General Information

**APPLICATION FOR CATEGORY 1™ CREDIT DESIGNATION FOR A SELF-STUDY ACTIVITY**

The University of Michigan Medical School (UMMS) is accredited by the Accreditation Council for Continuing Medical Education (ACCME) to provide continuing education for physicians. As an accredited sponsor, the University of Michigan Medical School, through the Office of Continuing Medical Education and Lifelong Learning (OCME&LL), can designate an activity developed by the Medical School for AMA PRA Category 1 credit.

Each section of this application is designed to meet various ACCME, AMA, and UMMS requirements. In completing the application, the applicant (UMMS Faculty Planner) is assisting the OCME&LL in documenting that all of the requirements will be met. ACCME randomly audits category 1 CME activities to verify compliance (and documentation of compliance) with ACCME requirements.

Offering an enduring material as a self-study for CME credit involves requirements, planning, and ongoing operational issues beyond those for live CME activities. Individuals considering developing enduring materials for CME credit should read through the information on this site (especially the requirements summary and the application form), then contact OCME&LL to discuss specific plans for developing an enduring material CME activity.

**Requirements for Enduring Materials Used as Self-Study CME Activities** This 2-page summary provides an overview of requirements and operational issues.

OCME&LL maintains an infrastructure for on-line knowledge tests and scoring, activity evaluation, registration certificates, and participation records. For a separate fee, this on-line infrastructure can be used with educational content delivered in any enduring format. Charges depend on the extent of work involved. For further information, please contact OCME&LL.

**Planning**

Planning a self-study CME activity based on an enduring material involves several interrelated considerations:

**Basic educational content**
Educational Planning for A CME Activity: Linking Problems and Results - This one-page document illustrates planning terminology from ACCME that is used when completing the application for CME credit.

Planning CME Presentations that Facilitate the Translation of New Knowledge into Practice - This one-page document illustrates how to plan not only for learning, but also for that knowledge to be implemented. A limitation of self-studies is the inability for learners to interact directly with presenters/authors.

Method for learner assessment (e.g., case-based knowledge test)

Developing Test Questions and Responses for Self-Study CME Activities - This one-page overview addresses developing a case-based knowledge test and accompanying answers.

Fees
- For activities including non-UMHS personnel (with or without UM Personnel, the fee is $750 for designating credit for the activity plus an additional charge (based on the work involved) for recording and maintaining a record of credit each individual who receives credit
- For activities including only UMHS personnel, no separate fee is charged. The UM Faculty Group Practice annually funds this cost.

APPLICATION: TIPS & TRICKS

All progress is automatically saved. If you don't finish the application in one sitting, the form will remember where you left off and bring you back to that point the next time you sign in.

The link you are using to access the application is unique. It can be shared with anyone else who may need to access, review, or edit the application prior to submission to OCME&LL.

Navigate using the "Previous" and "Next" buttons, not the browser buttons.

Only relevant questions will display. Built-in logic displays only those questions that you need to answer, and skips those that aren't relevant to your activity.

Click on the blue links for additional information (ie., examples, additional required documentation).

Attach additional documentation at the end of the application. If you don't have everything gathered and in PDF format, you can always come back (remember, your progress will be saved).

Incomplete applications will not be processed until all required documentation is attached and submitted.
DEPARTMENTAL APPROVAL PROCESS

- Electronic signature now required for Faculty Planner. The Faculty Planner completing this form (or his/her designee) will be required to enter an electronic signature, indicating that the Faculty Planner agrees the activity will adhere to all ACCME and UMMS requirements as described in the application.

- A summary of the application and attachments will be emailed upon submission to the Faculty Planner, Administrative Contact (if applicable), and the Department Chair.

- Department Chair approval will be requested via the email sent upon submission (see above).

- Department Chair will approve application in one of two ways:
  - Reply to the automated email, indicating approval, questions, or comments. The reply email replaces the need for a physical signature.
  - Print the email, sign and date anywhere in the margin, and fax to 647-2928.

- Applications that are not returned signed within 30 days will be considered inactive and will need to be resubmitted by the Faculty Planner in order to receive credit.

GENERAL INFORMATION

What is the title of this activity?

The number of credits designated is the typical length in hours of time needed to study the content and participate in the learner assessment. Credit is rounded to the nearest quarter hour.

The typical time to complete the educational activity is:

<table>
<thead>
<tr>
<th>Hours</th>
<th>Minutes</th>
</tr>
</thead>
</table>

What is the proposed release date? (MM/DD/YYYY)
The period for which credit is designated to be available for studying the enduring material can be up to three years, based on how long the information is expected to remain up-to-date and accurate. The material must then be reviewed for appropriateness for the designation of credit to be extended.

For what time period should credit be available for this activity?

- Years
- Months

What is the format?

- Online, OCME&LL website
- Online, Other website
- Audio or Video recording (e.g., CD-ROM, DVD, Video or audio tape, MP3)
- Printed (e.g., monograph)
- Journal

The OCME&LL website will provide the following: (choose all that apply)

- Educational content
- Knowledge test
- Evaluation
- Certificate

The other website will provide the following: (choose all that apply)

- Educational content
- Knowledge test
- Evaluation
- Certificate

Why is the self-study format appropriate for the setting and expected results of this activity? (Check as many as apply.)
New information can be communicated to participants efficiently
Participants can check whether their understanding is correct
Participants can access the activity at a time and location convenient for the individual participant.

Other

The UMMS unit sponsoring this activity is:

The Internal Medicine Division is:

The Surgery Section is:

Faculty Planner
Faculty member with a Medical School appointment responsible for educational planning, content delivery, and financial oversight of this activity.

First Name
Last Name
Campus Address
SPC Code
Phone
Email

Activity Coordinator
Staff member assisting the Faculty Planner with the administrative and operational
functions of this activity.

First Name
Last Name
Campus Address
SPC Code
Phone
Email

Department Chair or equivalent leader authorizing this activity

First Name
Last Name
Email

CME activities are occasionally jointly provided with:
- **Other Schools at the University of Michigan**, e.g., School of Pharmacy, School of Engineering
- **Groups or organizations external to the University**, e.g., specialty societies, non-profit 501(c) organizations. If the external group or organization is not under the direct administrative and financial oversight of the University of Michigan Health System, the organization is considered to be a joint provider. *(Note: the Veterans Administration Ann Arbor Healthcare System is considered to be under UMHS due to joint oversight of physicians practicing there.)*

Whether a CME activity is directly or jointly provided, the chair of the sponsoring department within the University of Michigan Medical School and the UMMS faculty planner designated by the chair assume full responsibility for educational planning, content delivery, and financing of the CME activity and for meeting ACCME requirements for *AMA PRA Category 1 credit*.

**Is this activity jointly provided with a non-Medical School unit or external group/organization?**

- [ ] Yes
- [ ] No
What non-Medical School organization(s) is/are jointly providing this activity?

Name of Organization
Contact at Organization
Title
Address
City
State
Zip Code
Phone
Email

Did the University of Michigan Medical School Faculty Planner responsible for this activity participate in the assessment of the educational needs of the target audience before the activity was developed?

○ Yes
○ No

Did the University of Michigan Medical School Faculty Planner responsible for this activity participate in the development of the objectives of the activity?

○ Yes
○ No

Did the University of Michigan Medical School Faculty Planner responsible for this activity participate in the selection of speakers and content topics?

○ Yes
○ No

REQUIRED: A copy of the proposed budget for the expenses of this activity is required for the activity file. An example Budget for Jointly Provided

Does the University of Michigan Medical School Faculty Planner know the administrative arrangements regarding the activity, including the planned and actual expenditures and their appropriateness?

- [ ] Yes
- [ ] No

Will the Medical School's name appear prominently as a joint provider on all promotional materials and printed programs?

- [ ] Yes
- [ ] No

If the activity is audited by ACCME for compliance with the above requirements and adherence to policies in the application form (e.g., handling of commercial funds), can the Faculty Planner produce documentation demonstrating compliance?

- [ ] Yes
- [ ] No

Besides the Faculty Planner, are there other individuals who have a role in planning the content of this activity?

- [ ] Yes
- [ ] No

If yes, please list other individuals (e.g., co-planners) who have a role in planning educational content of the activity. If the activity is jointly provided, include planners representing the joint provider.

Co-planner

Co-planner

Co-planner

Co-planner

Co-planner
**EDUCATIONAL PLANNING**

**Target Audience**

Select the target audience below and then indicate the number of expected attendees:

- Non-UM practicing physicians: 0
- Full or part time UM faculty: 0
- House Officers: 0
- Medical Students: 0
- Other Disciplines (e.g., Nursing, Social Work): 0

**Total**: 0

Indicate the specialties of expected attendees within the target audiences chosen:

- Non-UM practicing physicians
- Full or part time UM faculty
- House Officers
- Medical Students
- Other Disciplines (e.g., Nursing, Social Work)

**Problem(s) with Current Professional Practice [Practice Gaps]**

Planning begins by identifying practice gaps (i.e. gaps between current practice and
ideal practice) found within the target audience (e.g., physician awareness, patient outcomes to improve, new methods of diagnosis and/or treatment to implement, not adequately implementing existing methods of diagnosis and/or treatment).

**Direct information about practice gaps within the target audience have been identified through:** *(Check all applicable statements.)*

- [ ] Medical audit or other patient-care reviews
- [ ] Problem cases and uncommon cases
- [ ] Referrals
- [ ] Participant perceptions of problems / needed change (e.g., group discussion, interview, questionnaire)
- [ ] Observations of CME planner, clinical leader(s), or others
- [ ] Other

**Broad-based information about practice gaps likely to apply to practices of the target audience have been identified through:** *(Check all applicable statements.)*

- [ ] Publications/scientific literature about clinical innovations in practice
- [ ] Reports on regional/national performance in practice
- [ ] Presentations at national professional meetings about needed change in practice
- [ ] Review of Board Exam requirements
- [ ] Planned periodic survey of the field
- [ ] Other

**Leaders in the sponsoring unit (e.g., department, division, section) who identified problems:** *(Check all applicable statements.)*

- [ ] Inpatient clinical activities (e.g., service chief)
- [ ] Outpatient clinical activities (e.g., clinic director, health center medical director)
- [ ] Quality improvement leader
- [ ] Compliance officer
- [ ] Other leader
What types of practice gaps in care provided by the target audience did you identify? (e.g., physicians not aware of new methods for diagnosis and treatment; aspects of care to improve; patients outcomes to improve.) For CME activities addressing many topics, the types of problems will necessarily be phrased in general terms with area of practice noted.

Example of a general practice gap: Physicians are not aware of new techniques in several aspects of pediatric liver transplant.

Please provide an example of a specific practice gap (i.e., for a specific medical condition) in physician awareness, patient care, or patient status that resulted in planning a specific session:

How to phrase a specific practice gap: Physicians are not aware of new anesthesia techniques in pediatric liver transplant.

Related Educational Needs of Individuals

Please provide a specific example of the educational need of participants that this activity will address for the specific practice gap in physician awareness, patient care, or patient status described immediately above.

How to phrase a specific educational need: Physicians need to understand new anesthesia techniques for pediatric liver transplant.
What are the general types of educational needs of the target audience that, if met, would help address the overall practice gaps and bring about desired change(s) in the practice of the target audience?

Educational needs typically include both:

- **Knowledge/skills** – information about new scientific knowledge/skills and review of current knowledge/skills

- **Ability to implement changes to apply knowledge/skills in practice** – i.e. how to identify and overcome barriers and how to recognize and build on facilitating factors (e.g., quick references, patient education material, reminders, use of health care team members).

