

Review Proposal Form for a Cochrane Intervention Review

Based on ERC approved best-practice template version 1.2 [May 2016]

Please complete this form to outline your proposal for a Cochrane Review related to hypertension. Send the completed form by email to Ciprian Jauca, Managing Editor, Cochrane Hypertension at <u>cochrane@ti.ubc.ca</u>

Before completing this form:

- Make sure that your proposal falls within this group's scope and that it has not already been covered in another Cochrane Review. <u>Search the Cochrane Library</u> for published reviews and protocols, and browse unpublished registered titles on the Cochrane Hypertension website: <u>http://hypertension.cochrane.org</u> Please submit your proposal to only one Cochrane Group.
- This form is for Cochrane Reviews of interventions. Do not complete this form if you are proposing an overview, a diagnostic test accuracy review, or another type of systematic review.
- Note that all authors must follow the <u>Cochrane Handbook for Systematic Reviews of Interventions</u> and the <u>Methodological Expectations of Cochrane Intervention Reviews</u>.
- Read Managing expectations: what does Cochrane expect of authors, and what can authors expect of <u>Cochrane?</u>
- Be aware that preparing a Cochrane Review requires a significant, long-term commitment. At least two authors are required before a title can be registered and at least one of the proposed authors must have been an author on a previously published Cochrane systematic review.

Proposed title

See Handbook section 4.2.1

Contact person

See <u>Handbook section 4.2.3</u>

Review proposal and inclusion criteria

See Handbook Chapter 5

Motivation for the review:

Review objective:

Types of study (see <u>Handbook section 5.5</u>):

Participants/population (see <u>Handbook section 5.2</u>):

Intervention (see <u>Handbook section 5.3</u>):

Comparisons (see <u>Handbook section 5.3</u>):

Outcomes and adverse effects (see <u>Handbook section 5.4</u>):

Primary:

Secondary:

Subgroup analyses (see <u>Handbook section 9.6</u>):

Other information:

Related Cochrane Reviews, protocols or registered titles:

Priority and impact:

Why is this title a priority and how might it impact patients and healthcare professionals?

Authors' responsibilities

By completing this form, you accept responsibility for preparing, maintaining and updating the review in accordance with Cochrane policy. The Cochrane Review Group (CRG) will provide as much support as possible to assist with the preparation of the review.

A draft protocol must be submitted to the CRG within six months. If drafts are not submitted before the agreed deadlines, or if we are unable to contact you for an extended period, the CRG has the right to de-register the title or transfer the title to alternative authors. The CRG has the right to de-register or transfer the title if it does not meet the standards of the CRG or Cochrane.

You accept responsibility for maintaining the review in light of new evidence, comments and criticisms, and other developments, and updating the review at least once every two years, or, if requested, transferring responsibility for maintaining the review to others as agreed with the CRG.

Publication in the Cochrane Database of Systematic Reviews

The support of the CRG in preparing your review is conditional upon your agreement to publish the protocol, finished review and subsequent updates the *Cochrane Database of Systematic Reviews*. By completing this form you undertake to publish this review in the *Cochrane Database of Systematic Reviews* before publishing elsewhere (concurrent publication in other journals may be allowed in certain circumstances with prior permission from the CRG).

I understand the commitment required to undertake a Cochrane Review, and agree to publish first in the Cochrane Database of Systematic Reviews.

Signed on behalf of the authors:

Form completed by:

Name:

Date:

Declaration of interest

All authors of Cochrane Reviews are required to declare any conflicts of interest at the beginning of the review process, when submitting this form.

