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## Guidelines for Preparation of Review Protocols

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A Campbell Systematic Review is meant to review and synthesize evidence on social and behavioural interventions and public policy, including education, criminal justice, and social welfare, among other areas. The primary concern is with evidence on overall intervention or policy effectiveness and how effectiveness is influenced by variations in process and implementation, intervention components and recipients, as well as other factors.

A Review Protocol is a document that sets out the reviewers' intentions with regard to (a) the topic and (b) the methods to be used in carrying out a proposed review for inclusion in the Campbell Database of Systematic Reviews, a component of the Campbell Library. Editors of Collaborative Review Groups and other referees as deemed appropriate by the Editors appraise and give feedback on protocols before actual reviews are conducted. The protocols are published in the Campbell Database of Systematic Reviews and are subject to comments and criticisms from users of that Database.

People considering taking on the preparation and maintenance of a Campbell Review first need to discuss and register the title with one of the Campbell Collaborative Review Groups. This is done to help to avoid duplication of effort and the unhappy situation that two separate teams begin work on two separate reviews addressing the same (or similar) questions, only to find out about this duplication of effort late on in the process.

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### I. RATIONALE FOR PROTOCOLS

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Preparing a review is a complex process that comprises many judgments and decisions. As in any scientific endeavour, the methods to be used should be established beforehand, although the methods used will evolve somewhat during the course of the project. Setting out methods prior to beginning work on a research review is especially important because (a) the studies to be included are usually identified after they have been completed and reported and (b) the results of many of these studies may already be known to the reviewers. The reviewers' knowledge of the results of studies may influence:

- the definition of the systematic review question;

- the criteria for study selection;
- the comparisons for analyses;
- the outcomes to be reported in the review.

Therefore, it is important to make the review process as well-defined, systematic, and unbiased as possible while maintaining a practical perspective. Requiring detailed protocols is one way to (a) allow the editorial referees to provide guidance and advice, (b) prevent problems from occurring during the review process, and (c) ensure that final products will meet the standards of the Campbell Collaboration.

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## II. CONTENTS OF A PROTOCOL

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A protocol for a Campbell Review should consist of the following sections:

1. Cover Sheet
2. Background for the Review
3. Objectives of the Review
4. Methods
  - a. Criteria for inclusion and exclusion of studies in the review
  - b. Search strategy for identification of relevant studies
  - c. Description of methods used in the component studies
  - d. Criteria for determination of independent findings
  - e. Details of study coding categories
  - f. Statistical procedures and conventions
  - g. Treatment of qualitative research Timeframe
5. Plans for Updating the Review
6. Acknowledgments
7. Statement Concerning Conflict of Interest
8. References
9. Tables

A brief description of each section follows.

### *1. Cover Sheet*

The cover sheet of the protocol should include:

- the title of the review
- the names of the reviewers
- contact information for the lead reviewer
- sources of support.

### *2. Background for the Review*

Well-formulated questions for research reviews occur in the context of an already formed body of knowledge. This context should be addressed in the background section of the review protocol. The background section sets out the rationale for the review and explains why the questions being asked are important.

The background for a systematic review sets the stage for the empirical results that follow. It should contain a conceptual discussion of the research problem and a statement of the problem's significance. Reviewers should attempt to present a brief overview of the research question, including its theoretical, practical, and methodological history. The background statement must pay attention to the

qualitative and historical debates surrounding the research question. The reviewers should answer questions such as:

- From where do the problem, approach, and/or intervention in the research come?
- Do debates exist surrounding the meaning of the problem or utility of the intervention?
- Do theories predict how the major variables involved in the review will relate to one another?
- Do different theories or philosophies of treatment yield conflicting predictions?

The background statement should also contain a discussion of previous reviews of the research topic. This review of reviews should highlight what we have learned from past efforts as well as point out their inconsistencies and methodological strengths and weaknesses. The contribution of the new effort should be emphasized by clearly stating the unresolved empirical questions and controversies addressed by the new review.

