

ETHICS



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, \$27). 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 **April 2010 Monitor Home Study** is based on the following three articles in this issue:

- 1. Ethical Challenges of New Discoveries: A Sponsor's Viewpoint**
Bartholomew J. Tortella, MTS, MD, MBA, FACS, FCCM, Senior Director of Clinical Research, Novo Nordisk
- 2. Informed Consent: A Case Study of Three Novel Consent Procedures**
Carlotta M. Rodriguez, BS, CIP, Director, Newark Campus IRB, University of Medicine and Dentistry of New Jersey | Amy L. M. Lallier, BA, CIM, CIP, Assistant Director, Newark Campus IRB, University of Medicine and Dentistry of New Jersey
- 3. Ethical Issues in Clinical Research for Dietary Supplements**
Denise L. King, MS, PhD, Associate Director, Nutrition Coordinating Center, University of Minnesota | Joy L. Frestedt, PhD, RAC, CCTI, President and CEO, Frestedt, Inc.

HOME STUDY LEARNING OBJECTIVES

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

1. develop a working knowledge of the ethical challenges facing the pharmaceutical industry in modern clinical research.
2. discuss the novel consent processes presented and evaluate the application and implementation of these processes across varied research types and subject populations.
3. understand what dietary supplements are and how they are regulated, and recognize associated ethical issues.

CONTINUING EDUCATION INFORMATION

The Monitor home study tests offer ACRP, nursing, pharmacy, and continuing medical education credits.



The Association of Clinical Research Professionals (ACRP) provides 3.0 continuing education credits for the completion of this educational activity. These credits can be used to meet the certification maintenance requirement under provider number ACRP-2010-HMS-004.



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

ACRP designates this educational activity for a maximum of 3.0 AMA PRA Category 1 credits™. Each physician should only claim credit commensurate with the extent of their participation in the activity.



Continuing Nursing Education: The California Board of Registered Nursing (Provider Number 11147) approves the Association of Clinical Research Professionals as a provider of continuing nursing education. The CBRN program number is 11147-10-004. Each home study offering grants 3.0 nursing credits.

DISCLOSURES

The following persons who have access to influence the content of *The Monitor* have the following affiliations to disclose:

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QUESTIONS 1–10

Ethical Challenges of New Discoveries: A Sponsor's Viewpoint

- 1** The first document to codify research ethics was:
- the Nuremberg Code.
 - the Declaration of Helsinki.
 - the International Ethics Guidelines for Biomedical Research.
 - the Council for International Organizations of Medical Sciences.
- 2** Which organization is working to unify regulatory guidelines for clinical research?
- World Health Organization
 - The Indian Council of Medical Research
 - The Council for International Organizations of Medical Sciences
 - The International Conference on Harmonization of Technical Requirements
- 3** What action was taken by Congress to improve research in rare diseases?
- The Onchocerciasis Control Program Act
 - The Orphan Drug Act
 - The Biotechnology Industry Organization Act
 - The Omnibus Reconciliation Act
- 4** What drug is used to control river blindness?
- Anthelmintic
 - Ivermectin
 - Onchocerciasis
 - Horrobin
- 5** What is the current approximate cost for development of a single drug entity?
- \$82 million
 - \$502 million
 - \$802 million
 - \$1002 million
- 6** One of the most costly parts of drug development is:
- clinical trials.
 - basic science research.
 - manufacturing.
 - sales and marketing.

CORRECTIONS

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

- 7** What action was taken by Congress to increase pediatric drug development?
- The FDA Pediatric Rules
 - The Orphan Drug Act
 - NIH Pharmaceuticals for Children Act
 - The FDA guidance on pediatric research
- 8** Which document or website provides uniform publication standards for clinical trial reporting?
- WHO International Clinical Trials Registry
 - ClinicalTrials.gov
 - Clinicaltrials.ifpma.org
 - CONSORT guidelines
- 9** Clinical trial data in the U.S. must be published within what period of time, according to U.S. Public Law 110-85, Title VIII?
- 6 months
 - 12 months
 - 18 months
 - 24 months
- 10** Who bears the primary responsibility for the presentation of results in a publication?
- The manuscript authors
 - The principal investigators
 - The sponsor
 - The National Institutes of Health

QUESTIONS 11–20

Informed Consent: A Case Study of Three Novel Consent Procedures

- 11** Informed consent is built upon which ethical principal of the Belmont Report?
- Justice
 - Beneficence
 - Respect for Persons
 - Conflict of Interest Disclosure

12 Three types of novel consent processes discussed in this article are the:

- Designation of a bilingual consent aide
- Surrogate consent process
- Use of translated short-form consents
- Identification of a consent proxy

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

13 Which consent process seeks to ensure that all patients, particularly those who do not understand English, are provided the same rights and opportunities in participating in clinical trials as English-speaking patients?

