Core Competencies Form

Name	
Role	
Date completed	

Domain	Competency	Level	Training Planned
1 Scientific concepts & research design: encompasses knowledge of scientific concepts related to the design & analysis of clinical trials	1.1 Apply principles of biomedical science to investigational product discovery & development & health-related behavioural interventions	☐Fundamental ☐Skilled ☐Advanced ☐Not Applicable	
	1.2 Identify scientific questions that are potentially testable clinical research hypotheses	☐Fundamental ☐Skilled ☐Advanced ☐Not Applicable	
	1.3 Identify the elements and explain the principles and processes of designing a clinical study	☐Fundamental ☐Skilled ☐Advanced ☐Not Applicable	
	1.4 Critically analyze clinical study results	☐Fundamental ☐Skilled ☐Advanced ☐Not Applicable	
2 Ethical and Participant Safety Considerations:	2.1 Differentiate between standard of care and clinical study activities	☐Fundamental ☐Skilled ☐Advanced	

Encompasses care of patients, aspects of human subject protection, and safety in the conduct of a clinical trial		☐Not Applicable	
	2.2 Define the concepts of “clinical equipoise” and “therapeutic misconception” as they relate to the conduct of a clinical study	☐Fundamental ☐Skilled ☐Advanced ☐Not Applicable	
	2.3 Apply relevant national and international principles of human subject protections and privacy throughout all stages of a clinical study	☐Fundamental ☐Skilled ☐Advanced ☐Not Applicable	
	2.4 Explain the evolution of the requirement for informed consent from research participants and the principles and content of key documents that help ensure the protection of human participants in clinical research	☐Fundamental ☐Skilled ☐Advanced ☐Not Applicable	
	2.5 Describe the ethical issues involved when dealing with vulnerable populations and what additional safeguards should be in place for those populations	☐Fundamental ☐Skilled ☐Advanced ☐Not Applicable	
	2.6 Evaluate and apply an understanding of the relevant ethical issues and cultural variation as it applies to the commercial aspects of the clinical research and investigational product development process	☐Fundamental ☐Skilled ☐Advanced ☐Not Applicable	
	2.7 Explain why inclusion, exclusion, and other criteria are included in a clinical protocol to assure human subject protection	☐Fundamental ☐Skilled ☐Advanced ☐Not Applicable	
	2.8 Summarize the principles and methods of distributing and balancing risk and benefit; through selection and management of clinical study subjects	☐Fundamental ☐Skilled ☐Advanced ☐Not Applicable	

3 Investigational Products Development and Regulation: Encompasses knowledge of how investigational products are developed and regulated	3.1 Discuss the historical events that precipitated the development of governmental regulatory processes for investigational products	☐Fundamental ☐Skilled ☐Advanced ☐Not Applicable	
	3.2 Describe the roles and responsibilities of the various institutions participating in the investigational products development process	☐Fundamental ☐Skilled ☐Advanced ☐Not Applicable	
	3.3 Explain the investigational products development process and the activities which integrate commercial realities into the life cycle management of medical products	☐Fundamental ☐Skilled ☐Advanced ☐Not Applicable	
	3.4 Summarize the legislative and regulatory framework that supports the development and registration of investigational products and ensures their safety, efficacy and Quality	☐Fundamental ☐Skilled ☐Advanced ☐Not Applicable	
	3.5 Describe the specific processes and phases that must be followed for the regulatory authority to approve the marketing authorization for a medical product	☐Fundamental ☐Skilled ☐Advanced ☐Not Applicable	
	3.6 Describe the pre- and post- approval safety reporting requirements of regulatory agencies	☐Fundamental ☐Skilled ☐Advanced ☐Not Applicable	
	3.7 Appraise the issues generated and the effects of global expansion on the approval and regulation of medical products	☐Fundamental ☐Skilled ☐Advanced ☐Not Applicable	
4 Clinical Study Operations (Good Clinical Practice):	4.1 Explain how the design, purpose, and conduct of individual clinical studies fit into the goal of developing a new intervention	☐Fundamental ☐Skilled ☐Advanced	

