Continuing Medical Education and Professional Development

Regularly Scheduled Series (RSS)

Program Manual & Guide
2017
Continuing Medical Education and Professional Development
School of Medicine
University of Louisville
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# RSS Program Manual and Guide

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University of Louisville
Continuing Medical Education
Planning Document & Application for
CME Programming Contained In A
Regularly Scheduled Series (RSS)

The University of Louisville CME&PD retains the right to withhold/withdraw/adjust credit at any time, should it determine that the ACCME Essentials, Policies, ACCME Standards for Commercial Support and/or the University of Louisville Continuing Medical Education & Professional Development policies and procedures are not being followed.

Preliminary Note: Please read and respond to each question completely; this will ensure compliance with the CME accreditation criteria we are required to follow at the University of Louisville. The Regularly Scheduled Series presented in your application, whether it is grand rounds, case conferences, journal club meetings, or other should be described in general terms, addressing the general medical practice gaps and the general educational objectives pertinent to the discipline and the nature of the meeting. The documentation references should contain generic educational and research data related to the discipline in support of the identified medical practice gaps. This application is for approval of RSS programming between the dates January 1, 2018 through December 31, 2019.

📝 COURSE INFORMATION

INSTRUCTIONS: Place your cursor over the “Click here to enter text“, and you may type or cut and paste any amount of material in response to the question. For X answers, hover your cursor over the box and left click. Please provide answers to all questions. Problems? Contact us at 502-852-5329 or klnapo01@louisville.edu.

1) Department/Organization making request:  

2) ☐ U of L Provided Program
   ☐ Jointly-Provided Program (Organization outside of U of L)

3) Title of this Regularly Scheduled Series (is this a Grand Rounds, Case Conference, Journal Club or . . . .); name the discipline, and then the type of RSS:  

4) Dates of Regularly Scheduled Series (or indicate “3rd Monday”, “1st Friday”, “weekly on Thursday”, etc.):
5) **Course location (include street address, building, room number or name):**
   Click here to enter text.

6) **Number of CME credits requested for each event:**
   Click here to enter text.

7) **Number of Nursing CEUs requested for each event:**
   Click here to enter text.

**COURSE CONTACTS**

8) **Name/credential of Course Director:**
   (Note: the course director must be a physician, Ph.D. educator, registered nurse or equivalent medical professional.)
   Click here to enter text.

   **E-mail:**
   Click here to enter text.

   **Telephone:**
   Click here to enter text.

   **Fax:**
   Click here to enter text.

   **Name of Course Coordinator** (contact person responsible for filing reports with CME & PD after every event)
   Click here to enter text.

   **E-mail:**
   Click here to enter text.

   **Telephone:**
   Click here to enter text.

   **Fax:**
   Click here to enter text.

10) **Planning Committee Members – Please list individuals who are planning committee members.**
   (Note: a minimum of three persons is required with at least one physician faculty member. The use of owners and/or employees of ACCME-defined commercial interests as planners and/or faculty is strictly prohibited in CME activities. Planning committee members must provide current disclosures, and the committee should not schedule its first meeting until CME & PD approval has been obtained.)

<table>
<thead>
<tr>
<th>Planning Committee Member</th>
<th>Telephone Number</th>
<th>E-mail Address</th>
</tr>
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<tbody>
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</tbody>
</table>

**Date of first Planning Committee Meeting:**
Click here to enter text.

**CONTENT DEVELOPMENT**
Click here to enter text.
11) Screening Criteria: In order to be considered for a Regularly Scheduled Series, all of the criteria listed below must be met. Planners confirm that...

(please check each box indicating your planning committee’s acceptance of these continuing education principles)

a) The content of this RSS will be based on evidence that constitutes “best practices.” Agree ☐

b) Planners have identified a defined gap that exists between current and best practice. Agree ☐

c) This RSS will provide educational content aimed at closing the defined gap to result in improved knowledge, competence, and/or performance, which could result in improved patient outcomes. Agree ☐

d) All of the recommendations involving clinical medicine in this CME activity are based on evidence that is accepted within the profession of medicine as adequate justification for their indications and contraindications in the care of patients. Agree ☐

e) All scientific research referred to, reported on, or used in this RSS will support or justify patient care recommendations that conform to the generally accepted standards of experimental design, data collection, and analysis. Agree ☐

12) This Regularly Scheduled Series is planned to meet the needs of what groups of practicing healthcare professionals (target audience)? List all groups, beginning with physicians who will most benefit by attending these RSS sessions:

Click here to enter text.

13) Based on a review of medical practice literature and/or input from an expert panel of physicians in practice and/or previous RSS course feedback, please identify the practice gaps that will be addressed in this RSS series. Also, summarize basis of the learner’s educational gap, the desired results (outcome) you intend to achieve, and the type of gap (educational need) that will be met.

<table>
<thead>
<tr>
<th>EDUCATIONAL GAP current practice (What physicians are not currently doing)</th>
<th>WHAT IS BEHIND THE GAP (Why they aren’t doing it)</th>
<th>DESIRED RESULTS (Outcomes as best-practice)</th>
<th>TYPE OF GAP (The educational need being addressed)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td>☐ Knowledge</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>☐ Competence</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>☐ Performance</td>
</tr>
</tbody>
</table>

Click here to enter text.
14) Please provide at least three peer-reviewed articles (scientific/medical journals, etc.) that support the Professional Practice Gaps for this Regularly Scheduled Series and include the specific URL Address for each article. For more than three entries, hit "tab" and an additional row will appear.

<table>
<thead>
<tr>
<th>Peer-reviewed articles that support the Professional Practice Gaps including URLs</th>
</tr>
</thead>
<tbody>
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15) What procedures were used to identify the existing gaps? Please check all that apply. Documentation for each procedure indicated must be attached.

- Clinical practice data
- Quality assurance data
- Requirements by state licensing board, specialty societies
- Previous course evaluations
- Literature search (articles must be cited above in question #14)
- Case Studies
- Other, please list: Click here to enter text.

16) Based on the desired results described above, list the learning objectives for this group of activities. The learning objectives are the bridge to address the GAP between current practice and best/better practice, and the objectives should specify the learner result, using action verbs, (those abilities that the learner can expect to achieve by participating in this educational activity).
17) How does this regularly scheduled series of learning events match your learners’ scope of practice?  
Click here to enter text.

18) What are the likely and possible educational formats that will be used for this Regularly Scheduled Series (check all that apply):

☐ Didactic lecture  
☐ Question and answer session  
☐ Skilled demonstration  
☐ Roundtable discussion  
☐ Panel discussion  
☐ Case studies  
☐ Lab activity  
☐ Audience Response System  
☐ Simulations  
☐ Internet

19) Explain how those formats checked in question 18 support the objectives and desired results.  
Click here to enter text.

20) Based on the Maintenance of Certification (MOC) competencies designed by the American Board of Medical Specialties (ABMS), the competencies established by the Accreditation Council for Graduate Medical Education (ACGME), and the desirable physician attributes established by the Institutes of Medicine (IOM), what competency areas will you address in this Regularly Scheduled Series?  
Check only those that apply.

☐ Patient Care (provide care that is compassionate, appropriate and effective treatment for health problems and to promote health).

☐ Medical Knowledge (demonstrate knowledge about established and evolving biomedical, clinical and cognate sciences and their application in patient care).

☐ Practice-based Learning and Improvement (investigate and evaluate patient care practices, appraise and assimilate scientific evidence and improve practice of medicine).
**Systems-based Practice** (demonstrate awareness of and responsibility for larger context and systems of healthcare; call on system resources to provide optimal care, e.g., coordinating care across sites or serving as the primary case manager when care involves multiple specialties, professions, or sites).

**Professionalism** (demonstrate a commitment to carrying out professional responsibilities, adherence to ethical principles and sensitivity to diverse patient populations).

