



SELF-REPORT CREDIT FORM

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 live activity for 1 credit per session for a maximum of 44 *AMA PRA Category 1 Credit(s)*TM. Physicians should claim only the credit commensurate with the extent of their participation in the activity.

Clinical Center Grand Rounds – Ethics

Lipsett Amphitheater
12 Noon – 1 p.m.
October 5, 2011

The Current Proposal to Amend the Federal Human Subjects Research Regulations: Is It a Good Idea?
Greg Koski, M.D., Ph.D., Associate Professor of Anesthesia, Senior Scientist, James Mongan Institute for Health Policy, Massachusetts General Hospital, Harvard Medical School, Former Director, Office for Human Research Protections, Department of Health and Human Services

NOTE: To receive credit for attendance, this form must be returned to the Office of Clinical Research Training and Medical Education by 4 pm on the day of the lecture. Please fax forms to 301-402-2158. For CC Grand Rounds CME inquiries, contact Avril Bertrand at 301-496-9425 or bertranda@cc.nih.gov

Date(s)	Maximum Approved Hours per session/per week	Earned Hours
October 5 , 2011	1 hour per session/per week	1.0*

Please Print Clearly

Please check one: Physician Non-Physician

NAME - LAST FIRST MI PROFESSIONAL DEGREE

NIH BADGE NUMBER (IF NIH EMPLOYEE)

PHONE EMAIL ORGANIZATION INSTITUTE/CENTER DEPT/BRANCH

ADDRESS CITY STATE ZIP + 4

SIGNATURE REQUIRED for ALL ATTENDEES:

I attest that the above number credit hour(s) is correct.

X _____
Signature of Attendee Date

*These hours will be verified by the Office of Continuing Medical Education (OCME) and recorded on your official Transcript.



FULL DISCLOSURE POLICY AFFECTING CME ACTIVITIES

Clinical Center Grand Rounds – Ethics

Lipsett Amphitheater

Bethesda, Maryland

October 5, 2011

As a provider approved by the Accreditation Council for Continuing Medical Education (ACCME), it is the policy of the Johns Hopkins University School of Medicine Office of Continuing Medical Education (OCME) to require signed disclosure of the existence of financial relationships with industry from any individual in a position to control the content of a CME activity sponsored by OCME. Members of the Planning Committee are required to disclose all relationships regardless of their relevance to the content of the activity. Speakers are required to disclose only those relationships that are relevant to their specific presentation. **No** relationships have been reported for this activity:

SPEAKERS NAME	RELATIONSHIP(S)
Greg Koski, M.D., Ph.D.	The Massachusetts General Hospital is the recipient of an independent investigator-initiated research grant in Greg Koski's name from Pfizer, Inc. The grant supports research studying the knowledge and preparedness of currently active clinical investigators.

No other speakers have indicated that they have any financial interests or relationships with a commercial entity whose products or services are relevant to the content of their presentation(s).

No planner has indicated that they have any financial interests or relationships with a commercial entity

Note: Grants to investigators at The Johns Hopkins University are negotiated and administered by the institution which receives the grants, typically through the Office of Research Administration. Individual investigators who participate in the sponsored project(s) are not directly compensated by the sponsor, but may receive salary or other support from the institution to support their effort on the project(s).

OFF-LABEL PRODUCT DISCUSSION

The speaker has indicated that he will **not** reference unlabeled/unapproved uses of drugs or products.

EVALUATION FORM

Clinical Center Grand Rounds at the National Institutes of Health

October 5, 2011

Please complete the Continuing Medical Education Questionnaire. To indicate your answers, use the rating scale that is shown by circling the number that represents your answer.

Scale:

1 - None or Not at all 2 - Very little 3 - Moderately 4 - Considerably 5 - Completely N/A - Not applicable

Speaker: Greg Koski, M.D., Ph.D.

Objective: To give participants an understanding of and appreciation for the proposed revisions to the existing federal regulations for human subject protections by assessing their potential impact, feasibility and desirability.

A. Rating of Objectives and Activity

- 1. Please rate the attainment of objectives:
a. Define options and alternatives that will guide clinical practice
b. Evaluate practical information about clinical research principles based on state-of-the-art information about scientific discovery and clinical advances
c. Analyze information and opportunities to increase and improve collaboration between investigators
2. The overall quality of the instructional process was an asset to the activity:
3. To what extent did participation in this activity enhance your professional effectiveness?
4. Will you change your practice in any way as a result of attending this activity?
5. Did you perceive any commercial bias? Use the following criteria to judge?
a) The content presented was balanced, evidence-based, demonstrated scientific rigor, and was without commercial bias.
b) I was informed about the existence and resolution of relevant financial relationships/conflicts of interests of planners and presenters prior to the presentation.
c) Speakers who discussed off-label, investigational, or alternative uses of products, devices, or techniques disclosed this in their presentation.

B. Comments:

- 1. What comments or suggestions do you have for the faculty presenter(s)?
2. Are there any other speakers or new topics you would like to have covered in this or a related activity?
3. Do you have additional comments to enhance the utility or impact of the activity?
4. May we contact you in several week's time with a very brief survey to assess the usefulness of this CME activity? Yes No If yes, please provide your email: