

EXHIBIT 166

From: [Karen Robinson](#)
To: [Jamie Feldman](#)
Cc: [Blaine Vella](#); gail.knudson@gmail.com; [Paula Neira](#); [jgreen](#); [Lin Fraser](#); [education SOC 8](#)
Subject: Re: Disclosure Forms to Blaine
Date: Friday, December 21, 2018 3:44:19 PM

It is important that competing interests are disclosed. Competing interests include financial and non-financial interests and relationships that might be considered likely to interfere with, or could reasonably be perceived as interfering with, full and objective decision-making and presentation of guidelines or which readers or users of the guideline might reasonably wish to know. Examples to disclose include being an investigator on studies likely to be considered in developing the recommendations, or being a member of a group that did or may issue policy or recommendations related to SOC8 work. We would expect many, if not most, SOC8 members to have competing interests.

Disclosure, and any necessary management of potential conflicts, should take place prior to the selection of guideline members. Unfortunately, this was not done here but the decision was made to adhere as much as possible to best practice for guideline development. To that end, disclosures are being collected now from SOC8 members. The SOC8 chairs will review all forms and, as needed, bring any issues forward to the Board.

I know that disclosure forms are challenging, or even painful, to complete. I can't speak to any technical issues with spacing on the PDF form. A solution may be to submit a supplementary sheet.

thanks,
Karen

From: Jamie Feldman <feldm010@umn.edu>
Sent: Friday, December 21, 2018 9:21:10 AM
To: Karen Robinson
Cc: Blaine Vella; gail.knudson@gmail.com; [Paula Neira](#); [jgreen](#); [Lin Fraser](#); [education SOC 8](#)
Subject: Re: Disclosure Forms to Blaine

Do you have a copy of a similar disclosure form from guideline/organization of similar interdisciplinary breadth and worldwide scope? By interdisciplinary, I mean psychology, legal, ethics, social sciences topics and recommendations in the work, as well as professionals in these areas?

The above makes WPATH fairly unique compared to most medical guidelines, which are dealing with a relatively narrow medical topic (compared to all of trans health), and involve a fairly limited number of closely related fields, and professionals.

Other concerns:

1. Conflict of interest is a well defined concept with specific implications for author/participant, Almost all the questions about "nonfinancial conflict of interest" are so broad and are encompassing of the author's past and present affiliations, publications, public

JHU_000001539

speech, affiliations of the family; any advocacy statements, etc. It does not fall into any understanding of "conflict of interest" as previously understood.. It does fall into an attempt to outline potential bias, but in the topic of trans health, one would need to go much into much greater depth, include private information (gender, sexual orientation, religion, etc) to really be transparent about bias. It would be helpful if some explanation of what the goal of this breadth of information was, and how one intends to use it--will it be published as an appendix to the SOC? If so, then I would need to re-submit my answers.

2. The questions themselves in the non financial conflict of interest section are worded so broadly, that a description of that interest would take pages in many cases, as it may cover a persons entire professional career. It would be helpful to give an example of how much detail or what kind of detail is desired, from the point of view of various people who could be responding (MD, PhD psychologists, advocacy professionals, etc)

3. Unlike other medical guidelines, trans health care is a socially and politically charged issue, and often subject to laws and policies outside the authors' control. These also can change anytime in the future, prior or after the SOC8 are published. The question about the author now or in the future subject to being in conflict to the SOC8 recommendations is impossible for many of use to answer "no" to.

4. Remember, that even though some of us are only involved in 1 or 2 chapters, our practice overlaps many or most chapters of SOC8. None of the recommendations are written yet, so to state that I would not otherwise be in conflict with the SOC8 recommendations when I don't know them is not an option.

Since this document is a departure from standard conflict of interest documents, I strongly recommend rewriting it and having it signed when the SOC8 is closer to a full rough draft that every one has read. If you still wish to use this version, then I recommend explaining why, how to fill it and in what detail---with an example(s), and how it will be used in the context of SOC8. I would again recommend not doing it until there is more of a document that everyone can read.

Jamie Feldman

On Thu, Dec 20, 2018 at 9:22 PM Karen Robinson <REDACTED> wrote:

All -

I drafted the disclosure form for consideration by the SOC8 Chairs and the WPATH Board. The form was developed based on standard disclosure forms for guideline panels and other groups doing similar work. I would also refer you to the standards for guideline development, such as the principles from the IOM, outlining the importance of disclosure of interests (<http://www.nationalacademies.org/hmd/Reports/2011/Clinical-Practice-Guidelines-We-Can-Trust.aspx> see Standard 2).

Other than what seems like a part of this email chain, I have not seen any comments. Let me know if there are specific concerns or questions that I may address.

thanks,
Karen

JHU_000001540

From: Blaine Vella <blaine@wpath.org>

Sent: Thursday, December 20, 2018 8:54:19 PM

To: gail.knudson@gmail.com

Cc: jgreen; Lin Fraser; feldm010@umn.edu; Education SOC 8

Subject: Re: Disclosure Forms to Blaine

The form was developed by Karen Robinson, our SOC methodologist and was reviewed and approved by the SOC8 co-chairs and the WPATH Board of Directors.

I have also shared Paula's concerns / recommendations with the same group.

Best regards

Blaine

Mrs. Blaine Vella

Associate Director

WPATH

1061 East Main Street, Suite 300 |

East Dundee, IL 60118

Office: [847-752-5328](tel:847-752-5328)

Fax: [224-633-2166](tel:224-633-2166)

Email: blaine@wpath.org

On Dec 20, 2018, at 8:51 PM, Gail Knudson <gail.knudson@gmail.com> wrote:

The form originated from Karen and she expects that people will have conflicts of interest. The point is not to disqualify people, it is to promote transparency.

