



NEW ACTIVITY INFORMATION SHEET
Office of Continuing Medical Education
Division of Coordinated Activities

ACCREDITATION/COMPLIANCE GUIDELINES/INSTRUCTIONS FOR ALL APPLICATIONS

REQUIREMENTS

_____ **New Activity Agreement Form:** This affirms that the Department is aware of the activity and its financial commitment. All information is required including the departmental internal order number (ION), the budget administrator and contact information. Both the Activity Director and the departmental or divisional Chairperson must sign the form. Once fully completed, the form should be submitted to the CME Office.

_____ **Planning Committee:** The Activity Director will need to provide his/her email address along with the names and email addresses of the planning committee members. This information will be added to our database for recordkeeping purposes and an e-mail invitation will be sent to the Activity Director along with an ID and Password to access and complete the online CME application.

_____ For new activities, the planning committee must consist of at least two (2) full time Hopkins faculty members and a non-conflicted (no financial relationship) faculty member to act as peer reviewer for the application. For repeat activities, only one full-time Hopkins faculty member is required.

DISCLOSURES

_____ **Activity Director and planning committee members** must disclose globally, listing all financial or in-kind relationships with commercial pharmaceutical or device companies, regardless of relevance to the activity. If they are also presenting at the activity they will be required to disclose again for their relevant relationships specific to their presentation(s).

_____ **Speakers** are required to disclose only those relationships that are relevant to their respective presentations. They must also provide at least one objective for each presentation. A disclosure summary will be provided to all attendees, along with each lecture's objective(s) prior to the start of the activity.

COMPONENTS OF THE APPLICATION

_____ **Needs Statement:** This statement must identify a gap in knowledge or practice.

_____ **Needs Methods:** To substantiate the gap identified in the Needs Statement, at least 3 different types of Needs Assessment Methods are required. The different type of documents include planning notes, literature review, recent research, expert opinion {NOTE: expert opinion cannot be that of the Activity Director(s), etc.}

_____ **Objectives:** The CME application must include 3-5 measurable learning objectives that tie into the statement of need.

_____ **Outcomes Survey Questions:** These are measurable questions that address what has changed in patient management/practice. The survey questions must include 3 questions that relate to the Needs Statement/Objectives and 2 questions regarding barriers to change (sample questions/language are included in the online application).

_____ **Agenda and Proposed Faculty:** An agenda including faculty names and titles must be included in each application.

NOTE: Any non-CME lectures must be clearly noted and *cannot* be mixed in with CME lectures or offered during competing time slots.

_____ **Bios/Biosketches:** Required for all guest speakers and the Activity Director(s).

_____ **Activity Evaluation:** Participants will be required to also complete an evaluation directly following the conclusion of the activity to assess speakers, bias, and whether the objectives were met (a sample evaluation tool is included in the online application).

ACTIVITY PRESENTATION MATERIALS

_____ Educational materials including slides, abstracts and handouts, etc. cannot contain any advertising, corporate logo, trade name or a product-group message.

COMMERCIAL SUPPORT: Educational Grants and the Sunshine Act

_____ **Educational grant funding:** Grant funding must be deposited into the CME activity budget account. All educational grants must have a Letter of Agreement (LOA) with the company providing the funds and the provider (Johns Hopkins). The Associate Dean of CME is the only authorized signer on behalf of Johns Hopkins. This LOA must be fully executed before the start of the activity.

_____ Grant support is completely separate from promotional/exhibit support. For exhibit support, please refer to the Exhibitor Guidelines.

_____ No perks are allowed, such as free registrations for grantor employees or free exhibit space. Grantor employees who want to attend the activity (listen in on the lectures) must pay the full registration fee. They cannot be a guest of the activity.

Sunshine Act: The Physician Payments Sunshine Act was enacted by Congress to increase public awareness of financial relationships between drug and medical device manufacturers and physicians. **To comply with the requirements of this Act, commercial supporters may require JHSOM to report certain professional information (such as name, address, National Provider Identifier (NPI), and State License number) of physician attendees who receive complimentary food and beverage in conjunction with a CME activity.** The commercial supporter is required to submit the collected data to the Centers for Medicare and Medicaid Services which will then publish the data on its website. It is recommended that the grant budget submitted for this activity only include costs of the educational components and none of the cost of food/beverages.

EXHIBITS

Exhibits: Exhibiting space requires a separate Exhibit Booth Agreement signed by the exhibiting company. Company products are not permitted for display on the exhibit table – only literature review material will be allowed. The registration fee for two company representatives will be waived for them to attend the lectures/presentations. If more than two have interest in attending, they will be required to pay the full registration fee.

SPEAKERS FROM INDUSTRY & SPEAKERS' BUREAU POLICY

Speakers who are on a Speakers' Bureau are not permitted to lecture at Johns Hopkins activities.

Definition: *Speakers' Bureaus are speaking arrangements with any of the following characteristics:*

- a. *A company has the contractual right to dictate what the faculty member says.*
- b. *A company (not the faculty member) creates the slide set (or other presentation materials) and has the final approval for all content and edits.*
- c. *The faculty member serves as the company's employee or spokesperson for the purposes of dissemination of company-generated presentation materials.*
- d. *A company controls the publicity related to the event.*

Speakers from Industry should not be invited to speak at an activity unless the lecture topic is completely **different from his/her position/research/products. Their presentation must not include any clinical treatment strategies or recommendations** and must be peer-reviewed prior to the presentation and on-site.

MARKETING/STANDARD WORDING

CME Standard Wording for marketing will be provided and facilitated by the assigned coordinator.

All marketing/printed material must be reviewed by the CME office PRIOR to distribution.