

## 3017

**Regulatory Science in Translational and Regenerative Medicine Biomedical Education: A Pilot Course**

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**OBJECTIVES/SPECIFIC AIMS:** **INTRODUCTION:** Many of the innovative therapies used in regenerative medicine, such as additive manufacturing and stem cell engineering, rely on novel technologies and techniques for which standards for safety, efficacy, and quality have not been fully explored and established. As these therapies and technologies develop at a rapid pace, there is a need for the development of scientifically-based metrics to assess whether new treatments are effective and safe for clinical translation. Research and development of such standards is known as “regulatory science,” and is needed by the United States Food and Drug Administration (FDA) to support the creation of the evidence-based guidances and regulations that are used in review of product submissions. As outlined by the FDA’s description of their Centers for Excellence in Regulatory Science and Innovation (CERSIs) and the Association for Clinical and Translational Science’s (ACTS) Regulatory Science Working Group, here is a need to train investigators and clinicians to conduct regulatory science research to support successful clinical translation of regenerative treatments. **OBJECTIVE:** To develop a course to expose scholars to regulatory science concepts, to empower them to apply these concepts to their personal areas of research, and to challenge them to engage in the dialogue surrounding regulatory science on a national level. **METHODS/STUDY POPULATION:** **METHODS:** The “Introduction to Regulatory Science” course was developed jointly by the Yale-Mayo CERSI and the Mayo Clinic Center for Clinical and Translational Science (CCaTS) in 2017 as a didactic in-person survey course. The course objectives included exposing scholars to the ideas of regulatory science and affairs; reviewing the FDA’s Priority Areas for Advancing Regulatory Science; and determining what safety, quality, and efficacy concerns may need to be addressed when using new technologies, such as those used in regenerative medicine research. To meet these intended learning objectives, the course addressed one FDA Priority area each week, with a team of experts providing one-hour of lecture and discussion each class session. Regenerative medicine-related topics included a bioethics of stem cell therapy development, evaluation of additive manufacturing as an emerging technology, and the application of cGMPs to the manufacture of new therapies. Assignments and assessments included a quiz each week, which served as a knowledge check of that week’s lecture content, and a final paper analyzing regulatory concerns associated with a technology or product of the scholar’s choosing. **RESULTS/ANTICIPATED RESULTS:** **RESULTS:** The course was first delivered as an elective in 2017, with an enrollment of 8 scholars and 3 auditors. Scholars enrolled included 7 trainees and established investigators from Mayo Clinic Rochester and one from Arizona. Of the 8 scholars enrolled, 7 completed the post-course survey. Scholars strongly agreed that the “course objectives were met” (7/7) and that the “course was well worth the effort I put into it” (7/7). Five scholars stated that they learned “a lot” during the course; two said they learned “an incredible amount.” Scholars unanimously gave the course a grade of “A.” Qualitative feedback was positive, indicating that the team-taught and in-person course design choices were highlights for trainees. The course is currently in its second delivery (2018), with an enrollment of 16 scholars across Mayo Clinic Rochester, Arizona, and Florida.

**DISCUSSION/SIGNIFICANCE OF IMPACT: CONCLUSIONS:** The developed course was successfully piloted and well-received. Scholars reported that they agreed that the course aims were achieved, and indicated that they would like to see additional coursework to continue to learn how to engage in regulatory science. Next steps include utilizing course feedback to iterate on the current course, expanding course delivery to include scholars at the Yale site of the Yale-Mayo CERSI, and the creation of a second course.

## 3351

**Research training and career development in junior investigators at a multi-institutional CTSA**

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**OBJECTIVES/SPECIFIC AIMS:** The study aims to understand the characteristics of junior investigators who are supported by the CTSA, their knowledge of CTSA services and resources, as well as the perceived effectiveness of CTSA research training and career development. The primary outcome is scientific productivity that enhances career development and promotion. The secondary outcome is to inform and improve CTSA research training and career development, not only for the UCLA CTSA hub but also for the CTSA Program nationally. **METHODS/STUDY POPULATION:** The study sample includes post-doctoral and junior investigators who have received UCLA CTSA support between 2011 and 2017 (n=319). These junior investigators conduct research at our four partner sites (UCLA-Westwood, Cedars-Sinai Medical Center, The Los Angeles Biomedical Research Institute at Harbor-UCLA Medical Center, Charles R. Drew University of Medicine and Science). The CTSA administered the LSAS and the Career Development module in 2018 using Qualtrics, a subscription software for collecting and analyzing survey data. In order to reduce the burden on the survey respondents, the survey team pre-populated their previously reported publication in the Qualtrics survey system. Qualtrics sends customized email invitations containing a link to start the LSAS survey and subsequently automated sequences of reminder messages for non-responders and partial completers. The survey team initiated telephone call-backs and engaged partner site leaders to achieve a high response rate. **RESULTS/ANTICIPATED RESULTS:** Preliminary results show a response rate of 83% (n=264). Respondents include K-to-R workshop participants (n=192), core voucher co-investigators (n=38), Training Program in Translational Science (TPTS) trainees (n=82), and junior investigators who participated in two or more of these activities (n=48). Trainee characteristics include degree, gender, and partner site location. The distribution of advanced degrees among the junior investigators include: PhD (29%), MD (55%), MD/PhD (13%), or other degree (3%). Forty-four percent (44%) respondents are male and 56% are female. Seventy-two percent (72%) have a primary appointment at UCLA-Westwood, while 28% have academic appointments at the partner institutions. Twenty-five percent (25%) received CTSA research training and 49% received CTSA career development support. Regarding scientific productivity, 58% reported having at least one peer-reviewed publication and 29% reported subsequent grant funding. **DISCUSSION/SIGNIFICANCE OF IMPACT:** We are in the process of identifying the predictors of scientific productivity and the characteristics of the junior investigators most significantly correlated with productivity using multiple logistic regression analysis. We will analyze qualitative responses to examine the facilitators

and barriers to conducting research at the CTSI and explore ways to improve administrative and clinical research processes. The significance of this research is to inform research training and career development programs within our CTSA hub and the CTSA Program nationally.

