

# Cochrane Conflict of Interest Policy Revision Project (2018-2019)

## Governing Board Paper

<b>Agenda item:</b>	COI policies
<b>Submitted for Governing Board meeting:</b>	7 <sup>th</sup> October 2019
<b>Submitted by:</b>	Ruth Foxlee (Senior Programme Manager) on behalf of the Project Team
<b>Sponsored by:</b>	Karla Soares-Weiser, Editor in Chief
<b>Decision or information:</b>	For decision
<b>Resolution for the minutes:</b>	The Board approves the recommendations and the implementation plan for the revised conflict of interest policy.
<b>Executive summary:</b>	<p>This paper provides a brief description of the key recommendations for areas in the current Conflict of Interest policy that should be remain unchanged and the most important changes and clarifications. In addition, a detailed rational for the recommendations is provided in <a href="#">Appendix 1</a>, a proposed implementation plan in <a href="#">Appendix 2</a>, a table of the definitions in <a href="#">Appendix 3</a>, and details of the Project Team and Project Board membership in <a href="#">Appendix 4</a>.</p> <p>After the recommendations are agreed, the policy will be draft and presented to the Board for final approval.</p>
<b>Consultation with Cochrane Council:</b>	The current recommendations are also shared with the Council.

## Background

Cochrane's current [Commercial Sponsorship Policy](#) was published in 2014. In 2018 the Governing Board asked the Editor in Chief to revise the policy. Cochrane currently has a strong policy which not only requires interests to be declared, it also rules that some conflicts will prevent authors from conducting Cochrane Reviews. If a review breaches the policy a Cochrane Review Group may be required to add unconflicted author to the line-up, update within a relatively short time frame, or in some cases withdraw the review from the Cochrane Library.

The first part of the project involved gathering useful background information to inform the new Conflict of Interest (Conflict of Interest) policy. This came from:

- An online survey of the views of Cochrane members and other interested respondents, which had nearly 1,000 responses and gave both quantitative and qualitative data.
- An assessment of the conflict of interest policies of 33 other healthcare-related organizations including journals, guideline producers and research funders.
- Semi-structured interviews with 16 Cochrane stakeholders and Conflict of Interest opinion leaders.

All three pieces of work were considered in the revision of the policy. In summary, they confirmed broad support for the current policy but suggested that clarifications were needed. There was a call for greater declaration of non-financial interests, but it was generally felt that these should not prevent authorship. There were varying opinions about whether the policy on barring authors with financial conflicts of interest should be stricter, but overall, a majority (especially of survey respondents) believed that the current policy was correct.

The findings from the interviews, survey and organizational policy review, together with expertise from the Project Board and knowledge of the cases that had been referred to the Funding Arbiters and Panel over the past four years, were used to generate a set of recommendations for change. The Project Team and Project Board were also guided by the considerable body of research which indicates that financial conflicts of interest may consciously or unconsciously bias researchers and impact on research findings. The recommendations set out in this document have been discussed by the Project Board members, who were aware of the need to balance the desire to see a much more rigorous policy, which excluded any type of conflict, financial or otherwise, with the practical problems of recruiting authors with essential topic expertise, especially in very specialized health areas. Once the recommendations have been discussed and approved by the Governing Board a new Conflict of Interest policy will be drafted. We will consider linkages between the Conflict of Interest policy and Cochrane's *Principles of Collaboration* and *Complaints procedures*, particularly in regard to areas where the three policies overlap or complement each other.

The new draft policy aims to minimize the existence of authors' and editorial teams' conflicts of interest that are associated with bias in results of Cochrane Reviews and other Cochrane Library content. It also aims to bring greater transparency and accountability to authors' and editors' diverse interests, while accepting that everyone comes to the systematic review process with interests. It includes several significant changes, as well as clarifications of some parts of the current policy that appeared to be ambiguous or hard to interpret. Overall it is more rigorous in its approach to financial conflicts of interest and clarifies that broad categories should be considered when declaring other (non-financial) interests. It

**Trusted evidence.**  
**Informed decisions.**  
**Better health.**

also clarifies the levels of responsibility for ensuring adherence to the policy.

This background section of this paper summarizes the most important changes, clarifications and areas where change was not thought necessary. In addition, a detailed rationale for the recommendations is provided in [Appendix 1](#), a proposed implementation plan in [Appendix 2](#), a table of the definitions in [Appendix 3](#), and details of the Project Team and Project Board membership in [Appendix 4](#).

