# CPI Certification Guide – March 2009


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# Introduction

The Academy of Pharmaceutical Physicians and Investigators (APPI) is a non-profit association dedicated to:

Enhancing the proficiency of pharmaceutical physicians;
Promoting the acquisition and dissemination of knowledge concerning the therapeutic action, investigation, and development of medicines and diagnostics; and
Protecting the welfare of patients and study subjects.

APPI offers the Certified Physician Investigator (CPI™) examination to qualified physician investigators. Region-specific exams are offered for North America, Europe, and ICH (rest of the world). Certification as a CPI™ signifies that a physician possesses knowledge sufficient for the safe and ethical conduct of a clinical trial in accordance with the appropriate ethical, medical, scientific, legal, and regulatory standards.

The written CPI™ examination is a measure of a candidate's general skills and knowledge of the information needed for the CPI™ to perform this role effectively. Certification is granted in recognition of the applicant's documented education, training, and experience as a primary, sub- or co-investigator OR monitor, supervisor, or designer of clinical trials and based upon successful completion of the written CPI™ examination. By awarding the title of Certified Physician Investigator (CPI™), APPI is formally recognizing the professional physician investigator who has provided evidence that he or she meets accepted professional standards.

# Physician Investigator Definition

A physician investigator is a physician (M.D. or equivalent degree) who serves as the primary, sub- or co-investigator or monitors, supervises, or designs clinical trials and accepts responsibility for the safe and ethical conduct of a clinical trial, herein defined as a systematic experiment designed to evaluate the pharmacokinetics, pharmacodynamics, pharmacoeconomics, safety, efficacy, and effectiveness of a drug, biological, medical device (therapeutic or diagnostic), procedure or other intervention involving human participants.

# Application Process Overview

To take the CPI™ examination, applicants must submit a completed application along with collateral materials including CV, copies of current medical licenses and registrations, employment verification, and sponsor or IRB approval letters or regulatory forms. The application steps include:

1 Review the candidate handbook prior to completing the application. Follow the instructions given, and address any questions to APPI. Failure to follow the instructions can lead to the denial of an application.
2 Review the competency requirements. To take the CPI™ examination, an applicant must meet certain educational, employment, training, and professional competency requirements. **All accrued education, work experience, and training must be completed prior to the exam date. DO NOT submit an application before you have acquired all the work experience, education, and training needed for eligibility.**

3. Complete and mail the application. The completed application must include: 1) a current signed and dated CV, 2) a copy of all current state medical license(s)/registration(s), and 3) three copies of signed regulatory forms, such as the 1572, IRB approval letters, or protocol approval letters that cover the last two years that demonstrates your involvement in clinical research.

1 Mail the application and application fee. A completed application must be received at APPI, by the deadlines above, before processing begins.
2 Allow sufficient time for application review. Applicants are encouraged to submit their applications and collateral materials as early as possible to allow for any unanticipated delays. APPI may confirm an applicant's employment and work experience and will process the application as quickly as possible. Major delays are often caused by incomplete applications or by missing collateral information.
3 Taking the examination. If an applicant is approved to take the CPI™ examination, they will be informed via email that they are now eligible to take the examination.
4 Wait for the examination results. In order for statistical analyses to be completed on the CPI™ examination, examination results will be mailed approximately six weeks after the examination date.

**Examination results will be released in writing via mail only. Examination results will not be given via telephone or fax.**

## Competency Requirements

To be eligible for the certification examination, an applicant must meet specific education, employment, training, and professional competency requirements.

***Education:*** Complete all sections of the application that pertain to education. The applicant must hold a medical physician degree (M.D. or equivalent degree) and be active and in good standing with all state/province/locality licensing and regulatory authorities and certifying bodies.

***Employment:*** Complete all sections of the application that pertain to employment. Employment is broadly defined to include paid services, fellowships, internships, and volunteerism. Employment experience must include service as a primary, sub-, or co-investigator in one or more clinical trials for the last two (2) years, **OR** a medical monitor, supervisor, or designer of one or more clinical trials for the last two (2) years, **OR** the successful completion of an accredited clinical research degree or clinical fellowship program of at least one (1) year's duration. Include a notarized letter from your supervisor(s) that covers your two years of experience and verifies the job functions performed.

