

## **Policies for Managing Commercial Support and Conflicts of Interest**

The policies of the National Foundation for Infectious Diseases (NFID) are based on the 2004 ACCME Standards for Commercial Support (SCS) and are informed by the ACCME's Frequently Asked Questions regarding Independence that was updated in June 2010 ([link to ACCME](#)). These policies are designed to ensure independence in CME activities. All individuals in a position to control the content of NFID's educational activities will be provided a copy of relevant policies.

### **Standard 1: Independence**

NFID maintains a strict separation of the CME program and any commercial interests. A commercial interest is defined as any entity producing, marketing, re-selling, or distributing healthcare goods or services consumed by, or used on, patients. NFID's CME Committee, activity planning committees and CME office are solely responsible for needs assessment, educational objectives, content and its control, educational methods, and activity evaluation. Commercial support for NFID CME activities is in the form of unrestricted educational grants.

Employees of commercial interests will not be involved in the planning of educational activities and will have no control over the content. Employees of commercial interests will not be invited as speakers in plenary sessions or symposia.

Employees of commercial interests may submit abstracts to be considered for oral or poster presentation at the Annual Conference on Vaccine Research. The members of the Scientific Planning Committee for the conference will review and validate the research process, the results and the conclusions of each abstract. The selection of content for presentation will be based on its relevance and importance to the conference attendees. If selected for oral presentation, potential conflicts of interest will be resolved using the process described in Standards 2.3.2 (alter control over content) and 2.3.3 (peer review of content) below.

### **Standard 2: Resolution of Personal Conflicts of Interest**

- 2.1 Anyone with opportunity to influence or control content is required to disclose any relevant financial relationships, including all members of Scientific Program and Organizing Committees, CME Committee members, Course Co-chairs, Content Reviewers, Speakers and NFID staff. Signed disclosure forms are maintained on file for every educational activity.
- 2.2 Anyone refusing to disclose relevant financial relationships is disqualified from any involvement in NFID's CME program.
- 2.3 NFID is committed to identifying and resolving all conflicts of interest prior to the educational activity being delivered to participants. As an added step (as part of the post-activity evaluation), participants and faculty are asked about whether disclosure was done and whether each presentation was free of commercial bias. In advance of the activity, conflicts of interest may be resolved by one of three mechanisms:

- 2.3.1 **Alter financial relationship** – Individuals may choose to discontinue or alter their relationship with a commercial entity and eliminate any bias associated with the proposed CME content.
- 2.3.2 **Alter control over content** – Individual and/or NFID can elect to alter the educational design, format or content or individual responsibilities to maintain the scientific rigor, integrity and balance of the CME activity. These options include:
- Select someone else to present/author that portion of the content.
  - Alter the focus of the activity to broaden the discussion and focus on issues rather than products or services.
  - Alter the individual’s responsibilities in planning and implementation to areas not related to products or services.
  - Limit the content to a report on the “current state of the art” without recommendations.
  - Limit the source of recommendations to evidence-based sources that provide systematic and clearly defined parameters.
- 2.3.3 **Peer review of content** – Independent review and validation of content to verify the scientific bases and integrity of the content. Recommendations will be based on evidence currently accepted within the profession of medicine as acceptable justification for indications and contraindications for the care of patients. Scientific research referenced, utilized and/or included in CME will conform to generally accepted standards of experimental design, data collection and analysis.

### **Standard 3: Appropriate Use of Commercial Support**

- 3.1 NFID makes all decisions regarding the disposition and disbursement of commercial support.
- 3.2 NFID maintains written documentation of letters of agreement, specifying that all support is in the form of unrestricted educational grants. The supporter agrees not to be involved in any aspect of the planning or implementation of the activity.
- 3.3 All commercial support is given with the full knowledge and approval of NFID. Commercial support is disclosed in all promotional material and at the educational activity.
- 3.4 Letters of agreement outline the terms, conditions and purposes of the commercial support.
- 3.5 The name of the commercial supporter is clearly stated in each letter of agreement.
- 3.6 All letters of agreement are signed by the supporter and NFID.
- 3.7 Written policies and procedures for honoraria and reimbursement of out-of-pocket expenses for planners, speakers and authors are maintained.
- 3.8 All honoraria and expenses are disbursed directly by NFID.
- 3.9 No other payments are made to anyone involved in the educational activity.

- 3.10 Speakers are not given any additional funds outside of honoraria or reimbursable expenses, as outlined in NFID's policies and procedures.
- 3.11 Social events or meals at CME activities do not compete with the educational activity.
- 3.12 Commercial support is used only for expenses and honoraria of speakers, authors, employees or volunteers. Funds are not given to any other individuals participating in a CME activity.
- 3.13 Documentation of the receipt and expenditure of commercial support is maintained by NFID.

#### **Standard 4: Appropriate Management of Associated Commercial Promotion**

- 4.1 Commercial exhibits or advertisements do not influence the planning or interfere with the presentation of CME activities. Exhibit space is never given in exchange for commercial support.
- 4.2 Promotional material or advertisement is never allowed during CME activities. NFID does not allow advertising in any printed CME materials. During live activities, advertisements and promotional materials are not displayed in the educational space. Exhibits are physically separated from the educational activity.
- 4.3 All educational materials (including slides, abstracts and hand-outs) are reviewed in advance to ensure that they do not contain any advertising, trade names or product-group messages.
- 4.4 NFID does not advertise or promote commercial products in any of its materials.
- 4.5 NFID maintains a strict separation of the CME program from any commercial supporters. Commercial interests are never used to distribute CME activities to participants.

#### **Standard 5: Content and Format without Commercial Bias**

- 5.1 The content of all CME activities promote improvements or quality in healthcare and not a specific proprietary business interest of a commercial interest. Content validity is ensured in two ways:
  - 5.1.1 Speakers are required to provide a copy of their presentation to NFID in advance of the activity for the purpose of peer review. Speakers are notified in writing of NFID's requirements, and must sign and return an attestation form that they will comply with the following requirements:
    - Balance and scientific accuracy in the presentation, with content free of influence by industry or financial contributors.
    - If discussing any product use that is off-label, disclose that the use or indication in question is not currently approved by the FDA for labeling or advertising.
    - Provide evidence validating any clinical content (i.e., literature references) that is accepted within the profession of medicine as adequate justification and ensuring that all scientific research referred to, reported, or used in your presentation regarding

patient care recommendation conforms to the generally accepted standards of experimental design, data collection, and analysis.

- 5.1.2 NFID's medical director, CME director and activity planning committees work closely with all speakers to ensure understanding and adherence to these requirements. NFID's CME director attends every educational activity in person to monitor compliance.
- 5.2 All presentations give a balanced view of therapeutic options. Speakers attest in writing that they will comply with the following requirements:
  - If providing recommendations involving clinical medicine, they will be based on evidence that is accepted within the profession of medicine as adequate justification for their indications and contraindications in the care of patients.
  - All scientific research referred to, reported, or used in support of justification of a patient care recommendation will conform to the generally accepted standards of experimental design, data collection, and analysis.
  - If discussing specific health care products or services, use generic names to the extent possible. If trade names need to be used, use trade names from several companies when available, and not just trade names from any single company

## **Standard 6: Disclosures Relevant to Potential Commercial Bias**

- 6.1 For every educational activity, all relevant financial relationship(s) of any individual involved in the planning or implementation of the activity are disclosed to participants. These disclosures are published in written form in the activity materials (program or syllabus) and presented as a PowerPoint slide before each presentation. Speakers are also required to provide their disclosure information verbally before their presentation. Information provided includes the name of the individual, the name of the commercial interest and the nature of the relationship.
- 6.2 For individuals with no relevant financial relationship(s), this information is provided to participants in advance of the activity in the activity materials, on PowerPoint slides, and verbally.
- 6.3 The source and nature of commercial support is provided to participants in the activity materials.
- 6.4 Disclosures do not include the use of a trade name or product-group message.
- 6.5 All of the disclosure information is provided to participants prior to the beginning of the activity in the program materials and before each session.

**These policies and procedures will be reviewed annually by the CME Committee.**

**Updated and Approved in September 2010**