CCR "Online" Research Orientation Evaluation

Documenting, Recording, and Reporting of Adverse Events and Unanticipated Problems

Directions: *Please print the evaluation, complete the evaluation, and fax to Liz Ness; 301-496-9020.*

Name: _____

Date: _____

1. Please rate the following:

- Technical level of module Too High____ Appropriate____Too Low____
- Length of module Too Short____ Appropriate____Too Long____
- Slide content and layout Poor Quality____Adequate____High Quality____

2. What percentage of the module content was new to you?

<25%____ 25% -50%____ >50%____

3. Listed below are the objectives for the module. Please rate the extent to which you are now able to meet each of the objectives on a scale of 1 (not able to meet the objective) to 5 (fully able to meet the objective):

• Define what constitutes an adverse event.	1	2	3	4	5
• Describe the elements required to document adverse events.	1	2	3	4	5
• Discuss how the Common Terminology Criteria for Adverse Events (CTCAE) is used for assessing AEs.	1	2	3	4	5
• Define serious and unexpected adverse events and how to report these types of events to various regulatory/oversight groups.	1	2	3	4	5
• Discuss the purpose and processing of an IND Safety Report.	1	2	3	4	5
• Define what an unanticipated problem is and learn how to report an unanticipated problem to the IRB.	1	2	3	4	5

4. General Comments: