

NIH FAQ

The following have been developed to assist you through the application process. If you have other questions or need assistance, email the [CME Program](#) or call 410-955-2959. We are available to assist you in any way possible. If this is the first time you are submitting a CME application, we encourage you to contact us for an orientation meeting that will be telephone-based.

Anita Beyer, Accreditation Specialist, Johns Hopkins University CME

General

Q. Who can be an Activity Director?

A. Activity Directors must be physicians or scientists employed by the NIH and intimately involved with the planning and production of the educational activity for which accreditation is being sought. If there is any question as to your eligibility, please contact us.

Q. Who is eligible to work with the Activity Director on the application?

A. The Activity Director may delegate portions of writing the application and production of the activity to staff.

Q. Can retroactive accreditation be granted?

A. No, retroactive accreditation is not permitted. Applications should be submitted 5-6 months prior to the start date of a "live" activity or 4-5 months prior to the start date of a RSC.

Q. What if an application for CME credit is submitted and the activity start date is less than eight weeks away?

A. The CME Committee and staff will do everything possible to move the application through the review process. If you know you will be late, please alert us as soon as possible.

Q. Is it okay to submit an incomplete application and add or forward missing documents or information later?

A. Yes, just be sure to inform us of what is missing and when omitted items can be expected so we are aware you know what is pending. You will still be able to add to your application for a limited time after submission.

Q. What if the content (speakers/topics/curriculum, etc) is pending confirmation or not yet final?

A. We understand that you may not have every topic and every speaker selected in time to apply for credits. Please work out the time schedule including start, stop, and break times. Note "TBA" and/or "invited" for topics and speakers not yet finalized. If this is a repeating event or series, it may help to also provide the prior schedule as an example. Do not delay your application submission because of missing details.

Q. What happens when a CME application is submitted incomplete?

A. If you haven't alerted us, we will contact you to request the missing items. Be aware that submission of incomplete applications is likely to slow down the approval process.

Q. Can I send out publicity before my application is approved?

A. No. Applications should be approved before your publicity is disseminated. Plan early and submit your application at least 4 weeks prior to the publicity print date. If you plan to send an advance "Save the Date" card, please contact us for guidelines.

Q. Can publicity contain the phrase "CME APPROVED" or "CME CREDITS PENDING" or other similar advisements?

A. No. Only the official Accreditation and Credit Designation Statements may be used. If the statements appear elsewhere on the brochure, you may also note (for example on the front of the brochure) the following: "This activity has been approved for *AMA PRA Category 1 Credit™*".

Q. What if printing deadlines for publicity materials occur before anticipated credit approval? Can we still include CME information?

A. No. Contact us as soon as you realize you have this problem. All publicity must be reviewed and approved by us before printing and distribution. Advertising your activity prior to approval will invalidate your application! Applications must be approved before publicity so that all publicity can carry the Accreditation and Credit Designation statements.

Q. What if post-activity documentation cannot be submitted or only partial information is available three weeks after the end date of the activity?

A. Simply inform us of the delay, and let us know when submission can be expected. If you have most of the documentation and are waiting for one or two items, submit what you have and let us know when the remainder can be expected, or what problem you are experiencing.

Q. Why should I have to provide written disclosure information on speakers who have nothing to disclose?

The ACCME requires that for all speakers, the full disclosure information must be provided to the audience prior to the presentation. In order to comply with this requirement, several mechanisms were discussed at the training sessions. The best method is to include it in any syllabus materials that may exist and to have the speaker include a disclosure slide in his presentation.

Q. What if I forget my login information (user name and password)?

A: If you remember your user name then just click on the "forgot your password" link and it will be provided to you. If you have forgotten your user name then please contact CME tech support at Johns Hopkins at the link listed in the last bullet on the page under "Contact us".

Q: Who is required to earn CME credit?

A: CME credit is understood by our office to mean *AMA PRA Category 1 Credits™* or their equivalent, if available by reciprocal agreement. In most states, housestaff are not required to earn CME credits, but all practicing physicians are required. If the housestaff are licensed to practice in a state then they may need CME credits. Other healthcare providers also may require continuing education credits and, if not available by reciprocal agreement, will require an additional application and possibly additional fees, (i.e. nurse, nurse practitioner, pharmacist or specific specialty organizations). Please make sure your application and subsequent

communication clearly states the need for specific accreditation by these outside organizations as opposed to non-physician attendees accepting a certificate of attendance.

Q: At Case Conference, Research Conference, and similar meetings faculty and fellows discuss their ongoing research. Do we need to have biosketches and objectives for each?

A: Our policy for the open discussion forum series, like M&M and case conferences is that no additional objectives are required other than those created for the whole series and submitted with the application. For speaker-based series, like grand rounds or for a research conference, the series objectives are required as part of the application and a focused objective is required for each speaker/lecture. Biosketches/CVs are only mandatory for presenters.

Q: If our Grand Rounds program was approved 3 years ago, do we now submit it as a new program?

A: Yes, this would be considered a new program. All programs will be accredited as part of a cycle, with the present NIH cycle being March 1, 2008 to February 28, 2009.

Q: How do we communicate the objectives to the learners before the activity?

A: For all RSCs, the series objectives (the objectives submitted with the application) should be communicated by email to all faculty immediately upon receiving an approval letter from the CME office for that activity. The CME office should be copied on that message for the files. An individual speaker's objectives must be provided to the learners in advance of the presentation. The four most common mechanisms to handle this include:

- A slide placed on screen as everyone enters
- A slide embedded in the speaker's slides (at the beginning) **
- Signage at the point of entry into the lecture site
- Signage on the sign-in table.

Remember to have a copy of these objectives, for each episode, in the file with a statement as to how the learners were made aware in advance of the learning.

** denotes the preferred mechanism

Q: If my department has several RSCs, do I have to submit an application for each?

A: Yes. OCME must receive an application for every RSC for which the department would like to have CME credit awarded.

Q: How would a case-based conference handle submitting a prospective list of topics if the topics are driven by recent cases?

A: The preliminary list submitted in the application is not going to have a specific topic per week because you don't know what the topics are at the time of application submission. Each week would be labeled as Hot Topics of the Week or Hot Topics of Month as examples. Then when the activity is completed a final version of the program would be submitted which would list each week and what actually was discussed. For example, March 5, Polycythemia vera by Dr. Heme, etc.

Q: Can we get accreditation for other professionals that may need specific credits other than AMA?

A: When you fill out your application explicitly communicate with us the other types of credit(s) you are interested in obtaining for the activity. If reciprocity exists with the AMA process, then nothing else is required. If reciprocity doesn't exist for that group, then we work with you to apply for credit by that group's accreditation system. If the group doesn't truly need a special credit certificate/transcript then please don't request one as they require additional work at the time of the application, they require additional fees and they can add layers of documentation and lead to some interesting credit statements (e.g. AMA can say it was accredited for 23 hours, the American Association of Nurse Practitioner can say it is accredited for 21 hours, nursing can say its accredited for 20, pharmacy can say for 18, and so on and so forth).

Q: When you provide a needs assessment document, does it have to apply to a specific audience or can it apply to national standards?

A: Documentation of needs at a national level is acceptable.

Q: When you write objectives, are you looking for time sensitive or when we will be able to have some results?

A: No, time sensitivity related to a measurable outcome is not needed in the objective. Outcomes though are best assessed at the end of an activity and again at a more remote time interval (e.g. 3 months after an activity)

Q: Can a speaker receive cme credit?

A: A speaker can't be a learner and speaker at the same time and so they should not submit for credit an attestation for the times in which they were speaking. For example, if an activity was accredited for 21 credits and you spoke for an hour at the meeting, you could submit for 20 credits, but shouldn't submit for 21 credits. If a speaker wants credits for the learning that was involved in putting their original presentation together, the AMA has a process for direct credit for teaching activities that they should utilize.

Q: Are international physicians able to receive credits?

A: Yes, the AMA process considers all physicians the same as of about 2 years ago, so they would attest to attendance like all other physicians and would subsequently receive a certificate/transcript of credit.

Q: When the application is submitted and we don't obtain the appropriate materials (disclosure forms), can we apply for less credit and just have those presentations not CME covered?

A: The ACCME rule states that a speaker cannot speak at a CME activity if they don't disclose. In the application we require all planners to disclose. Speaker disclosures are not due at the time of the application but acquired after the activity is approved. We do not recommend mixing accredited and non-accredited activities at the same venue, on the same day as this can lead to confusion for the learners as to what is accredited and what isn't accredited material.

Q: Is there a manual available that explains the information that is required as we're preparing promotional material for the activity instead of having it after the application?

A: There will be style sheets and standard wording documents available that will provide guidance so that development of these materials can be facilitated. Once the materials are in proof phase they will have to be reviewed/approved before they can be marketed. Part of the review will include making sure that your NIH logo is in the right color, etc and that the Hopkins logo is the right color based upon the brand etc. So it is more than just the accreditation statements, its looking at it to see if it meets all of the standards before this material

can be distributed. Please also remember, it must be approved each time before distribution including any derivatives of the materials.

Q: Will you be continuing to give credits for web based courses that we have right now?

