



Poster #1

Title: The Influence in Patients with Amyotrophic Lateral Sclerosis of Prior Participation in Minimal Risk Studies on Recruitment and Retention of Subjects in Studies Involving More than Minimal Risk

Authors: Karen Overstreet, Pamela DeSaro, Amelia Johnston, and Kevin Boylan

Institution/Organization: Mayo Clinic Jacksonville

Background/Rationale: Amyotrophic lateral sclerosis (ALS) is a terminal, rare, progressive neurodegenerative motor neuron disease. Recruitment and retention of subjects with rare disorders provide a unique challenge. In therapeutic studies, subjects may discontinue their participation when they feel they have been randomized to placebo or that the intervention being investigated is not improving their condition. It can be difficult to recruit a sufficient number of qualified subjects from within a reasonable geographic area.

Goal(s)/Objective(s): In the ALS Research Center at Mayo Clinic in Jacksonville, Florida, we run several minimal risk and greater than minimal risk studies concurrently. We wanted to determine what the influence of initially participating in a minimal risk study may have on a subject's willingness to enroll and remain in a study involving greater risk.

Strategy/Methodology: A total of 1213 patients with ALS and related motor neuron diseases were seen in the Department of Neurology from January of 2006 to the present. We did not have regularly ongoing minimal risk studies prior to January of 2006, so only subjects who were recruited for their first study after this date were included in our analysis. For the purposes of this review, a study was considered to be minimal risk when procedures were limited to questionnaires and/or a single blood draw. Studies were considered to be greater than minimal risk when they included a skin biopsy, repeated blood draws, lumbar puncture, and drug or device intervention. Of the patients seen in this period of time, 644 (53%) of them participated in a minimal risk study, and 163 (13%) of total patients seen were successfully recruited for greater than minimal risk studies. We looked at the number of subjects who participated in a minimal risk study prior to their enrollment in a greater than minimal risk study. We then compared the retention of subjects in greater than minimal risk studies who had initially participated in a minimal risk study to those who did not.

Outcomes: Of the 163 patients recruited, 102 (63%) subjects who participated in a minimum risk study participated in a study involving greater risk, while the remaining 61 did not (Fisher exact test, two-tailed, $P = .0112$). The difference in retention rate in therapeutic studies for subjects who participated in a minimum risk study prior to a greater than minimal risk study

versus those who participated in a greater than minimal risk study first is negligible, at withdraw rates of 3% and 2%, respectively.

Conclusions/Future Directions: Based on our findings, the recruitment success rate of subjects from minimal risk studies is higher than from other sources of subjects. Initial participation in a minimum risk study does not seem to influence the subject retention rate of a therapeutic study. Subjects who are willing to participate in a minimal risk study may have a greater interest in research participation in general. It may be more efficient for sites to focus their recruitment resources on subjects who previously enrolled in a minimal risk study.

Poster #2

Title: Relationship Building Component to Maximize Recruitment and Retention: A Project Director's Perspective

Authors: Amy C. Fansler, MPH; and Karen C. Johnston, MD, MSc for the SHINE Trial

Institution/Organization: University of Virginia

Background/Rationale: Recruitment and retention are leading challenges in the timely and successful completion of all large phase III clinical trials. Acute clinical trials and non-acute or prevention clinical trials have vastly different approaches to recruitment and retention. In the process of designing and implementing the Stroke Hyperglycemia Insulin Network Effort (SHINE) Trial, we identified the importance of building relationships. The SHINE Trial is an acute stroke trial with a short enrollment window that makes recruitment a particularly important area of focus for the study. We outline numerous approaches that successfully build relationships between the project director and the study site and the study site and study participant that are critical to promoting engagement and achieving recruitment and retention success.

Goal(s)/Objective(s): Share approaches to relationship building that promote clinical trial recruitment and retention success.

Strategy/Methodology: Strong relationships between the study team and sites and relationship building between the site and study participant are key components to engagement and successful clinical trial recruitment and retention. While quantitative approaches to project management including metrics and timelines provide a framework for the conduct of large clinical trials, the value of building genuine relationships cannot be overstated.

The conceptual themes of relationship building that are important to clinical trial recruitment and retention include communicating effectively, establishing trust, considering unique issues and tailoring approach and resources, identifying unique and individualized factors to engage and motivate, publically recognizing contributions and successes, and encouraging peer communication.

We have established a comprehensive recruitment and retention program that links each of these concepts with a step-by-step model that we have implemented in our trial and can be applied to maximize recruitment and retention success in other studies. Each concept and the related components of the recruitment and retention program will be detailed in the poster for both the project director to study site relationship and study site to study participant relationship.

Outcomes: We have established a multidimensional model tailored to meet the needs of different stakeholders to promote recruitment and retention in a large phase III acute stroke trial and offer this model as a resource for other acute studies.

Conclusions/Future Directions: Genuine relationships and tailoring to the needs of the individual and the site are important components of clinical trial recruitment and retention approaches to maximize success. Identifying mechanisms of sharing successes among similar clinical trials is an important next step.

