# SCREENING VISIT

Date of Screening Visit / /

  *D D M M Y Y Y Y*

# INFORMED CONSENT

Date of Informed Consent / /

 *D D M M Y Y Y Y*

|  |  |
| --- | --- |
| Informed consent process documented in the medical notes including details of any relevant discussions with the participant? | ☐ Yes ☐ No |
| The participant signed and dated the Informed Consent form prior to any study procedures? | ☐ Yes ☐ No |
| Copy of the completed consent form provided to the participant? | ☐ Yes ☐ No |

# PARTICIPANT DEMOGRAPHICS

*Please use this page to record any patient demographics information required by the protocol. Please be aware that personal data should only be recorded if considered absolutely necessary for the trial.*

|  |
| --- |
| Participant Information (delete/add as required – Only collect data required by Protocol) |
| Date of birth: / |
|  *M M Y Y Y Y* |
| Gender at birth/Gender identity (depending what is important for study): ☐ Male ☐ Female |
| Height: . cm Weight: . kg |
| Ethnicity: ☐ White ☐ Asian/Asian Scottish/Asian British ☐ African, Caribbean or Black ☐ Mixed or multiple ethnic groups ☐ Other ethnic group ☐ Refused/Not provided |
| Employment Status: ☐ Employed (full time) ☐ Employed (part time) ☐ Student ☐ Retired ☐ Not currently working ☐ Carer |

|  |
| --- |
| Smoking History  |
| Participant smoking status | ☐ Current Smoker ☐ Former Smoker ☐ Never Smoked |
| If current or former smoker, number of years smoked: |
| If current of former smoker, number of packs smoked per day: |

|  |  |  |
| --- | --- | --- |
|  |  |  |
| *Form completed by Signature* | *Print Name* | *Date (DD/MM/YYYY)* |

*Please use the following pages to record any medical history, physical assessments, scans, blood analysis or any relevant assessments required by the protocol for the screening visit. Some common examples of screening tests are included below.*

# MEDICAL HISTORY

|  |
| --- |
| Please list all relevant conditions – if exact dates are unknown the year alone can be sufficient  |
| Diagnosis | Date of Diagnosis*(D D / M M / Y Y Y Y)* | Condition Ongoing | If no, stop date*(D D / M M / Y Y Y Y)* |
|  |  | ☐ Yes ☐ No |  |
|   |  | ☐ Yes ☐ No |  |
|  |  | ☐ Yes ☐ No |  |
|  |  | ☐ Yes ☐ No |  |
|  |  | ☐ Yes ☐ No |  |
|  |  | ☐ Yes ☐ No |  |

|  |  |  |
| --- | --- | --- |
|   |  |  |
| *Form completed by Signature* | *Print Name* | *Date (DD/MM/YYYY)* |

|  |
| --- |
| Concomitant Medications  |
| Does the participant use any concomitant medications? | ☐ Yes ☐ No |
| If yes, please complete the Concomitant Medications CRF |

|  |  |  |
| --- | --- | --- |
|  |  |  |
| *Form completed by Signature* | *Print Name* | *Date (DD/MM/YYYY)* |

# VITAL SIGNS

|  |
| --- |
|  |
| Time of assessment |  : *(24 hr clock)* |
| Blood pressure | / mm/Hg |
| Heart Rate |  bpm |
| Temperature |  **°**C |

|  |  |  |
| --- | --- | --- |
|  |  |  |
| *Assessment completed by Signature* | *Print Name* | *Date (DD/MM/YYYY)* |

# PREGNANCY TEST

|  |
| --- |
|  |
| Was a pregnancy test carried out? | ☐ Yes ☐ N/A  |
| If yes, result was | **☐ Positive ☐ Negative** |
| If N/A state reason  | ☐ Participant is male☐ Participant is female but not of child bearing potential☐ Other *(please list as required by protocol)*  |
| Contraceptive requirements discussed as per protocol? | ☐ Yes ☐ N/A  |

|  |  |  |
| --- | --- | --- |
|  |  |  |
| *Pregnancy test conducted by Signature* | *Print Name* | *Date (DD/MM/YYYY)* |

# PHYSICAL EXAM

Time of assessment: : *(24hr clock)*

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| System | Normal | Abnormal | If abnormal, clinically significant? | If abnormal, please detail |
| General Appearance | ☐ | ☐ | ☐ CS ☐ NCS |  |
| Cardiovascular | ☐ | ☐ | ☐ CS ☐ NCS |  |
| Respiratory | ☐ | ☐ | ☐ CS ☐ NCS |  |
| Abdomen | ☐ | ☐ | ☐ CS ☐ NCS |  |
| Neurological | ☐ | ☐ | ☐ CS ☐ NCS |  |
| Other (please detail) | ☐ | ☐ | ☐ CS ☐ NCS |  |
| Additional comments |  |

|  |  |  |
| --- | --- | --- |
|  |  |  |
| *Physical exam completed by Signature* | *Print Name* | *Date (DD/MM/YYYY)* |

# LABORATORY TESTS

*Samples listed are examples, please amend to include only laboratory tests required by study protocol.*