## Key Recommendations for the Revised Policy (Brief)

We recommend that the following elements from the current policy are left unchanged:

1. That Cochrane’s robust approach to **limiting financial conflicts** in the author team should be maintained. We recommend continuing to require that **first authors** be free of all conflicts, and that the policy be further strengthened (see *Changes to the current policy*).
2. That we continue to not specify a **threshold for financial conflict**.
3. That people who are **employed by a commercial organization** with a real or potential financial interest in the outcome of the review (including but not limited to drug companies or medical device manufacturers) remain prohibited from Cochrane review authorship.
4. That commercial organizations with real or potential financial interests in the outcome of a review (including but not limited to drug companies or medical device manufacturers) are not permitted to **fund Cochrane Reviews**.

For more information about these recommendations click [HERE](#).

We recommend the following changes to existing elements of the current policy:

1. That ‘**Transparency**’ be added as a fourth principle.
2. That the scope of this new policy is narrowed to **apply solely to those people involved in the production of Cochrane Library content** (excluding Cochrane Central Register of Controlled Trials (CENTRAL) and federated search content). It is anticipated that this policy be adapted for application to other groups of people in Cochrane, such as members of the Governing Board, Fields, Centres and the Consumer Network but until then the current policy remains in force for those not directly involved in producing Cochrane content.
3. That the title of the policy be changed to ‘**Conflict of Interest Policy for the Cochrane Library**’.

**Trusted evidence.**  
**Informed decisions.**  
**Better health.**

4. That in addition to the requirement that the first and last authors be free of conflict, for any Cochrane Review with titles registered after January 2020 the **proportion of authors in the team who are free of conflicts** should increase from >50% to ≥66% (two-thirds).
5. That for Cochrane Library Content, **the last author** as well as the first author should be free of all financial conflicts and that these conflicts count when determining the overall proportion of authors on the team with permissible conflicts.
6. That the relationship between producers of Cochrane content and clinical studies be made explicit and the differences between **industry-funded** clinical studies and clinical studies with **material support only** be defined (see definitions table).
7. That **named authors of industry-funded clinical studies be prohibited from being first or last author** on a Cochrane Review in which these clinical studies are, or could be, included and that these conflicts count when determining the overall proportion of authors on the team with permissible conflicts.
8. That named authors on clinical studies that are, or could be, included in a Cochrane Review (on which those named authors wish to work) must declare their level of industry involvement, cannot carry out the risk of bias assessment and data extraction, and **also cannot be involved in determining the inclusion and exclusion criteria or making study-eligibility decisions**.
9. That, in cases where payments are made to the individual's employer or home institution rather than to them personally, the factor which will determine **indirect financial interests** and whether or not this represents a relevant financial conflict of interest is the extent to which the individual has any direct access to or control of the funds.
10. That, when not-for-profit organizations that employ authors or fund reviews are considered to have a specific interest in the outcome of the review, this should be raised with the Conflict of Interest Arbiters and the Editor in Chief as early as possible.
11. That all **Cochrane Review Group and Editorial and Methods Department** staff should be free from relevant financial conflicts of interest at the time of appointment. Those currently in post who have such interests should divest themselves of them within five years.
12. That **peer reviewers** should complete a Declaration of Interest form every time they undertake peer review of a Cochrane Protocol or Review, or annually if doing so more than once a year.
13. That **non-adherence** to the policy, including wilful failure to disclose relevant conflicts of interest, be stated as being a form of scientific misconduct.
14. That the Funding Arbiters and the Funding Arbitration Panel be renamed as **Conflict of Interest Arbiters** and the **Conflict of Interest Panel**.
15. That the Conflict of Interest Arbiters will be **accountable to the Editor in Chief** rather than the Governing Board.
16. That **appeals** against the decisions of the Conflict of Interest Arbiters and Panel be to the Editor in Chief rather than the Governing Board.

**For more information about these recommendations click [HERE](#).**

**Trusted evidence.  
Informed decisions.  
Better health.**

## We recommend the following clarifications to the current policy:

1. That a **process and framework** which encourages producers of Cochrane content to think critically about their perspectives and positions (i.e. “other relevant” non-financial interests), and account for the influence of them on the review, be developed. We recognise that all individuals possess perspectives and positions thus no declarations will prevent people from creating Cochrane content (as per the current policy).
2. That the meaning and implications of receiving **royalties** be clarified.
3. That the requirements for declarations of interest when **reviews are updated** and when new authors are involved be set out.
4. That more information be provided about the **timeframes** in which conflicts are considered current.
5. That descriptions of the **responsibilities** of Authors and of Cochrane Review Groups and Editorial and Methods Department staff be provided.
6. That a **peer reviewer** with a direct financial interest associated with an organization that has a real or potential material interest in the findings of a specific Cochrane Review (including for-profit and not-for-profit organizations) cannot be involved in that review.

