Commercial Support & Exhibit/Promotional Guidelines

Please review the following guidelines, which ensure that our activities are fully compliant with ACCME’s Standards for Commercial Support and free from commercial influence.

Commercial Support Definition
Commercial Support is financial or in-kind contributions given by an ACCME-defined commercial interest. The ACCME defines a commercial interest as any entity producing, marketing, re-selling, or distributing health care goods or services consumed by, or used on, patients such as a pharmaceutical or device company. The ACCME does not consider providers of clinical service directly to patients to be commercial interests - unless the provider of clinical service is owned, or controlled by, an ACCME-defined commercial interest. TUSM OCE follows the ACCME’s Standards for Commercial Support (SCS). When a commercial interest provides financial or in-kind support for an educational activity they are referred to as a commercial supporter of the activity.

The two types of commercial support are defined below:

- **Financial Support**: A monetary donation in the form of an educational grant, used to pay all or part of the costs of a CE activity
- **“In-kind” Support**: Non-monetary resource(s) (the loan or donation of equipment, supplies, and/or services) provided by a commercial interest in support of the educational activity

All commercial support (financial or in-kind) associated with an educational activity must be given with the full knowledge and approval of TUSM OCE and documented in a written agreement between TUSM OCE and the commercial supporter (and joint provider/educational partner, if applicable).

For further information on ACCME’s Standards for Commercial Support, please visit [this link](#) to their website.

**TUSM OCE Commercial Support/Grant Application Process**
If you are interested in applying for commercial support, TUSM OCE will work with you on this process to ensure that appropriate information is included. In some instances, your department/organization can submit grant applications. As noted, we need to review applications in advance, but if the funder does not specifically request that the Accredited Provider (TUSM OCE) submit grants, then your organization can submit directly. Usually you can find this information in the company’s grants portal website.

Grant applications/requests for commercial support cannot include any exhibit opportunities. Arrangements for commercial exhibits cannot be a condition of the provision of commercial support for CE activities. Requests for exhibits and exhibit payments must be separate.
Disbursement of Commercial Support (Financial Support)

As the accredited provider, TUSM OCE is responsible for maintaining financial documentation for all CE activities, including those with commercial support. A commercial supporter may never disburse payments directly to faculty. Only TUSM OCE or the educational partner/joint provider if designated by TUSM OCE may disburse faculty honoraria or reimbursement for out-of-pocket expenses, as per written agreement with TUSM OCE. Funds from commercial supporters must be in the form of an educational grant.

Grant funds/payment is handled in one of the following ways:
1) Generally, grant funds are made payable to “Trustees of Tufts College” and sent directly to TUSM. A commercial supporter may never disburse payments directly to faculty.

2) In some cases, the grant may be made payable to a joint provider/educational partner/third party if designated by TUSM OCE. In this situation, the following information is included in our commercial support agreement:

‘Tufts University School of Medicine (TUSM) Office of Continuing Education (OCE) designates [Name of joint/provider/educational partner/designated payee] to receive $[Amount] for an educational grant from [Name of Commercial Supporter].’

3) Occasionally, TUSM OCE receives the grant funds and funds are transferred to our joint provider/educational partner/third party, with the agreement that TUSM OCE will oversee the budget and disbursement of funds.

Budget/Grant Management and TUSM OCE Fees

Grant Application & Submission Fee: $250 per application
Overhead & Maintenance Assessed (if applicable): 15% of Approved Funds (e.g., $5,000 approved = $750 assessed)

For all activities, activity budgets are reviewed and approved by OCE staff, and all efforts are made to ensure that activity expenses are closely monitored and managed to meet requirements. Requests for faculty honoraria and travel reimbursements from activity faculty or planners must include receipts/other appropriate documentation.

Reimbursements forms/invoices will be processed and paid upon receipt (typically within 30 days of the activity), once approved by OCE staff and the University’s Finance/Accounts Payable Department. When applicable, TUSM OCE will review grant reconciliations and ensure that unused funds are returned if applicable/required by commercial supporters.

For jointly provided activities --- if TUSM OCE designates the joint provider/educational partner to receive the grant, TUSM OCE works with them to ensure that the Standards for Commercial Support are followed. TUSM OCE reviews an estimated budget prior to the educational activity. Also, a final budget is submitted to TUSM OCE for review and approval to ensure that the commercial support was handled appropriately.

Appropriate Use of Commercial Support Funds

Commercial support funds should not be used to fund hospitality, entertainment, or recreation. A CE activity cannot be held in a lavish or extravagant venue, or at a location which will distract from the educational focus and agenda of the event. Commercial support should be used to pay for modest meals and social events at CE activities and should not compete with educational events. TUSM OCE will review income and expense statements for all CE activities. These statements must reflect all income received and expenses paid for the activity.

In-Kind Support

For in-kind support, particularly durable equipment, TUSM OCE and joint provider/educational partner will confirm disbursement of the equipment directly with funder and coordinate details/instructions for delivery and pick-up to/from the educational activity venue. The equipment must be delivered prior to the start of the activity; company representatives cannot be present/involved in the activity. We will confirm that the educational activity is planned by course director(s), planners, and TUSM OCE without any control from the commercial supporter. The commercial supporter cannot have any say in what procedures will be taught, and either an OCE staff member is present to oversee and participate in the actual instruction or we designate an appropriate faculty member. We require written documentation post-activity to verify that equipment demonstration was about the safe and proper use of the equipment and did not include clinical recommendations about the medical devices/equipment from the manufacturer(s). Other types of in-kind support (Facilities/Space, Disposable supplies (Non-biological), Animal parts or tissue, Human parts of tissue, or other), follow the same policy.
Compliance with ACCME Standards for Commercial Support

The OCE has developed the following procedures to assure compliance with the ACCME Standards for Commercial Support (SCS):

For all activities that apply for and/or receive commercial support (financial or in-kind):

- Estimated budgets must be submitted to the OCE for review prior to application.
- The OCE must have full knowledge and approval of any commercial support for an educational activity in advance.
- An ACCME-defined commercial interest may not be involved in activity planning, implementation, evaluation, or faculty selection.
- Commercial support agreements must be signed by the commercial supporter and the accredited provider (TUSM OCE) even if OCE designates the funds to go directly to the joint-provider/educational partner. The agreement must specify the source of commercial support (financial or in-kind) and document the terms of support and agreement to comply with the ACCME’s SCS and others as noted. Completed copies of the signed agreement along with a projected/final budget will be kept on file by the OCE.
- TUSM OCE Provider and Joint Provider Collaboration agreements must outline the roles and responsibilities of each party. As the accredited provider, the OCE is responsible for adherence to all ACCME, ANCC, ACPE, and other accreditation standards and requirements, and will work in concert with our joint providers/educational partners to meet these rigorous standards.

Regardless of whether or not there is commercial support for an activity:

- CME content must be valid, evidence-based, fair balanced and independently planned, free from commercial bias and do not display any logos or other trademarks.
- All marketing/promotional materials must be submitted to OCE staff for approval prior to print/distribution/launch to ensure that materials communicate appropriate accreditation requirements and are independent of commercial influence and/or promotion.
- Presenter materials as well as final syllabi or course materials are also submitted to OCE staff for review and final approval.
- All individuals who may be in a position to control the content of an activity must submit signed and dated disclosure forms in advance of the activity. Any individual who refuses to disclose relevant financial relationships to OCE will be disqualified from participating in the activity.
- If it is determined that a conflict of interest (COI) exists, OCE staff will address and resolve this COI using a combination of approaches that may involve some combination of the following individuals: TUSM OCE staff, TUSM OCE’s medical director, the course director/chair, TUSM OCE’s nurse planner (when applicable) and course planners prior to the start of the activity.
- Disclosure of relevant financial relationships with ACCME-defined commercial interests and disclosure of commercial support to the learners must occur prior to the beginning of any activity, with documentation submitted to TUSM OCE to verify that this occurred. Disclosure of commercial support is limited to the name of the commercial interest entity providing support.
- Social events and meals may not compete with or take precedence over the educational activity.
- Arrangements for commercial exhibits or advertisements cannot influence planning, presentation, or be a condition of support for the activity.
- Exhibits must be kept separate from all CE activities.
- Educational materials cannot contain any commercial interest logos, advertising, trade name, or product group messages.
- An ACCME-defined commercial interest may not serve as the vehicle to provide a CE activity to learners (e.g., distributing self-study materials or arranging electronic access).
Acknowledgement of Commercial Support
All commercial support (financial and/or in-kind) must be acknowledged in the course syllabus/handout materials, which TUSM OCE is required to review and approve prior to print/distribution. Please note that company logos are strictly prohibited when acknowledging an ACCME defined commercial interest.