- 1. An individual is not eligible to be an author on a Cochrane review if:
 - a. s/he is or has been employed by a company/entity that has a real or potential financial interest in the outcome of the review in the past three years;
 - **b.** s/he holds or has applied for a patent related to the intervention being investigated or a competing intervention
- 2. The first author of a Cochrane review must not have any of the conflicts noted above (i.e., direct employment and patents) and also must not have received any other type of financial support from a company that has a real or potential financial interest in the outcome of the review in the past three years. This includes (but is not limited to) funded attendance at meetings, work on advisory boards or fees for lectures, consultancies, royalty payments, holding stocks, etc.
- 3. Co-authors may have one or more of the conflicts noted in the final sentence of point 2, but more than half of the authors (>50%) overall must have no relevant conflicts.
- 4. The concept of "real or potential financial interests" encompasses the intervention(s) covered in the review and any potential comparator in the protocol.
- 5. Cochrane authors are not prohibited from being involved in primary research, even when funded by a relevant commercial sponsor, but they should declare this involvement and cannot data extract or assess the quality of their own studies.

All authors will be required to complete Cochrane's disclosure of potential conflicts of interest form. For information, a Word version of Cochrane's conflicts of interest form is appended to this form.

There is more information about the management of conflicts of interest in the <u>Cochrane Editorial and Publishing</u> <u>Policy Resource</u>. If there is any doubt about eligibility of authors, Cochrane Review Groups can consult the <u>Cochrane</u> <u>Funding Arbiter</u>.

Do the authors have any potential conflict of interest?

							CI • •	· · ·		<i>c</i>		
If y	/es,	describe	the na	ature of	the	potential	conflict	ot I	Interest	tor	each	author:

Author 1:		
Author 2:		
Author 3:		
Author 4:		
Author 5:		

Review context

Is the review subject to any specific funding?

Is there a deadline for completing the review?

Has the review already been completed or published elsewhere?

Proposed deadlines

Date you plan to submit a draft protocol: (within 6 months)

Date you plan to submit a draft review: (within 18 months)

Review authors

See Handbook section 4.2.2

Each person named as an author must make a substantial contribution to the conception and design, or analysis and interpretation of the data in the review. Please supply a brief CV for each author.

Contact person/author 1 (See <u>Handbook section 4.2.3</u>)

could offer translations for:

n an author of the review		
	Given name (名字 míngzi):	
	Family name (姓 xìng):	
):	Web address:	
	Given name (名字 míngzi): Family name (姓 xìng):	

Preferred full name for review byline: e.g. John Smith = Smith JB; Chen Ming Yu = Chen MY

Do you already have a user account and password for the Archie database?						
Email address(es):						
Job Title/Position:						
Department:						
Organization:						
Street/Address:						
City:		Post/Zip code:				
State/Province:		Country:				
Telephone number:		Fax number:				
Mobile/cell number:		Skype ID:				
Privacy:	As the contact person, your address and email will be published with the completed review. Your details will be stored on our central database, known as 'Archie', and may be accessed by Cochrane contributors. See <u>Archie Privacy Policy</u> . Within Archie, would you like to:					
	Hide your address and phone numbe	rs: Hic	le your email address:			
Country of origin:		Gender:				
What expertise do you bri (e.g. clinical, review methe	-					
Have you prepared a syste	ematic review before?					
If yes, have you prepared	a Cochrane Review?					
If yes, please state most re	ecent title:					
Are you already a membe	r of another Cochrane Review Group?					
If yes, which one(s)?	If yes, which one(s)?					
At what level are you able	At what level are you able to speak and write English?					
a vital role in Cochrane. If would be willing to do par	d in languages other than English is you speak any other languages and tial translations on behalf of other is know and which languages you					

6

Prefix (e.g. Ms, Dr):		Given name (名字 míngzi):		
Middle initial(s):		Family name	(姓 xìng):		
Suffix (e.g. MD, PhD):		Web address:	:		
Preferred full name for re	view byline: e.g. John	Smith = Smith	JB; Chen Ming Yu =	= Chen MY	
Do you already have a use	l for the Archie	database?	Yes 🗌 N	o 🗌	
Email address(es):					
Job Title/Position:					
Department:					
Organization:					
Street/Address:					
City:			Post/Zip code:		
State/Province:			Country:		
Telephone number:			Fax number:		
Mobile/cell number:			Skype ID:		
Privacy:	As the contact person, Your details will be stor by Cochrane contribute	red on our cent	tral database, know	vn as 'Archie',	and may be accessed
	Hide your address and			de your email	
Country of origin:			Gender:		
What expertise do you bri (e.g. clinical, review meth	-				
Have you prepared a syste	ematic review before?				Yes 🗌 No 🗌
If yes, have you prepared	a Cochrane Review?				Yes 🗌 No 🗌
If yes, please state most re	ecent title:				
Are you already a membe	r of another Cochrane R	eview Group?			Yes 🗌 No 🗌
If yes, which one(s)?					
At what level are you able					
Translating trials publishe a vital role in Cochrane. If would be willing to do par author teams, please let u could offer translations fo	guages and alf of other				

