**Clinical Trial Notification (CTN)**

Use this form to request University of Tasmania Clinical Trial Governance staff to notify the Therapeutic Goods Administration (TGA) of a Clinical Trial (CTN). Only Clinical Trial Governance staff can create, submit and modify CTN forms with the TGA.

The TGA no longer accepts paper applications, they require data-entry into an online system. Contact the Clinical Trials Governance Team (clinical.trials@utas.edu.au) for help with this form, or review the [TGA CTN help information](https://www.tga.gov.au/book-page/creating-new-ctn-form). Submit this form in MS-Word format to clinical.trials@utas.edu.au when complete.

Only use this form for Clinical Trials where the University of Tasmania is the sponsor. The submission of the CTN is the responsibility of the trial sponsor, if the Clinical Trial is sponsored by an external body, they will be responsible for the completion and submission of the CTN on the online system.

The TGA requires payment before they will process a CTN submission, an invoice for payment will be forwarded to you for action once the CTN has been submitted by the Clinical Trial Governance team.

1. **Application**

**Contact person**

|  |  |
| --- | --- |
| **Name** |  |
| **Email** |  |
| **Phone** |  |

**This is:**

[ ]  **A NEW Clinical Trial Notification (CTN)** [ ]  **An Amendment to an existing CTN**

|  |
| --- |
| **If this is an amendment to an existing CTN, please provide the TGA ID for this project** |
| e.g. CT-2015-CTN-00000-1. Please contact the TGA if you do not know the TGA ID(s). |

1. **Trial Details**

|  |  |
| --- | --- |
| **Study title** | Max 250 characters |
| **Protocol number** | Use your HREC reference number if the study doesn’t have a unique protocol identifier  |
| **Expected trial start date** | Click here to enter a date.NOTE: Please ensure that the start date is at least two weeks after the date that you submit this form  |
| **Expected completion date** | Click here to enter a date. |
| **Will this trial include the potential use of restricted goods?** | [ ]  Yes[ ]  No |
| **Trial type** (tick one) | [ ]  Phase 1[ ]  Phase 2[ ]  Phase 3[ ]  Phase 4[ ]  Bioavailability/Bioequivalence[ ]  Device |
| **This trial**(tick all that apply) | [ ]  Involves Animal excipients[ ]  Involves the use of a Medicine[ ]  Involves the use of a Therapeutic Device[ ]  Is placebo controlled[ ]  Involves a Genetically Modified Organism[ ]  Is a multicentre trial[ ]  Is being conducted in other countries[ ]  Involves the use of a Biological[ ]  Involves the use of a Medical Device[ ]  Is comparator controlled[ ]  Involves gene therapy[ ]  Has relevant preceding trials**See section 4 end of form for additional questions for each of these option**  |
| **Total number of participants to be enrolled (in Australia)** | [ ]  1-20[ ]  21-50[ ]  51-200[ ]  201-500[ ]  501+ |
| **Therapeutic Area** | [ ]  Cardiovascular System[ ]  Central Nervous System[ ]  Ear / Nose / Throat[ ]  Eye[ ]  Gastrointestinal System[ ]  Infections[ ]  Immune System / Inflammation [ ]  Musculoskeletal System[ ]  Neoplastic Disorder[ ]  Other[ ]  Respiratory System[ ]  Skin |

1. **Trial site details**

Note: You must specify at least one site. Please list additional (Australian) sites only if the research has been approved at that site and attach a site specific approval certificate for each site you list below. Copy and paste the following tables for any additional sites.

|  |  |
| --- | --- |
| **Name of site** |  |
| **Location** | [ ] Australian Capital Territory[ ] New South Wales[ ] Northern Territory[ ] Queensland[ ] South Australia[ ] Tasmania[ ] Victoria [ ] Western Australia  |
| **Site address** |  |
| **Expected site start date** | Click here to enter a date. |

**Principal Investigator details**

|  |  |
| --- | --- |
| **Title** |  |
| **Given Name** |  |
| **Last name** |  |
| **Email** |  |
| **Phone number** |  |

**Site Human Research Ethics Details**

|  |  |
| --- | --- |
| **HREC name** | Tasmanian Health and Medical Human Research Ethics Committee  |
| **HREC code**  | EC00337 |
| **Name of HREC contact officer** | Heather Vail |
| **Position** | Executive Officer |
| **Email** | Human.ethics@utas.edu.au  |
| **Phone number** | (03) 6226 6254 |

**Approving authority details**

|  |  |
| --- | --- |
| **Name of approving authority** | List the School or Institute involved in hosting the clinical trial (e.g. School of Medicine) |
| **Name of approving authority contact officer** | <Head of School or Centre>When the Principal Investigator is also Head of School/Centre, list here to whom the PI is responsible |
| **Position** |  |
| **Email** |  |
| **Phone number** |  |

