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Evaluation and structure of the pilot funding program at the University of North Carolina CTSA Hub (NC TraCS)

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OBJECTIVES/GOALS: The goals of this evaluation were 1) to describe the pilot grant application cycle and processes at NC TraCS, 2) to illustrate the impact of pilot grants on extramural grant funding, and 3) to provide a framework for other institutions to utilize for the evaluation of pilot grant programs. **METHODS/STUDY POPULATION:** From 2009-2019 the NC TraCS pilot program funded 925 projects, varying from \$2,000 to \$100,000. Pilot grants are available to any researcher affiliated with the university as well as partner institutions and community stakeholders. For this evaluation we analyzed data on pilot applicants (demographics, type of pilot, funding status, resubmissions, etc.) and outcomes (extramural funding, publications, etc.) yielded from funded pilots. In addition to summary statistics, we also calculated return on investment (ROI) for the program as a whole and by specific grant type. We will use bibliometric network analysis to assess productivity, citation impact, and scope of collaboration. **RESULTS/ANTICIPATED RESULTS:** There have been 2,777 submitted proposals with an acceptance rate of 33.3%. Unfunded proposals can resubmit, 61.8% of resubmitted applications are successfully funded, and 29.6% of funded applications are resubmissions. The \$2,000 awards accounted for 43.4% of all grants awarded but only accounted for 6.4% of all pilot funds awarded. Success of proposals was proportional to the number of applications from each academic unit. 60.8% of funded applicants were affiliated with the School of Medicine and account for 65.3% of all funding awarded from 2009-2019. Additionally, we plan on analyzing return on investment rates to illustrate the impact of pilot awards on future research funding. **DISCUSSION/SIGNIFICANCE OF IMPACT:** Pilot grants can lead to subsequent extramural grants, publications, and successful translation of research into practice. This evaluation will assist our institution in understanding the impact of pilot grants and will provide a road map for other institutions evaluating their own programs.

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Family-Based Study of Sleep in Autism Spectrum Disorder without Intellectual Disability*

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OBJECTIVES/GOALS: Autism spectrum disorder (ASD) is characterized by difficulties in communication and social interaction as well as restricted and repetitive behaviors. Sleep problems are a common concern in children with ASD that can persist into adulthood. This study aims to further explore sleep in ASD without intellectual disability (ASD w/o ID). **METHODS/STUDY POPULATION:** We recruited individuals of both sexes with ASD w/o ID (probands) and relatives as part of the Autism Spectrum Program of Excellence (ASPE) at the University of Pennsylvania. Actimetry data were collected via a wrist-worn tri-axial accelerometer for 21 days. Data from 212 participants were considered. We analyzed sleep data

using the algorithms GGIR, ChronoSapiens, and PennZzz. The sleep traits of proband and sibling pairs were compared using paired t-test or Wilcoxon signed-rank test. We used the Social Responsiveness Scale, Second Edition (SRS-2) to assess social impairment and restricted/repetitive traits. We compared SRS-2 scores to sleep traits using partial Spearman or Pearson correlations adjusting for age (171 participants). **RESULTS/ANTICIPATED RESULTS:** Probands demonstrated later sleep onset ($p = 0.03$), decreased M10 average (10-hour period of highest activity/day; $p = 0.006$), decreased relative amplitude (measure of rest-activity rhythm; $p < 0.001$), and decreased total daytime activity ($p = 0.005$) compared to siblings. Regarding social function and restricted/repetitive traits, adult males showed an inverse correlation between SRS-2 total score and sleep efficiency ($r = -0.2$, $p = 0.04$) and a positive correlation between SRS-2 total score and intradaily variability ($r = 0.3$, $p = 0.02$). Adult females showed an inverse correlation between SRS-2 total score and M10 average ($r = -0.3$, $p = 0.02$) and between SRS-2 total score and relative amplitude (self-report $r = -0.4$, $p = 0.001$; informant $r = -0.3$, $p = 0.005$). **DISCUSSION/SIGNIFICANCE OF IMPACT:** This study focuses on the analysis of sleep traits in ASD including the relationship between social function and sleep. Thus far, the most robust findings are decreased daytime activity and relative amplitude in individuals with ASD w/o ID compared to siblings. We have also shown that ASD social impairment may be related to sleep dysfunction.

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Implementation and evaluation of a novel protocol that uses clinical biomarkers to promote early diagnosis and treatment of Neurodevelopmental Disabilities

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OBJECTIVES/GOALS: Our objective was to establish a new protocol to evaluate new biomarkers to detect Neurodevelopmental Disabilities (NDD) in high-risk infants. As early intervention results in better outcomes, our goal was to implement the protocol to promote earlier NDD diagnosis and referral for treatment. **METHODS/STUDY POPULATION:** We implemented a new protocol using the General Movement Assessment (GMA), Hammersmith Infant Neurological Examination (HINE), and Capute Scales to evaluate infants who were at high risk of NDD. To determine the success of our protocol with these biomarkers, we studied former premature infants who were evaluated in follow-up clinic from 10/1/2018-10/1/2019. We defined our primary and secondary outcomes as the ages of neurodevelopmental diagnoses and referral to early intervention services before and after implementation of the new protocol, respectively. Our hypotheses were that infants who were evaluated with these biomarkers would be diagnosed with NDD and be referred for treatment at younger ages than their counterparts. **RESULTS/ANTICIPATED RESULTS:** Approximately 120 patients were evaluated during the time period that was defined. About half were evaluated prior to implementing the GMA and HINE, and the remainder were evaluated using GMA and other developmental measures. We anticipate that infants who underwent GMA will be diagnosed with NDD and referred for therapies at a younger age than their counterparts. **DISCUSSION/SIGNIFICANCE OF IMPACT:** Through our translational research, we will transform the standard of care for high-risk infants by incorporating clinical biomarkers into

day-to-day clinical care for these infants. Implementation of this novel protocol will promote the early diagnosis and referral to treatment for NDD.

