Template for a Systematic Review Protocol

1. Change Record
This should be a list or table summarizing the main updates and changes embodied in each version of the protocol and (where appropriate), the reasons for these.

2. Background
a) explain why there is a need for a study on this topic
b) specify the main research question being addressed by this study
c) specify any additional research questions that will be addressed
d) if extending previous research on the topic, explain why a new study is needed

3. Search Strategy
a) specify and justify basic strategy: manual search, automated keyword-based search, automated citation-based search, or mixed
b) for automated keyword searches, specify search terms and compounds of these (and record results of any prototyping of the search strings)
c) for automated citation-based searches explain how the seed set of papers will be identified
d) for both types of automated searches, identify resources to be used (digital libraries and search engines)
e) for manual searches, identify the journals and conferences to be searched
f) specify the time period to be covered by the review and any reasons for your choice
g) identify any ancillary search procedures, e.g. asking leading researchers or research groups, or accessing their web sites; or checking reference lists of primary studies
h) specify how the search process is to be evaluated (e.g. against a known subset of papers; or against the results from a previous systematic review)
i) report the results of all initial trials of the search process

4. Selection Criteria and Selection Process
a) identify the inclusion criteria for primary studies
b) identify the exclusion criteria
c) define how selection will be undertaken (whether the selection process will be split into stages, how many reviewers will assess each candidate paper, how the process will be managed)
d) define how agreement among reviewers will be evaluated
e) define how any differences between reviewers will be resolved
f) if only one reviewer will assess the eligibility of some papers explain how the risk of personal bias has been addressed
g) report the results of any trials of the selection process

5. Study Quality Assessment aka Risk of Bias Assessment (RoB)
a) specify the quality RoB checklists to be used
b) specify how the checklist will be evaluated
c) identify how the assessment is to be undertaken and validated
d) define how many reviewers will assess the quality/RoB of each paper
e) if two or more reviewers will assess quality/RoB for each paper, define how disagreements will be resolved
f) if only one reviewer will extract data from some of the papers explain how the risk of personal bias has been addressed
g) identify how the results of the quality/RoB assessment will be used (e.g. partitioning the primary studies during aggregation or meta-analysis; explaining differences among the results of primary studies, supporting the process used to assess the strength of evidence)
h) report the results of any initial evaluations of the assessment process

6. Data Extraction
a) design data extraction form (and check via a dry run)
b) specify the strategy for extracting the data and the form (paper, on-line etc.)
c) identify how the data extraction process is to be undertaken and validated, particularly any data that require numerical calculations, or are textual (and may require coding)
d) define how many reviewers will extract data from each paper
e) if two or more reviewers will extract data from each paper, define how disagreements will be resolved
f) if only one reviewer will extract data from some of the papers explain how the risk of personal bias has been addressed
f) report the results of any trials of the data extraction process

7. Data Synthesis
a) specify the form of analysis to be used (e.g. narrative, tabulation, meta-analysis, thematic analysis)
b) assess the threats to validity (construct, internal, external), particularly constraints on the search process and deviations from standard practice
c) explain how the data synthesis activities will be organized to minimize any risk of personal bias influencing the results (for quantitative analysis, this can be done by providing analysis scripts that can be reviewed and run by other reviewers, for qualitative analysis, different reviewers can extract and code data from primary studies and can then discuss and combine their results for each paper)
d) report the results of any trials of the synthesis process

8. Assessing Strength of Evidence
a) Explain how the strength of evidence will be assessed for each finding/recommendation (i.e. how results of the individual primary study RoB assessment, will be integrated with any assessment of publication bias and other relevant issues.
b) If more than one reviewer assesses strength of evidence, report how disagreements will be resolved.
c) If only a single reviewer is intended to assess strength of evidence explain how the risk of personal bias influencing the assessment will be minimized.
d) Report any trials of the process for assessing strength of evidence

9. Study Limitations
Specify residual validity issues including potential conflicts of interest (i.e. that are inherent in the context of the study, rather than arising from the plan).

10. Reporting
Identify target audience, relationship to other studies, planned publications, authors of the publications.

11. Protocol Validation
a) Explain how the protocol was validated
b) Report the results of the validation

12. Schedule
Provide time estimates for all of the major steps.