

CME Activity Guide



SUNY
DOWNSTATE
Medical Center

Office of
Continuing
Medical Education

TABLE OF CONTENTS

Introduction	6
Mission Statement	6
Office of CME	8
Definition of CME	9
ACCME Essentials	9
Certification for Category 1	10
Policies	12
Commercial Support Policy	12
Speaker's Disclosure Policy	15
Joint Sponsorship Policy	17
Internet Policy	18
Journal CME Policy	19
Enduring Materials Policy	20
Promotional and Syllabi Policy	22
Statements	23
Accreditation Statements	23
Disclaimer Statements	23
Jointly Sponsorship Statements	23
ADA Statements	24
Planning and Needs Assessment	25
Planning	25
Needs	26
Learning Objectives	27
Evaluation	28
Sample Regularly Schedule Conference Evaluation	28
Sample Annual Conference/Symposium Evaluation	29
Commercial Support	31
ACCME Standards for Commercial support	31

Sample Letter of Agreement.....	34
Sample Letter of Agreement for Jointly Sponsored Activities	36
Faculty	38
Required Speaker Information	38
Sample Disclosure.....	39
Sample Flyer	40
Meeting Management Checklist.....	43
Final Documentation.....	44
OCME Services.....	45

INTRODUCTION

Purpose of Guide

The purpose of this Activity Development Guide is to facilitate the development and implementation of continuing medical education (CME) activities at SUNY Downstate Medical Center and our affiliated hospitals, and to ensure that these activities comply with the guidelines of the Accreditation Council for Continuing Medical Education (ACCME) for certification of category 1 credit. It contains guidelines, checklists, reference materials and other information you will need to take you through the development process.

All of the necessary data forms required to implement your activity will be included in the CME Certification Request packet, each time you apply for category 1 credit. Please retain this Guide as a handy reference. The OCME welcomes your calls, should you have any questions that have not been addressed in the Guide, or if you need assistance in planning your activity.

Mission Statement

Office of Continuing Medical Education
State University of New York Downstate Medical Center

SUNY Downstate is the sole academic medical center located in the heart of one of our nation's largest, most ethnically diverse, working-class urban communities. With our schools of higher education, our goal is to train the next generation of physicians, nurses, health-care professionals, and researchers serving our community and New York State. Through our research facilities, our mission is to advance the medical sciences to the community at large. Through our hospital and education affiliates, our mission is to serve the health-care needs of the 2.6 million residents of Brooklyn and Staten Island. Through graduate and continuing medical education, our mission is to provide lifelong learning opportunities for our physicians, nurses, and allied health professionals.

The CME mission embodies the following goals:

1. To enhance the quality of health care provided to the local and extended community, through emphasizing the importance of education and research as essential ingredients for excellence in patient care
2. To provide information and opportunities for physicians and other health care providers to learn about more effective, state of the art, and efficient means of delivering health care in new health care markets

3. To provide information and opportunities to develop a knowledge base and skills relative to the latest technological and scientific advancements in medicine
4. To provide continuing medical educational programs, which meet the criteria for Category I as, designated by the AMA Physician's Recognition Award, and follow the Essentials, Guidelines, and Standards of the Accreditation Council for Continuing Medical Education
5. To review the overall program and operational policies annually for consistency with the Mission Statement of OCME and SUNY/Downstate to ensure congruence and revise as necessary to meet the stated goals
6. To ensure balance, independence, objectivity, and scientific rigor in its sponsored activities

To accomplish these goals conferences, grand rounds, enduring materials, symposia and journal clubs are offered. By offering these various activities to our primary target audience of physicians, we expect that the overall medical knowledge of physicians will be enhanced. These goals are consistent with the overall mission of SUNY Downstate, and adhere to the three Essentials of the Accreditation Council for Continuing Medical Education.

Office of Continuing Medical Education Contacts

SUNY Downstate Medical Center
Office of Continuing Medical Education
450 Clarkson Avenue, Box 93
Brooklyn, NY 11203

Tel: 718 270-2422

Fax: 718-270-4563

www.downstate.edu/ocme
ocme@downstate.edu

JoAnn Bradley, EdD
Executive Director

Edeline Mitton, MEd, CPP
Director

Cassandra Greene
Assistant Director

Judith Ruddock
Director of Conferences

Roseme Compail
CME Affiliates Coordinator

Nathalie Deare
Certificate and Website Coordinator

Henrietta Livingston
Database Coordinator

Donna Handley
Staff Assistant

AMA Definition of Continuing Medical Education

"Continuing Medical Education consists of educational activities that serve to maintain, develop, or increase the knowledge, skills, and professional performance and relationships a physician uses to provide services for patients, the public, or the profession. CME represents that body of knowledge and skills generally recognized and accepted by the profession as within the basic medical sciences, the discipline of clinical medicine, and the provision of health care to the public."

American Medical Association (AMA)

ACCME Essential Areas of Accreditation for Sponsors

The Office of Continuing Medical Education (OCME) must follow three Essentials in order to comply with the ACCME Standards. Below are the three (3) Essential Areas of Accreditation which accredited providers must strictly adhere to, when administering category 1 CME activities.

- Essential Area #1: The Purpose and Mission: There shall be a written statement of CME mission, formally approved by the governing body. This shall include the CME purpose, content areas, target audience, type of activities provided, and expected results.
- Essential Area #2: Educational Planning and Evaluation: There shall be established procedures for identifying and analyzing the continuing medical educational needs and interests of prospective participants, and linking them with the desired goals and objectives. The needs and objectives will be communicated to the participant. The CME activities and the overall CME program will be effectively evaluated to assess whether they meet the stated educational needs.
- Essential Area #3: Administration: There must be appropriate resources and management procedures available to effectively fulfill the continuing medical education mission. The CME activities must be run in compliance with the ACCME's policies for disclosure and commercial support. There must be adequate supervision to assure the optimum quality and content in all activities, including enduring materials.

CERTIFICATION OF CATEGORY 1 CREDIT FOR CME ACTIVITIES

The following data will provide you with essential information, which you should be aware of when developing your CME activity, and submitting your CME Certification Request for category 1 credit. This information has been established to conform to the Essential Areas and Policies of the ACCME. To receive category 1 credit, a CME Certification Request form must be submitted to the OCME for your activity. The request is submitted for the following:

Regularly scheduled activities (grand rounds, morbidity and mortality conferences)
Annual activities (conferences, seminars, etc.), Enduring materials (monograph, CD-ROM, videotape)

1. All CME activities must 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. This means that any documents or research use in CME activities must use valid scientific data. Anything used to “have known risks or dangers that outweigh the benefits or known to be ineffective in the treatment of patients” would be considered invalid and not permitted to receive CME credits.
2. The requests must be received by the OCME before your activity begins. The starting point from which CME credit is calculated is based upon when the application is received in the OCME. For example: If your activity begins in July and you submit your request in August, your credit will begin from the month of submission.
3. Upon receipt of your request, the OCME will acknowledge to you that it is being reviewed and will contact you for further documentation, if necessary.
4. CME Certification Request forms submitted for category 1 CME credit will not be considered for approval without all required forms and documentation. The following documentation is required upon submission of your CME Certification Request Form:
 - a) Completed and signed request
 - b) Activity Director’s Letter of Agreement
 - c) Planning Minutes and Needs Statement with supporting documentation
 - d) Preliminary budget form
 - e) A sample flyer
 - f) A sample evaluation form (if different from the OCME form)
 - g) Certification Request fee
5. Once your program has started, you will need to forward the following documentation to the OCME on a monthly basis:
 - a. Attendance sheets
 - b. Evaluations forms
 - c. Speaker’s Disclosure forms
 - d. Commercial Support forms (if applicable)
 - e. Flyers announcing activity with the appropriate disclosure information

Failure to submit required documentation on a monthly basis may result in denial of category 1 certification status of your CME activity.

