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Prepared By	Ally Doyle

# Standard Operating Procedures

## Society for Integrative Oncology (SIO) Clinical Practice Guidelines (CPG) Committee

*Date approved by SIO CPG Committee: 11/08/2021*

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## **1. SIO CPG Committee Current Members and Terms**

### **Heather Greenlee, ND, PhD (Co-Chair)**

Past President, Society for Integrative Oncology  
Associate Professor, Cancer Prevention Program, Public Health Sciences and Clinical  
Research Divisions, Fred Hutchinson Cancer Research Center  
Associate Professor, Division of Medical Oncology, University of Washington School of  
Medicine  
Medical Director, Integrative Medicine Program, Seattle Cancer Care Alliance  
SIO CPG Committee Term: 2019 –

### **Debu Tripathy, MD (Co-Chair)**

Past President, Society for Integrative Oncology  
Professor and Chair, Department of Breast Medical Oncology, Division of Cancer Medicine, The  
University of Texas MD Anderson Cancer Center  
SIO CPG Committee Term: 2019 –

### **Suzanna Zick, ND, MPH (Co-Chair)**

Past President, Society for Integrative Oncology  
Research Associate Professor, University of Michigan Department of Family Medicine and  
Nutritional Sciences, School of Public Health  
Co-director, Integrative Family Medicine, University of Michigan School of Medicine  
SIO CPG Committee Term: 2019 –

### **Lynda Balneaves, PhD, RN**

Past President, Society for Integrative Oncology  
Associate Professor, College of Nursing, University of Manitoba  
Rady Faculty of Health Sciences, University of Manitoba  
SIO CPG Committee Term: 2019 –

### **Linda Carlson, PhD, CPsych (Liaison to SIO Communications and Liaison to the SIO Executive Committee)**

President, Society for Integrative Oncology  
Professor, Department of Oncology, University of Calgary  
Adjunct Professor Department of Psychology, University of Calgary  
Clinical Psychologist and Director of Research, Department of Psychosocial Resources,  
Tom Baker Cancer Centre  
SIO CPG Committee Term: 2019 –

### **Richard Lee, MD**

Past Treasurer, Society for Integrative Oncology  
Associate Professor, Department of Medicine Division of Hematology and Oncology,  
Case Western Reserve University School of Medicine  
Director of the Supportive and Integrative Oncology Program, University Hospitals Seidman  
Cancer Center  
SIO CPG Committee Term: 2019 –

**2. Purpose of the Standard Operating Procedures (SOP)**

The purpose of this document is to define the SOP for the CPG Committee, including:

- a. CPG Committee membership and selection on CPG Committee Co-Chairs
- b. Identifying and choosing specific clinical practice guideline topics, including requirements, methodology, internal and external review, and final approval
- c. The process for partnering with external individuals and organizations on clinical practice guidelines, including developing and approving communication, media releases and dissemination plans
- d. Assembling the CPG Panels, including identification and selection of CPG Panel Co-Chairs and CPG Panel members
- e. Developing the guideline manuscript, including drafting the recommendations, drafting the manuscript, and authorship requirements

This SOP is to be used together with other SIO policies and SOPs.

**3. SOP Approval Process**

- a. The contents of this document will first receive approval by the CPG Committee by a simple majority.
- b. Then, this document will be presented to the SIO Executive Committee for approval.
- c. Then, the SIO Board will be notified of the processes by the SIO Executive Committee.
- d. Please see Appendix A for an organizational chart representing the relationships describe herein.

#### 4. CPG Committee

##### 4.1 Membership

- a. The CPG Committee will be comprised of three (3) to eight (8) SIO members and predominately populated by individuals with a) past or current experience on the SIO Executive Committee, and b) experience with guidelines and systematic reviews (strongly preferred but not required).
- b. One member in the CPG Committee will be designated as the Liaison to the SIO Executive Committee, and an alternate will be named as back-up. Ideally, these individuals will also be standing members of the SIO Executive Committee to facilitate communication.
- c. Membership in the CPG Committee will be a two (2) year term, and members may serve up to three (3) consecutive terms. After three (3) consecutive terms and one (1) year off, members can return if deemed the best choice by the current CPG Committee.
  - i. Note, Heather Greenlee, ND, PhD currently serves as the Principal Investigator/Project Lead for the subcontract from SIO to Fred Hutchinson Cancer Research Center to direct and coordinate the SIO clinical practice guideline activities. We anticipate that these activities under the initial grant funding will last for five (5) years. Dr. Greenlee will lead the project for the five (5) year period, and we will evaluate at the end of that time if she will continue in this role or if it will be transferred to another CPG Committee member. At that time, we will need to develop a process on how to select a PI/Project Lead and host institution. A special term limit may need to be developed for this role.
- d. Nominations for the CPG Committee will come from the current CPG Committee members, the SIO Executive Committee, and SIO Past Presidents. Eligible individuals will be identified and an invitation to submit a nomination will be made. Nominations will be reviewed by the current CPG Committee and applicants selected will be forwarded to the Liaison to the SIO Executive Committee for review and approval by the SIO Executive Committee.
- e. Changes to the CPG Committee membership can be made at any time by the current CPG Committee membership with the approval of a simple majority of the SIO Executive Committee via email or via teleconference.
- f. The CPG Committee may use ad hoc internal and external consultants on a time-defined basis or for specific questions if their expertise is critical and not represented by the SIO membership. The CPG Committee should justify and specify the questions posed to the external consultants, scope of work required and either agreement of the provision of pro bono services by the consultant, or a budgetary plan with a budget approved by the SIO Executive Committee.
  - i. Consultants will sign a mutual indemnification and confidentiality agreement stating the terms of payment (or pro bono nature of the work) and that work will be done in good faith that advance the stated

mission/goals of the SIO CPG Committee and/or specific clinical practice guideline.

#### **4.2 Responsibilities and Duties of the CPG Committee**

The CPG Committee will have the overall responsibility for implementing this SOP.

