ACADEMY
OF CLINICAL RESEARCH PROFESSIONALS

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

(Effective May 1, 2017)

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.

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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.

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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)