**CTN submission and variation application form – for HNELHD sponsored clinical trials**

For new HNE Sponsored clinical trials requiring CTN: this form is to be submitted with your REGIS Site Specific Application

For variations to original CTN for HNE Sponsored clinical trials: only complete the fields that require changing and submit via REGIS Site Amendment

All fields must be completed and signed by the HNE Principal investigator

HNELHD Research Office will submit the CTN/amendment via the TGA portal on behalf of the Principal Investigator after site authorisation/amendment has occurred and will forward the invoice for payment to the PI.

It is the PI responsibility to pay the invoice related to CTN submission or amendment.

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| --- | --- | --- |
| REGIS STE reference number |  | |
| HNELHD Principal Investigator (full name) |  | |
| HNELHD Principal Investigator email address |  | |
| I confirm that the details below are true and correct | YES / NO | |
| I confirm I will pay any associated fee with the CTN submission | YES / NO | |
| I confirm I will not start recruitment until the HNE Research Office has |  | |
| HNELHD Principal Investigator | Signature |  |
| Date |  |

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **1.0 TRIAL DETAILS** | | | | | |
| 1.1 Protocol Number \* | |  | | | |
| 1.2 Expected trial start date\*  *The date you estimate that product supply for the trial will commence at the first Australian site, in the format dd/mm/yyyy. This date****cannot be retrospective****.* | |  | | | |
| 1.3 Expected completion date\*  *The date you estimate that product supply will be completed at all Australian sites, in the format dd/mm/yyyy.* | |  | | | |
| 1.4 Potential use of restricted goods\*  *If this trial involves the use of a medicine, the importation of which is prohibited under the Customs (Prohibited Imports) Regulations 1956, select 'Yes', otherwise select 'No'*. | | Yes  No | | | |
| 1.5 Title of study\*  *Title should indicate the aim, and give a broad description, of the trial. Include, for example: phase, indication(s) being treated, main investigational product and comparators, use of placebo-control, focus of the study, patient population and any other significant or novel aspects.* | |  | | | |
| 1.6 This trial\*:  *Select any check boxes which are relevant to your trial. If you select a checkbox with 2A-H next to it, you must complete the relevant sub-section (2A-H) of the form below.*  *Please note that* ***SOFTWARE*** *is considered a medical device for the purposes of the Therapeutic Goods Act.* | | Involves the use of a Medicine |  | Is comparator controlled |  |
| Involves the use of a Medical Device |  | Involves Animal Excipients |  |
| Involves the use of a Biological |  | Has relevant preceding trials |  |
| Involves a Genetically Modified Organism |  | Is a multicentre trial in Australia |  |
| Involves gene therapy |  | Is being conducted in other countries |  |
| Is placebo controlled |  |  |  |
| 1.7a Trial type (if necessary)  *Indicate the phase/s the trial will encompass.* | | Phase 1 |  | Phase 4 |  |
| Phase 2 |  | Bioavailability/ Bioequivalence |  |
| Phase 3 |  | Device |  |
| 1.7b Trial type description  *Provide any additional information relating to the 'Trial Type' (if required), e.g. information relating to the stage of development of a device under clinical investigation* | |  | | | |
| 1.8 Total number of participants to be enrolled in trial (in Australia)\* | | 1-20  21-50  51-200  201-500  501+ | | | |
| 1.8 Therapeutic area\*  *Select the therapeutic area the investigational product will be used for in this trial, from the drop down menu (click in cell to activate).* | |  | | | |
| 1.9 OTHER COUNTRY DETAILS  Please provide a list of countries, other than Australia, in which the trial is taking place. | |  | | | |
| **2.0 MEDICINE DETAILS**  *Fill out the following sub-sections of this form as necessary (i.e. if you selected any of the check boxes with the appropriate section MUST be filled out). Delete those sections which do NOT apply* | | | | | |
