

Cochrane Conflict of Interest Policy for Cochrane Library Content

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1 Introduction

Cochrane strives to attain the highest levels of objectivity and to ensure user confidence in the quality of Cochrane Library content. We recognize the importance of conflicts of interest and the way they can affect our relationships with healthcare consumers and the public, practitioners, policy makers and healthcare managers, researchers and research funders. The aims of this policy are to identify, prevent, or manage conflicts of interest. This policy is an update of the policy originally written in 2003 and revised in 2006 and [2014](#).

The policy applies to all those involved in the creation of Cochrane Library content, defined at the time of this policy revision as the Cochrane Database of Systematic Reviews (Cochrane Reviews, Cochrane protocols, editorials, commentaries and supplements) and Cochrane Clinical Answers. The policy was approved by the Cochrane Governing Board in February 2020 and it will apply prospectively from October 14, 2020 to all those involved in the production of new Cochrane Library content. The policy will be revised periodically.

2 Principles

Cochrane's policy is based on the following principles:

Independence: Cochrane Library content should be independent, avoiding conflicts of interest associated with commercial sponsorship. It should also be produced by people or organizations that are free from such conflicts.

Freedom from interference: the process for conducting Cochrane Reviews, and the Cochrane groups and contributors responsible for producing Cochrane Library content, should be free from interference.

Assurance: users of the Cochrane Library should be assured that the content is produced in an independent manner.

Transparency: authors' financial and non-financial interests, and their management, should be clear to users of the Cochrane Library.

Although Cochrane has adopted many of the [International Committee of Medical Journal Editors \(ICJME\) recommendations](#) on disclosing financial and non-financial relationships and activities, and conflicts of interest, this policy differs from that of many journals in the following ways:

- some types of financial sponsorship and support are forbidden;
- anyone involved in the creation of Cochrane Library content must disclose their conflicts of interest at the earliest opportunity in the editorial process: for Cochrane Reviews this would be at title registration stage;
- the first and last authors and at least two-thirds of the author team must be free of relevant financial conflicts of interest;
- authors must declare relevant non-financial interests.

3 Scope

This policy applies to all those engaged in producing content for the Cochrane Library (as defined in Section 4 below) including:

- Cochrane Review Group (CRG) editorial team members (paid and unpaid);
- authors of Cochrane Reviews and other Cochrane Library content;
- peer reviewers;
- Cochrane Editorial and Methods Department (EMD) staff;
- Cochrane Editorial Board.

4 Definitions

In relation to conflicts of interest the following definitions are relevant.

Conflict of interest	A conflict of interest is defined as a set of conditions in which professional judgement concerning a primary interest (such as patients' welfare or the validity of research) is unduly influenced (consciously or unconsciously) by a secondary interest (such as financial gain).
Cochrane Library content	Defined as the Cochrane Database of Systematic Reviews which includes Cochrane Reviews, Cochrane protocols, editorials, commentaries and supplements; and Cochrane Clinical Answers. The Cochrane Central Register of Controlled Trials (CENTRAL), federated search content, podcasts, translations of Cochrane content into other languages, and other knowledge translation products published in the Cochrane Library are specifically excluded from this definition.
Cochrane Review	The term 'Cochrane Review' refers to the published stages of a review, that is, the protocol, review, and any updates.
Cochrane Review Group editorial team members	Managing Editor, Assistant Managing Editor, Co-ordinating Editor, Deputy Co-ordinating Editor, Contact Editor, Statistical Editor/Statistician, Methods Editor, Information Specialist, Assistant Information Specialist and other methodologists (whether paid or unpaid).
Funder of a Cochrane Review	An organization which provides a grant, contract, or any form of financial support to one, several, or all authors, or funding that goes directly to their employer, home institution, or to the CRG, specifically for the purposes of undertaking a Cochrane Review.