***Licenses and Registrations:*** A current medical license to practice medicine in the state/province/locality is required of all CPI™ exam candidates. Complete all sections of the application that pertain to state licenses and registrations. The applicant is responsible for including copies of all current state licenses and registrations held by the applicant. Failure to include this documentation may delay the processing of the application.

***Sponsor or IRB Approval Letters:*** The applicant is responsible for including three signed sponsor letters or IRB approval letters or regulatory forms (e.g., Form 1572 or IRB approval letter) that demonstrates involvement in clinical research in the last two years. Failure to include this documentation may delay the processing of the application, or may result in ineligible status.

***CV:*** **A (no less than one-year-old) signed and dated CV is required and must be included with the application. By signing and dating the CV, the applicant affirms that the information** contained in the CV is truthful and current. Failure to include this documentation may delay the processing of the application, or may result in ineligible status.

**Additional Application Information**

***Personal Information:*** Complete all sections of the application that pertain to personal information. This information is needed in order to facilitate communication with the applicant. Applicants should include maiden names if they are needed to confirm education, work experience, or training requirements. Provide complete information including all zip/postal codes, telephone numbers, and e-mail addresses in order to expedite processing. During the application and certification process, it is the applicant's responsibility to keep APPI informed of current addresses so that he or she will continue to receive all certification updates, exam scores, training information, and renewal notices.

***Original Signature and Verification of Information:*** An original signature must be on the application. Applicants are expected to provide truthful and complete information. Any application missing information or found to be dishonest will not be considered for the certification program. Should falsification of the application be discovered after the exam has been taken, passed and certification awarded, the certification will be revoked.

## Certification Maintenance

The Academy of Pharmaceutical Physicians & Investigators (APPI) certification maintenance program is based on:

1) Demonstrating continuing involvement as a licensed physician in clinical research activities, whether at the sponsor or site; and;

2) Submitting a copy of certificant's current medical license and;

3) Continuing medical education in clinical research and therapeutic area educational offerings.

CPI maintenance is required every two (2) years from the date of your initial certification date and is based on achieving 24 points, 12 each in the areas listed above. There are multiple ways to attain the points, as outlined in the table below. Should the activity you want to use to demonstrate your continued involvement not be included in the listing, you may request individual approval by the CPI Exam Committee upon written request to certification@acrpnet.org.

NOTE:

1) **For AAPP certificants:** Once you have reached the initial five (5) year expectation for maintenance, you will be subject to the above described maintenance program. There is no retesting requirement for continued CPI certification.
2) **For DIA licensed physician certificants:** Once you have reached the initial three (3) year expectation for maintenance, we will accept the 30 continuing education credits

required as part of the DIA certification program. Moving forward, you will need to comply with the APPI maintenance requirements every two (2) years with the 12 points demonstrating continuing involvement and the 12 points in continuing medical education.

3) **For ACRP physician certificants:** The new certification maintenance requirements will go into effect January 1, 2008. Maintenance through 10/31/2007 will continue to submit 24 continuing education credits, 12 of which must be in clinical research topics.

The following table outlines the points needed to fulfill the two arms of the maintenance program. Please note the maximum points allowed for each activity and the documentation needed for verification. These verification documents should be retained in your personal records, if requested for a maintenance audit. You only need to list the information on the summary record that will accompany the maintenance renewal application when you are due to renew.