**The following ACGME/ABMS Core Competencies will be addressed by this activity:** *(Check all that apply.)*

### Medical Knowledge

<table>
<thead>
<tr>
<th>Knowledge/Skills</th>
<th>Ability to implement changes</th>
</tr>
</thead>
<tbody>
<tr>
<td>Know &amp; apply basic and clinically supported sciences</td>
<td>☐</td>
</tr>
<tr>
<td>Investigatory and analytical thinking approach to clinical situations</td>
<td>☐</td>
</tr>
<tr>
<td>Know how to perform medically-related research</td>
<td>☐</td>
</tr>
</tbody>
</table>

### Patient Care

<table>
<thead>
<tr>
<th>Knowledge/Skills</th>
<th>Ability to implement changes</th>
</tr>
</thead>
<tbody>
<tr>
<td>Informed decisions about diagnosis, treatment, and management</td>
<td>☐</td>
</tr>
<tr>
<td>Knowledge/Skills</td>
<td>Ability to implement changes</td>
</tr>
<tr>
<td>---------------------------------------------------------------------------------</td>
<td>------------------------------</td>
</tr>
<tr>
<td>Perform medical and invasive procedures</td>
<td></td>
</tr>
<tr>
<td>Preventive health care services and maintaining health</td>
<td></td>
</tr>
</tbody>
</table>

**Practice-Based Learning and Improvement**

<table>
<thead>
<tr>
<th>Knowledge/Skills</th>
<th>Ability to implement changes</th>
</tr>
</thead>
<tbody>
<tr>
<td>Analyze practice experience and improve practice</td>
<td></td>
</tr>
<tr>
<td>Use information technology, locate and assess evidence</td>
<td></td>
</tr>
</tbody>
</table>

**Interpersonal and Communication Skills**

<table>
<thead>
<tr>
<th>Knowledge/Skills</th>
<th>Ability to implement changes</th>
</tr>
</thead>
<tbody>
<tr>
<td>Patient relationship; effective listening and effective information provision</td>
<td></td>
</tr>
<tr>
<td>Work effectively with others in health care team and professional group</td>
<td></td>
</tr>
</tbody>
</table>

**Professionalism**

<table>
<thead>
<tr>
<th>Knowledge/Skills</th>
<th>Ability to implement changes</th>
</tr>
</thead>
<tbody>
<tr>
<td>Respect, compassion, integrity; medical ethics; medico-legal issues</td>
<td></td>
</tr>
<tr>
<td>Sensitivity to diverse patient population (culture, age, gender, etc.)</td>
<td></td>
</tr>
</tbody>
</table>

**Systems-Based Practice**
<table>
<thead>
<tr>
<th>Knowledge/Skills</th>
<th>Ability to implement changes</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cost-effective health care that does not compromise care quality</td>
<td>☐</td>
</tr>
<tr>
<td>Multispecialty/multidisciplinary coordination of care</td>
<td>☐</td>
</tr>
</tbody>
</table>

**PROGRAM CONTENT AND FORMAT**

Does the content match the target audience's current or potential scope of professional activity?

- ☐ Yes
- ☐ No

Does this activity address any of the institutional priorities listed below? *(Check all that apply.)*

<table>
<thead>
<tr>
<th></th>
<th>Yes</th>
<th>No</th>
</tr>
</thead>
<tbody>
<tr>
<td>Medical discovery</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>Patient quality/safety</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>Health promotion</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>Professional development</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>Health equity</td>
<td>☐</td>
<td>☐</td>
</tr>
</tbody>
</table>

Does this CME activity address public health priorities in any of the following ways?

<table>
<thead>
<tr>
<th></th>
<th>Yes</th>
<th>No</th>
</tr>
</thead>
<tbody>
<tr>
<td>Teaches about the collection, analysis, or synthesis of health/practice data, AND uses health/practice data to teach about healthcare improvement.</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>Addresses factors beyond clinical care that affect the health of populations (e.g., health behaviors, economic, social, environmental conditions; healthcare and payer systems; access to care, health disparities; or the population's physical environment).</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>Collaborates with one or more healthcare or community organizations that augment the institution's ability to address population health issues.</td>
<td>☐</td>
<td>☐</td>
</tr>
</tbody>
</table>
Does this CME activity **promote team-based education** in any of the following ways?

<table>
<thead>
<tr>
<th>Yes</th>
<th>No</th>
</tr>
</thead>
<tbody>
<tr>
<td>Includes both planners AND faculty presenters/authors from more than one profession (e.g., nursing, social work), AND is designed to change competence and/or performance of the healthcare team.</td>
<td>○</td>
</tr>
<tr>
<td>Includes both planners AND faculty presenters/authors who are patients and/or public representatives.</td>
<td>○</td>
</tr>
<tr>
<td>Includes both planners AND faculty who are students of the health professions.</td>
<td>○</td>
</tr>
</tbody>
</table>

Is this CME activity designed to **enhance skills** in any of the following ways?

<table>
<thead>
<tr>
<th>Yes</th>
<th>No</th>
</tr>
</thead>
<tbody>
<tr>
<td>Designed to improve, evaluate (in person or video), and provide formative feedback to the learner about their communication skills.</td>
<td>○</td>
</tr>
<tr>
<td>Addresses technical and/or procedural skills, evaluates those skills (in person or video), and provides formative feedback to the learner.</td>
<td>○</td>
</tr>
<tr>
<td>Tracks the learner's repeated engagement with a longitudinal curriculum/plan over weeks or months AND provides individualized feedback to the learner to close practice gaps.</td>
<td>○</td>
</tr>
<tr>
<td>Utilizes support strategies (e.g., reminders) to enhance change as an adjunct to CME activities AND conducts a periodic analysis to determine the effectiveness of the support strategies AND plans improvements of those support strategies.</td>
<td>○</td>
</tr>
</tbody>
</table>

**Content Validation**

Accredited providers are responsible for validating the clinical content of their CME activities. Specifically:

- 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.
- 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.

**Will the faculty planner assure the validity of the clinical content in planning the activity and overseeing its presentation?**

○ Yes

○ No
**Balance in content**

Faculty presenters/authors for the CME activity should be aware that:
- Presentations, individually or in combination during the activity, must give a balanced view of the therapeutic options.
- Generic names of products contribute to impartiality. If trade names are used, those of several companies should be used.
- For FDA regulated products, unapproved uses (i.e. “off-label” uses) must be identified as such.
- If information is to be presented that is not established medical practice, the information must be identified as such.