A: Yes, if reapproved. All present accreditation ends as of February 28th.

Q: Is there a way to find out how many people have actually requested CME credit to see if it's appropriate to keep offering it?

A: In theory yes, but I don't think there is any record of the number of total attendees versus those that requested credit. We can query the database to see. Contact our IT tech help and make the request after March 25th when the web site switches over to our office and we have had a chance to complete the transition.

Q: Do we have to submit each email every week for a RSC?

A: If you submit several in a row to us and show us that you do indeed use a standardized template, that the wording is correct and that you understand and defend the rules correctly we would then approve you to continue without weekly approval. For all subsequent weeks you would send out your email and copy us so that we can do ongoing monitoring.

Q: Do all presenters need a disclosure, no matter how lengthy the presentation?

A: Yes, the ACCME requires every presenter to disclose.

Q: If there are repeat speakers that have nothing to disclose do they have to re-sign the disclosure?

A: If the topic is the same and nothing has changed regarding their relationships, we permit the older form to be used for a 12 month window of time. Otherwise, a new disclosure is required.

Q: Do all attendees have to turn in an evaluation to get their credit?

A: There is no requirement that every single person must evaluate an activity to receive credit. It is nice if everyone did and one can package it that way, but there is no national regulation or Hopkins regulation requiring it. Attendees at "live" activities attest to attendance for a specific number of credits. Attendees at a RSC are tracked by sign in. Attestation and sign in are required for credit. Attestation must be submitted no later than 45 days after an activity. Beyond that date, credit cannot be provided.

Q: Can speakers get CME's for speaking?

A: The speaker cannot be a speaker and a learner at the same time. The AMA has a process through the AMA called direct credit (teaching credit) where the speaker can go and say that there was learning involved in putting together my presentation.

Q: Developing online courses- What is the process and can the CME office help set it up?

A: It's a separate application, and yes the CME office can provide advice and direction on how to proceed.

Q: Do we continue to log in with the same user ID on the new website?

A: For the NIH aspect of the NIHandHopkinsCME website your NIH user password isn't changing. It still works for NIH related functions, like application submission and credit checking.

Q: Can you have the brochure approved before it is designed?

A: All brochures should be crafted based upon the style sheet and standard wording documents provided. When in proof stage, they should be approved prior to printing.

Q: We would like to have a couple of sessions this year over at ESU. Are there any issues since these activities are sponsored by JHU?

A: No, it can be an NIH function that is held at a hotel, held at ESU etc. We could be the accreditor. We would need to know if they are educational partners, meeting planners or other organizations involved because a signed LOA is required.

Q: Does a physician have to retain old files for 6 years?

A: Yes, files should be stored for 6 years.

Q: Is there a duplicate application feature?

A: There is a duplicate application on the NIH application web site.

Q: What do we have to submit to get CME for a weekly activity?

A: First, one would apply through the website. After application approval, one would conduct the activity as planned. Then documentation is due back to our office as follows; if the activity is a "live" or coordinated activity then all materials are due to our office no later than 45 days after the last day of the activity. If the activity is a RSC, then all materials are due to our office every 2 months. Since the accreditation cycle starts March 1, the materials would first be due the last day of April.

Q: For monthly series that are video cast, if the slide has CME information on it, is that considered marketing?

A: Yes, any mention of CME information is considered marketing and the regulatory statements would have to be included and the JHU/OCME would need to review/approve. If you don't mention CME, then this is not considered marketing. Please remember, that one can never state that CME credit has been applied for.

Q: Who do we contact in your office to review brochures, save the date, announcements, etc.?

A: You would need to contact our accreditation and compliance office at accreditationandcompliance@jhmi.edu or as an alternate contact Rhonda Myers at rmyers20@jhmi.edu

Q: For video cast talks where they watch it live a week later, can CME be offered?

A: Yes, this would be considered enduring material and a separate application would need to be submitted for credit approval.

Record keeping

Q: Can we send in the sign-in sheets, etc. from the previous years and get credit?

A: Prior to March 1, 2008, JHUSOM OCME was not the accreditor for NIH activities and so can't provide credits for previous years. The web site will permit attendees to attain a transcript for the activities they attended prior to March 1, 2008.

Q: If a NIH physician/employee earns credit elsewhere by attending or participating in a CME activity, is Hopkins going to track these credits for him/her?

A: No, not at this time. We are only tracking the CME credit faculty earn in NIH accredited RSCs or coordinated activities through the sign-in sheets, etc., so that OCME can issue certificates. If the NIH employee earns CME credit elsewhere, they should get a CME certificate/transcript for that activity from that accredited provider. Physicians should be aware that it is their responsibility to maintain documentation of CME credits earned for 6 years.

