

## Identification and Mitigation of Conflicts of Interest

### Introduction

The American Society of Retina Specialists provides accredited continuing medical education (“CME”), advocacy and public information to enhance the retina specialist’s ability to deliver the highest possible quality of eye care for patients.

The ASRS has a profound duty to its members, the larger medical community and the public to ensure the integrity of all of its scientific, educational, advocacy and consumer information activities and materials. Thus, each Board member, committee Chair, committee member, taskforce chair, taskforce member, and representative to other organizations (“ASRS Leader”), as well as the ASRS staff and those responsible for organizing and presenting CME activities must disclose interactions with retina Companies<sup>1</sup> and manage conflicts of interest or the appearance of conflicts of interest that affect this integrity. Where such conflicts or perceived conflicts exist, they must be appropriately and fully disclosed and mitigated.

### I. COLLECTION OF DISCLOSURES OF INTERACTIONS WITH COMPANIES

- A. All ASRS Leaders and persons/speakers in a position to influence the content of ASRS-sponsored CME must submit a Disclosure Form of all financial relationships in any amount and uncompensated interactions with retina companies within the previous 24 months prior to their participation in the activity. In the context of this Conflict of Interest policy, “CME” encompasses the ASRS’s full spectrum of educational activities, including those qualifying for CME credit, as well as the ASRS’s non-credit-bearing educational initiatives, programming and products, including but not limited to non-accredited content, practice management resources, Retina Times, and Journal article authorship, selection and review.
- B. Members of the Board of Directors and members of ASRS Committees will be asked to disclose additional information on the ASRS Leader Disclosure Form indicating whether their disclosed direct financial relationships with Companies are under or over twenty-five thousand dollars at the time of disclosure.
- C. Annually, ASRS staff shall send a financial disclosure form to ASRS Leaders to be completed by January 1. The Journal and Annual Meeting/Business of Retina Meeting/webinar authors, planners, and speakers will follow the disclosure submission procedures established for these activities.
- D. The ASRS may disqualify anyone who does not complete (or revise as appropriate) the applicable disclosure form after a second reminder.
  - 1. A second reminder will state that the individual may not participate in relevant Board, committee, ASRS Representative activities, or in planning, developing or delivering any ASRS CME without a current Disclosure on file. In addition, such

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<sup>1</sup> “Companies”, or ineligible companies (previously known as commercial interests), as defined by the ACCME are entities whose primary business is producing, marketing, re-selling, or distributing healthcare products used by or on patients. In accordance with the CMSS Code for Interactions with Companies, this definition shall also include for-profit entities that develop, produce, market or distribute drugs, devices, services or therapies used to diagnose, treat, monitor, manage, and alleviate health conditions.

notice will explain the consequences of not providing the Disclosure.

2. If the member does not provide adequate Disclosure within thirty days of the receipt of the second notice, the member will become ineligible to participate in the accredited CE activity in any manner until the form is received. For ASRS Leaders, failure to submit the ASRS Leader Disclosure Form within thirty days of the second notice will disqualify the member from participation in the committee, other ASRS body or representative activities until the disclosure is received. If the ASRS Leader is unwilling to complete the form or otherwise refuses to disclose, (s)he will be asked to resign from the committee, other ASRS body or representative position.
  3. The appropriate Chair shall be notified of the disqualification. If the disqualification is of a Board member, the disqualification shall be reported to the Executive Committee.
- E. ASRS Leaders, authors and CME planners and speakers are responsible for updating their Disclosures throughout the year for every change in actual or potential conflicts of interest, whether financial or non-financial.

