ACRP

ACRP CERTIFIED PROFESSIONAL

ACRP CERTIFIED PROFESSIONAL
ACRP-CP

Certification Handbook

Association of Clinical Research Professionals
99 Canal Center Plaza, Suite 200
Alexandria, VA 22314
acrpnet.org

Table of Contents

APPLYING FOR CERTIFICATION

Welcome and Congratulations

ACRP would like to congratulate you on your decision to pursue certification in your chosen field of work. As a professional in clinical research, you deserve to be recognized and appreciated for what you do, and like most professionals, you want to become better at it. You look for opportunities for ongoing professional development and practical ways to evaluate your own work that will help you develop as a professional.

ACRP Certification Overview

In order to achieve certification, all applicants must meet the eligibility requirements and pass an exam**.** Exams are administered twice annually, Spring and Fall, at over 600 testing centers in more than 80 counties**.**

The applicant should determine his/her own eligibility before submitting an application to the program. Upon submission of a complete application, an eligibility review is conducted by the Academy. The candidate is then notified of the eligibility review outcome via e-mail. All eligible candidates must then schedule an appointment to take the exam.

Candidates who meet the eligibility requirements and pass the exam will be certified as having met the Academy standards for becoming an ACRP-Certified Professional (ACRP-CP). Maintenance of one's certification is required every two (2) years.

Application Deadline

All application materials, including application, CV or resume, job description(s) and payment must be received by February 9, 2018 for the February/March examination. Applications received by December 1, 2017 qualify for the Early-Bird rate.

Confidentiality

Application for, and achievement of, certification is between ACRP and an individual candidate. Therefore, ALL application, eligibility, and exam details are confidential to the individual and cannot be disclosed, regardless of payer. Only the candidate is permitted to withdraw an application or cancel an exam appointment, regardless of payer.

Application Process and Requirements

Professional Level Experience Requirements

To be eligible for the examination, an applicant must have the required minimum number of hours in the professional practice of clinical research. Internship (paid or unpaid) or volunteer experiences will not count toward the hours requirement.

NOTE: ACRP reserves the right to request backup documentation to substantiate the reported information at any time during the application process and/or once the candidate has been certified.

ACRP-CP Eligibility Requirements

As defined by ACRP, and determined through its 2017 Job Analysis Survey, in order to be deemed eligible to take the ACRP-CP exam, applicants must be able to provide evidence through a detailed job description, detailed CV, or other documentation that they are involved in at least one of the following:

- Planning – protocol design, feasibility assessment, business operations (budgeting, contracting, billing compliance), site selection activities, regulatory document preparation, collection, and/or submission, site management activities, clinical operations role within site, academic medical centers or CROs.
- Conducting – conduct of clinical trials with participants
- Overseeing (management, administration) – study site management (Site, CRO, Sponsor, monitoring activities (including in-house, central and remote monitoring), project management, quality control, quality assurance, data management, medical monitoring, safety monitoring (medical safety liaison, pharmacovigilance, IRB professional).

Hours performing the requirements for the ACRP-CP certification **can include hours** documented up to the date of the exam and/or through previous employment. The required number of hours is dependent upon one's educational background. See below:

ACRP-CP Eligibility Requirements

At least one of the options below should be met **before applying** for the ACRP-CP program.

	Education	Minimum Hours Performing Essential Duties	Required Documentation of Performed Essential Duties
Option 1	▪ Bachelor's Degree (or higher)	3,000 hours*	Detailed CV/résumé ***and*** Job Description

Option 2	▪ Associate's Degree OR ▪ LPN, LVN, RN	4,500 hours*	Detailed CV/Résumé ***and*** Job Description
Option 3	▪ High School Diploma OR ▪ Medical Assistant or Lab Technician	6,000 hours*	Detailed CV/Résumé ***and*** Job Description

*see section for options of substitutions for work experience

Substitution for Work Experience Requirements

Applicants may only choose one option below as a valid substitute. Under no circumstance will an applicant be permitted to use more than one substitution for the same application.

Clinical Research Certifications (Option 1)

ACRP acknowledges that there is a shared knowledge base between CCRA, CCRC, and CPI designation holders and those who seek the ACRP-CP designation. Any candidate for the ACRP-CP designation who has a current CCRA, CCRC, or CPI designation will have achieved a valid substitute for 1,500 hours of the required professional experience for the ACRP-CP exam.

Clinical Research Education Programs (Option 2)

ACRP considers applicants who have completed a clinical research education program that meets the following standards to have achieved a valid substitute for 1,500 hours of professional experience for the ACRP-CP program.

Acceptable programs must:

- Be at least 216 contact hours in length (at least 15 semester credits) ***and*;**
- Cover content that substantially maps to the topics found on the **Detailed Content Outline (DCO) *and*;**
- Be accredited by an accrediting agency recognized by the Council on Higher Education Accreditation (CHEA) or the appropriate authorizing authority in the country in which the institution operations. A list of recognized US accrediting agencies can be found from the CHEA website: www.chea.org**.**

If an applicant opts to use an educational program as a substitute, he or she may send an email to certification@acrptnet.org for additional requirement details.

Application and Exam Fees

The cost to apply includes an exam and application fee, paid together at the submission of the application. Credit card, check, or bank transfers are acceptable forms of payment. The fees are as follows:

	Member	**Non-Member**
EARLY BIRD DATES October 16 – December 1, 2017	$135 application fee	$135 application fee
	$300 exam fee	$350 exam fee
	Total - $435	Total - $485

	Member	Non-Member
REGULAR DATES December 2 – February 2, 2018	$135 application fee	$200 application fee
	$325 exam fee	$400 exam fee
	Total - $460	Total - $600

The application fee is non-refundable regardless of eligibility status or cancellation.
Submission of the application confirms your understanding and agreement.

If the applicant wishes to switch program type, they will be charged an additional application fee.

All Non-Members who apply will receive ***one free year of ACRP Membership*** upon successful passing of the exam.

Application for Certification

Once an applicant has carefully self-determined he/she meets the eligibility requirements, the application process can begin. Applications are submitted online.

If the applicant wishes to switch program type, they will be charged an additional application fee.

The following must be submitted together by the due date to be considered for review of eligibility:

1. Application Form ***AND***
2. Supporting documents—curriculum vitae (CV)/ résumé ***AND***
3. Detailed job description(s)* for positions listed on the CV/ résumé ***AND***
4. Full payment

*If you cannot obtain a job description from your (former) employer, you may create and supply your own. If necessary, you may email certification@acrpnet.org for a sample CV or job description.

All documentation must be provided in English. If the original documentation was translated into English, it must also be submitted in the original language, with the certified translated document.

