The ABCs of RSCs

Todd Dorman
Patricia Bowman
Carlita Kearney
Anita Beyer
Jeanne Ryan
No Relevant Financial Relationships with Commercial Interests

Dr Todd Dorman
Patricia Bowman
Carlita Kearney
Anita Beyer
Jeanne Ryan
Overall Approach

• Keep as much the same as possible
• Improve what has to be improved to meet accreditation standards
• Make process transparent
• Train, train, train
• Enhance system as we go!
Major Alterations

• Application
  – Submission timeline
  – Documentation of 3 recent needs are required
  – Planner disclosures
  – NIH Cmte followed by Hopkins Advisory Board review

• Marketing rules and reviews
• Elimination of post-activity web site
• E*Value
Continuing Medical Education

Welcome

Continuing Medical Education (CME) activities offered by NIH are now jointly sponsored in partnership with The Johns Hopkins University School of Medicine. CME activity directors will continue to develop programs that meet the needs of NIH’s unique community. The Johns Hopkins Office of Continuing Medical Education, which is accredited by the Accreditation Council for Continuing Medical Education, will work with NIH’s CME activity directors to assure compliance with accreditation guidelines through all phases from program application to post-program documentation.

* To view the calendar of CME activities, your credits, and to obtain printed transcripts, go to NIH CME website at https://www.nihandhospitals.cme.org. CME credit for the NIH programs will be awarded by The Johns Hopkins University School of Medicine.

If you have questions about CME at NIH, contact Accreditation and Compliance in the Office of Continuing Medical Education at Johns Hopkins:

* Email: accreditationandcompliance@jhmi.edu
* Phone: 410-955-6085 or 410-944-8813
* Fax: 1-866-480-2456.
Welcome to CME Online

The Johns Hopkins University School of Medicine is the accredited provider for NIH CME activities as of March 1, 2008.

If you would like to learn more about the Johns Hopkins University School of Medicine Office of Continuing Medical Education, please visit http://www.hopkinscme.edu

- Submit an Application
  If you are already an NIH CME Activity Director, just Login at left, to be taken to your Activity Director home page.

  If you are new to the CME program, please visit the CME Activity Information Page for more information.

- Submit an Attendance Roster:
  1. Download the Attendance Roster worksheet (.xls)
  2. Email the completed spreadsheet to the CME Office

- Calendar of CME Activities

- View Your CME Credits or Obtain a Transcript
  Click the "My CME Reports" tab at left and login to view your personal CME records. (More Info)

- Contact Us:
  If you have a question about accreditation, please call 410.955.2959 or email us at accreditationsandcompliance@jhu.edu

  If you need CME Tech support, please call 410.955.7932 or email CMEtechSupport@jhu.edu

  If you would like to speak to the NIH CME contact, please call 301.496.9425 or email cc_od_ocrne_cme@mail.nih.gov

Please note that the site is still under development. Any feedback would be appreciated. Feedback.
Your Number One Resource for CME

Welcome to our new website!
Our enhancements will hopefully better serve your needs. A profile is not required to access standard information regarding our office, its practices or offered activities, but we strongly recommend you create a profile whether you are a registrant or active faculty as this will expand the services available to you. Please peruse the site and let us know what you think.
Send to a Colleague

Course Highlights

March 24, 2007
07-551005: Fourth Annual Cardiac CT: CTA and Myocardial Perfusion Beyond 64 Slice
Ernest N. Morial Convention Center
New Orleans, LA

June 15-16, 2007
07-550979: Annual American Conference on Pain Medicine
New York Marriott Marquis
New York, NY

November 1, 2006 - October 31, 2007
07-550959: Influenza Educational Initiative
Multiple Locations

July 1, 2006 - June 30, 2007
07-530232: Cardiac CT Practicum
Johns Hopkins Bayview
Baltimore, MD

March 24, 2007
80016986: AC8 & Biomarkers: From Molecules to Clinical Management

Contact Info
General Info: 410.955.2959
Mailing Address:
Johns Hopkins University School of Medicine
RSC Support Material

Sample Disclosure Slides (PPT)
The ABCs of RSCs (PDF)
Writing Better Objectives (PDF)
Educational Needs Assessment (PDF)
Approved RSCs (Excel)
RSC Sign Sheet Process
RSC FAQ
Required Record-keeping Documents (PPT)

If you have questions or need further information concerning RSCs and CME, please contact:
Trish Bowman
RSC Compliance Specialist
(410)955-3168
tbowman@jhmi.edu
Goals

• Define RSCs
• Application process
  – Administrative issues
  – Application components
• Record keeping
  – Planning notes
  – Overall objectives communication
  – Lecture objective(s) communication
  – Activity announcements or marketing material
  – Disclosure forms and public release
  – Letters of agreement/acknowledgement of support
  – Summary budgets
  – Evaluations / Outcomes
  – CVs of all speakers
  – Sign-in lists
  – Final list of speakers/topics
  – Post-activity materials
• CME tracking
• Marketing
• Services/support/monitoring
• Q&A
Regularly Schedule Conferences

• Definition
  – Educational activities that occur on a recurring basis within a defined year aimed primarily at NIH faculty

• Examples
  – M&M
  – Case Conference
  – Tumor Board
  – Grand Rounds
Application: Admin

• Accreditation cycle
  – 1 year
  – Records submitted every 2 months

• Dates
  – Mar 1 to Feb 28, 2009
  – Plan to submit 3-4 months in advance of expiration
  – All activities that were submitted previously and that started before Mar 1 and are planned to continue beyond Mar 1 are being processed
Application Components

- Administrative data fields
- Needs
- Objectives
- Instructional design/methods
- Results/evaluations
- Director/planner disclosures

- Also let us know if attendees include groups other than physicians
Statement of Need

• Statement of need is the overall need for the educational activity that relates to the target audience and derived from the Needs Assessment

• Educational needs provide the reason for offering CME activities. They may imply a deficit in knowledge, skills, attitudes and/or behavior among prospective participants
Sample Statement of Need

- Rheumatic diseases are common in the population, and are causes of significant morbidity. The diseases are complex, and in many cases, pathogenesis remains incompletely understood. Furthermore, knowledge about the mechanisms, diagnosis and therapies of rheumatic diseases continues to evolve rapidly, making ongoing educational updates essential for state-of-the-art practice of this discipline. This activity is designed to provide both theoretical and practical information to clinicians and healthcare professionals who care for patients with the rheumatic diseases, and to offer practical and effective guidelines to understanding and managing these diseases and syndromes.
Needs

The ACCME requires each provider to use needs assessment data to plan CME activities.

- What sources/data did you use to identify your intended audience’s educational needs for your activity
- Summarize the type(s) of data and how you incorporated that data into the planning of your CME activity
- Three separate needs assessments are required for all activities and they must be recent (within 24 months of application submission)
Why is it necessary to collect Needs Assessments?

- To determine what training is relevant
- To determine what training will improve performance
- To determine if training will make a difference
- To distinguish training needs from organizational problems
- To link improved performance with the organization’s goals and bottom line
Needs

• A decision-aiding tool for activity planning and evaluation
• A systematic set of procedures for setting priorities and making decisions
• A total decision-making process in which data are but one component
• A process that looks at the problem at hand from many perspectives

<table>
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<tr>
<th>Expert</th>
<th>Participant</th>
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<th>Environmental Screening</th>
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<td>Focus panel</td>
<td>Clinical observation</td>
<td>Lay Press</td>
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<td>M&amp;M</td>
<td>Direct to consumer ads</td>
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<td>Requests</td>
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Needs Linkages

- Identified needs
- Objectives
- Desired results
- Instructional design (methods)
Objectives

- The provider must communicate the purpose or objectives of the activity so the learner is informed before participating in the activity.

