

Education and Training

HS

In this issue of the ACRP *Monitor*, three articles have been selected as the basis for a Home Study test that contains 30 questions. For your convenience, the articles and questions are provided in print as well as online (members only) in the form of a PDF (requires Adobe Reader and text file). This activity is anticipated to take three hours.

Answers must be submitted using the electronic answer form online (members only, \$32). Those who answer 70% of the questions correctly will receive an electronic statement of credit by e-mail within 24 hours. Those who do not pass can retake the test for no additional fee.

Hardware/Software Requirements: Home Study tests require version 4.x browsers or higher from Internet Explorer, Mozilla Firefox, or Safari. A browser that can run Adobe Flash 9.0 is required to view the digital edition of *The Monitor*, and Adobe Acrobat is required to view PDFs of the Home Study test.

The **February 2011 *Monitor* Home Study** is based on the following three articles in this issue:

- 1. A Roadmap to Establishing Institutional Clinical Research Training Policies and Plans for Academic Health Centers: Focus on Quality and Performance**
Erika J. Stevens, MA, Director, Dartmouth Clinical Trials Office, Dartmouth Hitchcock Medical Center
- 2. Investigator Meetings: Focus on Protocol Execution Performance**
Bree Martin, Independent Clinical Operations Strategic Consultant | Maria Shabe, Advance Research Associates | Liz Wool, RN, BSN, CCRA, CMT, President and Chief Executive Officer, QD-Quality and Training Solutions, Inc.
- 3. Educating and Training CRAs for the Field: The Pursuit of Excellence**
Jill Matzat, RN, BSN, CCRA, CCRT, Founder, Course Designer, and Primary Instructor, Medical Research Management, Inc.

HOME STUDY LEARNING OBJECTIVES

With knowledge inferred from the articles above, respectively, learners should be able to:

- analyze the risks associated with conducting clinical research and explain the process for training plan implementation.
- explain investigator meeting attributes, methods, and content that focus on site performance for a clinical trial.
- discuss the recommended approach to standardized CRA training, which includes evaluation through competency assessment.

This test expires on FEBRUARY 29, 2012

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The Association of Clinical Research Professionals, Inc. (ACRP) is an approved provider of medical, nursing, and clinical research continuing education credits.



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The Association of Clinical Research Professionals (ACRP) is accredited by the Accreditation Council for Continuing Medical Education to provide continuing medical education for physicians.

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QUESTIONS 1–10

A Roadmap to Establishing Institutional Clinical Research Training Policies and Plans for Academic Health Centers: Focus on Quality and Performance

- 1** At which academic health center (AHC) did the death of Ellen Roche occur?
- University of Pennsylvania
 - Johns Hopkins University
 - Duke University Medical Center
 - Virginia Commonwealth University
- 2** What federal office directly manages cases of research misconduct?
- OHRP
 - FDA
 - ORI
 - HHS
- 3** On average, how many cases of allegation of research misconduct does ORI receive annually?
- 50
 - 100
 - 150
 - 200
- 4** Which of the following are typical sanctions for findings of research misconduct?
- Probation
 - Oversight
 - Suspension
 - Prison
- 1, 2, and 3 only
 - 1, 2, and 4 only
 - 1, 3, and 4 only
 - 2, 3, and 4 only
- 5** Scientific misconduct cases include which of the following?
- Falsification
 - Plagiarism
 - Fabrication
 - Mishandling
- 1, 2, and 3 only
 - 1, 2, and 4 only
 - 1, 3, and 4 only
 - 2, 3, and 4 only

6 Training in GCP ensures ethical and scientific standards for which of the following in clinical research?

- Publication
 - Monitoring
 - Auditing
 - Conduct
- 1, 2, and 3 only
 - 1, 2, and 4 only
 - 1, 3, and 4 only
 - 2, 3, and 4 only

7 Key stakeholders have direct or indirect _____ over the organization's policies and procedures?

- Responsibility
- Influence
- Manipulation
- Decision-making

8 Who are the key stakeholders in AHCs influencing training policies?

- Provosts
 - VPs for Research
 - Department Chairs
 - Compliance Officers
- 1, 2, and 3 only
 - 1, 2, and 4 only
 - 1, 3, and 4 only
 - 2, 3, and 4 only

9 Institutional audit findings typically do NOT result in which type of sanction?

- Oversight
- Education
- Suspension
- Debarment

10 Which of the following is not part of the training implementation process?

- Stakeholder identification
- Gap analysis
- Gantt Chart development
- Project plan

QUESTIONS 11–20

Investigator Meetings: Focus on Protocol Execution Performance

11 Recent FDA Warning Letters focus on which of the following areas of investigator and/or sponsor non-adherence?

- Contract deliverables
 - Good clinical practices
 - Investigational plan
 - Delegation of responsibilities
- 1, 2, and 3 only
 - 1, 2, and 4 only
 - 1, 3, and 4 only
 - 2, 3, and 4 only

12 Lake reports investigator meetings receiving the highest scores by attendees are those conducted as:

- lecture presentations.
- interactive sessions.
- live webinars.
- pre-recorded self-study sessions.

