SOCRA® EXAM OUTLINE

FOR CLINICAL RESEARCH EXCELLENCE

EXAMINATION CONTENT

The CCRP ® certification examination is organized into three major content areas derived from the 2017 SOCRA Job/Task Analysis. The examination content outline provides a detailed description of the content areas including topic areas and knowledge domains. Each question on the exam is based on the content outline. To prepare for the exam, a candidate should study the detailed outline and consider the knowledge, skills, and abilities needed to perform the duties of a CRP. Satisfactory completion of the CCRP® certification examination indicates that the candidate has met all the eligibility criteria and has demonstrated knowledge of the key duties/tasks of a CRP.

The questions assess understanding and application, not just the ability to recall facts. The questions are intended to evaluate a candidate's ability to abstract information and do not require clinical (medical) experience.

Each test question has only one correct answer. Each question is weighted equally, and there is no penalty for an incorrect answer. Therefore, it is advantageous to answer all questions.

The CCRP® certification examination consists of 130 multiple choice questions. Thirty (30) of these questions are "beta test" questions and will not affect the candidate's score (unscored). These items are not identified to the candidate. The data collected on the unscored items is used to evaluate the psychometric soundness of each CCRP® test item. The number of scored items on the exam is 100.

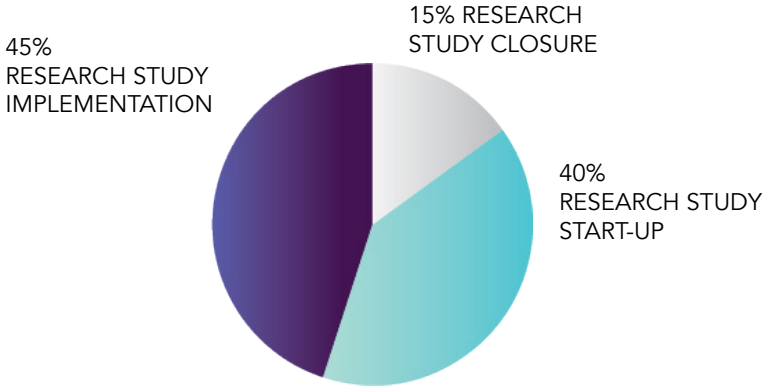
The passing score is determined by a panel of experts using the "Modified Angoff Method".

THREE CONTENT AREAS AND PERCENT OF SCORED TEST ITEMS

Content areas on the examination involve topics/duties clinical research professionals perform in the conduct of their job. The content is defined into three (3) major content areas:

MAJOR CONTENT AREA	BRIEF DESCRIPTION	APPROX. QUESTIONS ON EXAM
Research Study Start-Up	Regulatory Requirements of IRB/IEC, sponsors and investigators related duties/task related to study start up	40
Research Study Implementation	Regulatory Requirements of IRB/IEC, sponsors and investigators related duties/task related to conduct of the study	45
Research Study Closure	Regulatory Requirements of IRB/IEC, sponsors and investigators related duties/task related to study close out and record maintenance	15

Clinical Research Professionals perform an array of duties/tasks. Not everyone performs all the duties outlined in the content areas. The Content areas on the examination that deal with topics concerning your daily job requirements should not require extensive study on your part; it is anticipated that this is part of your working knowledge. Content areas appearing on the examination that are not part of your daily job requirements may require some research and study. For instance, if you do not deal with Institutional Review Boards (IRB), you will want to study the requirements of this aspect of clinical research.



Please remember that the examination assesses your knowledge and understanding of the following:

- United States Code of Federal Regulations (CFR)
  - 45 CFR Part 46
  - 21 CFR Part 11
  - 21 CFR Part 50
  - 21 CFR Part 56
  - 21 CFR Part 312
  - 21 CFR Part 812

- FDA Regulatory Forms.:1572, 3454, 3455, IND, IDE, Medwatch (3500 and 3500A)

- The International Conference of Harmonisation E6 (R2) - (ICH/GCP)

- Ethical Principles with their foundation in the following documents:
  - Nuremberg Code
  - Belmont Report
  - Declaration of Helsinki

The CCRP Examination does NOT assess state, local, provincial, Ministry of Health, or institutional policy.