**How will faculty be informed of these requirements concerning presentation content?** *(Check all that apply.)*

- [ ] Verbally by the Faculty Planner
- [ ] Written communication by the Faculty Planner
- [ ] Other

Since learners will not interact directly with faculty presenters/authors, the content should include bibliographical or other appropriate resources for further study.

**Will the content include resources for interested participants?**

- [ ] Yes
- [ ] No

**Method of Learner Assessment**

Since learners will not interact directly with faculty presenters/authors, the enduring material must include a component that measures achievement of the educational purpose of the activity with an established minimum performance level.

**How will learners be able to confirm that they have understood key points of the educational activity?**

- [ ] Knowledge post-test
- [ ] Other

**What is the minimum performance level to receive credit for participation?**
70% or more answers correct
Other percent or more answers correct
Other performance level measure

How will learners be provided explanations regarding why correct answers were correct and wrong answers were not correct?

- Immediately online
- Directed to another site online
- By email
- By mail
- Other

Expected Results

The ACCME now requires that a CME activity be designed to change physician competence, performance, or patient outcomes. Activities designed only to change or confirm knowledge will not meet requirements for credit designation.

By the end of this activity, participants will intellectually know:

By the end of this activity, participants will be able to implement:
Reminder: This statement should reference being able to implement new knowledge or new skills into practice.
Following this activity, it's expected that the participant will be able to routinely perform:

Following this activity, the following patient outcomes are expected to be improved:

Is this CME activity designed to achieve outcomes in any of the following ways?

| Measures performance changes of learners AND demonstrates improvements in their performance. | Yes | No |
| Demonstrate improvements in healthcare quality. | | |
| Demonstrate improvements in patient or community outcomes. | | |

CME Activity Evaluation

To designate *AMA PRA Category 1 credit™*, we are required to demonstrate a formal process to evaluate the educational effectiveness of the activity.
**How will questions evaluating the CME activity be presented and recorded?**

- Presented online and recorded in your own database
- Presented online and recorded in the OCME&LL database
- Presented on paper and recorded in an electronic database
- Presented on paper, the paper copies retained, and summary information compiled
- Other

You may choose to use the evaluation form provided by OCME&LL or develop one specifically for this activity.

**NOTE:** A measure of the participant’s intention to change practice must be included on the evaluation form. Additionally, at the end of the reporting period for the activity, the Faculty Planner will be asked whether the activity changed physician performance and/or patient outcomes, and if so, to provide an example. Click for an example of a commonly used evaluation form.

**Which evaluation form will be used?**

- OCME&LL evaluation form
- An equivalent evaluation provided by the sponsoring unit

**Participant Record**

In order to designate *AMA PRA Category 1 Credit™*, we are required to maintain participant records for six years for each activity.

**NOTE:** In addition to identifying information (name, address), record must indicate whether the individual is a physician or non-physician.

**How will participation in the activity be recorded?**

- Automated recording in your online database
- Automated recording in the OCME&LL database
- Manual recording in an electronic database
- Paper record
- Other
You may choose to use the standard OCME&LL Certificate of Participation or create your own.

**Will OCME&LL supply the Certificates of Participation for your learners?**

- Yes
- No

**If no, what documentation of participation will you provide to participants?** *NOTE: OCME&LL must pre-approve the record of participation the sponsoring unit will be using in place of the standard OCME&LL-issued certificate.*

- An equivalent certificate of attendance provided by the sponsoring unit
- Other

**How will the certificates be provided to participants?**

- Automated certificate online for participant to print
- Certificate sent by mail
- Certificate sent by email
- Other

**FINANCIAL MANAGEMENT**

**Budget/Finances**

**What funds will pay for the expenses of this CME activity?** *(Check as many as apply.)*

- Internal funds of a UM Medical School Unit
- Participant registration fees of $___________ (fee per person)
- Financial or “in-kind” (e.g., equipment loan) support from a commercial company
- Other support (e.g., federal grant)
Will the Faculty Planner for this activity assure that the management of all of the funds for the CME activity adhere to University policies and procedures?

○ Yes
○ No

Guest Faculty Honoraria

Will this activity involve honoraria paid to non-Medical School personnel?

○ Yes
○ No

The Medical School has established general guidelines for guest faculty honoraria and should approve, in advance, any proposed honorarium over $1,500.

Will any honorarium payment for guest faculty associated with this activity exceed $1,500?

○ Yes
○ No

If yes, approval for an exception to the honoraria guidelines (any honorarium over $1,500) must be obtained in advance of the activity. Reasons for higher than normal honoraria include an unusually high number of hours worked or the honorarium being part of a special recognition (e.g., a named lectureship). Contact the Assistant Dean of Faculty Affairs to discuss your specific situation. Without prior approval, amounts outside the guidelines may not be paid.

Approval letters must be submitted with this application. If honoraria will be paid by another method (e.g., contracted services through the Purchasing Office), please contact OCME&LL.

Will the Faculty Planner provide a copy of the approval letter for honoraria over $1,500?

○ Yes
○ No
MANAGING RELATIONSHIPS WITH INDUSTRY

Expectations, Definitions, and Resources (Information)

Expectations. ACCME requires a sequence of the following related actions:

1. Identification of relevant financial relationships at both the activity level and individual level. If the content planned for the CME activity includes content related to the products or services of an ACCME-defined commercial interest, all individuals in control of educational content, e.g., planners and presenters/authors, must disclose the presence or absence of relevant financial relationships.
   • NOTE: The phrase "planners and presenters/authors" within this application refers to all individuals in control of educational content, including but not limited to planners, planning committee members, presenters, teachers, authors, or anyone else who has control of, or responsibility for, content.