Poster #3

Title: Using the Survos Posse Platform to Recruit, Monitor, and Incentivize Research Participants

Author: Michael "Tac" Tancelosky

Institution/Organization: Survos

Background/Rationale: Survos has provided participant management tools for a variety of studies involving the use of cigarettes, nicotine replacement therapy (NRT), and e-cigarettes. The Posse Platform has provided the ability for surveys to be given to participants via text message surveys (SMS), phone surveys (Interactive Voice Response [IVR]), and our mobile app.

Goal(s)/Objective(s): The goal of the Survos Posse Platform is to provide a comprehensive, integrated system for researchers to manage their study participants and to collect participant survey data.

Strategy/Methodology: Participants can apply to be part of a research study via the website, or they can be added manually by a research assistant. Once a participant is enrolled in the study, researchers can engage with the study participant via random or fixed scheduled surveys, and that survey data is accessible in realtime. Payment incentives are provided to study participants to comply with the study protocol, such as reporting behaviors or other relevant information. These ecological momentary assessments can replace traditional user experience diaries. Since participants' survey data is streamed into the repository in realtime, the Posse Platform allows researchers to monitor potential issues with participants and address any challenges, which may result in higher retention rates. Incentivizing participants is often expensive due to the administrative burden associated with making payments, particularly for small-scale studies. Additionally, it may be difficult to motivate study participants to comply with all required study protocols. The Posse Platform tracks the completion of each survey and can be configured to reward study participants for compliance.

Finally, the system can automatically monitor participant activity, triggering an alert when participants have disengaged from the study protocol. Incentive payments to participants can be made via PayPal or Amazon, eliminating the costly process of writing checks or managing gift cards.

Outcomes: The Posse Platform is currently being piloted at the American Legacy Foundation, New York University, Stanford University, and others.

Conclusions/Future Directions: The next generation of the Posse Platform will make it easier to recruit study participants by leveraging the crowdsourcing reach of Amazon's Mechanical Turk, an on-demand, scalable workforce.

Poster #4

Title: The Intramural Parkinson Clinic: Unique Challenges and Opportunities

Author: Codrin Lungu, M.D., Nora Vanegas, M.D., and Beverly McElroy, CNRN

Institution: NINDS, PD Research Team

Background: We are a centralized clinical core facility in charge of recruitment and clinical activity for multiple research programs. As such, we not only recruit Parkinson's Disease patients for multiple research studies, but also provide clinical care and research interventions consistent with the changing landscape of research priorities of the NIH.

Goal: To provide seamless integration of research and clinical activities and to provide clinical research support for a variety of projects in the NIH community and beyond.

Objectives: (1) To be well established as the Parkinson disease resource for new and ongoing research studies. (2) To engage in and complete research Parkinson disease studies that involve patients with Parkinson disease (PD), as well as other related movement disorders. (3) To perform high-quality assessments and treatments as part of collaborative research

Strategy: (1) Extensive community outreach and engagement with organizations and community resources. This includes lecture series and participation as medical board members. (2) Prompt response to internal and external inquiries. (3) Maintenance of a database of NIH-wide investigators and studies interested in PD patients. (4) Coordination of clinic assessments with potential studies throughout NIH. (5) Quarterly meetings with inter-institutional stakeholders. (6) Providing PD support group leaders and participants with information on how to connect with study opportunities—Clinicaltrials.gov, Foxfindertrials.com, study coordinators' contact information, and PRPL contact information. (7) Meeting quarterly with NINDS staff to refine study referrals and follow up. (8) Providing patient satisfaction through a multidisciplinary and integrated team approach, as demonstrated by our high enrollment rates and 100% patient retention on the DBS program

Outcomes: (1) Following presentations at conferences or support groups, the call volume increases by 25%–30% for the period immediately following the event. (2) Once a patient has been seen in the Parkinson disease clinic and referred to other research studies, an appointment for their study usually occurs within 2–4 weeks. (3) Increasing support and collaboration with NIH investigators and other institutions.

Future Directions: (1) Improving the availability and user-friendliness of a dedicated website for the Intramural Parkinson Disease Program. This will increase our enrollment rates and ability to support NINDS and other NIH institutes' PD research studies. (2) Additions to available resources in order to meet the increasing demand for PD study evaluations. (3) Expansion of our community outreach to underserved communities. (3) Continuing and expanding

collaborative efforts with colleagues in NIH and other institutions. (4) Maintaining a dynamic and flexible approach to research priorities, to allow us to expand and adapt to the fast pace of discovery in our field.

Poster #5

Title: Alzheimer's Prevention Registry: A Shared Resource to the Scientific Community to Facilitate Enrollment in Studies

Authors: Nellie High, M.Ed., Jessica B. Langbaum, Ph.D., Eric M. Reiman, M.D., and Pierre N. Tariot, M.D.

Institution/Organization: Banner Alzheimer's Institute, Phoenix, AZ, USA

Background/Rationale: Recruitment and enrollment into clinical trials is a major obstacle faced by researchers and study sponsors. It has been estimated that fewer than 10% of Americans participate in clinical trials, mostly due to lack of awareness about study opportunities, resulting in approximately 80% of research studies failing to meet their enrollment goals in the stated timeframes. Given the growing number of preclinical treatment trials being conducted or in the planning stages, we developed a web-based Alzheimer's Prevention Registry ("Registry") to help studies make enrollment more efficient and timely.

Goal(s)/Objective(s): The Registry, which aims to eventually enroll at least 250,000 individuals, is intended to provide a shared resource to the Alzheimer's disease scientific community to facilitate enrollment in preclinical studies and to complement and enhance local recruitment efforts.

Strategy/Methodology: Interested adults of all ages, with and without memory and thinking problems, are eligible to join at www.endALZnow.org. At enrollment, individuals are asked to provide their email address; after enrollment, they can complete additional contact and demographic information at their convenience and discretion. Enrollees receive regular email communication to keep them apprised of the latest news in Alzheimer's prevention research. In addition, enrollees receive email notifications when study opportunities become available in their communities, with information on whom to contact to explore the possibility of their participation.

Outcomes: As of June 2014, over 37,500 individuals have joined the Registry. Registrants are predominantly women (78%), report a family history of dementia (72%), and have no diagnosis of cognitive impairment (95%); 36% of enrollees are between the ages of 46 and 60, and 37% are between the ages of 61 and 75. A/B testing is used to refine messaging and collection of demographic information to increase enrollment. Beginning in Q3 2014, a Researcher/Study Opportunities Portal will be available that will allow reporting of de-identified study enrollment metrics to help demonstrate the utility and impact of the Registry.

Conclusions/Future Directions: The Registry is an engaged community of individuals who want to stay abreast of the latest in Alzheimer's news and scientific advances and to be connected to research studies taking place in their communities. The Registry has been well-received, and enrollment continues to increase; results from A/B testing and the impact that website

modifications had on enrollment will be discussed. Preclinical treatment trials such as the ADCS “A4” Trial, the Takeda/Zinfandel TOMMORROW study, and the Alzheimer’s Prevention Initiative (API) APOE4 Trial will utilize the Registry to aid with recruitment. The Registry is open to support enrollment for additional early-stage trials.

Poster #6

Title: Recruitment and Retention in a Long-Term Prospective Observational Investigation of Pregnant Women with Epilepsy

Authors: D. Ippolito¹, K. Meador², P. Pennell³, E. Moore⁴, and N. Browning¹

Institution/Organization: 1. EMMES Corporation, 2. Stanford University, 3. Brigham & Women's Hospital, and 4. Emory University

Background/Rationale: The Maternal Outcomes and Neurodevelopmental Effects of Antiepileptic Drugs (MONEAD) study (previously called the NEAD study) is an NIH-funded prospective observational multi-center investigation of pregnancy outcomes for both the mother and child. The study has been conducted for over a decade, providing a rich experience in recruitment and retention techniques. From 1999 to 2004, the NEAD component enrolled 305 pregnant women with epilepsy. The MONEAD study began in 12/2012 by enrolling 550 women (350 pregnant women with epilepsy, 100 pregnant women without epilepsy, and 100 non-pregnant women with epilepsy).

Goals/Objectives: Review the approaches, problems, and solutions identified from the NEAD/MONEAD Study regarding successful recruitment and retention.

Strategy/Methodology: Factors affecting recruitment and retention were considered in the original design and then monitored during the study in order to make changes in response to observed problems. Factors considered included design complexity, inclusion/exclusion criteria, recruitment sources, patient "load" (e.g., visits and tests), incentives to patients, multiple contact points for patients, frequency of patient interactions, feedback to patients, individual center performance, and reimbursements to centers linked to performance. Examples are given in the Outcomes section.

Outcomes: The NEAD study ultimately met its recruitment and retention goals, but it faced multiple problems. It began with 17 centers, deleted 5 centers due to poor performance, and added 14 new centers to meet enrollment goals. Two deleted centers were expected to enroll over 40% of the patients, based on pre-study estimates, and several other centers performed poorly. Ultimately, over 78% of subjects enrolled came from only 34% of the centers. The original design included carbamazepine, phenobarbital, and phenytoin, based on pre-study surveys. However, when initiated in 1999, very few patients were taking phenobarbital, so it was deleted and two AEDs that were commonly prescribed (i.e., lamotrigine and valproate) were added.

Conclusions/Future Directions: Lessons from NEAD were applied to the MONEAD study. Poorly performing centers were deleted, new centers were added, design factors were altered prior to the initiation of MONEAD, and an updated survey of the centers was performed to identify the AEDs most commonly prescribed to women with epilepsy of childbearing age. MONEAD

enrollment is on track to meet its goals, having enrolled over half of the subjects in each of the three study groups. No MONEAD centers have been dropped for lack of enrollment, and all sites are actively enrolling subjects. Critical factors in successful recruitment and retention include a practical design, recruitment sources, sharing of successful recruitment materials/strategies among centers, maintaining patient contact, feedback and incentive for participation, ongoing monitoring of center performance, and a reimbursement mechanism linked to recruitment and retention.

Poster #7

Title: Factors Influencing Participation in Neurological Emergency Treatment Trials (NETT) for Stroke

Authors: Adrienne Haggins, Michael Feters, Rob Silbergleit, and William Barsan

Institution/Organization: Department of Emergency Medicine, University of Michigan

Background/Rationale: Patients' perceptions of the potential benefit and burden of participating in a clinical trial, along with prior experiences with research, confidence in health providers, understanding of the study, and prior experiences in that health care setting influence, their decision to enroll.

Goals/Objectives: To understand the decision-making process in patients enrolling NETT stroke clinical trials and others who decline enrollment.

