



Collecting and managing declarations of interest: a webinar for MEs and AMEs

Oct 12th & Oct 13th 2020

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



Webinar format



PROCESS OUTLINE



**DISCUSSION &
QUESTIONS**



Preventing policy breaches

Collecting author declarations of interest (DoI) as early as possible to prevent a conflicted author team beginning work on a review



What the 2020 policy says

- 6.1 Rules for authors of Cochrane Library content
- 6.2 Rules for Cochrane Review Groups/Networks and the Editorial & Methods Department
- 7.1 Authors' responsibilities
- 7.2 Cochrane Review Group and Editorial Methods Department responsibilities

“Titles with author teams that breach the policy ...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.”



Resources and processes

- Review proposal form
- Archie workflows
- EMD support to create narrative DoI statements



Review proposal form

IMPORTANT: Disclosure of Conflicts of interest

Please read Cochrane's [Conflict of Interest Policy for Cochrane Library content](#) and confirm in Section 6 below whether any member of the author team has a potential Conflict of Interest.

If your title is accepted, the Review Group will request a full Declaration of Interest from each member of the author team. The title will not be registered until the Review Group has assessed any relevant Conflict of Interest.

EPPR review proposal forms -

<https://documentation.cochrane.org/display/EPPR/Review+proposal+forms>

Review proposal form

6. Declarations of interest

All authors must read [Cochrane's Conflict of Interest Policy for Cochrane Library content](#). Before the title can be registered, each author must declare any relevant Conflicts of Interest (financial and non-financial) that exist or existed in the 36 months prior to this form being submitted.

Important information

- The following individuals are prohibited from being an author on a Cochrane Review:
 - Anyone who is or has been employed in the 36 months prior to title registration by a commercial organization with a financial interest in the topic of the review.
 - Anyone who owns a commercial organization with an interest in the topic of the review.
 - Anyone who owns or has applied for a patent related to the topic of the review.
- Authors must declare all relevant financial interests within the 36 months prior to title registration. Such payments include (but are not limited to) speaker fees, honoraria, consultancies, membership of advisory boards and payment of travel, accommodation and conference registration expenses.
- Financial interests are considered relevant if a payment is made by a commercial organization that is developing, or manufactures, markets or distributes (anywhere in the world) an intervention or potential comparator related to the topic of the review. This applies regardless of the reported direction of effect and even if the payment was for work and advice that did not relate to the topic of the review.
- Overall, 67% (two thirds) of the author group must not have any relevant financial interests.
- The first and last author must not have any relevant financial interests and must not have been involved in industry-controlled studies (see [definitions](#) in the policy) that may be eligible for inclusion in the review.
- Anyone who has been involved in the conduct, analysis and publication of a study that could be included in the review cannot determine overall study inclusion and exclusion criteria or make study eligibility decision about, extract data from, carry out the risk of bias assessment for, or perform GRADE assessment of that study.
- Authors must remain in compliance with this policy through to the point that the review is published. If an author acquires any additional relevant financial interests while working on the review, they must inform the Review Group's Managing Editor immediately.

Have all members of the author team read [Cochrane's Conflict of Interest Policy](#)? Yes No

Do any members of the author team authors have a potential conflict of interest? Yes No

If yes, you should discuss these potential conflicts with the Review Group's Managing Editor before submitting this form.

Archie workflows (1)

Option 1 – create a vacant title record

- Request DoI forms from authors + send new system-wide workflow template email “NEW2020 CoI policy email for Authors” (optional)
- Request statement from EMD via Archie workflows - task assigned COI Arbiter email (optional)



Archie workflows (2)

Option 2 – register a title in Archie

- Request DoI forms from authors + template email (optional)
- The protocol workflow template should be amended to ensure that *Request Col forms (B3)* and *Confirm receipt of Col forms (B5)* tasks are inserted before the *Submit draft protocol for editorial approval (A2)* task.
- Pause the editorial process until all forms are returned
- Request statement from EMD via Archie workflows - task assigned COI Arbiter email (optional)
- ME adds collated statement to protocol template



