

CIP Preparation Course
Summer 2008: Week 1 (6/16/08)

Areas of Focus: Introduction, Overview, History, Common Terminology

Lecturers: Susan Rose, Gordon Olacsi, Peter Mestaz

I. Introduction

- A. Why CIP?
- B. Nuts and Bolts
- C. Team experience
- D. Registering for exam

II. Overview

- A. Human Subjects Research in a “nut shell”
- B. Handouts/books

III. History

- A. Events
 - 1. Nuremberg Trials
 - 2. Willowbrook Hepatitis Study
 - 3. Jewish Chronic Disease Hospital
 - 4. Beecher Articles
 - 5. Milgram Study
 - 6. San Antonio Contraception Study
 - 7. Tea Room Trade Study
 - 8. Tuskegee Syphilis Study
- B. Ethical Codes/Guidances
 - 1. Nuremberg Code
 - 2. Declaration of Helsinki (INTERNATIONAL)
 - 3. Belmont Report
 - 4. CIOMS (Council for International Organizations of Medical Sciences) (INTERNATIONAL)
 - 5. International Conference of Harmonization (ICH) / Good Clinical Practices (GCP) (INTERNATIONAL)
- C. Regulatory Bodies
 - 1. OHRP (formerly OPRR)
 - 2. FDA

IV. Common Terminology

- A. Overview of terms
- B. How to study

V. Pre-Test Questions

VI. Closeout