

CKA

ACRP CORE KNOWLEDGE
ASSESSMENT TEST GUIDE



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Questions?

If at any time you should have questions, or need to contact ACRP:

ACRP

Certification

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Reasons for contacting ACRP include, but are not limited to: change of contact information; hand-score requests; and cancellation requests. Any required fees must accompany the request in order to be processed.

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ABOUT THE CKA TEST

What is the Core Knowledge Assessment Test?

The CKA test assesses internationally accepted core concepts for conducting clinical trials and does not require the two years of experience required for ACRP's CCRA, CCRC or CPI exams. The test is a way to demonstrate to an employer or a regulatory authority that you possess a standard level of knowledge of the regulatory requirements for conducting clinical research studies and can serve as a first step in seeking certification.

The CKA assesses your knowledge at a specific point in time and is valid for three years. Over the course of the three years the guidelines and requirements may change and the CKA will change to maintain currency.

Requirements for Admission to the CKA Test

There are no prerequisites to take the CKA test. ACRP strongly recommends that candidates take an introductory education course in the fundamentals of clinical research.

Format of the CKA Test

The CKA test is an internet-based test offered through ACRP's testing partner, Prometric. Test from any computer compatible with Prometric's internet-based testing (IBT) web application system requirements (http://www.acrpnet.org/popups/practice_exam_requirements.html).

There are 75 multiple choice questions with four options and one best answer. All are at the recall level of complexity. Recall questions primarily test the recognition of isolated information. They include the recall of specific facts, concepts or principles. You are given 60 minutes to complete the test. A passing score is 70% or higher.

Test Preparation

Studying the following ICH guidelines (<http://www.ich.org>) will assist you in preparing for the test:

- Clinical Safety Data Management: Definitions and Standards for Expedited Reporting (E2A)
- Good Clinical Practice (E6)
- General Considerations for Clinical Trials (E8)

The Declaration of Helsinki* (<http://www.wma.net>)

*Note of clarification on paragraph 29 of the WMA Declaration of Helsinki. The WMA is concerned that paragraph 29 of the revised Declaration of Helsinki (October 2009) has led to diverse interpretations and possible confusion. It hereby reaffirms its position that extreme care must be taken in making use of a placebo-controlled trial and that in general this methodology should only be used in the absence of existing proven therapy. However, a placebo-controlled trial may be ethically acceptable, even if proven therapy is available under the following circumstances:

- Where for compelling and scientifically sound methodological reasons its use is necessary to determine the efficacy or safety of a prophylactic, diagnostic or therapeutic method; or

- Where a prophylactic, diagnostic or therapeutic method is being investigated for a minor condition and the patients who receive placebo will not be subject to any additional risk of serious or irreversible harm.

All other provisions of the Declaration of Helsinki must be adhered to, especially the need for appropriate ethical and scientific review.

Also refer to the CKA Detailed Content Outline and Sample Questions contained within this guide.

Reliability Measurements

After every certification exam, the Exam Committees review the results with the assistance of Prometric, one of the testing industry's leading firms. Each item is analyzed for appropriate psychometric characteristics. Those items with poor statistical results are reviewed by the appropriate Exam Committee to ensure that they have been scored properly. Participant feedback regarding the exam and its contents is also reviewed and taken into consideration when reviewing the exam and future test items.

DETAILED CONTENT OUTLINE

1. Clinical Research Overview (15 items)

- a. ICH Guideline
- b. Protection of Human Subjects / Informed Consent
- c. General Principles of Clinical Research / GCP

2. Investigational Product Research and Development (11 items)

- a. Discovery and Preclinical Research
- b. Investigational New Drugs
- c. Medical Devices
- d. Biologics
- e. Post-marketing

3. Clinical Research Methodology (24 items)

- a. Trial Design
- b. Research Protocols
- c. Source Documents
- d. Case Report Forms
- e. Regulatory Documents
- f. Investigator's Brochure
- g. Trial Conduct

4. Roles and Responsibilities (15 items)

- a. IRB/IEC
- b. Investigator/Staff
- c. Sponsor/Monitor
- d. CRO

5. Safety Reporting (10 items)

- a. Definitions
- b. Standards for Reporting

SAMPLE TEST QUESTIONS

1. *Please refer to the Detailed Content Outline (3.g).*

Which of the following would normally take place at a pre-study visit?