Blaine - please correct me if I am wrong.

I will send along a copy of mine in another email.

Thank you

Gail

Sent from my iPhone

JHU_000001541

Sent from my iPhone

On Dec 20, 2018, at 3:13 PM, Jamison Green <jgreenphd1@gmail.com> wrote:

I agree; the form was difficult for me, as well, and as I worked on it I actually thought the only reason I was able to summarize my potential conflicts was that I am NOT a clinician. I'm curious to know where the form originated, too. And I also have had problems with saving the form and having my input lost when I reopened the PDF file, which I've already communicated to Blaine.

Jamison

On Thu, Dec 20, 2018 at 3:50 PM Lin Fraser <linfraser@gmail.com> wrote:

Blaine, can you respond please? I have no idea..

Sent from my iPhone

On Dec 20, 2018, at 3:31 PM, Jamie Feldman <feldm010@umn.edu> wrote:

Who developed this form?

I would need to describe my entire practice, academic and advocacy history and anticipated future history in order to fill out this form.

Please advise.

Jamie Feldman MD

On 12/19/2018 10:04 AM, Lin Fraser wrote:

Dear Colleagues-

If you haven't already done so, please sign the disclosure form and send to Blaine.

Lin & Gail

Begin forwarded message:

From: Blaine Vella

JHU_000001542

<blaine@wpath.org>

**Subject: Please Remind
Your Chapter Members**

Date: December 19, 2018
at 7:40:47 AM PST

To: SOC 8 Chapter Leads
<soc8chapterleads@wpath.org>

Dear SOC8 Chapter Leads
To complete and send me
their signed Disclosure forms.
Here is a copy, if you want to
include as well.
Thanks much
Blaine

--

Jamie Feldman MD, PhD
Dept. of Family Medicine and
Community Health
University of Minnesota

JHU_000001543

From: [Karen Robinson](#)
To: [Blaine Vella](#); gail.knudson@gmail.com; [Paula Neira](#)
Cc: [jgreen](#); [Lin Fraser](#); feldm010@umn.edu; [education SOC 8](#)
Subject: Re: Disclosure Forms to Blaine
Date: Thursday, December 20, 2018 10:22:23 PM

All -

I drafted the disclosure form for consideration by the SOC8 Chairs and the WPATH Board. The form was developed based on standard disclosure forms for guideline panels and other groups doing similar work. I would also refer you to the standards for guideline development, such as the principles from the IOM, outlining the importance of disclosure of interests (<http://www.nationalacademies.org/hmd/Reports/2011/Clinical-Practice-Guidelines-We-Can-Trust.aspx> see Standard 2).

Other than what seems like a part of this email chain, I have not seen any comments. Let me know if there are specific concerns or questions that I may address.

thanks,
Karen

From: Blaine Vella <blaine@wpath.org>
Sent: Thursday, December 20, 2018 8:54:19 PM
To: gail.knudson@gmail.com
Cc: [jgreen](#); [Lin Fraser](#); feldm010@umn.edu; Education SOC 8
Subject: Re: Disclosure Forms to Blaine

The form was developed by Karen Robinson, our SOC methodologist and was reviewed and approved by the SOC8 co-chairs and the WPATH Board of Directors.

I have also shared Paula's concerns / recommendations with the same group.

Best regards
Blaine
Mrs. Blaine Vella
Associate Director

WPATH

1061 East Main Street, Suite 300 |
East Dundee, IL 60118
Office: [847-752-5328](tel:847-752-5328)

JHU_000001544

Fax: [224-633-2166](tel:224-633-2166)

Email: blaine@wpath.org

On Dec 20, 2018, at 8:51 PM, Gail Knudson <gail.knudson@gmail.com> wrote:

The form originated from Karen and she expects that people will have conflicts of interest. The point is not to disqualify people, it is to promote transparency.

Blaine - please correct me if I am wrong.

I will send along a copy of mine in another email.

Thank you

Gail

Sent from my iPhone

Sent from my iPhone

On Dec 20, 2018, at 3:13 PM, Jamison Green <jgreenphd1@gmail.com> wrote:

I agree; the form was difficult for me, as well, and as I worked on it I actually thought the only reason I was able to summarize my potential conflicts was that I am NOT a clinician. I'm curious to know where the form originated, too. And I also have had problems with saving the form and having my input lost when I reopened the PDF file, which I've already communicated to Blaine.

Jamison

On Thu, Dec 20, 2018 at 3:50 PM Lin Fraser <linfraser@gmail.com> wrote:

Blaine, can you respond please? I have no idea..

Sent from my iPhone

On Dec 20, 2018, at 3:31 PM, Jamie Feldman

JHU_000001545

From: [Karen Robinson](#)
To: [Eli Coleman](#)
Cc: [Blaine Vella](#); [Jon Arcelus](#); [Asa Radix](#); [Gail.knudson@vch.ca](#); [Donna Kelly](#); [Taylor O'Sullivan](#)
Subject: RE: Conflict of Interest Disclosures
Date: Thursday, August 23, 2018 4:47:00 PM
Attachments: [NHMRC example doi interactive guideline development 140331.pdf](#)
[NAS Example As2018 BI-COI.docx](#)
[AHRO EPCprogram Disclosure Policy and Form 4.12.18v2.pdf](#)

Eli –

It is a little more complicated than adding items to a form. I would suggest the COI/DOI policy and form is something that will need to be discussed and implemented by the Board.