6. Reference to CME credit before it has been approved with statements such as “CME credit is pending” or “CME credit has been applied for” may not be used. The activity must have OCME approval for certification of Category 1 prior to distributing any brochures or other materials that refer to CME credit.
7. The Accreditation and Disclaimer Statements must appear on all distributed CME activity materials i.e. brochures, flyers, posters, enduring materials, etc.
8. Speaker’s disclosures and disclosures of any commercial support must be included in your brochure or on your flyer, and acknowledged to participants prior to the CME activity, verbally and in writing, and in post meeting publications. Off-label drugs/devices and their usage must also be disclosed and included on your flyer at each meeting.
9. If you choose to use your own participant evaluation form, a copy of that form must be included for approval, when you submit your CME Credit Request for the new academic year. Each participant attending a live activity (annual conference, symposium, etc.) must complete an evaluation form. For regularly schedule conferences (grand rounds, etc.) evaluations must be completed at least on a monthly basis.
10. Honoraria and other CME activity expenses must never be paid directly by a commercial supporter. All commercial support funds must be paid directly to the OCME or to the appropriate clinical department (SUNY Downstate Only), who will then make the appropriate disbursements. Disbursement of those funds must be indicated on your final budget form. Please refer to the ACCME’s Standards for Commercial Support and the OCME’s Commercial Support Policy in this Guide.
11. A CME Certification Request Form for category 1 credit must include a statement of need for the activity. In addition, you must also submit documentation which supports your needs.
12. You must submit a CME Certification Request Form (CRF) annually to apply for category 1 credit for all regular schedule conferences.
13. CME Certification Requests are mailed at the end of May. If you have not received a request by the second week of June, please call the OCME. CME Certification Requests are mailed to department that currently have activities that are being sponsored by the OCME.
14. To ensure approval of your CME activity, all required documentation must be submitted in a timely manner.

COMMERCIAL SUPPORT POLICY

The CME Certification Request packet includes everything you will need to document your compliance with the Standards for Commercial Support of the Accreditation Council for Continuing Medical Education (ACCME). Continuing Medical Education (CME) must be free of the control of commercial interests. The ACCME believes that independence from commercial interests will help ensure that CME is free of commercial bias and, therefore be in the best interest of the public.

1. Commercial support shall be provided with the knowledge, consent, and written approval of the Office of Continuing Medical Education (OCME) and shall be in the form of an educational grant. No other payment from a commercial interest shall be given to the an Activity Director, planning committee members, faculty (speakers or presenters), authors, joint sponsor, or any others involved with the supported CME activity.

Content without commercial bias

2. CME certified activities will be free of control of commercial interests in both planning, and implementation. The use of peer and content review to ensure data validity is encouraged. A balanced view of therapeutic should be included in content and disclosure should be made to participants regarding the source and type of evidence use for content.

Disclosure of relationships to participants

3. All individuals who are involved with the content of an educational activity are required to disclose all relevant financial relationships in any amount occurring within the past 12 months related both to content and to commercial supporters of the activity including:
 - The name of the individual
 - The name of the commercial interest(s)
 - The nature of the relationship the individual has with each commercial interest.
 - Any individual who does not disclose relevant financial relationships will be disqualified from participating in the planning and implementation of educational activities.
 - All relationships and source of support whether in-kind or otherwise must be disclosed in a text format (print, slide, online) to participants prior to the presentation of the content of the activity; if no relationship exists, this must be disclosed in the same manner.
 - The source and type of evidence for key teaching points must be made clear to participants
 - The OCME will monitor all activities to identify and resolve all conflicts of interest prior to the educational activity being delivered to learners.

4. A commercial interest cannot take the role of non-accredited partner in a jointly sponsored activity.
5. All decisions regarding an OCME certified CME activity will be made free of the control of any commercial interest including:
 - a. Identification of CME needs
 - b. Determination of learning 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 activity.
 - e. Selection of educational methods
 - f. Evaluation of the activity
6. Commercial Support Letter of Agreement Forms must be completed and signed by both the Activity Director and company representative for each commercial support occurrence. All letters of agreement requires the signature of the accredited provider. This form may be duplicated and used for each commercial support occurrence. Letter of Agreement Form from Pharmaceutical companies may also be used.
7. Grants made payable to: SUNY - Office of CME. The OCME will process all disbursements to the appropriate parties. Please have the pharmaceutical representative contact the OCME for additional information.
8. Grants made payable to the Clinical Departments (SUNY and Affiliates). With "full knowledge and approval" of the OCME, the clinical departments at SUNY and at our affiliates may make all disbursements. A record must be kept of all disbursements and entered on your Final Budget form, which will be submitted to the OCME at the conclusion of the activity.
9. At no time should the commercial supporter pay an honorarium or other disbursements directly this includes catering expenses. You must follow the outlined policy. It has been established to make certain that the OCME receives all documentation necessary, to ensure that every CME activity held under the auspices of SUNY Downstate complies with the Standards of the ACCME.
10. CME Certification Request Form - On page 3 of the Credit Request Form form, you will find a section to indicate whether or not commercial funds will be used. In this section, you must indicate whether the activity will be funded all or in part by departmental funds, commercial support, etc. Please do not put "N/A", as this is not acceptable.
11. Preliminary Budget Form is to be submitted with your CME Certification Request form. The estimated costs for your activity, which includes your estimated commercial support funds, and the names of your supporters, must be included on the form.

12. Final Budget Form is to be submitted when your CME activity has concluded. It outlines total costs, which includes departmental or divisional funds, income from participant fees, and funding from commercial companies. It includes a breakdown of expenses, and a record of disbursements made from commercial support funding. Final budget information is essential to the completion and compliance of your CME activity.
13. Exhibit Fee: A fee paid by a commercial interest to display and promote their products. Exhibit fees are considered a business transaction – they are not considered commercial support.
14. Sponsorship: "SUNY Downstate Medical Center" is the sponsor of all CME activities accredited by ACCME, not the pharmaceutical company and not the Hospital. Therefore, when you read the Letter of Agreement, the word "sponsor" refers to SUNY Downstate.
15. Signature: All Letters of Agreement must be signed by the Office of CME at Downstate where "Provider" or "Sponsor" is indicated before the activity takes place.

Speakers' Disclosures Policy

The ACCME and the AMA Standards and Guidelines require that individuals attending continuing medical education activities be aware of relationships with commercial companies that could potentially affect the information presented. In keeping with these regulations, you are required to do the following:

1. Speaker's disclosure form must be filled out completely.
2. All speakers including individuals who are in a position to control the content of an educational activity must disclose all relevant financial relationships with any commercial interest to the OCME. This includes Activity Directors, planning committee members, peer reviewers, faculty/presenters/speakers, moderators, panel members, and administrative support staff. This information must include the following:
 - a. Name of individual
 - b. Name of commercial interest
 - c. Nature of the relationship with each commercial interest
3. Two or more speakers cannot sign the same disclosure form.
4. A speaker's disclosure form must be signed before a speaker makes his or her presentation.
5. Relationships with a commercial company must be indicated on the disclosure form. (Both the company's name and the relationship with that company must be indicated on the disclosure form.)
6. Any discussion of off-label, experimental or investigational use of drugs or devices must be indicated on the disclosure form.
7. If a speaker has no relationship with a commercial company or will not discuss off-label drugs or device usage, he or she must indicate that on the disclosure form.
8. A speaker's disclosure form must be completed whether or not a commercial company is supporting the CME activity.
9. To resolve conflicts of interest, all individuals who are in a position to control the content of an educational activity must sign an attestation that they have read and agreed to abide by this policy and that any and all clinical recommendations that are made for patient care as part of their planning and/or CME presentation materials will be based on the best available evidence, and that they will give a balanced view on therapeutic options, and that the content will be in accordance with the ACCME's Content Validation Statement. The attestation also delineates that they will provide the level of evidence for said recommendations in the CME activity materials.

