CME SELF-REPORT CREDIT FORM

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 through the joint providership of 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)™. Physicians should claim only the credit commensurate with the extent of their participation in the activity.

NIH Clinical Center Grand Rounds, Ethics Edition
Lipsett Amphitheater
12:00 Noon – 1:00 pm
December 7th, 2016

Consent for Online Research: When Is It Needed? How Does It Work?

Case Presenter: Elizabeth Buchanan, PhD, Endowed Chair in Ethics and Director, Center for Applied Ethics, University of Wisconsin-Stout

Case Discussant: Jerry Menikoff, MD, JD, Director, Office for Human Research Protections, Office of Assistant Secretary for Health, DHHS

Case Discussant: Franklin Miller, PhD, Professor of Medical Ethics in Medicine, Weill Cornell Medicine

Note: To receive CME credit, this form must be completed and returned to the Office of Clinical Research Training and Medical Education by 6 pm on the day of the lecture. Please fax forms to 301-435-5275 or scan and email forms to daniel.mcanally@nih.gov. For CC Grand Rounds CME inquiries, contact Daniel McAnally 301-496-9425

<table>
<thead>
<tr>
<th>Date(s)</th>
<th>Maximum Approved Hours per session/per week</th>
<th>Earned Hours</th>
</tr>
</thead>
<tbody>
<tr>
<td>December 7th, 2016</td>
<td>1 hour per session/per week</td>
<td>1.0*</td>
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Please Print Clearly
Please check one: _____Physician _____Non-Physician

NAME - LAST  FIRST  MI  PROFESSIONAL DEGREE

EMAIL  (REQUIRED)  PHONE

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.
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. The following relationships have been reported for this activity:

<table>
<thead>
<tr>
<th>SPEAKERS NAME AND LECTURE TITLES</th>
<th>RELATIONSHIP(S)</th>
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<tbody>
<tr>
<td>Elizabeth Buchanan, PhD</td>
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</tbody>
</table>

No speaker has indicated that they have any financial interests or relationships with a commercial entity whose products or services are relevant to the content of their presentations.

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 following speakers have disclosed that their presentation will reference unlabeled/unapproved uses of drugs or products:

<table>
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<tr>
<th>NAME AND LECTURE(S)</th>
<th>Product</th>
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No speaker has indicated that they will reference unlabeled/unapproved uses of drugs or products.
EVALUATION FORM
 NIH Clinical Center Grand Rounds
 December 7th, 2016

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

Speakers: Elizabeth Buchanan, PhD, Jerry Menikoff, MD, JD, Franklin Miller, PhD

Objectives:

A. Rating of Objectives and Activity

1. Please rate the attainment of objectives:
   a. Define options and alternatives that will guide clinical practice  1 2 3 4 5 N/A
   b. Evaluate practical information about clinical research principles based on state-of-the-art information about scientific discovery and clinical advances  1 2 3 4 5 N/A
   c. Analyze information and opportunities to increase and improve collaboration between investigators  1 2 3 4 5 N/A

2. The overall quality of the instructional process was an asset to the activity:  1 2 3 4 5 N/A

3. To what extent did participation in this activity enhance your professional effectiveness?  1 2 3 4 5 N/A

4. Will you change your practice in any way as a result of attending this activity?  1 2 3 4 5 N/A

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. ____No  ____Yes
      If no, please specify: ____________________________________________________________________
   b) I was informed about the existence and resolution of relevant financial relationships/conflicts of interests of planners and presenters prior to the presentation. ____No  ____Yes
      If no, please specify: ____________________________________________________________________
   c) Speakers who discussed off-label, investigational, or alternative uses of products, devices, or techniques disclosed this in their presentation. ____No  ____Yes
      If no, please specify: ____________________________________________________________________

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 weeks’ time with a very brief survey to assess the usefulness of this CME activity?  ____Yes  ____No
   If yes, please provide your email: ____________________________________________________________________