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Introduction/General Information

Tufts University School of Medicine (TUSM) Office of Continuing Education (OCE) ensures that all educational activities certified for *AMA PRA Category 1 Credit™* by TUSM OCE meet the standards and criteria set forth by the Accreditation Council for Continuing Medical Education (ACCME). See [http://www.accme.org](http://www.accme.org) for more information on accreditation requirements.

The ACCME defines a Regularly Scheduled Series (RSS) as an activity that is 1) planned as a series with multiple sessions that occur on an ongoing basis (offered weekly, monthly, at minimum quarterly); and 2) is primarily planned by and presented to the accredited organization’s professional staff. Examples of RSS include recurring educational activities such as Grand Rounds, Morbidity and Mortality conferences, Journal Club, Ethics Rounds, etc. These educational sessions must also take place within the institution.

Each year, TUSM OCE certifies approximately 150 RSS. TUSM OCE adheres to all ACCME requirements for RSS and other educational activities, including the Standards for Commercial Support. TUSM physicians who attend a certified RSS can earn *AMA PRA Category 1 Credit™*. TUSM OCE conducts orientation sessions to educate RSS organizers regarding the required procedures and forms. If this is the first time you are applying for certification of your RSS, please contact TUSM OCE at 617-636-6579 so that we can set-up a training to review the requirements and process. Attending a training is required for first time applicants.

**NOTE:** A one-time annual event/conference hosted by hospital departments are NOT considered RSS. These require submission of a separate non-RSS planning form, adherence to additional accreditation requirements, and will incur certification fees. If you would like more information on certification for a non-RSS educational activity, please contact us at 617-636-6579.

RSS Planning Form Overview

Please keep in mind that a series is considered the entire RSS and a session is considered one event within the series. RSS planning forms will be available each spring prior to the start of each academic year (July 1 - June 30). The due date for the Planning Form and completed materials will be announced via email.

For each series you must submit the following:

- Completed/Signed RSS Planning Form
  - (completed by RSS administrator or Course Director)
- Verification of Identified Learner Needs (one form of documentation required)
- Disclosure Forms for Course Director and Planning Committee Members
- Estimated budget (not required if indicated no expenses or funding for series/sessions)

All pages must be completed in full and supporting documentation must be attached in order for your RSS materials to be reviewed.

Please note that TUSM OCE cannot retroactively certify RSS for *AMA PRA Category 1 Credit™*. Certification of your RSS is contingent upon adherence to the CME requirements and guidelines as noted in this manual and as set forth by the ACCME. Failure to fulfill these requirements will result in denial of *AMA PRA Category 1 Credit™* for your RSS.

Please also note that an abbreviated renewal Planning Form will be available for completion if your RSS has been in compliance over the academic year.

Continuing education activities must be planned and implemented in accordance with the Accreditation Council for Continuing Medical Education (ACCME) Essential Elements and Areas. Please keep the following in mind:

- An appropriate NEEDS ASSESSMENT identifies the LEARNING GAP(S) to be addressed. Educational content is developed that addresses the stated need(s).
- The activity GOAL AND OBJECTIVES are established and derived from the identified needs, and are communicated in advance to participants.
— An appropriate EDUCATIONAL DESIGN has been developed to meet the educational needs and objectives of adult learners.

— All CME activities include a meaningful EVALUATION that links the stated goals and objectives to the effectiveness of the educational activity.

— All FACULTY DISCLOSURE/COI OR LACK THEREOF is provided and communicated (and resolved, if necessary) as well as any COMMERCIAL SUPPORT OR LACK THEREOF to all participants prior to the start of an activity.

Risk Management Credit
Under Massachusetts (MA) regulations, topics appropriate for risk management credit include: medical malpractice prevention, medical ethics, quality assurance, medical-legal issues, patient relations, non-economic aspects of practice management, or courses designed to reduce the likelihood of medical malpractice through means other than increasing the learner’s medical education and technical expertise.

In order for your RSS sessions to receive Risk Management credits, the following procedures must be executed:

- Identify a clear and specific topic/title for the Risk Management session and place it on all appropriate forms (content review form, sign-in sheet, Monitor Verification Form, etc.)
- Check off all applicable Risk Management topics that the session addresses on the Monitor Verification Form.

Professional Practice Gap (Learner Needs)
A practice gap is the difference between actual performance and ideal performance.

<table>
<thead>
<tr>
<th>Best Practice Available</th>
<th>Practice Gap</th>
</tr>
</thead>
<tbody>
<tr>
<td>Current Practice</td>
<td></td>
</tr>
</tbody>
</table>

Gaps are measured in terms of:

Knowledge: awareness or understanding
Ex. Read a book about flying a plane

Competence: knowing how to do something; knowledge in the presence of experience and judgment = ability; but not yet put into practice
Ex. Use a flight simulator

Performance: Transferring knowledge into practice; the skills, abilities, and strategies one implements in practice
Ex. Fly a plane

The course director and/or planning committee must identify the practice gap(s) for their RSS and link these gap(s) to the needs that support the gap(s). The content must close the gap(s), using learner objectives and evaluation as the means to measure the effectiveness in closing the gap(s). On your RSS planning form, please describe what the need is and the method used to determine the need for your series, by answering the following questions:

- Who is the target audience for this series?
- Why is this series being planned for this target audience?
- What are the gaps in clinical or organizational practice that will be addressed by this RSS?

NOTE: For M&Ms, Case Conferences and Tumor Boards the gap is not identified on the planning form prior to the series. Instead, the gap is identified at each session during discussion and reflection, e.g., what happened that caused an unexpected outcome? This information must be documented using the Practice Gap form and submitted to the OCE after each session. The Practice Gap form can be found on our website under Regularly Scheduled Series.
How are Practice Gaps identified? They are identified through needs assessment (please see below).

**Verification of Identified Learner Needs (Needs Assessment)**
Learner needs are defined as the need for education on a specific topic, which is identified by a gap in professional practice. The ACCME requires that “the provider incorporates into CME activities the educational needs (knowledge, competence or performance) that underlie the professional practice gaps of their learners.” Therefore, the need should be based on professional practice gaps in knowledge, competence, and performance and should be designed to change competence, performance, and/or outcomes.

You will need to indicate how you identified the gap in professional practice and attach supporting documentation.

**NOTE:** Your planning form will not be processed without Needs Assessment documentation. Please select only ONE source on the planning form and submit supporting documentation for that source. If you cannot provide documentation, DO NOT check that source.

**Competencies**
You will need to indicate the primary competency and up to two secondary competencies that your series will address.

**ACGME/ABMS:**

- **Patient Care** - provide patient care that is compassionate, appropriate and effective for the treatment of health problems and the program of health.

- **Medical/Clinical Knowledge** - demonstrate knowledge of established and evolving biomedical, clinical, epidemiological, and social-behavioral sciences.

- **Practice-based Learning and Improvement** - investigate and evaluate the care of patients, appraise and assimilate scientific evidence, and continuously improve patient care based on constant self-evaluation and life-long learning.

- **Interpersonal Skills and Communication** - demonstrate skills that are effective in the exchange of information and collaboration with patients, their families, and health professionals.

- **Professionalism** - demonstrate a commitment to carrying out professional responsibilities and an adherence to ethical principles including ability to demonstrate:
  - Compassion, integrity, and respect for others;
  - Responsiveness to patient needs that supersedes self-interest;
  - Respect for patient privacy and autonomy;
  - Accountability to patients, society and the profession; and
  - Sensitivity and responsiveness to a diverse patient population, including but not limited to diversity in gender, age, culture, race, religion, disabilities, and sexual orientation.

- **Systems-based Practice** - demonstrate an awareness of and responsiveness to the larger context and system of health care, as well as the ability to call effectively on other resources in the system to provide optimal health care.