Strategy/Methodology: We plan to examine patient decision-making through primary data collection using a combination of closed choice in-person/telephone surveys and semi-structured interviews. The respondent will be asked about their experience with the enrollment process (how they were approached) and what factors they considered in their decision-making, specifically assessing for which factor they considered most important. Additional Likert-scales will be used to determine whether additional reasons were factored in (e.g., family/companion influence, prior experience with a clinical trial). Within these domains, we will examine the perceived value of having family/companions involved in the discussion, patient understanding of the protocol, and concerns about safety/adverse effects. Interviews will allow for more in-depth exploration of trust and probe into participants' prior experiences at the facility, with health care, and with clinical trials.

The target population will be patients screened for NETT trials, deemed eligible, but who declined participation, as well as patients that enrolled in the study. NETT is a large multisite clinical trial network. Given that the respondents were previously screened, this will allow us to obtain their demographics, as well as information on the study site. We anticipate that 15 to 30 interviews will be needed to achieve thematic saturation, lasting approximately 1 hour in duration. We will aim to recruit at least 150 respondents, including those participating in the in-depth interviews.

Outcomes: We will then use chi-square testing to see whether these reasons differ between minorities and non-minorities. For the survey analysis, we will examine for whether demographic factors (race/ethnicity) are associated with attitudes in these content areas—personal factors, physician communication, family opinions, costs, and concerns about adverse effects—using logistic ordinal regression. We will also account for age, sex, trial site, month, year, and day. We expect that the themes elicited from the patient interviews will complement and enhance the quantitative findings.

Conclusions/Future Directions: Gaining a better understanding of patient preferences and concerns about participating in stroke clinical trials will inform recruitment and retention strategies to address preferences or concerns that affect willingness to participate.

Poster #8

Title: Recruitment Methods Employed in the NeuroNEXT SMA Biomarker Study

Authors: Amy M. Bartlett, John T. Kissel, and Stephen J. Kolb

Institution/Organization: The Ohio State University Wexner Medical Center

Background/Rationale: Effective recruitment and retention of research subjects are dependent on planning and study design. Recruitment strategies of vulnerable and rare populations require special consideration, particularly for natural history studies that involve multiple study visits over a prolonged period of time. The Spinal Muscular Atrophy (SMA) Biomarker Study recruits both infants with SMA and healthy controls. It is the first study funded by NIH to utilize the NeuroNEXT network. NeuroNEXT is an endeavor of the National Institute of Neurological Disorders and Stroke (NINDS) to improve research efficiencies, by providing an infrastructure to facilitate the development

Goal(s)/Objective(s): To recruit 27 infants with SMA and 27 healthy controls within 2 years of study initiation and to retain more than 80% of healthy participants.

Strategy/Methodology: We developed a marketing strategy and created a brand for the study focusing on an individual's sense of reciprocal altruism to promote enrollment. From the beginning, the study collaborated with the Families of SMA (FSMA) advocacy network and an SMA patient advocate. We created and circulated a YouTube recruitment video through FSMA and social media with over 2,800 views. The use of the NeuroNEXT infrastructure has also been advantageous in improving study start-up efficiencies and helping sites to be vested into recruitment for the study.

Outcomes: The SMA Biomarker study has exceeded recruitment expectations and achieved 98% retention for infants who did not expire. NeuroNEXT sites had enrolled 27 healthy controls in less than 10 months and 18 infants with SMA as of December 2, 2013. When compared with registry data from FSMA, the trial is recruiting approximately 40% of the infants registered who would meet eligibility criteria. Successful recruitment is attributable to several strategies and tactics.

Conclusions/Future Directions: We are collecting metrics via a patient questionnaire to learn what factors prompt enrollment and for what reasons eligible families decline participation. This inclusive and holistic approach using social marketing, social media, a patient advocacy group, and a defined infrastructure network may lead to improved recruitment for other studies in vulnerable populations.

Poster #9

Title: Personalized Recruitment and Retention in Large Clinical Trials: the CREST and CREST-2 Experience

Authors: Mary E. Longbottom, B.A., CCRP, Jamie Roberts, M.A., CCRP, MPH[c], and Thomas G. Brott, M.D.

Institution/Organization: Mayo Clinic Florida, 4500 San Pablo Road, Jacksonville, FL 32224

Background/Rationale: The importance of personalized communication and strong relationship-building in multisite clinical trials can be threatened by the increasing reliance upon multi-recipient emails and use of social media platforms, particularly in the recruitment and retention of clinical trial participants.

Goal(s)/Objective(s): Herein we share the mechanisms that were used to personalize recruitment and retention in CREST and that have been used in the early stages of CREST-2.

