit holder, corporate officer or partner.** |
|  | **Types of changes that cannot be applied for using this form**DO NOT USE THIS FORM, if:* The Permit holder is changing from an individual person to a Permit held by a corporation or partnership, or
* The Permit holder is changing from a corporation or partnership to an individual person or
* The business has a new owner.

These types of changes require the submission of a completely new application for a Research/Education Permit, found at: [Application forms for Licences and Permits](https://ww2.health.wa.gov.au/Articles/A_E/Application-forms-for-Licences-and-Permits)Permits cannot be transferred between one business entity and another. |
|  | There are five parts to this form:Part 1 – Sections 1 to 19: Application to change a Research/Education Permit.Part 2 – Sections 20 to 26: Personal Information: new individual Permit holder, corporate officer or partner Part 3 – Sections 27 to 31: Personal Information: new responsible person for a premisesPart 4 – Sections 32 and 33: Payment and checklist.Part 5 – Appendices |
|  | Fees are **not** payable for the following type of changes to a Research/Education Permit:* Change of postal addresses or other contact details
* Change to a person responsible for a premises
* Removal of premises from the Permit
* Removal of certain medicines or poisons from the Permit
* Upgrade of storage or security such as installation of CCTV.
 |
|  | A fee of **$87** is payable for the following type of changes to a Research/Education Permit:* Change of individual Permit holder (no change of ownership of the business)
* Change of a corporate officer (for Permits issued to a body corporate and not an individual person)
* Increase the quantity of medicines or poisons on the Permit
* Addition of medicines or poisons to the Permit
* Relocation of an existing premises to a new location
* Addition of a new premises to the to the Permit
* Change of business or trading name without changing legal entity (no change of ownership)
* Variation in the activities undertaken under the Permit

Note: some variations may require a new application and issue of a different Permit type) |
|  | **Changing the Permit holder for a Permit held by an individual person**The person nominated as the new Permit holder must also complete Part 2 Personal Information: Identification, Fitness and Probity and sign the declaration at Section 26.**6.1 Qualifications of person nominated as the new Permit holder:**The new Permit holder must:* be suitably qualified and either in charge of a laboratory or department involved in research, teaching and demonstration, analysis, study or other approved activity in which the medicines or poisons are to be used. An individual applicant can also be the Chief Investigator named in the Ethics Approval.
* provide a National Police Clearance (NPC) certificate less than 12 months old and
* have authority within the organisation to determine policies and procedures in relation to handling and managing the medicines or poisons on the Permit.

**6.2** **Permit holder responsibilities**It is the responsibility of the Permit holder to ensure compliance with the *Medicines and Poisons Act 2014* and Regulations 2016 and compliance with conditions placed on the Permit.The new Permit holder must also consider whether they have capacity to ensure compliance with the *Medicines and Poisons Act 2014* and Regulations 2016 and compliance with conditions placed on the Permit for every premises listed on the Permit. The Department may request further information in relation to this capacity.There are penalties under the Act for providing false or misleading information when applying for a change to an existing Permit. |
|  | **Changing the person responsible for a premises listed on the Permit** A new responsible person will have overall responsibility for and manage the medicines or poisons on a day to day basis and be the contact person if the Permit holder is not available. The responsible person for a premises must:* be employed or contracted by the Permit holder
* reside in WA
* complete Part 3: Personal Information: Identification, Fitness and Probity
* provide a National Police Clearance (NPC) certificate which is less than 12 months old and
* and sign the declaration at Section 31.

**7.1 Responsible person for a Permit issued to an individual person**The responsible person for a premises when a Permit is issued to an individual person can be:1. the individual Permit holder, only if the Permit is issued to a suitably qualified individual person and not a corporation or partnership

 **or**1. the most senior suitably qualified person at the premises.

**7.2** **Responsible person for a permit issued to a corporation or partnership**The responsible person for a premises when a Permit is issued to a corporation or partnership can be: 1. a suitably qualified person who is either:
	* in charge of a laboratory or department involved in research, teaching and demonstration, analysis, study or other approved activity in which the medicines or poisons are to be used, or
	* the Chief Investigator named in the Ethics Approval

 **or**1. the Research Director, Laboratory Director or equivalent position for the corporation or partnership

**or**1. another person who is the most senior suitably qualified person at the premises. Suitability of this person will be determined during the application process.

Please note: a responsible person must consider whether they have capacity to oversee the day to day management of the medicines or poisons at every premises for which they are responsible. Where a single person is responsible for multiple premises, the Department may request further information in relation to this capacity. |
|  | **Changing a corporate officer or partner for a Permit that is held by a corporation or partnership.**A new partner or corporate officer (directors, company secretary, chief executive officer or general manager and chief financial officer) must also complete Part 2: Personal Information: Identification, Fitness and Probity and sign the declaration at Section 26. |

|  |  |
| --- | --- |
|  | **Relocation or addition of a premises** If a premises listed on an existing Research/Education Permit:* is being relocated to a different premise **or**
* another premises is being added to the existing Research/Education Permit:

and the relocated or added premises (second premises) is currently listed on a different Permit:* + the application will not be processed until the Permit holder at the second premises has submitted an application to the Department to have their premises removed from their Permit.
	+ In such cases, Permit holders requesting the relocation or addition of a new premises should liaise with the Permit holder at the second premises to ensure the Department is appropriately advised.
 |
|  | **Schedule 2, 3, 4 and 8 medicines or Schedule 7 poisons** Sections 15 relates to the storage and use of Schedule of 2,3, 4 medicines and Schedule 7 poisons and Section 16 relates to Schedule 8 (Controlled Drug) medicines. |
|  | **Required documents** The applicant and responsible person are required to submit copies of certain documents. If documents are not in English, also attach a translation certified as completed by a National Accreditation Authority for Translators and Interpreters (NAATI) accredited translator.Copies of photographic identification documents, such as a driver’s licence or passport must be certified as a true copy. A list of people who can certify copies of documents is found in Appendix C. |
|  | **Signatures** All signatures must be signed in ink or via a verifiable electronic signature. An electronic signature is only acceptable if the submitted application allows the Department to verify the signature.A “signature” that is copied and pasted and a “signature” that is the person’s name in a font style resembling handwriting will not be accepted.The current Permit holder must sign the Declaration for making a change to the Permit at Section 19. **12.1 Who can sign for a change to a Research/Education Permit:**If the Research/Education Permit is held by an individual person and the change is to request a new individual Permit holder within the same business and the current Permit holder is no longer employed by the business:* the new Permit holder should sign the Declaration and provide the reason the current Permit holder cannot sign the Declaration.

If the Research/Education Permit is held by a partnership or body corporate, the person who signed the original Permit application should sign the Declaration. |
|  | **Approving a change to a Permit** Applying for a change to an existing Permit does not guarantee the requested changes will be approved. |
|  | **Processing applications** Applications will be processed in order of receipt after payment has been confirmed by Finance. To ensure a timely decision about your application please: * Complete all required sections of the application,
* **Attach** all requested documentation to the application,
* Respond to requests from the Department for additional information as soon as possible,
* Make sure appropriate staff are available if the Department needs to conduct a premises inspection,
* Do not submit your application as a digital image (photograph).
 |
|  | **Extra information** When applying for a change to an existing Permit, refer to the: [Guide to applying for a Licence or Permit](https://ww2.health.wa.gov.au/Articles/A_E/Application-forms-for-Licences-and-Permits) |
|  | **Submitting the application** Please email completed form and other requested documentation to: mprb@health.wa.gov.au |
| **Incomplete applications may be delayed or returned to the applicant** |
| **Please keep a copy of the completed application form for reference** |