Industry-controlled clinical study	Funding for the study is provided by a commercial organization. The commercial organization determines study design and methods (wholly or in part) and data analysis and reporting are controlled by that organization.
Industry-supported clinical study	A commercial organization provides some or all funding or material, non-financial support (e.g., placebo or active drugs, diagnostic or other test access) to the study, but independent researchers retain complete control over the study design, methods, data analysis and reporting.
Commercial organization with a financial interest	<p>Any for-profit organization with a financial interest in the topic of Cochrane Library content.</p> <p>This definition is not intended to include government departments, not-for-profit medical insurance companies, health management or health research organizations, or independent patient advocacy groups.</p>
Not-for-profit organization	An organization that operates as if it were a business but does not seek a profit. The primary focus is to pursue its objectives, and the money it raises is used to keep the organization operating. Examples include public universities, publicly funded health services, independent charities and non-governmental organizations such as the World Health Organization (WHO) but exclude those which are exclusively funded by a commercial healthcare organization that controls the funding (e.g. Foundation for a Smokefree World).
Personal relationships	Relationships with partner, spouse, immediate family member.
Private practice	A practice, outside the public healthcare system, in which a healthcare professional receives financial remuneration on a fee-for-service basis, rather than from a salary.
Relevant	<p>In this policy financial interests are considered to be relevant if the payment comes from a commercial organization that manufactures (or is known to be developing), or distributes (anywhere in the world), an intervention or potential comparator.</p> <p>This applies even if the payment was made for work or advice that did not relate to the topic of the Cochrane Library content. In the case of Cochrane Reviews this applies regardless of the reported direction of effect.</p> <p>Non-financial interests are considered relevant if they have a direct and obvious connection to the topic of the review or other Cochrane Library content (see definition above).</p>

Royalties	Income derived from the licensing or sale of healthcare-related goods or services. This may include income from books that promote an intervention, diagnostic test or prognostic marker that is relevant to the topic of the review or content of the article, electronic media (including apps), diagnostic and assessment tools, training programmes, and medical interventions and devices.
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5 Funding and interests

5.1 Funding of Cochrane Library content

If the creation of Cochrane Library content is supported by direct external funding, the following rules apply.

- Cochrane Library content cannot be directly funded or produced by any commercial organization with a financial interest in the topic.
- Funders of Cochrane Library content should be declared in the ‘Sources of support’ section of the review or protocol, including a statement that the funder had no role in the design, conduct, or publication of the review (or update).
- Funders of Cochrane Reviews cannot interfere with review production, that is, the design, conduct, or publication of a review or its update.
- Funding may come from external non-commercial granting bodies such as governments and not-for-profit organizations (see Section 6.4).

5.2 Direct financial interests (payments to individuals)

Direct financial interests refer to payments made directly to an individual. Financial interests must be declared by all CRG editorial team members and by all authors (see Section 5.6) and peer reviewers (see Section 6.3) involved in creating Cochrane Library content. Cochrane Review Group editorial team members (paid and unpaid) must also declare any financial interests that relate to the Review Group’s topic areas (see Section 5.5). All financial support must be declared and there are no thresholds.

For clarity, the funding or financial support of interest here is that which comes from a commercial organization with a financial interest in the topic of a specific review (e.g., it is developing, manufacturing or distributing an intervention or competitor product that is the subject of the review) or, for CRG staff only, in the broader topic area of the CRG.

The following **WILL prevent** authorship of Cochrane Library content and are prohibited for CRG editorial team members (see Section 5.5 for timeframes).

- Current or past employment (part-time or full-time) (see Section 5.5 for timeframes) by a commercial organization with a financial interest in the topic of specific Cochrane Library content.

- Ownership of a commercial organization with a financial interest in the topic of specific Cochrane Library content.
- Personal ownership of (or pending application for) a patent for an intervention, diagnostic test or prognostic marker that is relevant to the topic of specific Cochrane Library content. This does not include patents developed, but not owned by individuals.

The following **MAY prevent** authorship of Cochrane Library content (see Section 5.5 for timeframes) and are **PROHIBITED** for CRG editorial team members. Whether these prevent authorship of Cochrane Library content depends on whether a person is first or last author and the overall proportion of authors in the team who have a conflict (see Section 6.1). This list is not intended to be exhaustive; if there is any doubt refer to the Research Integrity Editors and Conflict of Interest Panel (see Section 8.1).