In sum, the background section of the protocol should present an overview of the theoretical, conceptual, and/or practical issues surrounding the research problem. It should present a general description of prior reviews, the controversies these reviews have created or left unresolved, and which of these will be the focus of the new review effort.

### *3. Objectives of the Review*

Systematic reviews can be undertaken for a number of reasons. For example, reviews can be conducted to (a) produce general statements about relationships and treatment effects through the synthesis of individual study results, (b) find reasons for conflicting evidence, (c) answer questions, using variations in studies, that could not have been answered in the individual component studies, (d) explain variations in practice, (e) review the evidence on the subjective experience of an intervention, and/or (f) build connections between related areas of research. While Campbell Reviews might be motivated by any of these and other reasons, their overarching aim should be to gather, summarize and integrate empirical research so as to help people understand the evidence.

In setting out the objectives, reviewers should keep in mind that Campbell Reviews should help people make practical decisions about social and behavioural interventions and public policy. This has important implications for deciding whether and how to undertake a Campbell Review, how to formulate the problem that a review will address, how to develop the protocol and how to present the results of the review.

The objectives of a review should address the choices (practical options) people face when deciding about whether or not to adopt a policy or practice. Reviews should address outcomes that are meaningful to people making decisions about public policy.

### *4. Methodology*

The purpose of the methods section of a protocol is to describe operationally how the review will be conducted. The methods section of a research review will be considerably different from that of a primary research report. Most review methods sections will need to address several separate sets of questions.

Criteria for inclusion and exclusion of studies in the review. The first topic that should be addressed in the methods section of the protocol is the criteria for

relevance that will be applied to the studies uncovered by the search. The reviewers should answer questions such as:

- What characteristics of studies will be used to determine whether a particular effort was relevant to the topic of interest?
- What characteristics of studies will lead to exclusion?
- Will relevance decisions be based on a reading of report titles? abstracts? full reports?
- Who will make the relevance decisions?
- How will the reliability of relevance decisions be assessed?
- The reviewers should give a few examples of studies that would be included and excluded.

A Campbell Review can include evidence from studies of the implementation of an intervention. These studies can identify factors that enable/impede the implementation process and they can describe the subjective experience of the people providing and/or receiving the intervention or the process of implementing a particular intervention. This evidence can derive from studies using a range of methods and include both qualitative and quantitative data.

When editors of the protocol examine the inclusion criteria they will be critically evaluating the reviewers' notions about how concept or intervention definitions correspond with research operations and outcomes. Considerable debate about the conclusions of a particular review may focus on these decisions by the reviewers. Some editors (and readers of the completed review) may find that the inclusion criteria were too broad – for example, they may believe that some intervention realizations and/or outcome measures were unrelated or irrelevant to the goals of an intervention. The reviewers should anticipate these concerns and propose to employ distinctions in outcomes as a potential moderator of study results (see below). Other editors may find the intervention and outcome definitions are too narrow. This may lead them to examine excluded studies to determine if they should, in fact, be included in the review.

Search strategy for identification of relevant studies. Second, the reviewers should present the details of their proposed search for studies. This should include a listing and description of the search strategy to be used to retrieve studies (e. g., reference databases, personal contacts, hand searches of journals). It is also good to include a rationale for the choice of literature sources, especially with regard to how different sources will be used to complement one another in order to reduce potential differences in the outcome of retrieved studies versus those that may go undiscovered.

The reviewers need to report the years covered and the keywords that will guide the search for reference databases and bibliographies. Information on the sources, keywords and the keyword searching strategies, and years covered by the literature search is a crucial aspect of the review methods. It gives the editors the best indication of the thoroughness and potential biases of the search and, therefore, how much credibility could be placed in the conclusions of the proposed review. Reviewers also need to describe the mechanisms they intend to use to retrieve potentially relevant documents, especially ones that are unpublished. In terms of future attempts at replication, it is the description of the literature search that would be first examined when other scholars try to understand why different reviews on the same topic area have come to similar or conflicting conclusions.

As far as is possible, it is important to take an international perspective when searching the literature. The evidence in a review should not be restricted by the nationality of investigators or samples or by language unless there is good justification for this.