# PART 1: APPLICATION to change a RESEARCH/EDUCATION PERMIT

|  |
| --- |
| General information |
| Permit number:  |       | Name of current Permit holder: |       |  |
| Postal address: |       | Suburb: |       | Postcode: |       |  |
| Telephone: |       | Fax: |       | Email: |       |  |
| **1.1 Type of change** |
| Please check whichever applies: |
| **Changes without a fee** | **Complete** |
| **[ ]**  | Change of postal addresses or other contact details | Part 1: Sections 2,19 |
| **[ ]**  | Change to a person responsible for a premises | Part 1: Sections 3,19Part 3: Sections 27 to 31 |
| **[ ]**  | Remove a premises from the Permit  | Part 1: Sections 4,6,19 |
| **[ ]**  | Remove certain medicines or poisons form the Permit | Part 1: Sections 5,6,19 |
| **[ ]**  | Upgrade to storage and securityUpgrade drug safe | Part 1: Sections 7,19 Part 1: Sections 7, 16.1, 16.3,19  |
| **Changes with a fee of $87** |
| **[ ]**  | Change of individual Permit holder | Part 1: Sections 8, 19Part 2: Sections 20 to 26 Part 4: Section 32 |
| **[ ]**  | Change of corporate officer or partner  | Part 1: Sections 9,19Part 2: Sections 20,23,24,25,26Part 4: Section 32 |
| **[ ]**  | Increase quantity of medicines or poisons already listed on the PermitIf increasing quantity of Schedule 8 medicines on the Permit | Part 1: Sections 10,19Plus Sections 16.1, 16.3Part 4: Section 32 |
| **[ ]**  | Addition of certain Schedule 2,3, and 4 medicines or S7 poisons to the PermitIf adding Schedule 8 medicines to the Permit | Part 1: Sections 11,19Plus Section 16Part 4: Section 32 |
| **[ ]**  | Relocation of an existing premises to a new premisesIf relocated premises will be storing Schedule 8 medicines  | Part 1: Sections 12,14,15,19Plus Section 16Part 4: Section 32 |
| **[ ]**  | Addition of another new premises to the PermitIf new added premises will be storing Schedule 8 medicines | Part 1: Sections 13,14,15,19Plus Section 16Part 4: Section 32 |
| **[ ]**  | Change of business or trading name without any change of the legal entity | Part 1: Section 17,19Part 4: Section 32 |
| **[ ]**  | Variation in activities undertaken under the Permit, including use of the medicines or poisons  | Part 1: Section 18,19Part 4: Section 32 |
| **Note: if making multiple changes, only pay one fee of $87** |
| **1.2** | Additional information to support application (optional): |
|  |       |  |
|  |       |  |
|  |       |  |
|  |       |  |
|  |

**PART 1: APPLICATION to change a RESEARCH/EDUCATION PERMIT**

|  |
| --- |
| Changes without a fee |

|  |
| --- |
| Change of postal address and other contact details |
| New Postal Address\*:  |       | Suburb:  |       | Postcode:  |       |  |
| Telephone:  |       | Fax:  |       | Email: |       |  |
| \* Renewal reminders will be sent to this address |

|  |
| --- |
| Change the person responsible for a premises listed on the Permit |
| Refer to instruction number 7 for information on the requirements for being a responsible person for a premises. |
| Premises name: |       |  |
| Address:  |       | Suburb:  |       | Postcode:  |       |  |
| Name of new incoming responsible person for this premises: |
| Title: |       | Forename(s): |       | Surname: |       |  |
| **3.1 Details about the new person responsible for a premises listed on the Permit** |
|  | Is the new responsible person also the Permit holder or responsible for another premises listed on the Permit? |
|  | [ ]  Yes: Confirm name: | Title: |       | Forename/s: |       | Surname: |       |  |
|  |  | There is no requirement to complete Part 3. |
|  | [ ]  No: the new responsible person for the above-named premises, must complete and **attach** Part 3: Personal Information: Identification, Fitness and Probity |

|  |
| --- |
| Remove a premises from the Permit  |
| Premises name: |        |  |
| Address:  |       | Suburb:  |       | Postcode:  |       |  |
| Date the business will cease trading at these premises:  |       |  |
| Is the premises being transferred to another Research/Education organisation? |
| **4.1** *[ ]*  Yes: please provide the name of the new organisation: |       |  |
|  | The Department requires the Permit holder for the new organisation taking over the premises to either:* apply to add this premises to their current Research/Education Permit, if they already have a Permit, or
* apply for a new Research/Education Permit in their name.
 |
| **4.2** [ ]  No, is there any remaining stock of medicines or poisons left?  |
|  | *[ ]* No *[ ]* Yes: please also complete Section 6 |

|  |
| --- |
| Remove certain medicines or poisons from the Permit |
| Premises name: |       |  |
| Address:  |       | Suburb:  |       | Postcode:  |       |  |
| **5.1** | Please list the medicines or poisons being removed from the above-named premises:  |
|  |       |  |
|  |       |  |
|  |       |  |
|  |
| **5.2** | Is there any remaining stock left of the medicines or poisons being removed from the Permit at the premises |
|  | [ ]  No *[ ]* Yes: please also complete Section 6 |

**PART 1: APPLICATION to change a RESEARCH/EDUCATION PERMIT**

|  |
| --- |
| **Changes without a fee** |
| Information about disposal of medicines or poisons  |
| Is there any remaining medicines or poisons left at the premises which is being removed from the Permit (Section 4) or is there any remaining stock of certain medicines or poisons being removed from the Permit (Section 5)? |
| [ ]  No |
| [ ]  Yes: complete Section 6.1 and 6.2  |
| **6.1 What will happen to the remaining Schedule 2, 3 and 4 medicines?** |
|  | [ ]  | Transferred to the Research/Education organisation taking over the premises: |
|  |  | Name of the new organisation: |       |  |
|  |  | **or** |
|  | [ ]  | Transferred to a different premise listed on the Permit |
|  |  | Name of premises: |       |  |
|  |  | **or** |
|  | [ ]  | Taken to a pharmacy or hospital for disposal 1 (not for Schedule 7 poisons) |
|  |  | Name of pharmacy/hospital: |       |  |
|  |  | **or** |
|  | [ ]  | Returned to wholesaler for disposal |
|  |  | Name of wholesaler: |       |  |
|  |  | **or** |
|  | [ ]  | *Destroyed* at the premises, placed into a sharp’s container, collected by a licensed clinical waste disposal serviceand incinerated2 |
|  |  | Name of licensed clinical waste disposal service: |       |  |
| **6.2 Schedule 8 medicines (Controlled Drug)** |
|  | Are any Schedule 8 medicines remaining? |
|  | [ ]  No |
|  | [ ]  Yes |
|  | [ ]  Please confirm an inventory of **S8** medicines will be conducted before being leaving the premises or removing the Schedule 8 medicines from the Permit. |
|  | What will happen to the remaining Schedule 8 medicines? |
|  | [ ]  | they will be transferred to the organisation taking over the premises, transferred to a different premises on the Permit, taken to a pharmacy/hospital or returned to the wholesaler as indicated in Section 6.1 **or**  |
|  | [ ]  | they will be destroyed at the premises and collected by a licenced clinical waste disposal service – please confirm the following: |
|  | [ ]  | S8 medicines will be *destroyed* by making them unidentifiable and unusable2 |
|  | [ ]  | destruction will be **conducted** by persons authorised by Medicines and Poisons Regulations 20163 |
|  | [ ]  | destruction will be **witnessed** by persons authorised by Medicines and Poisons Regulations 20163 |
| 1 Pharmacies and hospitals are not obligated to accept medicines for disposal if they have not supplied the medicine.2 [Disposal of medicines](https://ww2.health.wa.gov.au/Articles/A_E/Disposal-of-medicines)3 Persons authorised to destroy S8 medicines and witnesses include health professionals such as medical practitioners, registered nurses, dentists, pharmacists and must be two different people. |

**PART 1: APPLICATION to change a RESEARCH/EDUCATION PERMIT**

|  |
| --- |
| **Changes without a fee** |

|  |
| --- |
| Upgrading storage and security  |
| Premises name: |       |  |
| Address:  |       | Suburb:  |       | Postcode:  |       |  |
| Describe the change to the way the medicines are stored or the change to premises security: |
|  |       |  |
|  |       |  |
|  |       |  |
| **7.1 Upgrading a drug safe**  |  |
| If upgrading a drug safe for storing medicines in Schedule 8 please complete Sections 16.1 and 16.3 Do not make a payment if the Permit currently lists Schedule 8 medicines and the change is for upgrading the drug safe only. |

