

Careers in Clinical Research

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

1. **Human Research Protection: Not Just an Obligation, a Career**
Craig B. Caldwell, MBA, PhD, Assistant Professor, Butler University College of Business; Gretchen Miller Bowker, MS, RAC, Chief Operations Officer, Pearl Institutional Review Board
2. **Investigator Responsibilities in Clinical Research: ICH Viewpoint**
Charles H. Pierce, MSc, MD, PhD, FCP, CPI, Medical Director, CTI Clinical Trial and Consulting Services, and Vice Chair, Academy of Clinical Research Professionals; Howard E. Greenberg, MD, MSE, MBA, Adjunct Associate Professor, Department of Pharmacology and Experimental Therapeutics, Thomas Jefferson University, Philadelphia, Pa.
3. **Clinical/Regulatory Writing in the Pharmaceutical/Device Industry**
Kathy L. McDermott, MS, CCRA, RAC, Chief Manager, MedWrite Consulting Services, LLC

HOME STUDY LEARNING OBJECTIVES

At the conclusion of this course, participants should be able to:

1. describe the various career options in human research protection, define their roles, and recall key events in history that led to further role definition in the field of human research.
2. recognize and describe, in general terms, the overall responsibilities of the principal investigator as covered in the 13 subsections of ICH E6, Good Clinical Practices, section 4, "The Investigator."
3. describe the role that a medical writer plays in the development of clinical and regulatory documents and some of the qualifications and traits that allow a writer to excel at this role.

This test expires on SEPTEMBER 30, 2012

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CONTINUING EDUCATION INFORMATION

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



Contact Hours

The Association of Clinical Research Professionals (ACRP) provides 3.0 contact hours for the completion of this educational activity. These contact hours can be used to meet the certifications maintenance requirement. (ACRP-2011-HMS-009)



Continuing Nursing Education

The California Board of Registered Nursing (Provider Number 11147) approves the Association of Clinical Research Professionals (ACRP) as a provider of continuing nursing education. This activity provides 3.0 nursing education credits. (Program Number 11147-2011-HMS-009)



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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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ACRP members are often employed by commercial interests. However, if the content of the educational activity and/or committee responsibility deals with the regulatory and ethical requirements of the conduct of clinical research, it is not considered a conflict of interest. It is also not considered a conflict of interest if the content is not about or promoting products or services of commercial interests. If an individual has a relationship that is deemed a conflict of interest, the conflict must be resolved prior to the activity.

The intent of this policy is not to prevent individuals with relevant financial relationships from participating; it is intended that such relationships be identified openly so that the audience may form their own judgments about the presentation and the presence of commercial bias with full disclosure of the facts. It remains for the audience to determine whether an individual's outside interests may reflect a possible bias in either the exposition or the conclusions presented.

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QUESTIONS 1–10

Human Research Protection: Not Just an Obligation, a Career

- 1** The volume of clinical research is increasing due to:
- more patients being available.
 - an FDA request for more data.
 - an increased desire to run trials.
 - a lack of available drug candidates.
- 2** Large pharmaceutical companies have increased their pipeline through:
- use of IRBs and other ethics committees.
 - investing more money and capital.
 - increased partnering with other companies.
 - discovery of more suitable drug candidates.
- 3** The Gelsinger case involved complexity in:
- patient population.
 - the disease indication being studied.
 - proper consenting with a novel therapy.
 - the clinical site for the study being conducted.
- 4** Which of the following involved in clinical research are directly tasked with human research protection?
- The vendor management specialists
 - The IRB members
 - The data manager
 - The central lab director
- 5** Coast IRB was shut down because they did not:
- archive their meeting minutes.
 - train the PI appropriately.
 - follow their own SOPs on protocol review and approval.
 - adequately protect human subjects.
- 6** Historically institutional IRBs like those in hospitals and academic medical centers have used employees that:
- are volunteers who have a full-time job.
 - work at more than one hospital.
 - are on probation, but allowed to continue IRB work.
 - paid to participate in IRB activities.

- 7** By law, IRBs should include at least one member that:
- is an accountant.
 - is not a scientist.
 - lives in the same town as the potential subjects.
 - worked at FDA or another health agency.

- 8** Individuals involved with human subject protection are generally well-educated in:
- business.
 - science.
 - math.
 - English.

- 9** IRB coordinators have many roles, including:
- ensuring the protocol is followed.
 - archiving the trial master files associated with the protocol.
 - ensuring that the IRB runs in compliance with regulations.
 - providing medical care to the subjects according to IRB specifications.

- 10** The first line of human research protection is the:
- safety officer at a pharmaceutical company.
 - principal investigator.
 - FDA.
 - OHRP.

QUESTIONS 11–20

Investigator Responsibilities in Clinical Research: ICH Viewpoint

- 11** Which of the following pairings of a country and its Drug Regulatory Authority (DRA) are correct?
- Japan — PMDA
 - United States — FDA
 - Western Europe — EMA
 - Eastern Europe — EMEA
- 1, 2, and 3 only
 - 1, 2, and 4 only
 - 1, 3, and 4 only
 - 2, 3, and 4 only

- 12** Which of the following are responsibilities of the PI?