EXAM CONTENT OUTLINE

MAJOR CONTENT AREA	TOPICS AREAS
1. RESEARCH STUDY START-UP - 40%	
a. Coordinate the development of initial research study protocol	Determine if a research study design involves human subjects
	Develop Standard Operating Procedures (SOPs) for sponsors, clinical investigators, and IRBs
	Coordinate the expedited review of research study protocol
	Coordinate the development of emergency use research study protocol
	Coordinate the development of a research study protocol involving vulnerable subjects
	Coordinate the development of a research study protocol involving investigational products (e.g., pharmaceutical, biologic or device)
	KNOWLEDGE OF:
	Roles and responsibilities of the sponsor, clinical investigator and IRB in determination the applicable regulatory pathway for a clinical study (e.g. IND, IDE)
	Ethical concepts with foundation in:
	- Nuremberg Code
	- Belmont Report
	- Declaration of Helsinki
	Roles and responsibilities of the sponsor, clinical investigator and IRB in determining the applicable regulatory pathway for a clinical study (e.g. IND, IDE)
	- Development of Standard Operating Procedures (SOPs) for IRB/IECs, Sponsors and Clinical Research Sites
	Roles and responsibilities of IRB/IEC review and approval of clinical studies including:
	- Emergency use of a research product
	- Expedited Review clinical studies
	- Significant risk determination for medical device clinical studies
	Development of protocols (including study design with consideration of methods to reduce bias, objectives, endpoints, data safety monitoring)
	- Clinical trial phases (e.g. drug trials- phase 1, 2, 3 and medical devices- feasibility, pivotal)
	- Study design characteristics (e.g. Randomization and blinding)
	- Study objectives and purpose
	- Inclusion/exclusion criteria
	- Description of procedures
	- Statistical plan
	Roles and responsibility for protection of human subjects including:
	- Safeguards for children in clinical trials
	- Protection of vulnerable subjects
	- Emergency Use Research
b. Create or obtain research study documents (e.g., informed consent, essential documents, case report forms, financial disclosure statements)	Develop informed consent & informed assent documents
	Obtain financial disclosure from clinical investigators and sub investigators
	Develop case report forms
	Preparing a delegation log
	Identify the need to develop and submit an IND/IDE
	Obtain clinical investigator agreements for device trials
	Develop regulatory documents (i.e., essential documents)

MAJOR CONTENT AREA	TOPICS AREAS
1. RESEARCH STUDY START-UP - 40%	
(continued) b. Create or obtain research study documents (e.g., informed consent, essential documents, case report forms, financial disclosure statements)	KNOWLEDGE OF:
	Informed consent/assent process including development, content, review, approval
	Submission (obtain approval) of informed consent documents to reviewing IRB/IEC- original
	Informed consent essential and optional elements/information to be provided to subjects
	Requirements for documentation and reporting financial disclosure for clinical investigators including:
	- Form FDA 3454 and 3455
	- Definition of significant equity interest and significant payments in clinical trials
	- Definition of covered clinical trial
	- Record maintenance
	Investigational product brochure / Investigator's brochure
	IDE Significant Risk Determination
	Regulatory requirements related to essential documents for clinical studies (IRB/IEC, sponsor and clinical sites)
	Roles, responsibilities and obligations of the sponsor
	Roles, responsibilities and obligations of the investigator
	Delegation of duties
	Investigational New Drug (IND) development and submission to applicable authorities
	Investigational Device Exemption (IDE) development and submission to applicable authorities
	IDE Significant Risk Determination
	Regulatory requirement for protocol(s) and protocol related document(s) (e.g., informed consent)
	Essential study related documents (paper/electronic)
	Clinical investigator agreements (e.g FDA Form 1572, investigator agreement)
c. Obtain research study approval from necessary stakeholders (e.g., IRB, research study sponsor, and relevant regulatory authorities)	Obtain research study sponsor approval
	Obtain IRB/IEC approval
	Obtain relevant regulatory authority approval
	KNOWLEDGE OF:
	Regulatory requirements for submission of protocol(s) to applicable authorities, sponsor and IRB/IEC
	Regulatory requirement for protocol(s) and protocol related document(s) (e.g., informed consent documents, recruitment materials, safety reports, continuing review reports) development, review, and submission to reviewing authorities
d. Obtain research study product, related materials, equipment, tools and aids	Develop research study tools/aids
	Requirements for data management systems
	KNOWLEDGE OF:
	Development of data collection tools (e.g., essential documents such as case report forms, product accountability logs, delegation logs)
	Regulatory requirement for essential document development(electronic or paper based)
e. Select research study sites	KNOWLEDGE OF:
	Evaluating a clinical site to conduct a clinical study

