

Campbell Policies and Guidelines Series No. 1

May 2014

Campbell systematic reviews: policies and guidelines

Version 1.3



Colophon

Title	Campbell systematic reviews: policies and guidelines
Authors	The Campbell Collaboration
DOI	10.4073/cpg.2016.1
No. of pages	44
Last updated	24 November 2017
Citation	The Campbell Collaboration. Campbell systematic reviews: policies and guidelines Campbell Policies and Guidelines Series No. 1 DOI: 10.4073/cpg.2016.1
ISSN	2535-2458
Copyright	© The Campbell Collaboration This is an open-access article distributed under the terms of the Creative Commons Attribution License, which permits unrestricted use, distribution, and reproduction in any medium, provided the original author and source are credited.
Editors	Eamon Noonan, The Campbell Collaboration Simon Goudie, The Campbell Collaboration
Acknowledgement	Campbell systematic reviews: policies and guidelines was drafted by the Campbell Collaboration's Steering Group in May 2014.
Editor-in-Chief	Vivian Welch, The Campbell Collaboration, Canada
Chief Executive Officer	Howard White, The Campbell Collaboration, UK
Managing Editor	Chui Hsia Yong, The Campbell Collaboration, Norway
	The Campbell Collaboration was founded on the principle that systematic reviews on the effects of interventions will inform and help improve policy and services. Campbell offers editorial and methodological support to review authors throughout the process of producing a systematic review. A number of Campbell's editors, librarians, methodologists and external peer-reviewers contribute.
	The Campbell Collaboration P.O. Box 7004 St. Olavs plass 0130 Oslo, Norway www.campbellcollaboration.org

Table of contents

TAI	TABLE OF CONTENTS		
1	CAMPBELL COLLABORATION SYSTEMATIC REVIEWS: POLI	CIES	
AN	D GUIDELINES	5	
2	GENERAL CONSIDERATIONS IN PLANNING A CAMPBELL		
RE	VIEW	6	
2.1	What is a Campbell Systematic Review?	6	
2.2	Appropriate Topics for Campbell Reviews	6	
2.3	Methodological Standards for the Research Covered in Campbell Reviews	9	
2.4	Review Team for Conducting a Campbell Review	11	
3	PROPOSING, PREPARING, SUBMITTING, AND PUBLISHING	Α	
CA	MPBELL REVIEW	12	
3.1	The Key Documents	12	
	3.1.1 Title registration	12	
	3.1.2 Review protocol	13	
	3.1.3 Completed review	13	
	3.1.4 Expected timeline for completing a Campbell review	15	
3.2	Publication	16	
3.3	Disputes	16	
4	TITLE REGISTRATION	17	
4.1	Conflict of Interest	18	
5	REVIEW PROTOCOL	19	
5.1	Format of a Protocol	19	
5.2	Contents of a Protocol	20	
	5.2.1 Cover sheet	21	
	5.2.2 Background for the review	21	
	5.2.3 Objectives of the review	22	
	5.2.4 Methods	23	
	5.2.5 References	33	
	5.2.6 Sources of support	33	
	5.2.7 Declarations of interest	33	

	5.2.8 Review authors	34
	5.2.9 Roles and responsibilities	34
	5.2.10 Acknowledgments	34
	5.2.11 Expected Timeframe	34
	5.2.12 Plans for updating the review	34
	5.2.13 Authors' responsibilities	34
	5.2.14 Publication in the Campbell Library and in Campbell Systematic Reviews	35
	5.2.15 Appendices	35
6	COMPLETED REVIEW	36
6.1	Format of a review	36
6.2	Contents of a review	36
	6.2.1 Cover sheet	38
	6.2.2 Plain Language structured abstract	38
	6.2.3 Background for the review	38
	6.2.4 Objectives of the review	38
	6.2.5 Methods	38
	6.2.6 Deviations from the Protocol	39
	6.2.7 Results	39
	6.2.8 Conclusions	41
	6.2.9 References	42
	6.2.10 Sources of support	42
	6.2.11 Declarations of interest	42
	6.2.12 Acknowledgments	42
	6.2.13 Plans for updating the review	42
	6.2.14 Appendices	42
7	REFERENCES	43
8	APPENDICES	44

1 Campbell systematic reviews: policies and guidelines

The Campbell Collaboration is an international network that supports the preparation and dissemination of high quality systematic reviews of research evidence on the effectiveness of social programs, policies, and practices. The mission of Campbell is to promote positive social change by contributing to better-informed decisions and greater effectiveness for public and private services around the world.

This document articulates the policies that pertain to the nature and production of Campbell systematic reviews as approved by the Campbell Collaboration Steering Group. It is designed to inform review teams and potential review teams about the requirements for Campbell systematic reviews, guidelines for producing them, and selected sources of further information about systematic reviews that is consistent with those requirements and guidelines. As experience with these policies accumulates and the methods of systematic reviewing evolve, this document will be periodically revised. The most current version can be found on the Campbell website and will be identified by the version number and date of adoption by the Steering Group in the upper right corner of the heading. Suggestions for revisions and comments about these policies and guidelines are welcome and can be sent via email to the Campbell Collaboration Secretariat at info@campbellcollaboration.org.

2 General considerations in planning a Campbell review

2.1 WHAT IS A CAMPBELL SYSTEMATIC REVIEW?

A systematic review summarizes the best available evidence on a specific question using transparent procedures to locate, evaluate, and integrate the findings of relevant research. Campbell systematic reviews address the effectiveness of programs, policies, and practices (and, in some instances, closely related topics) in the areas of crime and justice, education, international development, and social welfare. Campbell systematic reviews are developed through a process that helps ensure that they are accurate, methodologically sound, comprehensive, and unbiased. Every Campbell review is required to have clear criteria for eligible research, an explicit and comprehensive search strategy, systematic and replicable coding and analysis of the key features and findings of the studies reviewed, and an integrative summary of those findings.

After peer and editorial review, approved systematic reviews are published in the *Campbell Systematic Reviews* monograph series and are freely accessible worldwide on the Campbell online library. The *Campbell Systematic Reviews* publication is supported by an editorial team that provides constructive assistance for the development of the systematic review as well as quality assurance for the completed review. Training in systematic reviewing methods is also offered at regular Campbell meetings and various occasional events around the world.

2.2 APPROPRIATE TOPICS FOR CAMPBELL REVIEWS

Campbell systematic reviews are intended to inform policymakers, practitioners, researchers, and other interested parties about the extent, quality, and findings of the available research evidence on the effectiveness of social programs, policies, or practices. Suitable topics, therefore, involve the synthesis of research that investigates the effects of deliberate, organized social interventions intended to bring about change on some set of targeted outcomes that represents improvement in the conditions the intervention is designed to address for a population experiencing those conditions. At the discretion of the sponsoring coordinating group, reviews may also be accepted on topics that are closely related to interventions, e.g., the predictive validity of diagnostic or risk instruments for identifying

individuals appropriate for intervention programs, factors related to successful implementation of an intervention, cost effectiveness of an intervention, and the like.

The focus on interventions can be described in the PICOS framework (Higgins & Green, 2011), where PICOS is an acronym indicating the *P*opulation with the condition of concern, the *I*ntervention for addressing that condition, the *C*omparison involved (i.e., the counterfactual condition), the *O*utcomes on which improvement should appear, and the *S*tudy Designs used to evaluate the effects of the intervention on those outcomes. One Campbell review, for example, synthesized research on the effects of anti-bullying programs (I) on the incidence of bullying and victimization (O) in school settings for school-aged children and youth (P) relative to control conditions without such programs (C) in studies using randomized controlled trials and high quality quasi-experimental designs (S).

The policy and practice areas in which Campbell is currently able to support systematic reviews include crime and justice, education, international development, and social welfare. As described later in this document, there are Campbell coordinating groups organized to support reviews in each of these areas. Though the range of each of these groups is rather broad, there are some social policy domains that are outside their ambit. Most notable among those are medical and primary health care interventions, which are the purview of Cochrane (http://www.cochrane.org/), Campbell's larger sister organization. On overlapping topics, joint reviews with the Cochrane can be arranged. If there are questions about the suitability of a topic for a Campbell systematic review, they are best resolved by contacting a representative of the most relevant Campbell coordinating group to discuss the matter. Contact information can be found on the Campbell website.

Within the Campbell policy domains, the scope of the intervention(s) addressed in a systematic review may range from narrow to broad depending on the purpose of the review and the availability of research. Generally speaking, Campbell reviews may define the focal intervention at any of three levels of breadth:

- Specific named programs. The intervention of interest in this instance is one that follows a defined protocol or manual that specifies what it is and how it is to be delivered as well as distinguishing it from similar interventions that follow a different protocol. Such interventions usually carry a specific name that refers only to that protocol and no other. Examples of programs of this sort that appear in Campbell reviews include Brief Strategic Family Therapy (BSFT), Multisystemic Therapy (MST), Mindfulness-Based Stress Reduction (MBSR), Motivational Interviewing, and Farmer Field Schools (FFS).
- Generic types of programs or practices. A common focus for Campbell reviews is a particular type of program or practice that is not limited to a brand name version but, rather, encompasses research on all programs or practices of that type. Within a generic category of this sort, the interventions will share key defining features, but their particular form may vary in any application. Examples of interventions with this scope

that have been the focus of Campbell reviews include stress management interventions, cognitive behavioral therapy, DNA testing in police investigations, volunteer tutoring programs, hot spots policing, work programs for welfare recipients, micro-credit, and cash transfers to influence educational outcomes.

• A range of programs for a problem or population. The reviews that typically have the broadest scope cover a range of different interventions that are included because they all address a particular problem or outcome or, perhaps, the needs or conditions of a particular population. These reviews are often comparative, that is, they compare different interventions with regard to their relative effectiveness and, perhaps, cost effectiveness. Examples of reviews of this scope include programs for reducing school dropout, interventions to reduce cyber abuse, interventions to reduce drug use among prison inmates, programs to reduce pregnancy among adolescents, and interventions to encourage school attendance in developing countries.

The research a Campbell review brings to bear on the topic addressed should include all available evidence that meets the eligibility criteria for inclusion, including the criteria specifying acceptable methodological quality. This means that all studies meeting the eligibility criteria should be included, whether or not they have been formally published. Thus, dissertations, technical reports, conference papers, and other such gray literature should be included along with studies more formally published in journals and books. Note that it is not required that studies be peer reviewed in order to be eligible and exclusion of studies because they do not appear in peer reviewed publications is not appropriate for Campbell reviews (and is a known source of bias).

Where appropriate, Campbell reviews also aspire to include the international research that meets the eligibility criteria. The relevance of this objective will vary with the purposes of the review and the nature of the review topic, not all of which will be the subject of research outside of certain settings, countries, cultural contexts, target populations, etc. Where appropriate, however, the broadest possible scope of eligible research should be included with corresponding attention to differences in findings associated with different contexts. When a more circumscribed literature is appropriate to the review topic, this should be made clear in the review protocol and an explicit justification should be provided. When international research is appropriate, it should be included irrespective of the language in which the eligible studies are reported. If translation presents an obstacle, the editor of the sponsoring coordinating group should be contacted to explore the potential for assistance from Campbell. When studies must be restricted to those reported in English, an assessment should be reported affirming that this constraint does not eliminate a large or important body of research.

2.3 METHODOLOGICAL STANDARDS FOR THE RESEARCH COVERED IN CAMPBELL REVIEWS

Campbell reviews are intended to summarize both the *best* evidence available about the effects of the focal intervention(s) and *all* the evidence that provides credible estimates of those effects. The critical feature of the research methods in this regard is the ability of the basic design to yield an unbiased estimate of the effects on the target outcomes relative to a defined counterfactual condition, that is, the *internal validity* of the research design (Shadish, Cook, & Campbell, 2002). With rare exceptions, the best evidence by this standard is provided by randomized controlled trials (RCTs). When RCTs are available for the relevant intervention, outcomes, and populations, they must be included in Campbell reviews.

In many intervention areas, the circumstances under which the available RCTs have been conducted tend to be somewhat circumscribed. Those studies may be more likely to be conducted as research and demonstration projects rather than evaluating routine practice, to involve the program developer or researcher in the implementation of the intervention, to occur in atypical settings such as university clinics or especially high functioning organizations, to use participants who have been selected or screened to be especially appropriate for the intervention or who are less diverse than the general population of application, and so forth. In those circumstances, the greater internal validity of RCTs comes at least partially at the expense of external validity, that is, the generalizability of the results of the research to other settings.

In addition, because RCTs may be more difficult to conduct as a practical matter for some interventions, there may be relatively few of them. When there are studies that provide credible estimates of the effects of interest using designs other than an RCT, they provide an additional evidence base for supporting conclusions about the effectiveness of the intervention. In this regard, it is useful for a review to include all of the methodologically credible evidence about the effects of an intervention so long as the limitations of the different types of research are explicitly recognized in the review.

It is thus generally acceptable and advisable for Campbell reviews to include research studies that use designs that have inherently weaker internal validity but stronger external validity than RCTs. The extent to which that is appropriate is a judgment call, but one that should reflect consideration of both the quantity and limitations of the available RCTs and the nature of the contributions of the non-RCTs to the evidence base. If there are questions about the inclusion of designs other than RCTs in a Campbell systematic review, they are best resolved by contacting the editor of the appropriate coordinating group and the editor of the Methods Group to discuss the matter prior to proposing a Campbell review. When both RCTs and non-RCTs are included in the review, they should be reported and analyzed separately or otherwise assessed for any differences in the results they produce. The studies in each design category should also be assessed for potential bias in estimating effects and for

generalizability to representative practice in the respective domain of application. Conclusions drawn from such mixed evidence should be tempered by the respective strengths and limitations of the various categories of evidence. More specific guidance on these matters is provided later in this document in the section on the content and structure of protocols and final reviews.

When non-RCTs are included in a review, whether as a supplement to RCTs or because no RCTs are available, they must meet explicit criteria that provide some assurance that the evidence they provide is credible. That is, the designs used must have sufficient claim to internal validity to provide a reasonable basis for informing policy or practice, albeit with a recognized degree of uncertainty. In all cases, the quality of the research should be carefully assessed and described and the conclusions drawn from it should be cautious and explicit about the limitations of both internal and external validity. Moreover, the criteria for accepting non-RCTs into the review should be relatively stringent within the context of the respective research domain. For non-randomized controlled studies, for instance, appropriate criteria might require evidence of equivalence at baseline on key variables, such as a pretest of the outcome measure and relevant demographic characteristics, and/or statistical control of such characteristics.

Though there are some research contexts where designs that are inherently weaker than those described above may provide sufficiently sound evidence to be included in a Campbell review, they would be acceptable only when a convincing case can be made for them. The most notable situation of this sort is when no stronger evidence is available, especially for an intervention of a sort where RCTs or strong comparison group studies cannot be done easily or at all. In such instances, a Campbell review of the best evidence available may be acceptable with two qualifications. First, the available evidence must be relatively strong in its own terms. Such evidence might include, for instance, time-series, single case studies, or multivariate observational and econometric studies with statistical controls with each of good quality by the standards for such research when it is used to estimate intervention effects. Second, the review must be very explicit about the circumstances that have restricted the available research to such designs and the potential for bias in the evidence they produce. More detail is provided on these matters later in this document when the content and structure of protocols and final reviews are described.

Even with the qualifications indicated above, some research designs have such weak internal validity that they are categorically unacceptable in Campbell reviews as the basis for conclusions about intervention effects. These include simple before-after intervention studies without comparison groups or appropriate counterfactual conditions, studies in which no counterfactual conditions are observed or, if observed, the respective outcomes cannot be compared with replicable procedures, and other such research designs that are recognized as providing inherently poor estimates of the causal effects of interventions. Such studies may

be included for contrast, however, if they are especially relevant to the topic, e.g., widely represented in the available research, but they must be reported separately.

It may happen that, for some interventions or outcomes of interest, there is no research of adequate methodological credibility available. A Campbell review for an intervention of sufficient interest may be undertaken and reported in such instances either because the absence of qualifying research was not evident until the review was well underway, or to demonstrate that the evidence base is deficient for an important intervention.

Qualitative studies cannot be used as the primary basis for Campbell reviews or as the primary basis for conclusions about intervention effects. However, this does not mean they should be excluded from Campbell reviews. Qualitative research and other forms of descriptive research can help paint a richer picture of the intervention, its effects, how or why it produces those effects (or not), and other such features that provide texture and explanatory context to a review. Where available, the applicable findings of such research should be incorporated into the review in summary form.

2.4 REVIEW TEAM FOR CONDUCTING A CAMPBELL REVIEW

Campbell systematic reviews should not be conducted by a single researcher. A team of individuals is required to provide the relevant expertise and perform the necessary functions. An appropriate team should represent content knowledge in the substantive area of the review, familiarity with research methods for investigating intervention effects, proficiency in information retrieval and systematic literature search techniques, knowledge of systematic review methods, and statistical expertise in meta-analysis. Though some individuals may have competencies in more than one of these areas, it would be rare for a single individual to have sufficient background in all of them. For the more specialized functions, such as information retrieval and meta-analysis expertise, the Campbell coordinating group in the relevant topic area may be able to provide assistance or consultation if the team lacks members with that expertise.

In addition to the range of expertise required to conduct a systematic review, multiple review team members are needed to provide essential reliability checks on important judgments that must be made during the review process such as identification of studies meeting the inclusion criteria, extraction of data from those studies, and data entry.

Proposals for Campbell reviews may be submitted by a review team or invited by one of the Campbell coordinating groups. In either case, once a review team has been organized and has a topic in mind, the Campbell Collaboration has a standard procedure for approving the topic and working with the research team to complete the steps that lead to a finished, published systematic review.

3 Proposing, preparing, submitting, and publishing a Campbell review

3.1 THE KEY DOCUMENTS

To publish a review in the *Campbell Systematic Reviews* monograph series, there are three documents that must be submitted in succession by the review team: (a) a Title registration form, (b) a protocol for the proposed review, and (c) the completed review. Each of these is described briefly here and in more detail afterwards.

3.1.1 Title registration

The Title registration form (described in more detail in Section III below) is sent to the managing editor of the relevant coordinating group (Crime and Justice, Education, International Development, or Social Welfare). Contact information for the managing editors can be found on the Campbell website along with a copy of the title Registration form (a copy is also provided in Appendix A). The submitted form will be reviewed by the coordinating group editor and co-chairs and the editor will correspond with the contact person on the review team regarding any questions about the proposed review. The criteria used to determine whether a title will be accepted are (a) whether the proposed review overlaps with any existing Campbell or Cochrane review; (b) the appropriateness of the topic for Campbell and the particular coordinating group; and (c) the ability and appropriateness of the review team to accomplish the work.

Some review topics may be suitable for more than one of the Campbell coordinating groups. In those instances, the review team may request that the title be co-listed with more than one coordinating group or select the one they believe to be most appropriate. The editorial process for co-listed reviews will be handled by a designated lead coordinating group editor, coordinating with the co-listed group(s). The designated lead may be selected by the review team or be left for the respective editors to decide.

The registration and approval of a title with Campbell grants the review team priority rights to the topic of the systematic review; no other review team will be approved by Campbell for a review on that specific topic as long as the team is making progress toward completing the review. If the review team fails to make consistent progress toward completing the review, e.g., does not meet the milestones set out below for completion of the protocol and final

review, the sponsoring coordinating group can deregister the title and allow another review team to address the topic.

3.1.2 Review protocol

Once the proposed title is approved and registered, the next formal step is for the review team to submit a protocol for the review. The protocol is a detailed plan that explains the rationale and background for the review, its objectives, and the procedures to be used for conducting the review (described in more detail in Section IV below). The content of the protocol will be carried forward to the final review (revised as appropriate) to provide the background and methods for the review. Systematic review teams are expected to submit a draft protocol to the editor or managing editor of the sponsoring coordinating group no later than one year after approval of the title.

The submitted protocol will be peer reviewed by one or more content experts knowledgeable about the topic area of the review and by one or more methods experts knowledgeable about systematic reviewing methods. The primary methods review is organized through the Campbell Methods Coordinating Group, and both content and methods reviews are coordinated by the editor of the coordinating group in the respective topic area. When the peer reviews are completed, the coordinating group editor will provide feedback to the review team and may request that the protocol be revised and resubmitted. Once the protocol has been revised to address the concerns of the coordinating group editor and the methods editor, it is submitted to the co-chairs of the sponsoring coordinating group for final approval. Approved protocols are then published online in the Campbell Library.

3.1.3 Completed review

After the review protocol is approved, the remaining step for the review team is to conduct the review that is described in the protocol and submit it to the editor or managing editor of the sponsoring coordinating group. Review teams are expected to submit a draft of the final review no later than two years after approval of the protocol. It is Campbell policy that a protocol that has not resulted in a full review within two years can be withdrawn from the Campbell Library with the review topic then available to other interested review teams. In exceptional cases where there is a high level of interest in a particular review topic, the protocol may be withdrawn earlier if no progress is being made toward completing the review during the first year after the protocol has been approved. Each coordinating group has some leeway in enforcing this policy, and extensions may be granted, but a review team that is delayed must provide evidence of progress toward completion of the review and a reasonable projected completion date. It is also advisable for review teams to update the coordinating group editor or managing editor on their progress at least every six months following the approval of the protocol and report on any problems that may impede timely delivery of the draft review. The draft review manuscript will be peer reviewed in much the same way as was done for the protocol, typically by the same peer referees. This will involve one or more referees with content expertise and one or more with systematic review methods expertise. When the peer reviews have been received, the coordinating group editor will provide feedback on the review manuscript and may request revisions which, when received, may or may not go out for further peer review at the editor's discretion. Upon approval of the final completed review by the coordinating group editor, the methods editor, the co-chairs of the sponsoring coordinating group, and the editors-in-chief, it will be published in the online *Campbell Systematic Reviews* monograph series and made available on an open access basis for download by all interested parties.

As is evident, this is a rather rigorous process designed to ensure the highest possible quality in published Campbell reviews. Nothing less is appropriate for a publication intended to provide sound summaries of the relevant evidence to policymakers and practitioners who want to know if the respective interventions are effective. At the same time, Campbell intends for this to be a supportive process that assumes at the outset that every review with an approved title registration will be completed and published in acceptable form. In this spirit, editors and other members of the respective coordinating groups will make every effort to help review teams develop acceptable protocols and complete publishable reviews. If these efforts do not result in an acceptable protocol or publishable review after successive attempts by all parties, or the process is unduly prolonged, the respective coordinating group editor, with the concurrence of the coordinating group co-chairs, can deregister the review and decline to publish the protocol and/or completed review.

In addition, there is another procedure for publishing a Campbell systematic review. Review teams that have completed a systematic review outside of the Campbell editorial process may submit it to the editor of the appropriate coordinating group. To be considered for publication in Campbell Systematic Reviews in this fashion, the review must conform to the Campbell standards for content and organization, as described later in this document. The coordinating group editor, in consultation with the Campbell Systematic Reviews editors-inchief, will determine whether the submitted review is appropriate for possible publication. If so, the editor will arrange for content and method peer reviews of the same sort described above. The editor will then provide feedback to the review team about what revisions, if any, are required for the review to be published, or will reject it if it is not judged to be publishable even with revision. Upon submission of a draft acceptable to the editor and approved by the co-chairs of the relevant coordinating group and the editors-in-chief, the review will be published in Campbell Systematic Reviews in the same fashion as a review developed through the usual Campbell editorial process, but with a statement indicating why a title registration and protocol are not available. Any systematic review accepted under this alternative procedure must not be a duplicate of a version published elsewhere. Though this procedure is available to interested review teams, the regular three-step process summarized

above is more likely to lead to a favorable outcome for any team that is not already very familiar with the Campbell standards and procedures.

To stay current, Campbell reviews must be periodically updated, and usually this is most easily done by the team that conducted the original review. That team, therefore, will have the opportunity to conduct an update during the first five years after a review is published without that option being available to any other team unless the original team explicitly waives their claim on that opportunity. After five years without an update, the topic will become open to any team interested in conducting a new review on that topic with or without collaboration with the original team. However, on topics with rapidly developing research, the sponsoring coordinating group may set an earlier date for expiration of the original review and offer the topic to another team if the original team declines to undertake an update. All updated reviews, or a new review that supplants an existing review, will go through the same full editorial review as a new review though, at the discretion of the respective editor, an expedited procedure may be used. If a review is updated by either the original team or a new team, the prior published review will remain in *Campbell Systematic Reviews* but a note will be added to indicate that it has been superseded by a more recent version.

3.1.4 Expected timeline for completing a Campbell review

For convenience, Campbell policies relating to timely completion of systematic reviews mentioned above are summarized here as follows:

- The process of producing a systematic review for publication in *Campbell Systematic Reviews* begins with submission of a title registration form.
- The review team is expected to submit a draft protocol to the editor or managing editor of the sponsoring coordinating group no later than one year after approval of the title.
- The review team is expected to submit a draft of the final review no later than two years after approval of the protocol.
- The original review team will have an exclusive option to update the review within the five years after it is published, after which the topic becomes open for any team to propose conducting a new review on that topic.

However, the sponsoring coordinating group may modify these policy guidelines according to the circumstances of any particular review. The time allowed may be extended if progress is being made despite exceeding the expected target date or, in rare instances, an earlier date may be set if no progress is being made and there are exceptional reasons why a timely review is desired.

3.2 PUBLICATION

Approved reviews are published in the online *Campbell Systematic Reviews* monograph series, usually within two months. Approved title registrations and protocols are published in the Campbell Library on a similar schedule.

Review authors retain rights to their work, and hence the right to publish the Campbell review findings elsewhere, in accordance with the Creative Commons Open Access license agreement. There is one condition of co-publication: the Campbell review must remain free for dissemination in any and all media without restriction. To ensure this, Campbell authors sign an open access license agreement, and may not sign over exclusive copyright of the Campbell review to any journal or other publisher. A journal or other publication is thus free to request a nonexclusive copyright that permits it to publish and re-publish a Campbell review, but this cannot restrict the publication of the review by Campbell or other parties.

Campbell reviews are monographs that are typically longer and more detailed than journal article versions of a systematic review and *Campbell Systematic Reviews* is explicitly presented as an online monograph series. Campbell places no restrictions on publication of the findings of a Campbell systematic review in a more abbreviated form as a journal article either before or after the publication of the monograph version in *Campbell Systematic Reviews* (note, however, that reviews co-registered with Cochrane must also adhere to the Cochrane publication policy). Some journals have restrictions that preclude publication of findings that have been, or will be, reported elsewhere and authors considering publication in such a journal should be aware of such possible conflicts with publication of the monograph version in *Campbell Systematic Reviews*. Publication in a journal after publication or in press status in *Campbell Systematic Reviews* should acknowledge the Campbell version and include a citation to it.

3.3 DISPUTES

The editorial work of Campbell is carried out primarily by the editors and managing editors of the coordinating groups, including the Methods Coordinating Group. Two editors-in-chief oversee the editorial process and are responsible for maintaining the quality of Campbell reviews and for final approval of all review protocols and completed reviews. In the event of a dispute between an editor and a review team that they are unable to resolve, the matter can be referred by either party to the editors-in-chief to mediate and, as needed, to make a final decision.

In the sections that follow, more detail is provided about the guidelines and policies that apply to title registration, review protocols, and completed reviews.

4 Title registration

The purpose of the title registration procedure is twofold. First, it allows the coordinating group editor to determine if the proposed review topic falls within the scope of the coordinating group and whether it is substantially similar to a review that has already been published in *Campbell Systematic Reviews* or the Cochrane Library, or one that is underway. Note that a prospective review team is advised to check for duplicates themselves before proposing their review. The Campbell Library, online at http://www.campbellcollaboration.org/, includes copies of all approved title registrations and protocols as well as completed reviews. On some topics, it may also be appropriate to check for overlapping reviews in the Cochrane Library (http://www.cochrane.org/). If similar work exists or is underway, the editor may suggest that the proposed team contact the existing or prior review team to consider coordinating their efforts.

The second purpose of the title registration process is to provide the editor with sufficient information to determine if the proposed review is generally in line with the standards and guidelines for Campbell systematic reviews. The title registration form asks the review team to specify the review question and provide basic information about the review topic, the target population, the outcomes of interest, and the nature of the research studies expected to provide credible evidence addressing the review question. It also asks about the composition of the review team and the planned completion date of the protocol and review.

The editor may ask for revisions in the title registration form to avoid overlap with another review or to bring it into better alignment with the expectations for a Campbell review. When the title registration describes an appropriate Campbell review and review team and is approved by the co-chairs of the sponsoring coordinating group, the editor will inform the review team so that they may proceed with the development of their protocol. The review title is then registered with the Campbell Secretariat and the title registration form is added to the online Campbell Library. Some review topics may be appropriate for co-registration with both Campbell and Cochrane. For more information about co-registration, contact the editor of the respective coordinating group.

The Campbell title registration form can be found on the Campbell website (<u>http://www.campbellcollaboration.org/</u>) and a copy is provided in Appendix A of this document.

4.1 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 policy that direct funding from a single source with a vested interest in the results of the review is not acceptable.

The members of a review team proposing a Campbell systematic review should read the Campbell conflict of interest policy (found on the Campbell website and in Appendix D). The title registration form includes an item asking about any potential conflict of interest by any member of the proposed review team, and each of them will be asked to provide a signed conflict of interest disclosure form at the time the review protocol is submitted (a copy is attached to the Campbell conflict of interest policy in Appendix D).

Members of review teams should report any conflict of interest that could be viewed as possibly influencing their judgments, including personal, political, academic, and other possible conflicts, as well as financial conflicts. 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 also be reported.

Disclosing a conflict of interest does not necessarily reduce the worth of a review and does not imply dishonesty. However, conflicts of interest can influence judgments in subtle ways, therefore members of review teams should identify potential conflicts even when they are confident that their judgments will not be influenced. In the rare cases where the conflict of interest is such that it may seriously compromise or have the appearance of potentially compromising the integrity of the review, the editors will consult the co-chairs of the respective coordinating group and the editors-in-chief of *Campbell Systematic Reviews* to determine whether the review should proceed under Campbell auspices.

5 Review protocol

A Review protocol is a document that sets out the intentions of the review team with regard to the background and purpose of the review and the methods to be used in carrying it out. The protocol has several purposes. It requires the review team to develop a detailed plan for completing the review that, in turn, allows the editor and peer referees to provide guidance and advice that will help ensure that the final completed review will meet the standards of Campbell. This is especially important for review teams that have not completed a prior Campbell review or that have limited experience conducting a systematic review. The protocol provides an opportunity for potential problems or misunderstandings to be identified and addressed during the planning stage to avoid as much as possible needing to redo aspects of the review itself to remedy problems.

Another purpose of the protocol is to help make the review process as well-defined, systematic, and unbiased as possible while maintaining a practical perspective. Preparing a review is a complex process that involves many judgments and decisions. As in any scientific endeavor, the results are better protected from bias if the methods for producing them are established beforehand rather than selected with knowledge of the results they produce. The protocol thus represents an a priori commitment to conduct the review in a certain way. Though the methods used may evolve during the course of the review as unanticipated limitations or issues are encountered, the protocol provides a touchstone for judging whether such changes might shape the results differently. Review teams are thus asked to note any departures from the protocol in their completed reviews and explain their rationale.

5.1 FORMAT OF A PROTOCOL

A template for the Campbell review protocol is available on the Campbell website (http://campbellcollaboration.org/) and in Appendix B of this document. It provides guidelines for the format of the protocol as well as the headings for the major sections expected in a Campbell review.

Any tables and figures included in the protocol should be embedded in the text in proximity to the discussion that refers to them. A table should not be split across pages unless it is too long to fit on a single page.

5.2 CONTENTS OF A PROTOCOL

The protocol for a Campbell systematic review should follow the outline provided below and use the headings indicated or analogous wording tailored to the specific review topic. Other sections and headings may be inserted in appropriate places, as needed, to address topics specific to the proposed review. The sections below, however, are required elements of the protocol. The template for a Campbell review protocol incorporates the appropriate formatting and structure for the protocol. Note that reviews that are co-registered with Cochrane may use a somewhat different format; consult with the managing editor of the respective coordinating group for details.

The major components of a Campbell review protocol are as follows:

- Cover sheet
- Background for the review
 - The problem
 - The intervention
 - The rationale for the intervention
 - Prior reviews
 - The contribution of this review
- Objectives of the review
- Methods
 - Characteristics of the studies relevant to the objectives of the review
 - Criteria for inclusion and exclusion of studies in the review
 - Search strategy for finding eligible studies
 - Data extraction and study coding procedures
 - Risk of bias
 - Synthesis procedures and statistical analysis
 - Treatment of qualitative research
- References
- Sources of support
- Declarations of interest
- Review authors
- Roles and responsibilities
- Acknowledgements
- Expected timeframe
- Plans for updating the review
- Authors' responsibilities
- Publication in the Campbell Library and in Campbell Systematic Reviews
- Appendices

Within this framework, review teams are strongly encouraged to make use of the MECIR *Methodological Standards for the Conduct of Cochrane Intervention Reviews* to ensure that all the relevant issues have been considered in the preparation of the protocol. Many elements of these standards are appropriate to all Campbell systematic reviews and addressing them will be expected by the respective coordinating group editor. Questions about the applicability of particular items should be addressed to that editor. Copies of the MECIR standards are available on the Cochrane website (<u>http://www.editorial-unit.cochrane.org/mecir</u>) and in Appendix E. When submitting a protocol, it should be accompanied by a checklist affirming that each of the above sections is represented in the protocol. Alternatively, a checklist identifying the MECIR items addressed may be submitted. A description of each section of the protocol follows with the relevant MECIR items for each identified.

5.2.1 Cover sheet

The cover sheet of the protocol should include:

- The title of the review. Titles should be as descriptive, direct, and self-explanatory as possible with regard to the intervention, the target population, and the outcomes; for example, "Self-control interventions for children under age 10 for improving self-control, delinquency, and problem behaviors" and "Home visits for prevention of impairment and death in elderly people." Titles should start with a label for the intervention if possible and should end with a colon and the phrase: "A systematic review."
- The names and affiliations of the authors in the expected order of authorship.
- Identification of the Campbell Coordinating Group to which the protocol is being submitted.
- Indication of any plans the authors have to co-register the review, e.g., with Cochrane, or co-publish it.
- The date on which the protocol is submitted.

5.2.2 Background for the review

The background section describes the intervention and its expected outcomes, explains why the issues being addressed are important or controversial, summarizes prior research reviews, and sets out the rationale for the proposed Campbell systematic review.

The topics appropriate to address in the background section of the protocol (and the later completed review) will depend in large part upon the nature of the intervention, its history and applications, and the findings of prior research. The following topics are generally pertinent to all intervention areas and are suggested as guidelines for the content of this section.

- The problem: A description of the problem, condition or issue that the intervention is intended to ameliorate and the population, settings, or situations in which those conditions occur.
- The intervention: A description of the intervention of interest for the review, its components, and its variants in terms that will be understandable to someone unfamiliar with the intervention. Examples will help the reader gain a better understanding of the intervention and its application. This description should be informative about the nature of the intervention and such particulars as how it is delivered, by whom, to whom, when, for how long, and the like. It should also set a tone that does not pre-judge the value of the intervention.
- The rationale for the intervention: A brief description of the theoretical underpinnings of the intervention and the mechanism by which it is expected to bring about the expected outcomes, that is, the presumed causal pathway between the intervention and its intended (and possibly some unintended) effects. A logic model might be an informative way to depict this (Anderson et al., 2011). The rationale should define the intervention of interest and its components, specify important outcomes, and indicate intermediate outcomes or pathways through which the intervention is intended to affect the outcomes. An explanation should be offered if only a component of an intervention is being reviewed and should identify other reviews that may be needed to complete the evidence picture.
- Prior reviews: A summary of the findings of prior research with particular attention to narrative and systematic reviews on the topic. This summary should highlight what has been learned from past efforts but also point out any inconsistencies, methodological strengths and weaknesses, gaps in the evidence, or ambiguities about the results of this research. The rationale for the proposed review should follow from this discussion of the current state of research and research synthesis on the topic of the review.
- The contribution of this review: A statement about the contribution the proposed review is intended to make against the background provided by the previous discussion. This statement should explain why the review is needed and what it will provide that is not already available in prior reviews. Particular attention should be given to the potential practical value of the proposed review—how it is expected to inform practice or policy.