| **Item** | **Points** | **Maximum points allowed per item** | **Documentation Required for Verification (kept in personal files and listed on summary record)** |
|---|---|---|---|
| **1) Proof of Continuing Involvement** | **Requires 12 points each 2 years** | 12 | Proprietary information should be obliterated |
| **Pharmaceutical Physician Activities** | | | |
| Attend investigator meeting | 2 | 4 | Copy invitation letter |
| Participate in initiation visit | 1 | 2 | Report signature page |
| Participate in monitor meeting | 1 | 2 | Report signature page |
| Participate in close out visit | 1 | 2 | Report signature page |
| Authorship of protocol | 2 | 4 | Protocol signature page |
| Medical monitor for clinical research trial | 1 | 3 | Letter from supervisor |
| Service on DSMB or equivalent | 2 | 4 | Letter from DSMB chair |
| FDA meeting attendance (regulatory) | 1 | 3 | Invitation communication |
| Sponsor audit | 1 | 3 | Report signature page |
| **Physician Investigator Activities** | | | |
| Authorship/review of clinical study report | 2 | 4 | Report signature page |
| Inclusion on 1572 as active investigator | 1 | 3 | Copy of 1572 (both sides) |
| Serve as director of research center | 12 per year | 12 | Copy appointment letter |
| Serve as compliance officer for institution | 12 per year | 12 | Copy of appointment letter |
| **Other (either/or)** | | | |
| Authorship of journal paper | 2 | 4 | Journal citation including authors |
| Authorship of journal paper on clinical research | 2 | 4 | Journal citation including authors |

| | | | |
|---|---|---|---|
| Continuing education presenter in clinical research or related topic | 2 | 4 | Copy of program with speakers and objectives |
| Presentation of research at scientific meeting (regional, national, local) | 2 | 4 | Presentation abstract including organization, locations, and dates |
| Presentation at investigator's meeting | 2 | 4 | Copy of program with speakers and objectives |
| Service on IRB | 3 | 3 | Letter from IRB chair |
| Regulatory document author/reviewer | 3 | 3 | Document signature page |
| Service on item writing committee | .5 points per question used | 4 | Copy of contact hour certificate |
| Service on exam committee | 4/day | 24 | Copy of contact hour certificate |
| Service on scientific review of peer reviewed grants | 2 | 4 | Report signature page |
| Peer reviewer of scientific articles | 1 | 3 | Report signature page |
| | | | |
| **2) Proof of Continuing Education** | **Requires 12 points each 2 years** | 12 | |
| CME hours | 1 per contact hour | Maximum 12, minimum 1 | Copy of contact hour certificate |
| CME related to clinical research | 4 per contact hour | Maximum of 12, minimum of 4 | Copy of contact hour certificate |
| FDA meeting attendance (educational) | 2 per contact hour | 12 | Copy of contact hour certificate |
| Monitor home study | 3 per issue | 12 | Copy of contact hour certificate |
| | | | |
| Other activities may be approved on a case-by-case basis by the CPI Exam Committee | | | |

APPI will attempt to notify all candidates three months prior to the expiration of their current certification. **However, certificants are ultimately responsible for maintaining their APPI certification.** Maintenance points and payment are due every two years.

# Certification Revocation/Application Refusal

Applications for the CPI™ examination may be refused or CPI™ certification may be revoked for any of the following reasons:

1 Falsification and/or misrepresentation of credentials or application data.

2 Restrictions placed on licenses by local, state, or national licensing bodies and/or regulatory authorities and certifying bodies.

3 Adverse judgment for poor conduct of a clinical trial.
4 Debarment by federal or state agencies or restrictions on participation in clinical research by recognized authorities.
5 Adjudicated penalty for violation of the APPI Code of Ethics.

If an individual is notified of revocation, he or she also will be notified of the available appeal process.

# Certification Examination Information

***Examination Development:*** The American Association of Pharmaceutical Physicians (AAPP), now the Academy of Pharmaceutical Physicians and Investigators (APPI) contracted with CASTLE Worldwide, Inc., to develop the certification examination. CASTLE Worldwide is a full-service testing company providing licensure, certification, and specialty examinations, including practical and written simulation tests, for associations, state boards, government agencies, and corporations.

The development of a valid examination for the AAPP certification process began with a clear and concise definition of the knowledge, skills, and abilities needed for competent job performance. Using interviews, surveys, observation, and group discussions, CASTLE worked with physician investigators to delineate critical job components. The knowledge and skill bases for the questions on the examination were derived from the actual practice of the physician investigators as outlined in the 2003 AAPP Role Delineation Study.

