

**The University of Texas M. D. Anderson Cancer Center
Department of CME/Conference Services**

**Guidelines for Requesting and Obtaining Continuing Medical Education Credit
AMA PRA Category 1 Credit™ for an Educational Enduring Material**

The Accreditation Council for Continuing Medical Education (ACCME) has established guidelines and policies to ensure that the content of educational activities that CME providers designate for *AMA PRA Category 1 Credit(s)™* are scientifically based, accurate, and are presented in an objective manner and in the best interest of the public. M. D. Anderson, as a nationally accredited CME provider, has implemented ACCME policies for M. D. Anderson to maintain its accreditation status and its ability to certify programs for physician credit. The program requirements and procedures described below have been established to assist program chairs and their faculty in providing continuing medical education activities that serve to maintain, develop or increase the knowledge, skills and professional performance of their physician audience and support departmental and institutional missions.

Definitions

Continuing Medical Education (CME): Continuing medical education consists of educational activities which serve to maintain, develop, or increase the knowledge, skills, and professional performance and relationships that a physician uses to provide services for patients, the public, or the profession. The content of CME is 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.

Enduring materials, as defined by ACCME, are printed, recorded, computer-assisted instructional materials, Internet programs, or other materials that may be used over time at various locations and, in themselves, constitute a planned CME activity. All enduring materials must adhere to the Accreditation Council for Continuing Medical Education (ACCME) *Guidelines for Enduring Materials*, and, if applicable, *Policies – Internet CME*.

I. Overview of the Application and Review Process

The application process for obtaining *AMA PRA Category 1 Credit™* for enduring materials is a two-part process.

- **Part 1 - Initial or “Concept” Approval**

The CME Advisory Committee reviews and approves the *Application for The University of Texas M. D. Anderson Cancer Center Sponsorship and Continuing Medical Education AMA PRA Category 1 Credit™ for an Educational Enduring Material* and required documentation. This initial or “concept” approval allows the program chair and educational partner/production company to begin to develop the activity/enduring material.

- **Part 2 - Final Approval of Enduring Material**

Program chair or educational partner submits a draft of the enduring material to CME/Conference Services. CME/Conference Services forwards the draft to the CME Advisory Committee and Senior Vice President for Academic Affairs for final review and approval. Program chair should allow approximately 3-4 weeks for approval from the time the draft of the enduring material is received by CME/Conference Services.

II. Application Approval Process

- Enduring material applications (with required documentation and signatures) should be completed nine to twelve months prior to the scheduled distribution of the enduring material to allow sufficient time for the two-part approval process. Applications without a 6-month “lead time” of the proposed enduring material distribution will not be accepted.
- The program chair/co-chair or one of the “active” members of the planning committee for the enduring material must be an M. D. Anderson clinical faculty (MD/DO) in order to request CME credit.
- Program chair obtains and completes the *Application for The University of Texas M. D. Anderson Cancer Center Sponsorship and Continuing Medical Education AMA PRA Category 1 Credit™ for an Educational Enduring Material*. Program chair forwards the completed application, including all *Disclosures of Relevant Financial Relationships for Program Chairs and Program Planning Committee Members* to CME/Conference Services, Unit 1381.
- CME/Conference Services forwards the application and supporting documents to the CME Advisory Committee for **initial concept review and approval** (Part 1), **and resolution of conflicts of interest**. Program chair should allow approximately 3-4 weeks for initial concept approval from the time the completed application and accompanying documentation is received by CME/Conference Services. **Final approval** (Part 2) is given after the CME Advisory Committee and Vice President for Academic Affairs have reviewed and approved the draft of the enduring material, prior to its production and distribution.
- CME Advisory Committee reviews application to determine that:
 - the enduring material appropriately fulfills the definition of CME;
 - the goals and objectives of the enduring material are consistent with M. D. Anderson’s mission;
 - adequate linkage exists between the needs assessment documentation and the proposed activity topics;
 - the activity content, as initially described, is based on the best available evidence and the information will be objectively presented and independent of commercial interests.
- Additionally, the CME Advisory Committee Members are charged with reviewing program chair(s)’ and conference planning committee members’ disclosure information so that conflict(s) of interest will be identified and resolved. Please see *Options for Resolving Conflicts of Interest* and/or PowerPoint slide information, *Managing Conflicts of Interest* (ACCME presentation). The CME Advisory Committee must resolve conflicts prior to activity approval.
- CME/Conference Services staff notifies program chair(s) once the concept of the enduring material has been approved (Part 1 approval).
- After the application has received concept approval, the program chair proceeds with developing content in accordance with *ACCME Guidelines*. Should additional information/clarification be needed, CME/Conference Services acts as the intermediary between program chair and the CME Advisory Committee members.
- If application was denied, CME/Conference Services notifies the program chair of this decision and any changes recommended or comments made by the CME Advisory Committee members.
- If a production company/educational partner is involved in program development/distribution, CME/Conference Services negotiates a contract with educational partner delineating CME requirements, procedures, and costs as well as the responsibilities of the company/educational partner that develops and/or distributes the program.

