|  |  |
| --- | --- |
|  | Questions are followed by answer fields. Use the ‘Tab’ key to navigate through. Replace Y/N or Yes/No fields with your answer. |
|  | |  |  | | --- | --- | | HREC Reference Number: Click or tap here to enter text. | | | Local Project Number/Protocol Number: Click or tap here to enter text. | | | Protocol Title: Click or tap here to enter text. | | | Expected Project Commencement Date: Click or tap to enter a date. | | | Expected Project Completion Date: Click or tap to enter a date. | | | Expected frequency of monitoring visits: Click or tap here to enter text. | | | Remote monitoring: | Yes No | | Name of site/s involved in the project: Click or tap here to enter text. | | | **Name of funding source:** Click or tap here to enter text.   |  |  | | --- | --- | | Departmental Research Funds | Research Institute | | Commercial Sponsor | ☐ Other | | University |  | | | |

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| --- | --- |
| IWRS/ IVRS system in use | Yes  No |
| Online accountability required | Yes  No |
| Destruction onsite required | Yes  No |
| Online destruction recording | Yes  No |
| Will supply be triggered automatically by IWRS | Yes  No  *If NO does pharmacy need to manually order?* Click or tap here to enter text. |
| Randomisation requirements by Pharmacist | Yes  No |
| Blinding requirements by Pharmacist | Yes  No |
| Investigation Product | Yes  No |
| Comparator Product/ SOC | Yes  No |
| Ancillary Medication(s)/ Clinical Supplies | Name/s: Click or tap here to enter text.  Provided by: Click or tap here to enter text. |
| Are all IP, including protocol mandated concomitant medicines, standard of care medicines or placebos supplied? | Yes  No  Name/s: Click or tap here to enter text.  Provided by: Click or tap here to enter text. |
| Will Pharmacy be required to source and/or purchase Investigational Product or Comparator Product/SOC? | Yes  No *(Please note that in addition to purchase cost, a handling fee may apply).*  *If yes, please provide details.* |
| Post Study Completion Medication Supply | Yes, provided by: Click or tap here to enter text.  No, reason: Click or tap here to enter text.  Not applicable, reason: Click or tap here to enter text. |
| Oversized product kit size  (o*versized product kit package > 40 cm x 40 cm*) | Yes  No |
| Is Aseptic or Cytotoxic Preparation service required? | Yes *specify medication and whether hazardous precautions are required*  No |
| Is the dispensing single item, multiple items or packs | Single  Multiple  Packs |
| Are any of the trial medicines classified as Schedule 8 | Yes  No |
| Please specify the storage conditions required | Room temperature  Refrigerated  Frozen  Schedule 8 - safe |
| Is Compounding /or Repackaging of medications required | Yes *specify medication*: Click or tap here to enter text.  No |
| Is On call and/or After-hours service required? | Yes *specify requirements*: Click or tap here to enter text.  No |
| Is there risk to the study if a pharmacist is not able to attend to a call-out until usual business hours? | Yes *please detail*: Click or tap here to enter text.  No |
| Will medications require re-test date relabelling? | Yes *specify requirements*: Click or tap here to enter text.  No |
| Will shipping materials be returned to depot or destroyed at site? | Returned to depot  Destroyed at site |
| Are any other services required? | Yes *specify requirements*: Click or tap here to enter text.  No |

ENDORSEMENT FROM DIRECTOR OF *<Royal Darwin and Palmerston Hospitals (RDPH)> / <Alice Springs Hospital (ASH)>* PHARMACY DEPARTMENT

|  |  |
| --- | --- |
| Full project title | |
| <*enter here>* | |
| Endorser’s Declaration | |
| I have discussed this study with the Principal Investigator. I have seen the application and protocol. Upon review:  Clinical trials pharmacy services not required, able to provide the services/ support requested within standard processes and resourcing of the *<specify here>* Pharmacy Department (nil reimbursement or assistance required).  OR  Able to provide the services/ support requested with reimbursement as per the Pharmacy [Fee schedule | NT Health](https://health.nt.gov.au/data-and-research/nt-health-research/fee-schedules). Additional assistance required detailed below.  OR  Unable to support as detailed below.    Comment (please specify estimated costs and nature of required assistance (if any)):  Additional assistance: *enter details if required*  Unable to support: *enter details*  I support/ do not support this research project (*please circle required response)*. | |
| Name of Director of Pharmacy Department: |  |
| Signature: | Date: Click or tap to enter a date. |