# Research activity

Applicable fee for each location = None

This activity is to allow the supply or administration of medicinal cannabis products (that do not meet the definition of a CBD product) to human subjects for the purpose of clinical trials.

You should not apply for this activity unless you have received a letter from Medsafe giving you approval to conduct a clinical trial. For more information on applying for a clinical trial approval, go to: <https://www.medsafe.govt.nz/Medicines/clinical-trials.asp>

Complete a separate Section D for each different location where the approved clinical trial is to be conducted. For more details on applying for this activity, refer to **Part 4: Guidance for Applicants for a Medicinal Cannabis Licence** of the *Guideline on the Regulation of Medicinal Cannabis in New Zealand*.

## Location of the activity

* + 1. Provide the physical address for the location where the clinical trial will be conducted and product will be stored.

|  |  |  |
| --- | --- | --- |
|  | Level/unit: |  |
|  |  |  |
|  | Street number and name: |  |
|  |  |  |
|  | Suburb: |  |
|  |  |  |
|  | Town/city: |  |
|  |  |  |
|  | Postcode: |  |
|  |  |  |
| [Reference attached document(s).] |

[Continue on additional sheets if necessary.]

* + 1. The following people are the responsible persons for the clinical trial at this location.

|  |
| --- |
|  |
|  |

[Continue on additional sheets if necessary.]

Each responsible person must complete Section A3: Responsible person details and declaration.

## Security arrangements at this location

* + 1. You must keep secure medicinal cannabis products to be given to subjects in a clinical trial.

Describe the arrangements for physical and procedural security as well as security of staff members. For guidance on what you should include in the security plan, refer to **Part 4: Guidance for Applicants for a Medicinal Cannabis Licence** of the *Guideline on the Regulation of Medicinal Cannabis in New Zealand.*

Describe how the medicinal cannabis trial medicine will be kept secure at the location.

|  |
| --- |
| [Reference attached document(s).] |

[Continue on additional sheets if necessary.]

## Registers and record-keeping

Regulation 64 of the Misuse of Drugs (Medicinal Cannabis) Regulations 2019 requires the licence holder to keep records of the amounts of cannabis starting material, cannabis-based ingredients and medicinal cannabis products held and the amounts of medicinal cannabis products supplied or administered during the period of the licence.

* + 1. Describe the record-keeping system and the location where the records will be kept. Describe what will happen to the unused medicinal cannabis product (for example, if the trial is discontinued).

|  |
| --- |
| [Reference attached document(s).] |

[Continue on additional sheets if necessary.]

## Medicinal cannabis product to be used in clinical trials

* + 1. Give details of the medicinal cannabis product to be administered in the clinical trial.

|  |  |
| --- | --- |
| Name of product: |  |
| Dosage form: |  |
| Active ingredients: |  |

|  |
| --- |
| [Reference attached document(s).] |

* + 1. Provide a copy of the letter from Medsafe giving its approval to conduct the clinical trial.

|  |
| --- |
| [Reference attached document(s).] |