Below are links to some details about COI and guideline development:

IOM Standards for guidelines: <http://www.nap.edu/read/13058/chapter/6#82>

Policy paper from Guidelines International Network:

<http://annals.org/aim/fullarticle/2450219/guidelines-international-network-principles-disclosure-interests-management-conflicts-guidelines>

I have attached a few examples of forms and can see about tracking down some more, if that would be helpful.

Again, I am also happy to discuss further.

Thanks

Karen

From: Eli Coleman [mailto:colem001@umn.edu]

Sent: Thursday, August 23, 2018 3:51 PM

To: Karen Robinson <REDACTED>

Cc: Blaine Vella <blaine@wpath.org>; Jon Arcelus <jon.arcelus@nottingham.ac.uk>; Asa Radix <asa.radix@gmail.com>; Gail.knudson@vch.ca; Donna Kelly <donna@wpath.org>; Taylor O'Sullivan <taylor@wpath.org>

Subject: Re: Conflict of Interest Disclosures

Karen,

Can you please simply suggest what we should do in addition to what we have already done. It looks like we need an additional form and signatures. Blaine you will need to figure out how best to do that.

Thanks

On Thu, Aug 23, 2018 at 2:47 PM, Karen Robinson <REDACTED> wrote:

We had an email exchange about the COI/DOI in July. I have copied my email from that time below. I don't recall any response and the forms sent earlier today are the same as those reviewed in July. I am happy to chat further. Thanks, Karen

From July:

On Jul 12, 2018, at 12:58 PM, Karen Robinson <REDACTED> wrote:

Blaine –

As noted in the methodology document, disclosures or conflicts of interest should be collected from all involved. Typically this is done as members are nominated as potential conflicts may cause some to be not selected as members. Collection early also facilitates ensuring that there is a balance amongst the group. I didn't see anything in the document you attached about conflicts and it does not contain any disclosures of (potential) conflicts. It also seems to be limited to Leads. All Chapter Members, the Chairs, and I should

JHU_000001682

complete the COI/DOI.

Also, on another note of clarification, the language about publishing “as systematic reviews” is incorrect. Chapter Leads and members can and should consider publishing a background paper, as noted in this document. However, these will not be reports of systematic reviews. The ERT may publish separate reports of systematic reviews.

Thanks,
Karen

From: Eli Coleman [mailto:colem001@umn.edu]

Sent: Thursday, August 23, 2018 3:41 PM

To: Blaine Vella <blaine@wpath.org>

Cc: Karen Robinson <REDACTED> Jon Arcelus <jon.arcelus@nottingham.ac.uk>; Asa Radix <asa.radix@gmail.com>; Gail.knudson@vch.ca; Donna Kelly <donna@wpath.org>; Taylor O'Sullivan <taylor@wpath.org>

Subject: Re: Conflict of Interest Disclosures

Thanks Blaine. Karen, is this sufficient?

On Thu, Aug 23, 2018 at 2:25 PM, Blaine Vella <blaine@wpath.org> wrote:

Hi Everyone

I know there has been some discussion about the COI documents that the leads and chapter members have signed. I am attaching the documents here.

Please let me know if we are adding an addendum for everyone to sign and if so who is putting this together?

Thanks
Blaine

--

Eli Coleman, PhD
Academic Chair in Sexual Health
Professor and Director



--

Eli Coleman, PhD
Academic Chair in Sexual Health
Professor and Director



JHU_000001683

BI/COI FORM 1

The National Academies of
SCIENCES · ENGINEERING · MEDICINE

BACKGROUND INFORMATION AND CONFIDENTIAL CONFLICT OF INTEREST DISCLOSURE *For Studies Related to Government Regulation*

NAME: ___

TELEPHONE: ___

ADDRESS: _

EMAIL ADDRESS: ___

CURRENT EMPLOYER: _

COMMITTEE: _

There are two parts to this form, Part I Background Information, and Part II Confidential Conflict of Interest Disclosure. Complete both parts, **sign** and **date** this form on the last page, and return the form to the responsible staff officer for the project and committee activity to which this form applies. **Retain a copy for your records.**

PART I BACKGROUND INFORMATION

INSTRUCTIONS

Please provide the information requested below regarding **relevant** organizational affiliations, government service, public statements and positions, research support, and additional information (if any). Information is "relevant" if it is related to -- and might reasonably be of interest to others concerning -- your knowledge, experience, and personal perspectives regarding the subject matter and issues to be addressed by the committee activity for which this form is being prepared. If some or all of the requested information is contained in your curriculum vitae, you may if you prefer simply attach your CV to this form, supplemented by additional responses or comments below as necessary.

I. ORGANIZATIONAL AFFILIATIONS. Report your relevant business relationships (as an employee, owner, officer, director, consultant, etc.) and your relevant remunerated or volunteer non-business relationships (e.g., professional organizations, trade associations, public interest or civic groups, etc.).

II. GOVERNMENT SERVICE. Report your relevant service (full-time or part-time) with federal, state, or local government in the United States (including elected or appointed positions, employment, advisory board memberships, military service, etc.).

III. RESEARCH SUPPORT. Report relevant information regarding both public and private sources of research support (other than your present employer), including sources of funding, equipment, facilities, etc.

IV. PUBLIC STATEMENTS AND POSITIONS. List your relevant articles, testimony, speeches, etc., by date, title, and publication (if any) in which they appeared, or provide relevant representative examples if numerous. Provide a brief description of relevant positions of any organizations or groups with which you are closely identified or associated.