Additional and supplemental mechanisms to resolve conflicts of interest include:

1. An individual without a conflict of interest replaces the conflicted individual.
2. The conflicted individual renounces the relationship(s) with the commercial interest(s).
3. The scope of the conflicted individual's role is restricted (the individual will not determine content or make recommendations for clinical practice limiting their role to review and discussion of epidemiology, pathophysiology, mechanisms of actions, etc.).
4. The conflicted individual attests in writing that the recommendations he/she will make for clinical practice will be based upon data derived from multiple randomized clinical trials or meta-analyses and will disclose this to the learners.
5. The CME materials (presentation, monograph, etc.) prepared by the conflicted individual will be peer reviewed for content validation and fair balance and modified accordingly, if necessary.

Off-Label Use Disclosure

1. Faculty (speakers/presenters), Activity Directors, and moderators are required to disclose to the learners:
2. When products or procedures being discussed are off-label, unlabeled, experimental, and/or investigational (not FDA approved).
3. Any limitations on the information that is presented, such as data that are preliminary that represent ongoing research, interim analyses, and/or unsupported opinion.

|

Joint Sponsorship Policy

Joint sponsorship occurs when a non-accredited provider wants to partner with the OCME to produce a CME activity, excluding our affiliates. A commercial interest, defined as any proprietary entity producing health care goods or services, with the exception of non-profit or government organizations and non-health care related companies, cannot take the role of non-accredited partner in a joint sponsorship relationship.

1. The appropriate accreditation statement must inform the learner of the joint sponsorship relationship between Downstate and the non-accredited provider, which includes all printed materials. (See Accreditation and Disclaimer Statements Section)
2. Jointly sponsored activities must be consistent with the OCME's mission statement. The OCME must review and approve all materials associated with the activity prior to their circulation.
3. A commercial interest cannot take the role of non-accredited partner in a jointly sponsored activity. All funds requested for a CME activity must either be received by the OCME or delivered to the joint sponsor, upon written authorization from the OCME.
4. The responsibilities of the joint sponsor will be clearly defined in a letter of agreement between the joint sponsor and the OCME. The OCME has the right to withdraw from any activity if the joint sponsor fails to meet its obligations as described in the letter of agreement or fails to comply with the OCME's policies and procedures.
5. The joint sponsor must submit a projected budget for each CME activity to the OCME for review and approval. The OCME will review the projected budget to ensure that adequate resources have been allotted to the development of an activity consistent with meeting the activity's objectives.
6. At the discretion of the OCME and with written authorization, the joint sponsor may solicit funds under the direction of the OCME, but may not make any representations or commitments to commercial supporters as to educational content, choice of speakers, learning objectives, marketing, and/or evaluation.
7. Commercial support shall be provided with the knowledge, consent, and written approval of the OCME and shall be in the form of an educational grant. (Provision of equipment for skills-based learning activities is permitted, but still requires a written letter of agreement.) No other payment from a commercial interest shall be given to the Activity Director, planning committee members, faculty (speaker or presenter), authors, joint sponsors, or any others involved with the supported CME activity.
8. The OCME will charge fees for services. These fees will be mutually agreed upon and clearly defined in the letter of agreement between the joint sponsor and the OCME.

Internet CME Policy

Live or enduring material activities that are provided via the Internet are considered to be "Internet CME." Internet CME must comply with all ACCME Essential Areas and Elements (including the Standards for Commercial Support) and Accreditation Policies. However, there are special requirements for Internet CME because of the nature of the activities:

1. **Activity Location:** CME activities cannot be placed on a pharmaceutical or device manufacturers' product website.
2. **Links to Product Websites:** With clear notification that the learner is leaving the educational website, links from the website of an ACCME accredited provider to pharmaceutical and device manufacturers' product websites are permitted before or after the educational content of a CME activity, but shall not be embedded in the educational content of a CME activity.
3. **Advertising:** Advertising of any type is prohibited within the educational content of CME activities on the Internet including, but not limited to, banner ads, subliminal ads, and pop-up window ads. For computer based CME activities, advertisements and promotional materials may not be visible on the screen at the same time as the CME content and not interleaved between computer 'windows' or screens of the CME content.
4. **Hardware/Software Requirements:** The accredited provider must indicate, at the start of each Internet CME activity, the hardware and software required for the learner to participate.
5. **Provider Contact Information:** The accredited provider must have a mechanism in place for the learner to be able to contact the provider if there are questions about the Internet CME activity.
6. **Policy on Privacy and Confidentiality:** The accredited provider must have, adhere to, and inform the learner about its policy on privacy and confidentiality that relates to the CME activities it provides on the Internet.
7. **Copyright:** The accredited provider must be able to document that it owns the copyright for, or has received permissions for use of, or is otherwise permitted to use copyrighted materials within a CME activity on the Internet.

Journal CME Policy

A journal-based CME activity includes the reading of an article (or adapted formats for special needs), a provider stipulated/learner directed phase (that may include reflection, discussion, or debate about the material contained in the article(s)) and a requirement for the completion by the learner of a pre-determined set of questions or tasks relating to the content of the material as part of the learning process. The educational content of journal CME must be within the ACCME's Definition of CME (ACCME).

The Office of CME at Downstate requires that all Journals CME meet the following criteria:

1. Evidence of learner participation in the activity must be forwarded to the OCME.
2. The learner should not encounter advertising within the pages of the article or within the pages of the related questions or evaluation materials.

Enduring Materials Policy

An enduring material is a non-live CME activity that "endures" over time. It is most typically a videotape, monograph, or CD Rom. Enduring materials can also be delivered via the Internet. The learning experience by the physician can take place at any time in any place, rather than only at one time, and one place, like a live CME activity.

Enduring materials must comply with all ACCME Essential Areas and Elements (including the Standards for Commercial Support) and Accreditation Policies.

The following must be communicated to participants prior to starting the educational activity:

1. Principal faculty and their credentials;
2. Medium or combination of media used;
3. Method of physician participation in the learning process;
4. Estimated time to complete the educational activity (same as number of designated credit hours);
5. Dates of original release and most recent review or update; and
6. Termination date (date after which enduring material is no longer certified for credit).

The enduring material cannot be certified for credit for more than three years without review on the part of the OCME to ensure that the content is still up-to-date and accurate. An additional fee will be charged for renewal.

To comply with the Standards for Commercial Support:

1. There must be no product specific advertising in enduring materials
2. Commercial support must be acknowledged in the enduring material
3. This acknowledgement must be placed only at the beginning of an enduring material
4. The institutional acknowledgement may state the name, mission, and areas of clinical involvement of the company or institution, and may include corporate logos and slogans, if they are not product promotional in nature
5. No brand names or product-group messages may be used in the acknowledgement, even if they are not related to the topic of the enduring material.

Post-Tests and evaluation required. The Office of Continuing Medical Education (OCME), at SUNY Downstate Medical Center, is the certifying agent. The OCME will oversee the production of the monograph.

Enduring Materials Policy (cont'd)

- ✚ The OCME will review and approve all printed material and the CD-ROM prior to final production and distribution to the target audience.
- ✚ The OCME will not enlist the assistance of commercial interests to provide or distribute enduring materials to learners.
- ✚ The OCME will also receive the post-test, grade them and issue the CME certificates. We will also keep the evaluation on file for a period of six years.
- ✚ The Activity Director takes responsibility for the content and scientific integrity of the monograph.
- ✚ The Communication Company is responsible for creative development, editorial development, and production of reference materials, letterhead, mailing and postage.