- Purpose or objectives of the activity express learning outcomes in terms of physician performance or patient health (i.e. in behavioral terms), and are communicated clearly and consistently to the learner.
Objectives

• All activities require objectives
  – For open discussion-based activities (i.e. M&M, Case conference) objectives for the year are adequate
  – For lecture-based activities (i.e. Grand Rounds) objectives for the year are required as part of the application and then a minimum of a single objective per lecture is also required
Communication Before Activity

• Series Objectives (e.g. those listed in application) shall be sent to all faculty via email with OCME cc’d

• Specific lecture objective (e.g. Grand Rounds) must be communicated to all learners in advance. Commonly this is accomplished by prominently displaying in learner environment
  – A slide could be displayed as people enter
  – An initial slide within speaker lecture
  – A print version placed with sign-in sheets/electronic system
  – A poster or sign on doors/at entry into room

• Documentation of these communications is required
  – This is a commonly missed step!
Writing Better Objectives
Definition

• Goal
  – Broad statement of purpose
  – The aim of the activity

• Objective
  – Clear statement of anticipated results
  – Focus primarily on what participants will do/learn as a result of attending the activity
  – Best when measurable
Components of High Quality Objectives

• Condition
  – Commonly a disease, state, process, step
• Behavioral verbs
  – Tells what is expected from the learner
• Published standard
  – Allows performance to be measured against some standard
Examples

• Goal
  – Improved behavior management in patients with dementia

• Objective
  After attending this activity, the participant should be able to-
  – Design treatment strategies based upon nationally published guidelines that improve behavior management in patients with dementia
  – According to NIH guidelines, select an appropriate treatment option for mood stabilization in a patient with dementia
Importance of Words

• Some verbs are better than others
• Those that relate to specific actions or behaviors are critical
Unacceptable Words

- Know, learn, understand, improve, increase
- Think critically, really know, expand horizons, appreciate, grow

- These words should be rarely if ever used as they are not measurable and are viewed as unacceptable words by the ACCME
Effective Words

• Involve cognitive outcome domains
  – Knowledge, application, synthesis, evaluation
• Involve affective outcome domains
  – Receiving, responding, valuing
• Involve psychomotor outcome domains
  – Perception, adaptation, origination

Bloom’s Taxonomy
Example of Effective Learning Objectives

After attending this activity, the participant should be able to-

• Outline the current clinical practice for the treatment of primary and metastatic brain and spinal cord tumors in adults and children
• Discuss the process of translating laboratory research into clinical trials for patients with malignant gliomas
• Describe current advances in molecular biology, immune therapy, stem cell therapeutics and drug delivery systems for brain tumors
• Review challenges caregivers face in caring for patients with brain tumors
• Identify quality of life issues for patients with brain tumors and the effectiveness of measurement tools
### Behavioral Verbs: Cognitive

<table>
<thead>
<tr>
<th>Knowledge</th>
<th>Comprehension</th>
<th>Application</th>
<th>Analysis</th>
<th>Synthesis</th>
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<td>Diagnose</td>
<td>Evaluate</td>
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<td>Describe</td>
<td>Demonstrate</td>
<td>Analyze</td>
<td>Propose</td>
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<td>Explain</td>
<td>Illustrate</td>
<td>Compare</td>
<td>Design</td>
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<td>Identify</td>
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<td>Contrast</td>
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<td>Judge</td>
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<td>Recognize</td>
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<td>Categorize</td>
<td>Summarize</td>
<td>Rate</td>
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<td>Appraise</td>
<td>Plan</td>
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<td>Use</td>
<td>Classify</td>
<td>Formulate</td>
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<td>Convert</td>
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<td>Estimate</td>
<td>Predict</td>
<td>Differentiate</td>
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## Behavioral Verbs: Affective

