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Implementation of a Translational Science Research Center in a high education level institution in Colombia - Latin America: Unisabana Center for Translational Science (UCTS)

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OBJECTIVES/GOALS: To establish and develop a high-level, dynamic, and self-sustainable Translational Science – research center in Colombia that promotes and articulates collaborative participation among different disciplines at Universidad de La Sabana to generate impactful solutions in health to transfer the knowledge to the local community. METHODS/STUDY POPULATION: With the support of core units of the University, internal funding was given for the establishment of the Research Center. An internal call was performed for recruiting researchers for multiple disciplines interested in joining the UCTS. After the researchers were selected, training of the research community in translational science and funding acquisition was performed towards the objective of interdisciplinary projects with impact in the local community. Project management strategies have been used for the follow-up of the advancements of the implementation of the UCTS. Operational structure and business plan for future self-sustainability are being designed. UCTS is proposed as an articulating party among different actors in clinics, research, and industry, for science and funding management. RESULTS/ANTICIPATED RESULTS: As an starting point, 8 research groups of different disciplines of the University have been integrated with the UCTS, increasing the research capacity in translational science. Internal administrative processes have been articulated within the institution and unified processes for international grants applications have been established in order to optimize the funding acquisition and management. Training programs for the research community, and community engagement activities have been offered as well. Networking relationships have been strengthened among the researchers enhancing international collaborations. Novel research projects are being designed towards real solutions in health for the local community, promoting the transference of knowledge from the benchside to the community. DISCUSSION/SIGNIFICANCE: The implementation of the UCTS led to the integration of disciplines within the University, towards new research projects with common interests for the local community. It has been an enriched experience using the project management approach, fulfilling a huge milestone for the University, aligned with the internal strategic priorities

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Alternative Clinical Trials Staffing Models for Improved Efficiency, Retention, and Profitability

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OBJECTIVES/GOALS: High turnover rates of clinical trials staff pose obstacles to the quality and efficiency of conducting clinical trials. We have explored alternative staffing models to address these translational barriers and to improve the financial viability and return on investment of a centralized clinical trials office. METHODS/STUDY POPULATION: Implementation of an alternative clinical trials staffing model that leveraged burnout rates in clinical service areas by hiring APPs, RNs, EMTs, OTs and PTs in tandem with traditional CRAs/CRCs. Financial modelling of employing higher salaried clinical professionals was analyzed with regards to greater staff retention, trials efficiency, and operational cost savings. RESULTS/ANTICIPATED RESULTS: Since 2014, 30 of 51 (59%) staff left the clinical trials office with 49% of these leaving prior to 2 years employment. Using average local CRCII compensation values, the costs associated with these transient staff amounted to $2.51 million (i.e., recruitment, replacement, and training). Models of staffing that replace 2 CRAs, 2 CRCIs and 2 CRCIIs with an RN, APP, CRCI and 3 CRAs increases compensation by 24.1%. This increase, however, is offset by greater workload capacity, retention, and more efficient trials operations. In addition, revenue generating PI clinical activity is sustained by employing credentialed APPs for study visits. DISCUSSION/SIGNIFICANCE: Long-term financial savings and greater clinical trial operational efficiency may be accomplished by seeking clinical professionals looking for alternative opportunities with greater work-life balance while leveraging their advanced clinical skills and licensing.

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The Development of New Institutional Policies on Mitigating Unacceptable Behavior and Managing Disruptive Research Participants

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OBJECTIVES/GOALS: In a 2022 NASEM Report, "... successful inclusion of underrepresented populations in research is investing in diverse research teams to enhance congruence and to optimize recruitment and retention success." Thus, academic research institutions must provide safe, respectful and inclusive work environments to support diverse research teams. METHODS/STUDY POPULATION: Resources, policies and protocols related to disruptive research participants have not been well articulated at our institution. Given this dearth of information, we launched a new initiative across our CTSA, IRB, Office of General Counsel and Department of Population Health. The multipronged approach includes: 1) Conduct a scoping review of published and gray literature to identify best practices, trainings and resources to mitigate discrimination, harassment of research team members; 2) Co-develop new institutional policies and procedures to ensure safety and respect for both research staff and participants; 3) Develop an online training on research team field and workplace safety; and 4) Widely disseminate policies and resources to address the overall gap in academic research. RESULTS/ANTICIPATED RESULTS: Our ongoing scoping review has shown that here is an overall lack of information on bias, discrimination and harassment perpetrated by research participants towards research teams. Based on our activities, new Human Research Protection policies were launched. These include defining what disruptive participant behavior in research is, the introduction of a Statement on the Conduct of Participants in Research Studies, and steps study teams may implement to manage disruptive behavior initiated by a research participate. Next steps include the development of training resources for study teams on the new policies and to introduce de-escalation

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and situational awareness strategies and trainings. DISCUSSION/SIGNIFICANCE: As research teams become increasingly diverse, there is a need to better support them and ensure that the research field and work settings are safe, inclusive environments with articulated policies that mitigate/prevent discrimination, bias and harassment perpetrated by study participants.