**IOM:**

- Provision of patient-centered care
- Work in interdisciplinary teams
- Effective use of evidence-based medicine
- Use of informatics in patient care, clinical decision-making; error reduction, and/or knowledge management
- A quality improvement project or process

**Areas for Improvement and Learner Objectives**
You must identify at least two overall learner objectives that are measurable. Measurable objectives are precise statements that identify observable and assessable learner behaviors using measurable action verbs. These objectives must address the learner needs that were identified in the overall practice gap of the series and can fall under competence or performance in areas for improvement (see examples below).
**Competence**: What learners need to know how to do in practice (based on knowledge)

Ex: As a result of this series, learners will be able to *explain* the different symptoms of hypertension and hypotension materialize.

**Performance**: What learners need to do in practice (based on strategy or skill)

Ex: As a result of this series, learners will be able to *develop* new treatment options for hypertension using case evidence from various patients.

For help writing measurable objectives and for a list of acceptable action verbs, please view the following reference document: **Verb Worksheet**.

**Potential/Real Barriers Facing Target Audience If the Need or Gap is to be Addressed**

Barriers are events outside your control that can prevent the expected result from being realized. The course director should employ strategies to overcome or eliminate identified barrier(s) in the RSS.

**Evaluation**

Evaluating the effectiveness of CE activities in meeting identified learner needs is an essential component of educational planning and ongoing quality improvement. Evaluation provides an opportunity to analyze changes in learners (competence, performance, and/or patient outcomes) achieved as a result of the CE activity as well as learner commitment to change, barriers to change, and activity quality.

A monthly evaluation is required to be distributed to participants. Participant responses are not mandatory; however, participants must still be given the opportunity to provide feedback during the series.

**NOTE**: You must submit summaries of these evaluations to the OCE every month if there were any responses. The OCE will not accept individual evaluation responses. **If your session has commercial support, an evaluation must be conducted immediately after the session.**

**Impact of Education on Outcomes/Follow-up**

Your department should measure the relevance and impact of the series on practice application, clinician performance, or health outcomes through an Impact of Education on Outcomes/Follow-up evaluation. This is separate from the session evaluations, which measure intent to change but not actual change. This requirement can be accomplished in various ways including:

<table>
<thead>
<tr>
<th>• Post-series participant survey (Survey Monkey instructions available on OCE Website)</th>
<th>• Quality assurance data/review (with explanation)</th>
</tr>
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<tbody>
<tr>
<td>• Post-course test/assessment (with summary of findings)</td>
<td>• Utilization management data (with explanation)</td>
</tr>
<tr>
<td>• Focus group (with summary of findings)</td>
<td>• Morbidity/mortality data (with explanation)</td>
</tr>
<tr>
<td>• Certification exam outcome (with explanation)</td>
<td>• Claims data/review (with explanation)</td>
</tr>
<tr>
<td>• Patient satisfaction survey results (with summary of findings)</td>
<td>• Maintenance of certification outcome (with summary of findings)</td>
</tr>
<tr>
<td>• New system, practice or policy (with explanation)</td>
<td>• Other audit/review (specify; e.g., Joint Commission)</td>
</tr>
</tbody>
</table>

**Disclosure**

ACCME’s Standards for Commercial Support require that all persons in control of content, including faculty presenters, course directors, moderators, planning committee members, reviewers, staff and editors, must complete and sign a disclosure form stating the presence or absence of relevant financial relationships. These forms must be submitted to the course director well in advance of the session for his/her review.

**Content Review & Resolution of Conflict of Interest (COI)**

The course director or independent reviewer for Tufts University School of Medicine (TUSM) Office of Continuing Education (OCE) **must review the content prior to each session** in order to:
• Ensure that the session content is fair, balanced and free of bias toward the commercial supporter(s) of the activity (if applicable) and/or manufacturers of products discussed in the activity.

• Scrutinize patient treatment recommendations to ensure that they represent a standard of practice within the profession in the United States.

