

COLLABORATIVE INSTITUTIONAL TRAINING INITIATIVE (CITI)

HUMAN SUBJECTS RESEARCH PROTECTIONS CURRICULUM COMPLETION REPORT

Printed on 03/25/2014

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EXPIRATION DATE 03/24/2017

GROUP 7 CITI & GCP TRAINING FOR INVESTIGATORS AND STAFF : (Choose this group to satisfy GCP AND satisfy CITI training requirements for investigators and staff involved in human subject research)

COURSE/STAGE: Basic Course/1
PASSED ON: 03/25/2014
REFERENCE ID: 12664573

REQUIRED MODULES	DATE COMPLETED	SCORE
Belmont Report and CITI Course Introduction	03/25/14	3/3 (100%)
History and Ethics of Human Subjects Research	03/25/14	7/7 (100%)
Basic Institutional Review Board (IRB) Regulations and Review Process	03/25/14	5/5 (100%)
Research With Protected Populations - Vulnerable Subjects: An Overview	03/25/14	4/4 (100%)
The CITI Good Clinical Practice Course for Clinical Trials Involving Drugs and Devices	03/25/14	3/3 (100%)
Overview of New Drug Development	03/25/14	5/5 (100%)
Overview of ICH GCP	03/25/14	4/4 (100%)
FDA Regulated Research and ICH for Investigators Archived 1353	03/25/14	5/5 (100%)
ICH - Comparison Between ICH GCP E6 and U.S. FDA Regulations	03/25/14	4/4 (100%)
Conducting Investigator-Initiated Studies According to FDA Regulations and GCP	03/25/14	3/3 (100%)
Investigator Obligations in FDA-Regulated Clinical Research	03/25/14	5/5 (100%)
Managing Investigational Agents According to GCP Requirements	03/25/14	5/5 (100%)
Overview of U.S. FDA Regulations for Medical Devices	03/25/14	3/3 (100%)
Informed Consent in Clinical Trials of Drugs, Biologics, and Devices	03/25/14	4/4 (100%)
Detecting and Evaluating Adverse Events	03/25/14	4/4 (100%)
Reporting Serious Adverse Events	03/25/14	4/4 (100%)
Monitoring of Clinical Trials by Industry Sponsors	03/25/14	8/8 (100%)
Audits and Inspections of Clinical Trials	03/25/14	5/5 (100%)
Completing the CITI GCP Course	03/25/14	No Quiz
Stanford University Module	03/25/14	No Quiz

For this Completion Report to be valid, the learner listed above must be affiliated with a CITI Program participating institution or be a paid Independent Learner. Falsified information and unauthorized use of the CITI Program course site is unethical, and may be considered research misconduct by your institution.

Paul Braunschweiger Ph.D.
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Director Office of Research Education
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