MAJOR CONTENT AREA	TOPICS AREAS
1. RESEARCH STUDY START-UP - 40%	
f. Train research study staff members	Evaluate research study staff member qualifications (e.g., clinical investigator, research coordinator, study monitors)
	Develop training program for all personnel involved in the study
	Administer training program
	KNOWLEDGE OF:
	Clinical site and personnel for qualifications to conduct a clinical study
	Site/investigator training (GCP, investigational product, study, reporting requirements, compliance with protocol)
g. Evaluate research study's compliance with relevant local, state and provincial laws	Evaluate IRB compliance with applicable regulations
	Submit relevant studies to clinicaltrials.gov
	Evaluate compliance with relevant local, state and provincial laws
	KNOWLEDGE OF:
	Roles and responsibilities of the IRB/IEC for review and approval of study
	Standard operating procedure development and implementation for the IRB/IEC
	IRB / IEC membership requirements
	IRB / IEC protocol review requirements
	IRB / IEC protocol amendment review requirements
	IRB / IEC expedited protocol review requirements
	IRB evaluation of significant risk/non significant medical device study determination
	Requirements for documentation of IRB/IEC meeting minutes, reviews and decisions
	Communication of IRB/IEC decisions
	Record retention for IRB/IEC documentation
	- Regulatory requirements for clinicaltrials.gov
	- Applicable studies
	Elements required in informed consent document
	Determine applicable requirements of regulatory agencies and any local (institution), state and provincial requirements
	Data Safety Monitoring Board (DSMB) responsibilities
2. RESEARCH STUDY IMPLEMENTATION - 45%	
a. Execute Research Strategy	Follow research study protocol
	Follow Standard Operating Procedures (SOPs) (e.g., IRB/IEC, study and sponsor)
	Evaluate research study protocol
	Develop & submit continuing review submissions
	Develop & submit research study protocol amendments to IRB/IEC sponsor and regulatory authorities
	KNOWLEDGE OF:
	Roles and responsibilities of IRB/IEC, sponsor and clinical investigator in the conduct of clinical research
	Regulatory requirements to conduct a study in accordance with an investigational plan
	- Investigator agreement, and applicable regulations
	Evaluating clinical site and personnel for ability to conduct a clinical study

MAJOR CONTENT AREA	TOPICS AREAS
2. RESEARCH STUDY IMPLEMENTATION - 45%	
(continued) a. Execute Research Strategy	Implementation of Standard Operating Procedures (SOPs) for:
	- IRB/IECs
	- Sponsors
	- Clinical Sites
	Requirements for documentation, reporting and maintenance of financial disclosure for clinical investigators including:
	- Form FDA 3454
	- Form FDA 3455
	Regulatory requirements for Investigational site study reports and development and submission to reviewing authorities (e.g., progress reports, safety reports, final reports protocol changes, protocol deviations)
	Submission and review of protocol amendment(s)
	Regulatory requirements for submission of protocol amendment(s) to applicable authorities, IRB/IEC
b. Assure regulatory compliance	Comply with relevant local, state and provincial laws
	Comply with applicable privacy laws
	KNOWLEDGE OF:
	Regulatory requirements for confidentiality of a research subject's information
c. Manage research study product (e.g., treatment, procedure, medication, medical device, questionnaire)	Prepare research study product(s)
	Dispense research study product(s)
	Administer research study product(s)
	Store research study product(s)
	Verify research study product(s)' use
	KNOWLEDGE OF:
	Sponsor's roles and responsibilities for Investigational product accountability:
	- Regulatory requirements related to shipment and disposition of investigational products including:
	- Investigational product (e.g., package insert, report of prior investigations, Investigator's Brochure)
	- Documentation of randomization of investigational product
	- Investigational product accountability
	- Packaging and labeling of investigational products
	- Evaluation and documentation of investigational product compliance (e.g., protocol, standard operating procedures, local governance)
	Clinical Investigator's roles and responsibilities related to receipt and distribution of investigational product and other supplies at study site
	Regulatory requirements related to receipt and distribution of investigational product and other supplies at study site:
	- Documentation of randomization of subjects and investigational product
	- Packaging and labeling of investigational products
	- Evaluation and documentation of Investigational product compliance (i.e., according to protocol)
	- Documentation of Investigational Product Accountability and Subject training for the use of study agents

