



UNIVERSITY OF MIAMI
MILLER SCHOOL
of MEDICINE

**CITI GOOD CLINICAL PRACTICES COURSE
CREDIT REQUEST FORM**

To receive credit, mail this form to the University of Miami, Division of Continuing Medical Education at the address listed below (or fax with credit card payment).

Credit is available for the period of April 12, 2007 to May 30, 2010.

ACCREDITATION: The University of Miami Miller School of Medicine is accredited by the Accreditation Council for Continuing Medical Education to provide continuing medical education for physicians.

CREDIT DESIGNATION: The University of Miami Leonard M. Miller School of Medicine designates this educational activity for a maximum of **4.0 AMA PRA Category 1 Credits™**. Physicians should only claim credit commensurate with the extent of their participation in the activity.

Name:		Degree:	SSN: (Last 4 only):
Address:		City, State, Zip:	
Telephone:	FAX:	Email:	
Specialty	For verification purposes, please provide USERNAME :		

Complete below (Place a check mark in the appropriate box)

<input type="checkbox"/> Physician Category 1 AMA/PRA CME	<input type="checkbox"/> CERTIFICATE OF COMPLETION Nurses/Allied Health Professionals
<p>CERTIFY COURSE COMPLETION</p> <p><input type="checkbox"/> I certify that I have completed the CITI Good Clinical Practice Course as designed. Indicate the total amount of time you spent completing this educational activity: _____ <i>A maximum of 4 credits will be awarded for completion of all 12 modules.</i></p> <p>Signature: _____ Date: _____</p>	

TUITION: \$60

Check enclosed in the amount of \$ _____ (U.S. Dollars) made payable to: **UM, Division of CME.**

Please charge my registration fee in the amount of \$ _____ to my: **Visa®** **MasterCard®** **Discover®**

Card Number _____ CCV Number (3-digit code on back of card): _____

Expiration Date _____

Name on Card _____

Authorized Signature _____

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Please answer the following questions using the rating scale: 1 = Strongly Disagree4 = Strongly Agree

(Do not evaluate any objective listed below that did not apply to the modules you completed)

The program met the following objectives: Upon completion of this online course participant should be able to:

<ul style="list-style-type: none"> • International Conference on Harmonization <ul style="list-style-type: none"> ○ Identify the basic requirements for compliance with ICH and relate how ICH fits with U.S. federal regulations regarding clinical research 	4 3 2 1 <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>
<ul style="list-style-type: none"> • FDA Regulated Research and ICH <ul style="list-style-type: none"> ○ Explain the guideline that primarily affects investigators in the daily practice of clinical research is E6, "ICH Harmonized Tripartite Guideline: Guideline for Good Clinical Practice." 	4 3 2 1 <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>
<ul style="list-style-type: none"> • Managing Investigational Agents According to GCP Requirements <ul style="list-style-type: none"> ○ Identify regulatory obligations of investigators conducting clinical trials of investigational agents 	4 3 2 1 <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>
<ul style="list-style-type: none"> • Conducting Clinical Trials of Medical Devices <ul style="list-style-type: none"> ○ Define the responsibilities of investigators conducting clinical research involving medical devices 	4 3 2 1 <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>
<ul style="list-style-type: none"> • Informed Consent: An Ongoing Process <ul style="list-style-type: none"> ○ Describe the requirements for complying with informed consent regulations 	4 3 2 1 <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>
<ul style="list-style-type: none"> • Detection and Evaluation of Adverse Events <ul style="list-style-type: none"> ○ Identify the factors to consider in assessing the severity and casualty of AEs 	4 3 2 1 <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>
<ul style="list-style-type: none"> • Reporting serious Adverse Events <ul style="list-style-type: none"> ○ Identify the criteria for reporting SAEs to regulatory agencies, sponsors, etc, and define "Serious" and "Unexpected" adverse events 	4 3 2 1 <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>

Participation in this activity has:	Yes	No
• Increased my knowledge	<input type="checkbox"/>	<input type="checkbox"/>
• Improved my competence (<u>ability</u> to perform)	<input type="checkbox"/>	<input type="checkbox"/>
• Enhanced my performance (<u>will practice regularly</u> in my workplace)	<input type="checkbox"/>	<input type="checkbox"/>
• Ensured that my patients will have improved outcomes (population health improvement)	<input type="checkbox"/>	<input type="checkbox"/>

I intend to make the following changes in my practice as a result of this learning activity:

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