Core Competencies in Clinical and Translational Research

Core Thematic Areas	Competencies
I. CLINICAL AND TRANSLATIONAL RESEARCH QUESTIONS	1. Identify basic and preclinical studies that are potential testable clinical research hypotheses. 2. Identify research observations that could be the bases of large clinical trials. 3. Define the data that formulate research hypotheses. 4. Derive translational questions from clinical research data. 5. Prepare the background and significance sections of a research proposal. 6. Critique clinical and translational research questions using data-based literature searches. 7. Extract information from the scientific literature that yields scientific insight for research innovation.
II. LITERATURE CRITIQUE	1. Conduct a comprehensive and systematic search of the literature using informatics techniques. 2. Summarize evidence from the literature on a clinical problem. 3. Describe the mechanism of a clinical problem reviewed in a manuscript. 4. Use evidence as the basis of the critique and interpretation of results of published studies. 5. Identify potential sources of bias and variations in published studies. 6. Interpret published literature in a causal framework. 7. Identify gaps in knowledge within a research problem.
III. STUDY DESIGN	1. Formulate a well-defined clinical or translational research question to be studied in human or animal models. 2. Propose study designs for addressing a clinical or translational research question. 3. Assess the strengths and weaknesses of possible study designs for a given clinical or translational research question. 4. Design a research study protocol. 5. Identify a target population for a clinical or translational research project. 6. Identify measures to be applied to a clinical or translational research project. 7. Design a research data analysis plan. 8. Determine resources needed to implement a clinical or translational research plan. 9. Prepare an application to an IRB.
IV. RESEARCH IMPLEMENTATION	1. Compare the feasibility, efficiency, and ability to derive unbiased inferences from different clinical and translational research study designs. 2. Assess threats to internal validity in any planned or completed clinical or translational study, including selection bias, misclassification, and confounding. 3. Incorporate regulatory precepts into the design of any clinical or translational study. 4. Integrate elements of translational research into given study designs that could provide the bases for future research, such as the collection of biological specimens nested studies and the development of community-based interventions.
V. SOURCES OF ERROR	1. Describe the concepts and implications of reliability and validity of study measurements. 2. Evaluate the reliability and validity of measures. 3. Assess threats to study validity (bias) including problems with sampling, recruitment, randomization, and comparability of study groups. 4. Differentiate between the analytic problems that can be addressed with standard methods and those requiring input from biostatisticians and other scientific experts. 5. Implement quality assurance systems with control procedures for data intake, management, and monitoring for different study designs. 6. Assess data sources and data quality to answer specific clinical or translational research questions. 7. Implement quality assurance and control procedures for different study designs and analysis.