**Interpersonal and Communication Skills** (demonstrate skills that result in effective communication and teaming with patients, their families and professional associates, such as fostering a therapeutic relationship that is ethically sound; using effective listening skills with non-verbal and verbal communications; working as both a team member and at times as a leader).

**Provide Patient-centered Care** (identify, respect, and care about patients’ differences, values, preferences and expressed needs; relieve pain and suffering; coordinate continuous care; listen to, clearly inform, communicate with, and educate patients; share decision making and management; and continuously advocate disease prevention, wellness, and promotion of healthy lifestyles, including a focus on population health).

**Work in Interdisciplinary Teams** (cooperate, collaborate, communicate, and integrate care in teams to ensure that care is continuous and reliable).

**Employ Evidence-based Practice** (integrates best research with clinical expertise and patient values for optimum care; participate in learning and research activities to the extent feasible).

**Apply Quality Improvement** (identify errors and hazards in care; understand and implement basic safety design principles; continually understand and measure quality of care in terms of structure, process and outcomes in relation to patient and community needs; design and test interventions to change processes and systems of care with the objective of improving quality).

**Utilize Informatics** (communicate, manage knowledge, mitigate error, and support decision making using information technology).

21) Each program course director should implement a mechanism to identify and resolve conflicts of interest (COI) by speakers/moderators/panelists prior to the RSS event using the conflict of interest form. CME & PD personnel will review Conflict of Interest disclosures of course directors/planners and coordinators. If there is a perceived conflict of interest, directors/planners, coordinators as well as content reviewers will be recused from planning, teaching, authoring, coordinating and evaluating an RSS, and replacements should be appointed by the department or organization. The RSS director and/or coordinator (those who have no COI) will review disclosures for speakers/moderators/panelists. If there is a perceived conflict of interest, speakers/moderators/panelists will complete and sign an Attestation form, and their presentation must be peer-reviewed for commercial bias prior to the presentation. Agree ☐
22) In order to encourage your learners to implement into their practice, some of the new ideas they have learned by attending this Regularly Scheduled Series, what non-educational strategies will you use? For example, “plan to send reminders to attendees to recall course topics that can be implemented,” or “brief discussion at each session regarding new ideas that have been adopted by peers.”

23) Please identify factors outside of a physician’s control that may negatively impact patient outcomes:

24) Please cite at least two educational strategies to remove, overcome or address barriers to physician change. 1) List the barriers that the participants may have in trying to implement the education delivered in this Regularly Scheduled Series (in the gray boxes below, left). Barriers may include: formulary restrictions, insufficient time for implementation of new skills or behaviors, lack of insurance reimbursement, lack of organizational support, lack of resources, policy issues within the organization. 2) Recommend educational strategies (in the gray boxes, right) that you will use at this activity to remove, overcome, or address these barriers.

<table>
<thead>
<tr>
<th>ANTICIPATED BARRIER(S) TO PHYSICIAN CHANGE</th>
<th>STRATEGIES YOU WILL USE IN THIS ACTIVITY TO ADDRESS THE BARRIER(S)</th>
</tr>
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25) Will commercial support be solicited for this Regularly Scheduled Series? 
☐ Yes or ☐ No

If yes, the coordinator must arrange for a Letter of Agreement (LOA) between the grantor and the University of Louisville (provider), to be executed prior to the RSS event (signed by the grantor and the UofL). The coordinator then shall provide an accounting of the grant funds (income and expenditures) in the summary report prepared after each RSS event. Providers of grants shall not participate directly in the educational activity (selection of content or speaker), shall not pay honoraria directly to speakers, nor shall they promote or advertise any medical product or device within the meeting space of the RSS event.

Agree ☐

26) Will any funding be provided for this series (e.g. exhibit fees, support for food to be served at the event) by an ACCME-defined commercial interest? 
☐ Yes or ☐ No
If yes, the CME & PD “Exhibit/Sponsorship” form must be completed and signed prior to the event and submitted along with the summary report as well as an accounting of the income received and expended.

This completes your RSS Credit Application. Please be sure you have addressed all items listed below before submitting. Also note the coordinator’s responsibilities as well as the RSS fee payment schedule.

Please sign the document and submit as a Word document file to CME & PD (klnapo01@louisville.edu).

BEFORE YOU SUBMIT THIS APPLICATION, ARE ALL OF THE FOLLOWING ITEMS ADDRESS OR INCLUDED?

☐ ALL QUESTIONS ON THE APPLICATION ANSWERED
☐ BOTH CONTACT PERSONS IDENTIFIED AND LISTED
☐ “NEEDS” DOCUMENTATION MATERIALS SCANNED AND ATTACHED (those items you checked in question #15)
☐ DISCLOSURE FORMS FROM THE REGULARLY SCHEDULED SERIES DIRECTOR, PLANNING COMMITTEE, COORDINATOR and CONTENT REVIEWERS COMPLETED, SIGNED AND ATTACHED AFTER DISCLOSURE INFORMATION IS REVIEWED. IF THERE WERE ANY DISCLOSURES INDICATED BY ANY OF THESE RSS PRINCIPALS, THEN THAT INDIVIDUAL IS TO COMPLETE AN ATTESTATION FORM PRIOR TO PLANNING THIS RSS AND SUBMITTED WITH THIS APPLICATION.

FINAL NOTES:

REPORTS
The coordinator of the RSS is responsible for reporting all RSS activities at least once per month. Reports delinquent more than 45 days after the receipt deadline will not be honored, and the CME credit will not be registered for attendees of those meetings. The report for each meeting/event will consist of:

• a report form cover page with coordinator’s signature
• summary of evaluations for each meeting
• copy of any promotional materials
• signed disclosure forms for every speaker and panelist, along with resolution of any conflicts of interest and attestation forms
• accounting of funds from grants or other sources of support
• a CV for each speaker if Nursing CEUs are requested

RSS FEES
The department/organization sponsoring the RSS will be billed for each meeting/event of this RSS series at the rate of $35.00 per session. Invoices will be issued by CME & PD semi-annually and should be paid within 30 days of receipt. The billing will be based upon receipt of summary reports from each meeting/event.

Signature of Regularly Scheduled Series Course Director
(electronic signature is acceptable)

Signature:  Click here to enter text.

Date:
REGULARLY SCHEDULED SERIES
COURSE COORDINATOR AGREEMENT
UNIVERSITY OF LOUISVILLE SCHOOL OF MEDICINE
Continuing Medical Education and Professional Development

The University of Louisville School of Medicine is accredited by the Accreditation Council for Continuing Medical Education (ACCME). As an accredited sponsor, Continuing Medical Education and Professional Development (CME & PD) is required to maintain appropriate records. By agreeing to be the CME & PD designee for this RSS, you agree that you will manage and provide documentation for the following:

Title of CME Program: _____________________________

I will attend the RSS sessions, and within one month of each of the sessions, I will submit the following:

- RSS Session Report Form.
- Tabulated Summary of Evaluations.
- Copy of Welcome Letter with disclosures listed.
- Disclosure Form. Please submit a copy of the signed Disclosure Form for all individuals in a position to control the content including the Course Director, Course Coordinator, Planning Committee Members, Presenter(s) and Reviewer(s) of each session. (Please document how conflict was resolved for all speakers/planners/reviewers who have a conflict of interest along with a Conflict Review Form if applicable.)
- Content Peer Review Form – if applicable. (Please submit a copy of the Peer Review Form signed for those who have a conflict of interest to document that any conflicts were resolved.)
- Letter of Agreement (LOA) – if applicable. (Please arrange for a Letter of Agreement (LOA) between the grantor and the University of Louisville (provider), to be executed prior to the RSS event signed by the grantor and the UofL’s Executive Vice President-Health Affairs Office. Please also provide a copy of the check and an accounting of the grant funds (income and expenditures) in the Budget Worksheet prepared after each RSS event. Providers of grants shall not participate directly in the educational activity (selection of content or speaker), shall not pay honoraria directly to speakers, nor shall they promote or advertise any medical product or device within the meeting space of the RSS event.
- Exhibit/Sponsor Form – if applicable. (Please ensure that a completed and signed Exhibit/Sponsor Form is completed prior to the event and submitted along with the Budget Worksheet documenting the income received and expended if any funding will be provided for the series to be used for exhibit fees, support for food to be served at the event, etc.)
- Copy of IUT/Disbursement Form/Commercial Support Budget Worksheet – if applicable. (Please document that the department paid the honorarium and travel expenses directly to the speaker. No commercial company is allowed to pay honoraria and expenses directly to speakers.)