See appendices E and F below (MECIR Standards)

5.2.3 Objectives of the review

This section should present a concise set of statements that identify the 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 intervention effects through the synthesis of individual study results; (b) find reasons for conflicting evidence; (c) answer questions using variation across studies that cannot be answered in the individual source studies; (d) identify and explore variations in practice; (e) review the evidence on the experience of an intervention; and/or (f) build connections between related areas of research. While Campbell systematic reviews might be motivated by any of these or other reasons, their overarching aim should be to gather, summarize and integrate empirical research so as to help readers understand the evidence that bears on the review topic. The review objectives, therefore, should be stated in such a way that they are readily understandable by a nontechnical reader and the context and motivation for each of them should be evident from the discussion in the prior background section.

In setting out the objectives, review teams should keep in mind that Campbell systematic reviews are intended to help readers make practical and/or policy decisions about social and behavioral interventions. This has important implications for deciding whether and how to undertake a Campbell systematic review, how to formulate the topic 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 be relevant to the choices decision makers face when deciding about adopting a policy or practice.

See appendices E and F below (MECIR Standards)

5.2.4 Methods

The purpose of the methods section of a protocol is to describe operationally how the review will be conducted (and it should, therefore, be written in the future tense). Campbell reviews should be based on explicit, transparent, and reproducible methods and procedures. This methods section, therefore, is central to the protocol and should be presented in sufficient detail to allow a knowledgeable reader to assess the quality and appropriateness of the plan for conducting the review and, if desired, to reproduce the main features and findings of the subsequent review by following that plan.

Production of the final completed review will be expected to follow the plan set out in the protocol except for any well-justified modifications required by experience with application of the plan. Any departures from the plan presented in the protocol should be identified and explained in the final review.

5.2.4.1 Characteristics of the studies relevant to the objectives of the review

This section of a protocol should describe the general nature of the research that will be reviewed pursuant to the objectives of the review. Its purpose is to provide a context for the proposed methods and procedures that follow and to acquaint peer referees and editors with the respective research domain. Of principal interest in this section are the methods used in the research that will be covered in the review. Features of interest, for example, might include the nature of the participant samples represented in the research and the sampling procedures used to obtain those samples; typical research designs and particular design issues or limitations inherent in the research domain; and the range and nature of the outcome variables examined, the types of measures used, and any recognized measurement issues. Where applicable, a distinction should be made between primary and secondary outcomes and the protocol should identify any specific focus on adverse outcomes or whether any adverse outcomes are relevant for consideration. Brief descriptions of two or three representative studies should be provided to illustrate the characteristic methods and methodological considerations in the respective research domain.

See appendices E and F below (MECIR Standards)

5.2.4.2 Criteria for inclusion and exclusion of studies in the review

Very explicit and well-defined criteria should be specified for the research studies that are deemed appropriate to include in the review. These criteria should allow for inclusion of all of the extant research that provides acceptable evidence directly related to the objectives of the review while also defining what constitutes acceptable evidence for the purposes of the review. Where the rationale for a criterion is not evident in relationship to the objectives of the review, an explanation for its application should be provided.

The inclusion criteria should be stated specifically enough, with key terms clearly defined, to be applied with consistent results by anyone screening candidate research studies. They should include features of the research such as the following, as well as any other features distinctive to the topic of the review, as appropriate to the objectives of the review.

- *Interventions:* Any defining features of the intervention(s) of interest and the acceptable variants. These criteria may also need to specify whether studies are eligible that only involve part of a multipart intervention or that combine the intervention with other interventions or components. Any interventions or variants of the intervention to be explicitly excluded should be noted as well.
- **Participants:** Any characteristics of the population, participants, or units to which the intervention is applied that make the study eligible and, conversely, the characteristics that exclude it. If relevant, these criteria should also specify whether studies with participant samples that include only some of the eligible participants are eligible and, if so, under what circumstances.
- **Outcomes:** Any specifications for the outcomes that are the focus of the review. Any applicable criteria should be specific with regard to how those outcomes are defined so they can be recognized even when they are characterized in different terms or with different labels in a research report. They might also specify any requirements for the kinds of measures used to assess those outcomes, the timing of measurement, how

the outcome data are collected, and the like. Any adverse outcomes of interest, or that might constitute negative side effects should also be specified in these criteria.

• **Research methods/designs:** These criteria should take account of the Campbell guidelines for the research methods that are viewed as providing appropriate evidence for Campbell reviews described above (Part I, Section C). Most critically, these criteria should specify the counterfactual conditions eligible for consideration and the acceptable research designs for estimating the effects of the intervention relative to the counterfactual on the outcomes of interest. The requirements for eligible methods should orient above all to minimizing the potential for bias in the research findings about the direction and magnitude of the effects of the intervention (internal validity). At the same time, they should not be so restrictive that they undermine the generalizability of the findings to the domains in which the intervention is actually used (external validity). These methodological criteria should also be explicit about any research methods known to be used in the topic area that are to be categorically excluded. Further criteria should be delineated for any other aspects of the research sample is selected, the statistical analyses performed, etc.

The specific research designs eligible for the review should be described in sufficient detail to allow independent researchers to replicate the inclusion/exclusion decisions. For example, simply stating that "experiments (RCTs) and quasi-experiments will be included" is not sufficient. What are the features an RCT must have to be eligible? And the term "quasi-experimental" refers to a large category of research designs, not all of which are likely to be appropriate. If, for instance, non-equivalent comparison group quasi-experimental designs with a pre-test baseline assessment are eligible, then that should be stated explicitly with a specification of the baseline measures that must be included. This is a complex but critical issue—review teams should err on the side of more detail rather than less.

• **Other criteria:** Any restrictions by date, language, geography, publication status, or other study characteristics. Any criteria of this sort should take into consideration the Campbell standards for inclusion of the relevant international literature and unpublished research (to avoid publication bias); see the guidelines for searching the research literature below. If the review is to include research other than that estimating intervention effects, e.g., qualitative or descriptive research, the criteria for selecting those studies should be itemized here as well.

These inclusion criteria should reflect the objectives of the review in a straightforward way. Where it is not readily apparent how particular criteria relate to those objectives, a justification should be provided for their appropriateness. This section of the protocol should also address the procedure for applying the inclusion criteria to candidate studies. This should include consideration of the decision rules for determining when more than titles should be examined, when more than abstracts should be examined, and when the full report should be examined. Further, the procedures for ensuring the reliability of the decisions made during the screening of studies should be described. The preferred procedure is for at least two members of the review team to independently screen candidate studies and resolve discrepancies by consensus. Where large numbers of studies are involved, samples of the candidate studies might be drawn and rescreened to estimate the reliability of the inclusion decisions.

See appendices E and F below (MECIR Standards)

Resources for review teams:

Campbell training videos on problem formulation

<u>Cochrane Handbook</u>, Chapter 5: Defining the review question and developing criteria for including studies

Petrosino, A.J. (1995). <u>Specifying Inclusion Criteria for Meta-Analysis</u>. Evaluation Review, 19, 274-295.

5.2.4.3 Search strategy for finding eligible studies

Campbell reviews should be based on a comprehensive search for eligible studies that includes the relevant international literature. Where a more circumscribed scope is appropriate to the nature of the topic or the purposes of the review, the rationale for that constraint should be explained. Campbell reviews should also include both formally published and unpublished research reports (referred to as the gray literature) such as dissertations, technical reports, and conference presentations. Multiple sources should be used to identify candidate studies, such as searches in electronic bibliographies, internet searches, review of citations in the relevant studies found and studies that, in turn, cite those studies, manual searches of highly relevant journals, correspondence with researchers active in the respective research area, and the like. The justification for any departures from these standards should be explained.

In addition, the search strategies used should be explicitly documented in sufficient detail to permit replication. This section of the protocol should present the details of the proposed search strategy. This should include a listing and description of the sources to be used and the rationale for those sources. The protocol should report the years to be covered in the search with each source and, where applicable, the specific keywords and keyword combinations that will be used in the search, e.g., in reference databases and bibliographies. It is advisable to consult with an information retrieval specialist when planning the search strategy and necessary to have someone on the review team, or available to the research team, who is experienced with systematic searches in research literatures.

The protocol should also describe the mechanisms that will be used to retrieve candidate studies, especially those that are unpublished. The nature of the available library resources should be described, for instance, and the procedures for locating potentially eligible studies that cannot be obtained through those library resources.

