murdoch children's research institute

CLINICAL TRIAL PROTOCOL REVIEW CHECKLIST - BIOSTATISTICS

Study no, abbreviation	
Protocol title	
Version no. and date	
Sponsor-Investigator (PI)	
Sponsor	
Study statistician	
Review Occurrence	☐ Prior to MCRI Sponsorship Committee submission ☐ Prior to HREC submission ☐ Prior to HREC re-submission

Required Elements		Yes	No	NA	If No, specify action taken or comment
1.	Title is clear and descriptive	☐	☐	☐	
2.	A trial schema is included and is clear and concise	☐	☐	☐	
3.	The schedule of assessments table contains all required baseline, treatment/intervention, safety and endpoint data (and nothing else)	☐	☐	☐	
4.	The hypotheses of the trial are clear and concise, if applicable	☐	☐	☐	
5.	The objectives of the trial are clear, concise and measurable	☐	☐	☐	
6.	The endpoints/outcomes of the trial are clear, appropriate and measurable (and a time point is specified)	☐	☐	☐	
7.	The eligibility criteria are internally consistent	☐	☐	☐	
8.	Recruitment strategy/sampling details are provided (e.g. number of study sites)	☐	☐	☐	
9.	Detail is provided on how informed consent will be obtained	☐	☐	☐	
10.	The number of study arms is clearly specified	☐	☐	☐	
11.	The treatment/intervention details (what and when) are clear for all arms of the trial (including the control arm)	☐	☐	☐	
12.	There is a clear description of the study design (e.g. parallel arm, crossover, etc.) and the study design is appropriate to address the objectives	☐	☐	☐	
13.	Randomisation details are clear and appropriate (allocation ratio, how sequence is generated, stratification, minimisation, blocked randomisation, level of randomisation [individual/ cluster]). If the trial is not randomised the decision is justified	☐	☐	☐	
14.	The blinding and unblinding details are clear and appropriate, including how to deal with data collected during the trial that may have the potential to unblind (e.g. concentration of lab parameters). If the trial is not blinded the decision is justified	☐	☐	☐	
15.	Timing of follow-up assessments and the data collected at each assessment is clear	☐	☐	☐	
16.	The protocol states that participants are to be followed to the end of trial if off study intervention (and if not, it is justified and appropriate). The plans for handling treatment discontinuation and withdrawal are clear and appropriate.	☐	☐	☐	

Required Elements		Yes	No	NA	If No, specify action taken or comment
17.	Study duration per participant is clear (screening and follow up)	☐	☐	☐	
18.	The sample size is clear, appropriate and justified; including justification for assumptions and enough details on calculation of sample size to repeat the calculation	☐	☐	☐	
19.	The analysis populations for each of the objectives (e.g. all randomised participants, all treated participants, all eligible participants) is stated. If a per protocol analysis is included, specify what steps are taken to reduce bias in this analysis	☐	☐	☐	
20.	Analyses are specified for each of the study objectives, and the statistical methods to be employed are appropriate. If an interim analysis is planned details are provided	☐	☐	☐	
21.	Replacement of participants is covered in the protocol and is appropriate	☐	☐	☐	
22.	Procedure for accounting for missing data is stated and appropriate	☐	☐	☐	
23.	Procedure for reporting any deviations from the original statistical plan or protocol is stated	☐	☐	☐	
24.	Study stopping rules (early termination criteria) are clear and appropriate (including the role of a data and safety monitoring board in relation to these rules)	☐	☐	☐	
25.	Pre-specification of any subgroup analyses or a statement that there are no planned subgroup analyses	☐	☐	☐	
26.	Information about safety monitoring e.g. a data and safety monitoring board is provided, or if not there is a justification for why this is not needed	☐	☐	☐	
27.	Information is provided about data storage (who has access, where and how long data are stored)	☐	☐	☐	

Statistician Review:

I confirm the protocol for the above trial has been reviewed according to the checklist.

Further comments:

Name:		**Date of Review:**	
Signature:			