The CPG Committee will be responsible for:

- a. Selecting new CPG Committee members, to be submitted to the Liaison to the SIO Executive Committee for review and approval by the SIO Executive Committee
- b. Putting forward suggestions for removal of CPG Committee membership, to be submitted to the Liaison to the SIO Executive Committee for review and approval by the SIO Executive Committee
- c. Putting forward suggestions for ad hoc internal and external consultants as outlined in 4.1.f.
- d. Guidance and mentorship of CPG Panel Co-Chairs and CPG Panel members
- e. Monitoring progress on guidelines and establishing agreed upon timelines
- f. Identifying organization(s) with whom to partner for collaborations and endorsements of guidelines, to be submitted to the Liaison to the SIO Executive Committee for review and approval by the SIO Executive Committee
- g. Recommending, pursuing, and reviewing opportunities for partnerships and funding, to be submitted to the Liaison to the SIO Executive Committee for review and approval by the SIO Executive Committee
- h. Identifying and proposing topics for clinical practice guideline development, to be submitted to the Liaison to the SIO Executive Committee for review and approval by the SIO Executive Committee
- i. Identifying candidates for CPG Committee Co-Chair(s), to be submitted to the Liaison to the SIO Executive Committee for review and approval by the SIO Executive Committee
- j. Identifying and proposing candidates for CPG Panel membership, along with recommendations from the SIO Executive Committee, the SIO Board, and the SIO membership
- k. Identifying internal and external reviewers for the draft clinical practice guidelines
- l. Compose external communications, press releases and guideline dissemination plans, to be submitted to the Liaison to the SIO Executive Committee for review and approval by the SIO Executive Committee

#### **4.3 CPG Committee Co-Chairs Selection**

- a. Nominations for CPG Committee Co-Chairs will come from within the CPG Committee, the SIO Executive Committee, and SIO Committee Co-Chairs.
- b. Nominees must hold an active membership in SIO and have been a member of the CPG Committee for at least one (1) year.
- c. Nominees will be put forth to the SIO Executive Committee for approval.
- d. The functional roles for the CPG Committee Co-Chairs include expertise in clinical oncology, integrative oncology research, SIO governance (structural and procedural), and implementation and project management. There may be two (2) or three (3) Co-Chairs, depending on CPG Committee needs.

- e. Please refer to the existing SIO SOP for information on the roles of SIO Committee Co-Chairs.

#### **4.4 Responsibilities and Duties of the CPG Committee Co-Chairs**

The CPG Committee Co-Chairs will be responsible for:

- a. Soliciting recommendations and nominations for the SIO CPG Panel Co-Chair(s) (when SIO is the Lead Organization)
- b. Reviewing Conflict of Interest (COI) disclosures of CPG Panel Co-Chairs and CPG Panel members in accordance with SIO's COI policy
- c. Reviewing and adapting materials provided by external organizations for SIO clinical practice guidelines (e.g., policies, document templates, etc.)
- d. Liaising with external funding organization on progress on guidelines and establishing agreed upon timelines



## **5. Administrative Infrastructure**

### **5.1 Guideline methodologist**

- a. The CPG Committee will contract with an external guideline methodologist to support the development of the guideline. The guideline methodologist will receive recommendation by the CPG Committee and be put forth for approval by the SIO Executive Committee.
- b. The guideline methodologist will be responsible for coordinating the expert panels, conducting the systematic reviews, drafting the manuscripts, and ushering the final manuscripts through the publication process.
- c. An Independent Contractor Agreement will outline the specific Scope of Work and Compensation. Under the current arrangement, this position is supervised by CPG Committee Co-Chair, Dr. Heather Greenlee, and coordinated out of Fred Hutchinson Cancer Research Center.

### **5.2 Project administrator**

- a. The PI/Project Lead will designate a project administrator to support the development of the guideline.
- b. The project administrator will be responsible for contracting, maintaining project documentation and processes, scheduling and coordinating work sessions for the CPG Committee, the CPG Panel Co-Chairs, the CPG Panels, the guideline methodologist, and external organizations, as well as maintaining project administrative databases. Under the current arrangement, this position is supervised by CPG Committee Co-Chair, Dr. Heather Greenlee, and coordinated out of Fred Hutchinson Cancer Research Center.

## 6. SIO Clinical Practice Guidelines

### 6.1 Requirements

- a. Guideline Topics: SIO clinical practice guidelines should address topics that are consistent with the mission of SIO, are novel, relevant, and will have significant impacts on the field of oncology practice. There should be consensus in the CPG Committee that there is a need for specific guidelines and due diligence review to avoid duplication of existing guidelines/recommendations.
- b. Guideline Methods: Clear, transparent, and scientific methods for creating the clinical practice guidelines need to be established at the start of the clinical practice guideline process and should be tailored to the subject matter and available level of existing evidence, following methods such as PRISMA guidelines ([www.prisma-statement.org](http://www.prisma-statement.org)). In addition, there must be a method specified for assessing the quality of the research using established metrics, such as AMSTAR 2 to assess the quality of systematic reviews and the Cochrane Risk Of Bias tool for randomized control trials. Clinical subject matter and treatment modalities need to be clearly specified. Search terms, the process for secondary hand searches and criteria for inclusion/exclusion of articles should be formalized and agreed upon by the panel members. Grading criteria and scheme for recommendations should be specified and should reference appropriate methods/process. We recommend referencing previously published SIO clinical practice guidelines (<https://integrativeonc.org/practice-guidelines/guidelines>), the United States Preventative Task Force Methods and Processes page for Clinical Practice Guidelines (<http://www.uspreventiveservicestaskforce.org/Page/Name/methods-and-processes>), and the Institutes of Medicine publication “Clinical Practice Guidelines We Can Trust”. SIO guideline recommendations will only be based upon randomized controlled trials (and systematic reviews and meta-analyses) as this will provide the strongest level of evidence upon which to base clinical recommendations.
- c. Internal and External Reviewers: All clinical practice guidelines will go through a two (2) week internal and external review process where stakeholders are solicited for feedback on the draft guideline recommendations put forth by the CPG Panel. A list of internal and external reviewers is generated by the CPG Committee as stated in 4.2.k. Internal reviewers may include the CPG Committee, the SIO Executive Committee, the SIO Board, the SIO membership, and other SIO Committees deemed relevant. External reviewers from outside SIO are invited as well. Internal and external reviewers are not listed as panel members but are typically credited in the manuscript in the acknowledgements. It is anticipated that an internal and external review will happen at least once but may be required several times.
  - i. Interested stakeholders must first sign a confidentiality non-disclosure agreement prior to viewing the draft recommendations.

- ii. Upon completion of the confidentiality non-disclosure agreement, a link to an online survey will be provided. The survey will contain all draft guideline recommendations, with the following response choices:
    - 1) Agree as written
    - 2) Agree with suggested modifications
    - 3) Disagree - see comments (a corresponding comment box is included for this response choice)
  - iii. All responses are sent to the guideline methodologist for compilation and initial review. The guideline methodologist then reviews with the CPG Panel Co-Chairs.
  - iv. Each comment is reviewed individually and addressed by the CPG Panel. The votes of the CPG Panel take precedence on any feedback received from the internal and external review. In the event of an overwhelming response of disagreement on any particular recommendation, the CPG Panel will consider and address the issue.
- d. Internal approval by SIO Executive Committee: Clinical practice guidelines will receive internal approval from the SIO Executive Committee before publication or other dissemination activities (e.g., conference presentations) related to the clinical practice guideline results. At such time, the SIO Executive Committee will present the guidelines to the SIO Board for review of the final product. The SIO Board will act as internal reviewers and experts on the subject matter. While not “panel members” of the guideline in a formal sense, the SIO Executive Committee will act as expert reviewers and representatives of SIO. SIO will liaise with any partnering organization on their internal approval process.