2. Individual identified to resolve conflicts of interest for planners and presenters/authors. If a planner has no relationships, he or she usually assumes this responsibility. If a planner has a relevant financial relationship to disclose, the leadership of the content unit (e.g., department, division, section) should identify a non-conflicted faculty member with content expertise to assure independence and balance of content by reviewing and resolving the COI's for all other co-planners and presenters/authors.

3. Resolution of conflicts of interest. For planners or presenters/authors with relevant financial relationships to disclose, a mechanism for resolving the conflict of interest (COI) must be performed and documented prior to the development of the self-study activity. For example, COI may be resolved by peer review or by not addressing the company's products.

4. Disclosure to the participants before they begin the self-study activity. The presence or absence of relevant financial relationships for all planners and presenters/authors must be disclosed to participants in the introductory material for the activity.
   • Disclosure to participants must occur even for those planners and presenters/authors who have no relationships.
   • For planners and presenters/authors with a COI, the name of the person, the nature of the relationship, and the name of the commercial interest must be disclosed to participants.

5. Documentation that disclosure to participants occurred must be submitted to OCME&LL with this application.

Definitions. “Relevant financial relationships” are those in which an individual (including spouse/domestic partner) has both:

1. a personal financial relationship (any amount) with an ACCME-defined commercial interest (any entity producing, marketing, re-selling, or distributing health care goods or services consumed by, or used on, patients) in the past 12 months, whether the relationship has now ended or is currently active.

2. control in planning or presenting educational content addressing specific products of the commercial interest with whom the relationship exists (not simply a whole class of products as a group).

Examples of an ACCME-defined commercial interest include, but are not limited to,
pharmaceutical companies and medical device manufacturers.

The ACCME does not consider providers of clinical service directly to patients to be commercial interests. The following are not considered to be a commercial interest:
- Government organizations
- Non-health care related companies
- Liability insurance providers
- Group medical practices
- For-profit hospitals, rehabilitation centers, nursing homes
- Blood banks
- Diagnostic laboratories
- 501-C Non-profit organizations (Note: ACCME screens 501c organizations for eligibility. Those that advocate for commercial interests as a 501c organization are not eligible for accreditation in the ACCME system. They cannot serve in the role of joint provider, but they can be a commercial supporter.)

Resources. To assist planners in documenting the steps outlined above, OCME&LL makes available a variety of information, forms, and templates:
- Flowchart for Addressing Conflicts of Interest (COI) in CME Activities
- CME Disclosure form
- Annual Disclosure Summary (provided to OCME&LL at the beginning of each calendar year)
- Printed Disclosure Summary (provided to OCME&LL after each session)
- ACCME website

Other methods for disclosure and documentation may be acceptable. Please check with OCME&LL for guidance on other acceptable documentation.

Identification of Activities that Involve the Use of Products in Patient Care

Will any part of this CME activity include content related to the products or services used on or consumed by patients? (e.g., medications or medical devices)

- [ ] Yes
- [ ] No

Based on your response to the previous question, no relevant financial relationships can exist.

Individual disclosure information from planners need not be collected. HOWEVER, disclosure to the participants and documentation of the disclosure must still occur:
- The absence of relevant financial relationships must be communicated to participants in the introductory materials of the activity.
- Documentation of the disclosure provided to participants must be sent to OCME&LL, e.g., a copy of the introductory materials of the activity.
Will the Faculty Planner provide OCME&LL with documentation that the absence of relevant financial relationships was disclosed to participants?

- Yes
- No

**Relevant financial relationships may exist.** Since the activity being planned may address products or services of an ACCME-defined commercial interest, the following documentation is required:

- **Completed CME Disclosure form for planners and presenters/authors.** With this application, submit CME Disclosure forms for all planners and presenter/authors of the activity.
  - If resolution of COI is performed by someone other than a planner or co-planner, submit a copy of that individual's CME Disclosure form with this application.
- **Individual CME Disclosure forms for all planners or presenters/authors with a COI.** With this application, submit completed CME Disclosure forms for all planners and presenter/authors with the "Resolution" section completed.
- **Documentation of the disclosure provided to participants.** With this application, submit a copy of the disclosure documentation of the presence or absence of relevant relationships of the planners and presenters/authors that will be provided to participants in the introductory materials of the activity.
  - Disclosure to participants must occur even for those individuals who have no relationships.
  - For individuals with a COI, the name of the person, the nature of the relationship, and the name of the commercial interest must be disclosed.

The steps for obtaining the documentation outlined above are described in the following sections.

**Identification of Relevant Financial Relationships at the Individual Level**

**Planners and presenters/authors:** Submit with the application for CME credit completed CME Disclosure forms for the planners and presenters/authors of the activity. The CME Disclosure form is available [here](https://umichumhs.ut1.qualtrics.com/ControlPanel/Ajax.php?action=GetSurveyPrintPreview).

**Does the Faculty Planner have a current relevant financial relationship with an ACCME-defined commercial interest whose products or services will be addressed in the CME activity?**

- Yes
- No
The individuals below were previously identified as co-planners for this activity.

- Submit with this application completed CME Disclosure forms for all individuals listed below.
- Indicate which co-planners have identified COI's. *(Check all that apply.)*

☐ ▶ Co-planner
☐ ▶ Co-planner
☐ ▶ Co-planner
☐ ▶ Co-planner
☐ ▶ Co-planner
☐ ▶ Co-planner
☐ ▶ Co-planner
☐ ▶ Co-planner
☐ ▶ Co-planner
☐ ▶ Co-planner

Individual Identified to Resolve Conflict of Interest for Planners and Presenters/Authors

Since the Faculty Planner does not have a current relevant financial relationship, he/she usually resolves the COI's of all other planners and presenters/authors.

The individual identified below will assume responsibility for the following two steps:

- **Identification of COI.** The presence or absence of relevant financial relationships with ACCME-defined commercial interests for all planners and presenters/authors should be collected and documented (typically using the CME Disclosure form) with sufficient lead time for any COI's to be identified and resolved prior to the development of the self-study CME activity.