- Program chair or educational partner submits a draft of the enduring material to CME/Conference Services who forwards the material to the CME Advisory Committee for review and approval. CME Advisory Committee notifies CME/Conference Services of final approval.
- CME/Conference Services forwards enduring material draft, completed application, required attachments, and comments from the CME Advisory Committee regarding application to the Senior Vice President for Academic Affairs for review and final approval. Should additional information or clarification be needed regarding the enduring material draft or application, CME/Conference Services acts as the intermediary between program chair, the CME Advisory Committee members, and the Senior Vice President for Academic Affairs.
- Program chair should allow approximately 3-4 weeks from the time the draft of the enduring material is received by CME/Conference Services for final approval.

III. Disclosure of Relevant Financial Relationships, Conflict of Interest Resolution, Disclosure of Off-label Use of a Commercial Product or an Investigational Product

- The ACCME has established standards and guidelines to insure that individuals participating in CME activities are aware of faculty/teacher/moderator/author, program chair, and planning committee member relationships with commercial interests that could potentially affect the information presented. M. D. Anderson has implemented a process whereby everyone who is in a position to control the content of an educational enduring material must disclose all relevant financial relationships with any commercial interest.
- CME/Conference Services obtains signed *Disclosures of Relevant Financial Relationships for Faculty/Teachers/Moderators/Authors* forms and forwards these documents to the program chair(s).
- If relationships are indicated, the completed disclosures must be reviewed by the program chair. Should a conflict of interest exist as a result of a financial relationship, it must be resolved by the program chair prior to the creation of the enduring material. Please see *Options for Resolving Conflict of Interest* and/or PowerPoint slide information, *Managing Conflicts of Interest* (ACCME presentation).
- According to the ACCME guidelines, an individual who refuses to disclose relevant financial relationships will be disqualified from being a planning committee member, a faculty/teacher/moderator, or an author of CME, and cannot have control of, or responsibility for, the development, management, presentation, or evaluation of the CME activity.
- Additionally, when an off-label use of a commercial product or an investigational product is discussed in an enduring material, the faculty/teacher/moderator/author must disclose this information to the participants.

Definitions:

Commercial Interest: ACCME Definition: A **commercial interest** is any entity producing, marketing, re-selling, or distributing health care goods or services consumed by, or used on, patients. (from ACCME Policy Updates, August 2007)

The ACCME does not consider providers of clinical service directly to patients to be commercial interests.

Conflict of Interest: When an individual's interests are aligned with those of a commercial interest, the interests of the individual are in 'conflict' with the interests of the public. The ACCME considers financial relationships to create actual conflicts of interest in CME when individuals have both a financial relationship with a commercial interest and the opportunity to affect the content of CME about the products or services of that commercial interest. The potential for maintaining or increasing the values of the financial relationship with the

commercial interest creates an incentive to influence the content of the CME – an incentive to insert commercial bias.

Circumstances create a conflict of interest when an individual has an opportunity to affect CME content about products or services of a commercial interest with which he/she has a financial relationship.