Services for People with Disabilities

ACRP is committed to ensuring that no individual with a disability is deprived of the opportunity to take an exam solely by reason of that disability. ACRP will provide reasonable accommodations for candidates with disabilities pursuant to the Americans with Disabilities Act (ADA). The following reasonable accommodations may be addressed:

- Wheelchair access is available at all established test centers.
- Candidates with visual, sensory, cognitive, or physical disabilities that would prevent them from taking an exam under standard conditions may request reasonable accommodations and arrangements.

To request a reasonable accommodation, one is required to check the designated box on the exam application and also submit:

- Special Accommodations Form, signed by a licensed health professional approving the request as accurate and reasonable. **This MUST be submitted at the time of application.**

Submitting the Application

The application process is now available online. The applicant will have the ability to start and save it prior to submitting for formal review. Please note that all required documents must be included with application before payment can be processed online with a credit card.

If paying by check, complete and save application online. As the website cannot process check payments online, please mail the check with your information clearly listed so that payment can be applied to your application for submittal.

Submission of the application constitutes agreement that the candidate has read, understood, and agrees to abide by the ACRP Code of Ethics and Professional Conduct**.** Applicants are required to sign a Candidate Statement of Authorization and Agreement attesting to the accuracy of the information provided as part of the application process. By submitting an application, the applicant consents to and authorizes the Academy to verify the candidate's academic and employment records.

Receipt of Application

An e-mail confirmation of payment is automatically sent once payment is processed. At that point, applications will enter the Eligibility Review process.

THE ELIGIBILITY REVIEW PROCESS

Eligibility Review

The eligibility review process includes determining completeness of the application and whether or not the applicant meets the eligibility criteria for the exam and performs all essential duties. Applicants should expect to receive an update on application status (via email) within seven to ten days after the application has been received.

Applicants will have seven (7) calendar days to respond to any request for additional information from an eligibility reviewer. These requests will only come via e-mail.

Incomplete Applications

Applicants who do not respond to the requests for additional or clarifying information will automatically have their applications determined ineligible and therefore will not be able to take the exam.

Eligibility Reviewers

An applicant may receive a request for additional and/or clarifying information from a reviewer in support of his or her application. This is not unusual or uncommon. Reviewers only communicate via email and are not available to speak with an applicant via phone concerning his or her application.

Therefore, it is imperative that an applicant contact ACRP in the event communication about the review outcome has not been received through email.

Confirmation of Eligibility

Upon conclusion of review, an applicant will be found to be: eligible or ineligible.

Eligible applicants will be e-mailed an Eligibility Notice, with instructions as to how to schedule an exam appointment. Exam appointments can only be scheduled *after* eligibility is determined.

Ineligible applicants *automatically* receive up to two levels of review. Applicants are notified via e-mail at each step of the review with an explanation of the deficiency identified. Each level of review can take up to seven days. If after two reviews and the applicant is found Ineligible, a review will be conducted by the Certification Manager and the applicant will be notified via email with the final result.

Ineligible applicants (who do not initiate the appeals process* within 15 days of notice) will be refunded the exam fee and will need to re-apply and pay all fees if they decide to pursue certification in the future.

*If the applicant is still determined to be ineligible after three levels of review, the applicant can choose to appeal to the Academy Board of Trustees. However, after the third review, applicants can no longer submit new documents to overturn an eligibility decision.

View ACRP's **Policy on Appeals.**

ACRP-CP EXAMINATION INFORMATION

Exam Structure

The ACRP-CP Exam is designed as a practice-based exam to assess proficiency of the six (6) core knowledge areas:

1. Ethical and Participant Safety Considerations
2. Investigational Product/Device Regulation
3. Clinical Trial Operations (GCPs)
4. Study and Site Management
5. Scientific Concepts and Research Design
6. Data Management and Informatics

Exam Delivery

The ACRP exam consists of 125 multiple-choice questions (25 of these questions are pre-test items, do not affect a candidate's score and are not identified to candidates). Each candidate is allowed a maximum of three (3) hours to complete the 125 questions. Candidates are presented with a question and are asked to choose the single **best** answer from the four options provided. Only one answer is correct. There are no "trick" questions on the exam and there is no penalty for guessing.

Language

The exam is provided in English.

Exam candidates may bring a hard-copy, **translation only** (word-to-word) dictionary to the exam. Electronic dictionaries are not permitted. Dictionaries containing any word definitions or other extraneous markings are strictly prohibited. The dictionary will be inspected by the proctor before and after the exam is completed. No additional time is given to those using a translation dictionary.

Exam Administration

The Academy partners with Prometric, a trusted provider of technology-enabled testing, to administer its exams. Once a candidate has been found eligible, coordination of scheduling (including confirming, rescheduling or canceling) his or her exam will occur directly through or with Prometric via online or phone.

Examination Window

The candidate must test during the window for which he or she is approved. The Academy offers its exams each year during two testing windows, March and September. The Spring 2018 testing window begins February 22, 2018 and concludes March 20, 2018. ***Candidates will not be permitted to schedule an appointment outside of this testing window under any circumstances***.

Exam Appointment Scheduling

The exams are administered via a secure network of computer-based testing sites. Over 600 locations in more than 80 countries are available at which to take the exam. All candidates who have been found eligible must schedule an appointment to take the exam. **Candidates who do not schedule an exam risk forfeiting all fees.**

Appointments can be scheduled online (recommended) or by phone. To view testing locations, visit **www.prometric.com/acrp** at any time.

Confirmation Number

When a candidate schedules his or her appointment, a confirmation number will be provided. Make sure to keep a record of your confirmation number and appointment information. You will need your confirmation number if you want to confirm, reschedule, or cancel your appointment with Prometric.

Confirming Your Appointment

It is the responsibility of a candidate to verify that they have been scheduled for the date, time, and place he or she has requested. One may confirm his or her appointment in two ways:

- Confirm an appointment online at www.prometric.com/ACRP
- Call (800) 967-1139 or the applicable international number and select the option for confirming your appointment

An appointment can be confirmed online even if scheduled via phone.

Rescheduling Your Appointment

Rescheduling an exam appointment is permitted by Prometric up to five (5) days BEFORE your scheduled appointment. There may be fees associated with appointment changes. Rescheduling availability may vary, depending on the test center location and number of days prior to the exam appointment date.

Candidates ***must*** contact Prometric directly to reschedule an exam appointment. ACRP cannot reschedule your appointment. You may reschedule by phone or online and the appointment

confirmation number will be needed.

Cancellations, No Shows, Re-Examination, Refunds and Transfers

Cancellations

Candidates who wish to cancel their application may submit an **Application Cancellation Request Form** to obtain a refund of the exam fee **only**. The application fee covers costs associated with reviewing the application and is non-refundable**.**

Emergency Cancellations

Candidate unable to keep their exam appointment due to an emergency situation within five (5) days of the exam date, must submit an **Emergency Cancellation Form** and official documentation to **certification@acrpnet.org**. This information may be received up to seven (7) calendar days after the candidate's scheduled exam date.

