

# Penn Clinical Research (CR): Certification Program – OCR eLearning Modules

## GCP for the Experienced CRC:

- Demonstrate qualifications and execute agreements to conduct clinical research with a research sponsor or institute;
- Provide adequate medical care to a subject throughout the conduct of the clinical trial;
- Compose communications with the IRB/IEC;
- Conduct the trial in compliance with the protocol to include randomization and unblinding procedures;
- Conduct Informed Consent (IC) Procedures according to local regulations, GCP and principles established by the Declaration of Helsinki; and
- Develop timely and accurate records and reports.

## Risk Based Monitoring: The Essentials for CRCs

- Define Risk-Based Monitoring (RBM);
- Describe significant differences in utilizing an RBM approach as compared to 100% on-site monitoring and 100% centralized monitoring
- Follow risk-management strategies as part of overall quality management procedures when setting up or evaluating a protocol and related activities; and
- Apply RBM without jeopardizing patient safety, quality of data and regulatory compliance.

## Site Quality Management Tools:

- Explain the importance of quality processes in clinical research conduct by providing a framework for the necessary elements and systems that should be implemented by a site to ensure quality.
- Set up a quality process for your site.
- Organize training sessions to ensure quality in clinical research.

## Mastering the Event Reporting Cycle:

- Define and describe clinical safety terminology;
- Report safety concerns to stakeholders via the correct form and per ICH E2a Section III Standards for Expedited Reporting and include the appropriate Key Data Elements according to Appendix I;
- Apply the guidelines for specific cases as defined under Miscellaneous issues (Section III E); and
- Explain when a sponsor should amend the Investigator Brochure.