- **Resolution of COI.** Usual mechanisms for resolving a COI are noted in the Resolution section at the bottom of the CME Disclosure Form. If using the CME Disclosure form as documentation, the individual resolving COI notes the process used, then signs and dates the form to indicate that resolution occurred. The person performing the resolution must have no current financial relationships relevant to the content of the activity.

**NOTE:**
- If no COI's are identified by planners or presenters/authors, a copy of the documentation of the disclosure provided to participants stating the individual's absence of relevant relationships is sufficient for the CME file. *(For information on disclosures provided to participants, see next section, "Disclosure to...)*
Participants & Documentation that Disclosure to Participants Occurred."

- If COI's are identified by either planners or presenters/authors, submit for the CME file a copy of the individual's CME Disclosure Form with the Resolution section completed. (Other methods of documentation of resolution may be acceptable. Contact OCME&LL for guidance.)

The individual **without a financial relationship relevant to this activity** who will be resolving COI is:

- Faculty Planner without a COI
- Faculty Co-Planner without a COI
- Other individual without a COI

Individual Identified to Resolve Conflict of Interest for Planners and Presenters/Authors

Since the Faculty Planner has a current relevant financial relationship, he/she should have the leadership of the content unit (e.g., department, division, section) identify a non-conflicted faculty member with content expertise to assure independence and balance of content by reviewing and resolving the COI's for all other co-planners and presenters/authors.

The individual identified below will assume responsibility for the following two steps:

- **Identification of COI.** The presence or absence of relevant financial relationships with ACCME-defined commercial interests for all planners and presenters/authors should be collected and documented (typically using the CME Disclosure form) with sufficient lead time for any COI's to be identified and resolved prior to the development of the self-study CME activity.

- **Resolution of COI.** Usual mechanisms for resolving a COI are noted in the Resolution section at the bottom of the CME Disclosure Form. If using the CME Disclosure form as documentation, the individual resolving COI notes the process used, then signs and dates the form to indicate that resolution occurred. The person performing the resolution must have no current financial relationships relevant to the content of the activity.

**NOTE:**

- If no COI's are identified by planners or presenters/authors, a copy of the documentation of the disclosure provided to participants stating the individual's absence of relevant relationships is sufficient for the CME file. (For information on disclosures provided to participants, see next section, "Disclosure to Participants & Documentation that Disclosure to Participants Occurred.")
- If COI's are identified by either planners or presenters/authors, submit for the CME file a copy of the individual's CME Disclosure Form with the Resolution

section completed. (Other methods of documentation of resolution may be acceptable. Contact OCME&LL for guidance.)

The individual **without a financial relationship relevant to this activity** who will be resolving COI is:

- Faculty Co-Planner without a COI
- Other individual without a COI

Disclosure to Participants & Documentation that Disclosure to Participants Occurred

ACCME requires the following:

- **Disclosure**. The absence of relevant financial relationships for all planners and presenters/authors must be communicated to participants in the introductory materials of the activity. The following disclosure wording should be used in the introductory materials:

  "Topics for this CME activity are not planned to address products or services of an ACCME-defined commercial interest. Therefore, the planners and speakers have no relevant relationships to disclose."

- **Documentation of Disclosure**. Documentation of the disclosure provided to participants must be provided with this application for the CME activity file, e.g., a copy of the introductory materials of the activity.

Submit required documentation to Julie ReBeau at juliwils@umich.edu

**Will the Faculty Planner include with this application a copy of the disclosure information that will be provided to participants?**

- Yes
- No

Disclosure to Participants & Documentation that Disclosure to Participants Occurred

ACCME requires the following:

- **Disclosure**. The presence or absence of relevant financial relationships for all planners and presenters/authors must be communicated to participants in the introductory materials of the activity.
- Disclosure to participants must occur even for those planners and presenters/authors who have no relationships.
- For planners and presenters/authors with a COI, the name of the person, the nature of the relationship, and the name of the commercial interest must be disclosed.

- **Documentation of Disclosure.** Documentation of the disclosure provided to participants must be provided with this application for the CME activity file, e.g., a copy of the introductory materials of the activity.

*Note: When an individual has no COI, submitting a copy of the final documentation of disclosure made to participants is sufficient; copies of CME Disclosure Forms need not be submitted to OCME&LL.*

Submit required documentation to Julie ReBeau at juliwils@umich.edu

**Will the Faculty Planner include with this application a copy of the disclosure information that will be provided to participants?**

- Yes
- No

**COMMERCIAL SUPPORT**

UMMS policy prohibits receiving funding to support UMMS CME activities from commercial companies that "produce, market, re-sell, or distribute health care goods or services consumed by, or used on, patients or biomedical research subjects." Funding includes gifts, grants, or exhibit fees. However, the policy allows in-kind commercial support (e.g., supplies, equipment).

**What is the source of commercial support for this activity?**

- None
- In-kind support

The CME activity and the in-kind commercial support must follow the ACCME Standards for Commercial Support as well as University of Michigan and Medical School policies. The ACCME Standards address: (1) independence, (2) resolution of conflicts of interest, (3) appropriate use of commercial support, (4) appropriate management of associated commercial promotion, (5) content and format without commercial bias, and (6) disclosures relevant to commercial bias. These Standards, in their entirety, are available for review at [www.accme.org](http://www.accme.org).

**Is this CME activity and the commercial support clearly within these Standards and policies?**
All in-kind commercial support must be documented with a written agreement signed by both parties. The agreement must be signed **before** the CME activity is developed. Documentation of all commercial support is to be maintained in the central file for the CME activity. A copy of every written agreement must be submitted to the OCME&LL with this application.

**Will the Faculty Planner will attach to this application copies of all signed agreements for all in-kind commercial support?**

- [ ] Yes
- [ ] No

All in-kind commercial support must be acknowledged to the participants and documentation that the acknowledgment occurred is required for the activity file in the OCME&LL. (Typically this information accompanies disclosures regarding the planner(s) and presenters/authors in the introductory materials of the activity.)