13 Malcolm Knowles notes that adults seek a learning/training environment that is which of the following?

- Directed
- Dictatorial
- Authoritarian
- Cooperative

14 According to Knowles's attributes for adult learning principles, adults:

- learn what they are told to learn.
- are not typically self-motivated to learn.
- need to know why they need to learn something.
- do not seek out learning opportunities.

15 International Society of Performance Improvement Human Technology Performance methodology focuses on which of the following?

- What is wrong and not working
- Fixing problems as soon as possible
- The gap between desired performance and reality
- Waiting until staff are available to fix problems

CORRECTIONS

Corrections to Home Studies can be found on the ACRP website and are incorporated directly into the online test.

16 GCP training needs to be targeted and relevant to which of the following?

1. Regions and countries of the study
2. Study population and therapeutic area
3. Protocol design and complexity
4. Maintenance of the site regulatory binder

- A. 1, 2, and 3 only
- B. 1, 2, and 4 only
- C. 1, 3, and 4 only
- D. 2, 3, and 4 only

17 Protocol training during investigator meetings should include sessions on which of the following?

- A. Enrollment criteria
- B. Final study report to the IRB
- C. Study budget and contract
- D. Study-specific financial disclosure

18 Study coordinator training sessions during the investigator meeting should address which of the following?

1. Study coordinator responsibilities
2. IRB responsibilities
3. Study implementation and challenges
4. Training required by the Office of Research Integrity

- A. 1 and 2 only
- B. 1 and 3 only
- C. 2 and 4 only
- D. 3 and 4 only

19 Investigator meetings focusing on proactive site performance and adult learning principles include sessions that:

- A. cover GCP training and PI responsibilities.
- B. are provided in lecture format.
- C. engage attendees via experiential learning.
- D. require prior completion by the PI.

20 The goal of an investigator meeting is to:

- A. create relationships between sites and the CRA/sponsor.
- B. provide training to support protocol execution performance.
- C. explain the marketing plan for the test article.
- D. negotiate the trial budget with the sponsor.

QUESTIONS 21–30 Educating and Training CRAs for the Field: The Pursuit of Excellence

21 FDA IND and IDE regulations identify monitor selection as a responsibility of which of the following?

- A. Principal investigator
- B. IRB
- C. Individual CRA
- D. Sponsor

22 Qualifications of monitors as recommended in ICH GCP E6 5.18.2 should include which of the following?

1. Appropriate training
2. Scientific or clinical knowledge needed to monitor the trial
3. a minimum of two years experience
4. Documented qualifications

- A. 1, 2, and 3 only
- B. 1, 2, and 4 only
- C. 1, 3, and 4 only
- D. 2, 3, and 4 only

23 Monitor or CRA experience can be measured best by evaluation of:

- A. certificates of training granted by professional training agencies.
- B. the CRA's years of experience on the job.
- C. an individual CRA's resume.
- D. competency and standardized testing.

24 CRA education should include the:

1. principles of good clinical practice (GCP).
2. regulations and guidance on human subject protection.
3. latest FDA guidelines and regulations.
4. most recent FDA IDE filings.

- A. 1, 2, and 3 only
- B. 1, 2, and 4 only
- C. 1, 3, and 4 only
- D. 2, 3, and 4 only

25 Training a CRA on reviewing source/medical records is important because it teaches the CRA:

- A. how to assess adequate documentation.
- B. that review of source/medical records may not be necessary.
- C. that proof of HIPAA compliance is not necessary.
- D. how to ensure understanding of the protocol.

26 Standardization of source document review among CRAs can be achieved by:

1. matching data and inventorying documents.
2. use of the same monitoring techniques.
3. verifying raw data are accurate and complete.
4. use of the same monitoring tools.

- A. 1 and 2 only
- B. 1 and 3 only
- C. 2 and 4 only
- D. 3 and 4 only

27 Training the CRA on how to adequately review source documentation will:

- A. ensure the site is following all GCPs.
- B. help determine more precisely the subjects' eligibility to enroll.
- C. identify if there are any missing CRF pages.
- D. negate the need for onsite monitoring visits once the site shows reasonable accuracy.

28 CRA development objectives should include which of the following?

1. Evaluation of knowledge and training gaps
2. Limited feedback to the mentor
3. Mentoring
4. Performance improvement plans

- A. 1, 2, and 3 only
- B. 1, 2, and 4 only
- C. 1, 3, and 4 only
- D. 2, 3, and 4 only

29 For CRA assessments, the mentor may review previously monitored cases to assess which of the following?

- A. Adequacy of documentation
- B. Coordinator handwriting
- C. Presence of the CRF
- D. CRF completion

30 On average, in a clinical operation budget, site monitoring comprises what percentage of the trial cost?

- A. 5%
- B. 15%
- C. 30%
- D. 50%