**For more information about these recommendations click [HERE](#).**

---

# Appendix 1: Key Recommendations for the Revised Policy (Detail)

The results of the interviews and survey, the review of policies from 33 organizations, the expertise of the Project Board, and the cases that had been referred to the Funding Arbiters over the past four years, were used to generate a set of recommendations for change.

## 1 Unchanged elements of the existing policy

### 1.1 Limiting financial conflicts in the author team

The current [Commercial Sponsorship Policy](#) states that “a majority of the review authors and the lead author should have no relevant conflict of interests”, although some members of an author team may have financial conflict of interest, but “only where a majority of the review authors and the lead author have no relevant conflict of interests”. We recommend that a strict approach to the first author be maintained but the Project Board also believed it was important to strengthen the policy in relation to last author and the proportion of authors with permissible conflicts overall (see 2.4 and 2.5).

### 1.2 Setting thresholds for financial conflicts

The current [Commercial Sponsorship Policy](#) does not specify thresholds for financial conflicts. The organizational policy review revealed that some organizations (e.g. the National Institutes of Health (USA) and the National Institute for Health Research (UK)) do set financial thresholds. There was a spectrum of opinions amongst interviewees, some believing that any financial interest may lead to bias, and others that small one-off payments (e.g. travel expenses) represented a lesser risk than larger payments (e.g. regular consultancy work). Geographical and medical specialty differences in Cochrane make it challenging to set and enforce thresholds fairly, therefore we recommend maintaining the current position of not setting them.

## 2 Changes to the policy

### 2.1 Transparency

Transparency has always been and should continue to be one of Cochrane’s underlying principles and the importance of this was emphasised in the survey results. While recognising that everyone comes to the systematic review process with perspectives and positions, we recommend processes to bring greater transparency to these influences. The way in which declarations of interest are made and published makes Cochrane authors’ financial and other (non-financial) interests, and how they have been managed, clear to users of the Cochrane Library. The Project Team recommends the addition of ‘transparency’ as an underlying principle of the policy.

### 2.2 Policy scope

The current [Commercial Sponsorship Policy](#) is aimed at people who conduct Cochrane Reviews - authors, peer reviewers, editors and *all* Cochrane groups. The definition of “Cochrane groups” is very broad and

**Trusted evidence.**  
**Informed decisions.**  
**Better health.**

includes the Governing Board, Cochrane Review Groups, Fields, Method Groups, the Consumer Network, and the Central Executive Team. Since the advent of [Cochrane Crowd](#) and [Cochrane Task Exchange](#) there have been suggestions that people engaged with these services should also be covered by Cochrane's Conflict of Interest policy. The scope of the current policy was not well understood by some interviewees. The Project Team and Project Board are concerned that the scope is too broad at present and recommend narrowing it to include only people who are directly involved in producing Cochrane Library content – authors, editors, peer reviewers and editorial base staff. We also recommend that companion policies be developed for those not directly involved in producing Cochrane content but until then the current policy remains in force for them.

### 2.3 Policy title

The current policy title indicates a focus on sponsorship and does not sufficiently describe the full range of issues that need to be covered in the policy. We therefore recommend that the policy be renamed 'Conflict of Interest Policy for the Cochrane Library'.

### 2.4 Last author

Under the current [Commercial Sponsorship Policy](#) some members of an author team may have a relevant financial conflict of interest, so long as the majority, and the lead author, do not. Most survey respondents and many interviewees felt this approach was acceptable. Some interviewees also stressed the importance of the last author, who is often the most senior, also having no relevant conflicts. A clear majority of survey respondents also agreed that the last author should be subject to the same restrictions as the first author. We therefore recommend that the policy be strengthened by excluding last authors who have a conflict of interest and that these conflicts count when determining the overall proportion of authors on the team with permissible conflicts. This approach should apply only to new reviews registered after the date the revised policy is launched.

### 2.5 Increasing the proportion of authors with no conflicts of interest

The current [Commercial Sponsorship Policy](#) states that the majority of authors, defined as >50%, should have no conflicts of interest. This threshold was arbitrarily set in the 2014 policy as a way of balancing the need to minimize the impact of commercial influence in Cochrane Reviews with the pragmatic concerns of Cochrane Review Groups. We recommend adjusting the threshold to require "a clear majority" (≥66%) of authors to be free of Conflict of Interest, however it is important to note that the Conflict of Interest Project Board did not reach consensus on this issue. The argument for the stricter threshold was focused primarily on the notion that such a change could strengthen the trustworthiness of Cochrane Reviews and provide a clearer policy profile. The arguments against a change centered on pragmatic concerns relating to implementation and additional burden on Cochrane Review Groups. Most survey respondents (76%) said the current policy of allowing no financial conflicts of interest for the lead author and the majority of the review team was either acceptable (61%) or too strict (15%). Some respondents and interviewees commented on the loss of topic expertise that might arise from a more stringent policy, but this concern should be considered in the context of reputational gain that may accrue from a more rigorous approach to limiting the number of permissible conflicts in an author team. We recommend that any policy change in this area, apply **only to new reviews registered after the date the revised policy** is launched.