V. ADDITIONAL INFORMATION. If there are relevant aspects of your background or present circumstances not addressed above that might reasonably be construed by others as affecting your judgment in matters within the assigned task of the committee or panel

on which you have been invited to serve, and therefore might constitute an actual or potential source of bias, please describe them briefly.

AHRQ Evidence-based Practice Center Policy on Financial and Nonfinancial Interests

Background and Purpose of Policy

To maintain public confidence in the scientific integrity and credibility of work produced by the EPC Program, it is essential that all aspects of the process and methodological approach on which the Evidence-based Practice Centers evidence reports rests are clear and respected. To ensure the credibility of evidence reviews and additional reports put forth on behalf of the EPC, objectivity must be maintained and the risk of bias reduced in the framing of questions and application of methods. Bias threatens the validity of clear and cogent findings and jeopardizes the public's trust in science and reporting.

While it is impossible to eliminate the potential for bias completely, policies and procedures can reduce the risk for bias and improve credibility and trust in the final product. Since its inception, the EPC Program has had an established policy for reducing the risk of bias from financial and non-financial interests. The Institute of Medicine defines conflict of interest (COI) as “a set of circumstances that creates a risk that professional judgment or actions regarding a primary interest will be unduly influenced by a secondary interest”¹. While COI is not an exact proxy for potential for bias, it is a concrete measure that can be identified or declared. While both financial and non-financial interests may influence the judgment of an individual synthesizing the evidence on a particular subject matter, use of financial COI as a proxy and measure of bias is a more established and accepted practice than collection of non-financial COI.

This document updates the previous policy and is intended for EPC reference and use. All individuals participating in a review (including the EPC Core Team, EPC Key Informants, EPC Technical Expert Panel members, and EPC Invited Peer Reviewers) should complete the Disclosure Form for COI in Appendix A.

The previous disclosure form, in use since the inception of the program, required individuals to self-report and perceived COI as mandated by federal regulations described in Title 45 Code of Federal Regulations (CFR), Part 94. However, open response resulted in high variability with both over- and under-reporting at times. In 2009, the International Committee of Medical Journal Editors (ICMJE) developed a COI reporting form for authors submitting manuscripts. The ICMJE form provided specific examples for which individuals needed to report any relevant financial interests, rather than leaving it open-ended for individual interpretation. Appendix A adapts this form for prospective use in conducting EPC projects, rather than for retrospective COI evaluation in a manuscript submission.

Both the previous form and the ICMJE form request disclosure of other non-financial COI, but provide little specific guidance and generally leave it up to individual judgment. Likewise, the Institute of Medicine (IOM) Standards of Systematic Reviews (2011) further emphasized the importance of non financial COI, but also provided little guidance on how to identify non-financial COE that pose the greatest risk of bias.

The EPC Program assembled a workgroup in 2012 to develop an approach to identifying and managing non-financial COI. Although still in progress at the time of this update, the Disclosure Form (Appendix A) incorporates and adapts the work group's specific questions to help individuals identify non-financial COI. It is important to note continued debate over whether non-financial COI, such as professional interests, relationships, and activities, automatically increase the risk of bias and whether the benefits of increased expertise or increased partnership by an organization that the individual represents may offset some of these risks.

Definitions of Varying Roles:

Different roles of individuals participating in the EPC report may necessitate different management of COI based on level of responsibility in making judgments and conclusions in the project. However, all must disclose COI related to the subject matter, including (as relevant):

- a) EPC Core Team (including the EPC Director and Lead Investigator)
- b) EPC Key Informants
- c) EPC Technical Expert Panel
- d) EPC Invited Peer Reviewers

EPC Core Team:

The EPC core team includes anyone who participates meaningfully in any of the key steps of the systematic review process such as:

- a) Design and execution of the literature search strategy
- b) Decisions on the final inclusion and exclusion criteria
- c) Decisions on which studies shall be included or excluded from the evidence report or other product (screening of abstracts and full-text studies)
- d) Abstraction of information from eligible studies
- e) Analyses of the evidence
- f) Grading or rating the quality of studies and body of evidence
- g) Writing or editing any portion of the evidence report or other product
- h) Administrative or logistical tasks

Decisions about who comprises the Core Team for COI purposes should be made based on the participation in one or more tasks as listed above. It is recognized that Core Team members may include different sorts of individuals for different projects or different EPCs including faculty, staff, students, fellows, librarians, and editors. This would also include any subcontractors participating in the conduct of the EPC project.

EPC Director:

The EPC Director is Principal Investigator for EPC-related work and is responsible for identifying and assembling the EPC Core Team. In many cases, the EPC Director may designate one person as the Lead Investigator and delegate some responsibilities as described below or may assume these responsibilities him/herself. The EPC Director maintains responsibility for collecting and assessing COI disclosures for the EPC Core Team members. Although the logistics of gathering COI disclosure forms may be delegated to a project manager, the EPC Director is responsible for evaluating any disclosed COI and developing a management plan.

EPC Lead Investigator:

If the EPC Director chooses, he or she may assign a separate Lead Investigator for a particular project. Either the EPC Director or the designated Lead Investigator leads the Core Team and is the primary person responsible for the overall design, conduct, or reporting of the systematic review. This person is responsible for collecting and assessing COI disclosures for Key Informants or Technical Expert Panel members. Although the logistics of gathering the COI disclosure forms may be delegated to a project manager, the Lead Investigator is responsible for evaluating any disclosed COI and developing a management plan. This role may be filled by or shared with the EPC Director.