Prefix (e.g. Ms, Dr):		Given name (名字 míngzi):		
Middle initial(s):		Family name	(姓 xìng):		
Suffix (e.g. MD, PhD):		Web address:	:		
Preferred full name for re	view byline: e.g. John	Smith = Smith	JB; Chen Ming Yu =	- Chen MY	
Do you already have a use	l for the Archie	database?	Yes 🗌 N	o 🗌	
Email address(es):					
Job Title/Position:					
Department:					
Organization:					
Street/Address:					
City:			Post/Zip code:		
State/Province:			Country:		
Telephone number:			Fax number:		
Mobile/cell number:			Skype ID:		
Privacy:	As the contact person, Your details will be stor by Cochrane contributo	red on our cent	tral database, know	vn as 'Archie',	, and may be accessed
	Hide your address and			le your email	_
Country of origin:			Gender:		
What expertise do you bri (e.g. clinical, review meth	-				
Have you prepared a syste	ematic review before?				Yes 🗌 No 🗌
If yes, have you prepared	a Cochrane Review?				Yes 🗌 No 🗌
If yes, please state most re	ecent title:				
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Do you already have a use	l for the Archie	database?	Yes 🗌 N	o 🗌	
Email address(es):					
Job Title/Position:					
Department:					
Organization:					
Street/Address:					
City:			Post/Zip code:		
State/Province:			Country:		
Telephone number:			Fax number:		
Mobile/cell number:			Skype ID:		
Privacy:	As the contact person, Your details will be stor by Cochrane contributo	red on our cent	tral database, know	wn as 'Archie',	, and may be accessed
	Hide your address and			de your email	
Country of origin:			Gender:		
What expertise do you bri (e.g. clinical, review meth	-				
Have you prepared a syste	ematic review before?				Yes 🗌 No 🗌
If yes, have you prepared	a Cochrane Review?				Yes 🗌 No 🗌
If yes, please state most re	ecent title:				
Are you already a membe	r of another Cochrane R	eview Group?			Yes 🗌 No 🗌
If yes, which one(s)?					
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Preferred full name for re	view byline: e.g. John	Smith = Smith	JB; Chen Ming Yu =	- Chen MY	
Do you already have a use	er account and password	for the Archie	database?	Yes 🗌 N	o 🗌
Email address(es):					
Job Title/Position:					
Department:					
Organization:					
Street/Address:					
City:			Post/Zip code:		
State/Province:			Country:		
Telephone number:			Fax number:		
Mobile/cell number:			Skype ID:		
Privacy:	As the contact person, Your details will be stor by Cochrane contributo	red on our cent	tral database, know	vn as 'Archie',	and may be accessed
	, Hide your address and			le your email	_
Country of origin:			Gender:		
What expertise do you bri (e.g. clinical, review meth	-				
Have you prepared a syste	ematic review before?				Yes 🗌 No 🗌
If yes, have you prepared	a Cochrane Review?				Yes 🗌 No 🗌
If yes, please state most re	ecent title:				
Are you already a membe	r of another Cochrane R	eview Group?			Yes 🗌 No 🗌
If yes, which one(s)?					
At what level are you able					
Translating trials publishe a vital role in Cochrane. If would be willing to do par author teams, please let u could offer translations fo	guages and alf of other				

Roles and responsibilities

Please advise who has agreed to undertake each of the following tasks:

Draft the protocol:

Develop and run the search strategy:

Obtain copies of studies:

Select which studies to include (2 people):

Extract data from studies (2 people):

Enter data into RevMan:

Carry out the analysis:

Interpret the analysis:

Draft the final review:

Update the review:

Team resources

Have you read the Cochrane Handbook for Systematic Reviews of	Yes 🗌 No 🗌	
(handbook.cochrane.org)		
Are you familiar with the Cochrane Editorial and Publishing Policy	Resource?	Yes 🗌 No 🗌
Please take particular note of these Cochrane policies and resour	ces:	
 <u>Plagiarism</u> <u>Conflicts of interest</u> 		
Do you require training?		Yes 🗌 No 🗌
If yes, in which areas:		
Have you attended a Cochrane Review training workshop?		Yes 🗌 No 🗌
If no, do you plan to?		Yes 🗌 No 🗌
If yes, which workshop did you/will you attend?		
Which computer operating system do you use?		
Have you downloaded and installed RevMan, the Cochrane review tech.cochrane.org/revman)	w software? (see	Yes 🗌 No 🗌
Have you seen the Cochrane Hypertension website?		Yes 🗌 No 🗌
Do you have access to these databases?		
Cochrane Library		Yes 🗌 No 🗌
MEDLINE		Yes 🗌 No 🗌
Embase		Yes 🗌 No 🗌
Do you have access to a medical library?		Yes 🗌 No 🗌
If yes, can you order journal articles not held in the library?		Yes 🗌 No 🗌
Do you have access to advice from a medical librarian?		Yes 🗌 No 🗌
Do you have access to reference management software (e.g. End	Note)?	Yes 🗌 No 🗌
If yes, which software, and what version?		
Do you have access to a statistician?		Yes 🗌 No 🗌
If yes, who?		
Do you have contact with consumer groups relevant to this review	w?	Yes 🗌 No 🗌
If yes, which one(s)?		
Have you identified appropriate time and resources to complete	the review?	Yes 🗌 No 🗌
Would you like to be assigned a mentor (an experienced author v help new authors)?	vho has volunteered to	Yes 🗌 No 🗌

Notes for authors completing the Review Proposal Form

Proposed title

There are standard formats for Cochrane review titles (see <u>Handbook section 4.2.1</u>). Examples include:

- [intervention] FOR [health problem / issue] e.g. St John's wort for major depression
- [intervention A] VERSUS [intervention B] FOR [health problem/ issue] e.g. Surgical versus non-surgical management for abdominal injury
- [intervention] FOR [health problem/issue] IN [participant group] e.g. Interventions for preventing obesity in children

Motivation for the Review

Why are you proposing to undertake this review? For example, is this review going to be part of a Masters or Doctorate; is it part of a larger project; is it particularly topical at the present time?

Description of proposal

Your proposal should not overlap with an existing Cochrane review. For a list of publications and registered titles, go to <u>Cochrane Summaries</u>. For further information, see <u>Handbook chapter 5</u>.

Objective

Give a short statement of the primary aim of the review, e.g. to assess the effects of your intervention.

Types of study

Outline the types of study that will be included in the review. Most Cochrane reviews of interventions focus on randomised controlled trials (RCTs). Are there any specific reasons why your review would need to include non-randomised studies? See <u>Handbook section 5.5</u>.

Participants

Outline the types of populations to be included and excluded, with thought given to aspects such as demographic factors, the type/stage of disease/condition, or their setting. See <u>Handbook section 5.2</u>.

Interventions and comparisons

Outline the details of the intervention you wish to investigate. Consider the dose, intensity, mode of delivery, and combinations of interventions. Are there variations you wish to exclude? What will the intervention be compared to, e.g. placebo, no intervention, standard care? See <u>Handbook section 5.3</u>.

Outcomes

List the primary and secondary outcomes you wish to measure, including outcomes important to those experiencing the disease/condition as well as those treating them. Give thought to the inclusion of adverse effects as a primary outcome. Also consider how your outcomes may be measured, e.g. the type of scale or count likely to be used, and the timing of the measurement. See <u>Handbook section 5.4</u>.