Financial Relationships: Financial relationships are those relationships in which the individual benefits by receiving a salary, royalty, intellectual property rights, grants/research support, honoraria, consultant fee, ownership interest (e.g., stocks, stock options or other ownership interest, excluding diversified mutual funds), or other financial benefit. Financial benefits are usually associated with roles such as employment, management position, independent contractor (including contracted research/educational grants), consulting, speaking and teaching, membership on advisory committees or review panels, board membership, and other activities from which remuneration is received, or expected. ACCME considers relations of the person involved in the CME activity to include financial relationships of a spouse, or partner. For this purpose M. D. Anderson considers the relevant financial relations of your spouse or partner, which you are aware of, to be yours.

Relevant Financial Relationships: ACCME focuses on financial relationships with a commercial interest in the 12 month period preceding the time that the individual is being asked to assume a role controlling content of the CME activity. ACCME has not set a minimal dollar amount for relationships to be significant. Inherent in any amount is the incentive to maintain or increase the value of the relationship. The ACCME defines “*relevant* financial relationships” as financial relationships in any amount occurring within the past 12 months that create a conflict of interest.

Commercial Bias: ACCME defines a commercial bias as a personal judgment in favor of a specific proprietary business interest of a commercial interest.

IV. **Correspondence with Faculty (Teachers/Moderators/Authors), Including Obtaining Disclosures of Relevant Financial Relationships for Faculty (Teachers/Moderators/Authors)**

- ACCME requires that certain information including the activity goal(s), educational objectives, and target audience be provided to activity faculty (teachers/moderators/authors) prior to the preparation of the educational content.
- CME/Conference Services suggests that the following verbiage be included in correspondence to faculty (teachers/moderators/authors):

Relevant Financial Relationships with Commercial Interests

The University of Texas M. D. Anderson Cancer Center is accredited by the Accreditation Council for Continuing Medical Education (ACCME). As such, we have made the choice to meet the ACCME’s expectations for our practice of continuing medical education. Our accreditation is important to us.

In accordance with the 2004 ACCME Standards for Commercial Support, The University of Texas M. D. Anderson Cancer Center has implemented a process whereby everyone who is in a position to control the content of an educational activity must disclose all relevant financial relationships with any commercial interest. In addition, should it be determined that a conflict of interest exists as a result of a financial relationship you may have, this will need to be resolved prior to the activity. In order to do this, please

complete the enclosed *Disclosure of Relevant Financial Relationships for Faculty/Teachers/Moderators/Authors and Attestation* Form and return it to us by <insert date>. This information will be forwarded to the program chair(s) for review and resolution of any potential conflicts of interests. This process is necessary in order for us to be able to move to the next steps in planning this CME activity. If you refuse to disclose relevant financial relationships, you will be disqualified from being a part of the planning committee and/or participating in the development/implementation of this CME activity.

We expect that all M. D. Anderson CME activities will adhere to the ACCME's content validation statements. Please refer to the *Disclosure of Relevant Financial Relationships for Faculty/Teachers/Moderators/Authors and Attestation* for specific information.

Include only scientific or generic names (not trade names) in referring to products. Should it be necessary to use a trade name, then the trade names of all similar products or those within a class should be used.

Educational Goals, Objectives, and Target Audience

Based on identified learning needs of the target audience, the program chair(s) have formulated specific educational objectives. To ensure the effectiveness and relevance of your presentation, please refer to the activity materials for a description of the goals, objectives, and target audience. (If materials with this information are not available, then this information must be included in the correspondence or as an enclosure/attachment).

- CME/Conference Services requires that a copy (example) of the faculty correspondence (letter/fax/email) including the items above be submitted for each activity. To assist you, CME/Conference Services will review a draft of the proposed correspondence to check that all required ACCME information is included.

V. Educational Grants from a Commercial Interest and Required Acknowledgment

- **CME Program Support Agreement**

If the enduring material receives support from a commercial interest, a CME Program Support Agreement must be completed, signed by the representative from the commercial interest and sent to the Department of CME/Conference Services for signature at least 4 weeks prior to the final production and distribution of the enduring material. If the commercial interest requests that their own support agreement be signed, **please DO NOT SIGN company's agreement, but forward the agreement to CME/Conference Services** for legal review, approval and signature. Many support agreements originated by commercial interests contain verbiage that cannot be agreed to by M. D. Anderson. It is important to remember that acknowledgment of the educational grant from the commercial interest can only occur after CME/Conference Services has received the fully executed support agreement (all signatures obtained).