Strategy/Methodology: Personalized communication to CREST site principal investigators (PIs) and research coordinators included site visits by the study national PI, the clinical research associates, and the recruitment director; site-specific recruitment plans; near-daily telephone calls to sites by the recruitment director and/or national study PI; individualized congratulatory emails by the recruitment director and the national study PI to the site CREST team for each participant randomized; random telephone calls to sites; newsletters with photos of site teams; and face-to-face and tele-conferences with site PIs and coordinators. Personalized communication to the study participants included study-update flyers and participant newsletters. Personalized communication regarding retention included emails from site coordinators to the National PI for every potential participant withdrawal; an email or telephone call from the National PI to the site PI and/or coordinator with resolution or approval of withdrawal; and retention tips and success stories in study newsletters to sites. Recruitment and retention were agenda items at every PI and coordinator meeting. Personalized CREST-2 communication has included teleconferences for and individualized emails to CREST PIs to obtain their input prior to the submission of the CREST-2 grant application and individualized emails to CREST PIs and coordinators updating on the progress of CREST-2. CREST and CREST-2 PI and coordinator face-to-face conferences have been combined to set the stage for CREST-2. The first CREST-2 PI face-to-face conference was held on June 21, 2014.

Outcomes: The CREST Lead-in registry enrolled 1565 participants. The CREST randomized trial enrollment was completed in July 2008 with 2,502 participants from 117 sites (total combined enrollment = 4,067). Of these 117 sites, 104 centers continue in the long-term follow-up period of CREST. The current mean age of the surviving cohort is 75.4 years with 70.2% remaining active in the long-term follow-up. Twenty-four participants have completed 10 years of follow-up. Additionally, as evidence of the commitment of CREST site teams, 19 coordinators have achieved 10 years or more in the study. In the current early start-up phase of CREST-2, site

invitation packets are being sent out in small groups of 20–30 sites at one time. To date, 68 CREST-2 sites have received invitation packets.

Conclusions/Future Directions: The use of multiple mechanisms for personalized communication to site PIs and coordinators in large multisite clinical studies builds strong relationships and promotes recruitment. Personalized communication to participants during the course of the study aids in long-term retention. Social media tools have the potential to diminish personalized communication if their use is not well planned. A concerted effort to foster individualized personalized communication is needed to balance the increasing use of social media tools.

Poster #10

Title: A Financial Assistance Program to Remove Barriers to Clinical Trial Participation: A Descriptive Study

Authors: Elizabeth Powell, Ryan D. Nipp, Karen Winkfield, Sanja Percac-Lima, Bruce A. Chabner, and Beverly Moy

Institution/Organization: Massachusetts General Hospital

Background/Rationale: Financial burdens faced by patients with cancer are well documented. The added financial strain of cancer clinical trial participation is not well understood and is likely to increase as patients seek “personalized” clinical trials at distant cancer centers. The Lazarex Cancer Foundation and the Massachusetts General Hospital (MGH) have jointly formed a Cancer Care Equity Program (CCEP). The aims of the CCEP are to quantify the financial impact of clinical trial participation and to remove barriers to participation by providing financial assistance for trial-related expenses, such as travel and lodging.

Goal(s)/Objective(s): The initial goal of this study is to describe the sociodemographics of patients requesting financial assistance through the CCEP to enable them to participate in cancer clinical trials.

Strategy/Methodology: We performed a cross-sectional analysis of cancer clinical trial subjects who enrolled in the CCEP over a seven-month period at the MGH Cancer Center. CCEP enrollees received reimbursement for clinical trial–related expenses on a monthly basis. The sociodemographic characteristics of enrollees were analyzed using descriptive statistics.

Outcomes: Between November 2013 and May 2014, a total of 112 subjects enrolled in the CCEP. Of these subjects, 29% were younger than 50 years old, 64% were women, 5% were non-English speaking, 14% were racial or ethnic minorities, 9% reported annual income of less than \$35,000 per year, and 66% lived out of state. Most cancer types were represented, with thoracic cancers comprising the largest proportion of participants (32%). The majority of subjects (73%) were enrolled in a phase 1 trial. The total reimbursement provided to all subjects was \$77,016. The average monthly assistance for in-state subjects was \$384 and for out-of-state subjects was \$1,007.

Conclusions/Future Directions: The CCEP has provided financial assistance for many cancer patients, thus facilitating their participation in clinical trials. A substantial proportion of these subjects were from vulnerable populations, such as racial/ethnic minority, non-English speaking, and low socioeconomic groups. Costs to subjects averaged \$384/month (local) to \$1007/month (out-of-state). The vigorous enrollment of these patients suggests a pressing need to reduce the financial burden placed on cancer clinical trial participants. Future studies should explore the financial burden of clinical trials and design further interventions to improve clinical trial participation.

Poster #11

Title: Development and Impact of an Intervention to Boost Recruitment in a Multi-Center Pediatric Randomized Clinical Trial

Authors: Sonika Bhatnagar, M.D., M.P.H.¹; Alejandro Hoberman, M.D.¹; Diana H. Kearney, RN, CCRC¹; Nader Shaikh, M.D., M.P.H.¹; Marva M. Moxey-Mims, M.D.²; Russell W. Chesney, M.D.³; Myra A. Carpenter, Ph.D.⁴; Saul P. Greenfield, M.D.⁵; Ron Keren, M.D., M.P.H.⁶; Tej K. Mattoo, M.D., D.C.H., FRCP (UK)⁷; Ranjiv Mathews, M.D.⁸; Lisa Gravens-Mueller, M.S.⁴; and Anastasia Ivanova, Ph.D.⁴