Subgroup analyses

Outline any subgroups you plan to investigate for their influence on the size of the treatment effect, e.g. subgroups of the population, variations of the intervention, etc (see <u>Handbook section 9.6</u>).

Other information relevant to this proposal

Outline any other factors you plan to consider in your review, or other information you would like to provide, e.g. relevance to consumers, how this review complements other published Cochrane reviews.

Provide contact details for everyone who you expect to be an author of the review. For more information on authorship, see <u>Handbook section 4.2.2</u>. You should have at least two authors, and should include someone with relevant content area expertise and someone with experience in writing a systematic review. Your team must possess, or have access to, the statistical skills required to extract, manipulate and interpret data from the included studies. Incorporating the perspectives of those affected by the intervention is highly recommended. Authors are responsible for ensuring the review will be updated in future.

Contact person

This person will be responsible for contact with the Review Group on behalf of the author team. The contact person does not have to be an author themselves. Contact details for this person will be published with the completed protocol or review. For more details, see <u>Handbook section 4.2.3</u>

Disclosure of Potential Conflicts of Interest

Based on the ICMJE form

Instructions

The purpose of this form is to provide readers of your review with information about your other interests that could influence how they receive and understand your work. The form is designed to be completed electronically and stored electronically. It contains programming that allows appropriate data display. Each author should submit a separate form and is responsible for the accuracy and completeness of the submitted information. The form is in five parts.

1. Identifying information.

Please complete.

2. The work under consideration for publication.

This section asks for information about the work that you have submitted for publication. The time frame for this reporting is that of the work itself, from the initial conception and planning to the present. The requested information is about resources that you received, either directly or indirectly (via your institution), to enable you to complete the work. Checking "No" means that you did the work without receiving any financial support from any third party -- that is, the work was supported by funds from the same institution that pays your salary and that institution did not receive third-party funds with which to pay you. If you or your institution received funds from a third party to support the work, such as a government granting agency, charitable foundation or commercial sponsor, check "Yes". Then complete the appropriate boxes to indicate the type of support and whether the payment went to you, or to your institution, or both.

3. Relevant financial activities outside the submitted work.

This section asks about your financial relationships with entities in the bio-medical arena that could be perceived to influence, or that give the appearance of potentially influencing, what you wrote in the submitted work. You should disclose interactions with ANY entity that could be considered broadly relevant to the work. For example, if your article is about testing an epidermal growth factor receptor (EGFR) antagonist in lung cancer, you should report all associations with entities pursuing diagnostic or therapeutic strategies in cancer in general, not just in the area of EGFR or lung cancer. Report all sources of revenue paid (or promised to be paid) directly to you or your institution on your behalf over the 36 months prior to submission of the work. This should include all monies from sources with relevance to the submitted work, not just monies from the entity that sponsored the research. Please note that your interactions with the work's sponsor that are outside the submitted work should also be listed here. If there is any question, it is usually better to disclose a relationship than not to do so. For grants you have received for work outside the submitted work, you should disclose support ONLY from entities that could be perceived to be affected financially by the published work, such as drug companies, or foundations supported by entities that could be perceived to have a financial stake in the outcome. Public funding sources, such as government agencies, charitable foundations or academic institutions, need not be disclosed. For example, if a government agency sponsored a study in which you have been involved and drugs were provided by a pharmaceutical company, you need only list the pharmaceutical company.

4. Other relationships.

Use this section to report other relationships or activities that readers could perceive to have influenced, or that give the appearance of potentially influencing, what you wrote in the submitted work.

5. Declarations of interest statement.

Use this section to write your declarations of interest statement for inclusion in the review.