• Review the studies cited in these materials upon which recommendations are made to ensure that those studies are scientifically objective and conform to research principles generally accepted by the scientific community.

• Look at the materials from the perspective of omissions and commissions.

• Review disclosure forms for speaker(s) and others involved in the activity.

• Resolve any conflicts of interest disclosed by speaker(s) and others involved in the activity.

If the content does not meet the CE requirements noted above, the speaker must make appropriate changes prior to the session. Once the changes have been made, the content should be reviewed again prior to the session. If the speaker refuses to make the required changes for CE compliance, you must find an alternate speaker for the session. Otherwise, this may jeopardize TUSM OCE’s ability to certify the session.

Also, in accordance with the ACCME requirements, TUSM OCE requires that anyone in a position to control content of an educational activity disclose all relevant financial relationships with any commercial interest as it pertains to the content of the presentation. All conflicts must be resolved prior to the activity start date. In cases where a presenter discloses a relevant financial relationship with a commercial interest, the course director or designated reviewer must resolve the conflict prior to the beginning of the session by completing the 2nd page of the RSS Content Review & Resolution of Conflict of Interest Form.

**Communication of Disclosure or Lack Thereof**

All disclosure information, including lack of relevant financial relationships, must be disclosed to learners prior to the beginning of the activity. This information must be included on the accreditation slides (if used), sign-in sheet cover page, and/or in the handout materials. It is also recommended that this information be announced verbally at the beginning of the session.

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**ACCME Information on Financial Relationships and Conflict of Interest:**

**Financial Relationships:** Financial relationships are those relationships in which the individual benefits by receiving a salary, royalty, intellectual property rights, consulting fee, honoraria, 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), 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 relationships of the person involved in the CME activity to include financial relationships of a spouse or partner. With respect to personal financial relationships, “contracted research” includes research funding where the institution gets the grant and manages the funds and the person is the principal or named investigator on the grant.

A conflict of interest (COI) is defined as when an individual who is in a position to control the content of an accredited CME activity has both 1) a relevant financial relationship with or interest in a commercial entity, and 2) has the opportunity to control the activity’s content relevant to the commercial entity’s products or services. 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.

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 ACCME considers “content of CME about the products or services of that commercial interest” to include content about specific agents/devices, but not necessarily about the class of agents/devices, and not necessarily content about the whole disease class in which those agents/devices are used. With respect to financial relationships with commercial interests, when a person divests themselves of a relationship it is immediately not relevant to conflicts of interest but it must be disclosed to the learners for 12 months.
National Faculty Education Initiative
TUSM OCE recommends that faculty visit http://www.nfeinitiative.org and participate in the free, online educational activity to become familiar with the responsibilities associated with involvement in certified educational activities. This activity explains the difference between certified CE activities and commercial marketing/promotional programs.

Commercial Support
Please note that TUSM OCE must submit all educational grant requests to potential funders. If your department wants to submit a grant request directly, you may do so as an activity not offered for CME (TUSM OCE will not offer credit(s) for those sessions).

There will be a fee associated with each grant request TUSM OCE directly submits and manages. A $250 grant submission/management fee will apply for each grant approved. If the grant is denied, this fee will not apply. When TUSM OCE applies for a grant, the transfer of funds from the commercial supporter may be designated in one of two ways as noted below:

1) Approved funds may be made payable to TUSM OCE. Once received, TUSM OCE will transfer funds to the department or division by requesting an invoice minus the grant submission/management fee. Please note that if the funds are required to come to TUSM OCE, it is subject to a 15% university O&M fee. This fee will be incorporated into the grant budget and the requested amount during the application.

2) If the funder allows, grant funds may be made directly payable to your department or division as an educational partner of TUSM OCE. In this case, the 15% university O&M fee would not apply.

To begin the grant submission process, please contact TUSM OCE at 617-636-6579.

Please allow 5-10 business days for TUSM OCE to review and submit your grant. Please keep this in mind if funder has a submission deadline.