Promotional and Syllabi Policy

The following guidelines must be strictly adhered to regarding the promotion of CME activities:

1. For print, advertisements and promotional materials will not be interleaved within the pages of the CME content. Advertisements and promotional materials may face the first or last pages of printed CME content as long as these materials are not related to the CME content they face and are not paid for by the commercial supporters of the CME activity.
2. For computer based, advertisements and promotional materials will not be visible on the screen at the same time as the CME content and not interleaved between computer 'windows' or screens of the CME content.
3. For audio and video recording, advertisements and promotional materials will not be included within the CME. There will be no 'commercial breaks.'
4. For live, face-to-face CME, advertisements and promotional materials cannot be displayed or distributed in the educational space immediately before, during, or after a CME activity. Providers cannot allow representatives of Commercial Interests to engage in sales or promotional activities while in the space or place of the CME activity.
5. For exhibits, all exhibitors must be in a room or area separate from the educational activity, and the exhibits must not interfere or compete with the learning experience.
 - a. Arrangements for 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.
 - b. Educational materials such as slides, abstracts, and handouts must not contain any advertising or trade names, when they are part of a CME activity.
 - c. If a presentation must mention a trade name, it must be for more than one company. Otherwise, generic names must be used.
 - d. Exhibit fees shall be set by the OCME for each activity and will be standard for that activity. Potential exhibitors shall have equal access to purchasing exhibit space. Exhibit fees shall be separate and distinct from educational grants (they are not considered commercial support).

This policy is relevant to printed materials (e.g. syllabi, brochures, etc.), Internet CME, enduring materials, and live CME activities.

Accreditation and Disclaimer Statements

The following accreditation, disclaimer and ADA statements must be included on all CME brochures, flyers, and enduring materials:

Accreditation Statements

1.) Directly Sponsored Activities

The State University of New York (SUNY) Downstate Medical Center is accredited by the Accreditation Council for Continuing Medical Education to provide continuing medical education for physicians.

The SUNY Downstate Medical Center designates this educational activity for a maximum of (# of credits) AMA PRA Category 1 Credit(s) TM. Physicians should only claim credit commensurate with the extent of their participation in the activity.

2.) Jointly Sponsored Activities

This activity has been planned and implemented in accordance with the Essential Areas and policies of the Accreditation Council for Continuing Medical Education through the joint sponsorship of SUNY Downstate Medical Center, and the (name of joint sponsor). The State University of New York (SUNY) Downstate Medical Center is accredited by the Accreditation Council for Continuing Medical Education to provide continuing Medical education for physicians.

The SUNY Downstate Medical Center designates this educational activity for a maximum of (# of credits) AMA PRA Category 1 Credit(s) TM. Physicians should only claim credit commensurate with the extent of their participation in the activity.

3.) Disclaimer Statement (Must be included with both statements)

SUNY Downstate Medical Center and its affiliates are committed to providing educational activities that are objective, balanced and as free of bias as possible. All participating faculty are expected to disclose to the audience, verbally or in writing, any commercial relationships that might be perceived as a real or apparent conflict of interest related to the content of their presentations, i.e. with companies whose products or services are related to the subject matter of the presentation; or products in the research and development phase.

Americans with Disabilities Act (ADA) Statement

The following ADA statement must be included on all brochures, flyers, and enduring materials:

In accordance with the Americans with Disabilities Act, (Name of Your Institution) seeks to make this conference accessible to all. If you have a disability, which might require special accommodations, please contact _____ at _____ or e-mail your needs to _____.

Planning Process and Needs Assessment

Planning takes place, whether formally or informally, to discuss how your CME activity will be organized, and to determine the perceived needs for the program. Whether you do all the CME activity planning, or request OCME assistance, the following outline must be followed:

- Planning Committee Process
- Needs Assessment
- Learning Objectives Worksheet
- Faculty Speakers

Planning Committee Process:

Involve others

- ✚ Faculty, learners, content experts, etc. Gather ideas; ask for feedback on them from committee members or ask for peer review of your program.

Determine Target Audience

- ✚ Your proposed learners – know your audience. (Educational content must match the audience).

Identify a need for activity

- ✚ Issues that have emerged, as a result of the planning committee's careful analysis, which can be developed into subsequent needs assessment activities.

Content Validation

- ✚ All CME activities will comply with the ACCME's content validation statement:
 1. All recommendations involving clinical medicine in a CME activity must be based on evidence that is accepted within the profession of medicine as adequate justification for their indications and contra-indications in the care of patients.
 2. All scientific research referred to, reported or used in CME in support or justification of a patient care recommendation must conform to the generally accepted standards of experimental design, data collection and analysis.

Needs Assessment:

The term "needs assessment" refers to any systematic approach to collecting and analyzing information about the educational needs of individuals or organizations. The ACCME mandates that needs assessment data must be used to plan CME activities. Before you can begin to develop your CME activity, whether it is grand rounds or a three-day conference in the Bahamas, you must have an expressed need for the activity. To make this determination you must do the following:

Determine data collection approach

- ✚ Decide types of data and data sources e.g. learner evaluations, self-assessment, Q.A. Committee minutes/reports, literature, experts in the field, patient records assessments

Collect the data

- ✚ Determine the types of data to be utilized

Analyze the data

- ✚ Examine the data to determine which needs are educational in which deficits in knowledge, skills and attitudes have been identified.

Respond to a need

- ✚ Areas of improvement that are needed in regard to skill, and present performance of target audience.

Supporting documentation of need

- ✚ The ACCME mandates that data, which supports the need for your activity, be collected and submitted with your documentation. When answering the question regarding how the educational needs of your target audience were identified on the CME Certification Request form, your response(s) must be supported by documentation. For example: you may indicate medical audit results – you must provide the results of that Q.A. study as supporting documentation.

Learning Objectives Linkage

The ACCME mandates that you utilize “a planning process that links identified educational needs with a desired result.” Your educational objectives are determined by your educational needs. What is it that you want the participant to learn or be able to do as a result of the activity? The worksheet will aid you in developing your activity, and to hopefully attain the desired results you planned to achieve. (See worksheet below)

Activity Name: _____ Date: _____

Activity Director: _____

Institution: _____

Department: _____

Identified Needs After analyzing your Needs Assessment data, list the needs to be addressed by this activity.	Objectives List a reason for the activity that achieves the particular needs or at least one objective for each need identified.	Format Indicate educational format to be used to accomplish stated objectives. More than one method may be used.	Desired Result List your expected outcomes, in terms of changed physician performance, skills, knowledge in practice, and patient health status, based on identified needs.

Educational methods

Proposed method could be lecture, workshop, case presentations, panel discussion, seminar, conference, etc. workshop etc. The methods are based on the objectives you want to obtain.

Promotional Materials - Promotional materials are the method in which you promote or advertise your activity. It may be either a brochure or flyer. Whatever choice you make, a draft copy must first be approved by the OCME, to ensure that it is compliant with ACCME guidelines.

Program Evaluation Form - The AMA requires that any CME activity being designated for category 1 credit must evaluate to assess the quality of the activity and its relevance to stated needs and objectives. You may use the standard evaluation, which is furnished by the OCME, or you may choose to create your own. If you create your own, it must first be approved by the OCME before use.

Budget and Finances

A preliminary budget form must be submitted, which estimates the expenses for your CME activity. Must also include estimated commercial support expected for the activity.

A fee schedule for various CME services provided by the OCME is available to you upon request. A list of those services is included in this Guide. Please note that an administrative fee will be payable for each activity, notwithstanding any other services requested. The administrative fee covers the day-to-day management of your CME activity file, which is payable at the time you submit your CME Certification Request form. Below is a breakdown of the fees for various CME activities, which includes series events:

Administrative Fees**:

Grand Rounds, Regularly Scheduled Conferences	\$ 150.00
One-time Conferences, Seminars, Courses	\$1500.00
Jointly Sponsored Activities	Contact the OCME
Conference, Seminar, Workshop Series - 2	\$2,500.00
Enduring Materials	Contact the OCME
Conference, Seminar, Workshop Series - 4	\$ 4,500.00
Transcript Fee	\$ 20.00
Certificate Fee	\$ 20.00

* There will be a 20% administrative fee charged for managing educational grants. (20% of the amount of the grant.)

