**Initial notification** (complete all sections of the form)

**Change to existing notification** (only complete the sections which have changed)

1. **INVESTIGATOR CONTACT DETAILS**

**1.1 Contact name**

**1.2 Contact phone number**

* 1. **Contact email**

1. **TRIAL DETAILS**

**2.1 Protocol number (must be a minimum of 4 and maximum of 20 characters)**

**2.2 Expected trial start date** The date you estimate the trial will be initiated at the first Australian site.

Click to enter a date or type dd/mm/yyyy

**2.3 Expected completion date** The date you estimate the trial will be completed at all Australian sites.

Click to enter a date or type dd/mm/yyyy

**2.4 Will this trial include the potential use of restricted goods?**

**Yes** **No**

**2.5 Title of study (max 250 characters)**

**2.6 Trial type:**

Phase I  Phase IV

Phase II  Bioavailability/Bioequivalence

Phase III  Device

**2.7 Brief Description of Trial**

**2.8 This trial:**

Involves animal excipients Is being conducted in other countries

Involves the use of a Medicine Involves the use of a Biological

Involves the use of a Therapeutic Device Involves the use of a Medical Device

Is placebo controlled Is comparator controlled

Involves a Genetically Modified Organism Involves gene therapy

Is a multicentre trial in Australia Has relevant preceding trials

For all checked boxes, complete the corresponding table/s below. Copy each table as required for each excipient, medicine or device involved in the trial. Delete the tables which are not applicable.

**Animal excipients**

|  |  |
| --- | --- |
| Product Name |  |
| Species of Origin |  |
| Tissue type |  |
| Preparation |  |
| Country of Origin |  |

**Medicine details**

|  |  |  |
| --- | --- | --- |
| Trade/Product/Code Name | |  |
| Is this a combination product? | | **Yes**  **No** |
| Container Type | |  |
| Dosage Form | |  |
| Presentation (eg 2ml ampoule, 5ml syringe, blister pack) | |  |
| Route of Administration | |  |
| Formulation  (duplicate for multiple ingredients) | Ingredient Name |  |
| Quantity |  |
| Unit |  |
| Indication | |  |
| Dosage and frequency | |  |
| Intended Use | | Comparator  Investigational Medicinal Product  Standard Care Therapy |
| Is the medicine manufactured in Australia? | | **Yes** **No** |
| Manufacturer details  (Please provide name, address and/or GMP licence number or relevant exemption) | |  |

|  |
| --- |
|  |
|  |

**Device details (Therapeutic or Medical)**

|  |  |
| --- | --- |
| Product Name (trade name if applicable) |  |
| Is this a: | Single Device  System  Procedure Pack  Software |
| Manufacturer (name) |  |
| GMDN search context (if known) | Name  Code |
| GMDN (if known) |  |
| Description (details of design, composition, specification, mode of action and application, method of use) |  |
| Intended Purpose | Comparator  Investigational Medicinal Product  Standard Care Therapy  Other |
| If ‘Other’ please provide a description |  |

**Biological details**

|  |  |  |
| --- | --- | --- |
| Trade/Product/Code Name | |  |
| Is this a combination product? | | **Yes**  **No** |
| Type of container | |  |
| Dosage Form | |  |
| Route of Administration | |  |
| Ingredients  (duplicate for multiple ingredients) | Ingredient Name |  |
| Quantity |  |
| Unit |  |
| Country of origin |  |
| Product description | |  |

**Placebo**

|  |  |
| --- | --- |
| Product Name |  |
| Route of Administration |  |
| Description (including dosage form) |  |

**Genetically Modified Organism**

|  |  |
| --- | --- |
| Description |  |

**Gene Therapy**

|  |  |
| --- | --- |
| Description |  |

**Trial also being conducted in other countries**

|  |  |
| --- | --- |
| List other countries |  |

**Preceding trials**

|  |  |
| --- | --- |
| Provide CTN application ID and trial name |  |

**2.9 Total number of participants to be enrolled in the trial**

Choose a number from the drop down list.

**2.10 Therapeutic area**

Select a therapeutic area from the drop down list

1. **TRIAL SITE DETAILS**

**3.1 Site**

|  |  |
| --- | --- |
| Name of site |  |
| Site address |  |
| State or Territory |  |
| Expected site start date | Click to enter a date or type dd/mm/yyyy |

**3.2 Principal Investigator**

|  |  |
| --- | --- |
| Name |  |
| Phone number |  |
| Email |  |

* 1. **Human Research Ethics Committee (HREC) details**

|  |  |
| --- | --- |
| HREC Name |  |
| HREC Code (NHMRC code) |  |
| HREC Contact Officer |  |
| Position |  |
| Contact Phone Number |  |
| Contact email |  |

* 1. **Approving authority details**

|  |  |
| --- | --- |
| Name of Authority |  |
| Authority Contact Officer |  |
| Position |  |
| Contact Phone |  |
| Contact Email |  |

1. **ADDITIONAL TRIAL SITE DETAILS** Add as many sites as required.

**4.1 Site**

|  |  |
| --- | --- |
| Name of site |  |
| Site address |  |
| Location (State or Territory) |  |
| Expected site start date | Click to enter a date or type dd/mm/yyyy |

**4.2 Principal Investigator**

|  |  |
| --- | --- |
| Name |  |
| Phone number |  |
| Email |  |

* 1. **Human Research Ethics Committee (HREC) details\***

|  |  |
| --- | --- |
| HREC Name |  |
| HREC Code(NHMRC code) |  |
| HREC Contact Officer |  |
| Position |  |
| Contact Phone Number |  |
| Contact email |  |

* 1. **Approving authority details**

|  |  |
| --- | --- |
| Name of Authority |  |
| Authority Contact Officer |  |
| Position |  |
| Contact Phone |  |
| Contact Email |  |

\* A copy of the ethics approval will be required to finalise the notification

Please return this completed form to [humanethics@latrobe.edu.au](mailto:humanethics@latrobe.edu.au)

**Fees**

Please refer to the TGA website for the current fees associated with CTN applications:

<https://www.tga.gov.au/book-page/clinical-trials-1>

The cost of the CTN submission is the responsibility of the Lead Investigator. A copy of the invoice received from the TGA will be provided to the Lead Investigator for payment.

The TGA will not acknowledge the CTN until payment has been made.