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: o Nuremberg Code o Belmont Report o 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) o 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: o Emergency use of a research product o Expedited Review clinical studies o 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) o Clinical trial phases (e.g. drug trials- phase 1, 2, 3 and medical devices- feasibility, pivotal) o Study design characteristics (e.g. Randomization and blinding) o Study objectives and purpose o Inclusion/exclusion criteria o Description of procedures o Statistical plan • Roles and responsibility for protection of human subjects including: o Safeguards for children in clinical trials o Protection of vulnerable subjects o 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)
	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: o Form FDA 3454 and 3455 o Definition of significant equity interest and significant payments in clinical trials o Definition of covered clinical trial o 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
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 - 50 %	
a. Execute research study	• 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
	• 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
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 • 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
	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.
h. 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

Research Study Closure—10 %	
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. 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
c. Archive/retrieve	