

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?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
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?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
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)?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
4.	Are data on compliance being collected (where relevant)?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
5.	Are all of the safety data detailed in the protocol being collected and in such a way that it can be analysed appropriately?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
6.	Are the data needed to ensure the eligibility of the participant being collected?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
7.	Are data captured in closed form wherever possible?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
8.	Is data coding consistent? (e.g. if 1 is coded yes and 0 is coded no, this is used consistently)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
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	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
10.	Are labels/descriptions meaningful?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
11.	Do all question have an "other" option (unless really not needed)? And if there is an "other" option, is there a "specify" field?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	

Required Elements		Yes	No	NA	If No, specify action taken or comment
12.	Where categories are specified, are they mutually exclusive and complete? i.e. all patients would fit into a category, and one category only	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
13.	Are dates captured appropriately? i.e. pay attention also to whether incomplete dates are captured appropriately	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
14.	Is date of completion collected for each CRF?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
15.	Are data collected only once at each time point?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
16.	Are raw values collected rather than calculated values?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
17.	Do the CRF follow the study schedule?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
18.	Are skip patterns appropriate? (where relevant)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
19.	Is it possible to capture "Unknown" where needed?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
19.	For a blinded trial does the CRF include any information that could unblind study staff?*	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
20.	Does the CRF collect any confidential information (names and phone numbers) that should not be in the database?*	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
21.	Are data being collected that are not specified in the protocol?*	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
<p>* Note, the answer to this question should be no.</p> <p>Statistician Review: I confirm the CRFs for the above trial has been reviewed according to the checklist.</p> <p>Further comments:</p>					
Name:				Date of Review:	
Signature:					