Section 1. Identifying Information

Given Name (First Name)	[your given name]			
Surname (Last Name)	[your given name]			
Effective Date	[your given name]			
Are you the contact person?	[your given name]			
If no, Contact Person's Name	[your given name]			
Review title:				
[your given name]				
Review identifying number:				
[your given name]				

Section 2. The Work Under Consideration for Publication

Did you or your institution at any time receive payment or services from a third party for any aspect of the submitted work (including but not limited to grants, data monitoring board, study design, review preparation, statistical analysis, etc...)?

Complete each row by typing 'Yes' or 'No' and providing any required information.

If you have more than one relationship, please add or copy additional row(s).

Туре	Money paid to you	Money to your institution*	Name of entity	Comments
1. Grant	[Yes/No]	[Yes/No]		
2. Consulting fee or honorarium	[Yes/No]	[Yes/No]		
3. Support for travel to meetings for the study or other purposes**	[Yes/No]	[Yes/No]		
4. Fees for participation in review activities such as data monitoring boards, statistical analysis, end point committees, and the like	[Yes/No]	[Yes/No]		
5. Payment for writing or reviewing the review	[Yes/No]	[Yes/No]		
6. Provision of writing assistance, medicines, equipment, or administrative support	[Yes/No]	[Yes/No]		
7. Other	[Yes/No]	[Yes/No]		

*This means money that your institution received for your efforts.

**For example, if you report a consultancy above there is no need to report travel related to that consultancy on this line.

Section 3. Relevant financial activities outside the submitted work.

Place indicate whether you have financial relationships (regardless of amount of compensation) with entities as described in the instructions. You should report relationships that were present during the 36 months prior to submission.

Complete each row by typing 'Yes' or 'No' and providing any required information.

If you have more than one relationship, please add or copy additional row(s).

Type of relationship (in alphabetical order)	Money paid to you	Money to your institution	Name of entity	Comments
1. Board membership	[Yes/No]	[Yes/No]		
2. Consultancy	[Yes/No]	[Yes/No]		
3. Employment	[Yes/No]	[Yes/No]		
4. Expert testimony	[Yes/No]	[Yes/No]		
5. Grants (awarded or pending)	[Yes/No]	[Yes/No]		
6. Payment for lectures including service on speakers bureaus	[Yes/No]	[Yes/No]		
7. Payment for review preparation	[Yes/No]	[Yes/No]		
8. Patents (planned, pending or issued)	[Yes/No]	[Yes/No]		
9. Royalties	[Yes/No]	[Yes/No]		
10. Payment for development of educational presentations	[Yes/No]	[Yes/No]		
11. Stock/stock options	[Yes/No]	[Yes/No]		
12. Travel/accommodations/meeting expenses unrelated to activities listed**	[Yes/No]	[Yes/No]		
13. Other (err on the side of full disclosure)	[Yes/No]	[Yes/No]		

*This means money that your institution received for your efforts.

**For example, if you report a consultancy above there is no need to report travel related to that consultancy on this line.

Section 4. Other relationships

Are there other relationships or activities that readers could perceive to have influenced, or that give the appearance of potentially influencing, what you wrote in the submitted work?

Please delete the row that doesn't apply.

No other relationships/conditions/circumstances that present a potential conflict of interest

Yes, the following relationships/conditions/circumstances are present (explain below):

At the time of review acceptance, will ask authors to confirm and, if necessary, update their disclosure statements.

On occasion, journals may ask authors to disclose further information about reported relationships.

Section 5. Declarations of interest statement

If your answer is different from 'No' to any of the questions above, you may have a competing interest which should be declared. Please draft a statement to publish with your review in the space below. This will be reviewed by the contact person and Cochrane Review Group editorial base staff for inclusion in your review.

Authors should not be concerned about answering 'yes' to any of the questions. 'Yes' answers do not indicate good or bad, but are simply something to declare on the form and consider for inclusion in the declarations section of the published review.

If you have answered 'No' to all of the questions above, please enter "None known".

This form is Cochrane's implementation of the International Committee of Medical Journal Editor's Form for Disclosure of Potential Conflicts of Interest. The ICMJE has not endorsed nor approved the contents of this version. ICMJE's version of the Form is is located at www.icmje.org. Users should cite this official version when citing the document.