# STUDY VISIT #

*Please use the following pages to record any assessments required by the protocol as part of the study visit; for example physical assessments, scans, blood analysis etc. Please remove any measurements which are not required as per protocol – for example height and weight may not be required at each study visit, especially if already collected at baseline*

Date of Study Visit / /

*D D M M Y Y Y Y*

|  |  |  |
| --- | --- | --- |
| Visit completed | Face to face ☐ Remote via NHS Near Me ☐ Remote via telephone ☐ | |
| 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 |

|  |  |  |
| --- | --- | --- |
|  |  |  |
| *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 |
| Height | . cm |
| Weight | . kgs |

|  |  |  |
| --- | --- | --- |
|  |  |  |
| *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)* |

# 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)* |

# IMP COMPLIANCE

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
|  | | | |  |  |
| Diary card reviewedduring visit (if applicable – see study protocol) | | | | ☐ Yes | ☐ No |
| If no please state reason | Diary card not returned *(remind before next visit)* | | | | ☐ |
| Diary card lost *(record protocol non-compliance)* | | | | ☐ |
| Other *(please state):* | | | | ☐ |
| IMP returned ☐ Yes | | | | ☐ No | ☐ N/A |
| If no please state reason | Participant forgot *(remind before next visit)* | | | | ☐ |
| Packs disposed of accidently *(record protocol non-compliance)* | | | | ☐ |
| Other *(please state)*: | | | | ☐ |
| Number of tablets returned |  | | | |  |
| Review of IMP compliance – Were issues with compliance identified?  *If yes record protocol non-compliance as required* | | | | ☐ Yes | ☐ No |
|  | |  |  | | |
| *Completed by Signature* | | *Print Name* | *Date (DD/MM/YYYY)* | | |

# SAFETY ASSESSMENT/IMP DOSE CHANGE

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
|  | | |  |  |
| On review of the study visit assessments were any stopping criteria met?  *List stopping criteria as defined in protocol*  *If yes complete withdrawal form, follow up as per protocol* | | | ☐ Yes | ☐ No |
| Current dose of IMP | | mg once daily (amend as per protocol) | | |
| All protocol required safety assessments reviewed by Investigator list as per protocol | | | ☐ Yes | ☐ No |
| IMP dose change required ☐ Yes | | | ☐ No | ☐ N/A |
| If yes, new dose of IMP | | mg once daily (amend as per protocol) | | |
| Comments: | Include justification of dose change if required by protocol | | | |

|  |  |  |
| --- | --- | --- |
|  |  |  |
| *Safety assessment and IMP dose change reviewed by Signature (medic only)* | *Print Name* | *Date (DD/MM/YYYY)* |

# IMP RESUPPLY

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
|  | | |  |  |
| Re-supply of IMP required | | | ☐ Yes | ☐ No |
| If yes prescription signed by delegated Investigator | | | ☐ Yes |  |
| Dosing instructions reviewed/given to participant *(delete as appropriate for study design)* | | | ☐ Yes | ☐ No |
| Quantity/pack numbers dispensed *(delete/add in name of drug as appropriate for study design)* | | |  | |
|  |  |  | | |
| *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)* |