Description of methods used in primary research. In addition to this general description of the included evidence, the methods section of a protocol should describe methodologies often found in the primary research covered by the review. This section focuses more on participant sampling procedures, research design, and measurement techniques than on conceptual intervention realizations. The reviewers should choose a few studies that exemplify the methods used by many studies and present the details of these investigations.

Criteria for determination of independent findings. A fourth important methodological topic involves how the reviewers intend to handle instances in which a single evaluation of effectiveness provides data on multiple outcome measures. This can happen because several types of outcomes are measured within the same study (e. g., recidivism and school attendance within a study of intervention effects on juvenile delinquency) and/or because the same outcome is measured at multiple points in time. In such cases, the outcome measures are taken on the same sample of participants and, therefore, are not independent estimates of intervention or treatment effect. An explanation of the criteria used to determine whether multiple outcomes from the same or related evaluations are independent data points should be carefully spelled out.

Details of study coding categories. A fifth subsection of methods should describe the characteristics of the included studies that will be retrieved and retained for examination as potential moderators of study outcomes. The study outcomes of interest also should be described and if some outcome measures are excluded a rationale should be given for this decision. All retrieved characteristics should be mentioned even if some of these characteristics eventually are not formally tested or discussed in the final paper. This will alert the editors to characteristics reviewers might have omitted but believe are important to include. Also, information on how coding reliability will be established and monitored should be described in this subsection.

Related to study-level mediators, the section should also describe how moderating (i. e., contextual factors that modify a process) and mediating variables (i. e., variables within a causal sequence that influence the effect of one variable on another) tested in the included studies will be represented in the review.

Statistical procedures and conventions. The sixth topic described in the methods section of a protocol are the procedures and conventions the reviewers intend to use to carry out the quantitative analysis of results. The reviewers should answer questions such as:

- What software package will be used to conduct the analyses?
- How will statistics describing the overall literature be presented?
- Why was a particular effect size metric chosen?
- Will any adjustments to effect sizes be used to remove bias?
- How will data that are missing be handled?
- What techniques will be used to combine results of separate tests? If no quantitative synthesis of results will be carried out, what is the rationale for the use of the alternative approach?
- What techniques will be used to assess and then analyze the variability in findings across tests?
- What sensitivity analyses (i. e., tests of the impact of such decisions on the results of the review) will be carried out and how?

This section should contain a rationale for each procedural choice and convention and consider what the impact of each choice might be upon the outcomes of the review.

Treatment of qualitative research. In the context of a Campbell review, qualitative studies in the relevant field can (a) contribute to the development of a more robust

intervention by helping to define an intervention more precisely, (b) assist in the choice of outcome measures and assist in the development of valid research questions, and (c) help to understand heterogeneous results from studies of effect.

When a review contains descriptions of qualitative research relevant to the topic of interest, the reviewers should operationally describe the (a) criteria for inclusion and exclusion of studies, (b) methods used in primary research, (c) criteria for determining independent findings and (d) characteristics of included studies in the same detail as they do for quantitative research.

### *5. Timeframe*

A timetable with target dates for accomplishing key tasks can help with scheduling the time needed to complete a review. Such a timeframe should be included in a protocol. Targets may vary widely from review to review depending on its scope and complexity, as well as the resources available. Reviewers, together with the editors of their Collaborative Review Group, must determine an appropriate timeframe for a specific review. Examples of some benchmarks to be used in setting targets are the anticipated dates for completion of:

- Searches for published and unpublished studies
- Pilot testing of inclusion criteria
- Relevance assessments
- Pilot testing of study codes and data collection
- Extraction of data from research reports
- Statistical Analysis
- Preparation of report

### *6. Plans for Updating the Review*

Reviews should include in the protocol specifications for how the review, once completed, will be updated. This should include, at a minimum, information on who will be responsible and the frequency with which updates can be expected.

### *7. Acknowledgments*

Acknowledgment should be made of all individuals contributing to the preparation of the protocol who were not listed on the cover sheet.

