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

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and inductive coding. RESULTS/ANTICIPATED RESULTS: Between February and April 2023, 10 interviews collected data from 7 research decision makers and 7 staff members across 7 sites. Most participants (n=13, 92%) agreed the diagram shown during the interview was representative of the local process. Organizations consistently identified strengths and weaknesses within the domains of study start-up, recruitment, budgets, and compliance. QI infrastructure was inconsistent (n=5, 36%) and all (n=14, 100%) saw potential for success in multisite QI initiatives to enhance efficiency. DISCUSSION/SIGNIFICANCE: NW PCI sites use similar processes, share common strengths and weaknesses, and universally reported interest in collaborating on QI. Study startup was reported as both a strength and weakness within the same organization, requiring unpacking of key elements before pursuing QI initiatives.

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Transforming a Pilot Grant Program to Advance Clinical & Translational Science

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OBJECTIVES/GOALS: A new mandate for Clinical & Translational Science Award (CTSA) Programs is for pilot grant funding to support clinical and translational science (CTS) projects that study challenges in the translational research pipeline. This pivot requires new structures and supports to help investigators design and implement high-quality CTS projects. METHODS/STUDY POPULATION: The Michigan Institute for Clinical & Health Research (MICHR) at the University of Michigan (U-M) has launched two rounds of pilot funding since March 2023. Faculty and staff across U-M's three campuses, community members, and those at collaborating institutions and hospitals were eligible to apply. New pre-award supports included a CTS project framework; a recorded webinar that educated about CTS and the funding opportunity; office hours to provide tailored project feedback; a letter of intent to screen for alignment with CTS; and reviewer training for academic and community reviewers. Funded projects operate like 'mini cooperative agreements", with MICHR experts partnering with awardees to refine evaluation plans, prepare work products, advise on dissemination, and navigate emergent challenges. RESULTS/ANTICIPATED RESULTS: The first round of funding was launched in the absence of pre-award supports; ten applications we received from faculty proposing translational research rather than CTS. We quickly re-released the FOA, expanding eligibility to staff. We received nine applications, ultimately funding four staff and one faculty studying operational challenges in translation and helping them create robust evaluation plans. We piloted the pre-award supports in our second round, with 40 individuals viewing our webinar and 11 attending office hours. Those who watched the webinar before attending office hours better understood how to embed CTS questions within their programs of research. We recently received 19 letters of intent, addressing both operational and scientific challenges, with 16 eligible to submit applications. DISCUSSION/SIGNIFICANCE: Education and personalized feedback seem to elicit a higher yield of CTS projects. Staff are already adept at solving operational challenges, so the pre-award supports were most critical for faculty accustomed to writing traditional translational research proposals. Staff have most benefited from guidance in evaluation and dissemination.

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Application of the CTME Maturity Model in a CTSA Hub: An Initiative to Improve Clinical Research Operations

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OBJECTIVES/GOALS: The CTSA consortium's Informatics Enterprise Committee has developed a maturity assessment model for Clinical Trial Management Ecosystems (CTME). This poster will show the improvements achieved using this model at the University of Iowa as well as guidance on how to apply it at other CTSA hubs. METHODS/STUDY POPULATION: The CTME maturity model consists of 11 categories including, study management; regulatory; financial; and reporting. Each category has 3 subcategories: standardization; complexity; and monitoring, while each subcategory is comprised of 1 to 5 maturity statements: initial; developing; aspiring; capable; and efficient. The maturity assessment team at Iowa—comprised of key personnel from clinical research and compliance, accounting, and administration—have used the CTME maturity model to assess Iowa's research performance across the 11 categories. The initial maturity ratings for each category revealed any gaps in research operations, which led to developing strategies to address the gaps. RESULTS/ANTICIPATED RESULTS: The assessment team initiated a CTME maturity planning project—holding regular meetings to review Iowa's CTME research maturity and plan changes to improve our CTME maturity ratings. This analysis is done at the statement level to minimize the scope of actions needed and keep resource loads for improvements low. Proposed improvements are assigned to a team member who serves as an "accountability leader." Such leaders develop action plans aimed at increasing maturity at least one level. The leaders are responsible for acquiring the resources to carry out the plan. Each action plan identifies qualifiers reviewed by the team to confirm that the maturity level has been met. DISCUSSION/SIGNIFICANCE: The CTME maturity model has been shown to be effective in identifying gaps in organizational operations at the University of Iowa, where it has led to incremental steps to improve clinical research operations. The utilization of the model at other CTSA hubs will be discussed at this session.

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Student Undergrad Researchers' Race, Ethnicity, And Language in a Student-Run Free Clinic (SURREAL)

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OBJECTIVES/GOALS: Our primary objective is to determine the demographic and linguistic characteristics of student research assistants (SRAs) in a large student-run free clinic associated with a mid-western university. Our secondary objective was to determine if the SRAs perceived any impact of those characteristics on their duties and ability to conduct research. METHODS/STUDY POPULATION: We plan to conduct a 15-question electronic survey of Student Research Assistants at the student run free clinic. There

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