**NEW TRIAL ASSESSMENT FORM**

**Principal Investigator Review**

|  |  |
| --- | --- |
| **Trial Details** | |
| **Protocol number** |  |
| **Protocol name** |  |
| **Protocol title** |  |
| **Sponsor / CRO** |  |
| **Phase** |  |
| **Patient cohort** |  |
| **Number of global sites** |  |
| **Number of Australian sites** |  |
| **Number of Victorian sites** |  |
| **Global accrual** |  |
| **Australian accrual cap** |  |
| **Ethics Submission** | |
| **Ethics committee** |  |
| **Coordinating principal investigator and site** |  |
| ***Participating sites, if lead*** | *Eg. This site will be a satellite site.*  *Site X is the primary site* |
| **Timelines** | |
| **Global first patient first visit** |  |
| **Global last patient last visit** |  |
| **Duration of recruitment** |  |
| **Duration of treatment** |  |
| **Duration of protocol** |  |
| **Ethics meeting dates** |  |
| **Unit submission timeline** |  |
| **Unit proposed SIV** |  |
| **Trial Unit** | |
| **Unit accrual target** |  |
| **Principal investigator** |  |
| **Associate investigators** |  |

**Principal Investigator Review**

|  |  |  |  |
| --- | --- | --- | --- |
| **Feasibility Assessment** | | | |
|  | **Yes** | **No** | **Comments** |
| **Has this trial been accepted by clinical dept.?** |  |  |  |
| **Has this trial been prioritised by the clinical dept. and trials unit to open?** |  |  |  |
| **Will this trial be run as a TeleTrial?**  If yes, please describe what procedures |  |  | *Eg. Cycle 2 onwards + follow up after end of trial.* |
| **Will we be able to meet the patient recruitment targets?**  Please comment on any difficulties with patient accrual you can identify |  |  |  |
| **Are there any competing trials open?** |  |  |  |
| **Are there any logistical issues in conducting the study?**  If so, please describe |  |  |  |
| **Does this trial have > $5000 in per patient payments?**  Most sponsored trials |  |  |  |
| **If the trial has < $5000 in per patient payments, have you received approvals from relevant departments to provide services at no cost?** |  |  |  |
| **If there are sub-studies in this protocol, are we participating in all of them?**  If not, please advise which ones we are not participating in |  |  |  |
| **Will males be enrolled in this study?**  Please note in comments ratio of males to females |  |  |  |
| **What is the median life expectancy of this patient population?** |  | | |
| **What is the estimated average time a patient will receive treatment on this trial for?** |  | | |
| **What is the standard of care treatment for this patient population?** |  | | |

**Principal Investigator and Trials Team Review**

**Version of the protocol:**

|  |  |  |
| --- | --- | --- |
| **Departments Utilised for Trial Activities** | | |
| **Department** |  | **Comments** |
| **Treatment** | Ward XX  Day unit XX  Apheresis  Radiology |  |
| **Overnight Admissions** | Ward XX  Ward XX |  |
| **ICU** | XX |  |
| **Interventional Radiology**  Fresh Tumour Biopsy | XX |  |
| **Local Pathology** | XX |  |
| **Outpatients Pathology** | XX |  |
| **Imaging** | CT  PET  MRI | Any central upload requirements? |
| **Nuclear Medicine** | MUGA ☐  XX |  |
| **Cardiology** | ECHO  XX | Any central upload requirements? |
| **Dermatology** | XX |  |
| **Ophthalmology** | XX |  |
| **Respiratory (bronchoscopy)** | XX |  |
| **Respiratory (lung function)** | XX |  |
| **Central Laboratory** | XX |  |
| **Specialist Clinics** | XX | Where patients will be consented |
| **Other Departments or Wards** | Surgery Dept.  XX |  |

**Trials Team Review**

|  |  |  |  |
| --- | --- | --- | --- |
| **Submission Complexity** | | | |
| **Regulatory approval required** | Is independent scientific review, biosafety review or any external review and approval required? If so, please state? | | |
| **Is this a first time in human clinical trial?** |  | | |
| **Is this an umbrella style clinical trial?** |  | | |
| **Number of consents** |  | | |
| **Amendments due** |  | | |
| **Document Availability** | | | |
| **Protocol** |  | | |
| **NHMRC customised PICFs** |  | | |
| **Patient Materials** |  | | |
| **IBs** |  | | |
| **Indemnity / insurance** |  | | |
| **Budget / contract** |  | | |
| **Pharmacy manual** |  | | |
| **Lab manual** |  | | |
| **Other manuals** |  | | |
| **Trial Coordination** | | | |
| **Is this trial being coordinated on SIP?** |  | | |
| **Trial equipment** (ECG, camera, QoL tablets) |  | | |
| **Vendors** (Imaging, central testings) |  | | |
| **eCRF Database** |  | | |
| **Training required for activation** |  | | |
| **Safety reporting requirements** |  | | |
| **Monitoring requirements** |  | | |
| **Is a site tour required?** |  | | |
| **Assessment of Workload Requirements** | | | |
| **Version of the protocol** |  | | |
| **Type of treatment and route of administration** |  | | |
| **Approximate length of treatment per visit** (In hours) |  | | |
| **Approximate length of inpatient admission, if applicable** |  | | |
| **Intensity of Pharmacokinetics** |  | | |
| **Will late evening stay be required?** |  | | |
| **Special processing and storage requirements for specimens** |  | | |
| **Special requirements for administration of IP** (Lines, syringe drivers or pumps) | Have you reviewed the pharmacy manual?  Any specific infusion administration requirements? | | |
| **Serial ECGs** | Y / N | | |
| **Virology sample requirements** (Mandated PCRs even if serology is negative?) |  | | |
| **Describe biopsy requirements** (Fresh, paired, archival, etc.)  Add as much details as possible | Have you reviewed the laboratory manual?  Will fresh biopsies occur at more than one location?  Is a pathologist review and report required? | | |
| **Central tests and special requirements** (Including imaging and ophthalmology) |  | | |
| **Any concerns regarding turnaround time of central tests?** |  | | |
| **Patient diary / QoL Format** (Paper or electronic) |  | | |
| **Budget items to be considered** (Overnight beds, tests not performed at site, medications required for known side effects) |  | | |
| **Other requirements or considerations** |  | | |
| **Final Assessment of Trial Feasibility** | | | |
|  | **Yes** | **No** | **Comments** |
| **Is this study able to be resourced?** |  |  |  |
| **Are there any competing studies open?** |  |  |  |
| **Are there any logistical issues in conducting the study?** |  |  |  |
| **Have you identified any issues in the protocol design?** |  |  |  |
| **Are the PICF complex?** |  |  |  |
| **After completing the above, do you recommend this study to open in approximately 5 months?** |  |  |  |