- Payment from organizations with a financial interest related to the topic area of the Cochrane Library content for work carried out on their behalf, such as speaker fees, honoraria, consultancies, and membership of advisory boards.
- Support for sabbaticals and study tours from organizations with a financial interest related to the topic area of the Cochrane Library content.
- Payment of travel, accommodation, subsistence and conference registration expenses from organizations with a financial interest related to the topic area of the Cochrane Library content.
- Ownership of stock/shares in healthcare-related companies with a financial interest.
- Payment for legal testimony or advice from a commercial organization with a financial interest in a topic related to specific Cochrane Library content.
- Royalties relevant to the topic of the Cochrane Library content.
- Funding for research received from a commercial organization with a financial interest in the topic area of specific Cochrane Library content.
- Financial support for fellowships and other professional placements from organizations with a financial interest related to the topic area of the Cochrane Library content.

Income from relevant private professional practice should be declared but will not normally prevent contribution to the creation of Cochrane Library content. If there are concerns that the author derives significant income from one particular intervention relevant to the topic under investigation, this should be discussed with the Research Integrity Editors and Conflict of Interest Panel (see Section 8.1).

5.3 Indirect financial interests (payments to institutions)

An indirect financial interest exists when payments from a commercial organization with a financial interest (as described in Section 5.2) are made to an individual's employer or home institution.

- All such payments must be declared.
- If the individual has any access to or control of the funds, this must be declared, and will be treated as explained in Section 5.2.
- If the individual has no access to or direct control of the funds, this should be declared, but does not constitute a conflict of interest.

5.4 Other (non-financial) relevant interests

Other, non-financial interests may result in a conflict of interest that could influence the development of Cochrane Library content. All those involved in the production of Cochrane Library content should think critically about how their perspectives, experiences, and positions have shaped their contribution to the development of the content. Transparency is key, however, declarations of non-financial interests **will not prevent participation** in the creation of Cochrane Library content.

The types of interests that should be considered, and declared, include, but are not limited to:

- publication in medical journals, the public press, broadcast and social media, of opinions relevant to the topic of the Cochrane Library content and interventions mentioned in the Cochrane Library content;
- work as a health professional or advisor on the topic or broader area relevant to the topic of the Cochrane Library content, whether in public or private practice;
- any affiliation to an organization (including not-for-profit) that has a declared ideological or political opinion relevant to topic of the Cochrane Library content.

5.5 Timeframes for declaration of interests

Authors of Cochrane Reviews should declare relevant conflicts of interests (financial and non-financial) that existed 36 months before the review title was registered, as well as any that arise during the writing of the review. Timeframes are as follows:

- Authors should declare all relevant interests that existed 36 months before title registration, through to review publication.
- If an author's contribution started after the date of title registration, the relevant timeframe is the 36 months before his/her involvement began, through to review publication.
- If a review is to be updated without the publication of a new protocol, the relevant timeframe is the 36 months before work started on the update, through to review publication.

For peer reviewers, the time period of interest is the 36 months before the invitation to referee the review.

CRG/Networks team members and EMD staff must declare all relevant interests in the past 36 months.

For all other types of Cochrane Library content, authors should declare all relevant interests that existed 36 months before work on the content started, through to publication.

5.6 Restrictions for authors of Cochrane Library content involved in clinical studies

Some additional restrictions are placed on people who have been involved in the conduct, analysis and publication of clinical studies.

- Anyone involved in writing a Cochrane Review, should declare whether they have had any direct involvement in the conduct, analysis, and publication of clinical studies (such as randomized clinical trials) that could be included in the specific review, and whether the study was industry-controlled or industry-supported (see Section 4, definitions). Direct involvement means named or other close involvement in the study design, conduct, analysis, or reporting. This would

include chief investigators and members of advisory boards, but not usually members of independent data and safety monitoring committees or site investigators.