## **6.2 Choosing topics for SIO clinical practice guidelines**

- a. Clinical practice guideline topics will be generated by the CPG Committee using guidance from the SIO Executive Committee, the SIO Board, SIO Committees, and the SIO membership, and priorities determined at SIO Board retreats and other policy/strategy initiatives.
- b. The CPG Committee will take the following information into account when considering topics:
  - i. Is there a need for guidelines for the proposed topic that is appropriate for SIO to pursue?
  - ii. What is the proposed topic and scope, clinical population of focus, and period of time of literature to be reviewed to be addressed by the guidelines?
  - iii. The amount and quality of the available evidence on the proposed guideline topic
  - iv. Whether a clinical practice guideline has been previously published on the topic or a similar topic by SIO or another organization. If yes, the reference, scope and date of publication of that guideline will be considered. The new SIO guideline should advance knowledge and/or distinguish itself compared to any previous guidelines.

- v. Whether it is a new guideline or update/extension of an existing SIO guideline
- vi. Proposed budget for the guideline, as applicable
- vii. Source of funding (if any) for the guideline and related dissemination activities
- viii. Other SIO resources (if any) that will be available for the development and dissemination of the guidelines (e.g., research assistant, communication expert)
- ix. Potential partnering organizations interested in collaborating on the topic
- c. No set number of topics per year will be designated; instead, it will be dictated by the state of scientific evidence, the clinical/scientific need for a clinical practice guideline, the availability of necessary expertise, and resources to complete the guideline. The topics will be generated and prioritized as follows:
  - i. The CPG Committee, with guidance from the SIO Executive Committee and the SIO Board, will draft the list of topics.
  - ii. The CPG Committee will send the list of topics via an online survey to the SIO Executive Committee, the SIO Board, and the SIO membership for ranking by priority.
  - iii. The CPG Committee will review all results of the survey and will confer with any partnering organization(s).
  - iv. Then, the CPG Committee will put forward a topic for recommendation, to be submitted to the Liaison to the SIO Executive Committee for review and approval by the SIO Executive Committee.

### **6.3 Partnering with external organizations on SIO clinical practice guidelines**

- a. The CPG Committee, upon the approval of the SIO Executive Committee, may seek to jointly develop clinical practice guideline topics with an external organization (e.g., the American Society of Clinical Oncology (ASCO)). In this case, SIO will be considered the “Lead Organization” and external organization(s) will be considered “Participating Organization(s)”.
- b. As Lead Organization, SIO will determine the guideline topic – with approval from Participating Organization(s) – and will develop the guideline at its expense and according to its policies and procedures.
- c. Participating Organization(s) acknowledge that a collaborative opportunity would serve to strengthen the quality, credibility and uptake of the guideline and avoid duplication of effort. They will join the effort of the Lead Organization.
- d. SIO may also serve as a “Participating Organization” if invited by another organization to participate in guideline development efforts. This will be determined on a case-by-case basis by the CPG Committee and approved (or amended) by the SIO Executive Committee.
- e. The responsibilities of the Lead Organization are as follows:
  - i. Identify and invite members of the CPG Panel, as defined herein
  - ii. Collect disclosures and administer mutually agreed COI policy
  - iii. Conduct a systematic review of evidence, according to its procedures

- iv. Coordinate the internal and external review of the draft guideline recommendations
  - v. Produce each draft of the guideline and prepare the final manuscript
  - vi. Incorporate the CPG Panel and internal and external reviewer feedback
  - vii. Lead the draft guideline manuscript through its own internal review and approval process
  - viii. Prepare the guideline for publication, including copyediting, sharing of edited Word documents, and sharing of corrected and final proofs
  - ix. In collaboration with the Participating Organization(s), develop and execute plans for communication, presentation, and dissemination of guidelines
- f. The responsibilities of the Participating Organization(s) are as follows:
- i. Identify their CPG Panel Co-Chair according to its own internal process
  - ii. Assist with identifying CPG Panel members
  - iii. Assist with external review of the draft guideline
  - iv. Lead the guideline through its own internal review and approval process
  - v. Participate in the writing, reviewing, and editing of the publication
  - vi. Agreed responsibilities with respect to preparing for publication

## **7. SIO/Participating Organization CPG Panel**

### **7.1 Affected companies**

- a. Please see Appendix B for a copy of SIO's COI policy.
- b. Once a topic is selected and approved, the guideline methodologist works with the CPG Committee to collect any pertinent information on the topic. Pertinent information on the topic means any detail that could help clarify the topic (e.g., population, interventions, outcomes, etc.).
- c. The guideline methodologist, the project administrator, and the CPG Committee Co-Chairs develop a preliminary affected companies list. The list is finalized upon CPG Committee approval. Please see Appendix C for the most updated list of the affected companies.

### **7.2 CPG Panel Co-Chair(s) Selection**

- a. SIO and the Participating Organization(s) will put forth one (1) Co-Chair each. The CPG Committee will request input from both SIO and the Participating Organization(s) on the selection of the appointed CPG Panel Co-Chairs.
  - i. If SIO is serving as the Participating Organization, SIO may or may not provide a CPG Panel Co-Chair but will still provide panel representation.
- b. The CPG Panel Co-Chairs need to jointly have a track record of publications, organizing people, and must make a clear time commitment and give priority to the project.
- c. The CPG Committee Co-Chairs will solicit nominations for the SIO CPG Panel Co-Chair from the SIO Executive Committee, the SIO Board, and SIO Committee Co-Chairs.
- d. All nominations will be evaluated by the CPG Committee. Nominees should have a proven track record of working on and publishing guidelines and be considered national and/or international leaders in their field; they will be asked to submit their CV.
  - i. The guideline methodologist provides the CPG Committee with the list of nominees, reiterating the COI Policy that CPG Panel Co-Chairs must be free of conflicting relationships with affected companies (see Appendix C), although one (1) CPG Panel Co-Chair may have research funding only.
  - ii. The guideline methodologist ensures the CPG Committee is aware of any conflicts of proposed CPG Panel Co-Chairs and requests approval of proposed CPG Panel Co-Chairs that are likely to be unconflicted (if not done already as above).
- e. Once a nominee is selected, the guideline methodologist invites the nominee to serve as the SIO CPG Panel Co-Chair using standard email, including any pertinent information on the topic if applicable.

- i. This invitation contains a survey link where the nominee can formally accept or decline the invitation. If accepted, the nominee continues the survey to submit their COI disclosures.
- ii. The guideline methodologist, the project administrator, and the CPG Committee Co-Chairs conduct the initial COI review.
  - 1) If the initial review is satisfactory, a summary is prepared for review and approval by the CPG Committee.
  - 2) If the initial review warrants further investigation, the guideline methodologist informs the nominee to provide more details to confirm the disclosures.
- f. Upon CPG Committee approval, the Liaison to the Executive Committee will put forth the SIO CPG Panel Co-Chair nomination to the SIO Executive Committee for approval.
- g. Upon SIO Executive Committee approval, the guideline methodologist sends the welcome package to the SIO CPG Panel Co-Chair.
- h. Once SIO has completed this process, the Participating Organization(s) will identify their CPG Panel Co-Chair according to its own internal process.

### **7.3 Panel membership where SIO is the Lead Organization**

- a. Prior to soliciting panel nominations, the CPG Committee will meet with the CPG Panel Co-Chairs to:
  - i. Discuss finalization of affected companies list
  - ii. Discuss panel membership using the panel composition criteria template
    - 1) In some cases, a COI pre-check should be conducted prior to sending the invitations.
  - iii. Discuss if any other organizations should provide representatives
    - 1) If there are other organizations providing representatives, their representatives will follow the same process as outlined below.
- b. The CPG Committees (SIO and the Participating Organization(s)) will consider CPG Panel nominations based on the following:
  - i. All SIO-representing Panel members must be SIO members in good standing, and Participating Organization(s)-representing Panel members may need to be members of the Participating Organization(s) if deemed necessary (e.g., Panel members nominated by the ASCO Panel Co-Chair do not need to be ASCO members to be on the panel). Outside Panel members may be invited if required critical expertise is not represented in the SIO or Participating Organization(s) membership.
  - ii. All CPG Panel members must agree to contribute to the guidelines according to ICJME guidelines (<http://www.icmje.org/recommendations/browse/roles-and-responsibilities/defining-the-role-of-authors-and-contributors.html>).
  - iii. CPG Panel members will include the following:
    - 1) The CPG Panel should include at least one (1) biostatistician (statistical expert), one (1) patient advocate familiar with the

patient population of interest, one (1) clinician who is working with the patient population of interest, and one (1) person who has conducted studies (similar to or those actually being reviewed) included in the clinical practice guideline.

- 2) Ideally, the CPG Panel should also include individuals who have previously published at least one (1) meta-analysis, systematic review, or clinical practice guideline; integrative/complementary practitioners of the modalities being included in the guideline (if relevant), and researchers, clinical researchers, and clinicians who have expertise in central clinical issues being addressed in the guideline.
  - 3) CPG Panel members should also be constituted of a diverse representation of professions (e.g., nurses, social workers, medical/radiation oncologists, licensed acupuncturist); geographic locations within the US (e.g., Midwest, East Coast, Mountain, West Coast, etc.); gender, and have at least two (2) international members (note: the number of international members can be greater than two (2) if there is appropriate expertise).
  - 4) The CPG Panel may include up to two (2) trainee members. These could include postdoctoral fellows or junior faculty, either clinical or research, with a focus on integrative oncology.
  - 5) CPG Panel members may not serve on more than one (1) guideline at a given time.
- iv. There should be approximately sixteen (16) members on each CPG Panel, with approximately ten (10) of those being SIO members and/or being members of the Participating Organization(s) inclusive of the two (2) Co-Chairs, one (1) patient representative, one (1) community oncologist, and up to two (2) SIO CPG Committee members. This number may fluctuate depending on the specific guideline. Moreover, the CPG Panel Co-Chairs will include one (1) SIO member and one (1) member of the Participating Organization(s).
- c. CPG Panel solicitation will be conducted as follows:
- i. The CPG Panel Co-Chairs use the information above, plus their own knowledge of leaders in the field, to draft a list of potential panelists, representing both SIO and the Participating Organization(s). The CPG Panel Co-Chairs email the list of suggested panelists to the CPG Committee, who is available to provide feedback and input as will be helpful.
  - ii. The CPG Committee engages the SIO membership to solicit nominations or self-nominations to be put forth to the CPG Panel Co-Chairs for consideration. Nominees are asked to complete an online survey to collect information on the following eligibility categories and are also asked to submit a copy of their CV.
    - 1) Demonstrated history of leadership skills (required)



- 2) Strong track record of excellence in integrative oncology (research or clinical) (required)
  - 3) Experience developing clinical practice guidelines (preferred)
  - 4) Conduct and publication of research in the specified guideline topic (preferred)
  - 5) Past/current involvement with SIO (required)
  - 6) Any conflicts of interest that would prohibit participation
- d. CPG Panel nominations will be first reviewed by the CPG Panel Co-Chairs and the guideline methodologist per CPG Committee procedures. Then, the final list of nominations will be put forward to the CPG Committee for review and final approval.
  - e. Once nominees are selected, the guideline methodologist sends invites to serve on the CPG Panel using standard email, including any pertinent information on the topic if applicable.
    - i. This invitation contains a survey link where the nominee can formally accept or decline the invitation. If accepted, the nominee continues the survey to submit their COI disclosures.
    - ii. The guideline methodologist, the project administrator, and the CPG Panel Co-Chairs conduct the initial COI review.
      - 7) If the review is satisfactory, the nominee is confirmed and a summary is prepared for review by the CPG Committee.
      - 8) If the review warrants further investigation, the guideline methodologist informs the nominee to provide more details to confirm the disclosures.
  - f. The guideline methodologist and the project administrator will be responsible for communicating progress to the CPG Committee. The Liaison to the Executive Committee will then convey progress to the SIO Executive Committee.
  - g. In the event that the CPG Panel Co-Chairs identify deficiencies in panel membership, they will be allowed to add new panel member(s) through an expedited process under the condition that it must be done before the systematic review is completed.
    - i. The CPG Panel Co-Chairs will work with the CPG Committee Co-Chairs to resolve any deficiencies.
    - ii. The CPG Panel Co-Chairs may refer to the existing list of names that have been put forth as well as consider names who were not already included.
    - iii. The CPG Committee engages the SIO Executive Committee to solicit nominations or self-nominations to be put forth for consideration.
    - iv. Nominees must still submit their information as outlined in 7.3.c.ii.

#### **7.4 Panel membership where SIO is the Participating Organization**

- a. Panel membership qualities and qualifications will be determined by the Lead Organization.

- b. SIO CPG Panel members to be considered will be put forward to the CPG Panel Co-Chairs by the CPG Committee per CPG Committee procedures.
- c. The CPG Committee will consider all potential SIO CPG Panel members based on the following (note: this process is under development and will be refined; we may develop a selection committee.)
  - i. SIO-representing Panel members must be SIO members in good standing. Outside Panel members may be invited if required critical expertise is not represented in the SIO membership.
  - ii. All Panel members must agree to contribute to the guidelines according to ICJME guidelines (<http://www.icmje.org/recommendations/browse/roles-and-responsibilities/defining-the-role-of-authors-and-contributors.html>).
  - iii. SIO Panel members may not serve on more than 1 (one) guideline at a given time.
- d. CPG Panel solicitation will be conducted as follows:
  - i. The CPG Committee engages the SIO membership to solicit nominations or self-nominations to be put forth to the CPG Panel Co-Chairs for consideration. Nominees are asked to complete an online survey to collect information on the following eligibility categories and are also asked to submit a copy of their CV.
    - 1) Demonstrated history of leadership skills (required)
    - 2) Strong track record of excellence in integrative oncology (research or clinical) (required)
    - 3) Experience developing clinical practice guidelines (preferred)
    - 4) Conduct and publication of research in the specified guideline topic (preferred)
    - 5) Past/current involvement with SIO (required)
    - 6) Any conflicts of interest that would prohibit participation
  - ii. The CPG Committee reviews all nominations, keeping in mind that there are a set number of panel slots available. The CPG Committee selects the final candidates, which can include no more than two (2) CPG Committee members as outlined in 7.5.
  - iii. The CPG Committee then puts those names forward as recommendations to the Lead Organization, who will make the final decision.

### **7.5 CPG Committee members serving on CPG Panel**

- a. Up to two (2) CPG Committee members may serve on an SIO guideline panel. CPG Committee members can serve as CPG Panel Co-Chairs. CPG Committee members who serve on the panel will fully participate as CPG Panel members.
- b. CPG Committee members who are interested in serving on the panel may submit their names and expertise to the CPG Committee Co-Chairs for review.

- c. The CPG Committee Co-Chairs will review the candidates' credentials and expertise and will put forward two (2) names to the CPG Panel Co-Chairs for consideration to be included in the panel.
- d. If a CPG Committee Co-Chair submits their name for consideration, they will be recused from the discussion and decision-making process, and another member of the CPG Committee will be asked to participate in the decision-making process.
- e. When it comes time for the CPG Committee to review and approve the guideline, they will be recused from the CPG Committee vote.
- f. CPG Committee members cannot participate on multiple panels at the same time or on consecutive guideline panels (beginning in March 2020).

## **8. Manuscript Development**

### **8.1 Drafting the recommendations**

- a. The CPG Panel will be divided into subgroups. Subgroups are determined by categories of modalities or interventions, and Panel members are assigned to a subgroup based on expertise.
- b. Subgroups are responsible for drafting the recommendations for the modalities or interventions in their group. The guideline methodologist will provide each subgroup with clear instructions and examples on the recommendation drafting structure.
  - i. Subgroups review the literature for their group to:
    - 1) Define an intervention: action and actors, population and circumstances, benefit vs. harm, cost(s)
    - 2) Rate the quality or strength of evidence for recommendations: high, intermediate, low, insufficient
    - 3) Determine the type of recommendation: evidence-based, formal consensus, informal consensus, no recommendation
    - 4) Determine the level of obligation: should, may
- c. The guideline methodologist will work with each subgroup individually to ensure maximum productivity and output.
- d. Once all drafts are complete, the CPG Panel Co-Chairs, along with the guideline methodologist, will review the drafts, edit as needed, and combine to develop the list of draft recommendations.

### **8.2 Drafting the manuscript**

- a. The manuscript is drafted in accordance with the modified SIO-ASCO manuscript template for targeted submission to the Journal of Clinical Oncology (JCO).
- b. The CPG Panel will again divide into subgroups. Subgroups are responsible for writing their group's section of the manuscript. The guideline methodologist will provide each subgroup with clear instructions and examples on the manuscript writing structure.
  - i. For each recommendation, a double-spaced, five hundred (500) word maximum summary will be written.
- e. The guideline methodologist will work with each subgroup individually to ensure maximum productivity and output.
- f. Once all drafts are complete, the CPG Panel Co-Chairs, along with the guideline methodologist, will review the drafts, edit as needed, and combine to develop the draft manuscript.