Communication of Commercial Support or Lack Thereof
Commercial support or lack thereof must be disclosed to learners prior to the beginning of the activity on the sign-in sheet cover page, Accreditation Slides (if used), and/or verbally.

Series/Session Documentation Submission
Please note that starting July 1, 2016, each administrator will be given access to a folder that is specific to their series on Box.com, an online cloud system that is hosted by Tufts University. RSS documentation for each session must be uploaded to Box.com within 5 business days after the session has ended. Failure to comply with the submission guidelines will jeopardize certification of your sessions/series.

Prior to Series Implementation
- Conduct Course Director and Planning Committee meeting and identify practice gap and supporting documentation for identified learner needs (needs assessment).
- Plan the series based on ACCME Updated Criteria:
  - Identification of practice gap (learner needs)/needs assessment, goals and learner objectives, educational design, and evaluation
  - Standards for Commercial Support
  - Interactive learning
  - ACGME/ABMS/IOM competencies
- Complete Planning Form and submit required documentation including:
  - Course Director/Planning Committee Disclosure Forms
  - Verification of Identified Learner Needs Documentation (Needs Assessment)
  - Estimated Budget (if applicable)
• Review promotional or series materials with TUSM OCE before distribution to ensure appropriate accreditation language and information are included.

Prior to Each Session
• Speaker(s) must submit Disclosure Form to course director
• Speaker(s) submits their content/presentation slides
• Course Director or designated reviewer reviews content and resolves any conflicts of interest (if applicable) by completing the RSS Content Review & Resolution of Conflict of Interest Form
• Update OCE’s Sign-in sheet template and/or Accreditation Slides appropriately with disclosure and commercial support information
  o If using Accreditation Slides, update slides with course director/speaker disclosure information (or lack thereof) and series learner objectives. Send the slides to the speaker and confirm that they will include the slides at the beginning of their talk.

During the Activity
• Learners must sign in to verify their attendance
• Communication of Accreditation Information to learners is required and should be listed on the Sign-in Sheet cover page and/or Accreditation Slides (OCE templates to be used). The following information is required:
  o TUSM providership statement, accreditation language and # of AMA PRA Category 1 Credits™
  o Overall Series Learner Objectives
  o Faculty Disclosures; any reported relevant financial relationships with a commercial interest or lack thereof
  o Acknowledgement of commercial supporters or lack thereof
  o Requirements for Successful Completion

After Each Session
• Complete a Monitor Verification Form
• Complete a Practice Gap Form - For Case Conferences, M&Ms, or Tumor Boards ONLY
• Distribute and collect Evaluation Forms on a monthly basis. Instructions for setting up online evaluations are available on our website.

Post-Series (after end of academic year, June 30th)
• Submit OCE’s Attendance & Credit Tracking Spreadsheet available on our website. TUSM OCE will generate certificates and send them to your department for distribution to your attendees. Please note that only TUSM OCE can issue official certificates; not your department.
• Submit summary of Impact of Education on Outcomes. If using follow-up survey, please distribute to participants to complete after your last session in the series. Instructions on how to build the survey on Survey Monkey are available on the website. TUSM OCE will send an email to regarding the specific due date.
• Submit Final Budget (if applicable) on the appropriate budget template. Please include items such as food expenses, faculty honoraria, faculty travel expenses, etc. You must also specify the income to cover such expenses.

Audits/Record Keeping
Please note that your series is subject to periodic audit by TUSM OCE and/or the ACCME. Please keep all documentation on file in your department (originals or electronic copies) for at least 6 years for each RSS.

AMA PRA Category 2 Credit™
If you are not able to meet the documentation requirements for certification of your series, please keep in mind the option of AMA PRA Category 2 Credit™, which is self-designated and claimed by individual physicians for participation in activities not certified for AMA PRA Category 1 Credit™. For more information, please visit the AMA website.

References/Additional Resources
RSS Forms and Templates
Accreditation Council for Continuing Medical Education (ACCME)
ACCME’s Standard for Commercial Support
American Medical Association