## II. AWARENESS OF ACTUAL AND POTENTIAL CONFLICTS

- A. All Disclosures of financial and potentially relevant non-financial Relationships shall be sent to the Committee Chair responsible for the planning and implementation of ASRS activities. Disclosures from Board of Directors and officers shall be reviewed by the Conflict of Interest Committee (CoIC) , chaired by the President-Elect and comprised of the Treasurer, Immediate Past President, and two additional Board members selected by the Nominations Committee Chair, shall provide oversight of all leadership conflicts of interest and shall recommend to the Executive Committee the administrative actions required to avoid conflict of interests .Executive Committee members shall recuse themselves from reviewing their own disclosures.
- B. After review, the Chair shall alert all reviewers, panelists, committee members, and authors of their financial and non-financial conflicts of interest relevant to a particular activity. The following financial relationships are prohibited.
  1. Leadership
    - a. Board/committee members: Owners<sup>2</sup>, employees<sup>3</sup>, or C-Suite officers of ACCME defined ineligible retina Companies shall not serve on the Board.
    - b. Executive Committee: In addition to the above, Executive Committee members are prohibited from being owners, employees, or C-Suite Officers of ACCME defined eligible retina Companies.

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<sup>2</sup> Owners of companies are defined by the ACCME as individuals who have an ownership or controlling interest in a company, except for stockholders of publicly traded companies, or holders of shares through a pension or mutual fund. Stockholders of shares in a privately-owned company are considered owners/employees by the ACCME.

<sup>3</sup> The ACCME defines employees as individuals hired to work for another person or business for compensation and are subject to the employer's direction as to the details of how to perform the job.

## 2. CME Activities

- a. Planning Committee: Owners or employees of ACCME defined ineligible retina Companies shall not serve on the Board or as planning committee members.
  - b. Speakers: Owners or employees of Companies shall not be permitted to participate as speakers or other contributing faculty, except in three ACCME-permitted exceptions: 1) when the content is not related to the business lines or products of the employer/Company; 2) when the content is limited to basic science research and they do not make recommendations; and 3) when acting as technicians to teach the safe and proper use of medical devices and do not make recommendations.
- C. The Chair shall periodically remind all who are involved in planning and implementation of an activity to be cognizant of others' financial and non-financial disclosures and encourage all to identify and discuss potential conflicts.

## III. COMMUNICATION OF ACTUAL AND POTENTIAL CONFLICTS

- A. As set forth below, ASRS staff will ensure that all relevant relationships with retina Companies are made known to learners before engaging with the accredited education.
- B. For print, web-based or recorded non-live materials ("Enduring Materials"), it is staff responsibility to ensure that all appropriate Financial Disclosures are included in each document so that they may be viewed by learners prior to the start of the activity to meet ACCME requirements for disclosure to learners.
- C. For Journal Activities, Editor and Journal staff shall follow their own disclosure procedures.
- D. Committee staff are required to include the list of financial relationships for their committee members, including the Committee Chair, in any and all meeting agendas and minutes, including conference calls. At the beginning of each meeting/conference call, the Committee Chair should make note that the list is included in the agenda for everyone's reference.
- E. For all Live Activities (credited and non-credited), staff shall:
  - 1. Notify the activity organizer, all faculty, panelists, other presenters of their obligations to provide adequate disclosures prior to their participation in the activity.
  - 2. Disclosure of relevant financial relationships shall be published in the syllabus, handouts, and/or first slide of the activity so that it may be viewed by learners prior to the start of the activity.
  - 3. In addition, the "first slide" policy shall be enforced to ensure Financial Disclosure of presenters is included on the first presentation slide and is made know to all participants prior to the start of the activity.
  - 4. Ensure that the intent of the "first slide" policy is served by adequate "dwell time" of

the slide, commensurate with the length of the text shown; ideally with simultaneous verbal presentation of the first slide content.

5. Moderators of sessions during which audience members may speak or submit comments should actively participate to ensure that those comments are balanced, not commercially biased, and as much as possible, validated by evidence.
6. Monitor presentations as often as is practical to ensure that the intent of the disclosure procedures is served, including recommendations for modifications in requirements as circumstances may require.

F. Additional criteria for CME including Live Activities

1. All CME activities are planned under the guidance of an ASRS committee in accordance with the ACCME's accreditation criteria and Standards for Commercial Support.
2. Information from disclosure forms is analyzed by staff and a mechanism to mitigate reported conflicts is selected as described in Section III.
3. The ASRS Education Committee or other committee designated by the Board of Directors shall review all Enduring Materials.
4. Staff will review checklists, disclosures, and materials for all submissions before credit assigned
5. Every CME activity must be evaluated by participant questionnaires.
6. Every evaluation questionnaire must address the participant's impression of the presence or absence of commercial bias.

#### IV. MANAGEMENT AND MITIGATION OF CONFLICTS

A. CME activities:

For CME activities, a system of planning committee recusals, peer review, committee review, staff review, and cross-checks to identify and recommend possible means of resolving a relevant conflict shall be maintained. The ACCME defines "'relevant' financial relationships" as financial relationships in any amount which relate to the content of the educational activity, causing a conflict of interest.

1. The respective committees or Annual Meeting Program committee shall review all submissions and abstracts as well as the Faculty Financial Disclosure for Live Activities.
2. Objectivity and the use of best available evidence should be encouraged.
3. The goal of the planning committee is to maintain a membership with an appropriate balance of, if not lack of, financial disclosures. Whenever possible, at least 1 committee

member should have no relationships with industry in order to act as CME reviewer of the committee's work, particularly if the Chair has financial relationships with commercial interests, as noted in Section I. 3. In the event that all of the committee members have relationships with industry, an Education Committee member with no relationships with industry will review the planning process in order to ensure that all decisions related to the planning and implementation of a CE activity are independent of commercial interests and that CME content (1) addresses professional practice gaps and learning needs; (2) is valid; (3) is aligned with the best interest of the public; and (4) does not promote the products or services of any commercial interest.

4. Each person involved in the planning or execution of a particular CME activity shall make the Chair or other person responsible for the activity aware of the need to manage a specified conflict. Planning committee members with potential conflicts of interest shall recuse themselves from relevant discussions or be removed from the position, if appropriate. For CME activities, the Chair or responsible person shall review all Faculty Financial Disclosure Forms and course content prior to the activity and recommend the best mechanism to mitigate the conflict of interest.
5. For Credit-Bearing activities, as stated above owners or employees of retina Companies shall not be permitted to participate as speakers or other contributing faculty, except in three ACCME-permitted exceptions: 1) when the content is not related to the business lines or products of the employer/Company; 2) when the content is limited to basic science research and they do not make recommendations; and 3) when acting as technicians to teach the safe and proper use of medical devices and do not make recommendations. These exceptions will be documented by staff and confirmed with subject matter experts. Their written materials will be reviewed by subject matter experts without relationships to the Company and may be subject to additional mitigation processes, as described below.
6. If potential conflict of interest is detected, corrections will be recommended and implemented:
  - a. Enduring Materials shall be edited as required.
  - b. Live Activity Presenters shall be notified of concerns regarding conflict or potential conflict of interest prior to the activity and the Chair/Program Director and Faculty shall work together to mitigate or manage that conflict. Some possible steps that can be taken are:
    - i. Have the content reviewed and revised as necessary by experts that do not have relationships with the entity where the conflict lies
    - ii. Limit the presentation to pathophysiology and mechanisms of disease rather than therapeutic recommendations
    - iii. Select another speaker to present clinical implications after the primary speaker (with COI) has reported scientific discovery
    - iv. Change focus of the presentation so that the content is not about products or services of the COI