- Anyone engaged in writing a Cochrane Review, who has had involvement in the conduct, analysis, and publication of a study that could be included in the review, cannot determine the overall study inclusion and exclusion criteria; and cannot make study eligibility decisions about, extract data from, carry out the risk of bias assessment for, or perform GRADE assessments of that study.
- Cochrane Review authors who have had direct involvement in the design, conduct, analysis and publication of industry-controlled clinical studies that are eligible for inclusion in a review **CANNOT** be the first or last author of that Cochrane Review. When authors have been involved in industry-supported clinical studies that are relevant to the topic of a review they **CAN** be the first or last author of that Cochrane Review.
- Direct involvement of an author in the design, conduct, analysis and publication of industry-controlled clinical studies that are eligible for inclusion in the review also counts as a conflict when determining the overall proportion of authors on the team with permissible conflicts.
- For Overview Reviews, the following restrictions are placed on people who are authors of included reviews:
 - Anyone involved in writing a Cochrane Overview Review should declare whether they are an author of any of the reviews that could be included.
 - Anyone engaged in writing a Cochrane Overview Review who is an author of any review that could be included in the Overview Review cannot determine the overall inclusion and exclusion criteria; and cannot make eligibility decisions about, extract data from, or assess methodological quality/risk of bias for that review.

6 Rules relating to declared interests

6.1 Rules for authors of Cochrane Library content

The following rules apply to authors of Cochrane Library content:

- A person who is currently employed (part-time or full-time) or was employed (part-time or full-time) in the recent past (see Section 5.5) by a commercial organization with a financial interest in the topic of the review **CANNOT** be an author of Cochrane Library content. For Cochrane Reviews this rule applies to the 36-month period before title registration through to publication of the completed review (see Section 5.5).
- A person who fully or partially owns an organization with a financial interest in the topic **CANNOT** be an author of any relevant Cochrane Library content.
- Someone who personally holds, or has applied for, a patent related to the topic **CANNOT** be an author of any relevant Cochrane Library content.
- Anyone engaged in writing a Cochrane Review, who has had any involvement in the conduct, analysis, and publication of a study that could be included in the review, is restricted in what they

can do with those data. They **CANNOT** determine the overall study inclusion and exclusion criteria; and they **CANNOT** make study eligibility decisions about, extract data from, carry out the risk of bias assessment for, or perform GRADE assessments of that study.

- Where Cochrane Library content has multiple authors, at least 67% (two-thirds) of them should have no relevant financial conflicts (see Section 5.2).
- The first and last authors of Cochrane Library content must have no relevant financial conflicts (see Section 5.2). For Cochrane Reviews this rule applies to the 36-month period preceding title registration through to publication of the completed review (see Section 5.5).
- Authors joining the author team of a Cochrane Review after the publication of the protocol or after publication of the full review (for an update) must be free of relevant financial conflicts of interest for 36 months before joining the team.
- For Cochrane Review updates the relevant time period is 36 months before the date the decision was made by the CRG and author team to update the review, through to publication of the completed update.
- When committing to produce Cochrane Library content authors must complete a 'Declaration of interest' form. For review authors this must be done at title registration, annually thereafter until publication (both protocol and review publication) and just prior to publication (both protocol and review publication). For authors of review updates, this must be done at the time of the decision to update the review, annually thereafter until publication, and just prior to publication.
- Declarations of non-financial interests **WILL NOT PREVENT** participation in the development of Cochrane Library content.

6.2 Rules for Cochrane Review Groups/Networks and the Editorial and Methods Department

The following restrictions apply to all CRG and Networks team members (paid and unpaid), Editorial Board members, and all staff of the EMD:

- No CRG or [CRG Network](#) is permitted to accept funding from any commercial organization with a financial interest in the CRG topic area.
- All editorial team members of CRGs (paid and unpaid), EMD staff and members of the Editorial Board must have **NO** relevant financial conflicts of interest (see Section 5.2 and 5.3).
- Anyone newly appointed to a role in a CRG or the EMD, or to the Editorial Board must be free of relevant financial conflicts of interest from the date of appointment.
- All CRG and EMD staff, including Co-ordinating Editors, and Editorial Board members in post at the time of this policy launch in October 14, 2020 who have financial conflicts of interest should not sign off reviews of topics relevant to those interests. If they remain in post, they should have divested themselves of those interests within five years from the date the policy took effect October 2020, and should not acquire any new relevant financial conflicts of interest so that by October 2025 they will be free of such interests.

- Editors with conflicts of interest, who have not yet divested themselves of those interests, should not undertake peer review or be a contact editor or provide sign-off on Cochrane Reviews to which their conflicts relate.
- Editors are prohibited from being employees of commercial organizations with a financial interest in the CRG topic area.
- All editorial team members of CRGs (paid and unpaid) EMD staff and Editorial Board members must complete the Declaration of interest form and update it annually (between January and March each year).

