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A Library-CTSI Collaboration to Support Researcher Compliance with the 2023 NIH Policy for Data Management and Sharing

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OBJECTIVES/GOALS: Seeking ways to support teams in the preparation for and the implementation of the new National Institutes of Health (NIH) Policy for Data Management and Sharing (DMSP), the integrated Translational Health Research Institute of Virginia (iTHRIV) partnered with the UVA Health Sciences Library to develop training and resources for researchers. METHODS/STUDY POPULATION: Health sciences librarians and iTHRIV (an NIH-NCATS supported Clinical Translational Research Institute) convened a Working Group, inviting representatives from central and unit-specific research support offices (e.g. the Comprehensive Cancer Center), research compliance, regulatory affairs, sponsored programs, institutional review boards, libraries, and data science to review and discuss the DMSP requirements. After an initial orientation to the policy, the group reviewed existing public resources and solicited feedback about steps to best support UVA researchers in compliance. Leveraging the broad expertise of the group, the team provides guidance to researchers on writing the DMS plan and choosing a data repository, and provides tools and templates to support implementation of the policy. RESULTS/ANTICIPATED RESULTS: A library-created website provided policy guidance, including links to NIH-hosted information, resources created by other institutions, and new UVA-specific templates and suggested proposal language. Librarians led a webinar on the new policy and UVA resources which included a speaker from UVA regulatory affairs to describe the new DMSP requirements, and a tour of the new guide. The guide has been viewed over 5000 times to date and librarians have provided consultations and training to individuals and departments. Current plans include developing a user satisfaction survey, reviewing DMSP feedback from submitted proposals, and incorporating lessons learned into the website and future training. DISCUSSION/SIGNIFICANCE: The collaboration between iTHRIV and the Health Sciences Library to support the NIH Data Management and Sharing Policy was a successful partnership that provided leadership at the institutional level to communicate with and engage researchers and utilized the library's web presence, expertise, and service model to provide direct support.

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Administrative Simplification of Committee Reviews through REDCap

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OBJECTIVES/GOALS: A Mayo Clinic in Florida committee completes 100+ Scientific Reviews annually through manual e-mail and Excel tracking, placing a manual burden on reviewers and coordinators. REDCap, an electronic data capture system, was leveraged to reduce the administrative burden.#_ftn1 #_ftnref2 METHODS/STUDY POPULATION: Historically, emails were sent by a coordinator to physicians, requesting their initial review and following up with reminders. This process was tracked using Excel, presenting a need to make this process more efficient, so a workgroup was created. To ensure all perspectives were accounted for, the workgroup included the review coordinator, a physician reviewer, and study team members who submit development requests for studies. The process was mapped using the existing Excel spreadsheet, and email templates. Critical data elements were identified, ensuring the database would identify bottlenecks. Two REDCap instruments were then created: one to outline the coordinator workflow and a survey for physician reviewers to complete the scientific reviews. #_ftn2#_ftnref1 RESULTS/ANTICIPATED RESULTS: The workflow is live in REDCap and has effectively processed over 100 scientific reviews in <1 year. The system captures the review status and guides the coordinator through the workflow, capturing dates when tasks are completed. When review criteria are met, the database sends an email to the assigned reviewer. The email includes a link to a REDCap survey, containing all pertinent documents. The reviewer uploads their completed review form within the survey, if this is not completed within a given period, the database sends email reminders. Once the review is complete, a notification is sent to the review coordinator. The review workflow is accessible to the study team who requested scientific review, making them aware of their request status ad giving them access to the review the moment it is completed. DISCUSSION/SIGNIFICANCE: Leveraging REDCap has increased visibility, reduced overall manual processes, and simplified the reviewer burden by providing all the information needed in a single notification. REDCap is a cost-effective, impactful solution to simplifying administrative burden in managing committee reviews.

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Best Practices for Conducting Exit Interviews for Clinical Research Staff at Academic Medical Centers

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OBJECTIVES/GOALS: Identify causes for clinical research professional turnover Define data collection methods for exit interviews Provide institutions with resources to collect and analyze exit interviews Employ strategies to maximize the impact of exit interviews on retention METHODS/STUDY POPULATION: The Clinical Research Professional Taskforce (CRPT) exit interview Subgroup has met monthly since January 2023. Action items were agreed to and minutes were kept and reviewed at subsequent virtual working meetings. All members were given opportunity to speak and contribute. After a landscape analysis, conducted via survey, five institutions agreed to provide examples of their exit interview questions. Members spoke at length about goals, methods, collection techniques, institutional involvement, lessons learned and practical applications that could become best practices. RESULTS/ANTICIPATED RESULTS: The Subgroup aggregated all questions into categories and developed sample questions incorporating all data without using any word for word. In order to allow for quantitative assessment and standardized reporting the Subgroup formulated questions to be responded to utilizing a Likert scale with free text fields for select questions where further information is needed. The Subgroup developed best practices describing decision-making metrics, understanding reasons for turnover and reporting data back to leadership. Practical aspects such as method and time of survey collection, anonymity, and training staff are also included. DISCUSSION/SIGNIFICANCE: We are hopeful that sample questions and best practices will be helpful and widely utilized.

https://doi.org/10.1017/cts.2024.449 Published online by Cambridge University Press

Understanding the causes and impacts of CRP turnover are critical to meeting the current needs of clinical research. Further work is being done to calculate the cost of turnover to make the business case.