JHU_000001703

EPC Key Informant:

Key Informants are stakeholders who provide input on preliminary research questions, which are used to develop key questions that will guide the evidence reports on a particular topic. Key Informants are selected for their unique perspective on a topic and are asked to represent their viewpoints throughout the course of topic refinement in order to ensure a broad range of input. While the EPC Core Team considers the input of Key Informants, the key questions are not intended to reflect the consensus agreement of all Key Informants.

EPC Technical Expert Panel (TEP) Member:

Technical Experts provide clinical and methodological expertise to the EPC Core Team as they are developing the protocol. This engagement helps to ensure that the report is methodologically rigorous and reflective of current practice. The TEP members may not participate directly in writing or editing any portion of the draft or final EPC report and thus the report is not intended to represent the judgments or conclusions of the TEP.

EPC Invited Peer Reviewers:

The peer reviewer provides written input on the draft report. Because stakeholders and the public have an opportunity to comment on the draft report through the public comment mechanism, the EPC Program focuses on specifically inviting independent, unbiased experts to peer review EPC reports.

Disclosure of COI:

The recommended Disclosure Form for COI with instructions can be found in Appendix A.

Time period for financial interests disclosure: The instructions recommend a two year time window: 12 month “look back” period and to project any relationships for the next 12 months. If individuals develop any new relationships during the duration of their participation in the report, they must update and resubmit a disclosure form within 7 days. This may affect their role in the project. If an individual's involvement in the project lasts longer than 12 months, the EPC Director (or Lead Investigator, as appropriate) will obtain an updated Disclosure Form.

Whose financial interests to disclose: As guided by the Department of Health and Human Services Title 45 Code of Federal Regulations, Part 94², individuals are required at minimum to disclose not only their own personal financial interests, but those of their spouse or dependent children.

How much financial interest requires disclosure: Thresholds for the amount of financial conflicts of interest requiring disclosure differ depending on the level of responsibility in making decisions, judgments, and writing conclusion of the report. The EPC Core Team should report financial interests cumulatively involving \$1,000 or more, while Key Informants, TEP members, or Invited Peer Reviewers should report financial conflicts which cumulatively total \$5,000 or more. For example, if financial COI from all sources over a two year time window (within the past year and anticipated in the future 12 months) for the individual, spouse, and dependent children cumulatively total less than \$1,000 for EPC Core Team members or less than \$5,000 for Key Informants, TEP Members, or Invited Peer Reviewers, then they do not need to report anything on the Disclosure Form.

What financial interests to disclose: The Disclosure Form identifies 17 specific relationships related to the subject matter of the EPC report for which individuals must disclose the presence or absence of financial interests. This should include any ongoing interests, previous interests within the “look back” period, as well as any anticipated new interests in the ensuing 12 months as described above. For purposes of this document, individuals should disclose only related interests that apply to the topic of the EPC project. When listing competing interests, individuals should err on the side of being liberal in the disclosure.

According to Title 45 CFR Part 94, financial interests include anything of monetary value that when aggregated exceeds the minimum threshold value as described above or represents more than a five percent (5%) ownership interest in any single entity.

What financial interests not to disclose: Financial interests that do not need to be disclosed include:

- Ownership interests in an institution if the institution is an applicant under the Small Business Innovation Research (SBIR) program;
- Income from seminars, lectures, or teaching engagements sponsored by public or nonprofit entities;
- Income from service on advisory committees or review panels for public or nonprofit entities;
- Equity interest that represents less than a five percent ownership interest in any single entity, and when aggregated with all other financial interests does not exceed \$5,000 (or \$1,000 for EPC Core Team members) in value.

Disclosing Non-financial Interests

The Disclosure Form and instructions in Appendix A identifies nine specific questions related to non-financial interests that individuals must answer. The questions are geared to identify entrenched opinions that may not be open to alternative conclusions given adequate evidence to the contrary and interests or institutional relationships that are not direct financial COI but may influence or bias the individual.

Management of COI:

Management of Financial COI

The EPC Core Team is ultimately responsible for making final judgments, decisions, and assessments and writing the report, and thus must pass a higher standard. EPC Core Team members must not have related financial COI which cumulatively total greater than \$1,000. Depending on the nature of the financial COI, in some cases these conflicts may be managed by divestment (e.g., selling stock holdings).

In general, Key Informants, TEP members, and Invited Peer Reviewers should not have financial COI related to the EPC project cumulatively totaling more than \$5,000. However there may be extenuating circumstances in which a field has a limited number of experts. In these special circumstances, the EPC and the AHRQ official will ensure that the panel is balanced with individuals of differing opinions to ensure that not only one perspective is unfairly weighted. They may consider not only the nature of the COI but also the timing (whether present in the past 12 months or anticipated in the next 12 months). Other input from individuals with COI may be obtained through specified public comment periods.

Management of Non-financial COI

The Disclosure form asks specific questions in an attempt to identify entrenched opinions or other influences that are not directly related to financial COI. However, because current understanding is limited about how to use proxy questions to identify individuals at highest risk of bias without inappropriately excluding individuals with particularly relevant expertise, many situations of identified non-financial COI will need to be handled on a case-by-case basis until the field is further developed.

In general, the EPC and AHRQ need to consider whether the systematic review topic is the subject of advocacy or policy change, has inter-specialty variations, or is an area with a limited pool of experts. The existence of advocacy, policy change, or inter-specialty variations may affect the likelihood that institutional relationships or professional affiliations would increase the risk of bias and thus may be considered a higher risk for non-financial COI.