**PART 1: APPLICATION to change a RESEARCH/EDUCATION PERMIT**

|  |
| --- |
| Changes with a fee |

|  |
| --- |
| Change of individual Permit holder |
| Complete this section only if the new Permit holder is an individual person and not a corporation or partnership |
| Refer to instruction number 6, for information on the requirements for being an individual Permit holder. |
| **8.1 Name of new incoming permit holder:** |
|  | Title: |       | Forename(s): |       | Surname: |       |  |
|  | Address: |       | Suburb: |       | Postcode  |       |  |
|  | Telephone /Mobile: |       | Email: |       |  |
|  | Position in organisation: |       |  |
|  | A new Permit holder must complete and **attach** Part 2: Personal Information: Identification, Fitness and Probity. |

|  |
| --- |
| Change of corporate officer or partner  |
| **Note:** Only applicable if the permit has been issued to a body corporate or company and not to an individual person. |
| **9.1** | **Name of new incoming corporate officer or partner** |
|  | Title: |       | Forename(s): |       | Surname: |       |  |
|  | Address:  |       | Suburb: |       | Postcode: |       |  |
|  | Telephone/Mobile:  |       | Email: |       |  |
|  | Corporate officer/partner must complete and **attach** Part 2: Personal Information: Identification, Fitness and Probity |
| **9.2** | **Name of outgoing corporate officer or partner**  |
|  | Title: |       | Forename(s): |       | Surname: |       |  |
| **9.3** | Please **attach** a copy of the Current and Historical Company Extract from ASIC which includes details of all past and current corporate officers. |

|  |
| --- |
|  Increase quantity of medicines or poisons  |
| Premises name: |       |  |
| Address:  |       | Suburb:  |       | Postcode:  |       |  |
| **10.1 Medicines or poisons having their quantities increased at the above-named premises** |
|  | Medicines or poisons | Quantity on current Permit | Increase quantity to: |  |
|  |       |       |       |  |
|  |       |       |       |  |
|  |       |       |       |  |
|  |       |       |       |  |
| **10.2 Increasing quantity of Schedule 8 medicines**  |
| If increasing the quantity of a Schedule 8 medicine/s, complete Sections 16.1 and 16.3. The total number of human doses of Schedule 8 medicines stored at the premises will have to be calculated to determine if the current safe is still compliant. |

**PART 1: APPLICATION to change a RESEARCH/EDUCATION PERMIT**

|  |
| --- |
| **Changes with a fee** |

|  |
| --- |
|  Addition of Schedule 2,3,4,8 medicines or Schedule 7 poisons to the Permit  |
| Premises name: |       |  |
| Address:  |       | Suburb:  |       | Postcode:  |       |  |
| **11.1 Schedule 2,3,4 ,8 medicines or S7 poisons being added to the Permit** |
|  | [ ]  **11.1.1 Schedule 2, 3 or 4 medicines, plus** complete Section 11.2 |
|  | 1. Please list the name and quantity of individual Schedule 2,3 or 4 medicines being added to the Permit:
 |
|  |
|  | **Name and strength of S2, S3 or S4 medicines** | **Schedule of medicine****S2, S3 or S4** | **Approximate quantity required** |  |
|  |       |       |       |  |
|  |       |       |       |  |
|  |       |       |       |  |
|  |
|  | 1. Storage of non- refrigerated medicines in Schedule 2, 3, and 4 (Please check which one applies)
 |
|  | [ ]  Locked room [ ]  Locked cupboard |
|  | Storage of refrigerated medicines in Schedule 2, 3, and 4 (Please check which one applies) |
|  | [ ]  Locked room with refrigerator | [ ]  Locked refrigerator |
|  | Please indicate how the temperature of refrigerated medicines will be monitored |
|  | [ ]  Vaccine refrigerator with an inbuilt thermometer and data logger that can download data. |
|  | [ ]  Normal refrigerator with temperature data logger that can download data |
|  | 1. Loss or theft, record keeping of Schedule 4 medicines only being added to the Permit
 |
|  | [ ]  | Please check to confirm any loss or theft of Schedule 4 medicines will be reported to MPRB as soon as reasonably practicable using the form found at: [Reporting loss or theft of medicines and poisons](https://ww2.health.wa.gov.au/Articles/N_R/Reporting-loss-or-theft-of-medicines-and-poisons) |
|  | [ ]  | Check to confirm records of administration or use of S4 medicines will be kept for a minimum of 2 years |
|  | [ ]  | Check to confirm records of administration or use of S4 medicines will be maintained in patient’s/subject’s notes (for in-vivo research) or other recording system. |
|  | [ ]  **11.1.2 Schedule 8 medicines** (Controlled Drug): **complete Section 16** |
|  | [ ]  **11.1.3 Schedule 7 poisons** ((Dangerous Poison), **plus** complete Section 11.2 |
|  | 1. Please list the name and quantity of Schedule 7 poisons being added to the Permit
 |
|  |  | **Name and strength of Schedule 7 poisons** | **Approximate quantity required** |  |
|  |  |       |       |  |
|  |  |       |       |  |
|  |  |       |       |  |
|  |
|  | 1. Storage of Schedule 7 poisons being added to the Permit.
 |
|  | [ ]  Locked metal cabinet | [ ]  Locked cupboard  | [ ]  Locked shed | [ ]  Locked and covered caged area |
|  | [ ]  Other: please specify: |       |  |
|  | 1. Loss or theft of Schedule 7 poisons
 |
|  | [ ]  | Please check to confirm any loss or theft of Schedule 7 poisons will be reported to MPRB as soon as reasonably practicable using the form found at: [Reporting loss or theft of medicines and poisons](https://ww2.health.wa.gov.au/Articles/N_R/Reporting-loss-or-theft-of-medicines-and-poisons) |
| **11.2 Usage of the medicines or poisons being added to the Permit** |
|  | Will the medicines poisons being added, be used for the same purpose as other medicines or poisons on the Permit? |
|  | [ ]  Yes [ ]  No: please describe the purpose for which the medicines will used: |
|  |       |  |
|  | Some variations in the conditions of use may require a new application for a different type of Permit |

**PART 1: APPLICATION to change a RESEARCH/EDUCATION PERMIT**

|  |
| --- |
| **Changes with a fee** |

|  |
| --- |
| Relocation of an existing premises |
| **12.1** | **Current address of premises:** |
|  | Premises name: |       |  |
|  | Address: |       | Suburb:  |       | Postcode:  |       |  |
| **12.2** | **New address of relocated premises:** |
|  | Premises name: |       |  |
|  | Address: |       | Suburb:  |       | Postcode:  |       |  |
|  | Telephone: |       | Fax: |       | Email: |       |  |
|  | Date of possession of the premises (settlement date/lease commencement/handover of premises): |       |  |
|  | Note: Permit will be issued with “Valid from” date on or after this date. |
| **12.3** | **Plus,** complete Sections 14,15,16, 20 and 32 (payment) and complete all of Section 16 if Schedule 8 medicines will be stored at the relocated premises. |

|  |
| --- |
|  Addition of another new premises  |
| **13.1**  | Premises name: |       |  |
|  | Premises Address: |       | Suburb:  |       | Postcode:  |       |  |
|  | Telephone: |       | Fax: |       | Email: |       |  |
|  | Date of possession of the premises (settlement date/lease commencement/handover of premises) |        |  |
|  | Note: Permit will be issued with “Valid from” date on or after this date. |
| **13.2**  | **Plus,** complete Sections 14,15,19 and 32 (payment) and complete all of Section 16 if Schedule 8 medicines will be stored at the new added premises. |