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Implementation of Consent-to-Contact (CTC) initiative at an Academic Medical center: Initial operationalization and lessons learned

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OBJECTIVES/GOALS: The objectives of this presentation are to discuss 1) the implementation of Consent to Contact at an Academic Medical Center; 2) the access to lists of potential participants by study teams; and 3) the challenges and adjustments made to the initial conceptualized process. **METHODS/STUDY POPULATION:** Participant recruitment is critical to the success of all research studies. It is particularly challenging when investigators do not have a patient population from which to recruit. Thus, the University of Miami launched the CTC initiative in 2016 to facilitate study recruitment. Study investigators can request access to a registry of participants who agreed to be contacted and meet the initial study eligibility criteria. A multidisciplinary Operational Committee provides oversight and regulates access to the CTC registry. **RESULTS/ANTICIPATED RESULTS:** The registry has over 110K patients who have agreed to be contacted for eligible research studies. The demographic distribution of the patients in the registry mirrors the diversity of the UHealth population. As of January 2018, when the registry became available to the research community, 25 study teams from different departments, including the All of Us Research Program, have requested potential participant lists. The process of requesting access to patient lists is adapted to studies' needs, with particular reference to sensitive populations, such as HIV/AIDS, substance abuse, etc. Results on utilization and satisfaction of the CTC initiative are being collected and will be presented. **DISCUSSION/SIGNIFICANCE OF IMPACT:** The CTC initiative allows UHealth patients to opt-in to the registry for research studies. The Operational Committee continues to monitor the successful consent of patients to participate in individual research studies and improving the request process.

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Incidence, management, and outcomes of immune-related adverse events (irAEs): an analysis of a multidisciplinary toxicity team for cancer immunotherapy related irAEs

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OBJECTIVES/GOALS: This study aims to assess the outcomes of a new virtual multidisciplinary immune-related toxicity (IR-tox) team implemented at Johns Hopkins Hospital. In particular, to understand if the IR-tox team's input reduced the number of inpatient hospitalizations for irAEs for referred patients. **METHODS/STUDY POPULATION:** Since August 2017, nearly 250 patient referrals to the IR-tox team have been created and stored in an electronic database. Through retrospective chart review, hospitalization and irAE management data will be collected for these patients to assess whether rates for suspected

irAEs have decreased. These rates will be compared against historical controls. We will assess the features of hospitalized patients, their immunotherapy regimens, and management to identify high-risk groups who may require early intervention. Additionally, we aim to understand what patient features are associated with IR-Tox team referral and subsequent hospitalization. **RESULTS/ANTICIPATED RESULTS:** The IR-tox team provided a new multidisciplinary channel to help physicians diagnose and manage complex irAEs. The goal of the team was the reduce the number of irAE-related hospitalizations as, historically, 85% of high-grade irAEs have required hospitalization. A clinically meaningful reduction is defined as lowering the hospitalization rate to 75%. Planned analyses includes calculating the hospitalization rate, using descriptive statistics to summarize patient features, multivariate analyses to understand features associated with both IR-Tox team referral and hospitalization, and computing the relative risk reduction to assess the efficacy of subspecialist referral implementation. **DISCUSSION/SIGNIFICANCE OF IMPACT:** IrAEs are challenging to diagnose and treat. They contribute to a notable proportion of hospitalizations in those treated with immunotherapy. With expanding use of immunotherapy, widespread implementations of IR-Tox teams may help reduce hospitalizations and costs associated with care for irAEs.

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Infusing a CTSA Program with Causal Pathway Thinking to Transform Evaluation from Operations to Impacts

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OBJECTIVES/GOALS: Innovations with positive health impact are a high priority for NCATS and CTSA. Program design that uses the Causal Pathway approach incorporates performance indicators that assess impact. We applied Causal Pathway thinking to an ongoing national program to enhance the evaluation of program impact. We report Lessons Learned. **METHODS/STUDY POPULATION:** We conducted a day-long onsite workshop to introduce the model to the project team, build capacity, and map the existing program elements to Logic Models representing program Specific Aims. A local Causal Pathway (CP) champion was identified. Alignment of the Logic Models with the CP approach (input→activities→ outputs→effects/impact) developed iteratively through biweekly, then monthly conferral among stakeholders. Key tasks included distinguishing among activities, outputs, and effects (impacts), and identification of performance indicators for each stage of the Causal Pathway. Visualization tools and an additional late stage half-day workshop were used to foster consensus. Implementation of the CP model tested the feasibility of collecting specific indicators and prompted model revisions. **RESULTS/ANTICIPATED RESULTS:** Program leadership and team members (n = 30) participated in the kick-off workshop. Four Specific Aims were mapped to Logic Models. Multiple Causal Pathway (CP) diagrams, one for each project in the program, were developed and mapped to Aims. Alignment of CP threads to Aims and identification of performance indicators required iteration. CP threads converged onto common final Impacts, sometimes crossing to another Aim. Performance indicators for operations were readily accessible to team members, and less so for impacts. Assumptions about program effects were subjected to specific indicators. Over time, Leadership noticed more expression of CP thinking in daily activities. New projects developed during this period