MAJOR CONTENT AREA	TOPICS AREAS
2. RESEARCH STUDY IMPLEMENTATION - 45%	
d. Identify, document & report research study anomalies	Identify, document & report protocol deviations/violations
	Identify, document & report unanticipated problems
	Identify, document & report unanticipated adverse events and adverse device effects
	Identify, document & report adverse events/effects
	Identify, document & report serious adverse events/effects
	Identify, document & report research misconduct
	KNOWLEDGE OF:
	Sponsors and Clinical Investigator's roles and responsibilities for identification, documentation and reporting of unanticipated problems, unanticipated adverse device effects, adverse drug events, serious adverse events/effects.
	Requirements for informing subjects of safety concerns and any relevant changes to the study
	Subject safety issues –definitions, documentation, and reporting of adverse events, serious adverse events/serious adverse drug reactions, and unanticipated adverse device effects including the following:
	- Documentation
	- Expected or unexpected results associated with investigational products
	- Investigator's plan/protocol of action or management of adverse event (e.g., stop investigational product; call, retest, treat subject)
	- Follow-up to determine resolution of adverse events
	- Definition / classification of: adverse event, adverse drug reaction, serious adverse event, and unanticipated adverse device effects
	Documentation of serious adverse events/ serious adverse drug reactions, and unanticipated adverse device effects and relevant information in source documents and CRFs
	Regulatory requirements for reporting serious adverse event/ serious adverse drug reaction, and unanticipated adverse device effects to Sponsor/CRO and IRB/IEC
	Regulatory requirements for documenting reasons for subject discontinuation/ termination
	Regulatory requirements for documenting follow-up medical care for study subjects
	- Safety monitoring/reporting activities
	- Un-blinding
	Regulatory reporting and Medwatch [3500 and 3500A] requirements
	Identification and reporting of research misconduct:
	- Clinical Investigator Disqualification and debarment
	- Ethical concepts with foundation in:
	* Nuremberg Code
	* Belmont Report
	* Declaration of Helsinki
e. Manage subjects	Recruit subjects
	Evaluate subject eligibility
	Assess the capacity for consent of vulnerable populations
	Document subject eligibility
	Explain a research study methodology to subjects and associated family members and Caregivers
	Obtain informed consent

MAJOR CONTENT AREA	TOPICS AREAS
2. RESEARCH STUDY IMPLEMENTATION - 45%	
(continued) e. Manage subjects	Obtain informed assent
	Document informed consent
	Document reasons for subject discontinuation
	Coordinate subject interactions with associated family members and caregivers
	Document subject and associated family members and caregiver interactions
	Communicate with subjects and associated family members and caregivers
	KNOWLEDGE OF:
	Regulatory requirements for IRB review and approval of subject requirement materials
	Subject Scheduling, Screening, Recruitment, and Retention including:
	- Recruitment plan/strategies (including regulatory requirements for recruitment materials)
	- Subject compliance
	- Subject visits
	- Subject retention
	- Subject discontinuation/ study termination
	Regulatory requirements and ethical concepts related to protection of vulnerable subjects
	- Children
	- Prisoners
	- Pregnant Women,
	- Human Fetuses and Neonates
	Regulatory requirements related to source documentation (paper/electronic) –completion and review of
	Source documentation and case report forms (CRFs) of subject participation in a study including:
	- Subject eligibility
	- Informed consent (e.g. vulnerable subjects, legally authorized representative, & short form)
	- Safety- adverse events, adverse drug reactions, serious adverse effects, unanticipated adverse device effects
	- Study related visits, procedures, and assessments
	- Discontinuation/termination of study subjects
	- Maintenance of essential study related documents (paper/electronic)
f. Maintain the research study	Maintain training documentation
	Maintain research study equipment
	Maintain the delegation log
	Maintain essential documents
	Maintain medical records (source documents)
	Maintain information in clinicaltrials.gov
	Manage all regulatory documents (e.g., essential documents)
	Develop, initiate, and resolve data queries
	Verify the accuracy and completeness of site records
	Prepare for or perform for a site audit, a monitoring visit and a regulatory inspection

