

## Learner Notification

**The Society of Clinical Research Associates (SOCRA)**  
**Clinical Research Professional Certification Preparation and GCP Review Course**  
**April 30, 2025**  
**Live Online Activity**

### **Acknowledgement of Financial Commercial Support**

No financial commercial support was received for this educational activity.

### **Acknowledgement of In-Kind Commercial Support**

No in-kind commercial support was received for this educational activity.

### **Satisfactory Completion**

Learners must complete an evaluation form to receive a certificate of completion. Your chosen sessions must be attended in their entirety. Partial credit of individual sessions is not available. If you are seeking continuing education credit for a specialty not listed below, it is your responsibility to contact your licensing/certification board to determine course eligibility for your licensing/certification requirement.

### **Accreditation Statement**

The Society of Clinical Research Associates is accredited by the Accreditation Council for Continuing Medical Education to provide continuing medical education for physicians.

The Society of Clinical Research Associates is accredited as a provider of continuing nursing education by the American Nurses Credentialing Center's Commission on Accreditation.

### **Physicians (ACCME) Credit Designation**

The Society of Clinical Research Associates designates this live activity for a maximum of **6.5 AMA PRA Category 1 Credits™**. Physicians should claim only the credit commensurate with the extent of their participation in the activity.

### **Nurses (ANCC) Credit Designation Statement**

The Society of Clinical Research Associates is accredited as a provider of continuing nursing education by the American Nurses Credentialing Center's Commission on Accreditation. Successful completion of this program qualifies for up to 6.5 ANCC contact hours for nurses.

### **Objectives - After Attending This Program You Should Be Able To**

- Discuss the basic requirements necessary to meet the demands of a CRP in clinical practice
- Discuss the basic components of compliance - Law, regulation, guidance, policy and procedure
- Explain the drug/biologic development process
- Describe the device development process
- Outline concepts for Good Clinical Practice (GCP)
- Explain the elements of informed consent
- Describe the membership and reporting requirements of IRBs
- Explain rules relating to financial disclosure
- Discuss the basics of study design
- Explain the rules and reporting requirements for adverse events and serious adverse events
- Explain study closure procedures and record retention guidelines
- Outline the reasons for monitoring, audits and site visits
- Explain the Food and Drug Administration rules, regulations, and guidelines on research
- Discuss the importance of investigational drug accountability
- Demonstrate and describe how to read clinical reports and records
- Discuss Quality Assurance including, Monitoring and Auditing
- Explain issues that would constitute clinical fraud