University of Rochester School of Medicine & Dentistry
Office of Continuing Professional Education (CPE)

Accredited by the
Accreditation Council for Continuing Medical Education (ACCME)
to certify continuing medical education activities for physicians

Continuing Medical Education (CME)
Proposed
Activity
APPLICATION
PACKET
(Revised December 2011)

This application is to be used for:

*Regularly Scheduled Series (RSS)**

[e.g., Grand Rounds (formerly RSC)]

**For requests for certification for Activities only seeking CME Certification, Activities being Fully Coordinated by CPE, or Enduring Materials, please use applications specific to these types of activities*

601 Elmwood Ave., Box 677, Room G-8540
Rochester, NY 14642-8677
Phone: 585.275.4392
Fax: 585.275.3721
Email: cmeoffice@urmc.rochester.edu
Website: www.urmc.rochester.edu/cpe

CME Activity Application Packet
PROCESSING CRITERIA

- **Prior to the final selection of faculty and any sessions being held, the CPE Office must be contacted. This includes, but is not limited to, application submission and approval.**
- All forms MUST be completed in their entirety and all appropriate documentation attached for application to be reviewed.
- Incomplete or handwritten applications will be returned.
- MUST be submitted at least 90 days or one quarter in advance of proposed first session date.
  - Applications submitted less than 90 days or one quarter in advance may not be considered for certification.
- Please return completed packet to:

  University of Rochester School of Medicine & Dentistry
  Office of Continuing Professional Education
  601 Elmwood Ave., Box 677
  Rochester, NY 14642-8677
- **Approval by the CPE Office is required prior to confirming presenters.**
- Formal written approval by the CPE Office is required prior to advertising CME credit.

When *AMA PRA Category 1 credit*™ is awarded by the School of Medicine & Dentistry (SMD), the Office of Continuing Professional Education (CPE) is required by accreditation standards to document program development and implementation, and to insure that the activity meets all nationally established CME Guidelines.

TABLE OF CONTENTS

FORM A) **Preliminary Data for proposed Regularly Scheduled Series (RSS) CME Activity**
Definition - Regularly Scheduled Series:
Daily, weekly, monthly, or quarterly CME Activity that is primarily planned by and presented to the accredited provider's professional staff.

FORM B) **CME Activity Needs Assessment**
- Determination of the need for a continuing medical education activity is critical to the planning process.
- The need will lead directly to the formulation of program objectives and content.
- A comprehensive planning process will help ensure an educationally sound activity.
- Appropriate documentation of the need and planning process is required.

FORM C) **Learning Objectives for Content Validation**
- Objectives should describe overall learning outcomes desired for this series in terms of physician performance and/or patient health.
  - Indicate to the attending physicians for whom this activity is designed the instructional content and/or intended learning outcomes in terms of knowledge, skills and/or attitudes. *(The final version of these learning objectives/outcomes must be listed on the activity advertisement.)*
- Potential topics and speakers should be selected based on their ability to assist in achieving the identified learning outcomes for which this activity has been planned.

FORM D) **Outcomes Measurement and Financial Support**
- Evaluating the impact of the educational activity and how well the learning objectives were met.
- Any Financial Support should be identified and follow the Standards for Commercial Support.

FORM E) **Activity Director/Planning Committee Declaration**
- One form must be completed for each person who is in a position to influence the content of the activity
  - This includes, Activity/Course Director(s) and Planning Committee Member(s)

FORM A) PRELIMINARY DATA

I. RSS ACTIVITY DATA:

a. Proposed Title: _____

b. Proposed Meeting Time: (For Example: 8:00 – 9:00 am every other Tuesday)

_____

c. Proposed Location: _____

d. Check Type of RSS Activity (check one):

- ☐ Grand Rounds
- ☐ Mortality & Morbidity
- ☐ Journal Club
- ☐ Other _____

II. ACTIVITY DIRECTOR DATA:

a. Name/Title: _____

b. Department/Hospital: _____

c. Street Address: _____

d. City, State, Zip: _____

e. Phone: _____

f. Fax: _____

g. Email: _____

h. Admin. Contact: _____

Name/Phone Number/Email

III. PLANNING COMMITTEE DATA (if applicable):

Form E must be completed by each planning committee members for submission with application.

