

Education and Career Development Workgroup



*Core Competencies in Clinical and Translational Science
for Master's Candidates*

December 11, 2009

Project Timeline

- January 2008:
NCCR organizes a meeting of the training community to discuss Master's & doctoral level competencies in clinical-translational science
- April 2008:
Draft competencies are presented and reviewed at the 2008 National Annual Meeting of CTSA KL2, K12, and K30 Clinical Research Scholars
- April-November 2008:
Revisions continue by webcast meetings

Project Timeline

- November 2008:
Dr. Kathy Miner, Associate Dean at Emory University, is brought on as education/pedagogy consultant to the project
- March 2009 – April 2009:
Revisions continue via webcast meetings and comments solicited from the larger training community [National Clinical & Translational Research Education Meeting April 14-15, 2009]

Project Timeline

- June 9, 2009 the CTSA Executive Committee accept and endorse the core competency recommendations.
- July 2009 the implementation phase of the core competencies is launched by the Education Strategic Goal Committee #2 led by the co-chair, Dr. Rebecca Jackson, Ohio State University

Thematic Area Core Competencies:

PREREQUISITE COMPETENCE IN A BASIC SCIENCE OR CLINICAL DISCIPLINE

I. Clinical and Translational Research Questions

II. Literature Critique

III. Study Design

IV. Research Implementation

V. Sources of Error

VI. Statistical Approaches

VII. Biomedical Informatics

VIII. Responsible Conduct of Research

IX. Scientific Communications

X. Cultural Diversity

XI. Translational Teamwork

XII. Leadership

XIII. Cross-disciplinary Training

XIV. Community Engagement

Thematic Areas and Competencies

I. CLINICAL AND TRANSLATIONAL RESEARCH QUESTIONS

Competency

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.

Thematic Areas and Competencies

II. LITERATURE CRITIQUE

Competency

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.

Thematic Areas and Competencies

III. STUDY DESIGN

Competency

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.

Thematic Areas and Competencies

IV. RESEARCH IMPLEMENTATION

Competency

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.

Thematic Areas and Competencies

V. SOURCES OF ERROR

Competency

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.

Thematic Areas and Competencies

VI. STATISTICAL APPROACHES

Competency

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.

Thematic Areas and Competencies

VII. BIOMEDICAL INFORMATICS

Competency

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 of 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.

Thematic Areas and Competencies

VIII. RESPONSIBLE CONDUCT OF RESEARCH

Competency

VIII.A. Clinical Research Ethics Competencies

1. Summarize the history of research abuses and the rationale for creating codes, regulations, and systems for protecting participants in clinical research that requires community input.
2. Critique a clinical or translational research proposal for risks to human subjects.
3. Explain the special issues that arise in research with vulnerable participants and the need for additional safeguards.
4. Determine the need for a risk-benefit ratio that is in balance with the outcomes in clinical and translational research.
5. Describe the elements of voluntary informed consent, including increasing knowledge about research, avoiding undue influence or coercion, and assuring the decision-making capacity of participants.
6. Assure the need for privacy protection throughout all phases of a study.
7. Assure the need for fairness in recruiting participants and in distributing the benefits and burdens of clinical research.
8. Adhere to IRB application procedures.
9. Explain how the structural arrangement of science and the research industry may influence the behavior of scientists and the production of scientific knowledge.

Thematic Areas and Competencies

VIII. RESPONSIBLE CONDUCT OF RESEARCH, CONT'D

Competency

VIII.B. Responsible Conduct of Research Competencies

1. Apply the main rules, guidelines, codes, and professional standards for the conduct of clinical and translational research.
2. Adhere to the procedures to report unprofessional behavior by colleagues who engage in misconduct in research.
3. Implement procedures for the identification, prevention, and management of financial, intellectual, and employment conflicts of interests.
4. Apply the rules and professional standards that govern the data collection, sharing, and protection throughout all phases of clinical and translational research.
5. Apply elements of voluntary informed consent, of fostering understanding of information about clinical research, and for avoiding undue influence or coercion, and taking into consideration the decision-making capacity of participants.
6. Explain the need for privacy protection and best practices for protecting privacy throughout all phases of a study.
7. Explain the need for fairness in recruiting participants and in distributing the benefits and burdens of clinical research.
8. Explain the function of the IRB.
9. Complete an IRB application.

Thematic Areas and Competencies

IX. SCIENTIFIC COMMUNICATION

Competency

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.

Thematic Areas and Competencies

X. CULTURAL DIVERSITY

Competency

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).

Thematic Areas and Competencies

XI. TRANSLATIONAL TEAMWORK

Competency

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.

Thematic Areas and Competencies

XII. LEADERSHIP

Competency

1. Work as a leader of a multidisciplinary research team.
2. Manage a multidisciplinary team in 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.

Thematic Areas and Competencies

XIII. CROSS DISCIPLINARY TRAINING

Competency

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 emerging scholars from diverse backgrounds.

Thematic Areas and Competencies

XIV. COMMUNITY ENGAGEMENT

Competency

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.

Ongoing Activities

- Roll-out of final recommendations to the NCRR training community & leading experts
- Several programs have begun implementing the competencies and evaluating their effectiveness
- The University of Pittsburgh has begun developing core competencies for PhD candidates
- Strategic Goal #2 will begin aligning the core competencies with curriculum