|  |
| --- |
| **CRF REVIEW** |
| Study Details |
| Study Title |  |
| CI Name |  |
| Name of Statistician |  | Study Contact (e.g. trial manager)  |  |
| REC reference |  | Type of study |  |

|  |
| --- |
| CRF/Review Details |
| Format of CRF | Paper (pCRF) | [ ]  | Electronic (eCRF) | [ ]  |
| CRF for review Version (date) |  | Protocol used for review Version (date) |  |
| CRF developed by | ECTU [ ]  Clinical Research Facility [ ]  Other [ ]  If other please specify: |
| Date of review |  | Type of review | First review [ ]   | Amendment [ ]   |
| Name of reviewer |  |

*If reviewing an amendment to an existing CRF continue to amendment details section below. If first review continue to Section 1.*

|  |
| --- |
| Additional details for amendments |
| 1. Has a documented first review of the CRF been completed for this study?
 | Yes [ ]  | No [ ]  | If **no** section 1 should be completed, if yes continue to question 2 |
| 1. Does the amendment affect the trial data collected?
 | Yes [ ]  | No [ ]  | If **yes** section 1 should be completed for affected data only, if no continue to Section 2 |

**Section 1**

Section 1 is a comparison between data identified as required in the protocol and data collected in the CRF. The version of the protocol recorded in the CRF/review details section above should be the version of the protocol which the CRF is based on. This protocol should be reviewed and all data requirements identified listed in the table below. The corresponding version of the CRF should then be reviewed to ensure all data required by the protocol is captured. How data is captured and the documents which comprise the CRF will differ between studies. The table below should be made study specific and data requirement sections can be removed where not applicable.

Section 1 not required according to amendment details above [ ]

| Consistency between protocol and CRF |
| --- |
| Data requirement | Data required by protocol | Captured in CRF?Y/N | Source document for data? | Comments |
| Primary Outcome | *List data required for primary outcomes as defined in protocol* |  |  |  |
|  |  |  |  |
|  |  |  |  |
|  |  |  |  |
| Secondary outcomes | *List data required for secondary outcomes as defined in protocol* |  |  |  |
|  |  |  |  |
|  |  |  |  |
|  |  |  |  |
| Standard Requirements | Consent details |  |  |  |
| Subject ID |  |  |  |
| Eligibility criteria assessment |  |  |  |
| Confirmation of eligibility by medic |  |  |  |
| Medic oversight of test results |  |  |  |
| Sign off for completion of each section |  |  |  |
| Change of status/withdrawal |  |  |  |
| Investigator final sign off of data |  |  |  |
| Adverse events | Prompt to ask participant about AEs at each visit |  |  |  |
| Nature of event |  |  |  |
| Start/stop date |  |  |  |
| Seriousness |  |  |  |
| Severity |  |  |  |
| Relatedness |  |  |  |
| Expectedness (only if possibly related) |  |  |  |
| Outcome |  |  |  |
| PI oversight |  |  |  |
| MedDRA code |  |  |  |
| Concomitant medications | Name of medication |  |  |  |
| Indication |  |  |  |
| Start/stop date |  |  |  |
| Dose |  |  |  |
| Prohibited medications | *List prohibited medication checks as required by protocol* |  |  |  |
| Compliance data | *List compliance data to be collected as required by protocol* |  |  |  |
| Safety assessments | *List safety assessments as defined in protocol* |  |  |  |
| Randomisation | *List data required for randomisation e.g. minimization/stratification variables, Also consider requirement for randomisation number and whether participant received allocated treatment.*  |  |  |  |
| Study assessments | *List study assessments as defined in protocol* |  |  |  |
|  |  |  |  |
|  |  |  |  |
|  |  |  |  |
|  |  |  |  |
|  |  |  |  |
|  |  |  |  |
|  |  |  |  |
|  |  |  |  |
|  |  |  |  |
|  |  |  |  |

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Any data required by protocol not captured in CRF? | Yes | [ ]  | No | [ ]  |
| *If yes describe issues identified:* |
| Any additional data collected in CRF not identified as required by protocol? | Yes | [ ]  | No | [ ]  |
| *If yes list data identified (and justification for collection if appropriate):* |
| Where potentially identifiable personal data/information is collected in CRF and is considered absolutely necessary, is consent in place? | Yes | [ ]  | No | [ ]  | N/A | [ ]  |
| *If no describe issues identified:* |
| If the consent form includes optional consent questions (e.g optional data sharing or optional sample collection), are these questions and the participant answers documented in the CRF? | Yes | [ ]  | No | [ ]  | N/A | [ ]  |
| *If no describe issues identified:* |
| Are data points where CRF is identified as source listed in protocol/source data plan? | Yes | [ ]  | No | [ ]  | N/A | [ ]  |
| *If no describe issues identified:* |
| Where source data will be entered directly into an eCRF or collected centrally away from site (e.g participant report outcomes by questionnaire or text message) process agreed to ensure access to data by PI during trial and provide copy of data at end of trial? | Yes | [ ]  | No | [ ]  | N/A | [ ]  |
| *If applicable describe agreed process and who is responsible for provision of data:* |
| Is the format of data entry clear within the CRF (e.g times 12hr/24hr dates DD\_MMM-YY or DD/MM/YY)? | Yes | [ ]  | No | [ ]  |
| *If no describe issues identified:* |
| Are units and visits stated in CRF consistent with those defined in protocol? | Yes | [ ]  | No | [ ]  |
| *If no describe issues identified:* |

**Section 2**

To be completed for all reviews

|  |
| --- |
| Consistency within CRF |
| Does header/footer contain appropriate information to identify each page and is this consistent throughout CRF? | Yes | [ ]  | No | [ ]  |
| *If no describe issues identified:* |
| Is CRF appropriately version controlled and is this consistent throughout? | Yes | [ ]  | No | [ ]  |
| *If no describe issues identified:* |
| Does the CRF identify visit/data collection time points, the date of each of these and the person recording the data? | Yes | [ ]  | No | [ ]  |
| *If no describe issues identified:* |
| Does the CRF take into account the order of visits and record information in a logical and consistent order? | Yes | [ ]  | No | [ ]  |
| *If no describe issues identified:* |

**Section 3**

To be completed for all reviews

|  |
| --- |
| Communication of issues |
| Issues identified above communicated to CI/designee | Yes | [ ]  | No | [ ]  | N/A | [ ]  |
| *Comments:* |
| Issues identified above communicated to assigned statistician | Yes | [ ]  | No | [ ]  | N/A | [ ]  |
| *Comments:* |

|  |
| --- |
| Actions required  |
| Action required | Person responsible | Action completed (date) |
|  |  |  |
|  |  |  |
|  |  |  |
|  |  |  |
|  |  |  |
|  |  |  |

**Section 4**

|  |
| --- |
| Resolution of issues |
| Issues identified above resolved and CRF ready for sign off | Yes | [ ]  | No | [ ]  |
| *Comments (include versions of additional/updated documents reviewed and date of review):* |
| Confirm statistician agrees to final version [ ]  | Agreement confirmed by (name)  |
| Final version of CRF approved | Version xx Date DD-MMM-YYYY |
| Corresponding to protocol version | Version xx Date DD-MMM-YYYY |
| *Note: If corresponding protocol has not received all approvals for use prior to CRF review sign off study team must be informed that all approvals should be in place for protocol before CRF implementation.*  |
| Reviewer signature: |  | Date: |  |