_____

_____

_____

_____

_____

_____

_____

IV. SIGNATURES:

a. Activity Director:

I attest to the completeness and accuracy of this application; as well as, understand and agree to abide by the CME procedures and requirements described in the CME Live Activity Guidelines.

_____	_____	_____
Signature	Print Name	Date

b. Department Chair:

I support the concept of this activity, endorse Category 1 certification through the University, and authorize the sponsorship of my department/division.

_____	_____	_____
Signature	Print Name	Date

This activity proposal has been approved by a member of the CPE staff. (*This approval is based upon your adherence to the CME Guidelines and Standards provided by this office. Failure to follow these guidelines can result in this activity being denied CME credit.)*

CPE Staff Initials: _____

FORM B) NEEDS ASSESSMENT

Proposed RSS Activity TITLE/DATE:_____

1. **Departmental Goals:** Describe your departmental goals for mounting this educational activity:

_____

_____

2 **Purpose:** The purpose of this proposed educational activity, which **must** be met through appropriate **format and content delivery** and **measured** by appropriate outcomes evaluation, demonstrates that it is planned to specifically and directly address and measure the change in: (check all that apply and **describe** measurement of each on Form D #7)

2A☐	**physician competence**	Achieved by delivering new knowledge; **requires** Level 2 outcomes measurement (Form D #7)
2B☐	**physician performance**	Achieved by delivering new skills; **requires** Level 3 outcomes measurement (Form D #7)
2C☐	**patient health outcomes**	Achieved by measuring patient health before and after the educational intervention; **requires** Level 5 outcomes measurement (Form D #7)

3. **Needs Assessment:** Please provide a written paragraph from the physician perspective in which you describe the need for this proposed activity at this time and the choice of these particular topics. This paragraph should answer the following questions:
   - Who is the **target audience** for this activity?
   - Why is this activity being planned for this audience?
   - What are the **practice gaps** / issues / problems in clinical or organizational practice you wish to address?

_____

_____

_____

4. **Needs Documentation:** Please indicate the methods you have used to determine the clinical and/or organizational practice gaps listed above in your needs assessment and **include samples/examples of these documents as attachments**. Issues (gaps) stemming from Health Care Issues and/or Statistics are required for all RSS.

☐ **Health Care Issue**

_____ ( ) continuing review of changes in quality of care as revealed by medical audits or patient-care reviews
_____ ( ) on-going census of diagnosis made by staff physicians*
_____ ( ) summary of patient-problem logs kept by staff
_____ ( ) formal tests to determine physician competence (e.g., self-assessment tests)
_____ ( ) other or additional explanation: _____

☐ **Evidence-Based Medicine Resources**

_____ PubMed Clinical Queries
_____ TRIP Database
_____ Centre for Evidence-Based Medicine
_____ Centers for Health Evidence
_____ Evidence-Based Medicine*

☐ **Statistics**

_____ mortality/morbidity statistics
_____ QA/QI data*
_____ data from outside sources (e.g., public health statistics)

☐ **Literature review (Check journals or list specific articles/***List Journal articles by year, month and title***)**

_____ Academic Medicine _____
_____ American Journal of Medicine _____
_____ JAMA _____
_____ Journal of Family Practice _____

☐ **Internet (Please provide specific url)**

_____ _____

_____ _____

FORM C) LEARNING OBJECTIVES FOR CONTENT VALIDATION

Proposed RSS Activity TITLE/DATE:_____

5. LEARNING OBJECTIVES:

Please list what you hope participants will be able to achieve during this certification period in specific, measurable terms. As a guideline: Prepare 1 to 2 **overall** objectives for this RSS activity letting attendees know what they should be able to achieve by attending regularly. For your reference, a brief statement is provided to assist you in preparing educational objectives. (See guidelines section V.) *Objectives for individual sessions should be requested of each presenter 4-6 weeks prior to their scheduled lecture date (see Speaker-Author Content Proposal/Declaration form Part 2).*

By attending this RSS activity each week, participants should be able to:

_____

_____

_____

_____

_____

6. INSTRUCTIONAL DESIGN:

Please indicate the format(s) you plan to use to implement the identified objectives.