The following situations will be considered with documentation: Emergency room visit or hospitalization, severe medical condition requiring hospitalization, death of an immediate family member (e.g., spouse, child/dependent, parent, grandparent, sibling), call to active military duty, or jury duty.

No Shows and Missed Exams

If a candidate schedules an exam appointment and fails to take the exam, he or she forfeits all fees. If a candidate arrives late for a scheduled exam appointment, he or she may not be allowed to test and, subsequently, will not be eligible for a refund. Missed exams due to lateness are not eligible for a refund.

Re-Examination

Candidates who do not pass the certification exam on first attempt will be allowed to re-take the exam ONLY in the next examination period. A "Re-Examination Form" will be included with the official exam results confirmation letter.

Refunds

Refundable fee: examination fee only.
*The application fee covers the cost associated with reviewing the application and therefore is non-refundable**.***

No one other than the candidate may request a cancellation or refund.
Refunds are issued to candidates under two circumstances only: **ineligibility** or **cancellation**.

Ineligibility

Ineligible applicants will receive a refund of the exam fee, within three weeks of the final ineligibility notification.

Cancellation

To receive a refund, the cancellation request must be received at least five (5) calendar days ***BEFORE*** an exam appointment. Requests within five days of an exam appointment will not be honored.

Refunds are ***not*** available to candidates who do not schedule or attend the exam.

Refunds will be sent to the party who initially paid for the exam. If payment was made by credit card, that card will receive the credit. If that card is no longer valid, a check will be mailed. If the payment was made by check, the Academy will mail a refund check to the original payer.

Transfers
The Academy offers a **one-time** transfer from the current exam offering to the next. There are two situations in which candidates may take advantage of this:

1. If a candidate is determined **ineligible** for the current exam window, but will have met the eligibility requirements by the next exam window; or
2. If an **eligible** candidate withdraws from taking the original exam for any reason (up to five [5] days before a scheduled exam appointment)

Transfers are applied toward the next exam **only**. Transfer of eligibility and associated fees will be applied only to the original candidate and are not transferable to another person, even if paid for by a third party. Exam fees are transferred toward the next exam ***only*** and not toward other products or services.

If you choose to transfer to the next exam window for one of the two reasons above, you must submit a **Request to Transfer Exam Application Form** before the end of the exam window for which you had originally applied.

If you have an exam appointment scheduled, you must **first cancel** it directly with Prometric before submitting the **Request to Transfer Exam Application Form** to ACRP. *Fees, payable to Prometric directly, apply for appointment cancellations made within thirty (30) to five (5) days prior to an appointment date. Cancellations are not permitted less than five (5) days prior to an appointment.*

If a transfer candidate does not submit the request before the end of the current exam testing window, then all funds originally submitted will be forfeited. Transferring is not an option for re-examination candidates (from the previous exam cycle).

When a transfer request has been approved, all fees (application and exam fees) are applied automatically at the start of the next application period. All **eligible** transfer candidates will receive an email notice of Eligibility when the Eligibility ID has been reactivated and an exam appointment can be scheduled. Contact **certification@acrpnet.org** if you did not receive your new Eligibility notice. Candidates who are required to submit documentation for subsequent eligibility review must do so at the start of the next application period.

View full **Policy on Transfers, Cancellation, No Shows, Refunds and Re-Examination**

Preparing for the Exam

The best preparation is to understand the ACRP-CP knowledge requirements and their application to clinical research. You might want to review the *Detailed Content Outline* for topics or subtopics with which you are less familiar. If you find a particular area with which you are not familiar or comfortable, that would be an area on which to focus your study or review. Or, you may want to do a surface review of all the content areas, even those you believe you know well.

Because of the nature of the exam, there is not one comprehensive source to go to in order to study.

However, the Academy does recommend that you review the content areas covered on the exam by using the Detailed Content Outline.

What's Covered on the Exam?

Detailed Content Outline

The DCO is derived from the 2017 ACRP Job Analysis Survey, a careful description of the tasks performed by an ACRP-CP candidate. Each question on the exam is based on this outline. Therefore, to prepare to take the exam, one should study this outline and especially consider the underlying knowledge, skills, and abilities needed to perform in his/ her role as a Certified Professional.

Study Texts

ACRP Certification exams are based on four ICH Guidelines and the Declaration of Helsinki:

- Guideline for Good Clinical Practice E6(R2);
- Definitions and Standards for Expedited Reporting E2A;
- General Considerations for Clinical Trials E8;
- Statistical Principles for Clinical Trials E9;
- Clinical Investigation of Medicinal Products in the Pediatric Population E11

ICH Guidelines
Declaration of Helsinki

Preparation Support

Certification Abbreviation List

The Abbreviations List contains abbreviations that may be used throughout the exam and exam Detailed Content Outline. The abbreviations list is accessible on each screen during the exam and can be found on our website.

IMPORTANT: The Academy **DOES NOT** sponsor or endorse any specific educational courses; even if the course is advertised as a "prep" or "review" course for the exam. Those creating the course **do not have ANY** inside information about the exam. Participation in these courses may help you learn or review topics covered on the exam, **but you should not expect them to directly cover exam content**. The same information that is included in this handbook to help you prepare is publicly available to those creating educational content.

Taking the Exam

It is important for candidates to understand their rights and responsibilities in the secure testing environment of the Prometric test center. It is recommended that you review the full **Policy on Testing Experience Issues.**

Exam Appointment Arrival

It is the candidate's responsibility to arrive on time for the exam appointment. If the candidate is late by 15 minutes or more, the test center has the authority to turn the candidate away and not permit the candidate to take the test. Plan to arrive 30 minutes before your appointment. If you miss your scheduled exam appointment for any non-emergency reason (lack of child care, lateness due to work or traffic, etc.) your opportunity to test will be lost.

Required Identification

To access a secure testing center you must present proper identification (ID) containing your legal name. Examples of proper ID include a passport, driver's license, state or government-issued ID.

Your legal name MUST match the **first name** and **last name** listed on your Eligibility Notice (emailed from ACRP) and on the Appointment Confirmation (from Prometric). Middle names are excluded. Your ID must meet **each** of the following criteria:

- ☐ government-issued **AND**
- ☐ current (non-expired) **AND**
- ☐ photo-bearing **AND**
- ☐ signature-bearing identification (ID)

The photo must look like the examinee. Signature on ID must match the signature provided during the sign-in process. Major discrepancies will result in a candidate being denied from the testing center and result in forfeiture of all fees paid.

If the name listed with ACRP and Prometric is not your legal name, you must submit a **Name Change Request** to **certification@acrpnet.org** immediately.

Exam Security and Test Center Guidelines

Prometric is serious about test center security. You will be presented with **Prometric Test Center Regulations** upon arrival at the test site. Those who violate security will not have their exams scored or processed, and will be required to leave immediately. Attempting to remove exam material or content from the test center will result in severe consequences.