ACRP followed a similar process in the development of their physician investigator exam and contracted with Applied Measurement Professionals, Inc. (AMP), a testing agency out of Lenexa, Kansas, to provide exam development and maintenance services. AMP will be providing testing services to APPI in the future.

In September 2005, a joint task force of representatives of the AAPP and ACRP physician Exam Committees began work to integrate the two physician certification programs. An integrated CPI™ Exam Committee met and reviewed input from a recent ACRP job analysis survey to create an exam content outline based on the tasks performed by physician investigators. Exam questions from the AAPP CPI™ exam were reviewed by the integrated CPI™ Exam Committee and incorporated into the existing ACRP physician investigator exam. The first integrated exam was given on March 11, 2006 in conjunction with The Academy's CRA and CRC exams.

***Examination Content:*** Four major performance areas account for the examination content. The major content areas and the associated job tasks, as well as the number of exam questions in each area are listed below:

**I. Study Management (12 questions)**

A. Protocol Evaluation

1 Understand the trial design including its scientific, statistical and ethical integrity, as it applies to their situation
2 Comply with regulations and guidances regarding drugs, medical devices, and biologics

3 Assess protocol for clarity, thoroughness, logistical, operational and therapeutical feasibility, maintaining subject safety and welfare, inconsistencies, etc.
4 Determine subject population availability
5 Assure availability of qualified research staff and required equipment, facilities, and infrastructure
6 Develop timelines for conducting and completing the clinical trial
7 Address concerns and questions with the Sponsor/CRO (e.g., patient population, Sponsor/CRO expectations, enrollment, study procedures)
8 Negotiate alternatives to improve protocol implementation (e.g., inclusion/exclusion criteria, concomitant medications, protocol timelines, logistics)
9 Ascertain the safety and expected therapeutic effects of the investigational product by verifying the preclinical and clinical research done so far (using the investigator brochure)

B. Site Preparation and Initiation

1 Select the investigational staff and assign roles and Responsibilities
2 Assure appropriate training of the investigational staff and attend and participate in the study initiation meeting (e.g., Investigator meeting), if applicable
3 Ensure that a recruitment strategy and study management plan is developed to direct the successful conduct of the trial
4 Assure the availability of validated operational and administrative tools and processes (e.g., hardware and software, recording devices)
5 Ensure consistency between the sites' standard operation procedures (SOPs) and the study requirements
6 Check on congruence of data collection tools (e.g., case report form [CRF], electronic data capture [EDC]) with the study protocol
7 Collect and submit all essential pre-study documents required by ICH GCP and/or local regulatory requirements
8 Schedule and coordinate pre-study site visit with Sponsor/CRO's representative
9 Complete region/country specific regulatory documents for Sponsor/CRO.
10 Prepare space for study-related equipment and supplies (i.e., storage of study investigational products, laboratory supplies, CRFs/eCRFs)
11 Prepare and submit required IRB/IEC documents (e.g., informed consent, advertisements, protocol)
12 Integrate proposed clinical trials with current research Activity

**II. Project Activities (50 questions)**

A. Investigational Product Accountability

1 Receive investigational product from Sponsor/CRO and inventory supplies
2 Ensure investigational product supplies are kept in a secure location according to the required storage conditions
3 Dispense investigational product (e.g., calculate dosage) according to the protocol
4 Retrieve used/unused investigational product from subject and assess compliance
5 Verify the expiry date and arrange proper relabeling activities where needed
6 Monitor the investigational product stock and order supplemental supplies, if needed

7 Maintain randomization and emergency codes of investigational product dispensing

8 Keep an accountability log for each trial subject, documenting investigational product dispensed, returned and disposed

9 Manage controlled substances, if applicable

10 Prepare emergency use report, if applicable

B. Laboratory and Diagnostic Issues

1 Ensure proper collection, processing, and shipment of specimens (e.g., centrifuge, preparation of slides, freezing, refrigeration)