- ☐ Large Group Lecture(s)
- ☐ Workshops/Small Group Discussions
- ☐ Hands-On Training
- ☐ Case-Based
- ☐ Other (please specify:_____)

Please indicate why you feel the identified format(s) will benefit the content of this RSS activity?

_____

_____

Please indicate which ACGME Core Competency is being addressed in this activity. (✓ Check all that apply.) For your reference, brief descriptions of each competency are provided to assist you determine the appropriate context of this educational intervention (See RSS Guidelines section VI).

- ☐ Patient Care
- ☐ Practice Based Learning & Improvement
- ☐ Medical Knowledge
- ☐ Systems Based Practice
- ☐ Professionalism
- ☐ Interpersonal Skills & Communication

Please describe the proposed content for the annual series along with proposed speakers (where known). Be sure this description relates to the **clinical and/or organizational gaps** stated in the Needs Assessment on Form B.

PLENARY LECTURE/WORKSHOP/ SMALL GROUP TOPICS	PROPOSED SPEAKERS/AFFILIATIONS

FORM D) OUTCOMES MEASUREMENT & FINANCIAL SUPPORT

Proposed RSS Activity TITLE/DATE:_____

7. OUTCOMES MEASUREMENT:

How will you know if your activity makes a difference or helps change clinician behavior or patient health outcomes? Activities are required to measure participant competence, performance, and/or patient health (as defined on Form B #2) before and after the delivery of the education to determine their effectiveness. What changes should be made have been outlined through the identification of practice gaps (as defined on Form B #3) and selection of learning objectives (as defined on Form C #5). Please check all the levels of outcomes you intend to assess or measure and give a brief, written description of the format(s)/tool(s) you would like to use: **Attach proposed evaluation tool(s).**

Purpose	**Outcome Level** *(check all that apply)*	**Measurement Methodology**	**Expected Date Of Summary Completion**
Participant satisfaction with the activity	☐ Level 1	*self-reported at end of activity*	*30 days post activity*
Change in competence (2A) *(increased knowledge with the intent to change behavior or practice)*	☐ Level 2	*self-reported or objectively measured before & after activity* ***required*** *for Purpose 2A*	*30 – 120 days*
Change in performance (2B) *(participant behavior or practice improves to narrow their practice gaps)*	☐ Level 3	*self-reported or objectively measured before & after activity* ***required*** *for Purpose 2B*	*30 – 90 days*
Change in overall organizational practice	☐ Level 4	*objectively measured or observed before & after activity*	*30 – 90 days*
Change in patient health outcomes (2C)	☐ Level 5	*objectively measured before & after activity* ***required*** *for Purpose 2C*	*3-12 months*

_____

_____

_____

8. FINANCES & COMMERCIAL SUPPORT:

- How will this activity be financially supported? (select all that apply)

_____☐ Educational Grant(s) - Pharmaceutical Companies

_____☐ Educational Grant(s) - Medical Device Companies

_____☐ Departmental Support (list all) _____

_____☐ Exhibit Fees

_____☐ Attendee Registration Fees

_____☐ Grant (Other) _____

- The following must be submitted as an attachment:

☐**Draft operating budget** to include, but not limited to: anticipated commercial support (if applicable), anticipated revenue from registration fees, advertising costs, speaker honorarium and expenses, food and beverage, credit application fees, audio-visual fees, meeting space rental, and all other anticipated course expenses and income.

If additional space is needed please attach additional sheet.

FORM E) ACTIVITY DIRECTOR/PLANNING COMMITTEE DECLARATION

INSTRUCTIONS: *Complete Section A OR B as it relates to ALL relevant financial relationships with any commercial interests* ***in relation to your involvement with the content of this activity.*** *Then enter your name under the attestation, sign, date and submit to Department Chair for completion of Section C prior to submission of application packet.*

ACTIVITY TITLE / DATE:_____

SECTION A: Complete Section A ***if relationships exist*** *(Attach additional sheets if needed.)*

First, Check the box(es) that most accurately describe your role.