- v. Limit the presentation to research results and assign another speaker with no COI to the broader implications of clinical care if the speaker with COI is a principal investigator on a project funded by industry
  - vi. Ask the speaker with COI to recuse him/herself
  - vii. Ask the speaker to divest him/herself of all financial interests that have created the COI.
- 7. Resolution of COI documentation, including changes that were made to educational materials through implementation of the mitigation mechanism, shall be maintained in the CME activity files.
- 8. If the steps in Section III A. 6 are not sufficient or applicable for managing the conflict or perceived conflict, or the Chair or person responsible for a CME activity shall request that the Board of Directors or a committee assigned by the BOD determine an appropriate response, which shall include immediate cessation of the development of the activity.
- 9. If bias is detected from an individual during a live presentation in spite of a complete COI mitigation process, the Chair or person responsible for a CME activity shall request that the Board of Directors or a committee assigned by the BOD determine an appropriate response. The response may include:
  - a. Official notification and warning for the first occurrence, unless there is a failure to submit a required disclosure, as set forth in Section I above, which requires disqualification;
  - b. For repeat offenses - Banning for a period of 2 years of the individual from currently scheduled or future ASRS CME activity;
  - c. The ASRS Education Committee or responsible planning committee will notify the Executive Committee of repeat offenders.

## B. ASRS Leaders

The ASRS recognizes that Leaders often have a wide range of medical, scholarly, humanitarian and financial relationships, and participate in organizations and activities outside of the ASRS. As a natural consequence of these activities, conflicts or the perception of conflicts may arise from time to time for ASRS Leaders. These conflicts may be disclosed by the Leader, or identified by another Leader in an atmosphere of cooperation, rather than confrontation.

The CoIC shall review all leadership conflict of interest to identify activities that are either prohibited or require special review.

### 1. Prohibited Activities:

- For Board: Owners, employees and C-Suite Officers of ACCME defined Ineligible

Companies shall not serve in ASRS Leadership roles or as planning committee members.

- For Executive Committee: In addition to the above, Executive Committee members are prohibited from being owners, employees or C-Suite Officers of ACCME defined eligible retina Companies.

**2. Activities Triggering Special Review by the Conflicts of Interest Committee to determine eligibility to serve:**

- Serving on the board of directors a retina company
- Owning public stock, with a value or potential value of \$25,000 or more, in a retina related company
- Being a party to a royalty agreement, with an estimated present value of \$25,000 or more, with a retina related company

**Process for Reviewing and Mitigating All Disclosed Conflicts:** The goal of effective management of these conflicts is to arrive at a collaborative and consensual, mitigation, as set forth in the procedures below.

1. The ASRS Leader who discloses a conflict or potential conflict, or to whom a fellow Leader identifies a perceived conflict, prepares a statement describing the conflict and suggesting ways of resolving or managing it. If a challenged Leader believes that a conflict does not exist, a response may be submitted. If there is consensus that a conflict exists, methods for mitigation include highly specific confidentiality agreements, recusal from specific discussions, activities or votes, voluntary resignation from committee Chair or other leadership positions or by other means. A "Statement of Conflict Management" is submitted by committee members to their Committee Chair, and by BOD members to the Executive Committee. If a chairperson or Executive Committee member is submitting the statement, the ASRS Conflict Review Committee will appoint two of their members to review the Statement.
2. If the Statement of Conflict Management is accepted by the appropriate reviewer as sufficient to manage the conflict, the terms of the Statement will be accepted and distributed to the relevant committee or other ASRS body.
3. If the Statement of Conflict Management is not accepted, then the reviewer will submit the statement to the CoIC. The CoIC will work with the ASRS Leader to revise the Statement of Conflict Management such that the mitigation is acceptable to the Executive Committee.
4. If the revised statement is acceptable, it shall be accepted and disseminated as above, with additional dissemination to be determined by the "CoIC". Note that in some instances, an acceptable Statement may include the requirement that the ASRS Leader step down from a particular position of Leadership.
5. If no revised statement is agreed to by the ASRS Leader and the CoIC, the ASRS Leader will have an additional opportunity to be heard. The ASRS Leader and one member of the CoIC will present their respective positions to the Executive Committee of the BOD, which will make a recommendation of mitigation to the full BOD. The BOD vote will be binding on the Academy Leader.

Proposals for mitigation of a conflict may not affect an ASRS Leader's membership status. Egregious violations of this policy for which suspension or termination of membership may be appropriate shall be referred to the BOD.