- **Support Acknowledgment**

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. **Commercial interests cannot directly pay for any enduring material expense such as food and travel expenses for activity authors. All such items are considered a direct contribution to an activity and, therefore, a financial gift. Commercial interests may assist the conference with expenses only through educational grants for the enduring material.**

VI. Developing the Program Draft of the Enduring Material and Required Verbiage

- When developing any enduring material, the statements that follow must be included. Placement of these statements may vary to some degree, depending on the type of material produced, i.e., monograph, CD-ROM, or Internet material. Additionally, Internet enduring materials must follow ACCME policies for Internet CME. For specific questions, please contact CME/Conference Services.

The following information must appear prior to the content of the educational material:

- **The University of Texas M. D. Anderson Cancer Center** must be noted as the activity sole sponsor or joint sponsor.
- Term of approval. Example: September, 2007 – August, 2008
- Educational Objectives or Purpose Statements:
Example: This monograph is presented as an educational activity by The University of Texas M. D. Anderson Cancer Center. It is intended especially for (list specific audience i.e. medical oncologists, neuro-oncologists, etc).
Note: Should additional user skills be required, please state here. After (reading the monograph, viewing the CD-ROM, Internet material, etc.) the user should be able to:
- Target Audience: Identify the specific audience the educational material is intended for.
- Estimated Study Time:
The estimated study time for this activity is (0.0 – based on beta testing) hours. **Note:** Estimated study time is based on the average amount of hours necessary to complete the educational activity plus the post-test. Beta test results of the product must be submitted by the program chair, which includes a written statement of the estimated study time, to CME/Conference Services who will then assign the estimated study time and notify the educational partner/production company.
- Credit/Designation Information:
If activity is solely sponsored or co-sponsored (used if more than one of the sponsoring organizations are CME providers, and M. D. Anderson is the sponsoring organization that will provide *AMA PRA Category 1 CreditTM*).
The statements (two paragraphs) must be used verbatim.

The University of Texas M. D. Anderson Cancer Center is accredited by the Accreditation Council for Continuing Medical Education to provide continuing medical education for physicians.

The University of Texas M. D. Anderson Cancer Center designates this educational activity for a maximum of [number of credits] *AMA PRA Category 1 CreditTM*. Physicians should only claim credit commensurate with the extent of their participation in the activity.

If activity is jointly sponsored (used if M. D. Anderson is providing *AMA PRA Category 1 CreditTM* and sponsoring the activity with a non-accredited organization/sponsor/provider). **The statements (two paragraphs) must be used verbatim:**

This activity has been planned and implemented in accordance with the Essentials and Standards of the Accreditation Council for

Continuing Medical Education through the joint sponsorship of The University of Texas M. D. Anderson Cancer Center and [name of non-accredited provider]. The University of Texas M. D. Anderson Cancer Center is accredited by the Accreditation Council for Continuing Medical Education to provide continuing medical education for physicians.

The University of Texas M. D. Anderson Cancer Center designates this educational activity for a maximum of [number of credits] *AMA PRA Category 1 Credit(s)*TM. Physicians should only claim credit commensurate with the extent of their participation in the activity.

Ethics Designation Statement for an entire activity (if applicable):

This course/program has been designated by The University of Texas M. D. Anderson Cancer Center for [number of credits] *AMA PRA Category 1 Credit(s)*TM in medical ethics and/or professional responsibility.

Ethics Presentation within a larger activity (if applicable):

The presentation, [name of presentation], has been designated by The University of Texas M. D. Anderson Cancer Center for [number of credits] *AMA PRA Category 1 Credit(s)*TM in medical ethics and/or professional responsibility.

Note: Credits will be assigned by CME/Conference Services once beta-testing information (time to perform activity) is received from the production company or the program director.