Second, list the names of Commercial Interests with which you or your spouse/partner have, or have had, a relevant financial relationship within the past 12 months. For this purpose the ACCME considers the relevant financial relationships of your spouse or partner that you are aware of to be yours.

Role(s) *: The following could be perceived as a potential conflict of interest (COI). *Note: Employees of Commercial Interests are excluded from participation if the content relates to the business lines and products of their employer.*	**Name of Organization(s)** Entities producing, marketing, re-selling, or distributing health care goods or services consumed by, or used on, patients; with the exemption of non-profit or government organizations and providers of clinical services directly to patients.
☐ Grant/Research Support	
☐ Consultant	
☐ Speakers' Bureau	
☐ Major Stock Shareholder	
☐ Other Financial or Material Support	
☐ Other (please identify)	

SECTION B: Initial Section B ***if no relationships exist.***

INITIAL if NO COI: _____	**Neither I nor my spouse/partner has any RELEVANT financial relationships with any commercial interests in relation to my involvement with the content of the proposed activity.**

I, _____, attest to the accuracy of my potential Conflicts of Interest (COIs) or lack thereof as stated above pertaining to my participation in this activity and that the mark, typed name, or image file below is my personal electronic signature:

SIGNATURE: _____ **DATE:** _____

SECTION C: ACTIVITY DIRECTOR AND/OR DEPARTMENT CHAIR USE ONLY

After review, please initial one APPROPRIATE Conflict of Interest Statement from the following options:

For the Activity Director's form – only Dept. Chair initials are required

For Planning Committee forms – BOTH Activity Director and Chair must initial.

	ACTIVITY DIRECTOR	DEPARTMENT CHAIR
Option A: I have reviewed the above information and feel that no further examination is required pertaining to this individual's involvement with the proposed activity.	_____	_____
Option B: I have reviewed the above information and feel that further examination of identified conflict(s) is necessary. Explain concerns and suggest a review process based on the accompanying *Policy for Identifying and Resolving COI in CME*, Sec. IV. _____	_____	_____
Option C: I have reviewed the above information and feel that this person's identified conflict(s) are not resolvable and s/he must be removed from participation in the activity.	_____	_____

Your cooperation in complying with these guidelines is appreciated.

University of Rochester School of Medicine & Dentistry (URSMD)
Office of Continuing Professional Education (CPE)

Policy for Identifying and Resolving Conflicts of Interest in CME

I. Background:

This policy is designed to assist the institution in pursuing its academic and educational missions with regard to continuing medical education (CME) without undue influence by any individuals or groups associated with these CME activities. It is recognized that faculty and staff – both from the University of Rochester and from other institutions – may enter into financial and other materially beneficial relationships with commercial organizations. It is important, however, that CME content be based on learner needs and not be biased by commercial or marketing interests.

Although a conflict of interest may create the potential to bias a presentation, it is accepted that most professionals associated with CME do not knowingly bias information. They recognize the conflicts of interest and put their reputations, their institutions' reputations, and their positions of trust ahead of personal gain from their relationships with a commercial organization. In addition, the appearance of bias is an equally important concern, as the mere appearance of a conflict of interest may cast doubt on the objectivity of a presentation and undermine public trust.

Full disclosure of conflicting or potentially conflicting interests, and then the resolution of those conflicts, has been advanced as the primary and usual means to protect the integrity of CME activities.

II. Goals:

The purpose of this policy is to describe appropriate processes and procedures to identify all actual and/or potential conflicts of interest and describe ways to resolve them prior to the CME activity, resulting in a successful conclusion.

Any relationship that exists between an individual and a commercial organization that suggests or implies a financial or contractual relationship or one that if brought to the public attention would in any way diminish the reputation of the individual, the institution, or the commercial organization should be reported to the institution sponsoring the CME activity. In addition, teachers/authors will be expected to offer CME that is objective, balanced, scientifically rigorous, and in compliance with the *2004 Updated ACCME Standards for Commercial Support.*

ACCME Standards for Commercial Support of CME require that presentations be free of commercial bias and that any information regarding commercial products/services be based on scientific methods generally accepted by the medical community. When discussing therapeutic options, speakers are requested to use only generic names. If they use a trade name, then those of several companies should be used. If a presentation includes discussion of any unlabelled or investigational use of a commercial product, speakers are required to disclose this to the participants.