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Improving Clinical Trial Activation Timelines through Parallel Processing and Key Stakeholder Involvement

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OBJECTIVES/GOALS: A strategic initiative of Mayo Clinic is to decrease clinical trial activation timelines by 25% from 2022 levels. The team's goal is to streamline activation via parallel processing, improved collaboration with business units, project manager facilitation, and early study coordinator involvement. METHODS/STUDY POPULATION: The workgroup targeted industry trials, focusing on key financial, regulatory, and operational elements. Current state process workflows and pain points were prepared and opportunities for concurrent activities or automation identified. The scope of the project manager role from the Office of Clinical Trials was extended to guide each activation team, who have varying levels of experience, to maintain timelines until the trial is opened. Coordinators responsible for study conduct engaged in key operational discussions earlier to ensure the trial will be run successfully. A Pilot program is utilizing the identified concurrent activities, project manager support, and earlier coordinator involvement to gauge effectiveness of the proposed solutions. RESULTS/ANTICIPATED RESULTS: The goal is for 120 industry clinical trials to join the Pilot program and to open enrollment in less than 30 weeks from being document ready. As of Q3 2023, 109 clinical trials across multiple Mayo sites have enrolled in the pilot. Thirty-five (85 percent) of 41 Pilot trials have opened to enrollment and have met the goal, with a median timeline of 24 weeks. Twenty-one (21) trials opened to enrollment in Q3 2023 with a median timeline of 23 weeks, representing 24% of all industry clinical trials opened that quarter. Opening trials and monitoring is ongoing and PI and study team feedback is positive. DISCUSSION/SIGNIFICANCE: Using a team-based approach, we identified key areas for optimization and parallel processing. The solution reduces trial activation timelines, increases patient access to experimental therapies, and has been positively received by study staff. Future projects will focus on enterprise implementation, optimization, and automation.

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Strategic Reinvestment of Sponsored Trials Residuals for Research Portfolio Development

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OBJECTIVES/GOALS: Academic research is often viewed as a necessary core mission but a financial loss requiring central or clinical funds support. We present cases as evidence of sustaining academic unit research endeavors through strategic planning and reinvestment of sponsored clinical trials residuals. METHODS/STUDY POPULATION: Successful endeavors are presented that demonstrate strategic reinvestment of clinical trials residuals to develop robust academic self-sustaining research programs. A multi-year strategic plan was developed leveraging residuals from sponsored clinical trials to build an academic research infrastructure supporting extramural grant applications, pilot studies, pre- and post-award management, equipment investment, and faculty incentives. RESULTS/ANTICIPATED RESULTS: Example 1, pooling four existing department clinical trials generated yearly profits that expanded clinical trials capacity and used residuals to support a grant coordinator. Over 7 years, trial volume increased to near 50, revenue increased to $2.5 million annually, staffing increased to 20 FTEs, and extramural grant applications increased from 16 to 50. Example 2 started with a department with no infrastructure. Central support was leveraged for 6-months to support a coordinator to initiate a clinical trials program. The initial investment was offset by trials earnings by year 2, breaking even financially, while establishing a nascent yet robust infrastructure to build autonomously without additional central funding requests. DISCUSSION/SIGNIFICANCE: Utilizing sponsored clinical trials as a strategic investment fund, academic units can realize fiscally responsible expansion of research activities and national recognition through acquisition of extramural funding and investigator-initiated investigations.

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Johns Hopkins Institute for Clinical and Translational Research (ICTR) - Research Personnel Onboarding Program

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OBJECTIVES/GOALS: In Sep 2022, Johns Hopkins Research Coordinator Support Service launched Research Personnel Onboarding Program. The program on board in experienced individuals in 6-8 weeks, tailoring training plans to Investigator and study needs. It also offers Ongoing Support to enhance sustainability and adaptability. METHODS/STUDY POPULATION: * Assess Principal Investigator (PI)'s need Evaluate study's need Understand trainee's background Develop a personalized training plan (~6-8 weeks) Weekly updates Ongoing mentorship Research staff spend 200+ training hours, depending on their need. Training encompasses various modalities: Interactive 1:1 onboarding sessions, Online, and Instructor-led trainings and sessions cover a wide range of topics, including: * Mandatory JHU/Institutional Review Board trainings * Good Clinical Practice * Regulatory submissions * Screening/Consenting * Monitoring/Auditing * Visit conduct * Clinical skills * Soft Skills Figure 1. Chart shows cumulative onboarding hours that focus on "How" to do tasks Figure 2. Chart shows cumulative training hours that focus on regulations, ethics and "Why" for tasks RESULTS/ANTICIPATED RESULTS: * The program contributed nearly 4000 hrs. of research staff training in the past 1 year * The program received 26 requests from investigators; 14 Completed the onboarding program, 1 Active, 5 Projected (Future start date), and 6 Cancelled (HR issues, lack of fund, or hired a trained staff) * 22 requests opted in the "Ongoing Support" * Ongoing Support, is averaged at 1 hr./month for the first 3-6 months. This indicates program success in empowering independent task performance * Developing REDCap request had significantly reduced meetings and paperwork * Web-Based Clockify invoicing has drastically reduced monthly manually invoicing processing time DISCUSSION/SIGNIFICANCE: * Grow the next generation of clinical research professionals * Centralize and standardize expert onboarding throughout the University

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