** Make check payable to: SUNY OCME. A separate CME Certification Request form and administrative fee must be submitted for each CME activity.

Commercial Support – If you have requested educational grant support for your CME activity, you must include the commercial support letters of agreement. The letters of agreement must be completed and signed by both the Activity Director and representative from the company granting commercial support. Estimated commercial support must be included on your preliminary budget form. If you choose to have the OCME administer your grant, you must have the representative contact the OCME directly.* BE SURE TO READ OCME POLICY ON COMMERCIAL SUPPORT.

Activity Director's Letter of Agreement – Each Activity Director must sign a letter of agreement which ensures that he/she will comply with the requirements of the ACCME and forward all required documentation.

It is the responsibility of the Activity Directors to assure that all their programs are HIPAA compliant.

Evaluation

Sample Regularly Scheduled Evaluation Form

Thank you for participating in this CME activity. The Office of Continuing Medical Education would like to know if this was a valuable learning experience for you, and would appreciate your responses to the following questions.

Title of Activity _____		Date _____			
	1=Poor	2=Below Average	3=Average	4=Above	5=Outstanding
Presenter: _____					
The presenter's overall presentation was	1	2	3	4	5
The presenter's ability to respond to questions was	1	2	3	4	5
Presenter: _____					
The presenter's overall presentation was	1	2	3	4	5
The presenter's ability to respond to questions was	1	2	3	4	5
Was the objective of the activity met?	<input type="checkbox"/>				
Were the speakers knowledgeable?	<input type="checkbox"/>				
Were the topics or cases presented relevant to your needs?	<input type="checkbox"/>				
Was enough discussion time allowed?	<input type="checkbox"/>				
Did you:	Yes	Somewhat	No		
develop new clinical skills?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
develop interpretive and diagnostic skills?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
acquire new information on the subject?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
receive practical review of the subject?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
Did you have the opportunity to discuss practice-relevant issues with the speakers?	YES <input type="checkbox"/>	NO <input type="checkbox"/>			
Will you make any changes in your clinical practice based on information presented at this activity?	YES <input type="checkbox"/>	NO <input type="checkbox"/>			
Was there any apparent conflict of interest Shown by the speaker(s)? If your answer is yes, please explain.	YES <input type="checkbox"/>	NO <input type="checkbox"/>			
Was meeting room's conduciveness to learning	YES <input type="checkbox"/>	NO <input type="checkbox"/>			
Was food service adequate?	YES <input type="checkbox"/>	NO <input type="checkbox"/>			
Methods used by faculty to facilitate learning	1	2	3	4	5
Length of activity	Too short <input type="checkbox"/>	Adequate <input type="checkbox"/>	Too Long <input type="checkbox"/>		
General Comments:					
Name (optional):					
Affiliations/Specialty :	<input type="checkbox"/> Hospital	<input type="checkbox"/> Private practice	<input type="checkbox"/> Academic/teaching	<input type="checkbox"/> Managed care	
Other:	<input type="checkbox"/> MD/DO	<input type="checkbox"/> Nursing	<input type="checkbox"/> Student	<input type="checkbox"/> Other health professional	

Sample One-time Activity Evaluation Form

Thank you for participating in this CME activity. The Office of Continuing Medical Education would like to know if this was a valuable learning experience for you, and would appreciate your responses to the following questions.

Title of Activity _____

Date _____

	1=Poor	2=Below Average	3=Average	4=Above	5=Outstanding
Presenter: _____					
The presenter's overall presentation was	1	2	3	4	5
The presenter's ability to respond to questions was	1	2	3	4	5
Presenter: _____					
The presenter's overall presentation was	1	2	3	4	5
The presenter's ability to respond to questions was	1	2	3	4	5
Presenter: _____					
The presenter's overall presentation was	1	2	3	4	5
The presenter's ability to respond to questions was	1	2	3	4	5
Presenter: _____					
The presenter's overall presentation was	1	2	3	4	5
The presenter's ability to respond to questions was	1	2	3	4	5
Presenter: _____					
The presenter's overall presentation was	1	2	3	4	5
The presenter's ability to respond to questions was	1	2	3	4	5
Presenter: _____					
The presenter's overall presentation was	1	2	3	4	5
The presenter's ability to respond to questions was	1	2	3	4	5
Presenter: _____					
The presenter's overall presentation was	1	2	3	4	5
The presenter's ability to respond to questions was	1	2	3	4	5
Presenter: _____					
The presenter's overall presentation was	1	2	3	4	5
The presenter's ability to respond to questions was	1	2	3	4	5
Presenter: _____					
The presenter's overall presentation was	1	2	3	4	5
The presenter's ability to respond to questions was	1	2	3	4	5
Presenter: _____					
The presenter's overall presentation was	1	2	3	4	5
The presenter's ability to respond to questions was	1	2	3	4	5
Indicate the reason you came to the meeting:	Please check all that applied				
to develop clinical skills	<input type="checkbox"/>				
to develop interpretive and diagnostic skills	<input type="checkbox"/>				
to acquire new information on the subject	<input type="checkbox"/>				
to review the subject	<input type="checkbox"/>				
to meet CME requirements	<input type="checkbox"/>				
Did you:	Yes	Somewhat	No		
develop new clinical skills?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
develop interpretive and diagnostic skills?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
acquire new information on the subject?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		

receive practical review of the subject?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
Indicate which of the teaching formats helped you reach your goal:					
Lectures	<input type="checkbox"/>				
question/answer sessions	<input type="checkbox"/>				
case review sessions	<input type="checkbox"/>				
interpretation panels	<input type="checkbox"/>				
workshops/small group sessions	<input type="checkbox"/>				
Did you have the opportunity to discuss practice-relevant issues with the speakers?	YES <input type="checkbox"/>	NO <input type="checkbox"/>			
Will you make any changes in your clinical practice based on information presented at this conference?	YES <input type="checkbox"/>	NO <input type="checkbox"/>			
Was there any apparent conflict of interest shown by the speaker(s)? If your answer is yes, please explain.	YES <input type="checkbox"/>	NO <input type="checkbox"/>			
Was meeting room's conduciveness to learning?	YES <input type="checkbox"/>	NO <input type="checkbox"/>			
Was food service adequate?	YES <input type="checkbox"/>	NO <input type="checkbox"/>			
Methods used by faculty to facilitate learning	1	2	3	4	5
Length of activity	Too short <input type="checkbox"/>	Adequate <input type="checkbox"/>	Too Long <input type="checkbox"/>		
General Comments:					
Name (optional):					
Affiliations/Specialty :	<input type="checkbox"/> Hospital	<input type="checkbox"/> Private practice	<input type="checkbox"/> Academic/teaching	<input type="checkbox"/> Managed care	
Other:	<input type="checkbox"/> MD/DO	<input type="checkbox"/> Nursing	<input type="checkbox"/> Student	<input type="checkbox"/> Other health professional	

Reminder -- All Journal CME must include a set of questions related to the article(s) reviewed.

Standards for Commercial Support

Please review the following ACCME Standards for Commercial Support carefully, so that you are knowledgeable of all of the required guidelines. This information is essential to everyone involved in planning CME activities, but especially important to those who routinely request grants in support of their CME activities.

