JOINT TASK FORCE FOR CLINICAL TRIAL COMPETENCY

MULTI-REGIONAL CLINICAL TRIALS
THE MRCT CENTER of BRIGHAM AND WOMEN'S HOSPITAL and HARVARD

The Joint Task Force for Clinical Trial Competency and the Harmonized Core Competency Framework for the Clinical Research Professional

The Joint Task Force for Clinical Trial Competency (JTF) was formed during a meeting hosted by the Multi-Regional Clinical Trials Center of Brigham and Women's Hospital and Harvard (MRCT Center) in 2013. This multi-stakeholder group recognized the need for a single set of professional competencies for the clinical research enterprise and agreed to harmonize the then-existing role-based core competency statements to create a universal Core Competency Framework for the Clinical Research Profession. The Framework was originally published in 2014 and was the product of representatives from academia, industry, professional societies, and others. Since its release, the Framework has been widely utilized worldwide by organizations involved in clinical research, addressing a critical gap in clinical research.

In October 2016, the MRCT Center hosted the *Core Competencies in Clinical Research Workshop* that brought together the JTF and representatives from the clinical research community and stakeholders who had utilized the Framework in their own organizations. Case studies were presented highlighting real-world applications; the JTF discussed feedback on potential revisions and its future objectives. Two major suggestions resulted from the Workshop: 1) due to the dynamic nature of the clinical research enterprise, periodic updates to the Framework would be necessary to maintain relevance and 2) the individual competencies needed to be further categorized by level of expertise, since the experience, role and global location of the researcher differed.

Following this Workshop, a "Revisions" subgroup of the JTF evaluated suggested changes and updates and solicited public input and evaluation of the suggested revisions for impact, relevance across the clinical research community, global applicability, and necessity. The JTF removed redundancies between domains, clarified competency statements and enhanced the ability to assess and measure an individual's competency. The JTF made two global changes to the language of the Framework, replacing "Clinical trial" to "clinical study," in order to include different kinds of research, and changing "Medicines" to "investigational products," in order to include different interventions (e.g., medicines, devices, combination therapies).

The second suggestion from the October, 2016 workshop was to express the core competency statements at different levels of experience and expertise so as to enable the competencies to be used in the development of standardized role descriptions, assessments that could be utilized for evaluation (including potential self-evaluation) and potential promotion, assessments of educational and training needs, and individual portfolio creation. The JTF formed a multidisciplinary stakeholder group that is currently finalizing each Framework 2.0 competency statement at the Fundamental, Skilled and Expert levels, with specific examples of each to guide the user in their application.

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The Harmonized Core Competency Framework – Version 2.0, consisting of 8 domains and 48 specific professional competencies was posted to the JTF website (https://mrctcenter.org/clinical-trial-competency/) in September 2017, and is downloadable. Please do not hesitate to provide feedback and further suggestions to mrct@bwh.harvard.edu.

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VERSION 2.0 – Updated as of September 1, 2017

Introduction: The Joint Task Force for Clinical Trial Competency has updated its Core Competency Framework for use by clinical research professionals worldwide. The JTF recognizes the dynamic nature of the clinical research enterprise that will necessitate the continuing revision of the Framework. The Framework must continue to meet the latest scientific, ethical and research challenges of clinical researchers.

	Harmonized Core Competency Framework for the Clinical Research Professional
1	**Scientific Concepts and Research Design:** Encompasses knowledge of scientific concepts related to the design and analysis of clinical trials
1.1	Apply principles of biomedical science to investigational product discovery and development and health-related behavioral interventions
1.2	Identify scientific questions that are potentially testable clinical research hypotheses
1.3	Identify the elements and explain the principles and processes of designing a clinical study
1.4	Critically analyze clinical study results
2	**Ethical and Participant Safety Considerations:** Encompasses care of patients, aspects of human subject protection, and safety in the conduct of a clinical trial
2.1	Differentiate between standard of care and clinical study activities
2.2	Define the concepts of "clinical equipoise" and "therapeutic misconception" as they relate to the conduct of a clinical study
2.3	Apply relevant national and international principles of human subject protections and privacy throughout all stages of a clinical study
2.4	Explain the evolution of the requirement for informed consent from research participants and the principles and content of the key documents that ensure the protection of human participants in clinical research

2.5	Describe the ethical issues involved when dealing with vulnerable populations and what additional safeguards should be in place for those populations
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
2.7	Explain why inclusion, exclusion, and other criteria are included in a clinical protocol to assure human subject protection
2.8	Summarize the principles and methods of distributing and balancing risk and benefit; through selection and management of clinical study subjects
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
3.2	Describe the roles and responsibilities of the various institutions participating in the investigational products development process
3.3	Explain the investigational products development process and the activities which integrate commercial realities into the life cycle management of medical products
3.4	Summarize the legislative and regulatory framework that supports the development and registration of investigational products and ensures their safety, efficacy and quality
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
3.6	Describe the pre- and post- approval safety reporting requirements of regulatory agencies
3.7	Appraise the issues generated and the effects of global expansion on the approval and regulation of medical products

4	**Clinical Study Operations (Good Clinical Practice):** Encompasses study management and GCP compliance; safety management (adverse event identification and reporting, post-market surveillance, and pharmacovigilance), and handling of investigational product
4.1	Explain how the design, purpose, and conduct of individual clinical studies fit into the goal of developing a new intervention
4.2	Describe the roles and responsibilities of the clinical investigation team as defined by Good Clinical Practice Guidelines
4.3	Evaluate the design, conduct and documentation of clinical studies as required for compliance with Good Clinical Practice Guidelines
4.4	Compare and contrast the regulations and guidelines of global regulatory bodies relating to the conduct of clinical studies
4.5	Describe appropriate control, storage and dispensing of investigational product
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
4.7	Describe how global regulations and guidelines assure human subject protection and privacy during the conduct of clinical studies
4.8	Describe the reporting requirements of global regulatory bodies relating to clinical study conduct
4.9	Describe the role and process of monitoring a clinical study
4.10	Describe the role and purpose of clinical study audits
4.11	Describe the various methods by which safety issues are identified and managed in clinical studies
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
5.2	Develop and manage the financial, timeline, and personnel resources necessary to conduct a clinical study
5.3	Describe the management and training approaches to mitigate risk to improve clinical study conduct
5.4	Develop strategies to manage participant recruitment, retention, compliance and track study activities.
5.5	Identify the legal responsibilities, liabilities and accountabilities that are involved in the conduct of clinical studies
5.6	Identify and explain the specific procedural, documentation and oversight requirements of principal investigators, sponsors, CROs and regulatory authorities that relate to the conduct of a clinical study
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
6.2	Describe the origin, flow, and management of data through a clinical study
6.3	Describe best practices and resources required for standardizing data collection, capture, management, analysis, and reporting
6.4	Describe, develop, and implement processes for data quality assurance
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.

7.2	Identify ethical and professional conflicts associated with the conduct of clinical studies and implement procedures for their prevention or management.
7.3	Identify and apply the professional guidelines and codes of ethics that apply to the conduct of clinical research.
7.4	Describe the impact of regional diversity and demonstrate cultural competency in clinical study design and conduct
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.
8.2	Describe the components of a traditional scientific publication.
8.3	Effectively communicate the content and relevance of clinical research findings to colleagues, advocacy groups and the non-scientist community.
8.4	Describe the importance of team science and methods necessary to work effectively with multidisciplinary and inter-professional research teams.

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