See appendices E and F below (MECIR Standards)

Resources for review teams: Campbell training videos on information retrieval Information retrieval policy brief Cochrane Handbook, Chapter 6: Searching for studies PRISMA Flowchart for reporting results of searches

5.2.4.4 Data extraction and study coding procedures

Campbell reviews should be based on data that are extracted systematically and reliably from each eligible study using procedures that are sufficiently well documented to allow other researchers to replicate the production of those data from the same source studies. The data that result from the coding procedure should be compiled in a database that is also well enough documented to be used by another researcher to replicate the results of the review.

In this section of the protocol the review team should describe the coding scheme that will be used for data extraction from each study and the procedures planned for accomplishing the coding with a high degree of reliability. The coding scheme, at minimum, should be designed to provide data for three different purposes. One purpose of the coding is simply to provide a descriptive profile of the body of research included in the review. This profile should include such study features as the year in which the study was reported, the setting and other relevant contextual features, and the general characteristics of the participants, the interventions, the outcomes and the study methods. Some of the items coded to describe this profile may serve only to describe the body of research to readers of the review; some of them may also serve as moderator variables in the analysis, as described below.

A second purpose of the coding scheme is to extract information that can support the construction of moderator variables needed to explore differential effects associated with characteristics of the participant samples, variants of the intervention, differences in study method, or any other study features of interest. With rare exceptions, it is expected that Campbell systematic reviews will give some attention to moderator relationships in the analysis of the coded data.

The third and most important purpose of the coding scheme is to extract information from the source studies that allows representation of the effects of the intervention on the outcome variables of interest. This information includes indices of the direction and magnitude of the intervention effects and any associated data required for analysis of those effect indices (e.g., sample sizes). The outcomes for which effects will be coded should be identified as well as any outcomes for which effects will not be coded along with the supporting rationale. The index for representing intervention effects should be identified (see section below on synthesis procedures and statistical analysis) and the plan for handling studies that do not provide sufficient information to determine the value of that index should be discussed.

A copy of the coding form the review team plans to use, or a draft if it is not yet fully developed, should be provided in an appendix. If a separate codebook that provides the definitions and decision rules for the coding has been developed, that should also be included or, if not yet developed, plans for it should be described.

A second part of this section of the protocol should describe the planned procedures for extracting the data required by the coding form from each study in a systematic and reliable fashion. The preferred procedure is for at least two members of the review team to independently code each study and resolve any discrepancies through discussion and consensus. Where large number of studies makes this procedure too demanding, random samples of the studies can be drawn and recoded by a different team member so that the reliability of the coding can be assessed and reported. The procedures planned for training coders and checking their accuracy before they begin providing data for the review should also be described along with the relevant background of those expected to do the coding.

See appendices E and F below (MECIR Standards)

Resources for review teams:

Campbell training videos on coding

David B. Wilson's PowerPoint presentation, '<u>Constructing a database for a review</u>' <u>Cochrane training materials on collecting data from relevant studies</u> <u>Cochrane Handbook</u>, Chapter 7: Selecting studies and collecting data <u>Cochrane Handbook</u>, Chapter 13: Including non-randomized studies

5.2.4.5 **Risk of bias**

Attention should be given in this section to characteristics of the studies that relate to methodological quality and the potential for shortcomings in their methods or procedures to bias the findings of the systematic review. The plan for assessing the risk of bias and addressing it in the review should be described. This plan should identify the methodological and procedural features of the studies that are relevant to assessing potential bias and how they will be examined during the screening of study reports and captured in the coding protocol. Such features might include the basic study design (e.g., whether random assignment was used), the unit of assignment and unit of analysis, attrition, implementation fidelity for the intervention, and so forth. The plan should also describe how the risk of bias will be assessed and handled in the analysis and reporting of the results of the review. Risk of

bias, for example, might be addressed by eliminating studies from the review that have too much potential for bias, conducting sensitivity analysis to determine if the results of the review are altered if potentially more or less biased studies are included, using key methodological variables as moderators in the analysis to examine their influence on the results, and/or such techniques used in combination. If a particular risk of bias tool (e.g., Higgins & Green, 2011) or study quality index is to be used, it should be identified and described. The overall purpose of this plan should be to minimize bias in the results as much as possible given the objectives of the review, and to provide the reader with an assessment of the remaining potential for distortion of the results because of limitations in the source studies.

Among the considerations of potential bias, this section should describe the plan for assessing reporting bias in the collection of eligible studies that will be available to the review. Reporting bias includes publication bias (e.g., studies with nonsignificant findings less likely to be published) as well as selective omission of findings for some outcome variables, statistical results, and the like from study reports. This part of the plan should describe the data the review team will collect from the studies that will support analysis of reporting bias and the manner in which that analysis will be conducted. Though there are limited options available to review teams for reducing reporting bias, the purpose of this plan should be to assess the potential for it to distort the results of the review and to provide the reader with an appraisal of the extent of that potential.

See appendices E and F below (MECIR Standards)

Resources for review teams:

Campbell training videos on measuring and assessing study quality Cochrane Handbook, Chapter 8: Assessing risk of bias in included studies Cochrane Handbook, Chapter 10: Addressing reporting biases Cochrane Handbook, Chapter 13: Including non-randomized studies Rothstein, H. R., Sutton, A. J., Borenstein, M. (Eds.). (2005). Publication bias in metaanalysis: Prevention, assessment and adjustments. West Sussex, England: Wiley.

5.2.4.6 Synthesis procedures and statistical analysis

In this section of the protocol, the review team should describe how they plan to analyze and synthesize the data extracted through the coding procedure in order to address the objectives of the review. The key data element for this purpose is an index of the direction and magnitude of the effect of the intervention on each outcome of interest that is reported in each study. The first part of this section should define that index and explain why it was chosen. Unless a compelling rationale for an alternative is presented, that index should be one of the recognized effect size statistics, such as the standardized mean difference (i.e., Cohen's *d*; Hedges' *g*), odds ratio, risk ratio, or correlation coefficient. The following details should be provided for that effect size statistic:

- The basic formulation for computing it, its standard error, and any other relevant statistical representations and/or the software that will be used and the options to be selected for the relevant statistical representations.
- The statistics, as reported in the source studies, from which the effect size statistic will be estimated and how that estimation will be done when studies do not report the most desirable statistics for that estimate.
- Special issues that must be addressed, such as effect sizes from cluster-randomized studies, and how they will be handled (Hedges, 2011).
- Any adjustments to the effect sizes that are required or will be considered, e.g., for small sample sizes, empty cells in 2x2 tables, outliers, etc.
- What alternate record or index will be used for effects on the outcomes of interest when the designated effect size statistic cannot be computed.

The next issue to be addressed is how the effect indices will be analyzed. When the index is one of the conventional effect size statistics, the preferred method is meta-analysis, which should be used unless a compelling reason can be provided for doing otherwise. Metaanalysis involves statistical analysis of the effect size values to characterize their central tendency (means), heterogeneity (variances), relationships with moderator variables, and the like. When meta-analysis is the method of analysis, the following details should be provided:

- The weighting function that will be used, with the procedure for computing the weight for each effect size. For example, in the case of the standardized mean difference effect size, explicitly state that the inverse-variance weight will be used and show how it is defined or specify the software that will be used for computing it.
- The procedure planned for examining effect size heterogeneity and the test statistic that will be used to assess it, e.g., the *Q* test and/or *I*².
- Whether random effects or fixed effects analysis is planned. For random effects analysis, which is the preferred technique, the method for estimating the between studies variance should be identified. For fixed effects analysis, the rationale for selecting it instead of random effects should be explained and well justified in consultation with the editor of the Methods Coordinating Group.
- How missing effect sizes are to be handled in the analysis.
- How outlier effect sizes are to be handled in the analysis.
- How the statistical independence of the effect sizes in each analysis will be maintained or, if dependencies will be allowed, how they will be handled. The situation of primary concern here is multiple effect sizes from the same participant sample in the same study that might all be relevant to a given analysis. Studies that use more than two experimental groups and provide effect sizes that share one of those groups (e.g., different interventions compared with the same control group) may also be at issue.
- What *a priori* hypotheses (if any) will be tested and how.

- How moderator analyses (if any) will be conducted and how, e.g., the procedures for comparing subgroups of effect sizes or for using meta-regression analysis. Note that when there is evidence of between study variation in the effect sizes, some attempt to identify moderator variables related to those differences is desirable, especially for potential moderator variables with practical or policy implications.
- Any details of the analyses planned for risk of bias or reporting bias issues that are not provided in the previous section.
- Any sensitivity analyses planned to assess the impact of judgment calls made during the course of the analysis that might materially affect the conclusions of the review.
- The software that will be used to conduct the various analyses.

If meta-analysis will not be done, the rationale for this should be clearly presented and defended. Some circumstances that might justify this decision include reviews with a small number of rather heterogeneous effect sizes and situations where a common effect size metric that allows aggregation cannot be defined for the study findings. In such instances, the protocol should describe plans for displaying statistical information and descriptions of the patterns in the effects as much as possible. This presentation should go beyond simply indicating statistical significance; information about the size and precision of effects should also be included to the extent possible. For example, confidence intervals should be provided for each effect size if they can be estimated. The effect sizes might also be displayed in a forest plot or other graphical display, or several displays if needed.