2 Handle samples according to required standards

3 Ensure maintenance of equipment and documentation thereof (e.g., calibration reports, maintenance logs)

4 Interpret laboratory values and alerts according to protocol and subject safety

5 Assure current certification/licensure and normal ranges

C. Adverse Events

1 Determine causality of expected or unexpected results associated with investigational products

2 Document, classify, and manage adverse events

3 Assure proper medical care and follow-up until resolution or stabilization of adverse events

D. Closeout

1 Ensure timely completion of data collection tools

2 Assure a completed investigational product accountability, and organize the receipt and return/disposition of the investigational product and other supplies

3 Assure close-out reporting to the sponsor, IRB/IEC and/or other parties involved

4 Ensure filing, archiving, and retrieval of the essential Documents

5 Assure follow-up medical care for study subjects, as Applicable

6 Assure financial reconciliation against the (trial) agreement contract, including timely and accurate compensation to the staff and/or study subjects

7 Determine disposition of study-related materials per Sponsor/CRO requirements

8 Prepare for and respond to Sponsor/CRO, regulatory, or internal audits

E. Responsibilities and Obligations

1 Conduct research in accordance with the clinical trial agreement specific to the region/country

2 Facilitate or verify formal approvals according to ICH GCP and any regional or local requirements, if applicable.

3 Ensure that all required documents are submitted for approval to the IRB/IEC

4 Check whether the IRB/IEC approval letter is adequate and details of the IRB/IEC composition are on file

5 Assure that the IRB/IEC is in compliance with regulations and ICH guidelines

6 Provide progress reports to IRB/IEC annually, or as requested, and obtain re-approval

7 Ensure compliance with regional requirements (FDA, ICHGCP, European Union Clinical Trial Directive) as applicable.

8 Implement and document corrective actions

9 Maintain the continuity of the clinical trial while satisfying obligations to the Sponsor/CRO and/or monitor

10 Ensure site is prepared for any Regulatory/Sponsor/CRO audits (e.g., consequences, requirements, deficiencies)

11 Maintain current knowledge of clinical research issues (e.g., ICH/GCP guidelines)

12 Follow HIPAA regulations

13. Maintain communication with IRB/IEC regarding
- continuing review
- serious adverse events
- IND safety reports
- protocol amendments
- protocol deviations/violations
- informed consent modifications
- changes to investigator agreements
- final report

**III. Subject Management (50 questions)**

A. Recruitment

1 Participate in the selection of trial subjects according to the recruitment strategy

2 Ensure compliance with data protection legislation

3 Maintain subject screening/enrollment log

B. Informed Consent

1 Ensure the protection of human subjects (e.g., Declaration of Helsinki; ICH GCP and other regional standards, as applicable)
2 Explain study to subject (e.g., purpose, duration,risks/benefits)

3 Assess subject understanding of study requirements
4 Obtain all required signatures (e.g., legal guardian, assent of youth, physician) to document informed consent
5 Provide subject a copy of informed consent form
6 Document obtaining informed consent in source document

7 Obtain informed consent from vulnerable subject
Populations

C. Scheduling/Screening

1 Screen potential subjects to obtain medical history (medications/medical/surgical history)

2 Verify the eligibility of potential trial subjects to ensure that all entered subjects meet the inclusion/exclusion criteria
3. Schedule subjects
a. determine length and timing of visits
b. coordinate subject visits with support services (e.g., subject, physician, ancillary staff, coordinator)
c. determine pay or responsibility for designated study visit

D. Study Conduct

1 Perform and/or supervise the conduct of study-related procedures and monitor the safety of the trial subjects and investigational staff
2 Manage and motivate the investigational staff and other
disciplines involved, and take measures to minimize any potential risks

3 Establish and maintain professional relationship with trial subjects

4 Administer the investigational product following the randomization schedule and maintain the blind as applicable

5 Ensure that study related procedures and measurements are performed at the required time points, according to the study management plan

6 Enable monitoring activities, provide monitoring space and meet with the sponsor's monitor

7 Follow-up or take corrective actions when requested by the sponsor's monitor

8 Inform the sponsor and IRB/IEC of any changes to the protocol or safety concerns and submits

progress reports to the IRB/IEC, in full compliance with ICH-GCP and any other regional requirements.

