### AMERICAN COLLEGE OF MEDICAL GENETICS AND GENOMICS CME Policies and Procedures

It is the policy of the American College of Medical Genetics and Genomics to plan and implement all of its educational activities in accordance with the ACCME® Essentials and Areas and ACCME® Policies to ensure balance, independence, objectivity and scientific rigor. In accordance with the ACCME® Standards for Commercial Support, everyone (speakers, moderators, oral abstract presenters, all authors, committee members, and staff) who is in a position to control the content of an educational activity certified for AMA PRA Category 1 Credit™ is required to disclose all financial relationships with any commercial interests within the past 12 months that creates a real or apparent conflict of interest. Individuals who do not disclose are disqualified from participating in a CME activity.

Individuals with potential for influence or control of CME content include:

- planners, planning committee members, staff
- authors
- teachers
- educational activity directors
- educational partners
- others who participate, e.g. facilitators and moderators.

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This disclosure pertains to relationships with: pharmaceutical companies, biomedical device manufacturers, or other corporations whose products or services may be related to the subject matter of the presentation topic. Any real or apparent conflicts of interest related to the content of the presentations must be resolved prior to the educational activity Disclosure of off-label, experimental or investigational use of drugs or devices must also be made known to the audience.

# ACMG'S POLICY AND PROCEDURE FOR IDENTIFYING AND RESOLVING CONFLICTS OF INTEREST FOR CME EDUCATIONAL ACTIVITIES

The ACCME® Standards of Commercial Support (SCS) describe six Standards: (1) independence (2) resolution of personal conflicts of interest (3) appropriate use of commercial support (4) appropriate management of associated commercial promotion (5) content and format without commercial bias and (6) disclosures relevant to potential commercial bias. These updated Standards underscore continued voluntary self-regulation by the CME community, ensuring that physicians have opportunities to engage in commercially unbiased life-long learning facilitated by accredited providers. The purpose of this policy is twofold: [1] to establish guidelines and a mechanism for identifying and resolving conflicts of interest in CME educational activities as required in Standard 2 (see below), and [2] to be consistent with ACMG's policy for resolving conflicts of commitment and interest. Regardless of role, disclosure forms for speakers, moderators, all authors, program committee and staff participating in a CME activity will collected reviewed.

# <u>Standard 2: Resolution of Personal Conflicts of Interest in the Standards for Commercial Support</u> requires the following of ACCME accredited providers -

• Documenting that everyone who is in a position to control the content of an education activity has disclosed to the provider all relevant financial relationships with any commercial interests in any amount within the past 12 months that creates a conflict of interest. (SCS 2.1)

- Disqualifying individuals who do not disclose from participating in a CME education activity. (SCS 2.2)
- Identifying and resolving all conflicts of interest prior to the education activity. (SCS 2.3)

#### Terms as defined by the ACCME:

1. <u>Commercial Interest</u>: any entity producing, marketing, re-selling, or distributing health care goods or services consumed by, or used on, patients. For example, for-profit hospitals, group-practices, government organizations, etc., are not considered ACCME-defined commercial interest. However, device companies, pharmaceutical companies, academics and commercial laboratory selling or developing test are considered commercial interests.

Please note: ALL oral abstract authors are required to disclose all relevant financial relationship(s) with an ACCME-defined commercial interest ('industry'). No oral abstract author may be an employee of a commercial interest. Abstracts will NOT be accepted if any of the content authors are employees of a commercial interest.

- 2. <u>Financial Relationships</u>: relationships in which the individual benefits by receiving a salary, royalty, intellectual property rights, consulting fee, honoraria, ownership interest (e.g. stocks, stock options or other ownership interest, excluding diversified mutual funds), or other financial benefit. Financial benefits are usually associated with roles such as employment, management position, independent contractor (including contracted research), consulting, speaking and teaching, membership on advisory committees or review panels, board membership, and other activities from which remuneration is received or expected. ACCME considers relationships of the person involved in the CME activity to include financial relationships of a spouse or partner.
- 3. <u>Relevant financial relationships</u>: financial relationships with commercial interests in any amount occurring within the 12-month period preceding the time that the individual is being asked to assume a role controlling content of the CME activity that create a conflict of interest.
- 4. <u>Individuals with potential for influence or control of CME content</u>: Planners and planning committee members, authors, teachers, educational activity director(s), educational partner(s), and others who participate, e.g. facilitators and moderators.

Please note: The ACCME has not set a minimum dollar amount for relationships to be significant. Inherent in any amount is the incentive to maintain or increase the value of the relationship.

#### **ACMG's Procedures to Identify/Resolve Conflict:**

- 1. All individuals with potential for influence or control of content (defined in #4 above) must complete an ACMG's Disclosure Form prior to the education activity as a condition of invitation and acceptance to participate. ACMG staff, Education and CME Committee and Program Committee members are also required to complete an annual disclosure form.
- 2. An independent and unbiased assessment of content will be documented by one of the following methods to identify and resolve COIs
  - a. Content review by the program planning committee
  - b. Peer review committee not participating in the specific educational activity.

- 3. Disclosures of all individuals participating in the educational activity will be made known to the audience as required by the ACCME, in addition to a disclosure of any COIs that have been resolved with independence and without bias.
- 4. Speakers will be required to have a disclosure slide (1st or 2nd slide) identifying commercial relationships/interests in addition to any discussion of off-label use.
- 5. The audience will provide validation of absence of bias and COI for each speaker by the following summative methods:
  - a. Activity Evaluations
  - b. Session Monitor Evaluations

### Consequences of non-adherence to the ACMG's policy consist of:

- > Disqualified from speaking if no disclosure form is completed (SCS 2.2)
- ➤ Warning letter if the activity evaluation by the audience and session monitor comments indicates conflicts are present (1st occurrence)
- ➤ Not invited to speak or participate in any other role in a ACMG CME-certified educational activity. (2nd occurrence)