**Process for the online submission of CTN forms where the study sponsor is King Edward Memorial Hospital for Women**

The details from this from will be copied and pasted into the online CTN application.
Please enter the following details and send the completed from as a Word document to the WNHS Research Governance Office. This form will be checked and forwarded to Prof Jeff Keelan who will complete the online CTN submission on your behalf.

Email completed form to: ResearchGovernanceOffice.KEMH@health.wa.gov.au

**KEMH Details**

|  |  |
| --- | --- |
| HREC Name | Women and Newborn Health Service HREC EC00350 |
| HREC number  | 2015 EW |
| Notification Fee | $335 |

**Trial Details**

|  |  |  |
| --- | --- | --- |
| Contact Name: |  | *text* |
| Contact Phone Number |  | *number* |
| Contact Email |  |  |
| Protocol Number |  |  |
| Expected Trial Start Date  |  | *dd/mm/yyyy* |
| Expected Completion Date |  | *dd/mm/yyyy* |
| Potential Use of Restricted Goods |  | *YES or NO* |
| Title of Study |  | *text* |
| Trial Type | Phase 1 Phase 2 Phase 3 Phase 4 Bioequivalence/Bioavailability Device | *Select one**(delete others)* |
| Trial Type Description (if necessary) |  | *Optional text, if trial type not listed above* |
| Total Number of Patients to be Enrolled in Trial |  | *Enter number* |
| Therapeutic Area | Cardiovascular system Central Nervous SystemEar/Nose/Throat EyeGastrointestinal System Genitourinary SystemImmune System/Inflammation InfectionsMultiple Indications Musculoskeletal systemsNeoplastic disorder Respiratory SystemSkin Other | *Select one**(delete others)* |

**Please enter Yes or No to the following statements**

|  |  |
| --- | --- |
| This trial involves Animal exipients |  |
| This trial involves the use of a Medicine |  |
| This trial involves the use of a Therapeutic Device |  |
| This trial is placebo controlled |  |
| This trial involves a Genetically Modified Organism |  |
| This is a multicentre trial |  |
| This trial is being conducted in other countries |  |
| This trial involves the use of a Biological |  |
| This trial involves the use of a Medical Device |  |
| This trial is comparator controlled |  |
| This trial involves gene therapy |  |
| This trial has relevant preceding trials |  |

**Medicines (copy table for each medicine)**

A medicine is a therapeutic good (substance or preparation) that is represented to achieve (or is likely to achieve) its principal intended action by pharmacological, chemical, immunological or metabolic means in or on the body. It may be intended for administration to humans in order to:

• prevent, diagnose, alleviate or cure a disease, ailment, defect or injury; or

• test the susceptibility of a person to a disease or ailment; or

• influence, inhibit or modify a physiological process; or

• influence, control or prevent conception.

|  |  |
| --- | --- |
| **Trade/Product/Code Name** |  |
| Is this a combination product ? |  YES or NO |
| Presentation  |  |
| Dosage Form |  |
| Route of Administration |  |
| Indication |  |
| Dose and frequency |  |
| Is the medicine manufactured in Australia ? |  YES or NO |
| Manufacturer details(name, address, GMP licence #) |  |
| ***Enter the various ingredients of the medicine below******Each medicine may contain multiple formulations (copy extra rows as necessary)*** |
| **Formulation- Ingredient name** | **Formulation - Quantity** | **Formulation - Unit** |
|  |  |  |
|  |  |  |
|  |  |  |
|  |  |  |

**Biological (copy table for each biological)**

Biological products are products in which the active ingredient is a biological substance including antisera, antivenins, monoclonal antibodies and products of recombinant technology.

|  |  |
| --- | --- |
| **Trade/Product/Code Name** |  |
| Is this a combination product ? |  YES or NO |
| Presentation |  |
| Dosage form |  |
| Route of Administration |  |
| *Enter the various ingredients of the biological below**Each biological may contain multiple ingredients (copy extra rows as necessary)* |
| Ingredient name | Quantity | Unit | Country of origin |
|  |  |  |  |
|  |  |  |  |

**Devices (copy table for each device)**

|  |  |
| --- | --- |
| Product name |  |
| Is this a ?Select as appropriate, delete others | Single deviceSystemProcedure packSoftware |
| Manufacturer (name) |  |
| GMDN name |  |
| GMDN code |  |
| Description |  |
| Intended PurposeSelect as appropriate, delete others | ComparatorInvestigational productStandard Care TherapyOther (please provide description) |

**Placebos (copy table for each placebo)**

|  |  |
| --- | --- |
| Product Name |  |
| Route of Administration (ROA) |  |
| Description |  |
|  |  |

**Sites (copy table for each site)**

|  |  |
| --- | --- |
| Site | King Edward Memorial Hospital |
| Site Address | 374 Bagot Rd, Subiaco, Perth, Western Australia |
| Principal Investigator Name |  |
| HREC Name | Women and Newborn Health Service HREC EC00350 |
| Approving Authority Name | Women and Newborn Health Service (Metropolitan Health Service) |

|  |  |
| --- | --- |
| Site |  |
| Site Address |  |
| Principal Investigator Name |  |
| HREC Name |  |
| Approving Authority Name |  |

**Countries Trial is conducted**

Please name all countries trial is conducted in

|  |
| --- |
| Australia |
|  |
|  |
|  |
|  |