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| --- | --- | --- | --- | --- | --- |
| **Question** | **N/A** | **Yes** | **No** | **In the Protocol** | **Answer** |
|  | | | | | |
| What is the study purpose? | 🞐 | 🞐 | 🞐 | 🞐 |  |
| Who is the study target population? | 🞐 | 🞐 | 🞐 | 🞐 |  |
| What is the age range of the study population? |  |  |  |  |  |
| What is the overall study enrollment goal for all participating sites? | 🞐 | 🞐 | 🞐 | 🞐 |  |
| When is the projected study start date? | 🞐 | 🞐 | 🞐 | 🞐 |  |
| What is the projected study end date? | 🞐 | 🞐 | 🞐 | 🞐 |  |
| How many study sites are participating? | 🞐 | 🞐 | 🞐 | 🞐 |  |
| Is the study recruitment competitive? | 🞐 | 🞐 | 🞐 | 🞐 |  |
| Is there a sponsor contact list for study questions? | 🞐 | 🞐 | 🞐 | 🞐 |  |
| Is there a website or any literature regarding this study that we could reference? | 🞐 | 🞐 | 🞐 | 🞐 |  |
| What phase is this study? | 🞐 | 🞐 | 🞐 | 🞐 |  |
| What is the IRB of record? | 🞐 | 🞐 | 🞐 | 🞐 |  |
| What are the study visit window(s) parameters? | 🞐 | 🞐 | 🞐 | 🞐 |  |
| Who can perform the physical assessments? | 🞐 | 🞐 | 🞐 | 🞐 |  |
| Can study staff or non-research study staff family members enroll in this study? | 🞐 | 🞐 | 🞐 | 🞐 |  |
| Can employees or students enroll in this study? | 🞐 | 🞐 | 🞐 | 🞐 |  |
| Define physical assessment vs. physical examination? | 🞐 | 🞐 | 🞐 | 🞐 |  |
|  | | | | | |
| What is the randomization ratio? | 🞐 | 🞐 | 🞐 | 🞐 |  |
| Is the study medication blinded or un-blinded? | 🞐 | 🞐 | 🞐 | 🞐 |  |
| Are there contraindications for the study medication? | 🞐 | 🞐 | 🞐 | 🞐 |  |
| How should the study medication be stored? | 🞐 | 🞐 | 🞐 | 🞐 |  |
| Are study medication temperature monitoring required? | 🞐 | 🞐 | 🞐 | 🞐 |  |
| Is there an antibiotic wash-out period required before any blood draw? | 🞐 | 🞐 | 🞐 | 🞐 |  |
| What is the allowed time period between mixing the medication and giving it? | 🞐 | 🞐 | 🞐 | 🞐 |  |
| For investigational drugs given IV, should the line from the IV bag be primed with the study drug? | 🞐 | 🞐 | 🞐 | 🞐 |  |
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| If a blood draw is unsuccessful, can study subjects still be enrolled? | 🞐 | 🞐 | 🞐 | 🞐 |  |
| What is the minimum/maximum amount of blood needed for each study visit? | 🞐 | 🞐 | 🞐 | 🞐 |  |
| Is there a set centrifugation time for blood samples? | 🞐 | 🞐 | 🞐 | 🞐 |  |
| How should the study blood be stored (i.e. temperature)? | 🞐 | 🞐 | 🞐 | 🞐 |  |
| Does the blood samples have to be monitored prior to shipment? | 🞐 | 🞐 | 🞐 | 🞐 |  |
| How often should blood samples be shipped to the study sponsor or central lab? | 🞐 | 🞐 | 🞐 | 🞐 |  |
|  | | | | | |
| What supplies are being provided by the sponsor vs the study site? | 🞐 | 🞐 | 🞐 | 🞐 |  |
| Are there sponsor specific equipment (pumps, ECG machines, etc.) |  |  |  |  |  |
| What is the turnaround time for ordering study supplies? | 🞐 | 🞐 | 🞐 | 🞐 |  |
| Are source documents being provided by the sponsor? | 🞐 | 🞐 | 🞐 | 🞐 |  |
| What is the preferred amount of working days allowed for data to be entered into the EDC/RDC? | 🞐 | 🞐 | 🞐 | 🞐 |  |
| What is the required turnaround time for data queries? | 🞐 | 🞐 | 🞐 | 🞐 |  |
| If study subjects forget the study diary card, worksheet or questionnaires at subsequent study visits, can they recreate it? | 🞐 | 🞐 | 🞐 | 🞐 |  |
| Do solicited or unsolicited AE’s require an assessment by a medical provider? | 🞐 | 🞐 | 🞐 | 🞐 |  |
| Can parents or minor study subjects complete the study questionnaires and/or make corrections? | 🞐 | 🞐 | 🞐 | 🞐 |  |
| Can a study coordinator sign-off on data queries? | 🞐 | 🞐 | 🞐 | 🞐 |  |
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| Will monitors require access to the EMR (inpatient and/or ambulatory)? | 🞐 | 🞐 | 🞐 | 🞐 |  |
| What will be the monitoring frequency? | 🞐 | 🞐 | 🞐 | 🞐 |  |
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Printed Name of the person completing this document:

Date Completed: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_