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		_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.			-		-
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
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4. General Comments: