

AGENDA: ACRP Fundamentals of Clinical Research

The times listed here are approximate, and the duration of the sessions may be adjusted by the lecturers depending on the circumstances of the class.

Day One

7:30–8:00 Registration

8:00–8:15 Welcome and Introduction

8:15–10:30 SESSION ONE—INTRODUCTION TO CLINICAL RESEARCH

Lesson 1: Clinical Research Defined

Lesson 2: Good Clinical Practice (GCP)

Lesson 3: Historical Legislative Overview

Lesson 4: Drug Research & Development

Lesson 5: Biologics Research & Development

Lesson 6: Medical Device Research & Development

10:30–10:45 Coffee Break

10:45–12:00 SESSION TWO—HUMAN SUBJECT PROTECTIONS

Lesson 1: Human Subject Protections & History

Lesson 2: Institutional Review Boards

Lesson 3: Informed Consent

12:00–1:00 Lunch

1:00–2:30 SESSION THREE—CLINICAL RESEARCH ENTITIES & REGULATORY OBLIGATIONS

Lesson 1: Sponsor

Lesson 2: Contract Research Organizations (CROs)/Academic Research Organizations (AROs)

Lesson 3: Investigator Site

Lesson 4: FDA Centers & Bioresearch Monitoring

2:30–2:45 Coffee Break

2:45–4:45 SESSION FOUR—ESSENTIAL DOCUMENTS

Lesson 1: Essential Documents

Lesson 2: Regulatory Documents Binder

Lesson 3: Source Documentation & Research Practice

Lesson 4: Case Report Forms & Queries

4:45–5:00 Questions and Answers, Adjourn

DAY TWO

8:30–10:45 SESSION FIVE—SAFETY REPORTING

Lesson 1: Safety Definitions

Lesson 2: Safety Reporting Requirements & Sponsor Obligations

Lesson 3: Protocol & Safety Reporting

10:30–10:45 Coffee Break

11:00–12:00 SESSION SIX—CLINICAL TRIALS: START-UP AND CONDUCT

Lesson 1: Study Preparation and Start-Up

Lesson 2: Subject Recruitment/Retention/Compliance

Lesson 3: Protocol Implementation

12:00–1:00 Lunch

1:00–2:30 SESSION SIX—CLINICAL TRIALS: START-UP AND CONDUCT (cont'd)

Lesson 1: Study Preparation and Start-Up

Lesson 2: Subject Recruitment/Retention/Compliance

Lesson 3: Protocol Implementation

2:30–2:45 Coffee Break

2:45–4:45 SESSION SEVEN—QUALITY CONTROL: MONITORING OF CLINICAL TRIALS

Lesson 1: Monitoring Overview

Lesson 2: Site Qualification & Study Initiation Visits

Lesson 3: Routine & Close-Out Visits

4:45–5:00 Question and Answers Wrap-up

5:00 Adjourn