The clinical research operations program: Educating clinical research staff

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OBJECTIVES/SPECIFIC AIMS: The Clinical Research Operations Program is a free educational program designed to educate clinical research personnel on the conduct of clinical research (CR). The participant completes 16 required core sessions (24h), 4 elective sessions (4h), and passes the final exam to receive a certification in CR operations at Stanford. Sessions focus on the 9 domains of CR (established by the Joint Task Force for Clinical Trial Competency), such as Ethical & Participant Safety Considerations, Clinical Study Operations, & Data Management/Informatics. METHODS/STUDY POPULATION: Sessions are taught by volunteer lecturers. Participants may also attend the sessions without pursuing the certification. The program objective is to provide easy-access education in CR in order to increase regulatory compliance, staff retention, and improve CR at Stanford. The program targets CR coordinators, however, staff, postdocs, fellows, and faculty also participate.

RESULTS/ANTICIPATED RESULTS: Since the program’s launch in January 2017, 119 individuals have enrolled in the certification program. The most represented group is the Department of Medicine. Sessions consistently reach their maximum with a waiting list. Each core session requires that the participant complete an evaluation (Likert scale, 1–5) of the registration process (4.5/5), the class environment (4.6/5), the presented content (4.5/5), and the instructor (4.6/5). Data from these evaluations are positive to date and is used to continually refine the program.

DISCUSSION/SIGNIFICANCE OF IMPACT: N/A.

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The leveling of clinical research competencies

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OBJECTIVES/SPECIFIC AIMS: Objectives/goals: Describe the process used to develop leveled competencies and associated examples. Discuss the final leveled competencies and their potential use in clinical research professional workforce initiatives.

METHODS/STUDY POPULATION: The revised JTFCTC Framework 2.0 has 51 competency statements, representing 8 domains. Each competency statement has now been refined to delineate fundamental, skilled or advanced levels of knowledge and capability. Typically, the fundamental level describes the competency for a professional that requires some coaching and oversight, but is able to understand and identify basic concepts. The advanced level of the competency reflects the professional’s solid understanding of the competency and use of the information to take action independently in most situations. The advanced level embodies high level thinking, problem solving, and the ability to guide others in the competency. The process for developing both the three levels and examples involved 5 workgroups, each chaired by a content expert and comprising of national/international clinical research experts, including representatives from research sites, professional associations, government, and industry and academic sponsors.

RESULTS/ANTICIPATED RESULTS: The committee developed 51 specific competencies arrayed across 3 levels and examples of each to demonstrate an appropriate application of the competency. The competencies and examples, and potential utilization, will be described.

DISCUSSION/SIGNIFICANCE OF IMPACT: The use of competencies in the context of workforce development and training initiatives is helping to create standards for the clinical research profession. These leveled competencies allow for an important refinement to the standards that can be used to enhance the quality and safety of the clinical research enterprise and guide workforce development.

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The need for an evidence-based CTS specific IDP for early career training and for a long-term and sustainable career in clinical translational sciences

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OBJECTIVES/SPECIFIC AIMS: To establish a conceptual framework to develop a CTS-IDP with data analytics, and an e-Learning Faculty Development Guide on