III. Policy:

1. The University of Rochester Office of Continuing Professional Education (CPE) will provide a process for identifying, and mechanisms for resolving, actual or potential conflicts of interest (COI) prior to awarding AMA PRA Category 1 credit for CME activities.

2. Anyone in a position to control the content of a proposed CME activity will complete a *Speaker-Author Declaration Form.*

3. The primary responsibility to identify, address and attempt to resolve any COI belongs to the Activity Director. The CPE staff will be available to assist with this process.

4. All identified actual and potential COI, along with resolution mechanisms, will be disclosed to CME activity participants.

IV. Mechanisms for Resolving Conflicts of Interest:

The following are suggested mechanisms for resolving conflicts of interest (COI).

A. Attestation:

Persons who indicate the existence of potential or actual COI will be asked to agree in writing that said conflicts or relationships will not bias or otherwise influence their involvement in the CME activity. Furthermore, teachers/authors will be required to limit practice recommendations to those based on the best available evidence (or absence of evidence) and that such recommendations be consistent with generally accepted medical practice. The activity director will review and approve this approach on a case basis.

B. *Evaluation:*
Attendees will be queried regarding their impressions concerning bias (or absence of bias) within the activity. Activity Directors and teachers/authors will receive copies of the evaluation summaries and comments.

C. *Peer Evaluation:*
An informed learner or peer (not involved in the planning and/or teaching of the activity) will be present, to the fullest extent possible, at a particular CME activity. This evaluator will be asked to complete a formal detailed evaluation to measure any bias in the activity. This evaluation will be submitted to the activity director to determine further action.

D. *Independent content evaluation:*
Scientific abstracts and free-standing papers or articles in enduring materials are often peer-reviewed or judged against predetermined criteria to ensure the data supports the conclusions before they are accepted for presentation or publication. Similarly, individuals working together to do reviews of activity content can resolve COI by ensuring the content is valid, aligned with the interests of the public, and:

- All the recommendations involving clinical medicine are based on the best available evidence – 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 a CME activity in support or as justification of patient care recommendations conforms to the generally accepted standards of experimental design, data collection, and analysis.

E. *Altering financial relationships:*
An individual may change his/her relationships with commercial interests, e.g. discontinue contract services, and in doing so, no duty, loyalty, or incentive remains to introduce bias into the CME content. However, when individuals divest themselves of a relationship, it is immediately not relevant to conflicts of interest, but still must be disclosed to learners for 12 months.

F. *Altering control over content:*
An individual's control of CME content can be altered in several ways to remove the opportunity to affect content related to the products/services of a commercial interest. These can include:

- *Choose someone else to control that part of the content* – if a proposed teacher/author has an irresolvable COI related to the content, choose someone else who does not have a such a relationship
- *Change the content of the person's assignment* – The role of the person with a COI can be changed within the CME activity so that he/she is no longer teaching about issues relevant to the product/services of the commercial interest. For example, an individual with a COI regarding products for treatment of a disease state could address the pathophysiology or diagnosis of the disease rather than the therapeutics.
- *Limit the content to a report without recommendations* – if an individual has been funded by a commercial company to perform research, the individual's presentation may be limited to the data and results of the research. Someone else can be assigned to address broader implications and recommendations.
- *Limit the sources for recommendations* – Rather than having a person with a COI present personal recommendations or personally select the evidence to be presented, limit the role of that individual to reporting recommendations based on formal structured reviews of the literature with the inclusion and exclusion criteria stated (evidence based). For example, the individual could present summaries from the systematic reviews of a peer reviewed source, e.g. the Cochrane Collaboration (www.cochrane.org).

G. *Elimination:*
Activity Directors, activity planning committee members, and/or teachers/authors who are perceived as either manifesting irresolvable COI or being biased may be eliminated from consideration as resources for the CME activity.