I understand my role as the University of Louisville Continuing Medical Education and Professional Development RSS Coordinator.

Signature: _____________________________ Date: _____________________________

Title: _____________________________ Telephone Number: _____________________________
Regularly Scheduled Series (RSS)

Course Director's Agreement

University of Louisville School of Medicine
Office of Continuing Medical Education & Professional Development

Title of RSS CME Program: <Insert Program Name Here>

The University of Louisville School of Medicine is accredited by the Accreditation Council for Continuing Medical Education (ACCME). As an accredited provider of regularly scheduled series (RSS), programming the office of Continuing Medical Education and Professional Development (CME & PD) is required to follow all ACCME essentials, criteria and standards for commercial support. This includes identifying an RSS Course Director for each RSS program and charging her/him with responsibilities that include:

- oversight of the planning and development of effective CME-RSS topics.
- selection and vetting of qualified presenters.
- review and approval of presentations that are free of commercial bias.
- collection and maintenance of appropriate outcomes data records.
- appointment and oversight of a qualified RSS Course Coordinator.

Each of these responsibilities is executed with a full regard for, and adherence to, the stated mission of our UofL CME & PD program:

The mission of the University of Louisville Continuing Medical Education and Professional Development program (CME & PD) is to address the educational needs of physicians and other healthcare team members as they seek self-improvement through life-long learning. Accredited CME, developed and implemented by the University of Louisville, is rooted in evidence-based medicine and seeks to enhance patient care. Expected results of the University of Louisville CME program are to improve the professional competence of physicians and other healthcare team members which ultimately improves performance as well as outcomes in patient care.

Given this charge, the Office of CME & PD requires that each individual assuming the role of RSS Course Director agree to the following responsibilities at the time of their appointment, or at least biennially, when the RSS application is presented for approval:
As the **RSS Course Director** I agree to assume the primary role in organizing a planning committee and will conduct, with that committee - at least annually, a planning session for the purpose of selecting topics and speakers that will carry out the stated objectives and address the practice gaps as described in the biennial RSS application. I further agree that this process will be guided by feedback from learners who attended previous offerings of this program as well as a literature review of current best practices in the field of medicine represented in this RSS discipline.

As the **RSS Course Director** I will assume responsibility, or delegate same, for review of the Disclosure of Financial Relationships document (required of the presenter for each RSS session) prior to the time of the session presentation. Should a conflict of interest be disclosed by the presenter, relevant to the topic being presented, I will assume the responsibility, or delegate same, for the peer-review of the conflicted presenter’s presentation materials (e.g., slide set, narrative outline), and document the findings using the CME & PD Content Peer-Review form. If commercial bias or lack of fairness/balance is found in the presentation materials, the presenter will be directed to make appropriate changes prior to the RSS session presentation.

For the purpose of validating our mission, as described above, as the **RSS Course Director** for this program, I agree that I will manage and provide outcomes data documentation to the CME & PD office at least once annually, the process to include the following:

1. Create and implement a data collection plan, at a minimum to include evaluation of each RSS session.
2. Process the aggregated evaluation data and provide periodic reports to the CME & PD office.
3. Periodically, attempt to ascertain changes in patient outcomes related to RSS interventions and communicate those results with the RSS planning committee and with the CME & PD office.

I fully understand and accept my role as a University of Louisville School of Medicine Continuing Medical Education and Professional Development **RSS Course Director**.

Signature: ____________________________ Date: ______________

Printed Name: ____________________________
<table>
<thead>
<tr>
<th>Name and Degree (or credentials):</th>
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</tr>
</thead>
<tbody>
<tr>
<td>CME/CE Activity Name:</td>
<td></td>
</tr>
<tr>
<td>Presentation Title (if applicable):</td>
<td></td>
</tr>
<tr>
<td>Select Your Role(s):</td>
<td>□ Planner  □ Course Director  □ Moderator  □ Presenter/Author  □ Peer Reviewer  □ Other:</td>
</tr>
</tbody>
</table>

**CRITERIA AND INSTRUCTIONS FOR DISCLOSURE OF FINANCIAL RELATIONSHIPS WITH COMMERCIAL INTERESTS**

1. Instructors, planners, content reviewers and managers who affect the content of a CME activity are required to disclose financial relationships they and/or their spouse or life partner have with commercial interests.*

   *The ACCME definition of a "commercial interest" is: "any entity producing, marketing, reselling, or distributing health care goods or services consumed by, or used on, patients.

2. You are to disclose all financial relationships that you and/or your spouse/life partner have had with a commercial interest that have occurred in the past 12 months, which fall under the definition above.*

3. Financial relationships with governmental agencies (e.g., the NIH) and organizations that do not fit the above definition do not have to be disclosed.

4. Honoraria received, or consulting funds, from a CME provider, even though those funds may have been provided to that CME/CE provider through an educational grant from a commercial interest, do not have to be disclosed (per ACCME requirements).

5. If you are a principal investigator for a clinical research project, you must report that research relationship under "Contracted Research" even if those funds came to an institution. Non-PI investigators need not report this relationship.

6. In accordance with ACCME requirements, you may not participate as a member of a CME course planning committee or faculty if you are an employee or owner of a commercial interest (CI) such as a pharmaceutical/device or biologic company or any other CI as defined by the ACCME [i.e., any entity producing, marketing, re-selling, or distributing health care goods or services consumed by, or used on, patients].

7. In accordance with ACCME requirements, failure to provide disclosure information in a timely manner will result in your disqualification as a potential planner, course director, moderator, presenter, author or reviewer for this activity.

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**Page 1 of 3**
PART I: NATURE OF FINANCIAL RELATIONSHIPS BASED UPON THE ACCME DEFINITION* ON PAGE 1:
1. Are you or your spouse/life partner an employee or owner of a commercial interest?  
   □ Yes  □ No  
   If yes, name of commercial interest: ____________________________
2. Within the past 12 months, have you and/or your spouse or life partner received support from or had a relationship with a commercial interest?  
   □ Yes  □ No

Please include below only financial commercial interests based upon the ACCME definition* on Page 1.

<table>
<thead>
<tr>
<th>Check the Type of Financial Relationship</th>
<th>Indicate the Name of the Commercial Interest</th>
</tr>
</thead>
<tbody>
<tr>
<td>□ Speakers Bureau (paid directly by commercial interest)</td>
<td></td>
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<tr>
<td>□ Consulting/Independent Contractor Fee</td>
<td></td>
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<tr>
<td>□ Royalty</td>
<td></td>
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<tr>
<td>□ Receipt of Intellectual Property Rights/Patent Holder</td>
<td></td>
</tr>
<tr>
<td>□ Fees for Non-CME Services Received Directly from a Commercial Interest or its Agent</td>
<td></td>
</tr>
<tr>
<td>Grant/Contracted Research Support. If you are a PI, you must report a financial relationship (even if grant funds are managed by your institution). Non-PIs need not report.</td>
<td></td>
</tr>
<tr>
<td>□ Stocks, stock options, or other ownership interest (ownership of diversified mutual funds is not reportable)</td>
<td></td>
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<tr>
<td>□ Other (please describe):</td>
<td></td>
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</tbody>
</table>

If you reported financial relationships in the chart above, will any of these relationships impact your ability to present an unbiased presentation?  
   □ No  □ Yes

PART II: UNLABELED/UNAPPROVED DRUGS
Do you intend to reference unlabeled/unapproved uses of drugs or products in your presentation?  
   □ No. Skip to Part III below.  □ Yes. Provide the names of the drugs or products you will reference below.

PART III: ATTESTATION OF CME/CE VALUE STATEMENTS
Please indicate your understanding of and willingness to comply with each statement below. If any statements do not apply to your participation in this activity, please select “N/A.” If you require clarification of these statements or have questions regarding your ability to comply, please contact the University of Louisville CME & PD Office (cmepd@louisville.edu or 502-852-6294) immediately.
<table>
<thead>
<tr>
<th>Agree</th>
<th>Disagree</th>
<th>N/A</th>
<th>Value Statement</th>
</tr>
</thead>
<tbody>
<tr>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>I have disclosed all financial relationships and I will disclose this information to learners.</td>
</tr>
<tr>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>The content and/or presentation of the information with which I am involved will promote quality or improvements in health care and will not promote a specific proprietary business interest of a commercial interest. Content for this activity, including any presentation of therapeutic options, will be balanced, evidence-based and commercially unbiased.</td>
</tr>
<tr>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>I have not and will not accept any honoraria, additional payments or reimbursements directly from a commercial interest for my participation in this activity.</td>
</tr>
<tr>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>I understand that Office of CME &amp; PD may need to review my presentation and/or content prior to this activity, and I will provide educational content and resources in advance as requested.</td>
</tr>
<tr>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>If I am providing recommendations involving clinical medicine, they will 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 will conform to the generally accepted standard of experimental design, data collection and analysis.</td>
</tr>
<tr>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>If I am discussing specific healthcare products or services, I will use generic names to the extent possible. If I need to use trade names, I will use trade names from several companies when available, and not just trade names from any single company.</td>
</tr>
<tr>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>If I am discussing any product use that is off label, I will disclose that the use or indication in question is not currently approved by the FDA.</td>
</tr>
<tr>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>If I have been trained or utilized by a commercial interest or its agent as a speaker (e.g., speaker's bureau) for any commercial interest, the promotional aspects of that presentation will not be included in any way with this activity.</td>
</tr>
<tr>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>If I am presenting research funded by a commercial interest, the information presented will be based on generally accepted scientific principles and methods, and will not promote the commercial interest of the funding company.</td>
</tr>
</tbody>
</table>

My signature (or typed name for e-filing) below indicates that I have read and completed this form myself and to the best of my ability provided current and accurate information. I am aware that financial disclosure information provided on page 2 of this form will be shared with learners prior to their engagement in this CME activity.

Signature: ____________________________ Date: __________

INSTRUCTIONS:
Please e-mail a copy of this completed form to the course coordinator. You can save a copy to your computer file (PDF format) and then attach it to your e-mail. If you cannot save a PDF file on your computer, then print the form and fax it to the course coordinator. If you are having any difficulty you may contact the CME & PD office, cmepd@louisville.edu or (502) 852-6294, for assistance.
CONTENT PEER REVIEW FORM

Name of CME Program/Activity: ____________________________________________
Title and Type of Presentation: ____________________________________________
Presenter’s Name: ________________________________________________________

Instructions: Your primary concern will be to identify commercial bias and any concerns for fairness and balance in the presentation. We understand that in a slide review you will not have access to the accompanying narrative, so make your responses based solely on the data contained in the slides. Please reference slide number(s) where changes are to be addressed. In reviewing narrative material please make comments with reference to the page number.

Is this presentation/material free of commercial bias?

__ Yes __ No  If no, please comment, providing specifics below:

________________________________________________________________________

Are the slides/narrative for this presentation fair and balanced? __ Yes ___ No
If no, please explain:

________________________________________________________________________

Do any slides or narrative materials need to be revised or deleted? __ Yes ___ No
If yes, please be specific:

________________________________________________________________________

Are the patient treatment recommendations included in this CME presentation evidence-based?
__ Yes ___ No
If no, please comment below:

Reviewer Name: (please print) ______________________________________________
UofL. Department: _________________________________________________________
Reviewer’s Signature ___________________________  Date: __________
Continuing Medical Education and Professional Development

Guidelines for Commercial Support

The content of CME activities approved by CME & PD may not promote commercial interests (i.e., there can be no commercial bias within the content.) To document relevant financial relationships, all individuals in a position to control the content including the Course Director, Course Coordinator, Planning Committee Members, Content Reviewers, and Presenters are required to complete a Disclosure of Relevant Financial Relationships Form (see example that follows) as required by ACCME Standards for Commercial SupportSM. Subsequently, any individual who reports a relevant financial relationship with a commercial interest is also subject to having his/her presentation reviewed by an independent peer reviewer. Failure to complete a disclosure disqualifies a person from having involvement in the determination of the content or presentation of a CME program. At the time of the program, each speaker is required to disclose any relevant financial relationships, both in the welcome letter and as he/she begins his/her individual presentations. All non-speakers (planners, program staff, course directors and coordinators, and content reviewers) should disclose any relevant financial relationships in the welcome letter.

All commercial support (including in-kind value) must be formally arranged by the program planners using either:

- The CME & PD Exhibit/Sponsor Form (see example that follows on page 24).

- The CME & PD Letter of Agreement (LOA) (see example that follows). No commercial support (grants) may be given to the program without the full knowledge and approval of the CME & PD office and the office of Executive VP - Health Affairs. Grant LOAs must be executed prior to final preparation and presentation of the approved program. The LOA must be between the University of Louisville Research Foundation, Inc. and the funding grantor, and Letters of Agreement must be reviewed and signed by the University of Louisville Research Foundation, Inc. (the agent of the University of Louisville for receiving grants). Assistance with this procedure should be sought with the CME&PD staff.

Documentation of receipt and expenditure of all forms of commercial support including honoraria, speaker expense reimbursement, catering expenses and all other program-related expenses must be included in the Budget Worksheet (see example that follows).
Continuing Medical Education and Professional Development

**Exhibitor/Commercial Support Representative Guidelines**

Continuing Medical Education and Professional Development (CME&PD) has prepared these guidelines in order to promote open and spontaneous questions of faculty by participants and to assure compliance with all ACCME criteria and commercial sponsorship standards. The meeting provides a meaningful opportunity for commercial support representatives to interact with both presenters and learners, but should be limited to conversations on the exhibit floor. CME&PD, as an accredited ACCME provider of continuing medical education to physicians as well as other healthcare professionals, must assure that all interactions within the learning environment are free from commercial bias of any kind. We appreciate your cooperation as we strive to present a quality learning product to our participants.

♦ Commercial support representatives are expected to stand in the rear of the meeting room and observe the activity.
♦ Conversations between exhibitors/commercial support representatives and presenters will not be permitted in the meeting room.
♦ Conversations between exhibitors/commercial support representatives and learners will not be permitted in the meeting room.
♦ Conversations between exhibitors/commercial supporter representatives (of either the same company or another company), in which products are discussed, will not be permitted in the meeting room.
♦ Advertisement, promotional materials including flyers and business cards cannot be displayed or distributed in the educational space immediately before, during or after a CME activity.
♦ Should either a presenter or learner approach a corporate representative, the representative should explain that they are there to observe only, and product specific questions can be addressed at the corporate booth in the exhibit hall.
♦ Commercial support representatives cannot provide a CME activity to learners or distribute self-study materials or provide electronic access to CME activities.
♦ CME&PD does not provide continuing education credits to Exhibitor/Commercial Support Representatives who are acting in that capacity.

Please signify your acceptance of these guidelines:

[ ] I acknowledge the Exhibitor/Commercial Support Representative Guidelines as outlined above and agree that I will abide by those guidelines.