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VI. STATISTICAL APPROACHES	1. Describe the role that biostatistics serves in biomedical and public health research. 2. Describe the basic principles and practical importance of random variation, systematic error, sampling error, measurement error, hypothesis testing, type I and type II errors, and confidence limits. 3. Scrutinize the assumptions behind different statistical methods and their corresponding limitations. 4. Generate simple descriptive and inferential statistics that fit the study design chosen and answer research question. 5. Compute sample size, power, and precision for comparisons of two independent samples with respect to continuous and binary outcomes. 6. Describe the uses of meta-analytic methods. 7. Defend the significance of data and safety monitoring plans. 8. Collaborate with biostatisticians in the design, conduct, and analyses of clinical and translational research. 9. Evaluate computer output containing the results of statistical procedures and graphics. 10. Explain the uses, importance, and limitations of early stopping rules in clinical trials.
VII. BIOMEDICAL INFORMATICS	1. Describe trends and best practices in informatics for the organization of biomedical and health information. 2. Develop protocols utilizing management of information using computer technology. 3. Describe the effects of technology on medical research, education, and patient care. 4. Describe the essential functions of the electronic health record (EHR) and the barriers to its use. 5. Explain the role that health information technology standards have on the interoperability of clinical systems, including health IT messaging. 6. Access patient information using quality checks via electronic health record systems. 7. Retrieve medical knowledge through literature searches using advanced electronic techniques. 8. Discuss the role of bioinformatics in the study design and analyses of high dimensional data in areas, such as genotypic and phenotypic genomics. 9. Collaborate with bioinformatics specialists in the design, development, and implementation of research projects.
VIII. CLINICAL RESEARCH INTERACTIONS	A. REGULATORY SUPPORT AND KNOWLEDGE COMPETENCIES 1. Describe the fundamental principles of the protection of human subjects, the main authoritative bodies, key codes, and scope of enforcement. 2. Describe the Food and Drug Administration requirements for drug biologic products 3. Prepare an application for IRB approval. 4. Critique a proposal for risks to human subjects and protections of vulnerable populations. 5. Describe the essential elements of voluntary informed consent. 6. Describe the principles of research documentation, validation and audit. B. RESPONSIBLE CONDUCT OF RESEARCH COMPETENCIES 1. Explain the ways in which the principles of research ethics are integrated into the design, conduct, oversight and dissemination of research. 2. Describe the authority for and professional standards for the responsible conduct o research. 3. Explain the procedures for reporting and investigating misconduct in research. 4. Explain conflict of interest management in research. 5. Outline criteria for determination of authorship. 6. Describe the role of peer review in funding and publication. 7. Explain the purpose, policies and procedures to ensure ethical use, care, and animal safety in research.

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IX. SCIENTIFIC COMMUNICATION	1. Communicate clinical and translational research findings to different groups of individuals, including colleagues, students, the lay public, and the media. 2. Translate the implications of clinical and translational research findings for clinical practice, advocacy, and governmental groups. 3. Write summaries of scientific information for use in the development of clinical health care policy. 4. Translate clinical and translational research findings into national health strategies or guidelines for use by the general public. 5. Explain the utility and mechanism of commercialization for clinical and translational research findings, the patent process, and technology transfer.
X. CULTURAL DIVERSITY	1. Differentiate between cultural competency and cultural sensitivity principles. 2. Recognize the demographic, geographic, and ethnographic features within communities and populations when designing a clinical study. 3. Describe the relevance of cultural and population diversity in clinical research design. 4. Describe cultural and social variation in standards of research integrity. 5. Critique studies for evidence of health disparities, such as disproportional health effects on select populations (e.g., gender, age, ethnicity, race).
XI. TRANSLATIONAL TEAMWORK	1. Build an interdisciplinary/ intradisciplinary/ multidisciplinary team that matches the objectives of the research problem. 2. Manage an interdisciplinary team of scientists. 3. Advocate for multiple points of view. 4. Clarify language differences across disciplines. 5. Demonstrate group decision-making techniques. 6. Manage conflict. 7. Manage a clinical and/or translational research study.
XII. LEADERSHIP	1. Work as a leader of a multidisciplinary research team. 2. Manage a multidisciplinary team across its fiscal, personnel, regulatory compliance and problem solving requirements. 3. Maintain skills as mentor and mentee. 4. Validate others as a mentor. 5. Foster innovation and creativity.
XIII. CROSS DISCIPLINARY TRAINING	1. Apply principles of adult learning and competency-based instruction to educational activities. 2. Provide clinical and translational science instruction to beginning scientists. 3. Incorporate adult learning principles and mentoring strategies into interactions with beginning scientists and scholars in order to engage them in clinical and translational research. 4. Develop strategies for overcoming the unique curricular challenges associated with merging scholars from diverse backgrounds.
XIV. COMMUNITY ENGAGEMENT	1. Examine the characteristics that bind people together as a community, including social ties, common perspectives or interests, and geography. 2. Appraise the role of community engagement as a strategy for identifying community health issues, translating health research to communities and reducing health disparities. 3. Summarize the principles and practices of the spectrum of community-engaged research. 4. Analyze the ethical complexities of conducting community-engaged research. 5. Specify how cultural and linguistic competence and health literacy have an impact on the conduct of community engaged research.