Encompasses study management (adverse event identification and reporting, post-market surveillance and pharmacovigilance), and handling of investigational product.		☐Not Applicable	
	4.2 Describe the roles and responsibilities of the clinical investigation team as defined by Good Clinical Practice Guidelines	☐Fundamental ☐Skilled ☐Advanced ☐Not Applicable	
	4.3 Evaluate the design, conduct and documentation of clinical studies as required for compliance with Good Clinical Practice Guidelines	☐Fundamental ☐Skilled ☐Advanced ☐Not Applicable	
	4.4 Compare and contrast the regulations and guidelines of global regulatory bodies relating to the conduct of clinical studies	☐Fundamental ☐Skilled ☐Advanced ☐Not Applicable	
	4.5 Describe appropriate control, storage and dispensing of investigational product	☐Fundamental ☐Skilled ☐Advanced ☐Not Applicable	
	4.6 Differentiate the types of adverse events (AEs) that may occur during clinical studies and explain the identification process and reporting requirement to IRBs/IECs, sponsors and regulatory authorities	☐Fundamental ☐Skilled ☐Advanced ☐Not Applicable	
	4.7 Describe how global regulations and guidelines assure human subject protection and privacy during the conduct of clinical studies	☐Fundamental ☐Skilled ☐Advanced ☐Not Applicable	
	4.8 Describe the role and process of monitoring a clinical study	☐Fundamental ☐Skilled ☐Advanced ☐Not Applicable	

	4.9 Describe the role and purpose of clinical study audits	☐Fundamental ☐Skilled ☐Advanced ☐Not Applicable	
	4.10 Describe the various methods by which safety issues are identified and managed in clinical studies	☐Fundamental ☐Skilled ☐Advanced ☐Not Applicable	
5 Study and Site Management: Encompasses content required at the site level to run a study (financial and personnel aspects). Includes site and study operations (not encompassing regulatory/GCPs)	5.1 Describe the methods used to determine whether to sponsor, supervise or participate in a clinical study	☐Fundamental ☐Skilled ☐Advanced ☐Not Applicable	
	5.2 Develop and manage the financial, timeline, and personnel resources necessary to conduct a clinical study	☐Fundamental ☐Skilled ☐Advanced ☐Not Applicable	
	5.3 Describe the management and training approaches to mitigate risk to improve clinical study conduct	☐Fundamental ☐Skilled ☐Advanced ☐Not Applicable	
	5.4 Develop strategies to manage participant recruitment, retention, compliance and track study activities.	☐Fundamental ☐Skilled ☐Advanced ☐Not Applicable	
	5.5 Identify the legal responsibilities, liabilities and accountabilities that are involved in the conduct of clinical studies	☐Fundamental ☐Skilled ☐Advanced ☐Not Applicable	
	5.6 Identify and explain the specific procedural, documentation and oversight requirements of principal investigators, sponsors, CROs and	☐Fundamental ☐Skilled ☐Advanced	

	regulatory authorities that relate to the conduct of a clinical study	☐Not Applicable	
6 Data Management and Informatics: Encompasses how data are acquired and managed during a clinical trial, including source data, data entry, queries, quality control, and correction and the concept of a locked database	6.1 Describe the role and importance of statistics and informatics in clinical studies	☐Fundamental ☐Skilled ☐Advanced ☐Not Applicable	
	6.2 Describe the origin, flow, and management of data through a clinical study	☐Fundamental ☐Skilled ☐Advanced ☐Not Applicable	
	6.3 Describe best practices and resources required for standardizing data collection, capture, management, analysis, and reporting	☐Fundamental ☐Skilled ☐Advanced ☐Not Applicable	
	6.4 Describe, develop, and implement processes for data quality assurance	☐Fundamental ☐Skilled ☐Advanced ☐Not Applicable	
7 Leadership and Professionalism: Encompasses the principles and practice of leadership and professionalism in clinical research	7.1 Describe and apply the principles and practices of leadership, management and mentorship in clinical research	☐Fundamental ☐Skilled ☐Advanced ☐Not Applicable	
	7.2 Identify ethical and professional conflicts associated with the conduct of clinical studies and implement procedures for their prevention or management	☐Fundamental ☐Skilled ☐Advanced ☐Not Applicable	
	7.3 Identify and apply the professional guidelines and codes of ethics that apply to the conduct of clinical research.	☐Fundamental ☐Skilled ☐Advanced ☐Not Applicable	

	7.4 Describe the impact of regional diversity and demonstrate cultural competency in clinical study design and conduct	☐Fundamental ☐Skilled ☐Advanced ☐Not Applicable	
8 Communications and Teamwork: Encompasses all elements of communication within the site and between the site and sponsor, CRO, and regulators. Understanding of teamwork skills necessary for conducting a clinical trial	8.1 Discuss the relationship and appropriate communication between Sponsor, CRO and clinical research site	☐Fundamental ☐Skilled ☐Advanced ☐Not Applicable	
	8.2 Describe the components of a traditional scientific publication	☐Fundamental ☐Skilled ☐Advanced ☐Not Applicable	
	8.3 Effectively communicate the content and relevance of clinical research findings to colleagues, advocacy groups and the non-scientist community.	☐Fundamental ☐Skilled ☐Advanced ☐Not Applicable	
	8.4 Describe the importance of team science and methods necessary to work effectively with multidisciplinary and inter-professional research teams.	☐Fundamental ☐Skilled ☐Advanced ☐Not Applicable	