Signature: ________________________________

Date: ________________________________

Print Name: ________________________________

Company Name: ________________________________
ACCME Standards for Commercial Support: Standards to Ensure Independence in CME Activities

Definition: The “Provider” is the institution providing the CME credits (U of L).
The “Educational Partner” is the joint provider (not the commercial supporter.)

Standard 1: Independence
STANDARD 1.1 A CME provider must ensure that the following decisions were made free of the control of a commercial interest. (See www.accme.org for a definition of a "commercial interest" and some exemptions.) (a) Identification of CME needs; (b) Determination of educational objectives; (c) Selection and presentation of content; (d) Selection of all persons and organizations that will be in a position to control the content of the CME; (e) Selection of educational methods; (f) Evaluation of the activity.
STANDARD 1.2 A commercial interest cannot take the role of non-accredited partner in a joint provider relationship.

Standard 2: Resolution of Personal Conflicts of Interest
STANDARD 2.1 The provider must be able to show that everyone who is in a position to control the content of an education activity has disclosed all relevant financial relationships with any commercial interest to the provider. The ACCME defines "relevant financial relationships" as financial relationships in any amount occurring within the past 12 months that create a conflict of interest.
STANDARD 2.2 An individual who refuses to disclose relevant financial relationships will be disqualified from being a planning committee member, a teacher, or an author of CME, and cannot have control of, or responsibility for, the development, management, presentation or evaluation of the CME activity.
STANDARD 2.3 The provider must have implemented a mechanism to identify and resolve all conflicts of interest prior to the education activity being delivered to learners.

Standard 3: Appropriate Use of Commercial Support
STANDARD 3.1 The provider must make all decisions regarding the disposition and disbursement of commercial support.
STANDARD 3.2 A provider cannot be required by a commercial interest to accept advice or services concerning teachers, authors, or participants or other education matters, including content, from a commercial interest as conditions of contributing funds or services.
STANDARD 3.3 All commercial support associated with a CME activity must be given with the full knowledge and approval of the provider.
STANDARD 3.4 The terms, conditions, and purposes of the commercial support must be documented in a written agreement between the commercial supporter that includes the provider and its educational partner(s). The agreement must include the provider, even if the support is given directly to the provider's educational partner or a joint provider.
STANDARD 3.5 The written agreement must specify the commercial interest that is the source of commercial support.
STANDARD 3.6 Both the commercial supporter and the provider must sign the written agreement between the commercial supporter and the provider.
STANDARD 3.7 The provider must have written policies and procedures governing honoraria and reimbursement of out-of-pocket expenses for planners, teachers and authors.
STANDARD 3.8 The provider, the joint provider, or designated educational partner must pay directly any teacher or author honoraria or reimbursement of out-of-pocket expenses in compliance with the provider's written policies and procedures.
STANDARD 3.9 No other payment shall be given to the director of the activity, planning committee members, teachers or authors, joint provider, or any others involved with the supported activity.
STANDARD 3.10 If teachers or authors are listed on the agenda as facilitating or conducting a presentation or session, but participate in the remainder of an educational event as a learner, their expenses can be reimbursed and honoraria can be paid for their teacher or author role only.
STANDARD 3.11 Social events or meals at CME activities cannot compete with or take precedence over the educational events.
STANDARD 3.12 The provider may not use commercial support to pay for travel, lodging, honoraria, or personal expenses for non-teacher or non-author participants of a CME activity. The provider may use commercial support to pay for travel, lodging, honoraria, or personal expenses for bona fide employees and volunteers of the provider, joint provider or educational partner.
STANDARD 3.13 The provider must be able to produce accurate documentation detailing the receipt and expenditure of the commercial support.
Standard 4: Appropriate Management of Associated Commercial Promotion

STANDARD 4.1 Arrangements for commercial exhibits or advertisements cannot influence planning or interfere with the presentation, nor can they be a condition of the provision of commercial support for CME activities.

STANDARD 4.2 Product-promotion material or product-specific advertisement of any type is prohibited in or during CME activities. The juxtaposition of editorial and advertising material on the same products or subjects must be avoided. Live (staffed exhibits, presentations) or enduring (printed or electronic advertisements) promotional activities must be kept separate from CME. For print, advertisements and promotional materials will not be interleaved within the pages of the CME content. Advertisements and promotional materials may face the first or last pages of printed CME content as long as these materials are not related to the CME content they face and are not paid for by the commercial supporters of the CME activity. For computer based, advertisements and promotional materials will not be visible on the screen at the same time as the CME content and not interleaved between computer ‘windows’ or screens of the CME content. (Supplemented February 2014; the information that follows previously appeared in ACCME policies. No changes have been made to the language.) Also, ACCME-accredited providers may not place their CME activities on a Web site owned or controlled by a commercial interest. 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. Advertising of any type is prohibited within the educational content of CME activities on the Internet including, but not limited to, banner ads, subliminal ads, and pop-up window ads. For computer based CME activities, advertisements and promotional materials may not be visible on the screen at the same time as the CME content and not interleaved between computer windows or screens of the CME content. For audio and video recording, advertisements and promotional materials will not be included within the CME. There will be no ‘commercial breaks.’ For live, face-to-face CME, advertisements and promotional materials cannot be displayed or distributed in the educational space immediately before, during, or after a CME activity. Providers cannot allow representatives of Commercial Interests to engage in sales or promotional activities while in the space or place of the CME activity. (Supplemented, February 2014; the information that follows previously appeared in ACCME policies. No changes have been made to the language.) For Journal-based CME, None of the elements of journal-based CME can contain any advertising or product group messages of commercial interests. The learner must not encounter advertising within the pages of the article or within the pages of the related questions or evaluation materials.

STANDARD 4.3 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.

STANDARD 4.4 Print or electronic information distributed about the non-CME elements of a CME activity that are not directly related to the transfer of education to the learner, such as schedules and content descriptions, may include product-promotion material or product-specific advertisement.

STANDARD 4.5 A provider cannot use a commercial interest as the agent providing a CME activity to learners, e.g., distribution of self-study CME activities or arranging for electronic access to CME activities.

Standard 5: Content and Format without Commercial Bias

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

STANDARD 5.2 Presentations must give a balanced view of therapeutic options. Use of generic names will contribute to this impartiality. If the CME educational material or content includes trade names, where available trade names from several companies should be used, not just trade names from a single company.

Standard 6: Disclosures Relevant to Potential Commercial Bias

STANDARD 6.1 An individual must disclose to learners any relevant financial relationship(s), to include the following information: The name of the individual; The name of the commercial interest(s); The nature of the relationship the person has with each commercial interest.

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

STANDARD 6.3 The source of all support from commercial interests must be disclosed to learners. When commercial support is “in-kind” the nature of the support must be disclosed to learners.

STANDARD 6.4 ‘Disclosure’ must never include the use of a corporate logo, trade name or a product-group message of an ACCME-defined commercial interest.

STANDARD 6.5 A provider must disclose the above information to learners prior to the beginning of the educational activity.
EXHIBIT/SPONSORSHIP FORM

Program Title ____________________________________________

Date ____________________________________________________________________________

Course Director ________________________________________________________________

Company Name __________________________________________________________________

Contact Person ___________________________________________________________________

Telephone __________________ Fax _______ Email ________________________________

Mailing Address ___________________________________________________________________

City __________________________________ State ___________ Zip ____________

Exhibit/Sponsor AMOUNT (or describe in-kind value) ____________________________

THE SUPPORTER WISHES TO PROVIDE SPONSORSHIP FOR:

☐ Exhibit Space or ☐ Sponsorship

Exhibit/Sponsor AMOUNT (or describe in-kind value) ____________________________

If exhibiting, will you require an electrical outlet?  Yes ☐ No ☐

2 Ways to Pay

1. Prepare a check made payable to UofL CME & PD and mail to CME & PD Med Center One, 501 E. Broadway Suite 370, Louisville, KY 40202

2. Provide your credit card information on this form and MAIL it to CME & PD Med Center One, 501 E. Broadway Suite 370, Louisville, KY 40202 or FAX to (502) 852-6300

Note: DO NOT SEND BY EMAIL. This information cannot be received by email to remain in compliance with University PCI DSS policy.