Cochrane Editors and editorial staff can author Cochrane Reviews, but must exclude themselves entirely from the editorial process for that review to ensure separation of the author and editorial processes. These tasks should be taken on by another Editor or member of the editorial team. Authors who hold editorial positions in Cochrane should declare these positions in their Declaration of Interests forms for each review they author, and a statement that they were not involved in the editorial process for that review should be included in the 'Declarations of Interest' section of the Cochrane Review.

6.3 Rules for peer reviewers

Peer reviewers must complete a 'Peer reviewer declaration of interest' separately for each peer review of a Cochrane Review. They must do so before they undertake any work on a review and update their declarations if any conflicts of interest become apparent during review.

Peer reviewers must report any relationship with the authors of the Cochrane Review they are refereeing.

The following restrictions apply to anyone engaged in peer reviewing Cochrane Library content:

- Employees (full-time or part-time) of an organization with a financial interest in the topic of specific Cochrane Library content should not act as peer reviewers.
- Anyone who owns a commercial organization with a financial interest in the topic of the specific Cochrane Library content should not act as a peer reviewer.
- Anyone who personally owns a patent (or has a pending application) for an intervention, diagnostic test or prognostic marker that is relevant to the topic of the specific Cochrane Library content should not act as a peer reviewer. This does not include patents developed but not owned by an individual.
- Those with other direct financial interests (see Section 5.2) in an intervention or any comparators considered in the review should not usually act as peer reviewers.

It is the responsibility of the Editorial Team selecting peer reviewers (e.g. CRG or DTA Editorial Team) to decide whether the disclosed conflicting interests are sufficient to withdraw the participation of the peer reviewer and to invite an alternative peer reviewer. If the Editorial Team considers the conflict of interest to be minor and agrees that it is unlikely to affect the judgement of the peer reviewer, the Editorial Team must disclose the potential conflict of interest to the review authors when sharing the peer reviewer's comments. If the Editorial Team considers the conflict of interest to be major and agrees that it is possible that it will affect the judgement of the peer reviewer, the peer reviewer must be replaced.

6.4 Not-for-profit organizations

Not-for-profit organizations that employ Cochrane authors, or fund reviews, may have a specific interest in the conclusions of a Cochrane Review. While they may or may not gain financially as a result of taking a specific position about a healthcare intervention, they may try to influence the conduct, conclusions or publication of that review. For example, a high-profile charity or foundation that has a well-documented position on a particular healthcare intervention may fund a Cochrane Review or provide substantive primary research funding in the topic area of the review. Although it is not possible to draft specific rules about this issue, the CRG should raise this issue with authors, and, if there appears to be a risk of undue influence, the matter should be discussed with the Research Integrity Editors and Conflict of Interest Panel (see Section 8.1) and the Editor in Chief as early as possible.

7 Responsibilities

7.1 Authors' responsibilities

- Authors of Cochrane Library content must provide an accurate and complete declaration of relevant financial and non-financial interests.
- Declarations should be made at the earliest opportunity in the editorial process. For Cochrane Reviews, this is usually at the time of submitting a review proposal form.
- The declarations provided by authors should be clear and detailed enough for readers to be able to understand the potential implications of what is being declared.
- Authors of Cochrane Reviews should declare all relevant interests before title registration, annually thereafter until publication and just prior to publication (both protocol and review publication). Authors should also declare all relevant interests before publication of an amendment to a review if the amendment requires a new citation version of the review to be published.
- In addition to the specific time points above, if an author acquires a conflict of interest at any stage while the review is being written, this should be reported to the CRG immediately and referred to the Research Integrity Editors and Conflict of Interest Panel where necessary.

7.2 Cochrane Review Group and Editorial and Methods Department responsibilities

- Titles with author teams that breach the policy in any of the ways outlined above **MUST NOT** be registered until appropriate changes are made to ensure that the team is unconflicted. Once work on the review is underway, changes to the author line-up will generally not be permitted as a means of addressing a breach of this policy.
- Where there is concern about an author's declared interest at any stage during the review authoring process, CRG editorial team members should manage issues in line with the policy and, if necessary, should seek further advice from the Research Integrity Editors and Conflict of Interest Panel (see Section 8.1).
- The CRGs should check that peer reviewers' declarations comply with the policy at the time they are invited to peer review and when they submit their reports.