Edit Workflow Template

Group: ▼

Workflow template: ▼ Show old

Tasks | People | Gantt Chart

Task	Duration	Skip	Decision	Role	Default email template
A1 Notify Contact Person and provide support	<input type="text" value="7"/>	<input type="checkbox"/>		Editorial Base ▼	Confirmation of title r ▼
A2a Request Conflicts of Interest forms	<input type="text" value="1"/>	<input type="checkbox"/>		Editorial Base ▼	[Standard ticket emai ▼
A2b Confirm receipt of Conflicts of Interest forms	<input type="text" value="10"/>	<input type="checkbox"/>		Contact Person ▼	Conflict of interest for ▼
A2c Pause	<input type="text" value="1"/>	<input type="checkbox"/>			
A2 Submit draft protocol for editorial approval	<input type="text" value="180"/>	<input type="checkbox"/>		Contact Person ▼	[Standard ticket emai ▼
A - Draft protocol submitted for editorial approval					
B1 Decision: Draft ready for internal CRG check?	<input type="text" value="1"/>	<input type="checkbox"/>	Yes ▼	Editorial Base ▼	[Standard ticket emai ▼
B2 Resolve issues	<input type="text" value="1"/>	<input type="checkbox"/>		Editorial Base ▼	[Standard ticket emai ▼
B3 Request Conflicts of Interest forms	<input type="text" value="0"/>	<input checked="" type="checkbox"/>		Editorial Base ▼	[Standard ticket emai ▼
B4 Identify CRG Advisors	<input type="text" value="0"/>	<input checked="" type="checkbox"/>		Editorial Base ▼	[Standard ticket emai ▼
B5 Confirm receipt of Conflicts of Interest forms	<input type="text" value="0"/>	<input checked="" type="checkbox"/>		Contact Person ▼	Conflict of interest for ▼

Template email

- Central policy that applies to everyone involved in producing Cochrane Library content
- Our policy is stricter than many other scientific journals
- Important differences – some activities prevent involvement
- Declarations have to be made before work begins and throughout the production cycle
- Explains the 36-month timeframe
- Non-compliance may lead to rejection or withdrawal of the review



Writing DoI statements

- EMD can support CRGs by writing DoI statement at Vacant Title or Registered Title stage
- Optimal process is to use Archie
 - Easy to give the task to EMD (i.e. to Maria)
 - Statements stored in workflow file
- Responsibility for checking policy compliance remains with the CRG



Standardised DoI statements

- The DoI statement will contain information for each author
- Everything declared in the authors DoI forms will be included in the DoI statement
- Standard phrasing, e.g. when no financial interests declared: “XX: Has declared that they have no conflict of interest”

Updating Dols

- Authors “...should declare all relevant interests before title registration, annually thereafter until publication, and just prior to publication (both protocol and review publication)”