9 Prepare the study site for audits & inspections

10 Respond to or facilitate response to audit/inspection findings

11 Facilitate effective communications with sponsor, IRB/IEC, institution and regulatory authorities, if applicable

**IV. Documentation and Administration (13 questions)**

A. Case Report Forms

1. Review inclusion/exclusion criteria
   a. make required calculations (e.g., convert units of measurements)
   b. determine concomitant medications, therapies, and adverse events
   c. review medical history

1 Collect accurate and verifiable data and other essential study documents

2 Record the data in the CRF or other data collection tools (e.g., EDC)

3 Transmit data (e.g., fax, express mail) as required by Sponsor/CRO

B. Source Documentation

1 Confirm source documents to be used for the study

2 Confirm data which will be directly entered onto the Case Report Form

3 Collect the trial data and complete the appropriate source Documents

4 Assure access to source data by authorized parties, in accordance with ICHGCP, and protect confidentiality by limiting unauthorized access

5 Collect and file all other essential study documents as required per ICHGCP and or local regulatory requirements

6 Assure query resolution with the sponsor

7 Incorporate applicable historical documents (e.g., surgical reports, pathology reports, medical history)

8 Obtain and record ancillary services reports (e.g., x-ray, pathology, ECG, laboratory)

9 Maintain progress notes

10 Document written, electronic, and verbal communication with study contacts (e.g., subject, Sponsor/CRO, IRB/IEC, laboratory)

11 Prepare for monitoring visits

12 Document protocol deviations/violations

C. Financial/Budgetary Issues

1. Determine the site budgetary requirements
   a. determine anticipated study-related costs and profit margin (e.g., fixed fees, overhead, direct and indirect costs)
   b. negotiate fees for associated services (e.g., laboratory, radiology, study-specific services, advertising)

1 Negotiate budget and payment schedule with Sponsor/CRO

2 Review letter of agreement (contract) for completeness
3 Review sponsor indemnification
4 Reconcile outstanding financial considerations for physician payments and ancillary services (e.g., advertising, support services) sponsor/CRO payments to site subject reimbursement
5 Finalize the trial/financial agreement with the sponsor

**125 Total Questions**

***Practice Test:*** APPI offers an optional online Investigator practice exam to help candidates prepare for the CPI™ examination. In the Upcoming Events Box on the right side of the page, scroll down to FDA Investigator Practice Test and click the Register link.

Practice exams allow candidates to prepare for the CPI™ examination by familiarizing themselves with the examination format and question types. When a practice exam has been completed, the system immediately provides a candidate with results by displaying diagnostic feedback. This feedback may assist candidates reduce testing stress levels and enable candidates to make effective use of their study times.
Online practice tests allow access any time, any where, through any computer with Internet access. The cost of the online practice exam is $75. Payments for the practice exam are made directly to ACRP.

***Sample Questions:*** The following four questions were taken from the CPI™ examination question item bank and serve as samples of the question type and question content found on the CPI™ examination.

1. 1B 2 (Application)
All of the following are likely stratification factors in a randomization schedule EXCEPT

A. glucose level.

B. caloric intake.

C. disease severity.

D. prior study participation.

Answer: D Stratification is based on a factor that could potentially impact the outcome of the study and is performed to assure adequate numbers of subjects in each of the strata. The best answer is D. Glucose level, caloric intake, and disease severity all are common stratification practices. Although subjects may continue to another stage of a study based on prior participation, for example, after completing a double-blind portion of the study all subjects receive open-label drug, this would be

considered a study continuation or sub-study.