Disclosure information which has been obtained from all individuals who are in a position to control the content of the education activity must appear prior to the program content in an enduring material per *The University of Texas M. D. Anderson Cancer Center Disclosure Policy*, which follows.

The University of Texas M. D. Anderson Cancer Center Disclosure Policy

The Department of CME/Conference Services makes every effort to develop and implement educational activities that are scientifically based, accurate, current, objectively presented, and in the best interest of the public.

In accordance with the Accreditation Council for Continuing Medical Education (ACCME) *Standards for Commercial Support*, The University of Texas M. D. Anderson Cancer Center has implemented a process whereby everyone who is in a position to control the content of an educational activity (program chair, planning committee members, faculty/teacher/moderators/authors, CME committee reviewers) must disclose all relevant financial relationships with any commercial interests that could potentially affect the information presented. Individuals who have control of educational content must disclose to participants the existence or non-existence of financial relationships in place at the time of the activity or within one year prior to the activity.

The University of Texas M. D. Anderson Cancer Center has, through a formal review process, resolved all potential conflicts of interest prior to this activity. For information on this process, please contact the Department of CME/Conference Services at 713/792-5357.

- When an off-label use of a commercial product or an investigational product is discussed, this information must be disclosed to activity participants. Additionally, when activity faculty (teachers/moderators/authors) report they have no financial interest or other relationship with commercial interests or disclose that they will not discuss off-label or investigational products, this information must also be disclosed to activity participants.
- An Acknowledgment statement must be included if education grants or in-kind contributions from commercial interests were given in support of the enduring material. Acknowledgment of commercial support can be made only when a *Support Agreement* has been executed between M. D. Anderson Department of CME/Conference Services and the commercial interest and is on file in CME/Conference Services. The following is an example of acknowledgment.

The University of Texas M. D. Anderson Cancer Center wishes to thank [name of commercial interest] for an educational grant in support of this activity.

- An attestation statement must be included in the enduring material.
For example: To obtain *AMA PRA Category 1 Credit(s)TM* (include after educational text and before course evaluation): Please complete the statement, “I am claiming _____ *AMA PRA Category 1 Credit(s)TM*.” (Maximum ____), and remit this information, Self-Test, and Course Evaluation form via mail or fax to:

Department of CME/Conference Services, Unit # 1381
The University of Texas M. D. Anderson Cancer Center
P.O. Box 301439
Houston, TX 77230-1439
Fax: (713)-794-4734

- A registration form or other format that captures whether the participant is an MD or other allied health professional must be included. As the CME provider, M. D. Anderson must report the number of physicians (MD/DO) and number of non-physicians participating in the enduring material. It is recommended that this (highest degree) demographic information be captured on the registration form or other similar format.
- **Post-Test**
Participants must complete a post-test on the educational content of the educational material and attain a pre-determined accuracy rate to obtain *AMA PRA Category 1 CreditTM*. A score of 70% must be obtained to receive *AMA PRA Category 1 CreditTM*. A certificate documenting participation in this CME activity will be forwarded. **Note:** A processing fee may be charged if it was negotiated and included in the contract between the production company (or organizer of the educational product) and CME/Conference Services.

- **Enduring Material Evaluation**

The Enduring Material Evaluation is separate from the Post-Test and evaluates the overall quality and potential clinical outcomes of the enduring material. The evaluation form will provide participants with the opportunity to comment on the value of the program content to their practice decisions, performance improvement activities, or possible impact on patient outcomes. Participants will also have the opportunity to comment on any perceived commercial bias in the enduring material as well as to identify future educational topics, the degree to which the activity objectives were met, and the existence of possible commercial bias. Sample enduring material evaluation surveys are available from CME/Conference Services.

VII. Media Consent Forms

Program chair must provide copies of Media Consent Forms (obtained from faculty/teachers/moderators/authors) to CME/Conference Services.

VIII. Honorarium Policy for Faculty/Teachers/Moderators/Authors

Honoraria paid to guest faculty/teachers/moderators/authors will be paid by the sponsoring department and per M. D. Anderson's PRS Guidelines issued September, 2004. *"Limited to \$1,000 per visit. Up to \$1,500 per visit for exceptional speakers or events. Amounts above \$1,500 require the President's, or his designee's prior approval."* In enduring materials managed/produced by external communication companies or medical organizations, in which M. D. Anderson does not assume any financial liability, the program chair determines reasonable honorarium.