Below is sample language to be used:

If the activity received commercial support in the form of a monetary grant, include the following statement:
This activity is supported in part by an educational grant from the following company:
<insert Company Name>

If the activity received in-kind commercial support, include the following statement:
This activity is supported in part by an in-kind donation from the following company:
<insert Company Name & (Nature of in-kind support provided)>

Control of Contents & Selection of Faculty
ACCME-defined commercial interests shall not make support contingent on the acceptance of advice about speakers or educational matters, such as content, learner objectives/outcomes, or educational methods. TUSM OCE is solely responsible for the control of content; identification of educational objectives; evaluation of the activity, and selection of faculty, editors, presenters, or authors. Both TUSM OCE and its joint providers/educational partners shall ensure that the content, quality and scientific integrity of the activity is objective and that current information is based upon widely accepted scientific methods and publicly available data.

Separation of Content and Commercial Influence/Bias
The content or format of a CME activity or its related materials must promote improvements or quality in healthcare and not a specific proprietary business interest of a commercial interest. Presentations must give a balanced view of therapeutic options. Use of generic names will contribute to this impartiality. If the CE educational material or content includes trade names, where available trade names from several companies should be used, not just trade names from a single company.

TUSM OCE requires presentations from all speakers in advance for approval. This helps to ensure that the guidelines above are met prior to the educational activity.

Sunshine Act/Open Payments Reporting
The Sunshine Act/Open Payments Reporting requirements have become standard when receiving commercial support for an educational activity.

- Description - Open Payments Reporting is a national disclosure program created by the Affordable Care Act that increases public awareness of financial relationships between the health care industry (e.g., medical device manufacturers and pharmaceutical companies) and physicians or teaching hospitals. As of August 1, 2013, pharmaceutical and device manufacturers are required to report payments or transfers of value made to physicians or teaching hospitals to the Centers for Medicare and Medicaid Services (CMS). CMS collects this data annually, and makes it publicly available and searchable on their website. Payments and transfer of value include faculty travel expenses, meals, honoraria, and participant meal expenses. For more information about the Sunshine Act/Open Payments, please visit https://www.cms.gov/openpayments/.

- Importance - Collaboration among physicians, teaching hospitals, and health care manufacturing companies contributes to the design and delivery of many life-saving drugs and devices. However, sometimes these payments can also introduce conflicts of interest. Open Payments Reporting doesn’t identify which financial relationships are beneficial or which may cause conflicts of interest. Instead, the program is designed to increase public awareness about these relationships and promote transparency in the health care industry. The (CMS) fulfills the law’s mandate via the Open Payments Reporting Program. CMS makes this information available to the public to allow interested stakeholders to analyze, monitor, and use the data.

- Process - The commercial supporter will notify you that reporting of payments and transfers of value is required in their grant approval emails and/or LOA. The report is usually submitted during the grant reconciliation (post-activity). As a courtesy to your faculty, you should notify them in advance so that they have the option not to participate if they do not wish to be reported as receiving such payments. In addition, if you are offering any meals to participants that
will be covered by the grant funds, you will also need to notify your participants of the reporting requirements in advance.

The following information will need to be collected in advance and submitted to the commercial supporter if requested: speaker/participants’ name, address, NPI number, license number, transfer of value cost(s), and/or any other specific data requested by the commercial supporter.

If the commercial support funds were not used for any payments and/or transfer of value, you would let the funder know. However, this would be only after you have acquired other funds to cover those expenses (such as registration fees). This must be very clear in the final course budget, which is usually submitted to the commercial supporter with the grant reconciliation.

**Commercial Support FAQ**

Is a research company conducting clinical trials but not selling products considered a commercial interest?

If the company has a product that is in development (clinical trial), but not yet approved, the company is still considered a commercial interest. A company may not use accredited CME/CE to create a market for products it is developing, regardless of whether the product is commercially available.

If a donation is provided from a non-commercial interest, is that considered commercial support?

No, they would be considered a general supporter of the activity. The funds would not be acknowledged as commercial support.

Can a commercial interest provide both financial and in-kind support?

Yes, they may give an educational grant for a specified amount and donate equipment or other supplies. There must be separate Letters of Agreement (LOAs) in place that clearly specify both kinds of support.

If a commercial interest would like to pay for (sponsor) lunch on one of the conference days. Is this allowed?

Yes, a commercial interest can provide commercial support to sponsor lunch for a CE activity if a written agreement is in place, commercial support is acknowledged appropriately and follows ACCME’s SCS guidelines.

Can commercial interests be offered different levels of designation for different amounts of commercial support, e.g., gold, silver, and bronze categories for commercial support at three different levels?

Yes. You may designate different categories of commercial supporters for different amounts of support and recognize them accordingly in course materials.

Is TUSM OCE’s Letter of Agreement required, or can an agreement provided by the grantor be used?

Either is acceptable. If using an agreement provided by the grantor, TUSM OCE must review before signing and submitting.

The written agreement must be in compliance with the following:

- Both the Accredited Provider and commercial supporter must be listed in the written agreement as the parties entering into the agreement for commercial support (financial or in-kind).
- Must specify the organizational name of the commercial interest(s) that supplied the funds.
- Must specify what funds or in-kind services will be given by the commercial supporter to support the activity.
- Must be signed by both the accredited provider (TUSM OCE) and the commercial interest providing the commercial support. Third parties and/or joint sponsors may also sign the written agreement, but may NOT sign it as the Accredited Provider.
- Must be signed by all required parties prior to the activity taking place.

Are electronic LOAs acceptable?

Yes, electronic LOAs and signatures are acceptable as evidence that written agreements are signed, as long as signature dates are included (must be prior to the activity).
Can there be commercial support that the Accredited Provider (TUSM OCE) does not know about?
No, there should not be any commercial support that the TUSM OCE does not know about. Please see ACCME standard below.

**Standard 3.3** - *All commercial support associated with a CME activity must be given with the full knowledge and approval of the provider.*

Can a commercial supporter direct the educational content or provide suggestions related to topics or speakers for the activity?
No, a commercial supporter/ACCME-defined commercial interest cannot direct educational content or provide suggestions related to topics or speakers for an activity. The process to develop the CE must be independent of any commercial interest (see ACCME standards below).

**Standard 3.2** - *A provider cannot be required by a commercial interest to accept advice or services concerning teachers, authors, or participants or other education matters, including content, from a commercial interest as conditions of contributing funds or services.*

Are receipts required for the expenses paid with commercial support?
Yes, you should keep all receipts on file for a minimum of six years in case of an audit.

**Standard 3.13** - *The provider must be able to produce accurate documentation detailing the receipt and expenditure of the commercial support.*

Does the commercial supporter always need to be acknowledged in course handout/syllabus materials?
Yes, this is one of ACCME’s Standards for Commercial Support (see below), which requires that all commercial support must be communicated to learners.