Time sample taken: :  *(24 Hr clock)*

|  |  |  |
| --- | --- | --- |
| Sample Required | Tube | Sample taken |
| Full Blood Count | EDTA | ☐ Yes ☐ No ☐N/A |
| LFTsU&Es | Serum Gel | ☐ Yes ☐ No ☐N/A |
| Coag Screen | Citrate | ☐ Yes ☐ No ☐N/A |
| Research bloods | Serum Gel | ☐ Yes ☐ No ☐N/A |
|  |  |  |
| *Samples taken by Signature* | *Print Name* | *Date (DD/MM/YYYY)* |

|  |  |
| --- | --- |
| Research Bloods Processing  |  |
| Time sample into centrifuge : *(24hr clock)* | Time sample out of centrifuge : *(24hr clock)* |
| Time sample into freezer : *(24hr clock)*  | Freezer location: Box Position  |
| Sample processed as per protocol?  | ☐ Yes ☐ No *(If no record deviation)* |
| Comments: |

|  |  |  |
| --- | --- | --- |
|  |  |  |
| *Samples processed by Signature* | *Print Name* | *Date (DD/MM/YYYY)* |

## INVESTIGATOR REVIEW OF LABORATORY RESULTS

*This section assumes that laboratory results are being reviewed by the Investigator via TRAK or similar electronic health record system. In situations where there is a paper CRF, an electronic database and lab results are reported electronically, it is recommended that actual sample results are entered directly into the electronic database to avoid double transcription. Where this is not practical and transcription of results into the pCRF is required to facilitate review by the Investigator or data entry into the database a column can be added to the table below for ‘result’ and individual lab results recorded in the pCRF. Ensure unit of measurement for each result is clear.*

Date of sample reviewed: Time of sample reviewed: :

 *D D M M Y Y Y Y (24 hr clock)*

|  |  |  |  |
| --- | --- | --- | --- |
| Result | Within normal range? | If no, clinically significant? | Comment |
| Haemoglobin | ☐ Yes ☐ No  | ☐ CS ☐ NCS  |  |
| Platelets | ☐ Yes ☐ No  | ☐ CS ☐ NCS  |  |
| White cell count | ☐ Yes ☐ No  | ☐ CS ☐ NCS  |  |
| Bilirubin  | ☐ Yes ☐ No  | ☐ CS ☐ NCS  |  |
| ALT | ☐ Yes ☐ No  | ☐ CS ☐ NCS  |  |
| ALP | ☐ Yes ☐ No  | ☐ CS ☐ NCS  |  |
| Sodium | ☐ Yes ☐ No  | ☐ CS ☐ NCS  |  |
| Potassium | ☐ Yes ☐ No  | ☐ CS ☐ NCS  |  |
| Urea | ☐ Yes ☐ No  | ☐ CS ☐ NCS  |  |
| Creatinine | ☐ Yes ☐ No  | ☐ CS ☐ NCS  |  |
| Fibrinogen | ☐ Yes ☐ No  | ☐ CS ☐ NCS  |  |
| PT | ☐ Yes ☐ No  | ☐ CS ☐ NCS  |  |
| aPPT | ☐ Yes ☐ No  | ☐ CS ☐ NCS  |  |
| INR | ☐ Yes ☐ No  | ☐ CS ☐ NCS  |  |
|  |  |  |
| *Results reviewed by Signature (Medic only)* | *Print Name* | *Date (DD/MM/YYYY)* |

# ELIGIBILITY REVIEW

|  |  |  |
| --- | --- | --- |
| Inclusion Criteria *(all must be answered YES to proceed)* | Yes | No |
| *Enter all inclusion criteria outlined in the protocol* |
| 1. Provision of informed consent from the participant | ☐ | ☐ |
| 2. Aged ≥18 | ☐ | ☐ |
| 3. Clinical diagnosis of relevant condition  | ☐ | ☐ |
| 4. | ☐ | ☐ |
| 5. | ☐ | ☐ |
| 6. | ☐ | ☐ |
| 7. | ☐ | ☐ |
| 8. | ☐ | ☐ |
| 9. | ☐ | ☐ |
| 10. | ☐ | ☐ |
|  |  |  |  |  |
| Exclusion Criteria *(all must be answered NO to proceed)* | Yes | No |
| *Enter all exclusion criteria outlined in the protocol*  |
| 1. Inability or unwilling to give informed consent | ☐ | ☐ |
| 2. Previous recruitment into trial | ☐ | ☐ |
| 3. Female participant – pregnant/breastfeeding | ☐ | ☐ |
| 4. | ☐ | ☐ |
| 5. | ☐ | ☐ |
| 6. | ☐ | ☐ |
| 7. | ☐ | ☐ |
| 8. | ☐ | ☐ |
| 9. | ☐ | ☐ |
| 10. | ☐ | ☐ |

|  |  |  |
| --- | --- | --- |
| Review of Eligibility | Yes | No |
| Considering all inclusion/exclusion criteria is participant eligible to proceed in the trial? | ☐ | ☐ |
| If no state reason: |  |

|  |  |  |
| --- | --- | --- |
|  |  |  |
| *Eligibility confirmed by Signature* *(Medic only)* | *Print Name* | *Date (DD/MM/YYYY)* |

# VISIT REVIEW

|  |  |  |
| --- | --- | --- |
|  |  |  |
| Visit completed as per protocol*If no record protocol non-compliance as required* | ☐ Yes | ☐ No |
| Visit recorded in medical notes | ☐ Yes |  |
| Next visit booked for |  / / *(DD/MM/YYYY)* ☐ N/A if last visit  |
| Comments: |  |

|  |  |  |
| --- | --- | --- |
|  |  |  |
| *Completed by Signature* | *Print Name* | *Date (DD/MM/YYYY)* |