



FULL DISCLOSURE POLICY AFFECTING CME ACTIVITIES

Clinical Center Grand Rounds- Nurses Week

Masur Auditorium
Bethesda, Maryland
May 9, 2012

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:

SPEAKERS NAME AND LECTURE TITLES

Gwenyth R. Wallen, R.N., Ph.D.

Reframing Informed Consent: Understanding How Research Participants Make Decisions

Christine Grady, M.S.N., Ph.D.

Reframing Informed Consent: Understanding How Research Participants Make Decisions

Connie Ulrich, R.N., Ph.D.

Reframing Informed Consent: Understanding How Research Participants Make Decisions

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:

No speaker has indicated that they will reference unlabeled/unapproved uses of drugs or products.

EVALUATION FORM

Clinical Center Grand Rounds at the National Institutes of Health

May 9, 2012

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: Gwenyth R. Wallen, R.N., Ph.D.

Objective: To describe the legal, ethical and regulatory aspects and controversies in the clinical research informed consent process and to discuss how research participants make decisions in the context of informed consent.

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 week's time with a very brief survey to assess the usefulness of this CME activity? ___Yes ___No If yes, please provide your email: _____

EVALUATION FORM

Clinical Center Grand Rounds at the National Institutes of Health

May 9, 2012

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Scale:

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Speaker: Christine Grady, M.S.N., Ph.D.

Objective: To describe the ethical and regulatory basis for informed consent and to identify challenges to obtaining informed consent in research.

A. Rating of Objectives and Activity

5. 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

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

7. 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

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b) The content presented was balanced, evidence-based, demonstrated scientific rigor, and was without commercial bias. ___No ___Yes
If no, please specify: _____

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EVALUATION FORM

Clinical Center Grand Rounds at the National Institutes of Health

May 9, 2012

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Scale:

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Speaker: Connie Ulrich, R.N., Ph.D.

Objective: Identify factors associated with assessment of informed consent in cancer clinical trials.

A. Rating of Objectives and Activity

9. 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

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

11. 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?

c) 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: _____

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If no, please specify: _____

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