- 1. Source document review
 - 2. Review of protocol with an IEC member
 - 3. Assessment of the site's equipments relevant for the study
 - 4. Discussion of the storage and distribution requirements for the investigational product
-
- A. 1 and 2 only
 - B. 3 and 4 only
 - C. 2 and 4 only
 - D. 1 and 3 only

The correct answer is B; 3 and 4 only.

Explanation:

- (I) There cannot be any review of Source Documentation at the pre-study visit because the study has not yet started at the site
- (II) The purpose of the visit is to decide whether a site is suitable to conduct a study. The criteria are essentially the experience and availability of the investigator and other personnel and the facilities available including essential equipments. Discussions between the CRA and the ethics committee are not standard practice.

2. *Please refer to the Detailed Content Outline (1.a).*

The ICH GCP Guidelines require a PI to provide an IEC with all of the following EXCEPT

- A. Information about payments to subjects
- B. Significant changes in the protocol
- C. Information regarding all serious unexpected Adverse Drug Reactions
- D. Names of subjects prematurely terminated from the study ANSWER

The correct answer is D; names of subjects prematurely terminated from the study.

Explanation:

This question asks for the recognition of only the wrong answer.

(A) is stated in ICH GCP s3.1.8

(B) is stated in ICH GCP s3.1.2

(C) is stated in ICH GCP s3.3.8.c

3. *Please refer to the Detailed Content Outline (5.b).*

An event that has been associated with the use of the test article and is documented in the Investigator's Brochure is defined as:

A. mild

B. severe

C. serious

D. expected

The correct answer is D; expected

Explanation:

The applicable product information (e.g, Investigator's Brochure for an unapproved investigational product or package insert/summary of product characteristics for an approved product) describes the possible risks and adverse drug reactions to be expected on the basis of prior experiences with the product under investigation and with related products.

Ref: ICH GCP 1.60; 7.3.6

APPLICATION, TESTING PROCEDURES

Internet-Based Testing Requirements

Confirm that your system meets Prometric's IBT requirements

(http://www.acrpnet.org/popups/practice_exam_requirements.html)

Application Instructions

Apply online at <http://www.acrpnet.org/cka>.

A confirmation receipt will be emailed following your online purchase of the CKA test.

Costs

The CKA test costs \$99.00. Membership is not required to take the CKA test but is available at the time of purchase.

Accessing the Test

From the emailed confirmation receipt, retrieve your Voucher Number and the 'Go To' link to enter the online CKA testing site. If you do not receive the confirmation, please check your junk mail folder before contacting ACRP at certification@acrpnet.org.

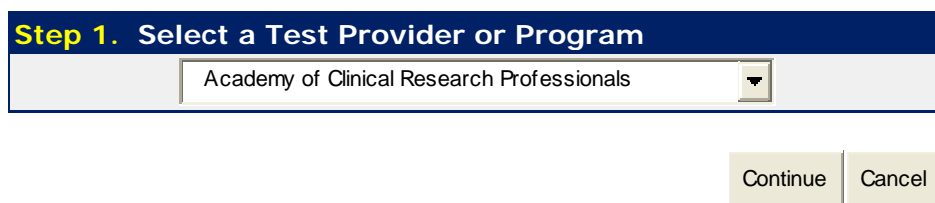
Once you enter the Prometric testing web site and complete a First-Time Registration, you can proceed from the main menu to take the test. Once you enter the test screen, a real-time timer will indicate the remaining time for you to complete the test. The test will terminate if you exceed the time allowed. Questions must be answered as they appear on the screen. Returning to the previous question is not permitted. Please read the following explicit instructions to accessing the test site and beginning the test.

First-Time Registration

Once you enter the Prometric Test Site, you will need to register as a first-time user if you have not previously used the site.

Visit <http://ibt.prometric.com/acrp-cka> and follow these steps:

1. Click 'First-Time Registrant'
2. In Step 1, click 'Continue'



Step 1. Select a Test Provider or Program

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Continue Cancel

3. Complete mandatory fields, and click 'Submit'
4. Click 'Continue' to get to the main menu

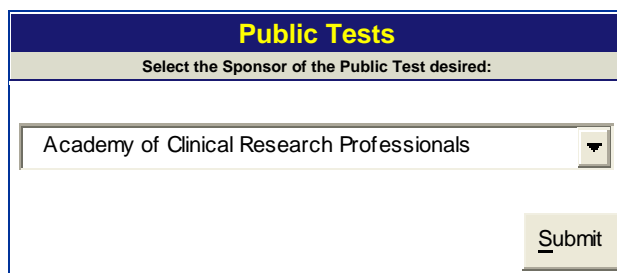
Returning users should sign in from the Secure Sign-In Link.