Once seated, you will follow a brief on-screen tutorial for navigating through the exam. Your exam will begin after the tutorial. Each exam will be delivered via individual video-monitored testing carrels. Immediately raise your hand at any time if your computer or any provided resources are not functioning properly!

What Not to Bring: Any and all personal items will be locked in a locker. Examples include a purse, keys, wallet, calculators, watch, cell phone, all electronic devices, tissues, outerwear (heavy coats), food, and all books and papers.

Attire: Prometric **will not** allow you to remove any article of clothing (headbands, jewelry, scarves, shoes, light sweaters, etc.) that you wear into the room. Whatever you choose to wear, please plan to wear the entire length of the exam.

Resources Available at the Test Center

The following resources will be available, issued only by the test center:

- An abbreviations list is also available on screen
- Hand-held calculator (an on-screen calculator is also available)
- Noise cancelling head set
- White board and dry-erase markers

Exam Scores

The passing scaled score for the exam is 600. A candidate scoring below 600 has not been successful on the exam and cannot be certified.

One point is granted for each correct answer. There is no penalty assessed for an incorrect answer. The number of questions answered correctly (or total points) is a candidate's "raw score." Prometric then converts a candidate's raw score to a scaled score. The "Total Scaled Score" will determine whether a candidate has passed the exam. The exam is not scored on a curve and there is no predetermined number of candidates permitted to pass. Your score does not depend on the other candidates testing with you that day.

Note: The passing point set for the exam cannot be appealed.

Specific questions on the exam and/or answers to exam questions will not be discussed or released. Due to the security of the item bank and because exam questions can be used on various exams, exam questions will not be discussed with candidates and candidates may not have access to the exam or their answers.

Note: For more information on scaled scoring, please contact us at certification@acrpnet.org.

Exam Results and Notification

The Score Report will be displayed at the end of the exam and emailed to the address that is provided to Prometric during the scheduling of the exam. It is a required field when scheduling both online and by phone. The email will also contain a link at the bottom that the candidate can click to Prometric's secured portal. The score report portal allows the candidate to log in with their appointment confirmation number, and their last name, to print out duplicates of their score report if needed, at any time. You will receive official confirmation of your certification status via email and postal mail, approximately 30 days following the close of the testing window.

https://scorereports.prometric.com/

Candidates, are not yet considered certified until *official* notification of certification status is received from the Academy.

Candidates who pass the exam will be sent an official letter, a certificate, a certification pin, and Maintenance of Certification information. They will also be added to the Academy Certification registry unless this option was de-selected at the time of application. The registry will be updated within 30 days following the close of the testing window and can be accessed at **www.avectraacrp.com/Certlist.**

Candidates who do not pass the exam are advised to review the content area proficiency ratings and use this information to assist in preparing for future exams. Final exam results will **not** be given out over the telephone or by fax, nor will results be sent to employers, schools, other individuals, or organizations under any circumstances.

Appendix – CP Detailed Content Outline (DCO)

ACADEMY
OF CLINICAL RESEARCH PROFESSIONALS

Association of Clinical Research Professionals – Certified Professional (ACRP-CP®) Examination Detailed Content Outline

(Effective May 1, 2107)

This document contains the Detailed Content Outline (DCO) for the ACRP-CP. Each question on the exam is based on this outline.

Introduction

In following best practices, the Academy conducted a Job Analysis Study to ensure content validity of the ACRP-CP Examination. Program content validity is demonstrated with a comprehensive job analysis conducted and analyzed by experts, with data gathered from practitioners within the profession. The process utilizes knowledge and task focused guidelines to assess clinical research professionals' competence, and determine the level of importance and frequency of specific knowledge and tasks required to perform in the role of an ACRP-CP.

ACADEMY
OF CLINICAL RESEARCH PROFESSIONALS

Using the ACRP-CP Detailed Content Outline (DCO)

The ACRP-CP DCO was constructed from the results of a Job Analysis Study conducted Spring 2017. The results of the study provided the framework for the knowledge and tasks important to the role of an ACRP- CP and therefore the content of the exam. To be certified, an ACRP-CP is expected to have proficiency in the six (6) main content areas of clinical research, displayed in the chart below. The percent of questions dedicated to each content area are provided.

	Content Areas	Percentage of Items on Exam
I.	Ethical and Participant Safety Considerations	19%
II.	Investigational Product/Device Regulation	16%
III.	Clinical Trial Operations (GCPs)	25%
IV.	Study and Site Management	23%
V.	Scientific Concepts and Research Design	8%
VI.	Data Management and Informatics	9%
	Total	**100%**

The specific knowledge and tasks identified as important are provided in the ACRP-CP DCO listed below. Therefore, to prepare to take the ACRP-CP Exam, one should study this outline and especially consider the underlying knowledge, skills, and abilities needed to perform as an ACRP-CP. It is recommended that an eligible candidate use this outline to identify knowledge gaps for constructing a relevant preparation plan.

ACADEMY
OF CLINICAL RESEARCH PROFESSIONALS

Association of Clinical Research Professionals – Certified Professional (ACRP-CP) Examination
Detailed Content Outline

(Effective May 1, 2107)

As defined by the most recent ACRP-CP Job Analysis Survey, an ACRP-CP® shall have proficient **knowledge** in the following six (6) content areas of clinical research. An ACRP-CP typically uses this knowledge to perform the **tasks** listed).

Content Area	CPs must demonstrate proficient knowledge within the following areas:	CPs typically perform the following tasks:
1. Ethical and Participant Safety Considerations (19%)	**1.1 clinical care and clinical management of research participants**	Compare and contrast clinical management of research participants (e.g., standard of care vs protocol requirements)
		Develop and/or review informed consent form
		Verify continuity of medical care is provided by study subjects
	1.2 "clinical equipoise" and "therapeutic misconception" as related to the conduct of a clinical trial	Compare and contrast clinical care and clinical management of research participants (e.g., standard of care vs. protocol requirements)
		Review the safety and expected therapeutic effects of the investigational product/device (e.g., using the investigator brochure)
		Identify and/or address potential and/or past ethical issues involved with study conduct (e.g., cultural variations)
	1.3 the requirements for human subject protections and privacy	Develop and/or review informed consent form
		Differentiate the types of adverse events (AEs) that can occur during clinical trials, and their identification and report process for AEs