**Will the Faculty Planner for this activity see that documentation of acknowledgment of support to participants is submitted to OCME&LL?**

- [ ] Yes
- [ ] No

### COMMERCIAL EXHIBITS, ADVERTISING, AND OTHER PROMOTIONAL ACTIVITIES

**Will **ACCME-defined commercial companies** have commercial exhibits, advertisements, or other promotional activities in conjunction with this CME activity?**

- [ ] Yes
- [ ] No

Exhibits, advertisements, and other promotional activities are allowed at UMMS CME activities. However, UMMS policy prohibits receiving funding (including exhibit fees) from commercial companies that “produce, market, re-sell, or distribute health care goods or services consumed by, or used on, patients or biomedical research subjects.” These commercial companies are permitted to exhibit, advertise, or engage in other promotional activities, but no fee can be charged. Other companies may be charged...
fees.

Will the Faculty Planner ensure that no ACCME-defined commercial companies be charged a fee for exhibits, advertisements, or other promotional activities in conjunction with this CME activity?

- Yes
- No

**MANAGEMENT OF COMMERCIAL EXHIBITS, ADVERTISING, AND OTHER PROMOTIONAL ACTIVITIES**

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.

**General restrictions** are listed below, followed by additional format-specific restrictions.

- Product-promotion material or product-specific advertisement of any type is prohibited in or during CME activities.
- Promotional activities must be kept separate from CME.
- Educational materials that are part of a CME activity, such as slides, abstracts and handouts, cannot contain any advertising, corporate logo, trade name or a product-group message of an ACCME-defined commercial interest.
- 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.

**Self-study: Online/internet**

- 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.
- ACCME-accredited providers may not place their CME activities on a Web site owned or controlled by a commercial interest.
- 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.
- 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.
- With clear notification that the learner is leaving the educational Web site, links from the Web site of an ACCME accredited provider to pharmaceutical and device manufacturers’ product Web sites 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.
Will the Faculty Planner ensure that the appropriate management of the commercial promotion of this CME activity take place?

○ Yes
○ No

**Self-study: Audio and Video Recording** (e.g., CD-ROM, DVD, Video or audio tape, MP3)
- 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.
- For audio and video recording, advertisements and promotional materials will not be included within the CME.

Will the Faculty Planner ensure that the appropriate management of the commercial promotion of this CME activity take place?

○ Yes
○ No

**Self-study: Print** (e.g., monograph)
- 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.
- The juxtaposition of editorial and advertising material on the same products or subjects must be avoided.
- 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.

Will the Faculty Planner ensure that the appropriate management of the commercial promotion of this CME activity take place?

○ Yes
○ No

**Self-study: Journal**
- 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.
• The juxtaposition of editorial and advertising material on the same products or subjects must be avoided.
• 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.
• None of the elements of journal-based CME can contain any advertising or product group messages of commercial interests.
• For journal-based CME, the learner must not encounter advertising within the pages of the article or within the pages of the related questions or evaluation materials.

Will the Faculty Planner ensure that the appropriate management of the commercial promotion of this CME activity take place?

○ Yes
○ No

INFORMATION TO COMMUNICATE TO LEARNERS ABOUT THE ACTIVITY

Communicate to Faculty Presenters/Authors

To guide faculty presenters/authors in developing specific educational content, they should be informed about:
• Target audience
• Practice problems
• Educational needs
• An overview of the content and format of the activity
• Method for learner assessment
• Expected results

How is/was this information communicated to the presenter(s)/author(s)?

○ Written communication by the Faculty Planner
○ Verbally by the Faculty Planner
○ Other

Communications to Participants

Introductory material should provide participants with several types of information about the activity. The types of information are outlined below. The order of presentation is not specified. For examples of how this information may be provided see current on-line enduring materials. OCME&LL can provide examples of enduring
materials in other formats.

- **General educational information**
  - target audience [required]
  - practice problems
  - educational needs
  - an overview of the content and format of the activity
  - method for learner assessment, including minimum performance level
  - expected results.
- **Disclosures of commercial relationships**
  - for individual planners and presenters/authors, the absence or presence of relevant financial relationships
  - for the CME activity, the provision of commercial support
- **Accreditation and credit designation statement**
  - The accreditation statement, the credit designation statement, and the time period of credit availability statement.
- **Additional information for enduring materials, if not already included:**
  - Principal faculty and their credentials
  - Medium or combination of media used
  - Method of participation in the learning process
  - Estimated time to complete the educational activity (same as number of designated credits)
- **Additional information for enduring materials available on-line:**
  - Hardware and software required to participate
  - Provider contact information if the learner has questions about the on-line CME activity
  - Policy on privacy and confidentiality that learners can easily access

**Will the Faculty Planner attach to this application a copy of the introductory material for the activity?**

- [ ] Yes
- [ ] No

**Advertising/Marketing the Activity**

Marketing the enduring material to prospective participants should include key elements of the information outlined above so that individuals have sufficient information to assess whether the activity is appropriate for their learning needs. While any of the above types of information (and additional information) could be appropriate, key information that should be included is:

**General educational information**

- Target audience [required]
- Overview of the content
- Expected results

**Accreditation and credit designation statement**
- The accreditation statement, the credit designation statement, and the time period of credit availability statement.

Additional information for enduring materials, if not already included
- Principal faculty and their credentials
- Medium or combination of media used
- Method of participation in the learning process
- Estimated time to complete the educational activity (same as number of designated credits)

Will the activity be advertised/marketed?

- Yes
- No

**MONITORING AND ONGOING REPORTING**

Since an enduring material is available to learners over an extended period of time, plans should be made to monitor the appropriateness of the activity and to provide periodic reports regarding the activity.

What procedure will be followed to check evaluations periodically to be aware of important feedback from learners that might result in altering the activity ahead of its scheduled end or formal review?

Who is responsible for monitoring developments in relevant fields that might result in altering or ending the activity ahead of its scheduled end or formal review?
In addition to maintaining records of individual participation, OCME&LL must prepare annual summary reports on each UMMS CME activity that are submitted to ACCME and to leadership within UMMS.