Using the Voucher Number

You must have a Voucher Number to enter the CKA Test. This Voucher Number may only be used once. Locate it in the confirmation receipt emailed to you immediately after purchase. Once you have the number, proceed through the five-step process to enter the test:

Start: From the Main Menu, click Take Test and follow the steps on the following screens.

Step 1: Click Submit in the Public Tests box. Do not enter any information on this screen.



Public Tests

Select the Sponsor of the Public Test desired:

Academy of Clinical Research Professionals

Submit

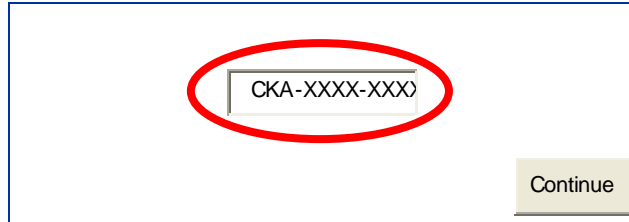
Step 2: Click on the title 'Core Knowledge Assessment Test.'

Step 3: Confirm Test Selection; Click 'Take this Test'

Step 4: This step is skipped

Step 5: Enter Voucher Number exactly as it appears on your confirmation email (e.g., CKA-1234-5678); click 'Continue'

Enter Promotion Code or Voucher



Done! At this final step, read the instructions and take a tutorial (optional). Once you click Begin Test, you will see the first question and cannot back out of the test. The timer has begun.

After the Test / Receive Your Score

Immediately following the test, candidates receive their test results on the screen. This report should be printed and retained as proof of passing this test for your records. A duplicate score report will not be provided. The overall percentage is shown, along with the number of correct answers for each of the five sections of the CKA Detailed Content Outline. A 70% or higher is a passing score.

If you do not successfully pass the test, you can take it again by re-submitting the application and payment. There is no limit on the number of times the test can be purchased and taken.

Scores Cancelled by ACRP or Prometric

ACRP and Prometric are responsible for the validity and integrity of the scores reported. On occasion, occurrences, such as computer malfunction, may cause a score to be suspect. ACRP and Prometric reserve the right to void or withhold test results if, upon investigation, violation of its regulations is discovered.

Copyrighted Test Questions

Each test question is the copyrighted property of ACRP. It is forbidden under federal copyright law to copy, reproduce, record, distribute or display these test questions by any means, in whole or in part. Doing so may subject you to severe civil and criminal penalties.

Cancellation/Refund/Transfer Policy

You will have 90 days from the date of purchase to complete the test. There are no refunds for expired tests or cancellations. Substitutions of other individuals are not permitted.

Additional Support

For technical support, contact Prometric (<http://www.prometric.com/TestTakers/ContactUs/email.htm>).

For all other needs, contact ACRP at certification@acrpnet.org or by phone at (703) 254-8100.

FREQUENTLY ASKED QUESTIONS

What is the Core Knowledge Assessment (CKA)?

The CKA is intended to demonstrate that the candidate possesses the knowledge contained in the ICH guidelines, specifically E2 (Safety Reporting), E6 (Good Clinical Practice), E8 (General Considerations for Clinical Trials) (<http://www.ich.org>)

Why should I take the Core Knowledge Assessment?

It is a way to demonstrate to your employer or a regulatory authority that you possess the standard of knowledge of the regulatory requirements for conducting clinical research studies. It is also useful to demonstrate to yourself that you have a comprehension of the ICH guideline content. It can serve as a first step in seeking certification. When the required number of years of work experience is reached, the ACRP certification exam application can be submitted.

What does it mean to pass the CKA?

The CKA assesses your knowledge at a specific point in time and is valid for three (3) years. Over the course of the three years the guidelines and requirements may change and the CKA will change to maintain currency. ACRP believes that clinical research professionals should seek professional certification to establish themselves with their peers, their employer, and regulatory authorities as competent in the conduct of clinical research. The expectation is that entry level research professionals who have passed the CKA apply to take one of ACRP's professional certification exams, as appropriate, when they have the required experience.