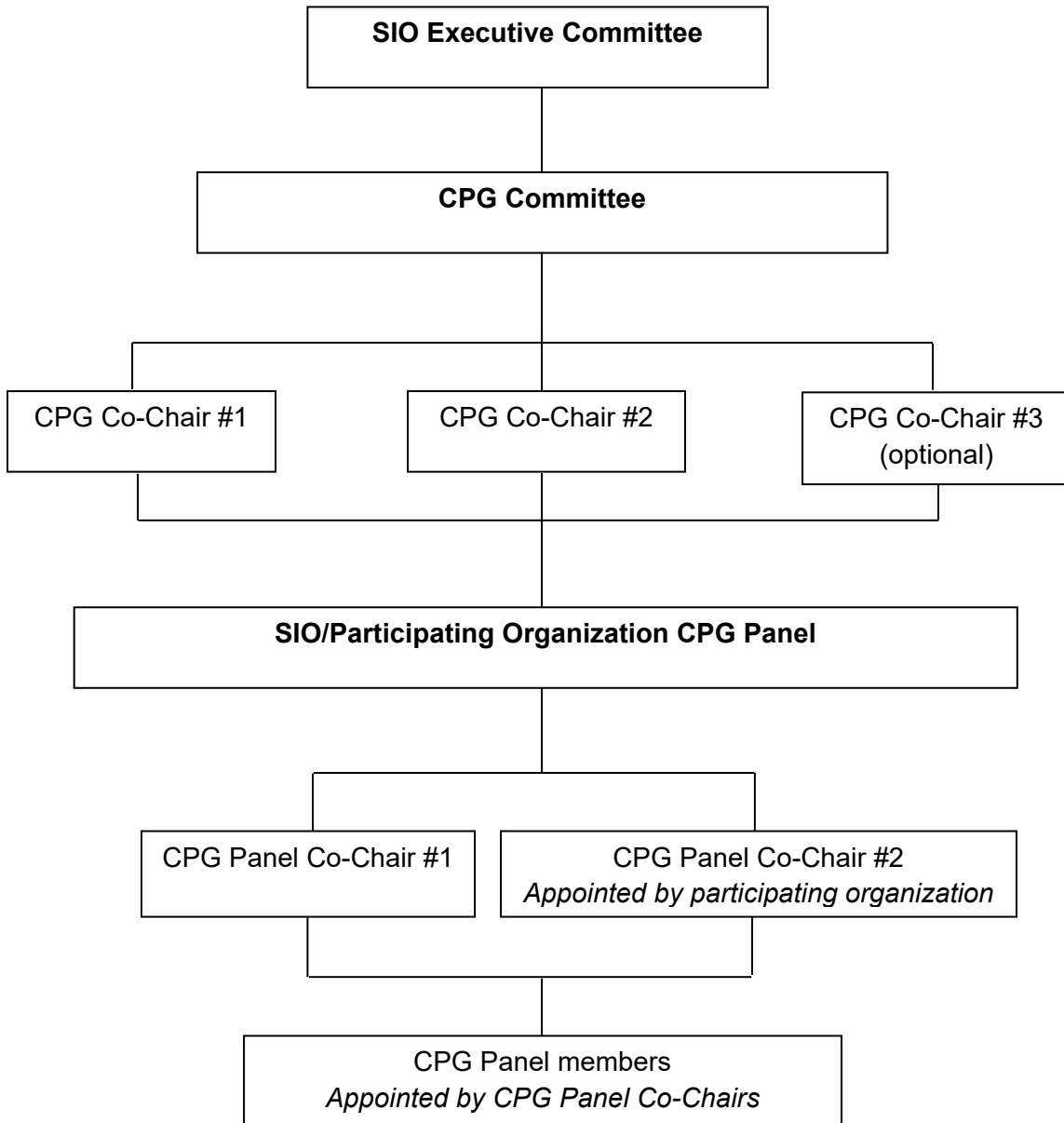
### **8.3 Authorship**

- a. SIO-led guidelines authorship will be as follows:
  - i. SIO Co-Chair: First author
  - ii. Participating Organization Chair: Last author

- iii. Guideline methodologist: 2nd author
- iv. Panel members: Listed in alphabetical order

**Appendix A**

**SIO Organizational Chart**



*Date approved by SIO CPG Committee: 08/02/2019*

*Date approved by SIO Executive Committee: 09/23/2019*

## Appendix B



### **Conflict of Interest Policy Implementation for Clinical Practice Guidelines of the Society for Integrative Oncology<sup>1</sup>**

The Society for Integrative Oncology (SIO) is dedicated to improving the lives of people affected by cancer through research, education, prevention and delivery of high-quality patient care. One of the primary ways in which SIO fulfills this responsibility is through the development of clinical practice guidelines. Provider and public confidence in these guidelines depend on the cultivation of expert opinions based on the best available evidence and in a manner designed to minimize actual and perceived conflicts of interest.

For SIO, guideline development is a multi-step process. Once drafted by a diverse panel of experts, guidelines must be approved by SIO's Clinical Practice Guideline (CPG) Committee (Committee) and peer-reviewed in accordance with rigorous standards set by high impact journals. The following procedures provide strategies for managing potential conflicts of interest (COI) through each phase of guideline development.

#### **I. General Policy**

SIO requires COI disclosure by individuals involved in drafting, reviewing, and approving guideline recommendations and sets limits on the financial relationships that panel members and reviewers can have with Companies that could reasonably be affected by care delivered in accordance with guideline recommendations.

SIO will also be adopting the Council of Medical Specialty Societies Code (CMSS) for Interactions with Companies<sup>2</sup> that requires the majority of panel members (51%), including the panel chair, to be free of certain relationships with affected Companies. The remaining 49% of panel members may be appointed to a panel if they hold some relationships with affected Companies. SIO defines a "Company" as a for-profit entity that develops, produces, markets, or distributes drugs, devices, services, products or therapies used to diagnose, treat, monitor, manage, and alleviate health conditions. The CMSS code was developed to ensure that societies' interactions with companies are independent and transparent, and advance medical care for the benefit of patients and populations.

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<sup>1</sup> The SIO's Conflict of Interest Policy Implementation for Clinical Practice Guideline for Panel Co-Chairs and Expert Panel Members was adapted from ASCO's Conflict of Interest Policy Implementation for Clinical Practice Guidelines in March 2020.

<sup>2</sup> Council of Medical Specialty Societies, Code for Interactions with Companies.  
[www.cmss.org/codeforinteractions.aspx](http://www.cmss.org/codeforinteractions.aspx)

## II. Identifying Affected Companies

Companies with products and/or services affected by a guideline are considered “affected Companies” for purposes of determining whether a COI exists in the development of SIO guidelines. A Company is an “affected Company” if there is a reasonable likelihood of *direct regulatory or commercial impact (positive or negative)* on the entity as a result of care delivered in accordance with guideline recommendations. Affected Companies will generally be identified at the time of development of the guideline protocol, prior to selection of panel members, chairs or co-chairs.

Affected Companies will generally be identified by members of the SIO CPG Committee and the SIO Executive Committee. In some cases, where identification is straightforward, an SIO guideline methodologist may identify affected Companies using criteria approved by the SIO CPG Committee. The list of affected Companies should remain consistent throughout guideline development and adoption. If changes in the marketplace or in the focus of the guideline make revisions necessary, a modified list may be developed or reviewed by the independent party. The list of Companies affected by a guideline will be made available to prospective guideline panel chairs and panel members and the Clinical Practice Guideline Committee.

## III. Disclosure

SIO’s policy is to promote the development of clinical practice guidelines in a manner that minimizes the risk of actual and perceived bias. Disclosure of relationships with Companies is the first step in SIO’s process of evaluating and managing relationships that could result in actual or perceived bias.

### a. General COI Disclosure

All prospective panel members, including prospective panel chairs and co-chairs, will disclose financial interests and other relationships with Companies in accordance with SIO’s Policy. All Committee members disclose the same information. These disclosures are general and may or may not identify relationships with affected Companies.

Disclosure categories include compensation received for employment, leadership positions, consulting activities, speaking engagements, and expert testimony; as well as ownership interests, research funding (to the individual or the institution), and licensing fees and royalties associated with intellectual property interests received by panel or Committee members themselves and their immediate family members.<sup>3</sup>

An individual’s COI disclosures must be current in SIO’s electronic system prior to appointment to a panel. Panel members and Committee members must keep their COI disclosures up to date.

### b. Additional Disclosure

After reviewing the general disclosures and the list of affected Companies, the Committee Chair or SIO guideline methodologist may request more detailed information from an individual about the nature, value, or extent of his or her disclosed relationship with an affected Company in order to apply this Policy.

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<sup>3</sup> American Society of Clinical Oncology, Policy for Relationships With Companies 2013 JCO2013.49.5002 <http://jco.ascopubs.org/content/early/2013/04/22/JCO.2013.49.5002>



Occasionally, an individual may have a relevant indirect or non-financial interest or relationship that is not covered by SIO's general COI disclosure, such as an intellectual property interest from which no royalties or other payments have yet been received; a strong professional or research opinion; or an outside affiliation. In these situations, the interest should be disclosed to the panel chair, co-chair or SIO guideline methodologist. Disclosure reports identifying panel members' relationships with affected Companies will be available to panel members throughout the guideline development process. The Committee will have this information available when considering guideline recommendations.