Please charge to my _____ MasterCard _____ VISA

Name as it appears on your card (please print)

Card Number ____________________________

Expiration Date _______________________

I understand that if I reserve exhibit space and do not show to claim such space, the exhibit fee is not waived and is due and payable to the University of Louisville or program planning department/org.
LETTER OF AGREEMENT

The following LOA template may be used in establishing an understanding of the use of funds designated as an educational grant. If the grantor prefers to utilize their own document, the University of Louisville reserves the right to review and amend that document to ensure that the legal protection and rights of the University are provided for. This document must be signed by the grantor and the University of Louisville Research Foundation, Inc. (the CME provider).

COMMERCIAL INTEREST NAME: ____________________________

COMMERCIAL INTEREST CONTACT PERSON: ____________________________

ADDRESS: ______________________________________________________

CITY: ______________ STATE: ________ ZIP: __________

TELEPHONE: ____________________________ FAX: ____________________________

EMAIL: ______________________________________________________

TITLE OF COURSE: __________________________________________

DATE(S): __________________________________________

LOCATION: __________________________________________

THE ABOVE COMMERCIAL INTEREST WISHES TO PROVIDE SUPPORT FOR THE NAMED CONTINUING MEDICAL EDUCATION COURSE BY MEANS OF:

AN EDUCATIONAL GRANT FOR SUPPORT OF THE COURSE THE AMOUNT OF: $ __________ TO BE USED FOR THE ABOVE STATED CME ACTIVITY.

Grantor ("Commercial Interest"):

____________________________________

Signature:

Name:

Title:

Date:

Accredited Educational Provider:

University of Louisville Research Foundation Inc.
CONDITIONS OF AN EDUCATIONAL GRANT

1. **Statement of purpose**: The CME program is for scientific and educational purposes only and will not promote the Commercial Interest’s products, directly or indirectly.

2. **Control of content, selection of presenters, etc.**: The Accredited Provider is responsible for all decisions regarding activity content, selection of presenters, moderators, needs assessment, determination of objectives and outcomes, methods, materials, delivery, budget and evaluation of the activity independent of commercial influence.

3. **Disclosure of financial relationships**: The Accredited Provider will ensure disclosure to the audience of: (a) commercial support/funding; (b) any relevant financial relationships between the Accredited Provider and the Commercial Interest or any relevant financial relationships between the individual speakers, moderators or the Commercial Interest. The Accredited Provider will ensure that the source of support from the Commercial Interest, either direct or “in kind”, is disclosed to the participants in program brochures, syllabi, and other program materials distributed to participants. This disclosure will not include the use of a trade name or product-group message. The acknowledgement of commercial support may state the name of the Commercial Interest, but may not include logos or slogans.

4. **Involvement in content**: There will be no “scripting”, emphasis, or influence on content by the Commercial Interest or its agents.

5. **Ancillary promotional activities**: No promotional activities will be permitted in the same room or near the educational activity. No product advertisements will be permitted in the educational activity room.

6. **Objectivity and balance**: The Accredited Provider will make every effort to ensure that data regarding the company’s products (or competing products) are objectively selected and presented, with favorable and unfavorable information and balanced discussion of prevailing information on the product(s) and/or alternative treatments.

7. **Limitations of data**: The Accredited Provider will ensure, to the extent possible, disclosure of limitations of data, e.g., ongoing research, interim analyses, preliminary data, or unsupported opinion.
8. Opportunities for debate: The Accredited Provider will ensure opportunities for questioning or scientific debate.

10. Independence of Accredited Provider in the use of contributed funds:
   a. Funds should be in the form of an educational grant made payable to University of Louisville Research Foundation, Inc. (Federal I.D. #61-1029626).
   b. Accredited Provider will make all decisions regarding the disposition and disbursement of all support/funding.
   c. All other support associated with this course must be given with the full knowledge and approval of the Continuing Medical Education and Professional Development Office, University of Louisville, School of Medicine.
   d. The Commercial Interest in no way will attempt to directly (SCS5a) or indirectly (SCS5b) control the planning or content development of the activity.
   e. No other funds from the Commercial Interest will be used to pay the program director, planning committee members, faculty, additional honoraria, extra social events, non-presenting attendees, or others involved with this course.
   f. Social events or meals at the CME activities cannot compete with or take precedence over the educational events.

11. No Commercial Supporter Endorsements: In no event shall the commercial supporter (or its successors, employees, agents and contractors) state or imply in any publication, advertisement, or other medium that Accredited Provider has tested, approved, or endorsed any Commercial Interest product. Commercial Interest agrees not to use the name, logo, or any other marks (including, but not limited to, colors and music) owned by or associated with Accredited Provider or the name of any representative of the Accredited Provider in any sales promotion work or advertising, or any form of publicity, without the prior written permission of the Accredited Provider in each instance.

12. Commercial Promotion: Product-promotion material or product-specific advertisement of any type is prohibited in or during the CME activity. The juxtaposition of editorial and advertising material on the same products or subjects is not allowed.) Live or enduring promotional activities must be kept separate from the CME activity. Promotional materials cannot be displayed or distributed in the education space immediately before, during or after a CME activity. Commercial Interests may not engage in sales or promotional activities while in the space or place of the CME activity.

13. The Commercial Interest agrees to: abide by abide by all requirements of the ACCME Standards for Commercial Support

14. The Accredited Provider agrees to: (1) abide by all requirements of the ACCME Standards for Commercial Support, (2) acknowledge educational support from the Commercial Interest in program materials, and (3) upon request, furnish the Commercial Interest a report concerning the expenditure of the funds provided.

15. No party shall be liable to any other for lost profits, or any other special, indirect or consequential damages of any kind. Notwithstanding the foregoing, Commercial Interest recognizes and acknowledges that in reliance on Commercial Interest’s commitment to provide funding, Accredited Provider may undertake financial commitments through agreements with third parties to provide services in connection with the program. In the event of Commercial Interest’s breach of this Agreement by, among other things, failing to provide funding, Commercial Interest shall be responsible for Accredited Provider’s direct damages, which shall include, but not be limited to, claims for payment by third parties.

UofL CME&PD
MedCenter One
501 E. Broadway, Suite 370
Louisville, KY 40202
Telephone: 502-852-5329 Fax: 502-852-6300 E-mail: cmepd@louisville.edu
TERMS, CONDITIONS AND PURPOSE OF COMMERCIAL SUPPORT

Disbursement of Commercial Support
1) The CME & PD will make all decisions regarding the disposition and disbursement of commercial support for all CME educational activities.
2) The CME & PD will not accept advice or services from a commercial interest concerning teachers, authors, or participants as a condition for receiving funds or services.
3) The CME & PD will not accept advice or services concerning education matters or content for a CME activity as a condition for receiving funds or services.
4) Full knowledge and approval is required by the CME & PD before commercial support can be provided for a CME & PD/CME activity.

Written agreement documenting terms of support
5) The CME & PD Letter of Agreement (LOA) delineates the terms, conditions and purpose of the commercial support.
6) The Letter of Agreement must be between the commercial supporter, the CME & PD and the educational partner or joint provider.
7) Commercial support may be disbursed to the CME & PD, educational partner or a joint sponsor with approval from the CME & PD.
8) The CME & PD Letter of Agreement specifies the commercial interest that is the source of commercial support.
9) The CME & PD, its educational partner or joint provider may use the commercial supporter’s letter of agreement as long as the LOA is between the commercial support, the CME & PD and the educational partner or joint sponsor, and the LOA adheres to the CME & PD and ACCME Standards for Commercial Support™, and it is reviewed and signed by the CME & PD prior to acceptance.
10) Both the commercial supporter and the CME & PD must sign the Letter of Agreement. The signature of the educational partner or joint provider is optional.

