

participants. Time and funding are 2 of the most important resources, and the majority of members agree that there is no substitute for “skin in the game.” Attempts at last minute, opportunistic engagement were provided as examples of what had not worked. One ongoing tension is the balance between process and product. Individual members are beholden to organizations to different degrees, and the need to produce something in the form of publications or grant money can limit the amount of time members can commit to the collaborative. At the same time, these products are unlikely to materialize if members are not invested in the process of growing and sustaining the collective. **DISCUSSION/SIGNIFICANCE OF IMPACT:** Out of the 7 community organizations who currently participate in ADAPT, only 1 is explicitly focused on health in the traditional sense. The others are primary service organizations, but because they understand the impact of the social determinants of health on the local community—including housing, employment, education, nutrition, among other factors—the research collaborative is able to leverage the knowledge and expertise of the academic researchers and the community partners to focus on health topics most salient to the local Chinatown community.

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Collaborative translational workforce development: Standardizing clinical research nursing education in good clinical practice

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OBJECTIVES/SPECIFIC AIMS: The proposed pilot study seek to enhance the network of CTSA at Rockefeller University, NYU, ISMMS, and other community members to support translational workforce development of clinical research nurses and establish a standardized nurse-specific training curriculum in GCP for use within the CTSA network, in other research centers, and in nursing school curricula. This will be coupled with a rigorous evaluation study to test the impact of the training and a comprehensive dissemination plan to make the training available to all nurses and nursing students via modern e-learning method. **Aim 1.** To create an integrated network of local CTSA and community partners to develop, validate, and refine a pilot e-learning GCP educational and training program and content and outcomes dissemination plan. It is vital to integrate the efforts of CTSA leaders, community partners, and nursing educators to develop a pilot e-learning nurse workforce training curriculum and the associated evaluation measures and assessment plan. Delphi methods will be employed, coupled with rigorous assessment of face validity, content validity, and item reliability. The resulting educational training program will then be used for an e-learning educational intervention study in CTSA, other sites, and nursing schools. **Aim 2.** To test the effect of the pilot GCP education and evaluation program for practicing clinical research nurses (CRNs) within the collaborating CTSA and community partners, we will perform a randomized controlled trial using a Solomon 4 group design. For the student nurse population, we will develop a randomized control trial using a Solomon 4 group design blocked on course section. As this is a pilot study, descriptive statistics and confidence intervals around parameter estimates will be constructed. In addition, inferential statistics will be calculated on primary outcome of interest (change scores in knowledge of GCP) and measures of heterogeneity of data, patterns of missing data, and reliability of evaluative tools will be analyzed. **Aim 3.** To implement a dissemination plan to reach both nurses practicing the CRN specialty within CTSA and other community settings. We will disseminate the program to other CTSA through the CTSA network communication resources. To broaden the reach to a population of nurses and student nurses with limited prior education or training in nurse-specific GCP competencies, but who provide care to research participants in nontraditional research settings, we will craft a novel set of dissemination methods, including the CITI Program electronic platform that can be accessed by nurses and nursing students across settings. In addition, dissemination will be at nursing education meetings and in nursing journals. **METHODS/STUDY POPULATION:** There are several components to this pilot program. The component that includes a research strategy is the testing of the effectiveness of the training and educational interventions on GCP knowledge and efficacy. **Study cohort:** Recruitment of study subjects will be in coordination with 3 CTSA collaborators and community partners for 2 samples: (1) nurses who provide care to clinical research participants across a variety of settings (health care systems, research hospitals, and care provider networks) and who are already trained according to current standard in GCP, (2) nursing students from the collaborative network of the 3 CTSA, NYU School of Nursing has agreed to pilot test the introductory student module. The methodological approach will be a random assignment control trial Solomon 4 group design for practicing CRNs within the collaborating CTSA and community partners. For student nurse population, the methodological approach will be a randomized-control

trial Solomon 4 group design blocked on course section. Survey measures of CRN GCP knowledge and efficacy will be obtained pre and post educational intervention. **RESULTS/ANTICIPATED RESULTS:** **Aim 1.** Expected outcomes are pilot e-learning nurse workforce training modules curriculum, and evaluation measures and plan appropriate for CTSA, community sites, and nursing schools. Specifically, 14 modules (averaging 30 minutes each) for practicing CRNs, and one 45 minute module for nursing students. The significance of these findings will provide a framework for the e-learning educational intervention study. CITI Program is enthusiastic about the module development and will provide direction for consistency in formatting with current CITI Program modules, set-up of learner groups for comparison, and evaluative measures such as completion data and scoring. **Aim 2.** Expected outcomes are an effective pilot educational intervention for practicing nurses and students and valid and reliable evaluation tools and plan that can be generalized to the larger CRN and nursing community. **Aim 3.** Expected outcomes are an enhanced CTSA dissemination plan that includes non-CTSA resources and reaches non-CTSA employed nurses and nursing students. **DISCUSSION/SIGNIFICANCE OF IMPACT:** The expected outcomes of this pilot study are: (1) an enduring GCP education that can be continually updated and training structure for CRNs, and nurses and nursing students throughout the United States; (2) a reproducible effective standardized basic nurse-specific GCP curriculum for dissemination; (3) assessment tools to evaluate programmatic success, nurse and nursing student knowledge and efficacy on nurse-specific GCP; (4) and a CTSA dissemination plan that to reach non-CTSA nurses and nursing students. Our ultimate goal is the development of a translational workforce educated and competent in GCP at CTSA sites, at non-CTSA sites, and in nursing schools so as to improve the quality of clinical research.