Institutions: ¹University of Pittsburgh School of Medicine, Children's Hospital of Pittsburgh, Division of General Academic Pediatrics, Pittsburgh, Pennsylvania; ²NIH/National Institute of Diabetes, Digestive and Kidney Disease, Division of Kidney, Urologic and Hematologic Diseases, Bethesda, Maryland; ³Le Bonheur Children's Medical Center, University of Tennessee Health Sciences Center, Memphis, Tennessee; ⁴University of North Carolina at Chapel Hill, Department of Biostatistics, Collaborative Studies Coordinating Center, Chapel Hill, North Carolina; ⁵Women and Children's Hospital of Buffalo, Division of Pediatric Urology, Buffalo, New York; ⁶The Children's Hospital of Philadelphia, University of Pennsylvania, Philadelphia, Pennsylvania; ⁷Children's Hospital of Michigan, Detroit, Michigan; ⁸The Johns Hopkins School of Medicine, Children's Urology Associates, Baltimore, Maryland

Background: Despite general and pediatric-specific challenges to recruitment in randomized controlled trials (RCTs), a paucity of evidence exists on effective recruitment strategies or assessment tools to reliably enhance recruitment. We developed a recruitment intervention for use in RCTs that enables clinical researchers to enhance recruitment.

Objectives: Our primary objective was to develop and evaluate an intervention to increase recruitment in a multi-center pediatric RCT. Our secondary objective was to assess the impact beyond 120 days.

Methodology: The study was conducted at 17 academic centers participating in a pediatric RCT. The intervention consisted of utilizing a recruitment assessment tool at a site visit or teleconference with key site personnel.

Outcomes: We found a significant increase in the number of subjects enrolled for all 17 sites at 120 days post-intervention (mean 1.12 per site; median 1 per site, 95% CI, 1–2; $P = .04$). No significant differences were apparent beyond the first 120 days post-intervention.

Conclusions: Successful recruitment in RCTs is essential to the quality, generalizability, and cost-effectiveness of clinical research. Implementation of this recruitment intervention may effectively increase recruitment in RCTs. Beyond the first 120 days post-intervention, repeated interventions may be required.

Poster #12

Title: Shared Decision Making for Participation in a Breast Cancer Clinical Trial

Authors: A. Leader, T. Avery, Q. Quinn, S. Keith, M. Cristofanilli, and R. Myers

Institution/Organization: Department of Medical Oncology, Thomas Jefferson University, Philadelphia, PA

Background/Rationale: Participation rates in adult cancer clinical trials are lower than desired and patients have reported numerous barriers to enrollment. Decision aids can be used to educate patients about available options and facilitate shared decision making between patient and provider. Members of the research team used the Decision Counseling Program (DCP), an interactive decision aid, with women who were eligible for a breast cancer clinical trial to assist them in deciding about participating in a clinical trial.

Goal(s)/Objective(s): Study objectives were to determine (1) the feasibility of integrating the DCP into an oncology clinical practice and (2) the effect of the DCP on rates of clinical trial participation.

Strategy/Methodology: Oncologists at the Jefferson Breast Care Center (JBCC) identified patients who were eligible for a clinical trial. The research assistant arranged to meet the patient ahead of her next appointment at the JBCC, obtained informed consent, and administered a baseline survey. A decision counselor reviewed informational material with the patient and conducted a decision counseling session. During decision counseling, the patient deliberated the pros and cons of participating in a trial and weighed her options according to her values and preferences. A summary report of the session was provided to both the patient and her oncologist to use for shared decision making during the clinical encounter. At 30 days, the research assistant administered an endpoint survey to the patient and at 90 days conducted a medical chart audit to determine the patient's trial enrollment status.

Outcomes: The oncologists identified 11 potentially eligible patients and all 11 agreed to participate. One patient was unable to participate because of scheduling logistics, but the remaining 10 patients enrolled in the study. Five patients were African American and 5 patients were White; none were Hispanic. Nine out of 10 patients had at least some college training. Five patients were under the age of 60 and 5 patients were over the age of 60. Six patients were unmarried. At baseline, the patients got, on average, 7 out of 10 knowledge questions correct. Patients reported high levels of decisional conflict, with a mean decisional conflict score of 1.8 (on a scale of 1–5; 1: high level of decisional conflict, 5: low level of decisional conflict). From decision counseling, 1 patient preferred not to participate in a clinical trial, 2 patients were neutral about participating, and 7 patients preferred to participate in a clinical trial. Aggregated together, patients identified 18 “pro” factors (reasons in favor of participating in a clinical trial) and 8 “con” factors (reasons against participating in a clinical trial). At 90 days, 2 patients had enrolled in a clinical trial, 1 patient who was interested in enrolling in a trial was

found to be ineligible during the medical screening process, and 7 patients were still deciding about enrollment.

Conclusions/Future Directions: Decision support educates patients about clinical trials and allows them to clarify their personal preferences, which may lead to more favorable views about trials and higher participation rates.