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### **Stressful experiences and adherence to HIV care among Black Women Living with HIV: A qualitative analysis**

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**OBJECTIVES/SPECIFIC AIMS:** Our primary objective was to understand the relationship between incident or recent stressful events and adherence to HIV care in the context of other person, environment, and HIV-specific stressors in a sample of Black women living with HIV (WLWH). **METHODS/STUDY POPULATION:** Thirty in-depth interviews were conducted with Black women living with HIV who receive care at an academic HIV primary care clinic in the Southern region of the United States to elicit stressful events influencing adherence to HIV care. Semi-structured interview guides were used to facilitate discussion regarding stressful events and adherence to HIV care. Interviews were audiotaped and transcribed verbatim. Transcripts were independently coded using a theme-based approach by two experienced coders, findings were compared, and discrepancies were resolved by discussion. **RESULTS/ANTICIPATED RESULTS:** Participants described frequently experiencing incident stressful events including death or serious illness of a close friend or family member, and relationship, financial, and employment difficulties. Furthermore, participants reported experiencing traumatic events such as sexual and physical abuse during childhood and adolescents. While experiencing traumatic events such as sexual and physical abuse during childhood and adolescence may be distressing, these events did not influence adherence to HIV care. However, incident stressful events as defined above did influence adherence to HIV care for some participants, but not for others. For participants who reported that stressful events did not influence adherence to HIV care, factors such as personal motivation, access to social support, and adaptive coping strategies facilitated their engagement in care. **DISCUSSION/SIGNIFICANCE OF IMPACT:** Experiencing stressful events, incident or traumatic, is common among Black WLWH and have the potential to negatively influence adherence to HIV care. Thus, Interventions aimed at identifying and addressing stress, social support, and coping are essential to improve adherence to HIV care behaviors.

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### **Student Leadership Training effects on team dynamics and collaborative work in high-pressure, interprofessional team environments**

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**OBJECTIVES/SPECIFIC AIMS:** We aimed to explore the impact of leadership training on student's abilities to work in interprofessional research teams successfully. The Translational Research Design and Interprofessional Skills Development Course (shortened,

Interprofessional Research Design) brings together students from different disciplines (science & medicine) and education tracks (PhD, MD, MD/PhD training) in a seven-week course to learn interprofessional collaborative skills and leadership styles that support success in translational research environments, while undertaking a research grant writing project. Part of the course involves a two-day leadership training workshop (12 hours) with the goal of understanding leadership styles and how to develop productive working relationships with team members to help students work more effectively in high-performance, interprofessional team environments. The course incorporates personality testing to develop self-awareness, with various exercises meant to build empathy, as well as knowledge of project management and effective leadership. **METHODS/STUDY POPULATION:** Nine teams of 32 students (23 MD; 9 Ph.D.) who took part in the Interprofessional Research Design course in 2017 and 2018 were required to write a reflective essay at the end of the course. We used an inductive thematic analysis to evaluate the essays. Reflective essays were coded openly by one study member. Codes were rationalized; then codes were collaboratively developed into themes by the study authors. We identified issues of integration between student groups that functioned well together and those that did not. Reflective writing responses were grouped into overall positive experiences and negative experiences. **RESULTS/ANTICIPATED RESULTS:** Seven of the nine teams collectively described their experiences positively. Themes related to positive team experience were "empathizing with group members", "sophisticated communication" and "collaborative workflow/styles." We found that those who had a positive experience utilized knowledge and skills learned during leadership training to better understand and communicate with their teammates leading to a more collaborative and dynamic workflow. These groups had higher degrees of communication both between their task assignments and within task completion periods. They also showed more awareness of others' needs in work and communication styles. For those that had a negative experience, themes were related to "basic communication", "poor integration" and "theory-practice gap of leadership training." Those who struggled showed much less in- and between-task communication and showed an inability to address the personal needs of other members in communication and workflow (while still often being able to identify them). **DISCUSSION/SIGNIFICANCE OF IMPACT:** These findings demonstrate the usefulness of leadership training that facilitates student self-awareness and empathy, as well as effective communication, leading to collaborative high-functioning interprofessional teams. Further work incorporating conflict management and exercises to overcome the theory/practice gap of leadership and teamwork training are recommended.

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### **The OHSU Physician-Scientist Experience: Integrating intensive translational research training for medical students into a competency-based educational framework**

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**OBJECTIVES/SPECIFIC AIMS:** The aim of this program is to provide early support to motivated medical students interested in a career as a physician-scientist in a framework of competency-based medical education. The CTSA creates an opportunity to provide clinical research education and protected time for research for medical students in clinical and translational research. **METHODS/**