### 2.6 Authors of Cochrane Library content involved in clinical trials

**Trusted evidence.**  
**Informed decisions.**  
**Better health.**

In the community survey the majority of respondents stated that it was acceptable for review authors who have been involved in clinical trials to be Cochrane authors and many recognised the importance of relevant topic expertise. The majority of respondents believed that a researcher on an industry trial should NOT be allowed to be the first author on the review (if the study was eligible for inclusion in a Cochrane Review they wished to work on). We recommend that named authors of industry-funded clinical studies be prohibited from being first or last author on a Cochrane Review in which these clinical studies are, or could be, included. These conflicts will also count when determining the overall proportion of authors on the team with permissible conflicts.

We also recommend that the difference between industry-funded clinical trials and clinical studies with material support only be defined. In an industry-funded clinical trial, some or all funding is provided by a commercial organization. In a material-support-only clinical trial, a commercial organization provides some materials (e.g. placebo or active drugs, testing) but does not directly fund the study. The Project Team and Board believe it is important to prevent those involved in industry-funded clinical trials from being the first or last authors of Cochrane Reviews. The Project Board did not have the same degree of concern about clinical studies in which industry provides some material-only support. Furthermore, it is recommended that an additional restriction be placed on authors directly involved in clinical trials to ensure that they neither decide the inclusion and exclusion criteria nor make study-eligibility decisions in the review. This is in addition to the current restrictions of authors being prevented from extracting the data and assessing the risk of bias on their own studies.

## **2.7 Indirect financial interests**

The issue of payments received by an author's home institution is not covered in the current policy, but in some cases commercial organizations provide funding to these institutions in return for work done by the Cochrane author. In this situation the individual does not receive payment directly. In the community survey opinion was split but a slightly larger proportion of respondents felt that receipt of funding by the home institution did not constitute a conflict if the author had no control over the use of the funds. We recommend that all such payments be declared and that individuals with access to or control of the funds be considered to have a conflict of interest which counts toward the calculation of the permissible proportion of authors with conflicts.

## **2.8 Not-for-profit organizations with a specific interest in the outcome of a Cochrane Review**

In certain circumstances not-for-profit organizations that employ Cochrane authors or fund reviews may have a specific interest in the outcome of a review. They may or may not gain financially as a result of taking a specific position in relation to a particular healthcare intervention, but they may try to influence the conduct, conclusions or publication of that review. An example of this situation might be a high-profile charity or foundation that: has a well-documented position on a particular healthcare intervention; funds a Cochrane Review directly or via an intermediary research organization; or provides substantive primary research funding in the topic area of the review. Although it is not possible to draft specific rules about this issue, we recommend that the Cochrane editorial base raise this issue with authors with a view to ensuring that the team is balanced. To avoid the potential for inappropriate interference we recommend that any such issues be raised with the Conflict of Interest Arbiters and the Editor in Chief as early as possible.

## **2.9 Cochrane editorial staff**

**Trusted evidence.  
Informed decisions.  
Better health.**



The current [Commercial Sponsorship Policy](#) states that “Coordinating editors with conflicts of interest should assign the relevant review to another editor within their group”. It does not cover other editorial base staff, despite the fact that they are all heavily involved in producing Cochrane Library content. The results of both the community survey and interviews highlighted an expectation amongst stakeholders that Cochrane Review Group Coordinating Editors should have no financial conflicts of interest. We recommend that anyone directly employed on a full-time, part-time or consultancy basis within the Editorial and Methods Department should have no financial conflicts of interest. We acknowledge that this proposed change to current policy would require a phased approach.

### **2.10 Peer reviewers’ declarations**

The current [Commercial Sponsorship Policy](#) states only that “Peer reviewers should be asked to declare Conflict of Interest using the International Committee of Medical Journals Editors framework”, while the current version of the [Conflicts of interest and Cochrane Reviews section](#) in the Editorial and Publishing Policy Resource states that anyone with a direct financial interest in a particular intervention should not be involved in the peer review of it. We recommend that the more rigorous approach set out in the Publishing Policy Resource be confirmed in the new policy. Peer reviewers who are employed by a commercial organization that has a real or potential interest in the findings of a specific review or who hold patents or trademarks for a relevant intervention (or comparator) must not be involved in the peer review of that review. In addition, peer reviewers should complete the Cochrane Declaration of Interest form in Archie every time they undertake peer review or annually if doing so more than once a year. The period of interest for these declarations should be 36 months before the invitation to act as peer reviewer.