#### **IV. Guideline Panels**

SIO's goal is to assemble a diverse and well-qualified group of experts to develop, approve, and adopt guideline recommendations in a manner that minimizes the risk of actual and perceived bias.

##### **a. Not Eligible to Serve on Panel**

Having a relationship with a Company does not necessarily mean an individual is biased or has a COI. However, SIO's policy is that certain financial relationships give rise to COIs that are not capable of being effectively managed and are, in fact, inconsistent with actual and perceived independence in the guideline development process. An individual is not eligible to serve on a clinical practice guideline panel if he or she:

1. participates in a speakers' bureau<sup>4</sup> (on any subject) on behalf of an affected Company;
2. is employed by an affected Company, or has been employed by an affected Company at any time during the year prior to appointment to the panel and to continue for one year after the publication of the guideline; or
3. holds a significant ownership interest in an affected Company<sup>5</sup>; or
4. holds a financial or other relationship whether with an affected Company or another interest that, in SIO's discretion, presents a risk of actual or perceived bias that cannot be effectively managed or could undermine public confidence in the guideline.

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<sup>4</sup> "Speakers' bureau" means a compensated role as a presenter for which any of the following criteria are met: (a) a Company has a contractual right to dictate or control the content of the presentation or talk; (b) a Company creates the slides or presentation material and has final approval of the content and edits; or (c) the presenter is expected to act as a Company's agent or spokesperson for the primary purpose of disseminating company or product information. SIO recognizes that some activities called "speakers' bureaus" may not meet these criteria and, conversely, that activities may meet these criteria and not be termed "speakers' bureaus." SIO will rely on the judgment and integrity of disclosing individuals to determine whether an activity constitutes a speakers' bureau under this Policy. This definition of "speakers' bureau" does not extend to employees of a Company who make presentations as part of their employment.

<sup>5</sup> "Significant ownership interest" means shares of a publicly traded Company greater than \$50,000 in value or an equity interest in a privately held Company greater than 5% at the time of disclosure. This does not include interests invested in diversified funds whose holdings cannot be controlled by the disclosing individual.

### **b. Eligible to Serve as Panel Chair or Co-Chair**

Generally, individuals who have disclosed financial interests in or relationships with affected Companies will not be appointed as panel chairs or co-chairs. A panel chair or co-chair must have been free of all interests and relationships for one year prior to appointment as chair and remain free of these interests and relationships at all times during the panel's work and through one year after the guideline is published.

However, the Committee may appoint one panel chair who receives research funding from an affected Company, if doing so would ultimately help the panel develop a higher quality guideline. In this case, the Committee must appoint a co-chair who has no relationships with affected Companies, including research funding.

If a panel chair or co-chair wants to continue to serve as chair for future guideline updates, he or she must remain eligible as described above. If, at the time of update, an individual is no longer eligible to serve as a chair, he or she will be eligible to serve as a panel member at the discretion of the Clinical Practice Guideline Committee and in accordance with this Policy Implementation.

### **c. Eligible to Serve in the Panel Majority**

In accordance with the CMSS Code, a majority of SIO guideline panel members must be free of conflicts of interest relevant to the subject matter of the guideline. All relationships with Companies must be disclosed as described in Section IIIa. The Committee Chair or SIO guideline methodologist may ask for additional information about a relationship with an affected Company, as described in Section IIIb, to apply this Policy Implementation.

For the purpose of appointing at least 51% of guideline panel members who are free of COI, SIO defines the following relationships as COIs:

1. Research funding from an affected Company, paid to the individual or his or her practice or institution if:
  - a. research payments are made directly from the affected Company to the individual;
  - b. the individual's salary is supported (in whole or part) through a research grant from an affected Company;
  - c. the individual is a national or overall principal investigator for a study funded by an affected Company;
  - d. the individual is a member of a steering committee of a study that does not have a principal investigator.<sup>6</sup>
  - e. in kind donations of products being tested by the manufacturers.
2. Compensation (including honoraria) from any one affected Company that equals, in aggregate, \$5,000<sup>7</sup> or more in a calendar year.
  - f. This includes fees and honoraria for leadership positions, consulting activities, speaking engagements, expert testimony, and patent or other licensing fees.
  - g. This excludes any compensation provided under any of the circumstances described in Section IVa.

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<sup>6</sup> Serving as a site or local PI, or a consortium PI without salary support are not considered conflicts of interest.

<sup>7</sup> This dollar value may be updated periodically to keep pace with current standards.

Individuals with any of these relationships are not eligible to serve in the panel majority, but may be eligible to serve in the panel minority. A member of the panel majority must remain free of these COIs from the time of his or her appointment to the panel through the end of the calendar year in which the guideline is published. If an individual's relationships change during that period such that he or she is no longer eligible to serve in the panel majority, the Committee chair will shift the individual to the panel minority. If that is not feasible given the panel composition, the individual must resign from the panel.

If an individual holds a patent in a technology that could be part of a guideline recommendation, the individual may be eligible to serve on the panel minority as described in Section IVc with special requirements for COI management, or SIO may find the individual ineligible to serve on the panel under Section IVa.4 above.

If an individual holds stock options in an affected Company, as defined in Section II above, the individual may be eligible to serve on the panel minority as described in Section IVc with special requirements for COI management, or SIO may find the individual ineligible to serve on the panel under Section IVa above.

#### **d. Voting**

At in-person and/or virtual meetings, panel recommendations must be adopted by a 75% majority of panel members in attendance at a meeting where a simple majority of panel members are present. When the panel votes electronically, recommendations must be adopted by a 75% majority of the entire panel.

Because of the supermajority voting standard, panel members who have disclosed financial relationships with affected Companies do not need to recuse themselves from discussing and voting on guideline recommendations on these grounds.

### **V. Clinical Practice Guideline Committee**

The roles and responsibilities of the Clinical Practice Guideline Committee is to identify and prioritize topics for guideline development, provide strategic direction in the development of guidelines, review and approve final drafts of the guidelines and provide recommendations regarding possible third-party guideline endorsement and joint guideline endeavors.

#### **a. Disclosure**

Committee members will generally disclose financial relationships with Companies as described in Section IIIa and make additional disclosures as described in Section IIIb. These disclosures will be compared with the list of affected Companies before a guideline is reviewed by the Committee.

Committee members' general disclosure reports, identifying relationships with affected Companies, will be available to Clinical Practice Guideline Committee members prior to Committee discussion of a guideline.

#### **b. Clinical Practice Guideline Committee Reviewers**

From time to time, the Committee Chair appoints Committee members to serve as reviewers of a guideline. Generally, the Committee Chair will select Committee members who have no financial relationships with affected Companies or products to serve as guideline reviewers.