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Midwest Translational Science (MTS): Building a regional CTSA community

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OBJECTIVES/GOALS: Our vision is to build community amongst the Midwest CTSAs, harnessing our collective expertise to collaborate on translational science challenges and meet the needs of our region. We aim to create opportunities to network, share ideas, brainstorm solutions, address translational science topics, and achieve a range of deliverables. METHODS/STUDY POPULATION: Three individuals from the Chicago CTSAs (NUCATs, CCTS, and ITM) had been networking for a year and desired to increase opportunities to collaborate amongst other CTSAs. We developed an initial vision for a new group that would extend across the region, and we invited the TIN POCs from 16 Midwest CTSAs to join. In September, 2022, the group was launched with 20 members from 12 CTSAs. We hosted 12 monthly meetings via Zoom to discuss various topics (i.e., staffing, career training, e-consent, research design, and recruitment tools) via round tables or presentations. We developed a Google Sites website with resources, a discussion forum, and a group calendar. We solicited feedback via survey and follow-up discussion (i.e., most valuable about the group and what can be improved). RESULTS/ANTICIPATED RESULTS: During the past year, our membership grew to more than 30 participants, representing 16 CTSAs in nine Midwest states (IL, IA, IN, MI, MN, MO, KT, OH, WI). We engaged a total of 45 individuals at our meetings, with an average of 11 participants per meeting. Our discussions were lively and stimulated additional conversations, requests for guidance, sharing resources, etc., beyond the meetings. Feedback from the group was overwhelmingly positive. Members found many aspects of the group to be valuable (i.e., learning initiatives, processes, and best practices at other CTSAs) and provided practical suggestions for improvement (i.e., themes across a quarter or year). Members expressed interest in additional collaborations such as subcommittees, papers, and other initiatives. DISCUSSION/SIGNIFICANCE: We created a regional CTSA community that is very enthusiastic to convene, share innovations developed at their CTSA hubs, and assist one other. Future directions include an in-person retreat in the spring. Our approach can serve as a potential roadmap for developing regional CTSA collaborative groups across the nation.

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Implementation of a Clinical Research Feasibility Program at an Academic Medical Center

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OBJECTIVES/GOALS: The objectives are 1) to describe the creation and implementation of a Clinical Research Feasibility Program at the University of Miami Miller School of Medicine (UMMSOM), and 2) to share early findings demonstrating its effectiveness in improving research operations which may be helpful for other academic medical centers. METHODS/STUDY POPULATION: Many clinical trials are closed prematurely because of low accrual or not being able to meet the target enrollment. The Miami CTSI and UMMSOM Executive Dean for Research office collaborated to establish the Research Feasibility Committee (RFC) focusing on clinical trial selection with upfront feasibility and recruitment planning. Program implementation included: 1) selecting faculty with successful clinical trial track records as committee members; 2) developing processes, tools, and governance; 3) feasibility pilot testing; and 4) feasibility program roll out and refinement. The feasibility review process starts with the PI/Designee completing a REDCap study intake form, followed by an administrative review to ensure completeness of the form. The RFC chair assigns reviewers for the studies. RESULTS/ANTICIPATED RESULTS: The RFC went live on September 1, 2022 reviewing industry sponsor clinical research studies. The RFC conducts a systematic feasibility assessment of the study protocol, operational requirements, enrollment barriers, institutional resources, and study budget (if available) for all applicable research studies prior to IRB submission and contract negotiation at the UMMSOM. To date, the RFC has received over 270 submissions. Based on feedback from users, the committee has made changes to improve the comprehension of questions and added questions to ensure capturing of critical information to assess study feasibility. Initial metrics suggest simply implementing the review process has decreased the number of clinical trial submissions: average number of studies per quarter was 41 pre-RFC vs 24 post RFC. DISCUSSION/SIGNIFICANCE: The development and implementation of the RFC involved many stakeholders from the research enterprise. Clear and frequent communication to the research community was a key factor in the program's success. The next phase is assessing the impact of the RFC, such as preserving vital resources for trials more likely to be successful.

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Understanding Strengths and Weaknesses of Clinical Research Operations in Regional Settings

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OBJECTIVES/GOALS: An environmental scansoughtto understand research processes, areas for improvement, and opportunities for collaborative quality improvement (QI)across the Northwest Participant and Clinical Interactions Network (NW PCI). METHODS/STUDY POPULATION: NW PCI site champions were invited for semi-structured single and group Zoom-based interviews. Interviewers asked participants about local research processes, strengths and weaknesses, existing infrastructure to support QI, and interest in collaborative QI across the Network. Audio transcripts were coded using Dedoose and analyzed with deductive

https://doi.org/10.1017/cts.2024.449 Published online by Cambridge University Press