Accreditation Council for Continuing Medical Education (ACCME)

STANDARDS FOR COMMERCIAL SUPPORT

Standards to Ensure Independence in CME Activities

PREAMBLE

The purpose of continuing medical education (CME) is to enhance the physician's ability to care for patients. It is the responsibility of the accredited provider of a CME activity to assure that the activity is designed primarily for that purpose. Accredited providers often receive financial and other support from non-accredited commercial organizations. Such support can contribute significantly to the quality of CME activities. The purpose of these Standards is to describe appropriate behavior of accredited providers in planning, designing, implementing, and evaluating certified CME activities for which commercial support is received.

STANDARD 1: Independence

1.1 A CME provider must ensure that the following decisions were made free of the control of a commercial interest. The ACCME defines a “commercial interest” as any proprietary entity producing health care goods or services, with the exemption of non-profit or government organizations and non-health care related companies.

- 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.

1.2 A commercial interest cannot take the role of non-accredited partner in a joint sponsorship relationship.

STANDARD 2: Resolution of Personal Conflicts of Interest

2.1 The provider must be able to show that everyone who is in a position to control the content of an education activity has disclosed all relevant financial relationships with any commercial interest to the provider. The ACCME defines “relevant” financial relationships” as financial relationships in any amount occurring within the past 12 months that create a conflict of interest.

2.2 An individual who refuses to disclose relevant financial relationships will be disqualified from being a planning committee member, a teacher, or an author of CME, and cannot have control of, or responsibility for, the development, management, presentation or evaluation of the CME activity.

2.3 The provider must have implemented a mechanism to identify and resolve all conflicts of interest prior to the education activity being delivered to learners.

STANDARD 3: Appropriate Use of Commercial Support

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

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.

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

Written agreement documenting terms of support

3.4 The terms, conditions, and purposes of the commercial support must be documented in a written agreement between the commercial supporter that includes the provider and its educational partner(s). The agreement must include the provider, even if the support is given directly to the provider's educational partner or a joint sponsor.

3.5 The written agreement must specify the commercial interest that is the source of commercial support.

3.6 Both the commercial supporter and the provider must sign the written agreement between the commercial supporter and the provider.

Expenditures for an individual providing CME

3.7 The provider must have written policies and procedures governing honoraria and reimbursement of out-of-pocket expenses for planners, teachers and authors.

3.8 The provider, the joint sponsor, or designated educational partner must pay directly any teacher or author honoraria or reimbursement of out-of-pocket expenses in compliance with the provider's written policies and procedures.

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

3.10 If teachers or authors are listed on the agenda as facilitating or conducting a presentation of session, but participate in the remainder of an educational event as a learner, their expenses can be reimbursed and honoraria can be paid for their teacher or author role only.

Expenditures for learners

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

3.12 The provider may not use commercial support to pay for travel, lodging, honoraria, or personal expenses for non-teacher or non-author participants of a CME activity. The provider may use commercial support to pay for travel, lodging, honoraria, or personal expenses for bona fide employees and volunteers of the provider, joint sponsor or educational partner.

Accountability

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

STANDARD 4: Appropriate Management of Associated Commercial Promotion

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.

4.2 Product-promotion material or product-specific advertisement of any type is prohibited in or during CME activities. The juxtaposition of editorial and advertising material on the same products or subjects must be avoided. Live (staffed exhibits, presentations) or enduring (printed or electronic advertisements) promotional activities must be kept separate from CME.

• For **print**, advertisements and promotional materials will not be interleaved within the pages of the CME content. Advertisements and promotional materials may face the first or last pages of printed CME content as long as these materials are not related to the CME content they face **and** are not paid for by the commercial supporters of the CME activity.

- For **computer based**, advertisements and promotional materials will not be visible on the screen at the same time as the CME content and not interleaved between computer ‘windows’ or screens of the CME content.

- For **audio and video recording**, advertisements and promotional materials will not be included within the CME . There will be no ‘commercial breaks.’

- For **live, face-to-face CME**, advertisements and promotional materials cannot be displayed or distributed in the educational space immediately before, during, or after a CME activity.

Providers cannot allow representatives of Commercial Interests to engage in sales or promotional activities while in the space or place of the CME activity.

4.3 Educational materials that are part of a CME activity, such as slides, abstracts and handouts, cannot contain any advertising, trade name or a product-group message.

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.

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.

STANDARD 5: Content and Format without Commercial Bias

5.1 The content or format of a CME activity or its related materials must promote improvements or quality in health care and not a specific proprietary business interest or a commercial interest.

5.2 Presentations must give a balanced view of therapeutic options. Use of generic names will contribute to this impartiality. If the CME 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.

STANDARD 6: Disclosures Relevant to Potential Commercial Bias Relevant financial relationships of those with control over CME content.

6.1 An individual must disclose to learners any relevant financial relationship(s), to include the following information:

- the name of the individual;
- The name of the commercial interest(s);
- the nature of the relationship the person has with each commercial interest.

6.2 For an individual with no relevant financial relationship(s) the learners must be informed that no relevant financial relationship(s) exist.

Commercial support for the CME activity

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.

6.4 ‘Disclosure’ must never include the use of a trade name or a product-group message.

Time of disclosure

6.5 A provider must disclose the above information to learners prior to the beginning of the educational activity.

Sample Commercial Letter of Agreement

This Letter of Agreement, entered into this _____ day of _____, 200__ by and among SUNY

Downstate Medical Center acting for and on behalf of the Educational Partner named below (if applicable); and the Commercial Interest named below, witnesses the following:

Date of Activity: _____

Location of Activity _____

Commercial company name: _____

Support Amount: _____

GRANT MADE PAYABLE TO: -- OCME --Clinical Department (SUNY Downstate ONLY)

GENERAL CONDITIONS (BASED ON ACCME STANDARDS)

STANDARD 1: Independence

1.1 A CME provider must ensure that the following decisions were made free of the control of a commercial interest. The ACCME defines a "commercial interest" as any proprietary entity producing health care goods or services, with the exemption of non-profit or government organizations and non-health care related companies. (a) Identification of CME needs; the Commercial Interest may not be the agent providing the CME activity to the learners.

STANDARD 3: Appropriate Use of Commercial Support

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

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 education matters, including content, from a commercial interest as conditions of commercial interest as conditions of contributing funds or services, contributing funds or services. 3.3 All commercial support associated with a CME activity must be given with the full knowledge and approval of the provider. 3.8 The provider, the joint sponsor, or designated educational partner must pay directly any teacher or author honoraria or reimbursement of out-of-pocket expenses in compliance with the provider's written policies and procedures. 3.9 No other payment shall be given to the director of the activity, planning committee members, teachers or authors, joint sponsor, or any others involved with the supported activity.

STANDARD 4: Appropriate Management of Associated Commercial Promotion

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. 4.2 Product-promotion material or product-specific advertisement of any type is prohibited in or during CME activities. The juxtaposition of editorial and advertising material on the same products or subjects must be avoided. Live (staffed exhibits, presentations) or enduring (printed or electronic advertisements) promotional activities must be kept separate from CME.

4.3 Educational materials that are part of a CME activity, such as slides, abstracts and handouts, cannot contain any advertising, trade name or a product-group message. 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 content descriptions, and may include product promotion material or product-specific advertisement material or product-specific advertisement. 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.

STANDARD 5: Content and Format without Commercial Bias

5.1 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. 5.2 Presentations must give a balanced view of therapeutic options. Use of generic names will contribute to this impartiality. If the CME 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.

STANDARD 6: Disclosures Relevant to Potential Commercial Bias/Relevant financial relationships of those with control over CME content

6.1 An individual must disclose to learners any relevant financial relationship(s), to include the following information:

- The name of the individual;
- The name of the commercial interest(s);
- The nature of the relationship the person has with each commercial interest.