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<tr>
<th>Receiving</th>
<th>Responding</th>
<th>Valuing</th>
<th>Organization</th>
<th>Value Complex</th>
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<td>Join</td>
<td>Adhere</td>
<td>Act</td>
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<td>Reply</td>
<td>Greet</td>
<td>Share</td>
<td>Integrate</td>
<td>Practice</td>
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<td>Accept</td>
<td>Read</td>
<td>Complete</td>
<td>Organize</td>
<td>Discriminate</td>
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<td>Show</td>
<td>Report</td>
<td>Follow</td>
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<td>Influence</td>
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<td>Perception</td>
<td>Set</td>
<td>Guided response</td>
<td>Mechanism</td>
<td>Complex</td>
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<td>Identify</td>
<td>React</td>
<td>Display</td>
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<td>Detect</td>
<td>Respond</td>
<td>Manipulate</td>
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<td>Differentiate</td>
<td>Start</td>
<td>Work</td>
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<td>Perform</td>
<td>Perform</td>
<td>Operate</td>
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</tbody>
</table>
Cognitive Pyramid

Knowledge

Comprehension

Application

Analysis

Synthesis

Evaluation

Higher

Lower
Examples

• Given a healthy child, list the routine vaccines for a two year old that are currently recommended by the CDC
• In a simulation of ventricular fibrillation, you will direct a team through appropriate ACLS protocol until the mannequin shows a normal cardiac rhythm
• For your terminally ill patient, successfully defend your position on physician assisted suicide in an ethics committee meeting
Instructional design/methods

- Research has repeatedly shown that learners’ attention and focus are significantly improved by the instructional design and assessment process.
  - If the instruction focuses primarily on the correct identification of factual information, learners will merely direct their time and energy toward the memorization of facts and definitions.
  - On the other hand, if the instruction requires learners to demonstrate a more complex understanding, learners will concentrate their effort on acquiring the relevant skills.
  - This leaves the instructor with the task of implementing measures that accurately reflect the desired educational objectives & outcomes.
Results/evaluations

• The provider **must** evaluate the effectiveness of it’s CME activities in meeting identified educational needs

• Accredited CME activities are to be evaluated consistently for effectiveness in meeting identified educational needs, as measured by practice application and/or health status improvement
  – Ideally evidence is sought for improvement in
    • Competency (knowledge + ability to act)
    • Practice
    • Outcomes
Disclosure

• The activity director(s) and planner(s) must include global disclosure as part of the applications
  – Forms completed, signed, and included
Evaluation Cycle

• Evaluations are **required** for all activities
• They **must be done** on at least a yearly basis and submitted with yearly material
• Ideally they would be done on an activity, monthly or quarterly basis in order to further improve the educational experience for all
2008-2012: New Standards

• Needs
  – Standards of care, gap analysis, barriers

• Objectives
  – Focus on application to practice, competency

• Design
  – Interactive, serial education, contracts to improvement

• Outcomes
  – Serial evaluations, vignette or assertions, pre/post,
  – Certificate based on completion of series
Record Keeping

- Planning notes
- Overall objectives communication
- Lecture objective(s) communication
- Activity Announcements or Marketing Material
- Disclosure forms and public release
- Letters of agreement/Acknowledgment of Support
- Summary budgets
- Evaluations / Outcomes
- CVs of all speakers
- Sign-in lists, electronically submitted on templated Excel spreadsheet
- Final list of speaker/topics (Program)
- Post-Activity Materials

Files must be saved for 6 years
Planning Notes

• As previously discussed, recent needs assessments are required for all activities.
• A planning session is required and is part of the needs assessment process and helps provide evidence of educational intent.
• The planning session also provides an opportunity to establish the linkage between needs, objectives, instructional design, and results/outcomes.
Sign-In Documents

- Every activity must maintain sign-in documents for 6 years
- They will be electronic in MS Excel, you can obtain this spreadsheet at [http://www.nihandhopkinscme.org/](http://www.nihandhopkinscme.org/)
- We must receive in our office after the conclusion of the activity for the year
- Email the spreadsheet to [CMETechSupport@jhmi.edu](mailto:CMETechSupport@jhmi.edu) and we will import the participants and credits into the CME database within two business days
- OCME will inform participants once the transcripts are available to print for the activity
- Certificates will not be printed unless requested by a participant
Sign-in Sheets