1. **Additional details – as indicated in section 2**

**Medicine Details (investigational *and* comparators, one table for each) (if applicable)**

|  |  |
| --- | --- |
| **Trade/product/code name** |  |
| **Is this a combination product?** | Yes or No (comprised of two (or more) active ingredients). |
| **Dosage Form** | e.g. tablet, injection, implant, spray, … |
| **Type of container** | How is the medicine presented (e.g. packaging, for example: 2mL ampoule, 5mL syringe, blister pack, bottle). |
| **Route of Administration** | e.g. oral, sub-cutaneous, intravenous  |
| **Active Ingredient(s)**(Repeat if more than one active ingredient) | Name: Quantity: Unit: (e.g. milligrams, milligrams/millilitre, allergy unit/millilitre) |
| **Indication** |  |
| **Dosage and Frequency** |  |
| **Intended use** | [ ]  Comparator[ ]  Investigational Medicinal Product[ ]  Standard Care Therapy |
| **Manufacturer:** | Name, address and/or GMP licence number (or relevant exemption) | Australian manufacture? [ ]  Yes[ ]  No |

[Copy this section for each additional medicine]

**Medical Device Details (if applicable)**

|  |  |
| --- | --- |
| **Product name** |  |
| **Is this a** | [ ]  Single Device[ ]  System[ ]  Procedure pack[ ]  Software |
| **Manufacturer**  |  |
| **Global Medical Device Nomenclature (GMDN)** |  |
| **Description** | Provide a description of the device including details of design, composition, specification, method of use, mode of action and application.Include the medical device classification (such as Class I, Class III etc. - refer to '[The regulation of medical devices](https://www.tga.gov.au/behind-news/regulation-medical-devices)').Include the unique product identifier (UPI) for any Class III, active implantable medical device (AIMD), or Class 4 IVD medical device, other than an immunohaematology reagent Class 4 IVD medical device (as outlined under regulation 1.6 of the [Therapeutic Goods (Medical Devices) Regulations 2002](https://www.legislation.gov.au/Series/F2002B00237)). |
| **Intended use** | [ ]  Comparator[ ]  Investigational Medicinal Product[ ]  Standard Care Therapy[ ]  Other (if other, please provide a description):  |

[Copy this section for each additional medical device]

**Therapeutic Device Details (if applicable)**

|  |  |
| --- | --- |
| **Product name** |  |
| **Manufacturer**  |  |
| **Global Medical Device Nomenclature (GMDN)** |  |
| **Description** |  Enter a description of the therapeutic device such as details of design, characteristics, composition, specification, method of use, mode of action and application. |
| **Intended use** | [ ]  Comparator[ ]  Investigational Medicinal Product[ ]  Standard Care Therapy[ ]  Other (if other, please provide a description): |

[Copy this section for each additional therapeutic device]

**Placebo Details (if applicable)**

|  |  |
| --- | --- |
| **Product name:** |  |
| **Route of Administration:** | e.g. oral |
| **Description (including dosage form):** | Enter a description of the placebo including dosage form, formulation (ingredients), composition, indications, directions for use, and type of container. |

**Biological Details (if applicable)**

|  |  |
| --- | --- |
| **Trade/product/code name:** |  |
| **Is this a combination product?** | Yes or No (comprised of two (or more) active ingredients). |
| **Type of container** | e.g. 2ml ampoule, 5ml syringe etc |
| **Dosage Form:** | e.g. tablet, capsule, injection – intravenous infusion, implant, spray, … |
| **Route of Administration:** | e.g. oral, buccal, endocervical, intracranial  |
| **Ingredients:** | Name: Quantity: Unit: (e.g. milligrams, acid lactase units, milligram/litre)Country of Origin:  |
| **Product description** | Enter a description of the biological under clinical investigation, including a name, biological class (e.g. Class 2 etc.), intended use, indication, details of the design, composition, specifications, mode of action and application, list any associated devices and/or medicines and the method of use of the whole biological product. |
| **Australian manufacture?**  | [ ]  Yes[ ]  NoManufacturer details (name, address and/or GMP licence):  |

[Copy this section for each additional biological]

**Animal Excipients (if applicable)**

|  |  |
| --- | --- |
| **Product Name** |  |
| **Species of Origin** | e.g. Mouse, Rabbit, Sheep, ... |
| **Tissue** | e.g. blood, bone, liver, ... |
| **Preparation** | e.g. live, killed, attenuated, extract, ... |
| **Country of Origin** |  |

[Copy this section for each additional animal excipient]

**Other information (if applicable)**

|  |  |
| --- | --- |
| **This trial is being conducted in the following countries** | If applicable.List all countries that are, or will be, conducting the trial  |
| **Relevant preceding trails(s) details** | If applicable.e.g. CT-2015-CTN-00000-1. |
| **Details of Genetically Modified Organism** | If applicable. |
| **Details of Gene Therapy** | If applicable. |