- Designation of a bilingual consent aide
- Surrogate consent process
- Use of translated short-form consents
- Identification of a consent proxy

14 Which New Jersey State law authorizes certain persons to give informed consent for medical research if the subject of the research is unable to give consent?

- Access to Medical Research Act
- Family Leave Act
- Safe Haven Infant Protection Act
- Worker Adjustment and Retraining Notification Act

15 Patients unable to voluntarily reason, understand, and appreciate the nature and consequence of research interventions may be enrolled using which state law consent variation?

- Designation of a bilingual consent aide
- Surrogate consent process
- Use of translated short-form consents
- Identification of a consent proxy

16 Which type of study may require investigators to provide additional safeguards to ensure the ongoing ability of participants to provide legally informed consent?

- Registry trials for subjects with ovarian cancer
- Retrospective chart reviews of inpatient studies
- Longitudinal studies of subjects at risk for cognitive decline
- Blood-draw research on healthy volunteers for meta-analysis purposes

- 17** Once a surrogate has provided consent for the enrollment of a subject,
- investigators are not required to reassess the subject for capacity.
 - capacity evaluations are needed only in greater than minimal risk studies.
 - the subject must continue in the protocol even if he/she no longer wishes to participate.
 - the subject has the right to refuse continuation once he/she has regained capacity.

- 18** Which of the following elements are considered part of the designation of a consent proxy?
- Reassessment tools for cognitive capacity
 - Assignment of the consent proxy form
 - Informed consent form document
 - Surrogate consent self-certification
- 1, 2, and 3 only
 - 1, 2, and 4 only
 - 1, 3, and 4 only
 - 2, 3, and 4 only

- 19** The statement “no one size fits all” addresses differences in subject capacity to provide:
- initial informed consent.
 - informed consent in English.
 - continued consent to participate.
 - consent of the subject's surrogate.
- 1, 2, and 3 only
 - 1, 2, and 4 only
 - 1, 3, and 4 only
 - 2, 3, and 4 only

- 20** Designation of a consent proxy allows for continued participation of a subject:
- in new research at any facility.
 - in a specific protocol at the given facility.
 - if the subject declines initial participation.
 - if the subject agrees to participate once he/she has regained capacity.
- 1 and 3 only
 - 1 and 4 only
 - 2 and 3 only
 - 2 and 4 only

QUESTIONS 21–30

Ethical Issues in Clinical Research for Dietary Supplements

- 21** Which of the following are examples of dietary supplements?
- Tobacco
 - Vitamin and mineral tablet
 - Herb extract
 - Antibiotic capsule
- 1 and 2 only
 - 1 and 4 only
 - 2 and 3 only
 - 3 and 4 only

- 22** According to the National Institutes of Health and U.S. Department of Agriculture, what percentage of adults consumes dietary supplements?
- 25%
 - 50%
 - 75%
 - 85%

- 23** A purpose of the Dietary Supplement Health and Education Act of 1994 was to:
- remove unlawful label claims.
 - define supplements as a medicine.
 - allow manufacturers to use new ingredients without notifying the FDA.
 - create the Office of Dietary Supplements.

- 24** A study of hospitalized patients indicated that dietary supplement use is associated with patients who:
- have informed their hospital medical team.
 - do not smoke.
 - have higher incomes.
 - have infectious diseases.
- 1 and 2 only
 - 1 and 4 only
 - 2 and 3 only
 - 3 and 4 only

- 25** Who is responsible for ensuring a dietary supplement is safe BEFORE it is placed on the market?
- Supplement manufacturer
 - Office of Dietary Supplements
 - Food and Drug Administration
 - Federal Trade Commission

- 26** Which of the following is a common criticism of dietary supplement research?
- Inadequate safety and efficacy information
 - Inaccurate manufacturer website information
 - Inappropriate financial incentives for clinical trial participants
 - Excessive data regarding the identity and purity of ingredients

- 27** Who is responsible for issuing a product recall if a dietary supplement is found to contain harmful or hazardous ingredients?
- USDA Test Laboratories
 - Office of Dietary Supplements
 - Food and Drug Administration
 - Federal Trade Commission

- 28** A General Accounting Office report on dietary supplements showed increased risks owing to which of the following primary issues?
- Insufficient consumer knowledge
 - Weak regulatory control
 - Full disclosure in advertising
 - Early publication of clinical trial data
- 1 and 2 only
 - 1 and 3 only
 - 2 and 4 only
 - 3 and 4 only

- 29** Dietary supplements containing ephedra were banned by the FDA owing to unreasonable risk of:
- liver damage.
 - headaches.
 - multiple sclerosis.
 - heart attack.

- 30** Which of the following are important considerations in the design of ethical dietary supplement clinical trials?
- Rigorous testing of marketing claims
 - Limiting expense of IRB review
 - Tracking of competitors' research
 - Surveillance of safety data
- 1 and 2 only
 - 1 and 4 only
 - 2 and 3 only
 - 3 and 4 only