**PART 1: APPLICATION to change a RESEARCH/EDUCATION PERMIT**

|  |
| --- |
| **Changes with a fee** |

|  |
| --- |
|  Information about the relocated or new added premises |
| Is this premises being transferred from another Research/Education organisation? See instruction number 9. |
| [ ]  No  |
| [ ]  Yes: | Name of previous Research/Education organisation: |       |  |
|  | The Department requires the previous Permit holder at the relocated or new added premises to remove the premises from their Permit. The application to remove the premises from the previous Permit holder’s Permit must be received by the Department prior to adding the relocated or new added premises to your Permit. |
| **14.1 Person responsible for the relocated or new added premises** |
|  | Title: |       | Forename(s): |       | Surname: |       |  |
|  | Position in organisation: |       |  |
|  | Is the responsible person for the relocated or new added premises also?* responsible for the premises at the current address or
* responsible for another premises listed on the Permit or
* the Permit holder?
 |
|  | [ ]  Yes  |
|  | [ ]  No: the responsible person for the relocated or new added premises must complete and **attach** Part 3: Personal Information: Identification, Fitness and Probity. |
| **14.2 Location of relocated or new added premises** |
|  | [ ]  University | [ ]  High school | [ ]  Hospital | [ ]  Commercial | [ ]  Industrial |
|  | [ ]  Other-please specify: |       |  |
|  | 14.2.1. Is local government approval required to operate the education/research facility from the premises? |
|  |  | [ ]  Yes: **attach** evidence of local government approval to operate the facility from the premises |
|  |  | [ ]  No: Local government may be asked to comment on applications which may increase processing time. |
| **14.3 Building /premises security for relocated or new added premises.** Please check all that apply: |
|  | [ ]  Dedicated monitored alarm system | [ ]  Video surveillance system (CCTV) | [ ]  Motion detectors  |
|  | [ ]  Perimeter fence with lockable gate | [ ]  Perimeter alarm |
|  | [ ]  Other – please describe: |       |  |
|  |

**PART 1: APPLICATION to change a RESEARCH/EDUCATION PERMIT**

|  |
| --- |
| **Changes with a fee** |

|  |
| --- |
| Schedule 2,3,4,8 medicines or Schedule 7 poisons at relocated or new added premises  |
| **15.1 Scheduled medicines or poisons required at relocated or new added premises** |
|  | Please check the schedule of medicines or poisons atrelaoacted or new added premises |
|  | [ ]  **15.1.1 Schedule 2, 3 or 4 medicines, plus** complete Section 15.2,15.3 15.4 and 15.5 |
|  | 1. Please list the name and quantity of individual Schedule 2,3 or 4 medicines:
 |
|  |
|  | **Name and strength of S2, S3 or S4 medicine** | **Schedule of medicine****S2, S3 or S4** | **Approximate quantity****required** |  |
|  |        |        |        |  |
|  |        |        |        |  |
|  |        |        |        |  |
|  |        |        |        |  |
|  |
|  | 1. Storage and temperature monitoring of Schedule 2, 3, and 4 medicines
 |
|  | Storage of non- refrigerated medicines in Schedule 2, 3, and 4 (Please check which one applies) |
|  | [ ]  Locked room [ ]  Locked cupboard |
|  | Storage of refrigerated medicines in Schedule 2, 3, and 4 (Please check which one applies) |
|  | [ ]  Locked room with refrigerator | [ ]  Locked refrigerator |
|  | Please indicate how the temperature of refrigerated medicines will be monitored |
|  | [ ]  Vaccine refrigerator with an inbuilt thermometer and data logger that can download data. |
|  | [ ]  Normal refrigerator with temperature data logger that can download data. |
|  | 1. Loss or theft, records keeping of Schedule 4 medicines only
 |
|  | [ ]   | Please check to confirm any loss or theft of Schedule 4 medicines will be reported to MPRB as soon as reasonably practicable using the form found at: [Reporting loss or theft of medicines and poisons](https://ww2.health.wa.gov.au/Articles/N_R/Reporting-loss-or-theft-of-medicines-and-poisons) |
|  | [ ]  | Check to confirm records of administration or use of S4 medicines will be kept for a minimum of 2 years |
|  | [ ]  | Check to confirm records of administration or use of S4 medicines will be maintained in patient’s/subject’s notes (for in-vivo research) or other recording system. |
|  | [ ]  **15.1.2 Schedule 8 medicines** (Controlled Drug): **complete Section 16** |
|  | [ ]  **15.1.3 Schedule 7 poisons** ((Dangerous Poison), **plus** complete Section 15.2,15.3, 15.4 and 15.5 |
|  | 1. Please list the name and quantity of Schedule 7 poisons at relocated or new added premises
 |
|  |

|  |  |
| --- | --- |
| **Name and strength of Schedule 7 poisons required** | **Approximate quantity required** |
|        |        |
|        |        |
|        |        |
|        |        |

 |
|  | 1. Storage of Schedule 7 poisons
 |
|  | [ ]  Locked metal cabinet | [ ]  Locked cupboard  | [ ]  Locked shed | [ ]  Locked and covered caged area |
|  | [ ]  Other: please specify: |       |  |
|  | c) Loss or theft of Schedule 7 poisons |
|  | [ ]  | Please check to confirm any loss or theft of Schedule 7 poisons will be reported to MPRB as soon as reasonably practicable using the form found at: [Reporting loss or theft of medicines and poisons](https://ww2.health.wa.gov.au/Articles/N_R/Reporting-loss-or-theft-of-medicines-and-poisons) |
| Section 15 continues next page  |

**PART 1: APPLICATION to change a RESEARCH/EDUCATION PERMIT**

|  |
| --- |
| **Changes with a fee** |
| **15.2 Storage area for Schedule 2,3 and 4 medicines or Schedule 7 poisons at relocated or new added premises**  |
|  | Please provide information of all areas storing Schedule 2,3 and 4 medicines or Schedule 7 poisons |
|

|  |  |
| --- | --- |
| Floor number, room number/room name  | Floor number, room number/room name  |
|       |       |
|       |       |
|       |       |

 |
|  |
| **15.3 Access to Schedule 2,3 and 4 medicines or Schedule 7 poisons**  |
|  | **[ ]**  | Please check to confirm only the Permit holder, responsible person or other authorised employees will have unsupervised access to medicines/poisons and keys/entry codes to storage rooms, cupboards and refrigerators. |
| **15.4 Preventing access to Schedule 2,3 and 4 medicines or Schedule 7 poisons** |
|  | Please describe how non-authorised staff such as reception staff, cleaners and members of the public (including family members and children) will be prevented from having access to the medicines or poisons. |
|  |       |  |
|  |       |  |
|  |       |  |
|  |
| **15.5 Usage of the medicines or poisons at relocated or new added premises** |
|  | Will the medicines being added, be used for the same purpose as other medicines listed on the Permit? |
|  | [ ]  Yes [ ]  No: please describe the purpose for which the medicines will used: |
|  |       |  |
|  |       |  |
|  |       |  |
|  | Some variations in the conditions of use may require a new application for a different type of Permit |

**PART 1: APPLICATION to change a RESEARCH/EDUCATION PERMIT**

|  |
| --- |
| **Changes with a fee** |
| Schedule 8 medicines (Controlled Drug) |
| Complete Sections 16.1 and 16.3 if the drug safe has been upgraded as per Section 7.1Complete Sections 16.1 and 16.3 if increasing the quantify of Schedule 8 medicines as per Section 10.2Complete all of Section 16 if adding Schedule 8 medicines to the Permit as per Section 11.1.2Complete all of Section 16 if a relocated premises will be storing Schedule 8 medicines as per Section 15.1.2Complete all of Section 16 if a new added premises will be storing Schedule 8 medicines as per Section 15.1.2 |
| Is this premises being acquired from another Research/Education organisation? See instruction number 9. |
| [ ]  No | [ ]  Yes: name of previous Research/Education organisation: |       |  |
|  | Are Schedule 8 medicines being transferred from the previous Research/Education organisation? |
|  | [ ]  No [ ]  Yes: please confirm an inventory of S8 medicines will be conducted at the time of handover |
| Will S8 medicines be stored in multiple areas/rooms at the premises? |
| [ ]  No: complete all of Section 16  |
| [ ]  Yes: complete all of Section 16 for the first drug safe and Sections 16.1 and 16.3 for every other drug safe. |
| **16.1 Required Schedule 8 medicines** |
|  | Confirm address of premises:  |       |  |
|  | 16.1.1 Location of drug safe (floor number, room number/name): |       |  |
|  | 16.1.2 Please list all required S8 medicines stored in the **drug safe** at the location named in Section 16.1.1 |
|  |
|  | Name, strength and form of medicine | Quantity required | Number of *human doses* |  |
|  |       |       |       |  |
|  |       |       |       |  |
|  |       |       |       |  |
|  |       |       |       |  |
|  |       |       |       |  |
|  | 16.1.3 Total number of *human doses* of S8 medicines stored in the drug safe: |       |  |
|  | **How to calculate the number of *human doses*:** |
|  | 1. For divided doses such as tablets, capsules, ampoules, patches: 1 tablet, 1 ampoule, 1 patch =1 dose, regardless of strength. For example, 1 fentanyl patch = 1 human dose, 1 ampoule = 1 human dose.
 |
|  | 1. For mixtures, calculate the number of doses in the bottle using the information in the following table:
 |
|  |
|  | **Preparation** | **Size of bottles** | **Human dose** | **Total doses per bottle** |  |
|  | Morphine mixture 2 mg per mL | 200 mL | 5 mg | 80 |  |
|  | Morphine mixture 5 mg per mL | 200 mL | 5 mg | 200 |  |
|  | Oxycodone mixture 1 mg per mL | 250mL | 5mg | 50 |  |
|  | Hydromorphone mixture 1 mg per mL | 473mL | 2mg | 237 |  |
|  | Codeine linctus 5 mg per mL | 100mL  | 5mL | 20 |  |
| **16.2 Number of human doses of Schedule 8 medicines and drug safe requirements** |
|  | The number of human doses of Schedule 8 medicines stored in the drug safe will determine the size of the safe. |
|  | **Number of human doses** | **Compliant drug safe** | **Motion detector**  |  |
|  | ≤ 250 | Small | Not required |  |
|  | Between 251- 500 | Small | Required |  |
|  | > 500 | Large | Required |  |
|  |

**PART 1: APPLICATION to change an AMBULANCE SERVICE PERMIT**

|  |
| --- |
| **Changes with a fee** |

|  |
| --- |
| **16.3 Number of Schedule 8 human doses and required drug safe.** Complete Section 16.3 for each dug safe. |
|  | Check to confirm the number of doses calculated at 16.1.3 stored in the drug safe identified in Section 16.1.1 |
|  | [ ]  ≤ 250: complete Section 16.3.1 |
|  | [ ]  250-500: complete Section 16.3.2 |
|  | [ ]  > 500: complete Section 16.3.3 and 16.3.3. a |
|  | 16.3.1 [ ]  **≤ 250** human doses will be stored in a small drug safe with no motion detector required. |
|  |  | Schedule 8 small drug safe make and model number: |       |  |
|  |  | What is the safe bolted to? |
|  |  | [ ]   | Concrete floor | [ ]  Brick wall | [ ]  Other, describe: |       |  |
|  |  | [ ]  | **If** the safe is not bolted to a concrete floor or brick wall, please check to confirm the safe is bolted to a structural element of the building such as a steel beam or floor joist. See Appendix A for information. |
|  |  | [ ]  | Check to confirm the safe is compliant with requirements for a small drug safe as per Appendix A. |
|  |  | Please **attach** photos showing:* safe with the door closed
* safe with the door open, with a ruler held against the door edge to show the thickness of the door plate
* how the safe has been bolted into place with four bolts as per Appendix A Requirements for a small safe
 |
|  | 16.3.2 [ ]  **251- 500** human doses will be stored in small drug safe and monitored by a motion detector device.1 |
|  |  | Schedule 8 small drug safe make and model number: |       |  |
|  |  | What is the safe bolted to? |
|  |  | [ ]  Concrete floor | [ ]  Brick wall | [ ]  Other, describe: |       |  |
|  |  | [ ]  | **If** the safe is not bolted to a concrete floor or brick wall, please check to confirm the safe is bolted to a structural element of the building such as a steel beam or floor joist. See Appendix A for information. |
|  |  | [ ]  | Check to confirm the safe is compliant with requirements for a small drug safe as per Appendix A. |
|  |  | [ ]  | Check to confirm safe is covered by motion detector linked to continuously monitored alarm system. |
|  |  | Please **attach** photos showing:* safe with the door closed.
* safe with the door open, with a ruler held against the door edge to show the thickness of the door plate
* how the safe has been bolted into place with four bolts as per Appendix A.
* location of motion detector/s in relation to the drug safe.
 |
|  |  16.3.3 [ ]  **>500** human doses will be stored in a large safe, continuously monitored by a motion detector device1. |
|  |  | Schedule 8 large drug safe make and model number: |       |  |
|  |  | [ ]  | Check to confirm the safe is compliant with requirements for a large drug safe as per Appendix B. |
|  |  | [ ]  | Check to confirm safe is covered by motion detector linked to continuously monitored alarm system. |
|  |  | Does the large safe weigh more than one tonne? |
|  |  | [ ]  Yes  |
|  |  | [ ]  No: check to confirm the safe is mounted on a concrete floor as per Appendix B |
|  |  | Please **attach** photos showing:* safe with the door closed
* safe with the door open, with a ruler held against the door edge to show the thickness of the door plate
* the locking mechanism as per Appendix B
* the door is secured with at least 2 locking bolts of at least 32mm
* how the safe has been bolted onto a concrete floor as per Appendix B if safe weights less than 1tonne
* location of motion detector/s in relation to the drug safe.
 |
|  | 16.3.3. a | Please **attach** evidence to show the safe was installed by a person licensed under the *Security and Related Activities* *(Control) Act 1996* to install safes. |
| 1Motion Detectors: drug safe must be covered by movement detector attached to a continuously monitored alarm system. |

**PART 1: APPLICATION to change a RESEARCH/EDUCATION PERMIT**

|  |
| --- |
| **Changes with a fee** |
| **16.4 Access to Schedule 8 medicines** |
| [ ]  | Please check to confirm only the Permit holder, responsible person or other authorised employees will have access to the keys or entry codes to the drug safe and to safe keys or codes |
| **16.5 Record keeping for Schedule 8 medicines**  |
|  | Check to confirm which type of recording system will be used to record administration or use of S8 medicines: |
|  | [ ]  Patient notes OR [ ]  Other- please describe: |       |  |
|  | Which type of drug register will be used to record the receival of and administration or use of S8 medicines1 |
|  | [ ]  Paper Schedule 8 register – HA14 OR  |
|  | [ ]  Department of Health approved Electronic Schedule 8 register |
|  | Name of approved electronic register: |       |  |
|  | [ ]  Check to confirm records of administration or use and registers will be kept for a minimum of 5 years1 |
| **16.6 Inventory, loss, theft and discrepancies of Schedule 8 medicines** |
|  | [ ]  Check to confirm an inventory (balance check) of S8 medicines will be conducted at least monthly2. |
|  | [ ]  Check to confirm any discrepancies that have not been accounted for are reported to MPRB ASAP2 |
|  | [ ]  Check to confirm loss / theft of S8 medicines will be reported to MPRB and police ASAP3 |
| **16.7 Disposal/destruction of Schedule 8 medicines atrelocated or new added premises** |
|  | 16.7.1 [ ]  Check to confirm an inventory of S8 medicines will be conducted prior to being disposed of or destroyed. |
|  | 16.7.2 Please indicate how expired or substandard Schedule 8 medicines will be disposed of: |
|  | [ ]  | Taken to pharmacy or hospital for disposal 4  |
|  |  | Name of pharmacy/hospital: |       |  |
|  |  | **or** |
|  | [ ]  | Returned to wholesaler for disposal |
|  |  | Name of wholesaler: |       |  |
|  |  | **or** |
|  | [ ]  | *Destroyed* at the premises, placed into a sharp’s container, collected by a licensed clinical waste disposal serviceand incinerated5 |
|  |  | Name of licensed clinical waste disposal service: |       |  |
|  |  | Please confirm the following: |
|  | [ ]  | Schedule **8** medicines will be *destroyed* by making them unidentifiable and unusable5 |
|  | [ ]  | destruction will be **conducted** by persons authorised by Medicines and Poisons Regulations 20165,6 |
|  | [ ]  | destruction will be **witnessed** by persons authorised by Medicines and Poisons Regulations 20165,6 |
| 1 [Schedule 8 drug registers](https://ww2.health.wa.gov.au/Articles/S_T/Schedule-8-drug-registers) 2 [Recording of Schedule 8 transactions in an approved register](https://ww2.health.wa.gov.au/Articles/N_R/Recording-S8-and-S9-transactions) 3 [Reporting loss or theft of medicines and poisons](https://ww2.health.wa.gov.au/Articles/N_R/Reporting-loss-or-theft-of-medicines-and-poisons) 4 Pharmacies and hospitals are not obligated to accept medicines for disposal if they have not supplied the medicine5 [Disposal of medicines](https://ww2.health.wa.gov.au/Articles/A_E/Disposal-of-medicines)6 Persons authorised to destroy and make S8 medicines unidentifiable and persons authorised to witness this process include health professionals permitted to possess S8 medicines such as medical practitioners, registered nurses, dentists, pharmacists. |

**PART 1: APPLICATION to change a RESEARCH/EDUCATION PERMIT**

|  |
| --- |
| **Changes with a fee** |

|  |
| --- |
| Change of business or trading name |
| Complete this Section if the business or trading name will change without any change in legal entity.If there is a change in ownership, an application for a new Permit is required. |
| **17.1** | **Previous business or trading name:** |       |  |
|  | New business or trading name: |       |  |
|  | **Attach** a copy of the Current and Historical Business Name Extract from ASIC |  |
| **17.2** | Australian Business Number: |       |  |
|  |  |

|  |
| --- |
| Variation in the activities undertaken under the Permit |
|  Please describe the proposed change in the way the medicines or poisons will be used: |
|   |       |  |
|  |       |  |
| Note: Some variations in the conditions of use will require a new application and issue of a different Permit type. |

|  |
| --- |
| Declaration by Permit holder |
| This declaration relates to the application to change the Permit and must be signed by the individual Permit holder, or if the Permit is issued to a corporation or partnership, the declaration must be signed by a corporate officer of partner.Please refer to Instruction 12 for information on acceptable signatures. |
| I am the: | [ ]  current Permit holder | [ ]  incoming Permit holder |
|  | [ ]  the corporate officer or partner who signed the original Permit application. |
| **If the current Permit holder cannot sign please provide the reason:** |
|  |       |  |
|  |       |  |
|  |       |  |
| I (provide full name):  |       |  |
| of (provide full address): |       |  |
| hereby declare:  |
|  | The information contained in this application form is true and correct |
|  | I am aware that penalties apply under the *Medicines and Poisons Act 2014* for providing false or misleading information in this application.  |
| Signature of applicant:  |       | Date:  |       |  |
|  |  |  |  |  |

# PART 2: PERSONAL INFORMATION: new PERMIT HOLDER

**Part 2** assesses identification, fitness and probity of the Permit holder.

If the new Permit holder is an individual person, all sections of Part 2 must be completed.

If the Permit is held by a corporation or partnership, and there is a new corporate officer or partner, all sections of Part 2 except Sections 21 and 22 must be completed by each new corporate officer or each new partner.

|  |
| --- |
| Identification of new Permit holder, corporate officer or partner |
| **20.1 Personal Details** |
| Title: |     | Forename/s: |       | Surname: |       | Date of birth: |       |  |
| Address: |       | Suburb: |       | Postcode: |      |  |
| Postal address:  |       | Suburb: |       | Postcode: |      |  |
| Mobile number: |       | Email:  |       |  |
| Position in organisation: |       |  |
| **20.2 Certified true copy of a photographic identification document** |
| **ATTACH** a certified 1 copy of a WA State Government or Australian Government issued photographic identification document such as drivers Licence or passport. Non-government issued identification documents will not be accepted. |
| 1Copy of photographic identification document must be certified as a true copy by a person authorised to witness statutory declarations (see Appendix C for a list of persons authorised to certify a true copy) |
| **20.3 Role in relation to the Permit**  |
|  | [ ]  | a new individual person who is suitably qualified and in charge of a laboratory or department involved in research, teaching and demonstration, analysis, study or other approved activity in which the medicines or poisons are to be used. Complete remainder of Part 2. |
|  | [ ]  | a new corporate officer. Type of corporate officer: |
|  |  | [ ]  Director | [ ]  General Manager | [ ]  Company secretary | [ ]  CEO | [ ]  CFO | [ ]  COO |
|  |  | Complete Sections 23,24,25 and 26 of Part 2 and **attach** a CV1 |
|  | [ ]  | a new partner  |
|  |  | Complete Sections 23,24,25 and 26 of Part 2 and **attach** a CV1 |
|  |  | 1A new **corporate officer or partner must provide a CV and qualifications.** These will be used to assess whether the corporate officer or partner meets the requirements of the *Medicines and Poisons ACT 2014.* |

|  |
| --- |
| Qualifications of new Permit holder |
| Complete this section if you are an individual person applying to be the new Permit holder.Do not complete this section, if the Permit has been issued to a corporation or partnership.  |
| Refer to instruction number 6, for information on the requirements for being an individual Permit holder. |
| **21.1** | Qualification/s: |       |  |
|  | **Attach** a copy of your qualification/s and CV. |
| **21.2** | Are you a health professional registered with the Australian Health Practitioner Regulation Agency (AHPRA) or a veterinary surgeon registered with the WA Veterinary Surgeons Board (VSB)?  |
|  | [ ]  No |
|  | [ ]  Yes, type of registration (e.g. AHPRA: medical practitioner, VSB) |       |  |
|  |  | Registration number: |       | Expiry date: |       |  |
|  | **Attach** a copy of your currentannual registration certificate or wallet card provided to you by AHPRA. (**do not** provide an extract of the information available on AHPRA’s public website) **or attach** the certificate of registration from the WA Veterinary Surgeons Board (VSB).  |

**PART 2: PERSONAL INFORMATION: new PERMIT HOLDER**

|  |
| --- |
| Authority, access, standard operating procedures (SOPs) |
| Complete this section if you will be the new individual Permit holder.Do **not** complete this section, if the Permit holder is a corporation or partnership. |
| [ ]  Please check to confirm that as the new Permit holder, you will have authority within the organisation to determine policies and procedures on the management, storage, use and/or administration of the medicines or poisons. |
| [ ]  Please check to confirm that you will always have access to the medicines or poisons listed on the Permit. |
| [ ]  Please check to confirm that only yourself, responsible person or other authorised employees of the organisation will have unsupervised access to the medicines. |
|  |

|  |
| --- |
| Prior permits/licences for medicines/poisons |
| To be completed by a new Permit holder, new corporate officer or new partner. |
| **23.1** | Have you (or a company of which you were a corporate officer or a partner) previously held a Permit or Licence , under the *Medicines and Poisons Act 2014* or a repealed corresponding law, or a corresponding law in another state or territory, that was suspended or cancelled? |
|  | [ ]  No |
|  | [ ]  Yes: please provide details of the Permit or Licence number, the name of the business, when the cancellation or suspension occurred, the reason for the cancellation or suspension and which state or territory the cancellation or suspension occurred in: |
|  |       |  |
|  |       |  |
|  |       |  |
|  |
| **23.2** | Have you (or a company of which you were a corporate officer) ever been refused a Permit or Licence under the *Medicines and Poisons Act 2014* or a repealed corresponding law, or a corresponding law in another state or territory? |
|  | [ ]  No |
|  | [ ]  Yes: please provide details of the name of the business, what type of Permit or Licence you applied for, why your application was refused and which state or territory the refusal occurred in: |
|  |       |  |
|  |       |  |
|  |       |  |
|  |