Poster #13

Title: AccrualNet™: Innovative Online Collaboration to Improve Clinical Trials Accrual Practice

Authors: Linda Parreco, RN, M.S.; Ellen Richmond, RN, M.S.; Lori Minasian, M.D.; Annette Galassi, RN, M.A., OCN; Harry Kwon, Ph.D., M.P.H.; and Katherine Jenkins

Institution/Organization: National Cancer Institute: Division of Cancer Prevention, Center for Global Health, Office of Communications and Education

Background/Rationale: The current scientific environment of rapid discovery coupled with restricted resources requires that clinical trial professionals use the most effective methods possible to recruit participants and complete clinical trials in a timely manner. Barriers to accrual are well documented, but “one size fits all” solutions simply do not exist. Formative research conducted by the NCI among academic and community-based professionals found that clinical trial professionals commonly expressed frustration with finding best practices and adopting them for their trials. Based on these findings, NCI developed and launched AccrualNet™ (<https://accrualnet.cancer.gov>), the first comprehensive solution platform for the oncology research community of clinical trial team members, academics, and advocates.

Goal(s)/Objective(s): Create and maintain an easily accessible, curated online repository of tools, literature, and educational resources for clinical trial professionals; serve as the recognized source for health professionals seeking evidence-based strategies for clinical trial recruitment; and address the accrual problem by removing the walls from the collective wisdom of the field and enabling knowledge-sharing among professionals

Strategy/Methodology: The familiar “protocol lifecycle” serves as the conceptual and organizational framework for the AccrualNet™ website by connecting relevant and useful content to the steps undertaken in the accrual process. This model provides the right information at the right time, thus encouraging examination of possible recruitment strategies and consideration of evidence-based approaches. The site connects useful content items to the pre-study, active study or post-study stage of a clinical trial. Educational materials are available for staff orientation and continuing education, a request frequently voiced by formative research participants. A section devoted to community-wide and private conversations facilitates knowledge development and sharing among AccrualNet™ members. Guest Experts, chosen for their community stature, experience, or unique perspective, present featured blog columns. The content blends the academic with the practical by encouraging professionals to utilize evidence-based accrual practices and to share locally developed tools and solutions.

Outcomes: AccrualNet™ fills the information gap. Today, AccrualNet™ hosts over 1,000 clinical trial resources, including annotated articles culled from over 90 journals, 93 education resources, 67 sample forms, materials and templates, and 120 blog posts, including 34 from recognized Guest Experts in the field of clinical trial recruitment. AccrualNet™ reaches the community. AccrualNet™ averages over 1,000 visits per month and has over 600 members,

including program managers (29%), clinical research associates (28%), nurses (14%), data managers (9%), and a variety of other roles including recruitment specialists, executives, study chairs, and educators. Members' experience in clinical trials ranges from novice (14% with < 3 years' experience) to expert (15% with > 20 years' experience). Members represent academic settings (39%), community settings and private practices (41%), industry (5%), government (8%), and nonprofit (1%).

Conclusions/Future Directions: By focusing on dynamic knowledge-sharing and collective problem-solving, AccrualNet™ builds capacity among professionals, resulting in a workforce equipped with the skills necessary to overcome accrual challenges. AccrualNet™ has wide-scale transferability beyond cancer and across Federal agencies, pharmaceutical companies, and non-profits.

Poster #14

Title: Successful Strategies for Engaging Women and Minorities in Clinical Trials

Author: Christine Lee Carter, Ph.D., M.P.H.

Institution/Organization: The Society for Women's Health Research

Background/Rationale: The diverse enrollment of subjects engaged in clinical trials research is critical to developing safer and more effective drugs and medical devices. However, in the United States, there are striking disparities in clinical trial participation. To address this issue, the Food and Drug Administration (FDA) Office of Women's Health and the Society for Women's Health Research (SWHR) together convened the 2-day meeting Dialogues on Diversifying Clinical Trials. The conference was held in Washington, D.C., on September 22–23, 2011.

Goal(s)/Objective(s): We present the major findings discussed at this meeting about female and minority patients and physicians, their willingness to participate in clinical trials, and the barriers that sponsors face in recruiting a diverse trial population. We also present some recommendations for improving trial diversity through new technologies and greater efficiency in trial regulation and review.

Strategy/Methodology: The 2-day meeting of stakeholders from government, industry, and the private sector examined the challenges and barriers to recruitment and retention of women and minorities into clinical trials.

Outcomes:

Strategies:

1. Recruit female and minority physicians
2. Build trust through communication
3. Educate to raise awareness
4. Involve communities

Conclusions/Future Directions:

Recommendations:

1. Reexamine trial design and ethics
2. Foster multisector collaborations
3. Incorporate new technology
4. Adapt to the changing face of medicine
5. Increase efficiency in regulation and review

Poster #15

Title: Tracking and Monitoring Trial Progress in NIDA-CTN Studies

Authors: Gaurav Sharma, Ph.D.; Paul Van Veldhuisen, Ph.D.; and Colleen Allen, M.P.H.

Institution/Organization: The EMMES Corporation

Abstract: The National Drug Abuse Treatment Clinical Trials Network (CTN), established by the National Institute on Drug Abuse (NIDA), conducts research to provide a broad and powerful infrastructure for rapid, multisite testing of promising science-based therapies and the subsequent delivery of these treatments to patients in community-based treatment. A comprehensive set of reports has been developed to use as a management tool to effectively monitor the progress of ongoing clinical trials. These reports track the progress of each protocol within the CTN from the date of first randomization to final closeout and publication of main results. The content includes areas from all aspects of the clinical trials: source of referral, recruitment rates, CONSORT flow diagram, participant's disposition, tracking and attendance of study participants, and post-trial communication. These reports provide both a big-picture view of the NIDA CTN protocols and a very detailed view to meet the needs of the varied audience, which include:

- The sponsor and study leadership to assess the overall progress of multiple ongoing protocols.
- The protocol lead teams to monitor their respective protocols in order to identify areas of concern on an individual site level.
- The investigators and staff at each participating community treatment program (CTP) within a protocol to monitor their individual site's performance against other sites.