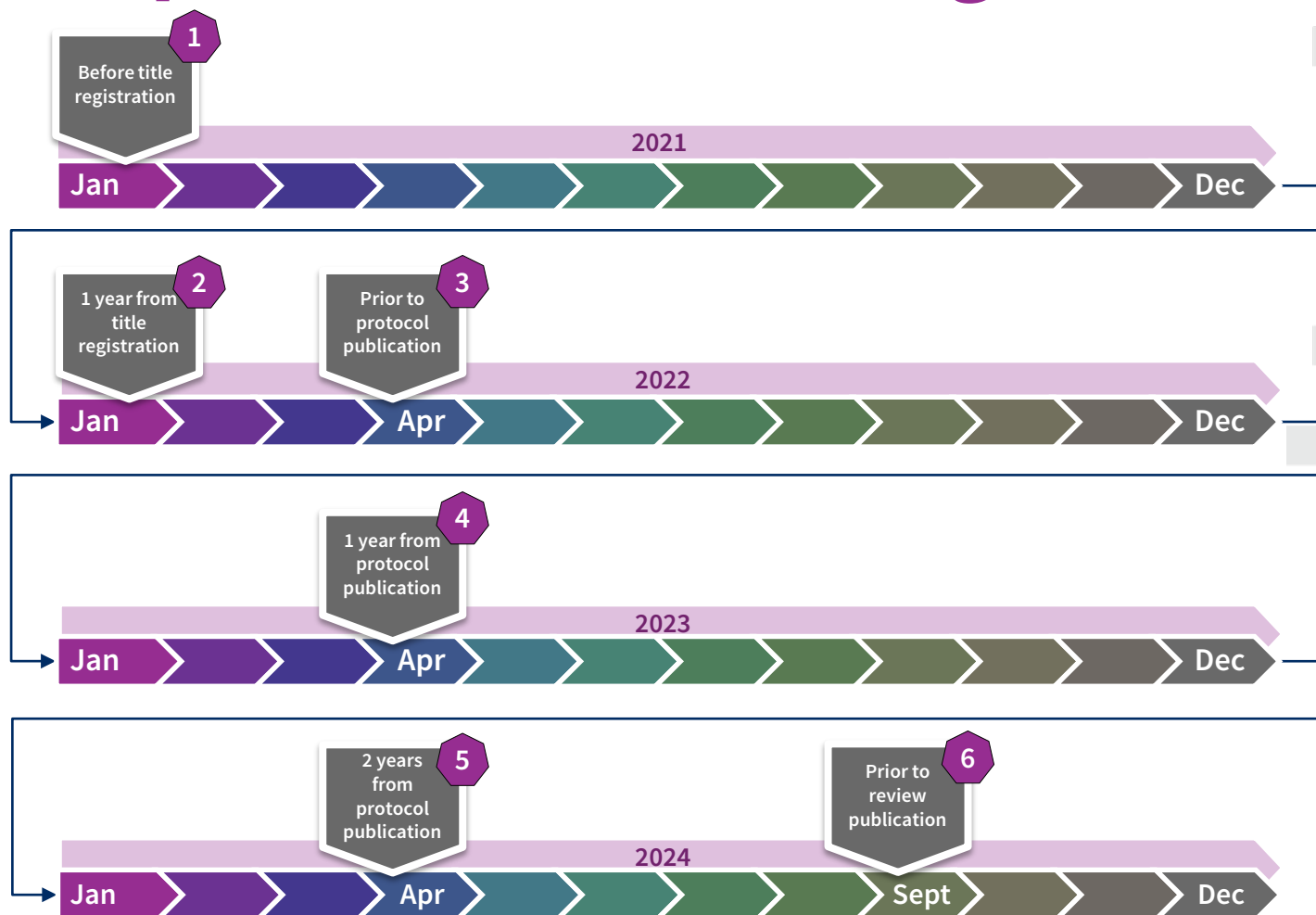
Updating Dols

All review authors must complete a DoI form at the following time points:

- Registered Title stage (for reviews) / point at which the decision is made to update (for updates)
- Annually until publication of the review
- Just prior to publication of the protocol
- Just prior to publication of the review
- When an author acquires a new financial interest(s)



Sample DoI collection diagram



Updating Dols

- Using workflows to set reminders to request Dols

D - Revised protocol submitted				29/09/2021	29/09/2021		
	E1 Decision: Does revised protocol reflect comments?	Fiona Russell	Editorial Base 2	29/09/2021	30/09/2021	1 day	356 days
	E3 Make revised protocol available to Sign-off Editor	Liz Dooley	Editorial Base	30/09/2021	01/10/2021	1 day	357 days
	E4a Request Conflicts of Interest forms	Liz Dooley	Editorial Base	01/10/2021	02/10/2021	1 day	358 days
	E4b Confirm receipt of Conflict of Interest forms	John Doe	Contact Person	02/10/2021	12/10/2021	10 days	368 days
	E4 Decision: Protocol ready for final copy editing?	Liz Dooley	Contact Editor	12/10/2021	19/10/2021	7 days	375 days
	E5c Send collated comments to Referees	Liz Dooley	Editorial Base	19/10/2021	20/10/2021	1 day	376 days
	E5b Confirm that comments are clear and complete	Liz Dooley	Editorial Base	19/10/2021	23/10/2021	4 days	379 days
	F1a Co-Eds to sign off	Mark A Jones	Editorial Base 3	23/10/2021	24/10/2021	1 day	380 days

New DoI form



New form to be deployed on Oct 14th



Changes in the new form



Guidance on completing the new form (COI portal + EPPR + Archie workflow email)



Demonstration – new DoI form on training Archie

<https://training-archie.cochrane.org/tools/form?submittedFormPK=z2009300914133943166855039660718&action=load>



COIarbiter@Cochrane.org



QUESTIONS



COMMENTS

