**Case Report Form (CRF) REVIEW Checklist - BIOSTATISTICS**

|  |  |
| --- | --- |
| **Study no, abbreviation** |  |
| **Protocol title** |  |
| **Version no. and date** |  |
| **Sponsor-Investigator (PI)** |  |
| **Sponsor** |  |
| **Study Statistician** |  |

| **Required Elements** | | | | **Yes** | **No** | **NA** | | **If No, specify action taken or comment** |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **1.** | Primary endpoint(s): Are all the data required for the primary endpoint being collected and in such a way that it can be analysed appropriately? | | |  |  |  | |  |
| **2.** | Secondary endpoints: Are the data being collected for all the secondary outcomes detailed in the protocol in such a way that they can be analysed appropriately? | | |  |  |  | |  |
| **3.** | Are all the data required to determine the analysis populations being collected e.g. identification of participants who are lost to follow-up (if applicable)? | | |  |  |  | |  |
| **4.** | Are data on compliance being collected (where relevant)? | | |  |  |  | |  |
| **5.** | Are all of the safety data detailed in the protocol being collected and in such a way that it can be analysed appropriately? | | |  |  |  | |  |
| **6.** | Are the data needed to ensure the eligibility of the participant being collected? | | |  |  |  | |  |
| **7.** | Are data captured in closed form wherever possible? | | |  |  |  | |  |
| **8.** | Is data coding consistent? (e.g. if 1 is coded yes and 0 is coded no, this is used consistently) | | |  |  |  | |  |
| **9.** | Is it always clear whether questions require just one answer or as many options as apply?  i.e. pay attention to whether data are collected as “choose one” or “select all that apply”, and whether this is appropriate | | |  |  |  | |  |
| **10.** | Are labels/descriptions meaningful? | | |  |  |  | |  |
| **11.** | Do all question have an “other” option (unless really not needed)?  And if there is an “other” option, is there a “specify” field? | | |  |  |  | |  |
| **12.** | Where categories are specified, are they mutually exclusive and complete? i.e. all patients would fit into a category, and one category only | | |  |  |  | |  |
| **13.** | Are dates captured appropriately? i.e. pay attention also to whether incomplete dates are captured appropriately | | |  |  |  | |  |
| **14.** | Is date of completion collected for each CRF? | | |  |  |  | |  |
| **15.** | Are data collected only once at each time point? | | |  |  |  | |  |
| **16.** | Are raw values collected rather than calculated values? | | |  |  |  | |  |
| **17.** | Do the CRF follow the study schedule? | | |  |  |  | |  |
| **18.** | Are skip patterns appropriate? (where relevant) | | |  |  |  | |  |
| **19.** | Is it possible to capture “Unknown” where needed? | | |  |  |  | |  |
| **19.** | For a blinded trial does the CRF include any information that could unblind study staff?\* | | |  |  |  | |  |
| **20.** | Does the CRF collect any confidential information (names and phone numbers) that should not be in the database?\* | | |  |  |  | |  |
| **21.** | Are data being collected that are not specified in the protocol?\* | | |  |  |  | |  |
| \* Note, the answer to this question should be no.  **Statistician Review:**  I confirm the CRFs for the above trial has been reviewed according to the checklist.  **Further comments:** | | | | | | | | |
| **Name:** | |  | **Date of Review:** | | | |  | |
| **Signature:** | |  | | | | | | |