IX. Reimbursement for Travel and Accommodation for Faculty

The University of Texas reimburses reasonable travel, accommodations, and meals for external faculty and authors.

Internal faculty expenses are also reimbursed when the production site is held outside of a fifty-mile radius of Houston. Reimbursement guidelines established by M. D. Anderson Travel Management Services are followed. Please see url: inside.mdanderson.org/departments/travel-mgt-services/guidelines.html.

It is against the ACCME Standards and Guidelines for anyone other than the provider (M. D. Anderson), or its agents, to receive direct financial benefit or payment from commercial support.

X. Reproducing and Distributing the Enduring Material (if applicable)

M. D. Anderson or educational partner reproduces the educational product and distributes it to the target audience. **Please Note:** Standard 4.5 of *ACCME's Standards of Commercial Support, 2004* state the following: "A provider cannot use a commercial interest as the agent providing a CME activity to learner, e.g., distribution of self-study CME activities or arranging for electronic access to CME activity."

XI. Providing Copies of the Enduring Material to CME/Conference Services (if applicable)

Program chair provides CME/Conference Services with five complete copies of the enduring material.

XII. Outcome Surveys

Program chairs will be asked to report the degree to which the desired results of the enduring material have been met, and changes/improvements that will be considered/made in future enduring materials.

Participants will be asked to evaluate the level to which overall knowledge gained has impacted their practice and/or barriers preventing proposed change(s).

Results of these surveys will be distributed to the program chair(s).

XIII. Final Financial Report

CME/Conference Services requires a final financial report on the enduring material expenses and income.

XIV. Summary of Compliance Responsibilities for Program Chair

As the CME/Conference Services designee, the program chair is responsible for compliance with ACCME essentials and other requirements as specified in Program Chair Responsibilities-Accountability and Attestation listed on the last page of the *Application for The University of Texas M. D. Anderson Cancer Center Sponsorship and Continuing Medical Education AMA PRA Category 1 CreditTM for an Educational Enduring Material*.

As required by ACCME, all activity documentation will be continuously monitored for compliance.

The University of Texas M. D. Anderson Cancer Center reserves the right to withhold or withdraw accreditation from any CME activity that is found to be non-compliant with any of the aforementioned policies and procedures.

Guidelines for Joint Sponsorship of an Enduring Material

For a jointly sponsored enduring material, CME/Conference Services requests that the preceding *Guidelines for Requesting and Obtaining Continuing Medical Education AMA PRA Category 1 Credit™ for an Educational Enduring Material* be followed. As M. D. Anderson will be involved in the planning and implementation of a jointly-sponsored event with a non-accredited organization, the following additional requirements apply specifically to jointly sponsored events.

Responsibility for Academic Standards and Compliance with ACCME Essential Areas and Policies

The Department of CME/Conference Services of M. D. Anderson is solely responsible for ensuring compliance with academic standards and adherence to the ACCME Essential Areas and Policies.

Eligibility

M. D. Anderson limits its joint sponsorship of CME activities to programs in which the primary non-accredited institutions/organizations are:

- Non-profit medical associations/organizations/colleges
- Non-profit healthcare associations/organizations
- Hospitals and healthcare facilities

Direct Conflict

M. D. Anderson will not jointly sponsor a CME activity that is being offered in direct conflict with an M. D. Anderson sponsored activity.

Demonstration of Need for the Educational Program

The non-accredited institution is responsible for demonstrating the need for joint sponsorship of the activity.

Subject Matter/Content

The subject matter, its intent, and philosophy of the educational activity must be within or an extension of the mission of M. D. Anderson and the Department of CME/Conference Services. One of the chairs of the organizing committee or the program chair for the conference must be from M. D. Anderson in order to request and receive co-sponsorship. Guideline: At least 50% of the educational content must be oncology-related; 50% of the expected target audience must be physicians.