Individuals with COI may be either restricted from participating in the review altogether or limited in their participation to certain aspects of the review. For example, individuals with a specific COI (e.g., authorship of a particular study) should not be involved in judgment or decision-making regarding any question that includes that particular study. Alternatively, individuals with a particularly entrenched opinion based on previously published opinion pieces may better serve as TEP members rather than on the EPC Core Team. For institutional conflicts, the EPC and AHRQ may choose to institute and implement a clear COI management policy and procedures. In fields with a limited pool of experts, the EPC and AHRQ may elect to balance COI across all involved individuals (as in the cases of professional interests or advocacy).

Responsibilities:

Responsibilities of the EPC

Prior to starting the project, the EPC Director and/or designated project manager will obtain a completed Disclosure Form from each potential member of the Core Team. The EPC Director will submit these forms to AHRQ along with justification of any issues presented therein prior to starting a project.

The Lead Investigator (or appropriate designee) will collect and review completed Disclosure Forms from Key Informants and TEP members. The Lead Investigator should provide justification to AHRQ for participation for inclusion of individuals with COI. Note that Key Informants and TEP members must be approved by AHRQ via an email confirmation before any individual can participate.

The EPC should update Disclosure Forms for any individual whose involvement in the projects extends beyond 12 months. The EPC should maintain the Disclosure Forms for 6 years past delivery of the final report.

Responsibilities of AHRQ:

AHRQ will review the Disclosure Forms for EPC Core Team members, Key Informants, TEP members, and Invited Peer Reviewers. AHRQ will consider whether any COI can be avoided without a damaging loss of expert review prior to disqualifying any proposed Key Informant, TEP member, and Invited Peer Reviewer from participating in the review. Any concerns about potential COI by AHRQ will be discussed with the EPC Director (for EPC Core Team members), or the Lead Investigator (for Key Informants or TEP members).

To ensure the transparency and credibility of the EPC program, AHRQ reserves the right to require that an individual with a COI not participate in the collection or analysis of data or in the writing or review of report findings or associated translation products. The affected EPC will be given an opportunity to substitute another investigator in a revised proposal.

References

1. Institute of Medicine. (2010). Committee on Conflict of Interest in Medical Research, Education, and Practice, edited by Bernard Lo and Marilyn J. Field.
2. “Responsible Prospective Contractors” Title 45 Code of Federal Regulations, Pt. 94 October 1, 2017. Available at: U.S. Government Printing Office. <http://www.gpo.gov/fdsys/>. Accessed April 2018.
3. “Uniform Requirements for Manuscripts Submitted to Biomedical Journals: Ethical Considerations in the Conduct and Reporting of Research: Conflicts of Interest” Available at: International Committee of Medical Journal Editors. http://www.icmje.org/ethical_4conflicts.html. Accessed July 2012.
4. Institute of Medicine. (2011). [Finding What Works in Health Care: Standards for Systematic Reviews](http://www.nationalacademies.org/hmd/~media/Files/Report%20Files/2011/Finding-What-Works-in-Health-Care-Standards-for-Systematic-Reviews/Standards%20for%20Systematic%20Review%202010%20Insert.pdf). Washington, DC: National Academies Press. Available at: Institute of Medicine. <http://www.nationalacademies.org/hmd/~media/Files/Report%20Files/2011/Finding-What-Works-in-Health-Care-Standards-for-Systematic-Reviews/Standards%20for%20Systematic%20Review%202010%20Insert.pdf>. Accessed July 2012.

From: [Karen Robinson](#)
To: [Eli Coleman](#); [Jon Arcelus](#)
Cc: [Blaine Vella](#); [Asa Radix](#)
Subject: RE: SOC8 Disclosure Form
Date: Tuesday, December 4, 2018 9:53:00 AM

Ideally these forms are completed during recruitment and nomination of guideline panel members. Who was it that made the decisions about the SOC members? I would use same group. I assume this was initially the Board and then the Chairs. The Board should review ours, and then we should review for the remaining members. We would bring to Board any concerns or issues. All forms need to be retained on file (assume by Board).

Let me know if you would like to discuss this proposal further.

Thanks,

Karen

From: Eli Coleman [mailto:colem001@umn.edu]

Sent: Tuesday, December 4, 2018 9:28 AM

To: Jon Arcelus <Jon.Arcelus@nottingham.ac.uk>

Cc: Blaine Vella <blaine@wpath.org>; Asa Radix <asa.radix@gmail.com>; Karen Robinson <REDACTED>

Subject: Re: SOC8 Disclosure Form

my specialty is psychology; my subspecialty is sexual health.

It is a good question of who to review these.

I am copying Karen to see what she thinks - in terms of who is most appropriate.

It may be that it needs to be someone or others than the existing SOC committee.

On Tue, Dec 4, 2018 at 3:43 AM Jon Arcelus <Jon.Arcelus@nottingham.ac.uk> wrote:

Thanks Blaine

I am Ok with it except this question which I don't understand;

3.4 Do you have a primary specialty or subspecialty?

I also don't know what we are doing with this information? Who is going to review all the answers and make the decision?

Regards

Jon

From: Blaine Vella [mailto:blaine@wpath.org]

Sent: 03 December 2018 17:11

To: Eli Coleman <colem001@umn.edu>; Jon Arcelus <mszja2@exmail.nottingham.ac.uk>; asa.radix@gmail.com

Cc: WPATH EC <wpathec@wpath.org>

Subject: SOC8 Disclosure Form

Good Morning Eli

Attached is the approved Disclosure Form from the WPATH Board.

Once you, Asa & Eli have reviewed, I would like to send out to all SOC8 members (chairs, leads, members, Karen) and ask for them to send back to me by 12/15/2018.