**PART 2: PERSONAL INFORMATION: new PERMIT HOLDER**

|  |
| --- |
| Criminal check for new Permit holder, corporate officer or partner |
| **24.1** | **Offences under the *Medicines and Poisons Act 2014* or a repealed corresponding law, or a corresponding law in another state or territory.** |
|  | Have you ever been convicted of or are there charges pending for an offence under the *Medicines and Poisons Act 2014* or a repealed corresponding law, or a corresponding law in another state or territory? |
|  | [ ]  No |
|  | [ ]  Yes: you must **attach** full details in the form of a Statutory Declaration. Your declaration must include the:* Name of the court including state/territory or country, all relevant dates and any sentences received
* The nature of the alleged offence and circumstances surrounding the offences
 |
| **24.2** | **NPC and Indictable offences1**  |
|  | 1. Please **attach** a copy of your **National Police Clearance certificate** (NPC), which is less than 12 months old.
 |
|  | 1. Have you been convicted of, or have pending charges for indictable1 offences since the date on your NPC?
 |
|  | [ ]  No |
|  | [ ]  Yes: you must **attach** full details in the form of a Statutory Declaration. Your declaration must include the:* Name of the court including state/territory or country, all relevant dates and any sentences received
* The nature of the alleged offence and circumstances surrounding the offences
 |
|  | 1 Minor traffic offences are not classified as indictable offences |

|  |
| --- |
| Financial resources of new Permit holder, corporate officer or partner |
| To be completed by a new Permit holder, new corporate officer or new partner. |
| **25.1** | Have you been declared bankrupt or a debtor under any bankruptcy law?  |
|  | [ ]  No |
|  | [ ]  Yes: What date was/will your bankruptcy be discharged? |       |  |
| **25.2** | Have you ever been a corporate officer of a company that was wound up or subject to an application for, or placed in, receivership or liquidation? | [ ]  Yes | [ ]  No |
|  |

|  |
| --- |
| Declaration by new Permit holder, corporate officer or partner |
| This declaration must be signed by the new individual Permit holder, corporate officer or partner and is about personal information and includes probity check consent.Please refer to instruction 12 for information on acceptable signatures. |
|  | In accordance with Section 39 of the *Medicines and Poisons Act 2014*, I give consent to the Western Australian Department of Health to carry out all relevant searches to determine my fitness and probity in relation to holding a Research/Education Permit. These searches may include (without limitation) corporate searches, checks with health professional registration boards (including registration status and release of information on any current or ongoing investigations) and criminal record checks. I also understand I may be requested to provide further information relevant to determining fitness and probity. |
|  | I am at least 21 years of age. |
|  | The information contained in this application form is true and correct. |
|  | I am aware there are penalties under the *Medicines and Poisons Act 2014* for providing false or misleading information. |
|  | I am aware of my responsibility or the responsibility of the body corporate (if applicable) for the safe storage and handling of scheduled medicines or poisons and will ensure compliance with the *Medicines and Poisons Act 2014* and Medicines and Poisons Regulations 2016, and compliance with conditions placed on the Permit. |
|  | I will notify the Department of Health **if** I leave the employment of the organisation or I am no longer a corporate officer of the company that holds the Permit. |
| Signature: |       | Name: |       | Date: |       |  |
|  |

#

# PART 3: PERSONAL INFORMATION: new RESPONSIBLE PERSON

|  |
| --- |
| Identification of new responsible person |
| The role of the responsible person is to manage the medicines or poisons on a day to day basis and be the contact person, if the Permit holder is not available.  |
| Refer to instruction number 7 for information on the requirements for being a responsible person for a premises. |
| **27.1** Is the new responsible person, also the Permit holder or responsible for another premises listed on the Permit? |
|  | [ ]  Yes: Confirm name: | Title: |       | Forename/s: |       | Surname: |       |  |
|  | There is no requirement to complete Part 3. |
|  | [ ]  No: complete remainder of Part 3. |
| **27.2 Personal details of responsible person**  |
|  | Title: |     | Forename/s: |       | Surname: |       | Date of birth: |       |  |
|  | Postal Address: |       | Suburb: |        | Postcode: |      |  |
|  | Mobile number: |       | Email: |       |  |
|  | Position in organisation: |       |  |
| **27.3 Certifiedtrue copy of a photographic identification document** |
|  | **ATTACH** a certified 1 copy of a WA State Government or Australian Government issued photographic identification document such as drivers’ licence or passport. Non-government issued identification documents will not be accepted. |
|  | 1 Copy of photographic identification document must be certified as a true copy by a person authorised to witness statutory declarations (see Appendix C for a list of persons authorised to certify a true copy). |
|  |

|  |
| --- |
|  Qualifications of new responsible person |
| **28.1** | Qualification/s |       |  |
|  | **Attach** a copy of your qualification/s and your CV. |
| **28.2** | Are you a health professional registered with the Australian Health Practitioner Regulation Agency (AHPRA) or a veterinary surgeon registered with the WA Veterinary Surgeons Board (VSB)? |
|  | [ ]  No |
|  | [ ]  Yes, type of registration: (e.g. AHPRA: medical practitioner, VSB) |       |  |
|  |  | Registration number: |       | Expiry date: |       |  |
|  | **Attach** a copy of your annual registration certificate or wallet card provided to you by AHPRA. (**do not** provide an extract of the information available on AHPRA’s public website) **or attach** the certificate of registration from the WA Veterinary Surgeons Board (VSB). |

**PART 3: PERSONAL INFORMATION: new RESPONSIBLE PERSON**

|  |
| --- |
| Prior permits/licences for medicines/poisons held by new responsible person |
| **29.1** | Have you (or a company of which you were a corporate officer or a partner) previously held a Permit or Licence, under the *Medicines and Poisons Act 2014* or a repealed corresponding law, or a corresponding law in another state or territory, that was suspended or cancelled? |
|  | [ ]  No |
|  | [ ]  Yes: please provide details of the Permit or Licence number, the name of the business, when the cancellation or suspension occurred, the reason for the cancellation or suspension and which state or territory the cancellation or suspension occurred in: |
|  |       |  |
|  |       |  |
|  |
| **29.2** | Have you (or a company of which you were a corporate officer) ever been refused a Permit or Licence under the *Medicines and Poisons Act 2014* or a repealed corresponding law, or corresponding law in another state or territory? |
|  | [ ]  No |
|  | [ ]  Yes: please provide details of the name of the business, what type of Permit or Licence you applied for, why your application was refused and which state or territory the refusal occurred in: |
|  |       |  |
|  |       |  |
|  |

|  |
| --- |
| Criminal check for new responsible person |
| **30.1** | **Offences under the *Medicines and Poisons Act 2014* or a repealed corresponding law, or a corresponding law in another state or territory.** |
|  | Have you ever been convicted of or are there charges pending for an offence under the *Medicines and Poisons Act 2014* or a repealed corresponding law, or a corresponding law in another state or territory? |
|  | [ ]  No |
|  | [ ]  Yes: you must **attach** full details in the form of a Statutory Declaration. Your declaration must include the:* Name of the court including state/territory or country, all relevant dates and any sentences received
* The nature of the alleged offence and circumstances surrounding the offences
 |
| **30.2**  | **NPC and Indictable offences1**  |
|  | 1. Please **attach** a copy of your **National Police Clearance certificate** (NPC), which is less than 12 months old.
 |
|  | 1. Have you been convicted of, or have pending charges for indictable1 offences since the date on your NPC?
 |
|  | [ ]  No |
|  | [ ]  Yes: you must **attach** full details in the form of a Statutory Declaration. Your declaration must include the:* Name of the court including state/territory or country, all relevant dates and any sentences received
* The nature of the alleged offence and circumstances surrounding the offences
 |
|  | 1 Minor traffic offences are not classified as indictable offences |

|  |
| --- |
| Declaration by new responsible person  |
| This declaration must be signed by the new responsible person and includes probity check consent.Please refer to instruction 12 for information on acceptable signatures. |
| 1. I acknowledge my role is to manage the medicines or poisons on a day to day basis and be the contact person, if the Permit holder is not available.
 |
| 1. I give consent to the Western Australian Department of Health to carry out all relevant searches to determine my fitness and probity to be named as the responsible person on the Research/Education Permit. These searches may include (without limitation) corporate searches, and criminal record checks. I also understand I may be requested to provide further information relevant to determining fitness and probity.
 |
| 1. I am at least 21 years of age.
 |
| 1. The information contained in this application form is true and correct.
 |
| Signature: |       | Name: |       | Date: |       |  |
|  |

#

# PART 4: PAYMENT and CHECKLIST

|  |
| --- |
| Payment (where required) |
| **Fee: $87** |
| 1. | [ ]  Credit Card – American Express and Diners not accepted |
|  | Card type: | [ ]  MasterCard | [ ]  Visa  |
|  | Name on card: |       | Card number:  |        |  |
|  | Expiry date: |       | Amount:  **$87** |
|  | Signature of cardholder: |       | Date:  |       |  |
|  |
| 2. | [ ]  Direct debit |
|  | **Please quote Permit number and business name in the reference when making a direct debit payment**  |
|  | Bank: Commonwealth Bank: | **BSB**: 066 040  | **Account number:** 13300018 | Amount: **$87** |
|  | Receipt Number: |       | Payment date:  |       |  |
|  |
| 3. | [ ]  Cheque or money order – made payable to DEPARTMENT OF HEALTH |