An annual count of the number of participants (separately for physicians and non-physicians) who participated in the activity during the calendar year must be submitted to ACCME.

**How will those participant counts be provided to OCME&LL?**

OCME&LL reviews a summary of information evaluating UMMS CME activities as part of ACCME requirements to assess the overall UMMS CME program. Key information includes items required to be in the evaluation forms for each activity, e.g., relevance to practice, intent to change practice (Y/N), and perceived commercial bias.

This information must be summarized at least once at the end of the activity and may be summarized at more frequent intervals.

**Who will provide the evaluation summaries to OCME&LL, and at what time period(s)?**

---

**REQUIRED STATEMENTS ABOUT CREDIT**

**Printed Accreditation/Credit Designation Statements**

The University of Michigan Medical School must be prominently displayed as the accredited provider.

**In addition, the following statements must be included in materials advertising the enduring material:**

The University of Michigan Medical School is accredited by the Accreditation Council for Continuing Medical Education (ACCME) to provide continuing medical education for...
The University of Michigan Medical School designates this enduring material for a maximum of ____ **AMA PRA Category 1 Credit(s)**™. Physicians should claim only the credit commensurate with the extent of their participation in the activity.

This CME activity was prepared for release in [month/year]. CME credit may be awarded for a maximum of three years from its release date, specifically from [month/year] through [month/year].

*Note: The number of credits will be calculated by OCME&LL and provided in the approval letter. Credit is calculated at a 1:1 ratio of one hour of instruction equals one credit hour.*

**Will the Faculty Planner ensure that the accreditation and credit designation statement will be used appropriately on all promotional materials?**

- [ ] Yes
  - [ ] No

**REQUIRED STATEMENTS ABOUT CREDIT**

**Printed Accreditation/Credit Designation Statements**

The University of Michigan Medical School must be prominently displayed as the accredited provider on the program announcement and/or promotional material (i.e., letter of invitation, email notice, promotional brochure or flyer).

**In addition, the following statements must be included on promotional materials associated with the activity:**

This activity has been planned and implemented in accordance with the accreditation requirements and policies of the Accreditation Council for Continuing Medical Education (ACCME) through the joint providership of the University of Michigan Medical School and [insert name of non-accredited provider]. The University of Michigan Medical School is accredited by the ACCME to provide continuing medical education for physicians.

The University of Michigan Medical School designates this enduring material for a maximum of ____ **AMA PRA Category 1 Credit(s)**™. Physicians should claim only the credit commensurate with the extent of their participation in the activity.

This CME activity was prepared for release in [month/year]. CME credit may be awarded for a maximum of three years from its release date, specifically from [month/year] through [month/year].

*Note: The number of credits will be calculated by OCME&LL and provided in the approval letter. Credit is calculated at a 1:1 ratio of one hour of instruction equals one credit hour.*
credit hour.

Will the Faculty Planner ensure that the accreditation and credit designation statement will be used appropriately on all promotional materials?

☐ Yes
☐ No

APPROVALS

Faculty Planner Approval

By typing your name below, the Faculty Planner or his/her administrative designee, attests this application accurately describes the CME activity. The Faculty Planner agrees to accept responsibility for all requirements as described in the application.

A copy of this application and all attachments will be emailed to the Faculty Planner, Administrative Contact (if applicable), and Department Chair upon submission.

Required Documentation

You’re almost done!

REQUIRED DOCUMENTATION

The list below was generated by the answers provided throughout this application. All of the items are required and must be submitted along with this application for credit designation. Please attach each document requested as a single file.

Remember that your progress is automatically saved. If you don’t have the required documentation gathered, simply close the window now and come back later using your unique application link. However, OCME&LL will not review the application until all documents are complete.

Note: Incomplete applications will be automatically deleted from the system after 30 days of no activity.

If you have difficulty attaching the documentation, you may mail it to: OCME&LL, 1301 Catherine St., 5101 Med Sci I, Ann Arbor, MI 48109-5611. Applications will not be processed until all required documentation has been received.
CME Disclosure Form ([Click for form.](#))
Please attach all planner, co-planner, and presenter/author disclosure forms in one file here.

You should include CME Disclosure Forms for the:
- Faculty planner
- All faculty co-planners and/or planning committee members
- The person designated to resolve COI's for this activity, if not one of the above
- Presenters/authors
- Faculty planner at the organization that is jointly providing this activity (if applicable)

Knowledge test and answers provided by the sponsoring Department that will be given to participants.

Introductory Materials which should contain:
- **General educational information**
  - target audience [required]
  - practice problems
  - educational needs
  - an overview of the content and format of the activity
  - method for learner assessment, including minimum performance level
  - expected results
- **Disclosures of commercial relationships**
  - for individual planners and presenters/authors, the absence or presence of relevant financial relationships
  - for the CME activity, the provision of commercial support
- **Accreditation and credit designation statement**
  - The accreditation statement, the credit designation statement, and the time period of credit availability statement.
- **Additional information for enduring materials, if not already included:**
  - Principal faculty and their credentials
  - Medium or combination of media used
  - Method of participation in the learning process
  - Estimated time to complete the educational activity (same as number of designated credits)
- **Additional information for enduring materials available on-line:**
  - Hardware and software required to participate
  - Provider contact information if the learner has questions about the on-line CME activity
  - Policy on privacy and confidentiality that learners can easily access
Draft Budget for a jointly provided activity. (Click for form.)

Record of Participation provided by the sponsoring Department that will be given to participants.

Evaluation Form provided by the sponsoring Department that will be given to participants.

Approval letter from Faculty Affairs for honoraria over $1,500. If honoraria will be paid by another method (e.g., contracted services through the Purchasing Office), please contact OCME&LL.

Written Agreement for Commercial Support/Letter of Agreement (Click for sample.)

Promotional/Advertising Materials
Additional Documentation
Attach as one file here.

Additional Documentation
Attach as one file here.

Additional Documentation
Attach as one file here.

If you are ready to **SUBMIT** your application, please choose the **NEXT** button.

To **SAVE** your application so that you can continue working on it, simply close the browser window.