|  |  |  |
| --- | --- | --- |
| **PARTICIPANT ID** | **SITE** | **PRINCIPAL INVESTIGATOR** |
|  |  |  |

|  |  |
| --- | --- |
| **Visit number** |  |
| **Date of Visit (DD/MM/YYYY)** |  |
| **Does the subject continue to meet Inclusion criteria? If no, please give details.** | YES NO |
| **Does the subject continue to not meet Exclusion criteria? If no, please give details.** | YES NO |
| **Does the participant continue ongoing consent?** | YES NO |

**CONCOMITANT MEDICATION**

|  |  |
| --- | --- |
| **Are there any changes to concomitant medications?** | YES NO  **If Yes, please report on the concomitant medications worksheet.** |

**ADVERSE EVENTS**

|  |  |
| --- | --- |
| **Are there any adverse events to report?** | YES NO  **If Yes, please report on the AE worksheet.** |

**VITAL SIGNS**

|  |  |  |  |
| --- | --- | --- | --- |
| **Has the subject sat for at least 5 minutes?** | **Yes - No** | | **INITIAL** |
| **On what date and time were the measurements performed?** | **DATE** | **TIME** |  |
| **Height (cm)** |  | |  |
| **Weight (kg)** |  | |  |
| **Temperature** | **OC** | |  |
| **Systolic Blood Pressure** | **mmHg** | |  |
| **Diastolic Blood Pressure** | **mmHg** | |  |
| **Pulse Rate** | **beats/min** | |  |
| **Respiratory Rate** | **breaths/min** | |  |
| **Oxygen Saturations** | **%** | |  |

**Page completed by:**

|  |  |  |
| --- | --- | --- |
| **Name** | **Signature** | **Date** |
|  |  |  |

**PHYSICAL EXAMINATION**

|  |  |  |  |
| --- | --- | --- | --- |
| **What was the physical examination date? (dd-mon-yyyy)** |  | | |
| **Body system examined** | **Normal** | **Abnormal** | **If abnormal what were findings? Clinically significant?** |
| GENERAL APPEARANCE |  |  |  |
| SKIN |  |  |  |
| NECK INCLUDING THYROID |  |  |  |
| HEENT |  |  |  |
| LUNGS |  |  |  |
| HEART |  |  |  |
| ABDOMEN |  |  |  |
| BACK |  |  |  |
| LYMPH NODES |  |  |  |
| EXTREMITIES |  |  |  |
| VASCULAR |  |  |  |
| NEUROLOGICAL |  |  |  |
| GENITOURINARY |  |  |  |
| OTHER (Specify) |  |  |  |

**Page Completed by Doctor:**

|  |  |  |
| --- | --- | --- |
| **Name** | **Signature** | **Date** |
|  |  |  |

**SAMPLES**

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| **Time of collection** | **DATE** | | | **TIME** | | |
| **Location of draw** |  | | | | | |
| **Chemistry** | YES NO | | | | | |
| **Haematology** | YES NO | | | | | |
| **Pregnancy test** | YES NO N/A | | | **Kit Manufacturer** | |  |
| **Kit Lot Number** |  | | **Kit Expiry** | |  |
| **Urinalysis** | YES NO | | | | | |
| **Time of processing** |  | | **Time of freezing** | |  | |
| **Ascension number** |  | | **Waybill number** | |  | |

**IMP RETURNS AND DISPENSING**

|  |  |  |  |
| --- | --- | --- | --- |
| **IMP RETURNED** | | YES NO | |
|  | **KIT NUMBER** | **RETURNED** | **EXPIRY** |
| 1 |  |  |  |
| 2 |  |  |  |
| 3 |  |  |  |
| **IMP DISPENSED** | | YES NO | |
|  | **KIT NUMBER** | **DISPENSED** | **EXPIRY** |
| 1 |  |  |  |
| 2 |  |  |  |
| 3 |  |  |  |

**Page completed by Nurse:**

|  |  |  |
| --- | --- | --- |
| **Name** | **Signature** | **Date** |
|  |  |  |

|  |
| --- |
| This Form is a controlled document. The current version can be viewed on the GCTU website.  Any copy reproduced from the website may not, at time of reading, be the current version. |