Checklist for the Approach section of grant submissions to fund observational, quantitative studies

Preliminary studies (optional and as appropriate):	✓
Describe the study team expertise.	
Describe previous supportive findings from the study team.	
Provide feasibility data (data from previous recruitment, previous exposure or outcome measurement, etc.).	
Describe supportive research infrastructure.	
Methods:	
Study design	
Present key elements of the study design, ***making sure that it aligns with the specific aims.***	
Setting	
Describe the setting, locations, and relevant dates, including periods of recruitment, exposure, follow-up, and data collection.	
Participants	
Provide the eligibility criteria, and the sources and methods of selection of participants. Describe methods of follow-up, if appropriate. For matched studies, provide the matching criteria and specify the number of exposed and unexposed participants (matched cohort study) or the number of controls per case (matched case-control study). For case-control studies, provide the rationale for the choice of cases and controls.	
Exposure variable(s)	
Clearly define the exposure variable(s), data source and/or method of data collection. Include estimates of reproducibility and validity, as appropriate. Describe comparability of exposure assessment if there is more than one study group.	
Outcome variable(s)	
Clearly define the outcome variable(s). Describe the data source and/or method and timing of data collection, with estimates of reproducibility and validity, as appropriate. Describe comparability of outcome assessment if there is more than one study group.	
Covariates	
Briefly describe additional variables used to characterize the study population, potential confounders, and effect modifiers. Include their data source and/or method and timing of data collection.	
Statistical analysis	
Describe all statistical methods, including how quantitative variables will be handled in the analyses (e.g., which groupings and why) and how confounding will be addressed. Describe any efforts to address potential sources of bias and sensitivity analyses. Describe any methods used to examine subgroups and interactions. Explain how missing data will be addressed. (*a*) *Cohort study*—if applicable, explain how loss to follow-up will be addressed. *(b) Case-control study*—if applicable, explain how matching of cases and controls will be taken into account. *(c) Cross-sectional study*—if applicable, describe how the sampling strategy will be taken into account. **** Make sure that the statistical analysis aligns with the specific aims.***	
Power and sample size considerations	
Explain how the study size was derived using power or sample size calculations. This also applies to pilot and feasibility studies, for which a confidence interval approach may be used for the feasibility outcomes. **** Do not use the fact that the proposed study is the same size as other studies as justification.***	
Limitations	
Discuss limitations of the proposed study, taking into account sources of potential bias, imprecision, and multiplicity of analyses. Discuss both the direction and magnitude of potential biases. Discuss the generalizability (external validity or applicability) of the proposed study results. Discuss steps taken to reduce methodologic limitations and increase generalizability, as appropriate.	

Adapted from the following three resources:

CONSORT 2010 checklist of information to include when reporting a randomised trial (www.consort-statement.org).
STROBE statement – checklist of items that should be included in reports of observational studies (www.strobe-statement.org).
Thabane et al. BMC Medical Research Methodology 2010. 10:1.