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| --- | --- |
|  | Questions are followed by answer fields. Use the ‘Tab’ key to navigate through. Replace Y/N or Yes/No fields with your answer. |
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| --- |
| 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.

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| --- | --- |
| [ ]  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 [ ]  NoName/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

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| --- |
| 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. |