**Please keep a copy of the completed application form for reference**

Please email completed form and other requested documentation to mprb@health.wa.gov.au

|  |
| --- |
| **A fee of $87 is payable** for the following types of changes to a Research/Education Permit:* Change of individual permit holder (no change of ownership of the business)
* Change of a corporate officer (only for Permits issued to a corporation and not an individual person)
* Increase quantity of medicines or poisons
* Add medicines or poisons to the Permit for an existing premises
* Relocation of an existing premises to a new location
* Addition of a new premises
* Change of business or trading name without changing legal entity (no change of ownership).
* Variation in the activities undertaken under the permit, including the use of the medicines
 |
| **Note: if making multiple changes, only pay one fee of $87** |
| **Fees are not payable** for the following type of changes to a Research/Education Permit:* Change of postal address and other contact details
* Change to a person responsible for a premises
* Removal of a premises from the Permit
* Removal of medicines or poisons from the Permit
* Upgrading storage or security including upgrading a drug safe
 |

**PART 4: PAYMENT and CHECKLIST**

|  |
| --- |
| Checklist: Please ensure all the appropriate requested documentation is attached for: |
| **Part 1 Application to change a Research/Education Permit** |
| [ ]  | If changing a responsible person for a premises: completed Part 3: Personal Information (Section 3.1) |
| [ ]  | If changing an individual Permit holder: completed Part 2: Personal Information (Section 8.1) |
| [ ]  | If changing a corporate officer/partner: completed Part 2: Personal Information (Section 9.1) |
| [ ]  | If changing a corporate officer/ partner: copy of the Current and Historical Company Extract from ASIC (Section 9.3) |
| [ ]  | If a premises is relocated or a new premises is added to the Permit, and the responsible person is not responsible for any other premises or is not the Permit holder: completed Part 3: Personal Information-Form(Section 14.1) |
| [ ]  | If applicable, evidence of local government approval to operate the facility from the premises (Section 14.2.1) |
| [ ]  | If storing Schedule 8 medicines, attach photos of safe etc as required in Section 16.3 |
| [ ]  | If storing S8 medicines in a large safe, evidence to show the safe was installed by a person licensed under the *Security and Related Activities* *(Control) Act 1996* to install safes. (Section 16.3.3.a) |
| [ ]  | If there is a change of business or trading name without a change of legal entity: copy of the Current and Historical Business Name Extract from ASIC (Section 17.1) |
| [ ]  | Declaration signed and dated by individual Permit holder, corporate officer or partner (Section 19) |
| **Part 2: Personal information, fitness and probity for new Permit holder, corporate officer or partner** |
| [ ]  | Copy of photographic identification which must be certified as a true copy by a person authorised to witness statutory declarations (Section 20.2). See Appendix C for a list of persons authorised to witness a signature |
| [ ]  | If there is a new corporate officer/partner, attach a CV and qualifications for each new officer/partner (Section 20.3) |
| [ ]  | If the applicant is an individual person, attach a CV and qualifications (Section 21.1) |
| [ ]  | If applicable, AHPRA or VSB registration certificate. **Do not** provide an extract of the information available on AHPRA’s public website (Section 21.2) |
| [ ]  | If applicable, a Statutory Declaration relating to an offence under the *Medicines and Poisons Act 2014* or a repealed corresponding law, or a corresponding law in another state or territory (Section 24.1) |
| [ ]  | A copy of the NPC Certificate which is less than 12 months old (Section 24.2.a) |
| [ ]  | If applicable, a Statutory Declaration relating to an indictable offence since the date on the NPC. (Section 24.2. b) |
| [ ]  | Declaration signed and dated by new Permit holder, new corporate officer or partner (Section 26) |
| **Part 3: Personal information, fitness and probity for new responsible person** |
| [ ]  | Copy of photographic identification which must be certified as a true copy by a person authorised to witness statutory declarations (Section 27.3). See Appendix C for a list of persons authorised to witness a signature |
| [ ]  | CV and copies of qualifications (Section 28.1) |
| [ ]  | If applicable AHPRA or VSB registration certificate. **Do not** provide an extract of the information available on AHPRA’s public website (Section 28.2) |
| [ ]  | If the new responsible person has been convicted of or there are charges pending for an offence under the *Medicines and Poisons Act 2014* or a repealed corresponding law or corresponding law in another state or territory, attach a Statutory Declaration relating to the offence (Section 30.1) |
| [ ]  | A copy of the NPC Certificate which is less than 12 months old (Section 30.2.a) |
| [ ]  | If applicable, a Statutory Declaration relating to an indictable offence since the date on the NPC. (Section 30.2.b) |
| [ ]  | Declaration signed and dated by new responsible person (Section 31) |
| **Part 4: Declaration and Payment** |
| [ ]  | Payment details completed with correct signature if paying by credit card (Section 32) |

#

# PART 5: APPENDICES

### Appendix A: Requirements for a small safe

The requirements for a small drug safe are set out in the Table.

**Table**

|  | Requirements |
| --- | --- |
| **Cabinet/body** | Must be made from solid steel plate at least 10 mm thick or a steel skin with concrete fill at least 50 mm thickAll joints must be continuously welded |
| **Door** | Must be made from solid steel plate at least 10 mm thick or a steel skin with concrete fill at least 50 mm thickMust be fitted flush to the cabinet/body with a maximum clearance of 1.5 mm when closedHinge system must be a system that does not allow the door to be opened if the hinge is removed |
| **Lock** | Must be a 6 lever key lock or a 4 wheel combination lock or a digital lock that provides security that is equivalent to a 6 lever key lock or 4 wheel combination lock |
| **Mounting** | Must be mounted on a concrete floor or a brick or concrete wall with at least 4 expanding bolts of at least 12 mm in diameterIf mounting on a concrete floor or a brick or concrete wall is not possible must be securely mounted on structural elements of the building such as studs or floor joists |

**PART 5: APPENDICES**

###  Appendix B: Requirements for a large safe

The requirements for a large safe are set out in the Table.

**Table**

|  | **Requirements** |
| --- | --- |
| **Cabinet/body** | Must be made from solid steel plate at least 10 mm thick or a steel skin with concrete fill at least 50 mm thickAll joints must be continuously welded |
| **Door** | Must be made from solid steel plate at least 10 mm thick or a steel skin with concrete fill at least 50 mm thickMust be fitted flush to the cabinet/body with a maximum clearance of 1.5 mm when closedHinge system must be a system that does not allow the door to be opened if the hinge is removedMust be secured with at least 2 locking bolts of at least 32 mm diameter |
| **Lock** | Must be a 6 lever key lock or a 4 wheel combination lock or a digital lock that provides security that is equivalent to a 6 lever key lock or 4 wheel combination lock |
| **Mounting** | Must be mounted on a concrete floor with an expanding bolt with a diameter of at least 16 mm unless the safe weighs more than 1 tonne |
| **Installation** | Must be installed by a person licensed under the *Security and Related Activities (Control) Act 1996* to install safes |
| **Weight** | Must have a minimum weight of 250 kg |

**PART 5: APPENDICES**

### Appendix C: Certifying true copies of photographic identification

Suggested wording for certification is as follows:

I certify that this appears to be a true copy of the document produced to me on <date>

Signature

Name

Profession or occupation group

| **Persons who can certify documents** |
| --- |
| Academic (tertiary institution) | Medical practitioner |
| Accountant | Member of Parliament |
| Architect | Minister of religion |
| Australian Consular Officer | Nurse |
| Australian Diplomatic Officer | Optometrist |
| Bailiff | Patent attorney |
| Bank manager | Pharmacist |
| Chartered secretary | Physiotherapist |
| Chiropractor | Podiatrist |
| Company auditor or liquidator | Police officer |
| Court officer (judge, master, magistrate, registrar or clerk) | Post Office manager |
| Defence Force officer | Psychologist |
| Dentist | Public servant |
| Engineer | Public notary |
| Industrial organisation secretary | Real Estate agent |
| Insurance broker | Settlement agent |
| Justice of the Peace | Sheriff or deputy Sheriff |
| Lawyer | Surveyor |
| Local government CEO or deputy CEO | Teacher |
| Local government councillor | Tribunal officer |
| Loss adjuster | Veterinarian |
| Marriage celebrant |  |