### **2.11 Non-compliance and scientific misconduct**

The current [Commercial Sponsorship Policy](#) (clause 12) states that published reviews or protocols that breach the policy will be withdrawn after consultation with the Funding Arbiters and Editor in Chief. This was seen as a strength by several interviewees. The policy does not however mention what approach should be taken with non-compliant, unpublished protocols or reviews, nor does it set out the consequences for making inaccurate declarations. The International Committee of Medical Journal Editors recently updated its recommendations to include wilful non-disclosure of conflicts (2018) and consider “purposeful failure to disclose conflicts of interest” as a form of misconduct. In the survey, it was suggested that the consequences of non-compliance with the policy would be part of the referrals and appeals policy information. We recommend that appeals and non-compliance be covered in the new policy and that deliberate failure to disclose relevant conflicts of interest will be considered to be a form of scientific misconduct. The new policy would include a link to the Scientific Misconduct Policy (under development) for guidance on how to manage such cases.

### **2.12 Funding Arbiter and Funding Arbitration Panel**

The Funding Arbiter and the Funding Arbitration Panel provide guidance on conflicts of interest in the context of Cochrane review production and adjudicate in cases where there is some doubt about policy breach. The title “Funding Arbiter” was queried by some interviewees who observed that it is not used in other Conflict of Interest policies. The term suggests a focus on commercial interests and possibly even on review funding only, rather than conflicts of interest in all their forms, therefore a change to *Conflict of Interest Arbiters* and *Conflict of Interest Panel* is recommended.

### **2.13 Accountability and appeals**

**Trusted evidence.**  
**Informed decisions.**  
**Better health.**

Conflict of interest plays a key role in the perceived quality of Cochrane Reviews and the Cochrane Library, which is the responsibility of the Editor in Chief. In addition, Conflict of Interest issues are central to the editorial process and closely aligned with the work of the Editorial & Methods Department. We therefore recommend changing the line of report of the Funding Arbiter and the Funding Arbitration Panel from Cochrane's Governing Board to the Editor in Chief. This approach aligns with the increased focus on strategic issues by the Governing Board.

## 3 Clarifications to the existing policy

### 3.1 Other (non-financial) interests

The current [Commercial Sponsorship Policy](#) states that “any other interests that others may judge relevant” should be declared. While there is little empirical evidence about the impact of other interests on research conduct or findings, the organizational policy review indicated that many organizations (e.g. the National Institutes of Health (USA), the National Institute for Health and Care Excellence (UK) and the Guidelines International Network) ask contributors to make declarations in one or a combination of categories, e.g. professional, intellectual, institutional and personal. However, policies vary significantly, with some specifically recommending that certain types of interests should not be declared. In the community survey, 52% of respondents supported the position that publishing a review previously or expressing an opinion publicly about the intervention(s) of interest in a Cochrane Review should be declared, although 68% did not think that this should prevent authorship. In the interviews several people noted that the policy did not include non-financial interests. They acknowledged the absence of empirical evidence but felt it represented a lack of transparency if non-financial interests were not included.

To clarify the current policy and promote transparency we recommend that those involved in the creation of Cochrane content be encouraged to think critically about, and account for, how their perspectives, experiences and positions have shaped the review. We recommend developing a framework that includes a brief list of questions which prompts authors to report and reflect on how their professional identities (e.g. employment, career stage, training, leadership roles) and perspectives (e.g. theoretical, advocacy, disciplinary) have shaped the questions, conduct, analysis and interpretation of the review. We further recommend that these declarations be actively monitored in the first year following the launch of the new policy with a view to understanding how the framework is being used and refining it if necessary. The current policy does not prevent authorship on the basis of particular perspectives, positions, identities and other declared interests, and we recommend that this approach is continued. We also recommend that declarations of other interests are collected and reported separately from financial declarations.

### 3.2 Royalties

The Funding Arbiters have over the past four years been referred cases which questioned whether some royalty payments (such from the publication of a general textbook) were in breach of the policy. They felt that the current policy was not clear enough and have therefore proposed this definition: ‘Income derived from licensing or sale of healthcare-related goods or services. This may include income from books, e-media (including apps), diagnostic and assessment tools, training programmes and medical devices.’