		Identify vulnerable populations and the additional safeguards required
	1.4 the principles and content of the key documents ensuring the protection of human participants in clinical research	Develop and/or review informed consent form
		Identify and/or mitigate safety risks
		Participate in and document the informed consent process(es)
	1.5 the ethical issue involved when dealing with vulnerable populations and the need for additional safeguards	Identify vulnerable populations and the additional safeguards required
		Develop, review, and/or implement study plans and/or tools (e.g., subject materials, recruitment plan, lab manuals)
		Evaluate potential conflicts of interest
	1.6 the past and current ethical issues, and cultural variations as they apply to the clinical development process	Identify and/or address potential and/or past ethical issues involved with study conduct (e.g., cultural variations)
		Identify vulnerable populations and the additional safeguards required
		Identify and/or mitigate safety risks
	1.7 why inclusion and exclusion criteria are included in a clinical protocol to assure human subject protection	Confirm the inclusion and exclusion criteria assures human subject protection
		Screen and/or confirm eligibility for trial subjects
		Review the protocol and supporting documentation (e.g., investigators brochure, instructions for use, package insert)
	1.8 the principles and methods of risk versus benefit through selection and management of clinical trial subjects	Identify and/or implement risk management strategies (e.g., subject, investigational product/device, data handling)
		Evaluate and/or explain the benefits versus risks for study subject protections
		Conduct initial risk assessment and ongoing risk assessment review
	1.9 adverse events classification, documentation, and reporting	Differentiate the types of adverse events (AEs) that can occur during

		clinical trials, and their identification and reporting process for AEs
		Escalate significant issues as appropriate
		Comply with the safety reporting requirements of regulatory agencies both pre- and post- approval
	1.10 blinding procedures	Review the protocol and supporting documentation (e.g., investigators brochure, instructions for use, package insert)
		Develop and/or review unblinding procedures as applicable
		Maintain unblinding procedures of investigational product/device
	1.11 components of subject eligibility requirements	Confirm the inclusion and exclusion criteria assures human subject protection
		Screen and/or confirm eligibility for trial subjects
		Assess, manage, and/or review subject test results/safety data (e.g., timeliness, accuracy, frequency, response)
	1.12 confidentiality and privacy requirements	Comply with subject privacy regulations
		Identify and comply with the requirements for human subject protections and privacy under different national and international regulations and ensure their implementation throughout all phases of a clinical study
		Comply with electronic data requirements (e.g., passwords and access)
	1.13 elements of the Investigator Brochure	Review the safety and expected therapeutic effects of the investigational product/device (e.g., using the investigator brochure)
		Review the protocol and supporting documentation (e.g., investigators brochure, instructions for use, package insert)

		Develop, update, and/or review the Investigator's Brochure
	1.14 elements of the informed consent form	Compare and contrast clinical care and clinical management of research participants (e.g., standard of care vs protocol requirements)
		Assess compliance and documentation of consent process(es)
		Participate in and document the informed consent process(es)
	1.15 informed consent/assent process requirements	Participate in and document the informed consent processes(es)
		Assess compliance and documentation of consent process
		Compare and contrast clinical care and clinical management of research participants (e.g., standard of care vs protocol requirements
	1.16 protocol deviation/violation identification, documentation, and reporting process	Identify, manage, and report any deviations from the protocol and document as appropriate
		Identify, investigate, and report potential fraud and misconduct
		Assess protocol compliance (visits, procedures, reporting)
	1.17 recruitment plan/strategies	Evaluate the conduct and management of clinical trials within the context of applicable plan (e.g., protocol, study plan, monitoring plan, data management plan)
		Continually evaluate subject recruitment strategy and study progress
		Develop, review, and/or implement study plans and/or tools (e.g., subject materials, recruitment plan, lab manuals)
	1.18 safety monitoring	Identify and/or mitigate safety risks
		Differentiate the types of adverse events (AEs) that can occur during

		clinical trials, and their identification and reporting process for AEs
		Assess, manage, and/or review subject test results/safety data (e.g., timeliness, accuracy, frequency, response)
	1.19 subject discontinuation criteria/procedures	Evaluate reasons for subject discontinuation (e.g., causes, contact efforts)
		Identify and/or manage adverse event(s), (e.g., treat subject, rechallenge, adjust treatment based on subject need and protocol)
		Verify continuity of medical care is provided for study subjects
	1.20 subject retention strategies	Develop, review, and/or implement study plans and/or tools (e.g., subject materials, recruitment plan, lab manuals)
		Evaluate reasons for subject discontinuation (i.e., causes, contact efforts)
		Continually evaluate subject recruitment strategy and study progress
	1.21 subject safety and privacy issue management	Identify and comply with the requirements for human subject protections and privacy under different national and international regulations and ensure their implementation throughout all phases of a clinical study
		Comply with subject privacy regulations
		Comply with electronic data requirements (e.g., passwords and access)
	1.22 Conflicts of interest in clinical research	Evaluate potential conflicts of interest
		Identify and/or implement risk management strategies (e.g., subject, investigational, product/device, data handling)

		Evaluate study for feasibility (e.g., site determining ability to successfully conduct the study)
2. Investigational Product/Device Regulation (16%)	**2.1 the roles and responsibilities of the various stakeholders and regulatory institutions in the clinical trials**	Evaluate and comply with the regulatory requirements that are applicable for investigational product/device development and/or research protocols
		Identify roles and responsibilities as defined by GCP guidelines
		Oversee vendors (e.g., labs, IRB/IEC, technology, subject recruitment, CRO)
	2.2 the legislative and regulatory framework that supports the development and registration of medicines, devices, and biologics and ensures their safety, efficacy, and quality	Evaluate and comply with the regulatory requirements that are applicable for investigational product/device development and/or research protocols
		Identify and comply with the requirements for human subject protections and privacy under different national and international regulations and ensure their implementation throughout all phases of a clinical study
		Identify the ICH/GCP requirements for data collection, corrections, and queries
	2.3 the specific processes and phases that must be followed in order for the regulatory authority to approve the marketing authorization for a medical product	Identify and/or describe study design
		Identify the ICH/GCP requirements for data collection, correction, and queries
		Comply with the safety reporting requirements of regulatory agencies for both pre-and post-approval
	2.4 regulatory reporting requirements (e.g., pre- and post-approval, safety)	Comply with the safety reporting requirements of regulatory agencies both pre- and post- approval
		Collect, maintain, verify, and/or store regulatory essential documents
		Differentiate the types of adverse events that can occur during clinical trials, and their identification and reporting process for AEs

	2.5 standards for handling hazardous goods, materials, and biological samples (e.g., International Air Transport Association (IATA)	Manage investigational product/device accountability, shipment, and use according to the research protocol
		Conduct quality control activities in the conduct of clinical research
		Develop and/or manage resources necessary to conduct a study (the financial, timeline, and cross-disciplinary personnel)
	2.6 audit and inspection processes (preparation, participation, documentation, and follow-up)	Identify the process and purpose for monitoring of the study
		Conduct quality control activities in the conduct of clinical research
		Participate in audits and inspections (e.g., prepare, support, respond)
	2.7 clinical trial registries and requirements	Inform study subjects of trail results, in accordance with regulatory requirements
		Evaluate and comply with the regulatory requirements that are applicable for investigational product/device development and/or research protocols
		Comply with the safety reporting requirements of regulatory agencies both pre- and post- approval
	2.8 what constitutes fraud and misconduct	Identify, investigate and report potential fraud and misconduct
		Participate in audits and inspections (e.g., prepare, support, respond)
		Assess investigator/site protocol compliance
	2.9 IRB/IEC reporting requirements	Comply with IRB/IEC requirements such as submission, review, and approval of documents
		Evaluate and comply with the regulatory requirements that are applicable for investigational product/device development and/or research protocols