Commercial Support Usage and Accountability
11) The CME & PD or its educational partner must not use commercial support to pay for travel, lodging, honoraria, or personal expenses for non-teacher or non-author participants of a CME activity.
12) The CME & PD or its educational partner may use commercial support to pay for travel, lodging, honoraria, or personal expenses for bona fide employees and volunteers of the CME & PD and its educational partner.
13) Social events or meals at a CME & PD educational activity cannot compete with or take precedence over the educational activity.
14) The CME & PD must produce accurate documentation of all expenses and income for an educational activity that receives commercial support.
15) If an educational partner has approval from the CME & PD to receive the commercial support, they must provide the CME & PD accurate documentation and a financial wrap-up of income and expenses.
16) Commercial and in-kind support must be disclosed to learners prior to an educational activity.
17) A commercial interest cannot take the role of a non-accredited partner in a joint sponsorship relationship.
COMMERCIAL SUPPORT
BUDGET WORKSHEET / FINANCIAL WRAP-UP

Documentation of receipt and expenditure of all forms of commercial support including honoraria, speaker expense reimbursement, catering expenses and all other program-related expenses must be included in the Budget Worksheet and submitted to the CME & PD office along with the Report Form within one week of each of the RSS sessions.

Name of Department/Program:

Title of the RSS Session Presentation:

RSS Session Date:

<table>
<thead>
<tr>
<th>ITEM</th>
<th>AMOUNT</th>
</tr>
</thead>
<tbody>
<tr>
<td>Catering and Site Arrangements</td>
<td></td>
</tr>
<tr>
<td>Faculty/Speaker/Moderator Honorarium</td>
<td></td>
</tr>
<tr>
<td>Faculty/Speaker/Moderator Travel</td>
<td></td>
</tr>
<tr>
<td>Source(s) and Income for this RSS Session</td>
<td></td>
</tr>
<tr>
<td>Name of Company: _______________________</td>
<td></td>
</tr>
<tr>
<td>Other Expenses</td>
<td></td>
</tr>
<tr>
<td><em>(Please list and provide amount.)</em></td>
<td></td>
</tr>
</tbody>
</table>
EXHIBIT SPONSORSHIP
BUDGET WORKSHEET / FINANCIAL WRAP-UP

Documentation of receipt and expenditure of all forms of support including faculty/speaker/moderator honorarium, travel expenses, catering expenses and all other program-related expenses must be included in the Budget Worksheet and submitted to the CME & PD office along with the Report Form within one month of each of the RSS sessions.

Name of Department/Program:

Title of the RSS Session Presentation:

RSS Session Date:

<table>
<thead>
<tr>
<th>ITEM</th>
<th>AMOUNT</th>
</tr>
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<tbody>
<tr>
<td>Catering and Site Arrangements</td>
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</tr>
<tr>
<td>Source(s) and Income for this RSS Session</td>
<td></td>
</tr>
<tr>
<td>Name of Company: __________________________</td>
<td></td>
</tr>
</tbody>
</table>

Source(s) and Income for this RSS Session

Name of Company: __________________________________

Other Expenses

(Please list and provide amount.)
“Must-Haves” for Welcome Letter

The RSS Coordinator is responsible for creating a Welcome Letter for each RSS session, and that letter must have certain elements in order to meet ACCME criteria and guidelines. Following is a contents listing of those required elements, and example templates are provided. Remember, you are a “provider” if you are a University of Louisville department; you are a “joint provider” if you are an organization outside of the University of Louisville.

- Name of the Organization/Department/Division/Office
- Date, Start and End Times and Title of the Course
- Location of the RSS
- Name, Title and Affiliation of the Course Speaker(s)
- Overall Learning Objectives for This RSS Session
- At Least One Learning Objective for Each Topic Presented

A learning objective states a specific, measurable task and behavioral change that the physician will be able to perform as a result of attending the CME presentation. The three essential elements of learning objectives are a statement of who (the learner), how (the action verb) and what (the content) such as:

<table>
<thead>
<tr>
<th>WHO</th>
<th>HOW</th>
<th>WHAT</th>
</tr>
</thead>
<tbody>
<tr>
<td>The learner will be</td>
<td>to list</td>
<td>three factors to consider in prescribing XYZ medication.</td>
</tr>
<tr>
<td>able</td>
<td></td>
<td></td>
</tr>
<tr>
<td>The participants will</td>
<td>to identify</td>
<td>the psychosocial factors important in the development of a crisis</td>
</tr>
<tr>
<td>be able</td>
<td></td>
<td>intervention plan.</td>
</tr>
<tr>
<td>The physician will</td>
<td>to explain</td>
<td>the dangers of using ABC medication in children under the age of eight</td>
</tr>
<tr>
<td>be able</td>
<td></td>
<td>years old.</td>
</tr>
</tbody>
</table>

- Target Audience

Accreditation Statements *(Please use one only of the two below.)*

- U of L Direct Providership Accreditation Statement
The University of Louisville School of Medicine is accredited by the Accreditation Council for Continuing Medical Education to provide continuing medical education for physicians.

**Jointly Provided Accreditation Statement**
*(Organizations outside of U of L -- Jewish Hospital, Sts. Mary and Elizabeth Hospital, KCPC, VA, Ireland Army Hospital, Humana, Lourdes Hospital, Taylor Regional Hospital)*

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 Louisville School of Medicine and *[insert your company name here]*. The University of Louisville School of Medicine is accredited by the ACCME to provide continuing medical education for physicians.

**Designation Statement**

The University of Louisville School of Medicine designates this “live activity” for a maximum of *[insert number here]* AMA PRA Category 1 Credit(s)™. Physicians should only claim credit commensurate with the extent of their participation in the activity. *(Please note that the phrase AMA PRA Category 1 Credit(s)™ is in italics, and the trademark symbol, ™, should appear following the phrase.)*

**Special Services Statement**

To request disability arrangements, call *[insert telephone number here]* at least 10 days prior to the program. The University of Louisville School of Medicine fully complies with the legal requirements of the ADA and the rules and regulations thereof.

**Acknowledgement of Commercial Support** *(Please use one only.)*

a. No commercial support was provided for this RSS session.

**OR**

b. This activity is supported by an educational grant from *[Insert company name here]*.

**Disclosure to Audience** *(Please see Welcome Letter samples in this RSS Manual.)*

Must include disclosures for all planners/managers, content reviewers and faculty/presenters

**Nursing Statement** *(Only include this statement if you receive nursing credit through University of Louisville Hospital.)*

This program has been approved by the Kentucky Board of Nursing for *[insert number here]* continuing education credits through University of Louisville Hospital, provider number 4-0068-7-18-???. The Kentucky Board of Nursing approval of an individual nursing education provider does not constitute endorsement of program content.
Welcome to the
Fun Community Hospital RSS Grand Rounds

Monday, August 4, 2017
Fun Community Hospital / Classroom A
1234 Any Street
Any City, KY 40121

Agenda:
7:00 a.m. Registration
7:05 a.m. – 8:05 a.m. “Welcome To Joyful Medicine”
8:05 a.m. Evaluation and Adjourn

Guest Faculty: Dr. Feel Better – Associate Professor, Department of Happiness, University of Louisville School of Medicine.

Objective(s):
Insert Learning Objective Here
Insert Learning Objective Here

Target Audience: Family practice physicians, pediatricians and all other interested health care professionals.

Accreditation Statement: The University of Louisville School of Medicine is accredited by the Accreditation Council for Continuing Medical Education to provide continuing medical education for physicians.