**Trusted evidence.**  
**Informed decisions.**  
**Better health.**

### 3.3 Conflict of interest timelines

The current [Commercial Sponsorship Policy](#) states that only conflicts which have occurred in the last 36 months should be considered, but there is no information about when this period starts. In practice, the Funding Arbiters have defined this as being 36 months before the publication of a review protocol. This definition cannot be applied to other Cochrane library content, and it is inappropriate when new authors are added to an author team during review development and when a review is updated by a changed author team without a new protocol. We recommend the following:

- At title registration the first and last authors and a clear majority” ( $\geq 66\%$ ) of authors should be free of conflict.
- The “start date” for conflict of interests for a new review is three years prior to publication of the protocol.
- For authors added to the review team the time period is within three years of the date that the review group agreed that addition. Similar rules apply to peer reviewers and authors of other Cochrane Library content.
- For a review update any conflicts existing within three years of protocol publication will be considered as expired, but any conflicts existing three years before the decision to update is made will be considered relevant.

### 3.4 Descriptions of the responsibilities of Authors and of Cochrane Review Groups and Editorial and Methods Department staff

The current policy does not specifically allocate responsibility for checking authors’ declarations of interest. The Funding Arbiters are aware from cases referred, and from the findings of the audits, that some review groups have not been as careful as others in checking for potential conflict of interests. The new policy is more explicit about responsibilities and introduces a requirement that all authors update their conflict of interest forms annually during review production. We should aim to ensure that the new Editorial Management System supports implementation of the new policy and minimizes duplication of effort.

### 3.5 Peer reviewers

Clause 5 in the current [Commercial Sponsorship Policy](#) says only that “Peer reviewers should be asked to declare conflict of interest using the International Committee of Medical Journal Editors framework”. However the [Conflicts of interest and Cochrane Reviews](#) section in the Editorial and Publishing Policy Resource says that anyone with a direct financial interest in a particular intervention should not be involved in the peer review of that intervention (see section 4). The approach described in the Publishing Policy Resource is recommended, so there is clarity and consistency in the new policy.

[Return to Background section](#)

**Trusted evidence.**  
**Informed decisions.**  
**Better health.**

---

# Appendix 2: Implementation Plan

## 1 Background

Implementation of the new Conflict of Interest Policy for the Cochrane Library will require specific resources to disseminate information about the changes, raise awareness of their implications, and ensure that Cochrane's systems accommodate and encourage consistent, long-term policy adherence.

## 2 Transitional arrangements

A comprehensive approach to implementation is required to ensure that everyone who produces Cochrane Library content is made aware of the new policy and its implications. The transition from the old policy to the new one will affect many Cochrane members around the world and several Central Executive Team departments. We suggest an 18-month transition period from the point of policy launch to the point at which it takes full effect. During this period we will:

- Develop detailed timelines for the transition.
- Communicate the transitional arrangements.
- Create and deliver a training package consisting of:
  - Workshops, colloquia and governance or local meetings.
  - Online learning modules and webinars.
- Develop a Cochrane Conflict of Interest portal.
- Revise the current Declaration of Interest form and ensure systems integration.
- Review the Conflict of Interest Arbiter and Conflict of Interest Panel Terms of Reference.
- Prepare a detailed compliance-monitoring plan.

A phased approach to implementation is necessary to allow Cochrane Review Group editorial staff, authors and peer reviewers to become familiar with the new policy and to allow for the fact that many reviews will already be underway when it comes into effect. The new policy will **only be applied prospectively**:

- At the point of policy launch the new rules will apply only to registered titles. If a protocol has been published and a review is underway the old policy rules will apply. Other Cochrane Library content not yet commissioned (e.g. editorial and Cochrane Clinical Answers) will be subject to the new policy.
- If a Cochrane review was published before the launch of the new policy and is non-compliant under the new policy, there is no expectation of adherence until it needs to be updated.

**Trusted evidence.**  
**Informed decisions.**  
**Better health.**

- If a review update begins after the launch of the new policy the Cochrane Review Group editorial team is responsible for ensuring that the update author team is compliant with the new policy.
- Six months after the policy launch an audit of all reviews and protocols published in the intervening period will take place to determine the level of adherence with the new policy.

### 3 Responsibilities during the transition

The Editorial and Methods Department and the new People Services Department (previously Membership, Learning & Support Services), supported by the Conflict of Interest Arbiters, will be responsible for managing the policy rollout, providing training and monitoring adherence.