### **c. Recusal**

To underscore the independence and integrity of the guideline adoption process, guidelines will be approved only by Committee members who do not have financial relationships with affected Companies or products. Therefore, disclosure of any financial relationship with an affected Company should be cause for recusal. Whether a relationship relates to the subject matter of the guideline is not a relevant consideration for purposes of determining recusal.

A Committee member recused from voting may take part in initial Committee discussion of the guideline manuscript, recognizing that there may be additional discussion by remaining Committee members after recusal and before the vote.

### **d. Voting**

Generally, guidelines will be reviewed and approved by a vote of the Committee at a meeting where a quorum is present. However, if the quorum is lost by virtue of recusals as described in Section Vc, the remaining Committee members in attendance will constitute a quorum as long as at least three voting members are present. Approval by majority vote of this group will be considered approval by the Committee.

## **VI. Publication and Peer Review**

When SIO publishes a guideline, all disclosures of panel members will generally be published concurrently. This Policy Implementation is also posted publicly on SIO's website. Panel members will be required to disclose COIs to the journal in which the guideline will be published, in accordance with the journal's policies.

## **VII. Joint Guidelines and SIO-Endorsed Guidelines**

From time to time, SIO may join another organization to create a guideline or may endorse a relevant guideline produced by another organization. In these instances, the COI management procedures used for the development of the joint or endorsed guideline must meet the requirements of CMSS Code for Interactions with Companies, as a baseline.<sup>2</sup>

## **VIII. Exceptions**

SIO's goal is to assemble a diverse and well-qualified group of experts to develop, approve, and adopt guideline recommendations. If required to achieve this goal, these procedures may be adapted by the SIO on a case-by case basis to the extent necessary.

## **IX. Decisions**

Questions about the application of this Policy Implementation will be decided by SIO. SIO will consider recommendations from the panel chair and co-chair and the Committee Chair (unless the question concerns their roles). SIO decisions can be made by the SIO CPG Committee and the SIO Executive Committee. Questions and decisions may concern, for instance, whether an individual is eligible to serve on a panel, or as a panel chair or co-chair, or in a panel majority, or as a Committee reviewer; whether an individual should be recused from voting; or whether an exception is warranted.

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**Application:** *Applies to SIO*

**History:** *Based upon the ASCO Guidelines Committee COI Policy and adopted by the SIO Guidelines Committee on April 3, 2020*

## Appendix C

### Conflict of Interest (COI) Frequently Asked Questions (FAQ)

#### **An integrative approach to cancer-related pain management clinical practice guideline panel**

This document answers some common questions about the SIO Conflict of Interest (COI) policy. Please feel free to contact the guideline methodologist (Dr. Nofisat Ismaila, [nofisat.ismaila@asco.org](mailto:nofisat.ismaila@asco.org)) and/or the SIO Clinical Practice Guidelines Committee Co-Chair (Dr. Heather Greenlee, [hgreenlee@fredhutch.org](mailto:hgreenlee@fredhutch.org)) if you have additional questions or concerns.

#### **1. What is an affected company? How are the affected companies identified?**

Answer: A Company is considered an “affected Company” if there is a reasonable likelihood of direct regulatory or commercial impact (positive or negative) on the entity as a result of care delivered in accordance with clinical practice guideline recommendations. In cases where identification of affected companies is straightforward, the guideline methodologist will identify affected Companies using criteria approved by an independent party. Categories of affected Companies will generally be identified at the time of development of the guideline protocol, prior to selection of panel members, chairs or co-chairs. Identification is done by using both private and public search engines. For the purposes of SIO Clinical Practice Guidelines, affected Companies extend beyond pharmaceutical companies and can also include companies, and products and clinical practices in a for-profit clinical setting, which could be impacted by clinical practice guideline recommendations.

#### **2. What is the list of affected companies?**

<b>Companies, Products and Practices</b>
Pharmaceuticals and Diagnostic/Health Equipment companies
<ul style="list-style-type: none"><li>• Any pharmaceutical or health care supply/service company</li></ul>
Companies related to Complementary, Alternative and Integrative Medicine (CAIM) Practices and Products
<ul style="list-style-type: none"><li>• Acupressure</li></ul>
<ul style="list-style-type: none"><li>• Acupuncture</li></ul>
<ul style="list-style-type: none"><li>• Biofeedback</li></ul>
<ul style="list-style-type: none"><li>• Cannabis</li></ul>
<ul style="list-style-type: none"><li>• Dietary supplements</li></ul>
<ul style="list-style-type: none"><li>• Energy therapies, including but not limited to:     Reiki     Qigong</li></ul>
<ul style="list-style-type: none"><li>• Herbs/botanicals</li></ul>
<ul style="list-style-type: none"><li>• Laser therapy</li></ul>
<ul style="list-style-type: none"><li>• Manipulation</li></ul>

**3. What sorts of relationships are considered conflicts that would preclude me from serving on a panel?**

Answer: SIO's policy is to promote the development of clinical practice guidelines in a manner that minimizes the risk of actual and perceived bias. Having a relationship with an affected Company does not necessarily mean an individual is biased or has a conflict of interest. However, some relationships cannot be managed and are inconsistent with reducing actual or perceived bias. Please refer to the COI Policy for an explanation of prohibited relationships for panel members and chairs. Generally, employees or major owners/stockholders of affected companies are not permitted to participate on guideline panels.

Individuals who receive research grant funding from an affected Company or in kind donations of products being tested by manufacturers must report the potential conflict, which will be evaluated on a case-by-case basis. In general, research involving human trials would be considered a COI, however in vitro and animal studies would not be considered conflicted.

Individuals who receive income royalties, consulting fees, clinical fees from a for-profit clinic, and/or other financial benefits from any potentially affected Company must report the potential conflict and whether the income is greater or less than \$5,000 USD.

SIO requires that panel Co-Chairs be free of conflicts with affected Companies, and one of the Co-Chairs can receive research funding from an affected Company. SIO requires the majority of panel members (51%), including the panel chairs, to be free of certain relationships with affected Companies. The remaining 49% of panel members may be appointed to a panel if they hold some relationships with affected Companies. The guideline methodologist can answer questions about your particular circumstances, if you have questions.

**4. Must all panel members be completely free of relationships with affected Companies?**

Answer: No, but a majority of panel members must be free of relationships with affected Companies. In addition, panel chairs must be free of all relationships with an affected Company, except in instances where one of two co-chairs may receive research funding from an affected Company.

**5. Are there any exceptions?**

Answer : Yes. SIO's goal is to assemble a diverse and well-qualified group of experts to develop, approve, and adopt clinical practice guideline recommendations. If required to achieve this goal, these procedures may be adapted by SIO on a case-by case basis to the extent necessary. All decisions about exceptions are made at the discretion of SIO.

**6. Are COIs made public?**

Answer: Yes. Any COIs will be disclosed in the journal where the guidelines are published.