- Do not utilize a page with signatures scribbled on it
- If tracking on paper, the name should be typed with a space for a signature next to it
- Check the excel spreadsheets as demographic info is needed
- Either have separate sheets for physicians and they should be labeled as such, or have a check box next to the name
Sample Excel Spreadsheet

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Disclosures

- All speakers **must** sign a disclosure form **before** the lecture begins.
- If the activity is open forum discussion in design, then only the moderator or facilitator must fill out the disclosure form in advance.
- Disclosure must be made to learner in advance of learning. The disclosure form does not suffice.
- A copy of actual disclosure that was made to learners is required in the file (slide, printed sheet, etc).
  - This is a commonly missed component!
LOA’S/FINANCIAL

- When seeking commercial support, an LOA (letter of agreement) must be executed. Signatures are required by the company representative, the activity director, and the Associate Dean for CME.
- Original will be sent to commercial supporter and a copy will be retained for the accreditation file for the RSC.
- Monies **must** come through our office.
- LOAs are required with any and all partners, like a MECC or meeting facilitator.
Food at CME Accredited Events

• A commercial supporter cannot provide food directly or arrange its delivery. Policy requires that an LOA be executed, the funds provided to the provider (CME office budget for RSC) and then the RSC sponsor (the NIH) orders, arranges delivery and pays for the food
  – Dennis Lott, Manager Accreditation, ACCME July 2005
Commercial Support from industry/control on the content of the CME activity (SCS 1.1)

- In past years it may have been acceptable to ask a commercial entity to suggest a speaker or a topic, while the activity still maintained ultimate control. Recently, the accrediting body for CME has changed the regulation.

- CME providers can receive commercial support from industry. CME providers **cannot** receive or request any advice or guidance, either nuanced or direct, on the content of the activity or on who should deliver that content. CME providers must ensure the content of the activity remains beyond the control of any commercial interest.
Evaluations are Required

- Suggest to have 5-10 questions
- Basic core questions to ask:
  - Was content appropriate?
  - Can you name any changes that should be made?
  - Was there any commercial bias? If so, when? By whom?
  - Have you changed your practice based upon the content of this activity? If so, please describe
- Followed by other related questions: topics for further lectures? Are there any topics unclear to you? Etc.
- We are working with E*Value to craft an evaluation system and process
Evaluations

- Each attendee should receive an evaluation to complete
- Course director should review for comments and/or suggestions by attendees
- Course director can use as a planning need for the renewal of the RSC
- Evaluations should be tallied and provided to us in a summary format and this should include all comments and any suggestions for future improvements
Additional Items

• CVs of all speakers
• Final list of speaker and associate topic
  – Simple list of dates, topics and presenters
Lessons from Onsite Monitoring

• Sign-in sheets (paper or electronic)
• Acknowledgement of commercial support
• Objective for that lecture
• Disclosures for speaker

• The last 3 are the most common cause of non-compliance during on-site monitoring
Suggestion

- Collect Disclosure and objectives from speaker
- Obtain our sample slides from web
- Make a disclosure and objective slide for the speaker
- Send these to speaker and have them add to the beginning of talk
- Ask for confirmation that they are received and embedded
Marketing vs Announcement

• Marketing
  – If CME is mentioned at all or it is distributed to non-NIH employees
  – An exception would be the weekly list of NIH activities
    • This can’t mention CME though

• Announcements
  – CME not mentioned anywhere
  – Not distributed to outside employees
Marketing Rules

• All material must include
  – Activity Description
  – Intended audience
  – Objectives
  – Accreditation statement
  – Credit designation statement
    • Cannot say AMA credit applied for or to be announced
  – Policy on speaker and provider disclosure

OCME must review and approve all marketing material in advance of distribution
Accreditation Statement

This activity has been planned and implemented in accordance with the Essential Areas and policies of the Accreditation Council for Continuing Medical Education through the joint sponsorship of The Johns Hopkins University School of Medicine and The National Institutes of Health. The Johns Hopkins University School of Medicine is accredited by the ACCME to provide continuing medical education for physicians.
Credit Designation Statement