- Hire the key staff of the research team
- Personally conduct or supervise the investigation per protocol
- Accurately report all AEs to the sponsor
- Read and understand the investigator's brochure

- 1, 2, and 3 only
- 1, 2, and 4 only
- 1, 3, and 4 only
- 2, 3, and 4 only

- 13** Major topics of ICH include which of the following?

- Q or quality topics
- S or safety topics
- E or efficacy topics
- M or manufacturing topics

- 1, 2, and 3 only
- 1, 2, and 4 only
- 1, 3, and 4 only
- 2, 3, and 4 only

- 14** AEs may be which of the following?

- Signs, including changes in blood pressure, temperature, rashes
- Subjects who do not like the investigational product
- Symptoms, such as lightheadedness, nausea, headache
- Lab results well beyond the “reference range”

- 1, 2, and 3 only
- 1, 2, and 4 only
- 1, 3, and 4 only
- 2, 3, and 4 only

- 15** Morally valid informed consent consists of which of the following components?

- Disclosure
- Voluntariness
- Literacy
- Understanding

- 1, 2, and 3 only
- 1, 2, and 4 only
- 1, 3, and 4 only
- 2, 3, and 4 only

CORRECTIONS

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

- 16** Informed consent is a:
- document.
 - process.
 - moment in time.
 - signature.

- 17** Regarding the IRB communications, the PI must assure the IRB:
- provides verbal approval before site initiation.
 - has a current investigator's brochure.
 - is informed of all protocol deviations when they occur.
 - approves each subject enrolled into the study.

- 18** The motto "if it is not documented, it did not happen" supports the acronym "ALCOA," which refers to which data properties?
- Accurate
 - Legible
 - Contemporaneous
 - On time
- 1, 2, and 3 only
 - 1, 2, and 4 only
 - 1, 3, and 4 only
 - 2, 3, and 4 only

- 19** The annual written progress report on each study to the IRB is authored by the:
- sponsor.
 - FDA.
 - PI.
 - CRO.

- 20** The randomization code of a blinded study is broken
- when the IRB requests it.
 - for subject safety reasons.
 - when a subject demands to know.
 - for drug accountability purposes.

QUESTIONS 21–30

Clinical/Regulatory Writing in the Pharmaceutical/Device Industry

- 21** The medical writer's audience may include:
- the FDA, IRB, and investigative sites.
 - the subjects in the study and the site personnel.
 - www.clinicaltrials.gov.
 - company press releases regarding the study.

- 22** Most clinical/regulatory documents follow a:
- stream-of-consciousness flow.
 - casual conversational dialog.
 - scientific, descriptive style.
 - cryptic, bulleted format as talking points.

- 23** A medical writer should:
- organize the information in a logical flow.
 - clarify complex data/concepts in understandable language.
 - make the results look favorable to the investigational product.
 - solicit sections from subject matter experts.
- 1, 2, and 3 only
 - 1, 2, and 4 only
 - 1, 3, and 4 only
 - 2, 3, and 4 only

- 24** When writing protocols, the medical writer should have a:
- good understanding of the product under investigation.
 - good understanding of patient flow through the clinic.
 - working knowledge of GMPs.
 - working knowledge of GCPs.
- 1, 2, and 3 only
 - 1, 2, and 4 only
 - 1, 3, and 4 only
 - 2, 3, and 4 only

- 25** The medical writer must:
- use the appropriate document template.
 - pull engineering specifications from the quality system.
 - determine appropriate data formats (table, graph, or figure).
 - conduct a literature review of the disease condition and available treatments.
- 1, 2, and 3 only
 - 1, 2, and 4 only
 - 1, 3, and 4 only
 - 2, 3, and 4 only

- 26** When the medical writer and the statistician work closely, the statistician focuses on the analysis and statistical significance, and the medical writer focuses on:
- the clinical relevance of the statistical significance.
 - ensuring the statistician has written in the most appropriate way.
 - whether the data are good enough for FDA approval/clearance.
 - how to make the data look the best in order to sell more product.

- 27** Multitasking is a desirable skill because writers must:
- answer the phone, schedule, and attend meetings.
 - delegate tasks/sections of the report and drive timelines.
 - be responsible for the content and accuracy of the report.
 - obtain, implement, and negotiate all reviewers' comments.
- 1, 2, and 3 only
 - 1, 2, and 4 only
 - 1, 3, and 4 only
 - 2, 3, and 4 only

- 28** The most important skills for a medical writer are:
- good organizational and writing skills, computer expertise in business applications, and people skills.
 - good graphic software skills and statistical knowledge for creating tables, charts, and figures.
 - good project management skills, medical transcription, and customer service skills.
 - good command of grammar and spelling and a large vocabulary, along with fast keyboarding skills.

- 29** Qualifications for a medical writer include:
- a life sciences background, knowledge of clinical research practices including database management and statistics.
 - a PhD in statistics and training in clinical research practices.
 - being a subject matter expert on the investigational product and knowledge of database management and statistics.
 - being a published book author (MD) in the life sciences.

- 30** Personal traits that allow a person to excel as a medical writer are:
- self-confident individual willing to take risks, out-of-the-box thinking, high-strung personality.
 - strong logical thinking processes, single-tasking, and methodical.
 - strong sense of ethics, organizational skills, and attention to small details.
 - an advocate for patient safety, a "do-it-by-the-book" persona.