**Standard 6.3** - *The source of all support from commercial interests must be disclosed to learners. When commercial support is “in-kind” the nature of the support must be disclosed to learners.*

Are there any circumstances when employees of ACCME-defined commercial interests can be in a position to control the content of accredited CME?
As noted above, employees of ACCME-defined commercial interests as faculty and planners cannot control the content of CE, except in the specific situations specified by the ACCME. Below are 3 special-use cases where employees of ACCME-defined commercial interests can have a specific, limited role in accredited CME activities. In each scenario—as in every accredited CE activity—the expectations of ACCME’s Accreditation Requirements, including the Standards for Commercial Support, must be met.

**NOTE:** TUSM OCE does not allow employees of an ACCME-defined commercial interest to be involved in planning of an activity.

1. Employees of ACCME-defined commercial interests can control the content of accredited CME activities when the content of the CME activity is not related to the business lines or products of their employer.

2. Employees of ACCME-defined commercial interests can control the content of accredited CME activities (e.g., as planners, authors, or speakers [including poster presentations]) when the content of the accredited CME activity is limited to basic science research (e.g., pre-clinical research, drug discovery) or the processes/methodologies of research, themselves unrelated to a specific disease or compound/drug. In these circumstances, the accredited provider must be able to demonstrate that it has implemented processes to ensure employees of ACCME-defined commercial interests have no control of CME activity content that is related to clinical applications of the research/discovery or clinical recommendations concerning the business lines or products of their employer.

3. Employees of ACCME-defined commercial interests can participate as technicians in accredited CME activities that teach the safe and proper use of medical devices. In this circumstance, the accredited provider must
demonstrate that it implements processes to ensure that employees of ACCME-defined commercial interests have no control of CME activity content that is related to clinical recommendations concerning the business lines or products of their employer.

Would it be appropriate for a commercial supporter to request to review educational content?
No, it would not appropriate for a commercial supporter to request to review educational content. This would be out of compliance with ACCME’s Standards for Commercial Support SCS 1.1 and 3.2 (see below). A content review by a commercial supporter as a condition of its contributing funds or services is prohibited.

**Standard 1.1** - A CME provider must ensure that the following decisions were made free of the control of a commercial interest. (See www.accme.org for a definition of a "commercial interest" and some exemptions.) (a) Identification of CME needs; (b) Determination of educational objectives; (c) Selection and presentation of content; (d) Selection of all persons and organizations that will be in a position to control the content of the CME; (e) Selection of educational methods; (f) Evaluation of the activity.

**Standard 3.2** - A provider cannot be required by a commercial interest to accept advice or services concerning teachers, authors, or participants or other education matters, including content, from a commercial interest as conditions of contributing funds or services.

Can a commercial supporter supplement their financial grant contributions to the activity with direct payments to faculty involved in the activity?
No, commercial supporters cannot supplement their financial grant contributions to the activity with direct payments to faculty involved in the activity. All commercial support must be stipulated by a written agreement and payment must be issued to the Accredited Provider and/or its joint provider/educational partner to make payments to faculty for their role(s) in the activity (see ACCME Standards below).

**Standard 3.1** - The provider must make all decisions regarding the disposition and disbursement of commercial support.

**Standard 3.9** - No other payment shall be given to the director of the activity, planning committee members, teachers or authors, joint provider, or any others involved with the supported activity.

How can meals or social events take precedence over educational events?
Commercial support should be used to pay for modest meals and social events at CME/CE activities. Meals or social events compete with educational events when they happen at the same time in a different location or when they are the main attraction at the educational activity. Making meals or social events longer or more important or more costly than the educational activity, for example, should be avoided.

**Standard 3.11** - Social events or meals at CME activities cannot compete with or take precedence over the educational events.

Can a CE activity be distributed via a television channel, website, or other type of communications vehicle that is owned by a commercial interest?
No. The ACCME requires that accredited providers to use their own distribution channels for CME activities. Communication or distribution mechanisms that are owned or controlled by a commercial interest cannot be used to transmit or distribute continuing medical education activities to learners (e.g., a cable TV network or website owned and controlled by a commercial interest).