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Competency-based training program for Research Professionals

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OBJECTIVES/SPECIFIC AIMS: To increase knowledge and application of clinical research coordinator competencies among Research Professionals at the University of Minnesota. **METHODS/STUDY POPULATION:** The UMN's CTSA developed and piloted a Foundations for Research Professionals training program comprised of: a baseline assessment, 7 online modules, 4 in-person training sessions, video and reading assignments and a post assessment, which totaled 30–35 hours of training and covered the following topics: preparing for a study, study management, participant recruitment and engagement, assessing capacity to consent and the informed consent process. This course also provides valuable resources and connections to online references and materials. The competencies for this program were based on work of the Joint Task Force for Clinical Trial Competency. **RESULTS/ANTICIPATED RESULTS:** 30 clinical research professionals completed the pilot program and averaged an increase of 6.5% from baseline assessment to post assessment. Participants were asked to rate their confidence on a variety of role-based competencies at the time of preassessments and postassessments. Trends show an increase in confidence for all competency areas after completion of the training program. **DISCUSSION/SIGNIFICANCE OF IMPACT:** Developing a workforce of competent research professionals is integral to improve the efficiency, quality, and ethics of research. The Foundations for Research Professionals training program increased knowledge of clinical research coordinator competencies. We will assess impact on application of the competencies 6 months after completion of the program. Our next steps include offering the training program as a 2-week session on an ongoing basis for new coordinators at the University of Minnesota.

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Best practices for social and behavioral research: Developing a competency-based elearning course in good clinical practice

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OBJECTIVES/SPECIFIC AIMS: Existing GCP training is geared primarily towards researchers conducting drug, device, or biologic clinical trials, and largely ignores the unique needs of researchers conducting social and behavioral clinical trials. The purpose of this project was to develop a comprehensive,

relevant, interactive, and easy to administer GCP eLearning course for social and behavioral researchers. **METHODS/STUDY POPULATION:** As part of the ECRPTQ project funded by the National Center for Advancing Translational Sciences (NCATS), a Social and Behavioral Work Group of ~30 experienced social and behavioral investigators and study coordinators was formed to develop GCP training for social and behavioral researchers. Existing GCP training programs were reviewed to identify relevant content that should be included as well as gaps specific to social and behavioral clinical trials where new content would need to be developed. In total, 9 specific modules—Introduction, Research Protocol, Roles and Responsibilities, Informed Consent Communication, Confidentiality/Privacy, Recruitment/Retention, Participant Safety/Adverse Event Reporting, Quality Control/Assurance, and Research Misconduct—were identified by the work group and the content was mapped to competency domains defined by the ECRPTQ project, as well as International Council for Harmonisation (ICH) GCP principles. Several investigators and study coordinators were identified as content experts for each module topic. Working with an instructional designer, these experts defined learning objectives and outlined content relevant for both study coordinators and investigators for inclusion in the modules. The curriculum was developed using Articulate Storyline that is SCORM 1.2 compliant making the course usable to the widest audience. The course was designed to be administered on laptop or desktop computers and is accessible for individuals with hearing or viewing impairments. To maximize learning, instructional designers used creative treatments including: narration to guide learners or offer tips; short video scenarios to introduce topics; interactive activities, such as drag and drop games and “click to learn more information”; knowledge checks with feedback; resources, including downloadable job aids; end of module quizzes, and documentation of course completion. The full curriculum takes 2–4 hours to complete, with individual modules taking 30 minutes to complete. **RESULTS/ANTICIPATED RESULTS:** Pilot testing to evaluate the effectiveness of the eLearning course is underway at 5 sites: University of Michigan, Boston University, University of Rochester, University of Florida, and SUNY Buffalo. **DISCUSSION/SIGNIFICANCE OF IMPACT:** This eLearning course provides relevant, comprehensive GCP training specifically for social and behavioral researchers. Unlike existing GCP training that is geared towards drug and device researchers, this course includes scenarios and examples that are relevant to social and behavioral researchers. The engaging, interactive nature of this course is designed to improve learning and retention, resulting in improved job performance. In addition, the modules are designed for both investigators and clinical research coordinators, thus eliminating the need for different training modules for different study team members.

