# BASELINE VISIT

*Please use the following pages to record any assessments required by the protocol as part of the baseline visit; for example physical assessments, scans, blood analysis etc.*

Date of Baseline Visit / /

*D D M M Y Y Y Y*

|  |  |
| --- | --- |
| Has the participant confirmed that they are still happy to continue with the trial? | ☐ Yes ☐ No |
| Have any adverse events occurred since last visit?  *If yes complete AE log* | ☐ Yes ☐ No |
| Any changes to concomitant medications since last visit?  *If yes update con med log* | ☐ Yes ☐ No |

# 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)* |

# 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)* |

# ECG

|  |  |
| --- | --- |
|  | |
| Time of ECG | : *(24 hr clock)* |
| Normal ☐ | Abnormal ☐ |
| If abnormal please detail: |  |
| *List specific results if required by protocol* |  |
|  |  |
|  |  |

|  |  |  |
| --- | --- | --- |
|  |  |  |
| *ECG completed by Signature* | *Print Name* | *Date (DD/MM/YYYY)* |
|  |  |  |
| *ECG reviewed by Signature (medic only)* | *Print Name* | *Date (DD/MM/YYYY)* |

# MRI SCAN

|  |  |
| --- | --- |
|  | |
| Date of MRI | / / *(DD/MM/YYYY)* |
| Normal ☐ | Abnormal ☐ |
| If abnormal please detail: |  |
| *List specific results if required by protocol* |  |
|  |  |
|  |  |

|  |  |  |
| --- | --- | --- |
|  |  |  |
| *MRI reviewed by Signature (medic only)* | *Print Name* | *Date (DD/MM/YYYY)* |

# QUESTIONNAIRE

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
|  | | | |  |  |
| QoL questionnaire completed | | | | ☐ Yes | ☐ No |
| If no state reason: |  | | | | |
|  | |  |  | | | |
| *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 |
| LFTs  U&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

*Some trials require a two-step eligibility where after baseline assessment the participant must be assessed as still being eligible for the study before continuing to randomisation. Please only include if required by protocol.*

Following baseline visit please re-confirm the following inclusion and exclusion criteria.

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| Inclusion Criteria *(all must be answered YES to proceed)* | | | | Yes | | No |
| *Enter all inclusion criteria outlined in the protocol that are to be reconfirmed at baseline* | | | | | | |
| 1. | | | | ☐ | | ☐ |
| 2. | | | | ☐ | | ☐ |
| 3. | | | | ☐ | | ☐ |
| 4. | | | | ☐ | | ☐ |
| 5. | | | | ☐ | | ☐ |
|  |  |  |  | |  | |
| Exclusion Criteria *(all must be answered NO to proceed)* | | | | Yes | | No |
| *Enter all exclusion criteria outlined in the protocol that are to be reconfirmed at baseline* | | | | | | |
| 1. | | | | ☐ | | ☐ |
| 2. | | | | ☐ | | ☐ |
| 3. | | | | ☐ | | ☐ |
| 4. | | | | ☐ | | ☐ |
| 5. | | | | ☐ | | ☐ |

|  |  |  |  |
| --- | --- | --- | --- |
| Review of Eligibility | | Yes | No |
| Is the participant still eligible to participate as per the inclusion/exclusion criteria? | | ☐ | ☐ |
| If no state reason: |  | | |

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

# RANDOMISATION

|  |  |  |  |
| --- | --- | --- | --- |
|  | |  |  |
| Is the participant deemed suitable for randomisation? | | ☐ Yes | ☐ No |
| If no state reason: |  | | |

|  |  |  |
| --- | --- | --- |
| Please indicate the participants allocated treatment arm: |  |  |
| Treatment Arm 1 – Please enter details for treatment arm | ☐ | |
| Treatment Arm 2 – Please enter details for treatment arm | ☐ | |
| *Please add any additional treatment arms as applicable to study design. If randomisation is blinded to a number then amend this section to capture number allocated by randomisation system. See study visit template for example.* | | |

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

# IMP SUPPLY

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
|  | | |  |  |
| Allocated IMP dispensed to participant | | | ☐ Yes | ☐ No |
| Dosing instructions reviewed/given to participant *(delete as appropriate for study design)* | | | ☐ Yes | ☐ No |
| *Add anything else specific to study design which needs to be given to participant e.g diary card, emergency card, NIMPs, any equipment required by participant to administer IMP* | | |  |  |
|  |  |  | | |
| *Completed by Signature* | *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)* |