5.2.4.6.1 Advanced methods

A number of advanced methods are now available for meta-analysis (e.g., Bayesian analysis, meta-analysis with individual participant data, multivariate meta-analysis, robust standard error techniques, etc.) and new developments are appearing regularly. If the review team proposes to use advanced techniques, the protocol should describe those techniques clearly and explain their application and value. These techniques may not be well known to the editors or peer referees and therefore should be described without assuming prior knowledge by the reader.

See appendices E and F below (MECIR Standards)

Resources for review teams: Computing effect sizes Campbell training videos on computing basic effect sizes Campbell training Video on computing advanced effect sizes Cochrane Training materials on dichotomous effect sizes Practical Meta-analysis Effect Size Calculator by David B. Wilson Campbell training video on cluster adjustments in computing effect sizes

Synthesizing effect sizes <u>Campbell training videos on basic meta-analysis</u> <u>Cochrane Handbook</u>, Chapter 9: Analysing data and undertaking meta-analyses <u>Campbell training video on fixed and random effects models</u> <u>Campbell training video on graphical displays in meta-analysis</u> <u>Campbell training video on moderator analyses</u> <u>Campbell training videos on using robust standard errors for dependent effect sizes</u>

Software resources <u>Cochrane Collaboration's RevMan software</u> <u>SPSS, Stata and SAS macros for meta-analysis by David B. Wilson</u> <u>Stata ado files for synthesizing effect sizes</u> <u>metafor: Meta-analysis package for R by Wolfgang Viechtbauer</u> <u>rmeta: Meta-analysis package for R by Thomas Lumley</u> Macros for robust standard error estimation by Larry V. Hedges and Elizabeth Tipton

5.2.4.7 Treatment of qualitative research

In the context of a Campbell review, qualitative studies in the relevant intervention domain and qualitative portions of quantitative studies can make important contributions such as (a) helping define the intervention more precisely and completely, (b) assisting in the choice of outcome measures and development of valid research questions, (c) providing insight into heterogeneous findings across studies, (d) addressing barriers and facilitators of intervention effectiveness, and (e) highlighting requirements for successful implementation and reasons for poor implementation. When a review team plans to include data or findings from qualitative research, the protocol should describe (a) the criteria for inclusion and exclusion of studies, (b) the methods used in the research to be included, (c) criteria for identifying independent findings, (d) the data extraction and coding procedures to be used, much as it is prescribed above for quantitative research, and (e) the criteria for assessing the quality of the qualitative evidence.

Review teams are especially encouraged to draw on both qualitative and quantitative information to address three especially important aspects of the intervention: implementation, external validity (generalizability), and cost.

Implementation: Attention to implementation might include, for example, an assessment of the quality of the implementation of the intervention in the available studies; identification of the characteristics associated with successful implementation; the nature of any problems that impeded implementation; and the extent to which the effects of the intervention are associated with variation in the quality or nature of the implementation.

External validity: With regard to external validity, the issue to be addressed to the extent possible is the generalizability of the results to different contexts, settings, cultures, populations, and the like. Attention to external validity might consider, for example, whether the inclusion criteria for studies limited the generalizability of the findings; what the

available evidence shows about the robustness of effects across different subgroups, settings, etc.; what subgroups, settings, etc. are not represented in the available research but might be appropriate for the intervention; and, what characteristics of the study samples, settings, etc. are associated with differential intervention effects (for instance, risk level of the recipients, prevalence of the targeted condition, cultural characteristics, etc.).

Cost: The cost and cost-effectiveness of an intervention are often of great interest to practitioners and policymakers. It is therefore useful if the review provides whatever information is available about these matters. The most basic information of this sort is simply the cost of implementing the intervention, which might be expressed as a range across all the studies for which it is reported, or may come from one or more studies specifically investigating cost. Similarly any available analyses of the cost-effectiveness or cost-benefit of the intervention would be informative to include in the review if possible.

See appendices E and F below (MECIR Standards)

Resources for review teams: <u>Cochrane Handbook</u>, Chapter 20: Qualitative research and Cochrane Reviews <u>Campbell Economics Methods Policy Brief</u>

5.2.5 References

The protocol should include complete references to all cited works. References and other stylistic considerations should follow the APA guidelines: American Psychological Association. (2009). *Publication Manual of the American Psychological Association* (6th edition). Washington, DC: Author. DOI numbers should also be included when available.

5.2.6 Sources of support

Describe the sources of support for conducting the review, including direct funding and any resources provided by contributing organizations, sponsors, or individuals whether financial or in some other form.

5.2.7 Declarations of interest

The Campbell Conflict of Interest form should be signed by each member of the review team and appended to the review protocol. A copy of that form is available on the Campbell website at http://campbellcollaboration.org/ and a copy is appended to this document in Appendix D. Editors may decide that further disclosure is not warranted in the published protocol or they may decide that readers should know about such a conflict of interest so that they can assess it for themselves. Decisions about whether or not to publish such information will be made jointly by the review team and the editors.

5.2.8 Review authors

Provide the names and contact information for each author with the lead author listed first. The protocol template form (Appendix B) provides details and a format for this information.

5.2.9 Roles and responsibilities

Provide a brief description of content and methodological expertise within the review team. The recommended review team includes at least one person with content expertise in the topic area of the review, at least one person with methodological expertise for systematic reviews, and at least one person with statistical expertise. It is also recommended to have one person with information retrieval expertise. In this section you will identify the person responsible for each of these areas. The protocol template form (Appendix B) provides a format for this information.

5.2.10 Acknowledgments

Acknowledgment should be made of all individuals and organizations contributing to the preparation of the protocol that are not listed on the cover sheet.

5.2.11 Expected Timeframe

This section of the protocol should provide a timetable with target dates for accomplishing the key tasks required to complete the review. The time required for the various tasks will vary for different reviews depending on their scope and complexity as well as the resources available and the circumstances of the review team. Examples of some benchmarks to be used in setting targets are the anticipated dates for completing:

- Training and pilot testing on the inclusion criteria
- Searches for eligible studies
- Screening the results from the literature search
- Training and pilot testing the study coding procedure
- Extraction of data from eligible research reports
- Statistical analysis
- Preparation of the final review report

5.2.12 Plans for updating the review

In this section of the protocol the review team should describe any plan for updating the review once it is completed. This should include information on who will be responsible and the intervals expected between the initial review and the subsequent updates. If the authors do not plan to update the review, this should be stated instead.

5.2.13 Authors' responsibilities

Read the statement of the authors' responsibilities in the Protocol Template form (Appendix B). This statement will be included in the protocol when the template is complete.

5.2.14 Publication in the Campbell Library and in Campbell Systematic Reviews

Read, sign, and date the statement about publication of the protocol and eventual completed review that appears in the Protocol Template form (Appendix B). This statement will be included in the protocol when the template is complete.

5.2.15 Appendices

Use appendices for any supplementary material, tables, etc. that do not fit conveniently within the main text.

6 Completed review

The completed Campbell review will build on the approved protocol in several ways. First, of course, the protocol is a detailed plan for completing the review so the final review will represent the results of implementing that plan. Also, much of the content of the final review will be drawn from the protocol, usually with only minor changes.

6.1 FORMAT OF A REVIEW

The format of the completed review should follow the same guidelines provided above for the protocol and in the protocol template form. Note especially that any tables and figures should be embedded in the text in proximity to the discussion that refers to them and that tables should not be split across pages unless too long to fit on a single page. The template to be used for the completed review is available in Appendix C and is on the Campbell website (http://campbellcollaboration.org/).

6.2 CONTENTS OF A REVIEW

The manuscript for a Campbell systematic review should follow the outline provided below and use the headings indicated. Other sections and headings may be inserted in appropriate places, as needed, to address topics specific to the proposed review. As noted, earlier, reviews that are co-registered with the Cochrane Collaboration follow a somewhat different format; details can be provided by the managing editor of the respective coordinating group.

- Cover sheet
- Plain language structured abstract
- Background for the review
 - The problem
 - The intervention
 - The rationale for the intervention
 - Prior reviews
 - The contribution of this review
- Objectives of the review
- Methods
 - Characteristics of the studies relevant to the objectives of the review
 - Criteria for inclusion and exclusion of studies in the review

- Search strategy for finding eligible studies
- Data extraction and study coding procedures
- Risk of bias
- Synthesis procedures and statistical analysis
- Treatment of qualitative research
- Deviations from the protocol
- Results
 - Study selection
 - Study characteristics
 - Study quality and risk of bias
 - Observed effects from individual studies
 - Synthesis of results
 - Summary of findings from qualitative evidence
- Conclusions
- References
- Sources of support
- Declarations of interest
- Acknowledgments
- Plans for updating the review
- Appendices

Review teams are advised to use the MECIR *Methodological Standards for the Reporting of Cochrane Interventions* as further guidance about the topics that should be included in the completed review. Many elements of these reporting standards are appropriate to Campbell systematic reviews and addressing them will be expected by the respective coordinating group editor. Questions about the applicability of particular items should be addressed to that editor. Copies of the MECIR reporting standards are available on the Cochrane website (<u>http://www.editorial-unit.cochrane.org/mecir</u>) and in Appendix F. A checklist affirming that each of the above sections is represented in the completed review should be submitted to the respective editor with draft review. Alternatively, a checklist identifying the MECIR reporting items addressed may be submitted. A description of each section of a completed review follows with the relevant MECIR items for each identified.