- The EMD should check and clarify all authors' declarations comply with the policy for other Cochrane Library content (i.e., editorials, commentaries, supplements and Cochrane Clinical Answers) at the time of commissioning, and before publication.
- A designated member of the EMD is responsible for checking that all members of the department comply with the policy.
- A designated member of the CRG is responsible for checking that all CRG members comply with the policy.

8 Policy governance

8.1 Conflict of Interest Panel

The Research Integrity Editors and the Conflict of Interest Panel provide guidance on conflicts of interest in the context of Cochrane Library content. They provide advice on implementation of the policy and arbitrate potential policy breaches. Further information about the Research Integrity Editors and Conflict of Interest Panel, including the terms of reference of the Conflict of Interest Panel is available [here](#).

The Conflict of Interest Panel reports to the Editor in Chief of the Cochrane Library.

Queries about the application of this policy can be referred to the Research Integrity Editors and Conflict of Interest Panel using the [referral form](#). The Conflict of Interest Panel is supported by a member of the EMD who can be contacted via coiarbiter@cochrane.org.

8.2 Appeals

Appeals against the decisions of the Research Integrity Editors and Conflict of Interest Panel should be made via coiarbiter@cochrane.org. For cases managed by the Research Integrity Editor, appeals will go to the Senior Research Integrity Editor for a final decision. For cases managed by the Senior Research Integrity Editor, appeals will go to the Editor in Chief and Conflict of Interest Panel (the final decision lies with the EiC). For cases that were jointly managed by the Senior Research Integrity Editor and the Conflict of Interest Panel the Editor in Chief will make the final decision.

8.3 Non-adherence

Unpublished Cochrane Library content that is considered to be in breach of this policy will be referred to the Research Integrity Editors and Conflict of Interest Panel and may be rejected for publication, subject to appeal.

Published Cochrane Library content that is considered to be in breach of this policy will be referred to the Research Integrity Editors and Conflict of Interest Panel and may not be published or may be withdrawn from the Cochrane Library).

Wilful failure to disclose relevant conflicts of interest will be considered a form of scientific misconduct.

8.4 Policy audit

A full audit of Cochrane Library content to determine adherence to this policy will be carried out every three years by the EMD in collaboration with the Conflict of Interest Panel. Partial audits and spot checks may be carried out at the discretion of the Editor in Chief.

A review of cases referred to the Research Integrity Editors and Conflict of Interest Panel and the results of the audits may be used to inform development of resources to support the implementation of the policy by those producing Cochrane Library content.

9 Version history

Version 1	2003	First Commercial Sponsorship policy
Version 1.2	April 2004	Policy revised after a consultation process arising from a letter to the Cochrane Steering Group from several Cochrane contributors who felt that the existing policy ought to be more restrictive. The 2004 policy limited or prohibited commercial sponsorship of reviews, entities or activities.
Version 1.3	April 2005	Amended following consultation at 11th and 12th Annual General meetings and Cochrane Steering Group meetings.
Version 2	March 2014	Policy revised and reorganized into two parts after consultation: one for Cochrane Groups and individuals, and one for Cochrane Reviews.
Version 3	October 2020	This policy replaces Cochrane's Commercial Sponsorship policy dated March 2014.
Version 3.1	January 2021	Minor edits to improve clarity of text plus two edits made with approval from the Editorial Board (section 5.2 updated to clarify that financial interests in the 'broader topic area of the CRG' applies only to CRG staff and section 6.3 to clarify that it is the responsibility of the Editorial Team selecting peer reviewers to decide whether the disclosed conflicting interests are sufficient to withdraw the participation of the peer reviewer).
Version 3.2	May 2021	Minor edits to improve clarity of text, including clarification on application of section 5.6 to authors of Cochrane Overview Reviews and clarification (section 6.3) that personal ownership of a patent or a commercial organization with an interest in the outcome of the Cochrane Library content prohibit being a peer reviewer.
Version 3.3	October 2021	Minor edits to improve clarity plus addition of points regarding Cochrane Editors who are authors of reviews (Section 6.2) and collection of Declarations of Interest for Amendments (Section 7.1).