- The Editorial and Methods Department will ensure that anyone who produces Cochrane Library content – in an authorial, editorial or peer-review capacity – has access to the finalised policy ahead of the official rollout.
- The Learning & Training Team from the People Services Department will develop training materials and events in collaboration with Editorial and Methods Department staff.
- Cochrane Review Group editorial teams will be responsible for familiarising themselves with the new policy details before the rollout.
- Cochrane Review Group editorial teams will be responsible for ensuring that all their authors are aware of the new Conflict of Interest policy.

### 4 Entities not covered by the new Conflict of Interest policy

The new Conflict of Interest policy applies to all those involved in producing Cochrane Library content. This policy may need to be adapted for those who hold other roles within Cochrane (for example the Governing Board, Cochrane Council, Fields, Method Groups, Geographic Centres, the Consumer Network, the Cochrane Executive Team, and members of Cochrane Crowd and Task Exchange). In cases where adaptation is required:

- Adaptation will be at the discretion of the Governing Board.
- The Cochrane Central Executive Team Senior Management Team should determine which Central Executive Team department is responsible for adapting the policy as outlined above.
- The relevant Central Executive Team department should draft a proposal, for approval by the Governing Board.
- Once companion policies have been developed, the Conflict of Interest Arbiters will arbitrate in cases relating to these additional policies.

- Until the policy is adapted the above-mentioned Cochrane staff and contributors should continue to be governed by the current [Commercial Sponsorship Policy](#).

## 5 Resources to support policy implementation and compliance

### Conflict of Interest portal

Currently the resources to support Conflict of Interest policy implementation are scattered across different webpages. We propose the development of a single Conflict of Interest portal to bring all relevant resources together, which may include:

- The Conflict of Interest Policy for the Cochrane Library.
- Links to legacy policies.
- Links to Conflict of Interest policies developed to cover other Cochrane members.
- An FAQ section detailing common questions (drawn from Conflict of Interest case history).
- Scenarios mapped to the new policy structure and clauses.
- Decision flowcharts to illustrate responsibilities and courses of action for producers of Cochrane Library content faced with Conflict of Interest queries.
- A library of anonymised past cases with details of their resolution.
- A link to the Conflict of Interest referral form.
- More detail about the appeals process and contact details of the Conflict of Interest administrator.
- An organizational chart.
- The identities of the Conflict of Interest Arbiters and other members of the Conflict of Interest Panel, along with contact details.
- The Conflict of Interest Arbiter and Conflict of Interest Panel Terms of Reference.

### Cochrane Handbook for Systematic Reviews of Interventions

The online version of the handbook should direct users to the Conflict of Interest portal (below) for information about the policy and its implementation.

### Declaration of Interest forms and platform integration

There are several Conflict of Interest forms currently in use, depending on the role of the person involved in producing Cochrane Library content. Some are accessed via Archie; those for reviews are in RevMan. The current 'Disclosure of potential conflicts of interest' form needs to be revised to ensure that the right information is collected and that the form is better understood by all users. During the transition phase we will work to ensure that:

**Trusted evidence.**  
**Informed decisions.**  
**Better health.**

- The new form(s) is integrated into the new Editorial Management System.
- Automatic reminders for authors and Managing Editors are built into in the new Editorial Management System.
- The Declaration of Interest section in RevMan is removed and replaced with just the section in the Editorial Management System that is published as part of the review.
- Any changes needed to Cochrane systems, including RevMan Web, are managed in collaboration with the Informatics and Technology Department.

## Training resources

Editorial and Methods Department staff will work the Learning & Training Team from the People Services Department, supported by the Conflict of Interest Arbiter, to:

- Deliver face-to-face training at national and international Cochrane meetings.
- Deliver targeted face-to-face training for key support staff, e.g. the Managing Editor Support Team.
- Deliver online training, which may include webinars and self-paced learning modules.
- Deliver online ‘virtual Conflict of Interest clinics,’ in which participants will have an opportunity to discuss real-life cases.
- Delivery one-to-one training sessions with groups that are struggling, e.g. have a new Managing Editor just in post.
- Integrate the new policy into all new staff-induction packages.

## 6 Governance activities in the transition period

During the 12-month transition period Editorial and Methods Department staff will work with the new Head of Governance and Strategy, the Knowledge Translation Department and the Conflict of Interest Arbiter to:

- Review the Conflict of Interest Arbiter and Conflict of Interest Panel Terms of Reference.
- Develop a compliance-monitoring plan with details of activities and the schedule that will be communicated clearly to all policy users.