Many parts of the final review manuscript will be straightforward and relatively minor adaptations of the corresponding material in the protocol that incorporate whatever updating is necessary. The methods section of the review manuscript will also largely mirror that in the protocol with the verb tense changed so that what the protocol described as a plan for what would be done appears in the review as a report of what was actually done. Typically, however, some of the methods actually applied to produce the review have changed from what was proposed in the protocol to adapt to unanticipated circumstances or reflect new understandings that developed once the review was underway. While every effort should be made to adhere to the protocol, it is recognized that this is not always possible or appropriate. However, 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 susceptible to bias and should be avoided. When possible, analyses should be performed to show the effect of the change on the results of the review. *In any event, all nontrivial changes in the methods applied from what was proposed in the protocol should be acknowledged and explained in the final completed review.*

Each of the sections of the review is described below.

6.2.1 Cover sheet

The cover sheet uses the same format as the protocol.

6.2.2 Plain language structured abstract

A structured abstract of no more than two pages is required for all reviews. It should be written in nontechnical language aimed at general readers who have limited familiarity with research and systematic review methods. This abstract should provide a brief description of the key information about the review under the following headings:

- Background
- Objectives
- Inclusion Criteria
- Search Strategy and Data Collection
- Analysis
- Results
- Conclusions

See appendices E and F below (MECIR Standards)

6.2.3 Background for the review

See appendices E and F below (MECIR Standards)

6.2.4 Objectives of the review

See appendices E and F below (MECIR Standards)

6.2.5 Methods

See the description in the protocol section.

See appendices E and F below (MECIR Standards)

6.2.6 Deviations from the Protocol

If the methods used in the review deviate from those proposed in the original protocol, those deviations should be described in this section and an explanation should be provided for why those deviations were made.

See appendices E and F below (MECIR Standards)

6.2.7 Results

This section should describe the results of the systematic review and (if appropriate) metaanalyses. The following sections should be included with other sections or subsections added under these headings as needed.

6.2.7.1 Study selection

This section should provide a summary of the number of studies screened, assessed for eligibility, and included in the review. The reasons for exclusions should be identified at each stage. A flow diagram of the sequence and selections made at each stage would be desirable to illustrate these stages. References for the studies selected for the review should be included along with a table providing key descriptive information for each study.

Selected studies that were excluded from the review should also be identified along with a brief indication of why they did not meet the eligibility criteria. This listing should include near miss studies and especially well known studies that a knowledgeable reader, or study author, might expect would be included in the review. For large reviews where the number of near miss studies is too large to itemize, a table should be provided that summarizes the number of such studies and the proportions excluded for various reasons. For instance, this table might provide such information for all studies that were not screened out based on the title and abstract, but were then excluded after examination in full text form.

The literature search that identified and located the candidate studies for screening and possible inclusion in the review should be recent, preferably completed no earlier than 12 months prior to the date on which the review is published. Review teams are strongly encouraged to update the literature search and add coding from any additional studies found to the database just prior to beginning the analysis that will be reported in the completed review. If there is an interval of more than 12 months between that analysis and the prospective date of publication, the review team is encouraged to further update the literature search, add coding for the additional eligible studies found to the analysis, and update the results just prior to publication. If that is not feasible, the literature search should nonetheless be updated and additional eligible studies should be cited and briefly described in the completed review even if their data cannot be included in the analysis.

At the discretion of the respective coordinating group editors, co-chairs, and the *Campbell Systematic Reviews* editors-in-chief, publication may be withheld for reviews with literature

searches judged to be too far out of date to be acceptable until the search is updated and more recent eligible studies are included in the completed review.

See appendices E and F below (MECIR Standards)

6.2.7.2 Study characteristics

Descriptive statistics and/or summaries of the primary characteristics of the studies from which data were extracted should be reported in this section (e.g., study size, participant characteristics, comparison conditions, outcome characteristics, measurement characteristics). In most reviews, it will also be appropriate to itemize the main characteristics for each included study in a summary table or a succinct set of abstracts.

See appendices E and F below (MECIR Standards)

6.2.7.3 Study quality and risk of bias

This section should summarize the relevant information about the methods and procedures of the included studies along with any indicators of study quality and the risk of bias assessment. In most reviews, it will be appropriate to summarize study quality for each included study, along with an overall summary of quality across all studies.

See appendices E and F below (MECIR Standards)

6.2.7.4 Observed effects from individual studies

For all primary and secondary outcomes of interest, this section should provide effect size estimates and confidence intervals for each study providing data for the respective outcome. The preferred display of this information is a forest plot.

See appendices E and F below (MECIR Standards)

6.2.7.5 Synthesis of results

When a meta-analysis or other integrative synthesis is conducted, the results should be presented in this section. The review should present point estimates for mean effect sizes with their corresponding confidence intervals (and prediction intervals, if appropriate) for each outcome of interest, and include measures of variability and heterogeneity (τ^2 , I², or *Q*). Results should also be presented for the following specific analyses, which should be appropriate in most reviews:

- Moderator analysis: Results for any subgroup analysis, meta-regression, or any other analysis examining the relationship of selected moderator variables to the effect sizes for one or more of the outcomes of interest.
- Reporting bias: Results from analysis of potential reporting or publication bias.

• Sensitivity analysis: Results from any additional sensitivity analysis exploring the influence of analysis decisions, variations on the studies included, methodological differences among studies, and the like.

See appendices E and F below (MECIR Standards)

6.2.7.6 Summary of findings from qualitative evidence

The findings from review of qualitative evidence about implementation, external validity, cost, or any other such matter should be reported in this section.

Across the results section, the following tables and figures are suggested and commonly included in Campbell reviews and may be required by the editor:

- Table summarizing the characteristics of individual studies
- Table assessing the risk of bias of individual studies
- Table of descriptive statistics for all relevant study characteristics
- Table summarizing the findings
- Forest plot of individual effect sizes and confidence intervals for each outcome
- Table with mean effect sizes and heterogeneity statistics for each outcome
- Table with summary findings from moderator analysis
- Funnel plot

See appendices E and F below (MECIR Standards)

6.2.8 Conclusions

In this section, the review should succinctly summarize the main findings and discuss any conclusions that can be drawn. When discussing findings, authors are encouraged to use nontechnical language that would be understandable to policymakers and practitioners without advanced statistical training. For instance, authors should consider translating mean effect sizes into more meaningful metrics to provide a substantive interpretation of results (e.g., "results indicated that intervention X was associated with a 30% reduction in criminal recidivism"). When drawing conclusions from a review, authors should not make overly broad conclusions or generalizations that go beyond the data presented in the review. Although it is important to address the implications of the findings for policy and practice, these conclusions should follow closely from the actual findings. Authors might also discuss implications for future research in this section. When discussing future research needs, authors should identify specific forms of research that are required to address unresolved issues or gaps that were revealed by the findings of the review.

See appendices E and F below (MECIR Standards)

6.2.9 References

The review should include complete references to all cited works. References and other stylistic considerations should follow the APA guidelines: American Psychological Association. (2009). *Publication Manual of the American Psychological Association* (6th edition). Washington, DC: Author.

See appendices E and F below (MECIR Standards)

- 6.2.10 Sources of support
- 6.2.11 Declarations of interest
- 6.2.12 Acknowledgments
- 6.2.13 Plans for updating the review

6.2.14 Appendices

See the description in the protocol section.

See appendices E and F below (MECIR Standards)

Anderson, L. M., Petticrew, M., Rehfuess, E., Armstrong, R., Ueffing, E., Baker, P., Francis, D., Tugwell, P. (2011). Using logic models to capture complexity in systematic reviews. *Research Synthesis Methods*, *2*(1), 33-42.

Hammerstrøm, K., Wade, A., Jørgensen, AMK. (2010). Searching for studies: A guide to information retrieval for Campbell Systematic Reviews. *Campbell Systematic Reviews, Supplement 1*.

Hedges, L. V. (2011). Effect sizes in three level designs. *Journal of Educational and Behavioral Statistics*, *36*,346-80.

Higgins, J.P.T., and Green, S. (eds.) (2011). *Cochrane handbook for systematic reviews of interventions*. <u>http://handbook.cochrane.org/</u>

Petrosino, A.J. (1995). Specifying Inclusion Criteria for Meta-Analysis. *Evaluation Review*, *19*, *274-295*.

Rothstein, H.R., Sutton, A.J., Borenstein, M. (Eds).(2995). Publication bias in meta-analysis: Prevention, assessment and adjustments. *West Sussex, England: Wiley*.

Shadish, W. R., Cook, T. D., Campbell, D. T. (2002). *Experimental and quasi-experimental designs for generalized causal inference*. Houghton Mifflin.

8 Appendices

- A. <u>Title registration form</u>
- B. <u>Review protocol template</u>
- C. <u>Completed review template</u>
- D. <u>Conflict of interest policy</u>
- E. <u>MECIR Methodological Standards for the Conduct of Cochrane Intervention Reviews</u>
- F. MECIR Methodological Standards for the Reporting of Cochrane Interventions