Designation Statement: The University of Louisville School of Medicine designates this live activity for a maximum of ?AMA PRA Category 1 Credit(s)™. Physicians should only claim credit commensurate with the extent of their participation in the activity.

Special Services: To request disability arrangements, call 555-5555 at least 10 days prior to the program. The University of Louisville School of Medicine fully complies with the legal requirements of the ADA and the rules and regulations thereof.

Disclosures:

<table>
<thead>
<tr>
<th>Name / RSS Role Today</th>
<th>Commercial Entity with Whom There is a Relevant Financial Relationship (Or None)</th>
<th>Nature of Relevant Financial Relationship with Commercial Entity (Speaker, Consultant, etc.)</th>
<th>Relevant Financial Relationship Conflict Resolved (Content Was Peer Reviewed and Determined to be Fair and Balanced and Without Commercial Bias)</th>
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<td>Dr. Karen Doe - Planning Committee Member</td>
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The University of Louisville CME and PD office staff and Advisory Board have nothing to disclose.

No commercial support was provided for this RSS activity.
Welcome to the
Fun Hospital Journal Club

Monday, August 4, 2017
Fun Hospital / Conference Room A, MedCenter One Building, University of Louisville School of Medicine

Agenda:
7:00 a.m. Registration
7:05 a.m. – 8:05 a.m. “Welcome to Joyful Medicine”
8:05 a.m. Evaluation and Adjourn

Guest Faculty: Dr. Feel Better – Associate Professor, Department of Happiness, University of Louisville School of Medicine.

Objective(s):
Insert Learning Objective Here
Insert Learning Objective Here

Target Audience: Family practice physicians, pediatricians and all other interested health care professionals.

Accreditation Statement: 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 Louisville School of Medicine and Fun Community Hospital. The University of Louisville School of Medicine is accredited by the ACCME to provide continuing medical education for physicians.

Designation Statement: The University of Louisville School of Medicine designates this live activity for a maximum of ?AMA PRA Category 1 Credit(s)™. Physicians should only claim credit commensurate with the extent of their participation in the activity.

Special Services: To request disability arrangements, call 555-5555 at least 10 days prior to the program. The University of Louisville School of Medicine fully complies with the legal requirements of the ADA and the rules and regulations thereof.

Disclosures:

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The University of Louisville CME and PD office staff and Advisory Board have nothing to disclose.

The Fun Hospital gratefully acknowledges ABC Company for providing a non-restricted educational grant in support of this RSS activity.
Sample Evaluation Form

Name of Department:

Title of the RSS Session Presentation:

RSS Session Date:

Speaker(s):

Do you think this session helped in changing your knowledge and competence?

__ NO  __ YES

If this session changed your knowledge and competence, please explain how:

______________________________________________________________

______________________________________________________________

What topics do you want to hear more about, and what issues in your practice will these topics address?

______________________________________________________________

______________________________________________________________

______________________________________________________________

Did you perceive any commercial bias in this presentation?

__ NO

If yes, please briefly explain below.

______________________________________________________________

______________________________________________________________

______________________________________________________________
TABULATION SUMMARY OF EVALUATIONS
To Be Submitted with the RSS Report Form

Name of Department:

Title of the RSS Session Presentation:

RSS Session Date:

Speaker (If Applicable):

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<th>Do you think this session helped in changing your knowledge and competence?</th>
<th>Did you perceive any commercial bias in this presentation?</th>
<th>Comment from RSS Coordinator to CME &amp; PD Office</th>
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### RSS Guest Attendance Sheet

**To Be Submitted With RSS Report Form**

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RSS SESSION REPORT FORM

RSS Program Name: ________________________________

Title of this RSS Session Presentation: ________________________________

RSS Session Date: ________________________________

Speaker(s) Name/Affiliation:

______________________________________________________________

Number of AMA PRA Category 1 Credit(s)™ for this session

______________________________________________________________

Number of new guest MDs/DOs. (If applicable, include Guest Attendance Sheet form provided.)

______________________________________________________________

Total number of fellows and residents

______________________________________________________________

Total number of students, DMDs, PhDs, nurses & others

PROVIDE THE FOLLOWING: (Please do not turn in this report unless everything listed below is included.)

_______ A copy of your Welcome Letter for this session.

_______ A signed copy of a Disclosure Form for each speaker. (Use form provided.)

_______ Content Review Form – completed by course director if COI for speaker is identified. (Use form provided.)

_______ A signed copy of a Disclosure Form for each COI peer reviewer (if slides were reviewed.)

_______ A completed Tabulated Summary of Evaluations form. (Use form provided.)

_______ An annual Disclosure Form for each planner/manager/course director/coordinator.

_______ Speaker/Presenter/Moderator CV if Nursing CEUs are provided by University of Louisville Hospital.

COMPLETE THE FOLLOWING ITEMS ONLY IF FUNDING WAS PROVIDED FROM AN EXTERNAL SOURCE SUCH AS A MEDICAL PRODUCTS OR PHARMACEUTICAL COMPANY

_______ Letter of Agreement and/or Exhibit/Commercial Sponsor Form – if applicable. Please provide a completed and signed Exhibit/Sponsor Form to be submitted along with the Budget Worksheet documenting the income received and expended if any funding was provided for this session. Document that your department paid the honorarium and travel expenses directly to the speaker. (No commercial company is allowed to pay honorarium and expenses directly to a speaker.)

Report Submitted By: ________________________________ Telephone: ________________________________
University of Louisville School of Medicine

Instructions to Create a Profile for U of L’s CME Programs

- To create your profile, please go to http://louisville.edu/medicine/cme and click on the “Your CME Transcript” button. You will then be directed to the CME Transcript Sign-In page.

- Click on the “My Profile” tab.

- Enter your e-mail address and click on the “I am a new user” radio button. (Note: you will create your password later.)

- You will be directed to a new page that will request your last name and cell phone number. (This information is necessary to retrieve and unify your credit information from a prior CME data base.)

- Click the red “Continue” button.

- You will be directed to an On-Line Registration Profile page. Complete this page. (This is the page on which you will create your personal password. Please be sure to do so before leaving this page and make note of your password for future reference. Note: Please use only your cell phone number, and document your username and password for future use as you will need this information each time you retrieve your transcript. Note: always use the same cell phone to register for credit. If you lose or get a new cell phone, please update your profile with your new cell phone number. A land line number will not get your future CME credits registered.)

- Click the red “Continue” button.

- This will route you back to the CME Profile. You will now have a valid password and can access your on-line transcript at any time.

Any problems or questions? Please contact Karen Napoliilli

502-852-5329 / knapo01@louisville.edu
University of Louisville School of Medicine

Transcript Retrieval

To retrieve your transcript, please go to http://louisville.edu/medicine/cme and click on the “Your CME Transcript” button. You will then be directed to the CME Sign-In page.

Enter your e-mail address and click on the “I am a new user” radio button. (Note: you will create your password later.)

Enter a begin date and end date for your transcript results.

Click on the red Sign-In button. This will take you to a new page on which you will create your profile. (Note: Please be sure that your browser is set to allow for pop ups.)

You will be directed to a new page that will request your last name and cell phone number. (This information is necessary to retrieve and unify your credit information from the prior CME & PD data base.)

Click the red “Continue” button.

You will be directed to an On-Line Registration Profile page. Complete this page. (This is the page on which you will create your personal password. Please be sure to do so before leaving this page and make note of your password for future reference. Note: Please use only your cell phone number. A land line number will not get your future CME credits registered.)

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This will route you back to the CME Transcript retrieval page. You will now have a valid password and can access your on-line transcript at any time.

Any problems or questions?
Karen Napoli
502-852-5329 / kinap001@louisville.edu
Julian Calendar

Day-of-Year Table for Non-Leap Years

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