6.2 For an individual with no relevant financial relationship(s) the learners must be informed that no relevant financial relationship(s) exist. 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. 6.4 'Disclosure' must never include the use of a trade name or a product-group message. 6.5 A provider must disclose the above information to learners prior to the beginning of the educational activity.

The Commercial Supporter agrees to abide by all requirements of the ACCME Standards for Commercial Support of Continuing Medical Education.

The Accredited Provider agrees to:

- < abide by all requirements of the ACCME Standards for Commercial Support of Continuing Medical Education; acknowledge educational support from the commercial company in program brochures, syllabi and other program materials; and upon request, furnish the commercial supporter with a report concerning the expenditure of funds provided.

Accredited Provider: SUNY Downstate Medical Center

Tax ID Number :14-6013200

Contact Person

E-mail Address

Phone Number & Fax Number

Educational Partner (Facility/Dept.):

Contact Person

E-mail Address

Phone Number & Fax Number

Commercial Interest:

Contact person

E-mail Address

Phone Number & Fax Number

AGREED:

Accredited Provider

Signature/Date

Print Name/Title

Educational Partner (if applicable)

Signature /Date

Commercial Interest

Signature/Date

Print Name /Title

Joint Sponsorship

SAMPLE JOINT SPONSORSHIP LETTER OF AGREEMENT INSERT

This Letter of Agreement, entered into this _____day of _____, 200__ among SUNY

Downstate Medical Center and/or on behalf of the Joint sponsor named below; and the Commercial Interest named below, witnesses the following:

Date of Activity: _____

Location of Activity _____

Commercial company name: _____

Support Amount: _____

GRANT MADE PAYABLE TO: -- OCME --Clinical Department (SUNY Downstate ONLY)

GENERAL CONDITIONS (BASED ON ACCME STANDARDS)

STANDARD 1: Independence

1.1 A CME provider must ensure that the following decisions were made free of the control of a commercial interest. The ACCME defines a "commercial interest" as any proprietary entity producing health care goods or services, with the exemption of non-profit or government organizations and non-health care related companies. (a) Identification of CME needs; the Commercial Interest may not be the agent providing the CME activity to the learners.

STANDARD 3: Appropriate Use of Commercial Support

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

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 education matters, including content, from a commercial interest as conditions of commercial interest as conditions of contributing funds or services, contributing funds or services. 3.3 All commercial support associated with a CME activity must be given with the full knowledge and approval of the provider. 3.8 The provider, the joint sponsor, or designated educational partner must pay directly any teacher or author honoraria or reimbursement of out-of-pocket expenses in compliance with the provider's written policies and procedures. 3.9 No other payment shall be given to the director of the activity, planning committee members, teachers or authors, joint sponsor, or any others involved with the supported activity.

STANDARD 4: Appropriate Management of Associated Commercial Promotion

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. 4.2 Product-promotion material or product-specific advertisement of any type is prohibited in or during CME activities. The juxtaposition of editorial and advertising material on the same products or subjects must be avoided. Live (staffed exhibits, presentations) or enduring (printed or electronic advertisements) promotional activities must be kept separate from CME.

4.3 Educational materials that are part of a CME activity, such as slides, abstracts and handouts, cannot contain any advertising, trade name or a product-group message. 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 content descriptions, and may include product promotion material or product-specific advertisement material or product-specific advertisement. 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.

STANDARD 5: Content and Format without Commercial Bias

5.1 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. 5.2 Presentations must give a balanced view of therapeutic options. Use of generic names will contribute to this impartiality. If the CME 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.

STANDARD 6: Disclosures Relevant to Potential Commercial Bias/Relevant financial relationships of those with control over CME content

6.1 An individual must disclose to learners any relevant financial relationship(s), to include the following information:

- The name of the individual;
- The name of the commercial interest(s);
- The nature of the relationship the person has with each commercial interest.

6.2 For an individual with no relevant financial relationship(s) the learners must be informed that no relevant financial relationship(s) exist. 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. 6.4 'Disclosure' must never include the use of a trade name or a product-group message. 6.5 A provider must disclose the above information to learners prior to the beginning of the educational activity.

The Commercial Supporter agrees to abide by all requirements of the ACCME Standards for Commercial Support of Continuing Medical Education.

The Accredited Provider agrees to:

- < abide by all requirements of the ACCME Standards for Commercial Support of Continuing Medical Education; acknowledge educational support from the commercial company in program brochures, syllabi and other program materials; and upon request, furnish the commercial supporter with a report concerning the expenditure of funds provided.

Accredited Provider: SUNY Downstate Medical Center

Tax ID Number :14-6013200

Contact Person

E-mail Address

Phone Number & Fax Number

Joint-Sponsor:

Contact Person

E-mail Address

Phone Number & Fax Number

Commercial Interest:

Contact person

E-mail Address

Phone Number & Fax Number

AGREED:

Accredited Provider

Signature/Date

Print Name/Title

Educational Partner (if applicable)

Signature /Date

Commercial Interest

Signature/Date

Print Name /Title

Faculty (Speakers)

Based on your educational needs, decide who will best be able to provide the information that meets those needs. Choose speakers who not only have the requisite store of information, but also have the ability to relate to your target audience. Provide your speakers with the course objectives, and any background data you feel are important. Faculty Disclosure Forms must be

completed by anyone who makes a presentation at your activity, including medical students, residents, faculty, allied health professionals, and private industry.

Speaker Information

When you have chosen your speakers for your CME activity, the attached forms must be utilized to be compliant with ACCME guidelines::

Speaker's Letter (Attached)

To be sent to speaker's along with Speaker's Disclosure form, before your meeting takes place. It explains the ACCME and AMA standards and guidelines regarding disclosure of significant relationships with commercial companies.

Speaker's Disclosure Form

The speaker's disclosure form must be signed and completed by each speaker presenting at a CME activity.

Flyer (Attached)

A flyer must be used to inform participants of disclosure information for all speakers/presenters for all regularly scheduled conferences.

Faculty Disclosure Declaration (Attached)

When presenting a program with multiple speakers (e.g. conference, seminar etc.), and there are many disclosures to be made, the Speaker Disclosure Declaration is to be used. You may include it in your syllabi or it may be given out with other handouts.

Please note: Verbal disclosure is always required, but documented disclosure is mandatory. Non-documented disclosure information means non-compliance to ACCME guidelines, which means you will not receive category 1 credit for your activity.

Sample Disclosure

Name of Organization	
Title of Activity	
Date of Activity	
Activity Director	
Speaker's Name	
Speakers' Institution	
Please return this form to:	
Please return this form by (date):	
ALL SPEAKERS AND PRESENTERS OF ANY FORM OF CME ACTIVITY MUST SIGN THIS FORM WHICH INCLUDES RESIDENTS/AND OR FELLOWS.	
<p>I understand that the SUNY Downstate Medical Center endorses the Guidelines of the American Medical Association and the Standards of the Accreditation Council for Continuing Medical Education that faculty or anyone involved with the presentation content for a CME activity disclose to participants the presence of any relationships with commercial companies whose products are discussed in the faculty member's presentation. Significant financial relationships include receiving (from a company) research grants, consultancies, honorarium and travel, or other benefits or having self-managed equity in a company. Individuals with substantive conflicts of interest cannot plan or speak. Faculties are also expected to openly disclose any off-label, experimental, or investigational use of drugs or devices discussed in their presentation. A financial relationship for this purpose is considered yours, your spouse or partner that you are aware of.</p>	
In regard to this requirement (please check one)	
<input type="checkbox"/> No disclosure I have a financial relationship with one or more organizations listed below. I have a significant relationship with one or more organizations listed below that could be perceived as a real or apparent conflict of interest in the context of the subject of this presentation.	
Organization	Type of Relationship
	<input type="checkbox"/> Grants/research support
	<input type="checkbox"/> Consultant
	<input type="checkbox"/> Stock holder
	<input type="checkbox"/> Honorarium
	<input type="checkbox"/> Other support
(If more companies are to be listed, continue on an attached separate sheet)	
I will discuss a drug or medical device that has not been approved by the FDA. " Yes " No	
If yes, drug or/and device name _____	uses _____
Signed: _____	Date: _____

Independent Content Validation, Fair Balance, and Level of Evidence
--

ACCME Content Validation Statement:

1. All the recommendations involving clinical medicine in a CME activity must 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.
2. All scientific research referred to, reported or used in CME in support or justification of a patient care recommendation must conform to the generally accepted standards of experimental design, data collection and analysis.

