# Research activity

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| **INFORMATION FOR APPLICANTS**   * Renewal fee applicable for a research activity at each location = No fee payable * Complete a separate Section RD for each research activity at each location to be renewed under the licence.   Where the information requested has been provided with the initial licence application or subsequent applications for amendment and has not changed, you do not need to resubmit the information. |

## Location of the activity

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

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

[Continue on additional sheets if necessary.]

* + 1. Responsible persons at this location

☐ I declare that there are no changes to the responsible persons at this location.

OR

☐ The responsible persons for the clinical trial at this location have changed. The new responsible persons are:

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| --- |
|  |
|  |
| (Continue on additional lines if necessary) | |

Each current or new responsible person must complete Section RA3: 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.

☐ I declare that there are no changes to the arrangements for physical and procedural security, as well as security of staff members.

* + 1. If the clinical trial is discontinued during the period of the licence, describe what will happen to the unused medicinal cannabis product(s) used in the trial.

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[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. ☐ I declare that there are no changes to the record-keeping system and the location where the records are kept.

OR

☐ The record-keeping system and where the records are kept have been changed.

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| [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: |  |

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

* + 1. If there have been clinical trial protocol amendments, provide a copy of the letter from Medsafe giving approval.

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| [Reference attached document(s).] |