The Johns Hopkins University School of Medicine designates this educational activity for a maximum of [number of credits] AMA PRA Category 1 Credit(s)™. Physicians should only claim credit commensurate with the extent of their participation in the activity.
Policy on Speaker and Provider Disclosure

It is the policy of The Johns Hopkins University School of Medicine that the speaker and provider disclose real or apparent conflicts of interest relating to the topics of this educational activity, and also disclose discussions of unlabeled/unapproved uses of drugs or devices during their presentation(s). The Johns Hopkins University School of Medicine OCME has established policies in place that will identify and resolve all conflicts of interest prior to this educational activity. Detailed disclosure will be made in the activity handout materials.

Don’t forget to disclose any CRADAs
Special Circumstances

A "save the date" announcement (such as on a card mailer with limited space) may indicate that AMA PRA credit will be provided without stating the exact amount, but only if the provider (program committee) has already certified the activity for *AMA PRA Category 1 Credit(s)™*. It may read, "This activity has been approved for *AMA PRA Category 1 Credit(s)™*." Providers may not indicate in any brochure or announcement that "AMA PRA credit has been applied for."
ACCME and The Johns Hopkins University School of Medicine Accreditation Policy(ies)

- The Accreditation Council for Continuing Medical Education (ACCME) policies do not permit an accredited activity to be subsequently or in parallel accredited by another organization. The Johns Hopkins University School of Medicine Office of CME has a policy that reflects this regulation.
- In addition, The Johns Hopkins University School of Medicine has a policy in place that states for the Hopkins name or the Hopkins campuses to be utilized for an accredited activity, the Office of CME shall be the accredited provider. If you are contacted by an outside entity please help enforce this policy. If there are questions, then please refer the entity to our offices where they can speak with our accreditation and compliance specialists.
Services/Monitoring

- Accreditation fee for AMA Cat 1 credit
- Yearly training sessions
- Help with applications
- Marketing approval
- Random monitoring
- On site monitoring
- Financial management
- Database management
- CME certificate preparation and distribution
Post-activity Materials Management

- At the conclusion of the activity, the director is responsible for providing this information on the post-activity material website:
  - Budget Information
  - Excel Spreadsheet
  - Final Agenda and Faculty
  - Additional Post-Activity Documents: Record Keeping (an upload link is provided for each document requested. If the document is not in electronic file format, please notify the CME Program office staff and forward it by fax or mail to:

    Johns Hopkins University, CME
    Attn: Accreditation and Compliance
    720 Rutland Avenue, Turner 20
    Baltimore, MD 21205
    Fax: 1-866-480-2456
Lessons from this year reviews

• Files not ready on time
• Disclosure
  ➢ The form is absent
  ➢ The form is not completed in advance
  ➢ Evidence of public disclosure is missing
• Objectives
  ➢ Copy of the email communicating the overall objectives (those listed in the application) to the speakers prior to the activity
  ➢ Grand Rounds - Copy of communication of lecture objective(s) to the learners prior to the activity
• Grant Letter of Agreement / Acknowledgement
  ➢ Letter of agreement not executed
  ➢ Evidence of public release missing
• Evaluations
  ➢ Evaluation tool and summary
• Marketing
  ➢ Regulatory statements absent
  ➢ OCME did not review/approve prior to distribution
• Sign-in sheets
  ➢ When electronic not in proper format for importing
Action for non-compliance

- Monthly attestation statements
- Loss of accreditation
Reminder

- Activities do not issue certificates, Johns Hopkins OCME does
- Each activity is accredited for its own cycle. Since the agreement only covers, at present, until Feb 28, 2009 no activity will be accredited beyond that date
- All accreditation before Mar 1, 2008 is from NIH, not Johns Hopkins
- All materials are due to Johns Hopkins OCME every 2 months for upload into system and compliance confirmation