		Oversee vendors (e.g., labs, IRB/IEC, technology, subject recruitment, CRO)
	2.10 IRB/IEC role, composition, and purpose	Oversee vendors (e.g., labs, IRB/IEC, technology, subject recruitment, CRO)
		Assess qualifications of IRB/IEC
		Identify and comply with the requirements for human subject protections and privacy under different national and international regulations and ensure their implementation throughout all phases of a clinical study
	2.11 protocol and protocol amendment submission and approval processes	Comply with IRB/IEC requirements such as submission, review, and approval of documents
		Identify issues potentially requiring protocol amendments
		Collect, maintain, verify, and/or store regulatory essential documents
	2.12 significant milestones in the evaluation of efficacy and safety (e.g., interim analysis result, DSMB review)	Conduct initial risk assessment and ongoing risk assessment review
		Confirm and instruct subjects on protocol requirements (e.g., investigational product/device, diaries, visits
		Confirm timely review of study data
3. Clinical Trial Operations (GCPs) 25%	**3.1 conduct and management of clinical trials within the context of applicable plans (e.g., protocol, study plan, monitoring plan, data management plan)**	Identify the process and purpose for monitoring of the study
		Evaluate the conduct and management of clinical trials within the context of applicable plans (e.g., protocol, study plan, monitoring plan, data management plan)
		Assess subject compliance (e.g., protocol, investigational product/device, dairies/logs)
	3.2 roles and responsibilities of the clinical investigation team as defined by GCP	Identify roles and responsibilities as defined by GCP guidelines
		Verify appropriate staff, facility, supplies, and equipment availability throughout the study

		Oversee vendors (e.g., labs, IRB/IEC, technology, subject recruitment, CRO)
	3.3 design, conduct, and documentation of clinical trials as required for compliance with GCP	Identify and/or describe study design
		Identify and/or implement risk management strategies (e.g. subject, investigational product/device, data handling
		Review the protocol and supporting documentation (e.g., investigators brochure, instructions for use, package insert)
	3.4 protocol required control, storage, and dispensation of investigational products/devices	Review and/or document the process of appropriate control, storage, and dispensing of investigational products
		Manage investigational product/device accountability, shipment, and use according to the research protocol
		Manage and/or review investigational product/device expiration and/or manage resupply or relabeling
	3.5 adverse events (AE's) that occur during clinical trials, and the identification process for AEs including SAEs and ADRs	Differentiate the types of adverse events (AEs) that can occur during clinical trials, and their identification and reporting process for AEs
		Identify and/or manage adverse event(s) (e.g., treat subject, rechallenge, adjust treatment based on subject need and protocol)
		Assess, manage, and/or review subject test results/safety data (e.g., timeliness, accuracy, frequency, response)
	3.6 regulations and guidelines assuring human subject protection and privacy during the conduct of clinical trials	Develop and/or review informed consent form
		Identify and comply with the requirements for human subject protections and privacy under different national and international regulations and ensure their implantation throughout all phases of a clinical study
		Comply with subject privacy regulations

	3.7 reporting requirements relating to clinical trial conduct (e.g., SAEs, deviations, INDs, IRB)	Identify, manage, report any deviations from the protocol and document as appropriate
		Comply with IRB/IEC requirements such as submission, review, and approval of documents
		Assess protocol compliance (visits, procedures, reporting)
	3.8 the processes and purposes for monitoring of the study	Identify the process and purpose for monitoring of the study
		Administer a data quality review (source data/document review (SDR) and/or verification (SDV))
		Develop or participate in protocol training
	3.9 the purpose and process of clinical trial audits and inspections	Participate in audits and inspections (e.g., prepare, support, respond)
		Create, document, and/or implement corrective and preventative action (CAPA)
		Manage study records, retention, and availability
	3.10 identification, management, and reporting requirements for protocol/GCP deviation/violation	Assess protocol compliance (visits, procedures, reporting)
		Provide or participate in study training
		Identify, document, communicate, and follow up on site issues
	3.11 IRB/IEC requirements such as submission, review, and approval of documents	Coordinate protocol and/or protocol amendments through appropriate approval processes (e.g., IRB/IEC, sponsor, regulatory authority)
		Comply with IRB/IEC requirements such as submission, review, and approval of documents
		Identify, manage, and report any deviations from the protocol and document as appropriate
	3.12 delegation of responsibilities	Collect, maintain, verify, and/or store regulatory essential documents

		Assess qualifications of the investigational site, site staff, and principal investigator
		Maintain and/or review study related logs (e.g., site signature/delegation log, screening log)
	3.13 elements of an effective corrective and preventive action (CAPA)	Create, document, and/or implement corrective and preventive action (CAPA)
		Identify and/or implement risk management strategies (e.g., subject, investigational product/device, data handling)
		Identify, document, communicate, and follow up site issues
	3.14 purpose and use of the investigator's brochure	Review the safety and expected therapeutic effects of the investigational product/device (e.g., using the investigator brochure)
		Develop, update, and/or review the investigators brochure
		Review the protocol and supporting documentation (e.g., investigators brochure, instructions for use, package insert)
	3.15 requirements of indemnification/insurance	Obtain and/or confirm presence of a signed indemnification/insurance, contracts, and/or budgets
		Develop and/or manage resources necessary to conduct a study (the financial, timeline, and cross-disciplinary personnel)
		Oversee vendors (e.g., labs, IRB/IEC, technology, subject matter recruitment, CRO)
	3.16 source data review and source data verification	Administer a data quality review (source data/document review (SDR) and/or verification (SDV))
		Record, and/or review data for accuracy and verifiability (e.g., completed eCRF/CRF)

		Manage source data/documents according to ALCOA-C standards (Attributable Legible Contemporaneous Original Accurate-Complete)
	3.17 site selection activities	Verify appropriate staff, facility, supplies, and equipment availability throughout the study
		Evaluate study for feasibility (e.g., site determining ability to successfully conduct the study)
		Assess qualifications of the investigational site, site staff, and principal investigator
	3.18 principal investigator responsibilities	Assess investigator/site protocol compliance
		Evaluate the conduct and management of clinical trials within the context of applicable plans (e.g., protocol, study plan, monitoring plan, data management plan)
		Verify appropriate staff, facility, supplies, and equipment availability throughout the study
	3.19 project feasibility considerations	Evaluate study for feasibility (e.g., site determining ability to successfully conduct the study)
		Verify appropriate staff, facility, supplies, and equipment availability throughout the study
		Evaluate protocol for practicality of execution
	3.20 roles of various clinical trial entities (e.g., CROs sponsors, regulatory authorities)	Oversee vendors (e.g., labs, IRB/IEC, technology subject recruitment, CRO)
		Verify appropriate staff, facility, supplies, and equipment availability throughout the study
		Identify roles and responsibilities as defined by GCP guidelines
	3.21 site initiation activities	Provide or participate in study training (e.g., site initiation visit, IM, webinar)