Please advise when this is OK to send as well as the message you would like to include with it.

Best

Blaine

This message and any attachment are intended solely for the addressee

JHU_000001811

and may contain confidential information. If you have received this message in error, please contact the sender and delete the email and attachment.

Any views or opinions expressed by the author of this email do not necessarily reflect the views of the University of Nottingham. Email communications with the University of Nottingham may be monitored where permitted by law.

--

Eli Coleman, PhD
Academic Chair in Sexual Health
Professor and Director



From: [Karen Robinson](#)
To: [Blaine Vella](#)
Cc: [Eli Coleman](#); [Jon Arcelus](#); [Asa Radix](#); [Donna Kelly](#)
Subject: RE: updated tracking document
Date: Thursday, July 12, 2018 1:35:00 PM
Attachments: [EPC-Disclosure Form.pdf](#)

Blaine –

I have attached the form we use for projects through the Evidence-based Practice Center. This is very detailed – I am not suggesting you need one this intense! This does give you an idea of what information is collected.

Collection of COI is part of standard of practice for guidelines (assessed with AGREE instrument) and a IOM Standard (see Standard 2 below and

<http://www.nationalacademies.org/hmd/Reports/2011/Clinical-Practice-Guidelines-We-Can-Trust/Standards.aspx>).

STANDARD 2

Management of conflict of interest (COI)

2.1 Prior to selection of the Guideline Development Group (GDG), individuals being considered for membership should declare all interests and activities potentially resulting in COI with development group activity, by written disclosure to those convening the GDG.

- Disclosure should reflect all current and planned commercial (including services from which a clinician derives a substantial proportion of income), non-commercial, intellectual, institutional, and patient/public activities pertinent to the potential scope of the CPG.

2.2 Disclosure of COIs within GDG

- All COI of each GDG member should be reported and discussed by the prospective development group prior to the onset of their work.
- Each panel member should explain how their • COI could influence the CPG development process or specific recommendations.

2.3 Divestment

- Members of the GDG should divest themselves of financial investments they or their family members have in, and not participate in marketing activities or advisory boards of, entities whose interests could be affected by CPG recommendations.

2.4 Exclusions

- Whenever possible GDG members should not have COI.
- In some circumstances, a GDG may not be able to perform its work without members who have COIs, such as relevant clinical specialists who receive a substantial portion of their incomes from services pertinent to the CPG.
- Members with COIs should represent not more than a minority of the GDG.
- The chair or co-chairs should not be a person(s) with COI.
- Funders should have no role in CPG development.

From: Blaine Vella [mailto:blaine@wpath.org]

Sent: Thursday, July 12, 2018 1:05 PM

To: Karen Robinson <REDACTED>

Cc: Eli Coleman <colem001@umn.edu>; Jon Arcelus <jon.arcelus@nottingham.ac.uk>; Asa Radix <asa.radix@gmail.com>; Donna Kelly <donna@veritasmeetingsolutions.com>

Subject: Re: updated tracking document

Thanks Karen

Is there a template document that you have that we could draw from? I have these from the co-chairs, chapter leads and workgroup members.

Best regards

Blaine

Mrs. Blaine Vella

Associate Director

WPATH

1061 East Main Street, Suite 300 |

East Dundee, IL 60118

Office: [847-752-5328](tel:847-752-5328)

Fax: [224-633-2166](tel:224-633-2166)

Email: blaine@wpath.org

On Jul 12, 2018, at 12:58 PM, Karen Robinson <REDACTED> wrote:

Blaine –

As noted in the methodology document, disclosures or conflicts of interest should be collected from all involved. Typically this is done as members are nominated as potential conflicts may cause some to be not selected as members. Collection early also facilitates ensuring that there is a balance amongst the group. I didn't see anything in the document you attached about conflicts and it does not contain any disclosures of (potential) conflicts. It also seems to be limited to Leads. All Chapter Members, the Chairs, and I should complete the COI/DOI.

Also, on another note of clarification, the language about publishing "as systematic reviews" is incorrect. Chapter Leads and members can and should consider publishing a background paper, as noted in this document. However, these will not be reports of systematic reviews. The ERT may publish separate reports of systematic reviews.

Thanks,

Karen

From: Blaine Vella [<mailto:blaine@wpath.org>]

Sent: Thursday, July 12, 2018 12:25 PM

To: Karen Robinson <REDACTED> Eli Coleman <colem001@umn.edu>; Jon Arcelus <jon.arcelus@nottingham.ac.uk>; Asa Radix <asa.radix@gmail.com>

Subject: RE: updated tracking document

Hi Karen

Looking at item 2, this is the document that all chapter leads and workgroup members have signed. Do you want copies of these? Is there something else you need from them?

JHU_000001822

Blaine

From: Karen Robinson <REDACTED>
Sent: Thursday, July 12, 2018 12:12 PM
To: Eli Coleman <colem001@umn.edu>; Jon Arcelus <jon.arcelus@nottingham.ac.uk>;
Asa Radix <asa.radix@gmail.com>
Cc: Blaine Vella <blaine@wpath.org>
Subject: updated tracking document

Thanks for the call today!

I have attached an updated tracking document.

Here are tasks based on call:

- KR will ask Blaine to set up call with Chapter Leads (start with existing SOC Chair calls for schedule)
- KR will ask Blaine re collection of COI/DOI from Chapter Leads and Members
- KR will flesh out the process for statements (item 2 on agenda) for review by Chairs. This will be provided to the Chapter Leads closer to date of call(s).
- KR will flesh out template for chapters, including guidance on length and a mockup (item #3 on agenda). This will be reviewed by Chairs but not yet provided to the Chapter Leads.
- Chairs will send KR the dates/info for SOC Chair calls and KR will join those, as possible.