**Standard 4.5** - A provider cannot use a commercial interest as the agent providing a CME activity to learners, e.g., distribution of self-study CME activities or arranging for electronic access to CME activities.
Exhibit/Promotional Guidelines

Commercial exhibits and advertisements are promotional activities and not continuing education. Therefore, funds paid by commercial interests for promotional activities are not considered to be commercial support. Requests for exhibits and exhibit payments must be separate from commercial support/educational grants approved/received. Commercial interests may not exhibit, promote or sell products or services during the introduction of an educational activity or any time while the educational activity takes place, regardless of the format of the educational activity. ACCME insists on the separation of education from all promotional activities, materials, and messages. Please review the ACCME guidelines noted below.

Exhibit Displays/Table Location

Exhibitors may not share the same space as the accredited activity. A separation of promotion from education must be maintained, which means that promotion cannot happen within the same room as the educational space. There must be a separate room designated for exhibitors only. Exhibitors can only display and promote their products in this designated area.

Exhibit tables must be set up in another room, separate from the conference room, even if the activity is not in session. Any/all promotion or discussion of products and/or services must take place in the designated exhibit space (at the booth or in the designated exhibit hall); it may never take place formally or informally in the actual educational space. Examples of educational space include lecture halls, break-out rooms, and laboratories.

Exhibitor Agreement

Every commercial interest must complete and submit TUSM OCE’s Exhibitor Agreement prior to the educational activity.

Acknowledgement of Exhibitors

Commercial interests who will be participating as exhibitors must be acknowledged in CE materials such as in the course syllabus/handout materials. However, these documents, in print or electronic form, are an integral part of the education and as such cannot have any advertising, trade name, or a product-group message of an ACCME-defined commercial interest associated with them.

Please note that company logos are strictly prohibited when acknowledging exhibitors who are considered an ACCME defined commercial interest.

Promotional Opportunities

Commercial interests can be offered other promotional opportunities to market their company, products and services in non-CE materials/non-educational spaces. If a prospectus will be developed it must be reviewed and approved by TUSM OCE prior to distribution to ensure compliance with the requirements.

NOTE: Advertising or promotional opportunities must not be part of the educational activity and must not be paid for by commercial support. Educational materials such as slides, abstracts, and handouts, cannot contain any advertising, trade name, or a product-group message of a commercial interest. If this is offered to a commercial interest, it must be offered as a separate handout from the educational materials.

NOTE: TUSM OCE requires review of all handouts to ensure compliance with the requirements.

Exhibit/Promotional FAQ

Can a commercial supporter be offered complimentary exhibit space as part of their grant support?

No, a company may not be given a complimentary booth, table or any other space to display their products or promote their company as a result of giving an educational grant. Grant support for CME activities must be used to cover the expenses associated with the educational activity and no other benefits can be offered along with such support.

A commercial supporter can pay for advertising and/or other promotion opportunities separately with resources designated for that specific purpose. This means that it must be separate from the written agreement for commercial support described in Standard 3 of the SCS.

Standard 4.1 - Arrangements for commercial exhibits or advertisements cannot influence planning or interfere with the presentation, nor can they be a condition of the provision of commercial support for CME activities.

Can industry reps sit in the educational activity?

Yes, industry reps can sit in strictly for their educational benefit; they cannot bring any products in the educational space for promotional purposes.
Can I share my attendee list with exhibitors?
No, TUSM OCE does not allow sharing attendee lists/participants’ information with exhibitors.

Is it appropriate for educational materials to include corporate logos and/or advertisements of products?
No, it is not appropriate for educational materials to include advertisements of products. Corporate logos of ACCME-defined commercial interests can be used ONLY in non-educational spaces and/or non-educational materials (see ACCME standards below).

**Standard 4.3** - Educational materials that are part of a CME activity, such as slides, abstracts and handouts, cannot contain any advertising, corporate logo, trade name or a product-group message of an ACCME-defined commercial interest.

**Standard 4.4** - Print or electronic information distributed about the non-CME elements of a CME activity that are not directly related to the transfer of education to the learner, such as schedules and content descriptions, may include product-promotion material or product-specific advertisement.

**NOTE:** TUSM OCE must review and approve all activity materials prior to distribution.