NSLHD CTN Summary

To be completed for studies in which NSLHD is the sponsor (eg. investigator initiated studies without a collaborative group or pharmaceutical company sponsor).

The CTN will be lodged by the Research Office on behalf of the Sponsor (ie. NSLHD), however it is the responsibility of the investigator to provide the information required for the CTN, as outlined from page 2 on. Please note that the information requested below is required by the TGA – further guidance regarding definitions is available via <https://www.tga.gov.au/completing-online-ctn-form>.

## PAYMENT

It is the responsibility of the investigators to pay the CTN lodgement fee. These fees are set by the TGA and are not negotiable.

To streamline CTN submission, however, in the first instance the invoice generated will be processed by the Research Office finance team. A journal transfer from the investigators’ relevant cost code will be made to recoup this fee. Unless the table below is completed, with signature, your submission to the Research Office is not valid.

|  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **INTERNAL - AUTHORISATION FOR TRANSFER OF PAYMENT FOR CTN LODGEMENT (to be completed by researcher prior to submission of this form)**   |  |  |  |  | | --- | --- | --- | --- | |  |  |  | 380 (GST exempt) | | Account | Cost centre | Fund | Total fee |   Reference Number: 20XX/STEXXXX  Study Title: Click here to enter text.  AUTHORISED BY:  Cost Centre Manager – Name:       Signature:  Contact No:       Email: NSLHD Finance WILL NOT accept forms without the  Cost Centre Manager’s signature |
| **Office use**  **NSLHD Reference:**  **Note to finance, if any:** |

Please continue to the next page to complete the relevant CTN details.

**1. TRIAL DETAILS**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| 1.1 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****.* |  | | | |
| 1.2 Expected completion date  *The date you estimate that product supply will be completed at all Australian sites, in the format dd/mm/yyyy.* |  | | | |
| 1.3 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 | | | |
| 1.4 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.* |  | | | |
| 1.5 Trial type  *Indicate the phase/s the trial will encompass.* | Phase 1 |  | Phase 4 |  |
| Phase 2 |  | Bioavailability/ Bioequivalence |  |
| Phase 3 |  | Device |  |
| 1.5b Trial type description (if necessary)  *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* |  | | | |
| 1.6 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 Animal excipients |  | Is being conducted in other countries (2A) |  |
| Involves the use of a Medicine (2B) |  | Involves the use of a Biological (2C) |  |
| Involves the use of a Therapeutic Device (2D) |  | Involves the use of a Medical Device (2D) |  |
| Is placebo controlled (2E) |  | Is comparator controlled |  |
| Involves a Genetically Modified Organism (2F) |  | Involves gene therapy (2G) |  |
| Is a multicentre trial |  | Has relevant preceding trials (2H) |  |
| 1.7 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).* |  | | | |

2. Fill out the following sub-sections of this form as necessary (i.e. if you selected any of the check boxes with 2A-H next to them in question 1.6 above, the appropriate section MUST be filled out). Delete those sections which do NOT apply.

**2A. OTHER COUNTRY DETAILS**

|  |  |
| --- | --- |
| 2A.1 Please provide a list of countries, other than Australia, in which the trial is taking place. |  |

**2B. MEDICINE DETAILS (if multiple drugs are to be used, duplicate table as necessary)**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| 2B.1 Trade/Product/Code name  *Enter an identifying name/s of the medicine under clinical investigation.* |  | | | |
| 2B.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 | | | |
| Is this a cannabis product? | Yes  No | | | |
| 2B.3 Dosage form  *Eg. capsule - hard, powder for injection etc.* |  | | | |
| 2B.4 Presentation  *This is* ***not*** *the medicine description (tablet/capsule).*  *Please describe how the medicine is presented (ie. packaging/container), eg. 2mL ampoule, 5mL syringe, blister pack, bottle etc. Note that incorrect completion of this question is one of the most frequent reasons for CTNs being rejected by the TGA.* |  | | | |
| 2B.5 Route of administration  *Eg. oral, IV injection, topical etc.* |  | | | |
| 2B.6 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.* |  | | | |
| 2B.7 Indication  *The specific therapeutic use(s) of the goods.* |  | | | |
| 2B.8 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.* |  | | | |
| 2B.9 Intended use | Comparator |  | Investigational product |  |
| Standard care therapy |  |  |  |
| 2B.10 Is the medicine manufactured in Australia? | Yes  No | | | |
| 2B.11 Manufacturer details  *Please provide name, address and/or  GMP licence number or relevant exemption* |  | | | |

**2C. BIOLOGICAL DETAILS (if multiple Biologicals are to be used, duplicate table as necessary)**

|  |  |
| --- | --- |
| 2C.1 Trade/Product/Code name  *Please enter the name of the Human Cell and Tissue under clinical investigation* |  |
| 2C.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 |
| 2C.3 Presentation  *Please describe how the Human Cell and Tissue is presented i.e. 2mL ampoule, 5mL syringe* |  |
| 2C.4 Dosage form  *Eg. capsule - hard, powder for injection etc.* |  |
| 2C.5 Route of administration  *Eg. oral, IV injection, topical etc.* |  |
| 2C.6 Formulation  *For* ***all*** *Biological ingredients list: ingredient, concentration with units, and country of origin* |  |
| 2C.7 Product Description   * *Please enter a description of the Biological under clinical investigation, including a name, description, details of the design, compositions, specifications, mode of action and application, list any associated devices and/or medicines and the method of use of the whole biological product* |  |
| 2C.8 For a biological not in Phase 1, is the biological manufactured in Australia? | Yes  No |
| 2C.9 Manufacturer details  *Please provide name, address and/or  GMP licence number or relevant exemption* |  |

**2D. DEVICE DETAILS (if multiple devices are to be used, duplicate table as necessary)**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| 2D.1 Product name (trade name if applicable)  *Please enter the product or trade name of the device under clinical investigation.* |  | | | |
| 2D.2 Is this a: | Single device |  | Procedure pack |  |
| System |  | Software |  |
| 2D.3 Manufacturer Please enter the name of the manufacturer of the device |  | | | |
| 2D.4 GMDN code or name  *The Global Medical Device Nomenclature code is assigned by the manufacturer. Obtain from the manufacturer or from the product information/advertising material.* |  | | | |
| 2D.5 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.* |  | | | |
| 2D.6 Intended Purpose | Comparator |  | Investigational product |  |
| Standard care therapy |  | Other |  |
| If ‘other’ please provide a description |  | | | |

**2E. PLACEBO DETAILS**

|  |  |
| --- | --- |
| 2E.1 Product name  *Enter the product name of the placebo used in the clinical investigation.* |  |
| 2E.2 Route of administration  *Eg. oral, IV injection, topical etc.* |  |
| 2E.3 Description  *For medicines, please include the dosage form. For devices, please provide a description of the device.* |  |

**2F. GENETICALLY MODIFIED ORGANISM DETAILS**

|  |  |
| --- | --- |
| 2F.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. |  |

**2G. GENE THERAPY DETAILS**

|  |  |
| --- | --- |
| 2G.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. |  |

**2H. RELEVANT PRECEDING TRIALS DETAILS**

|  |  |
| --- | --- |
| 2H.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.* |  |