### *8. Statement Concerning Conflict of Interest*

Campbell Reviews should be free of any real or perceived bias introduced by the receipt of any benefit in cash or kind, any hospitality, or any subsidy derived from any source that may have or be perceived to have an interest in the outcome of the review. It is a matter of Campbell Collaboration policy that direct funding from a single source with a vested interest in the results of the review is not acceptable.

Reviewers should report any conflict of interest capable of influencing their judgments, including personal, political, academic, and other possible conflicts, as well as financial conflicts. It is impossible to abolish conflict of interest, since the only person who does not have some vested interest in a subject is somebody who knows nothing about it. Financial conflicts of interest cause the most concern. They can and should be avoided, but must be reported if there are any. Any secondary interest (such as personal conflicts) that might unduly influence judgments made in a review (concerning, for example, the inclusion or exclusion of studies, assessments of the validity of included studies or the interpretation of results) should be reported.

Disclosing a conflict of interest does not necessarily reduce the worth of a review and it does not imply dishonesty. However, conflicts of interest can influence judgments in subtle ways. Reviewers should include statements in their protocol about potential conflicts even when they are confident that their judgments will not be influenced. Editors may decide that disclosure is not warranted or they may decide

that readers should know about such a conflict of interest so that they can make up their own minds about how important it is. Decisions about whether or not to publish such information should be made jointly by reviewers and editors.

### *9. References*

The protocol should include complete references to all cited works. References and other stylistic considerations should follow the guidelines of the American Psychological Association:

American Psychological Association. (1994). *Publication Manual of the American Psychological Association* (4th Ed.). Washington, DC: Author.

### *10. Tables and Figures*

Any tables and figures included in the protocol should appear after the text.

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## **III. REGISTERING A PROTOCOL**

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Once a proposed protocol has been completed it should be sent to the appropriate Collaborative Review Group editors. When the editors are satisfied that the protocol meets the standards of the Campbell Collaboration they will include it in the Review Group's module for publication in the Campbell Database of Systematic Reviews. Publishing protocols may encourage interested parties to contact the reviewers and may discourage others from undertaking a review on the same topic. Editors and reviewers should not include a protocol in a module unless there is a firm commitment to complete the review within a reasonable timeframe and to keep the review up-to-date once it is completed.

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## **IV. CHANGES IN PROTOCOLS**

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Just as protocols for primary research must frequently be changed to adapt to unanticipated circumstances (such as problems with participant recruitment, data collection, or unexpected events), changes in a review protocol are sometimes necessary. While every effort should be made to adhere to a predetermined protocol, it is recognized that this is not always possible or appropriate. Changes in the protocol should not be made on the basis of how they affect the results of the review. Post hoc decisions (such as excluding selected studies) that are made when the impact on the results of the review is known are highly susceptible to bias and should be avoided. As a rule, when possible analyses should be performed to show the effect of the change on the results of the review.

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## **V. PROTOCOL CITATION**

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When the protocol is converted into a full review, the fact that this review was preceded by a published protocol should be noted. It is Campbell Collaboration policy that protocols that have not been converted into full reviews within two years will be withdrawn from the Campbell Database of Systematic Reviews.

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## **VI. OTHER SOURCES OF ASSISTANCE WITH PROTOCOL DEVELOPMENT**

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In addition to the guidelines presented above, prospective reviewers will find sound advice for proposing and conducting Campbell Reviews in the following works:

(a) Clarke M & Oxman A. D. (Eds.). (2000). Cochrane reviewers handbook: Version 4.1. In: ReviewManager (RevMan) [Computer program]. Version 4.1. Oxford, England: The Cochrane Center. (Available on-line at: <http://www.cochrane.org/cochrane/hbook.htm>).

(b) Cooper, H. & Hedges, L.V. (Eds). (1994). The handbook of research synthesis. New York: Russell Sage Foundation.

(c) National Health Service Centre for Reviews and Dissemination. (2000). Undertaking systematic reviews of research on effectiveness. York, England: University of York. (Available at: <http://www.york.ac.uk/inst/crd/report4.htm> ).

Finally, reviewers may contact the Campbell Secretariat for further guidance in preparing Campbell Review protocols.