		Prepare, conduct, and/or participate in site monitoring (onsite, centralized, or remote)
		Develop or participate in protocol training
	3.22 site and study close-out activities	Manage investigational product/device recall
		Perform data validations (issue, resolve, close queries)
		Prepare, support, and/or participate in close out activities (site or study)
	3.23 study personnel training and qualifications requirements (e.g., phlebotomy, IP administration, ECG, psychometric testing validation)	Provide or participate in study training (e.g., site initiation visit, IM, webinar)
		Verify appropriate staff, facility, supplies, and equipment availability, throughout the study
		Assess qualifications of the investigational site, site staff, and principal investigator
IV. Study and Site Management (23%)	**4.1 quality management activities in the conduct of clinical research**	Conduct quality control activities in the conduct of clinical research
		Review Case Report Forms and completion guidelines (e.g., CRF/eCRF)
		Identify, document, communicate, and follow up on site issues
	4.2 resources necessary to conduct a study (e.g., financial, timeline, and cross-disciplinary personnel)	Develop and/or manage resources necessary to conduct a study (the financial, timeline, and cross-disciplinary personnel)
		Verify appropriate staff, facility, supplies, and equipment availability throughout the study
		Evaluate study for feasibility (e.g., site determining ability to successfully conduct the study
	4.3 methods used to track subject recruitment and study progress	Develop, review, and/or implement study plans and/or tools (e.g., subject materials, recruitment plan, lab manuals)

		Continually evaluate subject recruitment strategy and study progress
		Oversee vendors (e.g., labs, IRB/IEC technology, subject recruitment, CRO)
	4.4 responsibilities and obligations involved in the conduct of a clinical trial (e.g. legal, liabilities, accountabilities)	Obtain and/or confirm presence of a signed indemnification/insurance, contracts, and/or budgets
		Identify roles and responsibilities as defined by GCP guidelines
		Assess qualifications of the investigational site, site staff, principal investigator
	4.5 procedures, documentation, and oversight requirements of PIs, sponsors, contract research organizations (CROs), and regulatory authorities	Manage source data/documents according to ALCOA-C standards (Attributable Legible Contemporaneous Original Accurate-Complete)
		Identify the ICH/GCP requirements for data collection, correction, and queries
		Oversee vendors (e.g., labs, IRB/IEC, technology, subject recruitment, CRO)
	4.6 how to assess, manage, and/or report adverse event (AE) causality, severity, and relationship to investigational product/device	Review the safety and expected therapeutic effects of the investigational product/device (e.g., using the investigator brochure)
		Differentiate the types of adverse events (AEs) that can occur during clinical trials, and their identification and reporting process for AEs
		Comply with the safety reporting requirements of regulatory agencies both pre-and post- approval
	4.7 communication documentation requirements (e.g., telephone, email)	Manage study records retention and availability
		Collect, maintain, verify, and/or store regulatory essential documents
		Maintain and/or review study related logs (e.g., site signature/delegation log, screening log)
	4.8 contractual agreements (e.g., budgets, clinical trial agreement)	Oversee vendors (e.g., labs, IRB/IEC, technology, subject recruitment, CRO)

		Obtain and/or confirm presence of a signed indemnification/insurance, contracts, and/or budgets
		Evaluate potential conflicts of interest
	4.9 corrective and preventive action (CAPA) processes	Create, document, and/or implement corrective and preventive action (CAPA)
		Identify, document, communicate, and follow up on site issues
		Escalate significant issues as appropriate
	4.10 maintenance and use of equipment and supplies	Oversee vendors (e.g., labs, IRB/IEC, technology, subject recruitment, CRO)
		Perform and/or verify equipment calibration and maintenance
		Verify appropriate staff, facility, supplies, and equipment availability throughout the study
	4.11 investigational product/device accountability and documentation requirements	Maintain and/or review study related logs (e.g., site signature/delegation screening log)
		Assess protocol compliance (visits, procedures, reporting)
		Manage and/or review investigational product/device expiration and/or manage resupply or relabeling
	4.12 investigational product/device use (e.g., dosing schedule, frequency, expected side effects)	Review the protocol and supporting documentation (e.g., investigators brochure, instructions for use, package insert)
		Manage investigational product/device accountability, shipment, and use according to the research protocol
		Identify and/or implement risk management strategies (e.g., subject investigational product/device, data handling)
	4.13 investigational product/device reference materials (e.g., investigator brochure, instructions for use, user manual)	Develop, update, and/or review the Investigators Brochure
		Review the protocol and supporting documentation (e.g., investigators brochure, instructions for use, package insert)

		Maintain unblinding procedures of investigational product/device
	4.14 investigational product/device storage and disposition	Evaluate and comply with the regulatory requirements that are applicable for investigational product/device development and/or research protocols
		Manage investigational product/device recall
		Escalate significant issues as appropriate
	4.15 non-compliance management	Escalate significant issues as appropriate
		Assess protocol compliance (visits, procedures, reporting)
		Identify, document, communicate, and follow up on site issues
	4.16 sample collection, storage, disposal, and shipment requirements	Manage and/or review investigational product/device expiration, and/or manage resupply, or relabeling
		Manage study records retention and availability
		Development, review, and/or implement study plans and/or tools (e.g., subject materials, recruitment plan, lab manuals)
	4.17 how to assess subject compliance	Confirm and instruct subjects on protocol requirements (e.g., investigational product/device, diaries, visits)
		Assess subject compliance (e.g., protocol, investigational product/device, diaries/logs)
		Evaluate reasons for subject discontinuation (i.e., causes, contact efforts)
	4.18 subject responsibilities for study participation	Confirm and instruct subjects on protocol requirements (e.g., investigational product/device, diaries, visits)
		Assess protocol compliance (visits, procedures, reporting)
		Participate in and document the informed consent processes