How is the CKA different from existing ACRP certification programs?

Existing ACRP certification examinations are based on the ability to apply the knowledge of the regulatory requirements for clinical research in practical, real life situations. The CKA test assesses ones knowledge of the ICH guideline content.

Will I receive a designation?

No. This is not a professional certification examination. Certification examinations test your ability to apply the regulatory requirements in practical settings. The CKA assesses a specific knowledge base of the ICH guidelines that relate to the conduct of clinical research studies. Passing the CKA is an accomplishment and should be listed on your resume/CV and training portfolio.

Will I receive a formal certificate?

No. You will receive an official ACRP score report with results listed for each of the five sections of the CKA Detailed Content Outline. This score report can be used to determine areas of knowledge, strengths, and weaknesses to aid in your future study preparation should you need to retake the CKA.

What do I need to qualify?

There are no prerequisites to take the CKA. We do strongly recommend that a candidate takes an introductory education course in the fundamentals of clinical research.

Where do I take the exam?

The CKA Exam is an Internet Based Test (IBT) that can be taken from any computer meeting the testing vendor's (Prometric's) system requirements. The test does not require a proctor or travel and can be taken at any time of the day. Twenty-four hour support is available for technical assistance.

How do I apply to take the CKA?

The CKA test application is available online only. Once you have submitted the application, including the \$99 payment, you will receive a confirmation email containing the a web page link and Voucher # used to access the test.

How should I prepare for the CKA test and what is the format?

Studying the ICH guidelines (<http://www.ich.org>) and the Detailed Content Outline will assist you in preparing for the test. There are 75 multiple choice questions with four options and one best answer. All are at the recall level of complexity. Recall questions primarily test the recognition of isolated information. They include the recall of specific facts, concepts or principles. You are given 60 minutes to complete the test.

How much time do I have to take the CKA?

The test must be taken within 90 days of purchase. Once you have entered the test, the timer will begin. You will have 60 minutes to complete the test.

When will I receive the results of the CKA?

You will receive the results of your test and a detailed score report immediately after completing your test. This document should be retained for your records. A duplicate score report will not be provided.

If I do not pass the CKA, when can I retake it and what is the procedure for doing that?

If you do not successfully pass the test, you can take it again by simply re-submitting the application and payment. There is no limit on the number of times the test can be taken. It is recommended that returning candidates take remedial action to improve their comprehension of the ICH guideline content as the test questions change.

What is the CKA refund policy?

There are no refunds of the CKA application fee for cancellations or expired tests. The test must be taken within 90 days of purchase.

If I am unable to take the CKA, can I substitute another colleague?

Substitutions are not permitted. Each candidate must submit an application separately to take the test.

I have questions, who do I call?

For technical support, contact [Prometric](#). For all other needs, contact ACRP at certification@acrpnet.org or by phone at (703) 254-8100.

NON-DISCRIMINATION POLICY

It is ACRP/APPI's philosophy and policy to avoid discrimination based on race, color, national origin, sex, age, religion, marital status, sexual orientation, or other status or condition that is protected by applicable law.

CONFIDENTIALITY

ACRP protects the confidential information of applicants and certificants. In addition to personal information submitted in the application, exam results are also considered confidential. Unless otherwise required by law, confidential information will only be released to the individual applicant/certificant unless a signed release is provided.

DISCIPLINE AND COMPLAINTS POLICY

ACRP enforces the ACRP/APPI Uniform Code of Ethics and Professional Conduct for all CRA, CRC and CTI certificants and individuals in the process of obtaining CRA, CRC or CTI certification.

ACRP will investigate reported violations of the Uniform Code of Ethics and Professional Conduct. Complaints regarding alleged violations should be reported to ACRP in writing and should include a detailed description of factual allegations supporting the charges and any relevant supporting documentation.

Information submitted during the complaint and investigation process is considered confidential and will be handled in accordance with ACRP's Confidentiality policy. Adverse disciplinary decisions made by ACRP (or its sub-committees) may be appealed. A complete copy of the Discipline and Complaints policy and procedure and the Appeal policy and procedure may be requested by contacting the ACRP.