

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

are a variety of projects that require varying levels of commitment from researchers, which will be aggregated. This survey has been modified from a previously validated survey that focused on the demographic and linguistic characteristics of pediatric research coordinators. This survey will be emailed out to student research assistants and will be done over a period of 3 months. The study population will be predominantly undergraduate students who are all interested in a career in healthcare, ages expected to range from 18-25. RESULTS/ANTICIPATED RESULTS: We anticipate that the majority of student research assistants will be older students and will be students who identify as non-white/caucasian, as the majority of students volunteering at this free clinic do not identify as white. Additionally, we anticipate that students will feel that their racial/ethnic identity will positively impact their recruitment efforts. We also anticipate that the ability of a student research assistant to speak another language is expected to positively affect their perceived recruitment efforts. We also anticipate that gender will influence the student researchers' perceptions of their recruitment efforts. DISCUSSION/SIGNIFICANCE: An individual's background can directly impact how they perceive their contributions towards research. Considering the paucity in research for underinsured and uninsured and the rise in undergraduate student research assistants, optimizing research efforts and SRA confidence is essential to increase the accuracy and efficiency of research.

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#### **Forming a Translational Operations Group: Bridging the Gap to Enhance CTSA Hub Operational Efficiencies**

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OBJECTIVES/GOALS: CTSA Hubs represent complex centers where teams work to meet multiple goals of the CTSA grant. An existing challenge is to work collaboratively across teams. To address this challenge, a Translational Operations Group (TOG) was established. Results show enhanced intra-hub collaboration and communication while reducing inefficiencies. METHODS/STUDY POPULATION: The TOG is composed of all CTSA hub module program managers who are charged with operationalizing vision into reality. The TOG was formed in 2021 as a mechanism to integrate new team members, provide connection, and improve cross-core awareness and collaboration. Leveraging team science principles, a team charter was developed outlining specific TOG aims and objectives. Collectively, shared goals were identified with establishment of group norms, effective communication pathways, shared resources and knowledge and meeting cadence. Leadership of the group rotates among the TOG members annually further engaging all TOG members. Pre and Post (one year) surveys were developed and provided to TOG members to gauge TOG effectiveness and perceptions of TOG members. RESULTS/ANTICIPATED RESULTS: Survey results demonstrate the effectiveness of the TOG concept in promoting core/module awareness and goals, intra-core/module interconnectedness, and forming connections and integration into the CTSA hub ecosystem. Psycho-social questions demonstrated an increase in organizational self-esteem within the pre to post survey period in

relation to the specific TOG member's core/module and the CTSA hub as a whole. DISCUSSION/SIGNIFICANCE: Formation of a TOG has been successful within a virtual environment where connection is challenging. Integration of members to the operational activities is critical to foster a positive work environment, reduce silo effects, and provide a space for sharing resources and knowledge. Annual reflection of priorities contribute to the ongoing success.

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#### **Translational science vs. translational research in CTSA pilot projects: characteristics and perceptions**

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OBJECTIVES/GOALS: NCATS requires that CTSA-funded pilot projects focus on translational science (TS) and evaluate the translational process. However, a consistent understanding of TS remains elusive. This gap is being addressed by a consortium of 12 CTSA hubs aimed at identifying distinctive features of TS and translational research (TR) proposals. METHODS/STUDY POPULATION: CTSA External Review Exchange Consortium (CEREC) is a reciprocal review collaboration among CTSA hubs. Reviewers were CEREC members from hubs that submitted CTSA applications (PAR-21-293); read the Notice of Funding Opportunity (NOFO) Clinical and Translational Science Pilot Module; and discussed TS with their hubs "a fair amount" or "quite a bit" and then they independently categorized proposals. Proposals were labeled TS or TR if reviewers reached a consensus on category assignment; without consensus, proposals were labeled unclassified. In addition to category assignment, reviewers commented about their classifications. R was used to evaluate the comments and create word clouds with phrases/themes that distinguished between the categories of proposals. RESULTS/ANTICIPATED RESULTS: Twelve CEREC participating hubs submitted 26 proposals, which were funded prior to the new NCATS TS requirements. Eight reviewers from distinct CEREC hubs evaluated and classified each proposal as TS or TR. Consensus (at least 87% agreement) was reached for 12 proposals, 6 TS and 6 TR. Reviewers provided comments describing the rationale for their classifications for 70% of the proposals. Qualitative analysis of the reviewers' comments and rationale by classification (TS, TR, or unclassified) revealed common themes within and differences between groups and shed light on what defines TS and TR. The most frequent themes that distinguished TS from TR were generalizability across multiple diseases and a focus on increasing research efficiency. DISCUSSION/SIGNIFICANCE: NIH is focused on research that meets the new definition of TS. Investigators seeking to address this funding priority should explicitly state the relevance of their research to multiple diseases and to the acceleration of future research. Programs seeking to attract TS projects should instruct applicants to include this information.