## 7 Monitoring policy compliance

The following activities are proposed during the transition period and beyond:

- 18 months after policy launch, Editorial and Methods Department staff will carry out monthly spot checks of a random sample of registered titles and published protocols.
- 24 months after policy launch, Editorial and Methods Department staff will conduct an audit of all reviews and protocols published in the intervening period to determine the level of compliance with the new policy and how the proposed framework of collecting non-financial Conflict of

**Trusted evidence.**  
**Informed decisions.**  
**Better health.**

---

Interest is being used. The results of the audit will be used to adapt resources and improve adherence. We suggest that this audit should be repeated every three to four years.

- The Conflict of Interest Arbiters, the Conflict of Interest Panel, the Editor in Chief and Editorial and Methods Department staff will hold annual discussions about reports of breaches and actions taken.



## Appendix 3: Table of Definitions

Organization with a financial interest	<p>Any for-profit organization with a real or potential financial interest in the findings of Cochrane Library content.</p> <p>This definition is not intended to include government departments, not-for-profit medical insurance companies, and health management or health research organizations.</p>
Conflict of Interest	<p>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) may be unduly influenced by a secondary interest (such as financial gain) or may be perceived to be influenced by a secondary interest.</p>
Cochrane Library content	<p>The Cochrane Database of Systematic Reviews includes Cochrane Reviews, Cochrane Protocols, and Editorials. Derivative products are Cochrane Clinical Answers and podcasts. Translations are separate but will be included in this Conflict of Interest policy. Cochrane Central Register of Controlled Trials (CENTRAL) and federated search content are specifically excluded.</p>
Cochrane Review	<p>A “Cochrane Review” refers to the protocol, review and any update.</p>
Cochrane Review Group editorial staff	<p>Managing Editor, Assistant Managing Editor, Coordinating Editor, Deputy Coordinating Editor, Contact Editor, Statistical Editor/Statistician, Methods Editor, Information Specialist and Assistant Information Specialist.</p>
Funder of a review	<p>An organization which provides a grant, contract, gift or any form of financial support to one, several or all authors of a review, or funding that goes directly to their employer or home institution or to the Cochrane Review Group.</p>
Not-for-profit organization	<p>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 money raised is used to keep the organization operating.</p>
Industry-funded clinical study	<p>Some or all funding for the study is provided by a commercial organization. The study design and methods are determined by, and all data is controlled by, industry.</p> <p>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.</p>

Clinical study with material support only	Industry provides some material, non-financial support (e.g. placebo or active drugs, testing) but independent researchers retain control over the study design, methods, analysis and reporting.
Personal relationships	Relationships with partner, spouse, immediate family member or long-term close friend, <i>if relevant to the review</i> , should be declared.
Private practice	The practice in which a healthcare professional receives financial remuneration from fee-for-service rather than from a salary.
Royalties	Income derived from the licensing or sale of healthcare-related goods or services. This may include income from books, e-media (including apps), diagnostic and assessment tools, training programmes and medical devices.
Relevance	<p>In this document financial interests are considered to be relevant if the payment comes from a commercial organization that has developed (or is developing) or distributed (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 specifically to the topic of the published content.</p> <p>Non-financial interests are considered relevant if they have a direct and obvious connection to the topic of the review or other content.</p>

[Return to Background section](#)

## Appendix 4: Project contributors

### Project Team members

Name	Role
<b>David Tovey</b>	Editor in Chief (until 30 <sup>th</sup> May 2019) Editorial and Methods Department
<b>Karla Soares-Weiser (Project Sponsor)</b>	Editor in Chief (from 1 <sup>st</sup> June 2019) Editorial and Methods Department
<b>Ruth Foxlee</b>	Senior Programme Manager Editorial and Methods Department
<b>Kirsty Loudon</b>	Conflict of Interest Revision Project Officer (until 31 <sup>st</sup> July 2019) Editorial and Methods Department
<b>Graham Smith</b>	Project Manager Editorial and Methods Department
<b>Fergus Macbeth</b>	Funding Arbiter
<b>Angela Webster</b>	Funding Arbiter

### Project Board members

Name	Country	Cochrane affiliation
<b>Jordi Pardo</b>	Canada	Council/Governing Board
<b>Gail Quinn</b>	UK	Council
<b>Lisa Bero</b>	Australia	Editorial Board
<b>Michael Brown</b>	USA	Editorial Board
<b>Tammy Clifford</b>	Canada	Editorial Board
<b>Paul Garner</b>	UK	Editorial Board
<b>Asbjorn Hrobjartsson</b>	Denmark	Editorial Board
<b>Jan Clarkson</b>	UK	Governing Board
<b>Nicky Cullum</b>	UK	Governing Board
<b>Harriet MacLehose</b>	UK	Editorial and Methods Department
<b>Quinn Grundy</b>	Canada	External

[Return to Background section](#)

Trusted evidence.  
Informed decisions.  
Better health.