| 2.1 Medicine Details (if multiple drugs are to be used, duplicate table as necessary) |  | | | | |
| 2.2.1 Trade/Product/Code name  *Enter an identifying name/s of the medicine under clinical investigation.* |  | | | | |
| 2.2.2 Is this a combination product?  *Please select 'Yes' if the product under clinical investigation is comprised of two (or more) active ingredients.* | Yes  No | | | | |
| 2.2.3 Is this a cannabis product? | Yes  No | | | | |
| 2.2.3.1 if yes, Is the cannabis plant used in the manufacture of the product? | Yes  No | | | | |
| 2.2.4 Type of container |  | | | | |
| 2.2.5 Dosage form  *Eg. capsule - hard, powder for injection etc.* |  | | | | |
| 2.2.6 Route of administration  *Eg. oral, IV injection, topical etc.* |  | | | | |
| 2.2.7 Formulation  *For* ***all*** *active components, list: ingredient, quantity (strength) and unit (presentation), eg Albuterol sulphate, 2, mg/ml.*  *Excipients do not have to be listed. Note that incorrect completion of this question is one of the most frequent reasons for CTNs being rejected by the TGA.* |  | | | | |
| 2.2.8 Indication  *The specific therapeutic use(s) of the goods.* |  | | | | |
| 2.2.9 Dosage and frequency  *Number of doses per given time period; the time that elapses between doses or the quantity of a medicine that is given at each specific time of dosing* |  | | | | |
| 2.2.10 Intended use | ☐ Comparator  ☐ Investigational product  ☐ Standard care therapy  ☐ Other | | | | |
| 2.2.11 Is the medicine manufactured in Australia? | Yes  No | | | | |
| 2.2.12 GMP licence/clearance number or relevant exemption |  | | | | |
| **3.0 BIOLOGICAL DETAILS (if multiple Biologicals are to be used, duplicate table as necessary)** | | | | | |
| 3.1 Trade/Product/Code name  *Please enter the name of the Human Cell and Tissue under clinical investigation* |  | | | | |
| 3.2 Species of Origin |  | | | | |
| 3.3 Tissue |  | | | | |
| 3.4 Preparation |  | | | | |
| 3.5 Country of Origin |  | | | | |
| **4. DEVICE DETAILS (if multiple devices are to be used, duplicate table as necessary)** | | | | | |
| **4.1** Trade/Product/Code name  *Please enter the name of the Human Cell and Tissue under clinical investigation* |  | | | | |
| 4.2 Is this a: | ☐ Medical Device  ☐  In Vitro Diagnostic Medical Device (IVD) | | | | |
| 4.3 Classification |  | | | | |
| 4.4 GMDN Search Context | ☐ GMDN Name  ☐  GMDN Code | | | | |
| 4.5 GMDN |  | | | | |
| 4.6 Description  *Please provide a description of the device including details of design, composition, specification, method of use, mode of action and application. Please provide as much information as possible.* |  | | | | |
| 4.7 Intended Purpose | ☐ Comparator  ☐ Investigational product  ☐ Standard care therapy  ☐ Other | | | | |
| 4.8 Manufacturer |  | | | | |
| **5. PLACEBO DETAILS** | | | | | |
| 5.1 Product name  *Enter the product name of the placebo used in the clinical investigation.* |  | | | | |
| 5.2 Route of administration  *Eg. oral, IV injection, topical etc.* |  | | | | |
| 5.3 Description  *For medicines, please include the dosage form. For devices, please provide a description of the device.* |  | | | | |
| **6.0 GENETICALLY MODIFIED ORGANISM DETAILS** | | | | | |
| 6.1 Please provide a name, description, details of the design, compositions, specifications, mode of action and application of the genetically modified organism. List the method of use of the product. |  | | | | |
| **7.0 GENE THERAPY DETAILS** | | | | | |
| 7.1 Please provide a name, description, details of the design, compositions, specifications, mode of action and application of the gene therapy. List the method of use of the product. |  | | | | |
| **8.0 RELEVANT PRECEDING TRIALS DETAILS** | | | | | |
| 8.1 Please provide details of relevant preceding trials including a title.  *Relevant trials would include trials involving the same investigational product conducted by the same sponsor.* |  | | | | |