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Enhancing the clinical and translational enterprise through research staff development

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OBJECTIVES/SPECIFIC AIMS: Our objectives are to provide opportunities for graduate students, clinical interns, and postdoctoral fellows in traditional training programs to have immersive experiences in clinical research conduct from a CRP perspective. In addition, we aimed to address common causes of job dissatisfaction by providing professional development and networking opportunities for the existing CRP workforce. **METHODS/STUDY POPULATION:** In collaboration with the CTSA workforce development group, the Duke Office of Clinical Research hosted a site visit for 19 PhD scientists interested in nontraditional career pathways and a short lecture series on project management careers in clinical research. Additionally, we crafted specific clinical research training electives for 20 masters students and 10 dietetic interns. Finally, in collaboration with UNC-CH, we combined Research Professional Networks to provide a pilot joint professional development event for 109 CRPs from both schools. **RESULTS/ANTICIPATED RESULTS:** The number of Masters students enrolling in the CRP elective grew from 7 students in year 1 to 13 students currently enrolled. A retro-pre/postprogram adapted CRAI survey was issued following program completion. Students self-reported increases in competence across all 24 skills measured. Largest increases were seen in areas specific to CRP roles such as consenting patients, understanding the IRB, and reviewing key study documents. A baseline culture survey issued at the joint Duke/UNC CRP event garnered a 65% response rate and indicated that the principal gaps in professional training are in communications, teamwork, leadership, and professionalism. Moreover, respondents indicated that creating a sense of community and providing networking opportunities were the most important outcomes for future CRP collaborations. Future evaluations of both of these programs will allow us to tailor training to be most effective in strengthening our CRP workforce. **DISCUSSION/SIGNIFICANCE OF IMPACT:** These initiatives lay the groundwork for the development of a robust training pipeline into CRP careers. Future initiative will apply lessons

learned toward creating internship programs aimed at improving diversity and inclusion within these careers. In addition, by addressing the professional development needs of the existing workforce, we create a sustainable environment for well-trained professionals. By evaluating these primary initiatives, we can better define the critical elements that must be included in CRP educational, development, and support programs and subsequently apply these to ultimately improve the clinical and translational research being conducted in academic research settings.

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An education program for engineering students collaborating with clinician scientists to address priority hospital patient safety problems using an ethnographic research approach

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OBJECTIVES/SPECIFIC AIMS: Enhancing Patient Safety for hospitalized patients is a priority for healthcare facilities, providers, and federal funding agencies. Multidisciplinary partnerships in clinical and translational research better defines the scope of complex patient-safety issues, and is part of more effectively developing interventions. The discipline represented by engineering-trained partners brings valuable perspective to patient safety problems through their training background in human factors and systems analysis. The objective of this education program was to create and implement a collaboration between engineering students and clinical providers. Through the Johns Hopkins Institute for Clinical and Translational Research, a multidisciplinary partnership was created, to identify contributing factors, and suggest novel solutions, to key patient safety problems using an ethnographic research approach. **METHODS/STUDY POPULATION:** The collaboration was formed between the following Johns Hopkins (JH) groups: (1) The Institute for Clinical and Translational Research (ICTR), (2) The Armstrong Institute for Patient Safety, (3) The JH Hospital Clinical Engineering Services, (4) The Homecare Group, (5) The Masters of Science in Engineering Management Program at the Whiting School of Engineering, and (6) The JH Hospital Risk Management. All 6 provided representation to contribute to the planning, structure, and implementation of the project. The initial cohort was 24 masters students enrolled in the JHU Whiting School of engineering, and included 46% men, 54% women, and 75% international students. Students were placed in teams of 2–3 to work on 9 distinct patient safety concerns, as provided by the Armstrong Institute as priority. Potential clinical hosts from the appropriate clinical departments were vetted for feasibility and scope before students were assigned to them. Students and clinical hosts were oriented to the process. The students then spent 3–6 hours a week, for 7 weeks, observing and interacting with patients and health professionals at their specific clinical sites, conducting ethnographic research under the guidance of their hosts. Ethnographic research is the systematic investigation of a culture or system; in our application, teams were looking at the environment, culture, and its contributing factors, with respect to patient safety issues. Teams made observations, then formulated hypothesis and collected data relevant to what systems factors may be contributing to the patient safety issue. Following data collection and analyses, teams made recommendations for culture and/or systems shifts that could impact change and improve patient safety. Ethnography research process training is a tenet of the training undertaken by all Masters of Science in Engineering Management Students. **RESULTS/ANTICIPATED RESULTS:** At the end of the 7-week project, each team generated a comprehensive report suggesting potential solutions for each problem, and gave presentations on their findings to their peers, clinical hosts, and JHU steering committee representatives. Requirements on the student side included a midterm, final presentation, and report. Both students and site leaders submitted mid- and final program evaluations. Based on follow-up survey data, 71% of students said that the course may impact their career choice, 57% said the collaboration changed the way they viewed themselves, and 28% elected to continue working or were planning to work with their site in some fashion after the course ended. Nearly 60% of students believed additional funding or resources would benefit the course and 71% thought they would benefit from more or similar experiences with their clinical partners. Furthermore, 85% wanted to see the course expanded. Of the clinical hosts, 71% said that students added value, 86% believed students changed their perspective on their problem, unveiled new areas of investigation, and improved or likely would improve patient safety in their department. Seventy-one percent of hosts were actively acting on the students' findings, and over 86% shared findings with their colleagues. Following the 7-week program, 2 teams also presented their findings to committees within the hospital departments, 2 patient-safety projects are being continued with engineering teams, and 2 new collaborative projects have been initiated.