MAJOR CONTENT AREA	TOPICS AREAS
2. RESEARCH STUDY IMPLEMENTATION - 45%	
(continued) f. Maintain the research study	KNOWLEDGE OF:
	Regulatory requirements for maintenance and retention of study related essential documents, sources documents and equipment including:
	- Investigator qualification and financial disclosure
	- Research staff qualification and training
	- Informed consent documents
	- Study related visits, procedures, and assessments
	- Safety- adverse events, adverse drug reaction, serious adverse effect, unanticipated adverse device effect
	Regulatory requirements related to clinical.trials.gov
	- Informed consent documents
	- Covered studies
	Review of accuracy and completeness of site records including monitoring source documentation/case report forms: eligibility, product dosing and accountability, adverse events, study related visits and follow up care, and informed consent documentation
	Review of accuracy and completeness of site records including monitoring source documentation/case report forms: eligibility, product dosing and accountability, adverse events, study related visits and follow up care, and informed consent documents
	Preparation and follow-up for study site, IRB/IEC and sponsor regulatory agency inspections (including FDA Forms 482 and 483)
	Knowledge of principles of Quality Assurance and Corrective and Preventive Action Plans (CAPA)
g. Communicate with research study stakeholders	Communicate with the IRB
	Communicate with research study sponsor
	Communicate with Data Safety Monitoring Board (DSMB)
	Communicate with regulatory authorities
	Communicate with study sites
	Complete case report forms
	KNOWLEDGE OF:
	Regulatory requirements for communication with IRB/IEC, sponsor, investigational site and regulatory authorities including:
	- Annual progress reports
	- Safety reporting
	- Withdrawal of IRB approval
	- Deviations from the investigational plan
	- Use of investigational product without informed consent
	- Protocol amendments
	- IND/IDE amendments
	- Study/protocol termination/discontinuation
	- Recall of investigational product
	IRB/IEC communication with sponsor, clinical investigator and regulatory authorities
	Role and Responsibilities of Data Safety Monitoring Boards (DSMB)
	Regulatory requirements related to study documentation (paper/electronic) -completion/review. Development and maintenance of accurate, current and complete records relating to clinical studies.

MAJOR CONTENT AREA	TOPICS AREAS
3. RESEARCH STUDY CLOSURE - 15%	
a. Perform / participate a research study closeout visit	KNOWLEDGE OF:
	Study closeout visit
	- Essential documents, verification of study documentation
	- Resolution of monitoring queries
	- Accountability of investigational product
b. Perform / participate a research study audit	Regulatory requirements for maintenance and retention of study related essential documents, sources documents
	Quality Control and Quality Assurance
	Preparation and follow-up for study site, IRB/IEC and sponsor regulatory agency inspections
c. Develop & submit research study closure reports	Develop & submit closure report to IRB
	Develop & submit final report to research study sponsor
	Develop & submit final report to relevant regulatory authorities
	Develop & submit final report to clinicaltrials.gov
	KNOWLEDGE OF:
	Regulatory requirements for development and submission of study closure reports to IRB/IEC, sponsor and regulatory authorities:
	- Termination/discontinuation
	- Study completion
	Regulatory requirements related to clinical.trials.gov
	- Informed consent documents
	- Covered studies
	- Reporting
d. Archive / retrieve research study records	KNOWLEDGE OF:
	Regulatory requirements for maintenance and retention of study related essential documents, sources documents