Let me know if I have forgotten or misremembered anything.

I found the call very useful – thanks!

Karen

Karen A. Robinson, PhD
Director JHU Evidence-based Practice Center
Associate Professor of Medicine, Epidemiology, and Health Policy and Management
Johns Hopkins University

REDACTED

REDACTED

REDACTED

REDACTED

From: [Karen Robinson](#)
To: ["Eli Coleman"](#); [Jon Arcelus](#); [Asa Radix](#)
Cc: [Blaine Vella](#); [Gail Knudson](#); ["sue@wpath.org"](#)
Subject: WPATH SOC8: COI policy for guidelines?
Date: Friday, September 28, 2018 8:55:02 AM

All –

Especially as people argue for more limited consensus processes, noting quite rightly the polarization of the community, it is imperative that there is a clear and transparent COI policy in place. I have not yet seen one. What are plans for implementing a COI policy?

Thanks

Karen



WPATH Policy for Disclosures of Interests and Management of Conflicts

Standards of Care 8

The World Professional Association for Transgender Health (WPATH) develops the Standards of Care (SOC) for the health of Transsexual, Transgender and Gender Nonconforming People. Appointment to the SOC8 Committee as a Chair, Methodologist, Chapter Lead or Chapter Member is subject to approval of the WPATH Board.

Interests must be disclosed using the WPATH Disclosure Form. The Disclosure Form collects information about financial relationships with entities with direct interest in the SOC8 as well as any non-financial interests such as previously published opinions, institutional relationships, advocacy or policy positions, or specialty practice that may relate to the topics in SOC8.

Management of Conflicts of Interest

The WPATH Board reviews and assesses disclosure forms. Management of conflicts may include prohibiting membership in SOC8, open discussion with other chapter or SOC8 members, and/or recusal from decisions specific to disclosed interests.

Completed and signed forms should be submitted for review of the WPATH Board to blaine@wpath.org

Please complete and sign by December 22, 2018.

Part 1. Identifying Information

Name: Karen A. Robinson

Complete Mailing Address: REDACTED

Email Address: REDACTED

Telephone Number (Daytime): REDACTED

Current Employer/Affiliation: Johns Hopkins University

Chapter(s): member of SOC8 steering committee; Lead, Evidence Review Team

Complete All Parts of this Disclosure Form

- Check "No" if no disclosure exists.
- Check "Yes" – please provide the requested information next to each item where "Yes" was checked.

Part 2. Financial Activities Related to SOC8

For each of the items listed in Section 2, consider stocks, bonds, and other financial activities and investments including partnerships (but excluding broadly diversified mutual funds and any investment or financial interest valued at less than \$5,000 USD).

JHU_00003774



Item	No	Yes	Describe relationship, including name of entity and amount.
2.1 Do you or your partner/spouse or minor children or dependents own directly or indirectly (e.g., through a trust or an individual account in a pension or profit-sharing plan) any stocks, bonds or other financial investments that may in any way gain or lose financially from SOC8?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	
2.2 Do you or your partner/spouse or minor children or dependents hold or are you currently applying for any patents related to the content of SOC8?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	
2.3 Have you or your partner/spouse or minor children or dependents received research grants or contracts (restricted or unrestricted) from an organization that has interests or activities related to the content of SOC8?	<input type="checkbox"/>	<input checked="" type="checkbox"/>	Funding to support the systematic review +
2.4 Have you or your partner/spouse or minor children or dependents received reimbursements, fees or salary from an organization that has interests or activities related to the content of SOC8? (e.g., as a board member, advisor, consultant, payment for manuscript, speakers' bureaus, travel, expert testimony)?	<input type="checkbox"/>	<input checked="" type="checkbox"/>	Reimbursed for travel to WPATH conference +
2.5 Do you or your partner/spouse or minor children or dependents have any other financial interests related to SOC8?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	

Part 3. Non-Financial Activities Related to SOC8

Item	No	Yes	Describe Interest
3.1 Have you or your partner/spouse or minor children or dependents ever authored, coauthored, or publicly provided an opinion related to the topics in SOC8?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	
3.2 To the best of your knowledge, do you or your partner/spouse or minor children or dependents work for, or are you a member of an organization with a stated position (e.g., position statement,	<input checked="" type="checkbox"/>	<input type="checkbox"/>	

JHU_000003775



Item	No	Yes	Describe Interest
blog, editorial, legislature or legal testimony, or related document) related to SOC8?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	
3.3 Could recommendations in SOC8 conflict with policies you have promoted or are obliged to follow?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	
3.4 Do you have a primary specialty or subspecialty?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	
3.5 Do you prescribe or otherwise recommend a test, therapy, treatment or program to be considered in SOC8?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	
3.6 Do you or your partner/spouse or minor children or dependents have any other non-financial interests related to SOC8?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	
3.7 Are you or your partner/spouse or minor children or dependents employed by an organization/company or work in a field that is likely to be directly influenced by content in SOC8?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	

Part 4. Certification

I certify that the information above is true and complete. Further, I agree to update and resubmit this form if I enter into any new financial or non-financial relationships/roles related to SOC8.

Print Name: Karen A. Robinson

Signature:

Karen A. Robinson

Digitally signed by Karen A. Robinson
 DN: cn=Karen A. Robinson, o=Johns Hopkins University, ou, email= REDACTED c=US
 Date: 2018.12.12 14:33:57 -05'00'

Date:

JHU_000003776