2. 3A 67 (Analysis) In a Phase I oncology study, the MOST appropriate time to approach a patient about joining an experimental drug study as a research subject participant is when

A. their illness is becoming worse and they are not responding to conventional therapy.
B. they are feeling well and not experiencing a lot of stress.
C. they lose their health insurance plan and have to pay more than the co-pay for their visit.
D. they have been laid off from their job, and they have more time on their hands and less money.

Answer: A Because of the potency of antineoplasitic drugs, Phase 1 oncology studies are usually conducted in patients who have no other therapeutic alternatives. Patients volunteer to participate so that the basic pharmacokinetic information can be obtained. Although subjects may enroll when they are feeling well, the risk involved with these types of drugs may outweigh the benefits. Enrolling a subject because they have lost health insurance or their job may be considered coercive for the patient.

3. 3C 218 (Physician Only –Application) A protocol for a new drug used to treat cystic fibrosis (CF) excludes patients who have received antibiotics or corticosteroids within 2 weeks of screening, as well as patients who have started a new chronic medication for CF within 2 weeks of screening. Which of the following patients would be INELIGIBLE to participate in this study?

A. A patient who was diagnosed 2 weeks ago with allergic rhinitis for which a nasal antihistamine was prescribed to be taken on a p.r.n. basis.
B. A patient who is on longstanding treatment with prednisone to maintain pulmonary functions.
C. A patient who was admitted to the hospital one month ago and was put on IV antibiotics for a pulmonary infection and discharged after 3 days with a 1-week course of oral antibiotics.
D. A patient who was seen in the emergency department 10 days ago for symptoms presenting as a migraine headache. The patient was treated with an injection of Demerol and discharged.

Answer: B B is the only response where a corticosteroid (prednisone) is given and it is given to treat pulmonary function, which is a treatment for CF. Patient A has none of the exclusion criteria stated in the question. Patient C has met the 2 week time period since receiving antibiotics. Patient D was treated for a migraine headache, not CF, and Demoral is not a corticosteriod.

SCENARIO 9109.00 1

SCENARIO

The following question refers to this Scenario.

A research site is currently enrolling two studies for osteoarthritis (OA) of the knee. Entry criteria are listed in the table below.

| Study A | Study B |
|---|---|
| >/= 40 years of age | >/= 45 years of age OA of the knee for > 1 year OA of any site for > 6 |

months taking daily anti-inflammatory  reports daily pain due to OA cannot be taking aspirin for any
cannot take any antacids reason may use </=325 mg of aspirin QD during the study

4. 3C 243 (Physician Only – Application) A subject is in the office for a screening visit for Study A. Although he has osteoarthritis of the knee, he states he takes a daily anti-inflammatory for the OA pain in his hands.  He reports he takes acetaminophen for occasional headaches.  Which of the following is the investigator's BEST course of action?

A. Call the sponsor for an exception of daily anti-inflammatory use for OA other than knee.
B. Request the subject use only acetaminophen for pain relief during the study.
C. Decline the subject entry into Study A, but enroll into Study B.
D. Inform the subject he does not qualify for Study A or B.

Answer: C
Although the subject is not eligible for the study he was initially screened, he appears to be eligible for Study B. Upon signing that Informed Consent Form, the subject can be screened for Study B.  The sponsor should not permit this type of exception to the study. Option B does not make the subject eligible by discontinuing the anti-inflammatory drug. Option D is incorrect because the subject may qualify for Study B.

***Letter and Certificate:*** Candidates who pass the examination will receive a letter confirming their new certification status and a certificate with an expiration date. The letter can be photocopied and distributed to sponsors as needed. In addition, passing candidates will receive a certificate suitable for framing.

***Examination Retakes:*** Candidates who fail the examination must reapply to take the CPI™ examination.  The reapplication process includes submitting a current application and requested collateral materials as well as paying any current examination fees. There is no waiting period and no limit to the number of times a candidate can retake the examination.

## Contact Information

APPI
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Alexandria, VA 22314
Phone: 703-254-8100
Email: certification@acrpnet.org

## Non-Discrimination Policy

APPI does not discriminate on the basis of age, gender, race, disability, marital status, sexual preference, religion or national origin.