Based on the statement below, please attest to the following:

I understand that my CME presentation materials such as slides/abstract/monograph, etc. may be peer reviewed prior to the activity occurring (or being released) for fair balance and to validate content and may be edited accordingly.

I understand that my CME presentation will be evaluated by participants for fair balance (e.g. degree of commercial bias) and that enduring materials.

I attest that any and all clinical recommendations that I make for patient care as part of my planning and/or CME activity materials will be based on the best available evidence, that a balanced view of therapeutic options will be given, and the content will be in accordance with ACCME's Content Validation Statement. I will also provide the level of evidence for said recommendations in the CME activity materials.

SAMPLE FLYER

SUNY Downstate Medical Center

Department of Pediatrics
2002-2003 Practicing Pediatricians Lecture Series

September 25, 2002

Topic:	"Vaccination Update"
Date and Time:	Thursday – 9:00 A.M. – 10:00 A.M.
Location:	Lecture Hall 1-A, Education Building
Presenter(s):	Kenneth Bromberg, M.D. Division of Infectious Diseases Department of Pediatrics SUNY Downstate Medical Center
Target Audience:	General Pediatricians, Family Practitioners, and General Practitioners in private practice in Brooklyn and Western Queens
Objectives:	At the conclusion of this activity the participants will be able to: 1) Integrate state-of-the-art knowledge of topics discussed in the lectures into their own diagnoses and treatments of their patients. 2) Formulate for the topics discussed appropriate criteria for referral of children with complex health problems to pediatric sub-specialties. 3) In each lecture and in the whole series, attendees will be encouraged to develop ongoing, working relationships with our medical school community.
Off Label Drugs/Device Usage:	None
Disclosures:	None reported
Commercial Support:	Pfizer Pharmaceuticals

ACCREDITATION STATEMENT

The State University of New York (SUNY) Downstate Medical Center is accredited by the Accreditation Council for Continuing Medical Education to provide continuing medical education for physicians.

SUNY Downstate Medical Center designates this educational activity for a maximum of ____ category 1 credit(s) toward the American Medical Association Physician's Recognition Award (AMA/PRA). Each physician should claim only those credits that he/she actually spent in the activity.

DISCLAIMER STATEMENT

SUNY Downstate Medical Center and its affiliates are committed to providing educational activities that are objective, balanced and as free of bias as possible. All participating faculty are expected to disclose to the audience, verbally or in writing, any commercial relationships that might be perceived as a real or apparent conflict of interest related to the content of their presentations, i.e. with companies whose products or services are related to the subject matter of the presentation; or products in the research and development phase.

FACULTY DISCLOSURE SUMMARY
Management and Treatment of Stroke
October 15, 2003

ACCME guidelines require that speaker disclosures be made to the audience so that they are aware of any potential conflict of interest that a faculty member might have. Please note that a relationship with a commercial company does not speak to a faculty's ability to fairly, objectively, and professionally cover the topic that they have been asked to speak on.

The faculties listed below have reported no relationships with commercial companies, and will not refer to any off-label drug or devices



Faculty

John Smith, MD
 Mary Doe, MD
 Martha Sun, MD

The faculties listed below have reported relationships with commercial companies, and will refer to an off-label drug (XYZ)



Jane Doe MD
 Discloses a relationship with XYZ Medical, Inc. and will refer to ABC Drug.

The State University of New York (SUNY) Downstate Medical Center is accredited by the Accreditation Council for Continuing Medical Education to provide continuing medical education for physicians. SUNY Downstate Medical Center designates this continuing medical education activity for a maximum of 4 Category 1 credits toward the American Medical Association Physician's Recognition Award (AMA/PRA). Each physician should claim only those credits that he/she actually spent in the educational activity.

SUNY Downstate Medical Center and its affiliates are committed to providing educational activities that are objective, balanced and as free of bias as possible. All participating faculty are expected to disclose to the audience, verbally or in writing, any commercial relationships that might be perceived as a real or apparent conflict of interest related to the content of their presentations, i.e. with companies whose products or services are related to the subject matter of the presentation; or products in the research and development phase.







Meeting Management/Checklist

The success of your CME activity will depend largely on making sure that you have covered all aspects of your meeting. Ensure that:

- Meeting area is clean and properly prepared
- Lighting is adequate
- AV needs are met (including Biomedical assistance, if required), and that speakers can operate equipment
- Catering arrangements have been confirmed, and food will be set up in a timely manner, as requested
- Hotel/transportation for speakers
- Proper faculty/speaker disclosures and commercial support statements are made
- Program objectives are clearly stated to participants at the start of the meeting
- Registration/Attendance Records are accurate and legible
- Completed program evaluations are completed and collected
- Completed needs assessment forms, if applicable, are collected.

Final Documentation

The following documentation is required at the conclusion of your activity:

-  **Executive Summary**
A summary of the year's activity, including number of attendees, types of responses (based on results of total evaluations, and improvements, or changes to be made for the following year's activity. Also may be used as a needs assessment tool.
-  **Final Budget**
Final budget is the total expenses for your activity for the year, including commercial support. If commercial support is received, you must show how the grant was dispersed e.g. Name of payee receiving support (speaker, caterer, etc.), amount of payment, reason for payment and the company providing the grant.
-  **Summary of Expenses for Commercial support (if applicable)**
If you request a large number of grants, it may be necessary for you to submit a separate summary of those expenses. The format should be the same as previously indicated for the Final Budget Form.
-  **Attendance Roster**
All final attendance must be submitted no later than thirty (30) days after the completion of your activity. The later you submit your final attendance roster, the later your faculty will receive their requested transcripts for the academic year.

CAN THE OCME HELP YOU PREPARE YOUR CME ACTIVITY?

The following are just some of the services provided by the OCME that are available to assist you with any aspect of developing your CME activity. If you wish, we can plan the entire activity. A current fee schedule can be provided upon request. Please remember that if you wish to utilize any of these services, you must contact the OCME at least six (6) months prior to the activity date.

Document Coordination

- Preparation of Credit Request and accompanying forms
- Forwarding and collecting Commercial Support forms
- Forwarding and collecting Speaker's Disclosure forms

Marketing

Preparation of brochure/"Save the Date" cards (includes design, proofing, coordinating printing, etc. Arrangements for photographer, journal ads and other publicity, greeters, etc.

Mailings

- Preparation and mailing of "Save the Date" cards
- Preparation and mailing of activity brochure
- Obtain mailing labels
- Prepare mailing labels

From Our Biomedical Communications Department

- Design of brochures, flyers, posters, and banners
- Preparation of prints, transparencies, and slides
- Photography

From our Audio-Visual Department

- AV projectionist
- Teleconferencing services
- Videotaping services

Other Services

- Room reservations at DMC or hotel reservations
- Transportation arrangements
- Catering arrangements
- Registration assistance

We hope this CME Activity Development Guide, and the services we can provide will assist you in the preparation of your CME activity. As always, the OCME is available to answer your questions.

References & Sources

References

American Medical Association - www.ama-assn.org/

Accreditation Council for Continuing Medical Education - www.accme.org

Duke University - www2.mc.duke.edu/depts/som/docme/