Q: Does OCME have a template of the excel spreadsheet used to submit attendance?

A: Yes, the templates are available on the website

Q: Is there a cost for the new excel spreadsheet?

A: No. They are there for you to download.

Q: Our department's activities utilize a case discussion format. Does OCME need a list of topics at the end of the year?

A: It depends on the format. If the activity is an open discussion format driven by a recent case or M&M event then topics are not required. However, please keep in mind that in this domain, the more documentation, the better. So, if a list can be kept, that's ideal. If, on the other hand, a series of topics are planned, then the list of topics is required and must be submitted with all records at the end of the yearly cycle.

Q: If I want a CME certificate, do I have to pay?

A: No. If sign-in sheets are submitted using the approved excel spreadsheet, no additional fees will be assessed to the attendee.

Q: How often do we submit sign-in sheets to OCME?

A: For a "live" or coordinated activity all documentation is required in our office no later than 45 days after the last day of the activity. For a RSC activity, the materials are due in our office every 2 months. Since the accreditation cycle starts March 1, all materials will first be due by the last day of April.

Q: What record keeping documentation is due at cycle end?

A: The following documents are required:

- Planning notes
- Excel spreadsheet/sign-in sheets
- Disclosure forms and evidence of disclosure to learners in advance of learning
- All Letters of Agreement (LOA)
- A summarized budget
- Post-Activity Participant Evaluation Survey (tool) and Summary
- CVs or biosketch of all speakers
- Final lecture series title/speakers
- Objectives from each lecturer and evidence of objectives provided to learners in advance of learning
- For a complete list check training slides please

Q: Who keeps the files? The meeting planning organization/ medical education communication company or the activity office at the NIH?

A: What happens is through the memorandum of understanding or letter of agreement we can establish whether they are going to keep them or whether you are. With that being said, you still have a responsibility for making sure that they are accurate and you have a responsibility for helping us make sure they are complete and accurate. In the end, all materials will be do to us at Johns Hopkins no later than 45 days after the last day of a "live" activity.

Q: Does the spreadsheet need to include those who don't want credit?

A: We prefer to know about all attendees so that we can report total attendance and have data in the database for subsequent distribution lists. If a few of the folks that don't want CME are not included it is not the end of the world.

Conflict of Interest

Q: Is a government grant considered Commercial Support?

A: Grants from federal agencies or not-for-profit foundations are not considered commercial support.

Q: Do I have to disclose a CRADA?

A: Yes, a CRADA is seen as the same as a relationship with a commercial entity and thus must be disclosed.

Financial

Q: If we look for a sponsor to offset the cost of the program, would the program still be eligible for CME?

A: Yes, but I believe the Foundation would need to be involved and those details are still being worked through. Please keep in mind that no involvement by a commercial entity is permitted in any manner related to content or speakers.

Q: We have no budget for our activity. Is it okay to fill in with zeros?

A: The Johns Hopkins Office of CME must be aware of all sources of funds and support, and exactly how funds are spent. Please list the names of all NIH Institutes/Centers contributing to the activity, even if only "in-kind" contributions exist, such as staff time, office materials, and use of NIH facilities and equipment. An approximation of these contributions should be included in the budget as a dollar amount. It is difficult to conceive of an activity that would cost nothing.

Dealing with Commercial Interests

Q: Is it permissible for a drug representative from a pharmaceutical company to give an "update" on a product before the CME activity begins?

A: There is a risk in such an arrangement and thus it should be avoided. CME activities must be strictly educational and free of any commercial bias or influence. Therefore, at no time can materials with company information, logos or product names be displayed or left in the room during the CME activity (e.g. pens, pads, penlights). At no time should there be any opportunity to confuse the two "events." Nor should attendees be required to get the commercial-interest message in order to get to the bias-free education. Consequently, if the same room is used, please allow time for one to end before the other begins -- and make certain the room is "scrubbed" of all commercial material.

Q: If a speaker's relationships with pharmaceutical and equipment companies change during the course of the year, must she complete another financial disclosure form?

A: If his/her commitments change during the year, he/she should file a subsequent disclosure statement.

Q: Can the pharmaceutical company issue a check directly to the speaker as an honorarium for a CME lecture?

A: No, such direct payment would make the speaker a paid agent of the drug company and violate the activity's independence from the funder. All commercial support must be given in the form of an "Educational Grant" to the accredited sponsor: OCME. OCME issues all honoraria payments on behalf of the institution. In this way, the speaker's relationship is with the accredited provider, not a pharmaceutical company.