	4.19 subject visit activities	Assess subject compliance (e.g., protocol, investigational product/device, diaries/logs)
		Assess protocol compliance (visits, procedures, reporting)
		Assess, manage, and/or review subject test results/safety data (e.g., timeliness, accuracy, frequency, response)
	4.20 vendor management (e.g., labs, IRB/IEC, technology, subject recruitment, CRO)	Oversee vendors (e.g., labs, IRB/IEC, technology, subject recruitment, CRO)
		Evaluate study for feasibility (e.g., site determining ability to successfully conduct the study)
		Identify, investigate, and report potential fraud and misconduct
	4.21 principal investigator oversight requirements	Identify, investigate, and report potential fraud and misconduct
		Assess investigator/site protocol compliance
		Verify appropriate staff, facility, supplies, and equipment availability throughout the study
	4.22 identification and reporting requirements for protocol deviations/violations	Assess protocol compliance (visits, procedures, reporting)
		Assess subject compliance (e.g. protocol, investigational product/device, diaries/logs)
		Identify, document, communicate, and follow up on site issues
	4.23 study evaluation for feasibility (site determining ability to successfully conduct the study)	Evaluate study for feasibility (e.g., site determining ability to successfully conduct the study)
		Assess investigator/site protocol compliance
		Assess qualifications of the investigational site, site staff, and principal investigator
	4.24 reviewing and interpreting values for lab and test results	Assess, manage, and/or review subject test results/safety data (e.g., timeliness, accuracy, frequency, response)
		Confirm timely review of study data

		Identify and/or manage adverse event(s) (e.g., treat subject, rechallenge, adjust treatment based on subject need and protocol
	4.25 subject discontinuation process	Evaluate reasons for subject discontinuation (i.e., causes, contact efforts)
		Assess subject compliance (e.g. protocol investigational product/device, diaries/logs)
		Verify continuity of medical care is provided for study subjects
	4.26 protocol and protocol amendment implementation process (e.g., approvals, resubmission, re-consent)	Identify issues potentially requiring protocol amendments
		Implement the administrative and/or clinical tasks for protocol amendments
		Evaluate protocol for practicality of execution
V. Scientific Concepts and Research Design (8%)	**5.1 clinical trial design (e.g., double-blind, cross-over)**	Identify and/or describe study design
		Identify and/or describe study hypothesis, objective(s), and endpoints
		Evaluate the conduct and management of clinical trials within the context of applicable plans (e.g., protocol study plan, monitoring plan, data management plan)
	5.2 elements of a protocol	Review the protocol and supporting documentation (e.g. investigators brochure, instructions for use, package insert)
		Compare and contrast clinical care and clinical management of research participants (e.g., standard of care vs protocol requirements)
		Develop or participate in protocol training
	5.3 elements of an Investigational Brochure (IB) and/or investigational device use (instructions for Use)	Develop, update, and/or review the Investigators brochure
		Review the safety and expected therapeutic effects of the investigational

		product/device (e.g., using the investigator brochure)
		Review the protocol and supporting documentation (e.g., investigators brochure, instructions for use, package insert)
	5.4 rationale for subject eligibility requirements (e.g., vulnerable populations, safety)	Identify vulnerable populations and the additional safeguards required
		Identify and/or mitigate safety risks
		Screen and/or confirm eligibility for trial subjects
	5.5 rationale for complying and consequences for noncompliance with a protocol (e.g., scientific validity)	Assess protocol compliance (visits, procedures, reporting)
		Integrate risk-based approach to quality management and monitoring
		Create, document, and/or implement corrective and preventive action (CAPA)
	5.6 risk management strategies and principles (e.g., quality management systems)	Integrate risk-based approach to quality management and monitoring
		Conduct initial risk assessment and ongoing risk assessment review
		Identify and/or implement risk management strategies (e.g., subject, investigational product/device, data handling)
	5.7 study objective(s), hypotheses, and end points/outcomes	Identify and/or describe study hypothesis, objective(s) and endpoints
		Review the protocol and supporting documentation (e.g., investigators brochure, instructions for use, package insert)
		Identify and/or describe study design
	5.8 treatment assignments (e.g., randomization, open label, registries)	Identify and/or describe study design
		Review the protocol and supporting documentation (e.g., investigators brochure, instructions for use, package insert)
		Comply with randomization procedures of investigational product/device
VI. Data Management and Informatics (9%)	**6.1 basic concepts of biostatistics and informatics in research**	Perform data validations (issue, resolve, close queries)

		Identify and/or describe study hypotheses, objective(s) and endpoints
		Evaluate protocol for practicality of execution
	6.2 flow of data throughout a clinical trial	Confirm timely review of study data
		Identify the ICH/GCP requirements for data collection, correction, and queries
		Review Case Report Forms and completion guidelines (e.g. CRF/eCRF)
	6.3 process of electronic data capture (e.g., edit specifications, security, audit trails)	Develop and/or utilize study management tools
		Comply with electronic data requirements (e.g., passwords and access)
		Confirm timely review of study data
	6.4 requirements for data collection, correction, and queries (e.g., completion guidelines)	Confirm timely review of study data
		Administer a data quality review (source data/document review (SDR) and/or verification (SDV))
		Prepare, conduct, and/or participate in site monitoring (onsite, centralized, or remote)
	6.5 data quality systems	Administer a data quality review (source data/document review (SDR) and/or verification (SDV))
		Comply with electronic data requirements (e.g. passwords and access)
		Confirm timely review of study data
	6.6 data privacy principles	Comply with electronic data requirements (e.g. passwords and access)
		Identify the ICH/GCP requirements for data collection, correction, and queries
		Conduct quality control activities in the conduct of clinical research
	6.7 purpose of pharmacovigilance (e.g., CIOMS, IDMC/DSMB, safety databases)	Assess, manage, and/or review subject test results/safety data (e.g., timeliness, accuracy, frequency, response)
		Identify and comply with the requirements for human subject

		protection and privacy under different national and international regulations and ensure their implementation throughout all phases of a clinical study
		Differentiate the types of adverse events (AEs) that can occur during clinical trials, and their identification and reporting process for AEs
	6.8 essential documents for the conduct of a clinical trial (e.g., trial master file)	Manage study records retention and availability
		Maintain and/or review study related logs (e.g., site signature/designation log, screen log)
		Collect, maintain, verify, and/or store regulatory essential documents
	6.9 record retention and destruction practices and requirements	Collect, maintain, verify, and/or store regulatory essential documents
		Manage study records retention and availability
		Maintain and/or review study related logs (e.g., site signature/delegation log, screening log)
	6.10 source data/document review (SDR) and/or verification (SDV)	Administer a data quality review (source data/document review (SDR) and/or verification (SDV))
		Manage source data/documents according to ALCOA-C standards (Attributable Legible Contemporaneous Original Accurate Complete)
		Prepare, conduct and/or participate in site monitoring (onsite, centralized, or remote)
	6.11 study documentation practices (ALCOA-C)	Manage source data/documents according to ALCOA-C standards (Attributable Legible Contemporaneous Original Accurate-Complete
		Administer a data quality review (source data/document review (SDR) and/or verification (SDV))

		Prepare, conduct, and/or participate in site monitoring (onsite, centralized, or remote)
	6.12 PI responsibility to make all source records available for monitoring, auditing, and inspection	Manage study records, retention, and availability
		Identify, document, communicate, and follow up on site issues
		Participate in audits and inspections (e.g. prepare, support, respond)