In this poster, these strategies for tracking and monitoring clinical trial participation and post-trial communication will be presented in the context of a CTN clinical trial.

Poster #16

Title: Parkinson's Advocates in Research: Engaging People with Parkinson's in Clinical Study Education and Recruitment

Authors: David Blomquist, Karlin Schroeder, and Veronica Todaro

Institution/Organization: Parkinson's Disease Foundation

Background/Rationale: Recruitment and retention of study participants is critical to the timely completion of Parkinson's clinical studies. People living with Parkinson's who have participated in clinical research have insight and expertise that can inform and improve recruitment and retention efforts. The Parkinson's Disease Foundation's (PDF's) Parkinson's Advocates in Research (PAIR) program prepares and supports people with Parkinson's in their roles as PDF Research Advocates so that they can partner with the scientific community to address obstacles that impact the efficiency and effectiveness of clinical research. More than 230 Research Advocates from 42 states have worked with over 400 research professionals and 120 Parkinson's support groups around the United States in setting research priorities, designing clinical trials, and increasing study enrollment.

Goal(s)/Objective(s): To assess the clinical research education and study recruitment activities of PDF Research Advocates within a five-month period from January 2014 through May 2014.

Strategy/Methodology: An online activity report was administered to PDF Research Advocates on a monthly basis.

Outcomes: The survey was completed 320 times, with an average of 64 Research Advocates filling out the survey each month. Fifty-five percent ($n = 175$) of respondents engaged in outreach at a support group, event, or conference, reaching a total of nearly 23,000 people. Sixty percent ($n = 191$) engaged in one-on-one outreach, reaching over 1,800 people. Twenty-three percent ($n = 94$) of respondents stated that their outreach led to a person living with Parkinson's inquiring about (a total of 460 individuals) or joining (a total of 245 individuals) a study. Specific examples of clinical research education and recruitment efforts include arranging for a researcher to attend a support group meeting to inform the community about a specific clinical trial; advising the trial team on study informational materials; speaking at a regional meeting on study participation; and speaking one-on-one to individuals about their clinical trial volunteer experience and studies that are currently seeking participants.

Conclusions/Future Directions: Preliminary evidence shows that PDF Research Advocates can increase study enrollment. More formal partnerships are under way between the PDF PAIR program and specific clinical studies that are expected to further demonstrate the impact of PDF Research Advocates on study recruitment.

Poster #17

Title: Retention of Participants and their Children in a Multi-Center Randomized Trial of Thyroxine Therapy for Subclinical Hypothyroidism and Hypothyroxinemia in Pregnancy

Author: Elizabeth Thom for the *Eunice Kennedy Shriver* National Institute of Child Health and Human Development Maternal-Fetal Medicine Units (MFMU)

Institution/Organization: George Washington University Biostatistics Center

Background/Rationale: Overt hypothyroidism in pregnancy is known to be associated with poor neuropsychological outcome in the offspring. The evidence is less clear for subclinical hypothyroidism and hypothyroxinemia. The MFMU Network (which consists of 14 clinical centers), a coordinating center (CC), and NICHD undertook a placebo-controlled randomized trial to determine whether thyroxine therapy for subclinical hypothyroidism or hypothyroxinemia during pregnancy results in improved neuropsychological outcome in the child. 1,203 women meeting criteria for these conditions were randomized to thyroxine or placebo before 21 weeks' gestation. Children undergo neuropsychological testing yearly until age 5. The Network has success in retention through delivery. However, retention of women and their children long after delivery presents additional challenges, including low motivation to bring back mainly healthy children versus children at risk for delay or disability; a large proportion of low socioeconomic status (52% have family income below \$25,000) and minorities (53% Hispanic, 16% African-American); families having fewer resources to commit to follow-up; families moving, sometimes several times (to date, 100 have moved to a different city or out of the country); children sent into foster care or adopted; having an adequate budget for follow-up; and a need for multispecialty expertise (e.g., obstetrics, psychology).

Goal(s)/Objective(s): The primary outcome is IQ, measured at 5 years of age by a trained psychologist. Our goal was to enroll 1,170 women, accounting for up to 15% loss to follow-up.

Strategy/Methodology: Establish relationship with participant—stay in touch with greeting cards, calls, e-mail. Encourage women who discontinue study medication to stay in trial and bring their children back. Provide participant incentive at each visit as allowed by local IRBs. Obtain contact information for multiple family members/friends in case they lose touch. Use internet and social media to locate mothers. Check hospital records for other visits (e.g., pediatric, subsequent births). Set up a site and trained psychologist in Mexico City for approximately 30 families that moved back to Mexico. Travel expenses within Mexico are reimbursed. If a participant moves within the United States, follow-up can be done at a closer center, and/or families are reimbursed for travel. When families cannot travel, a “travelling examiner” goes to the participant’s home, even outside the country. Work with authorities in foster care/custody situations. Centers are paid “capitation” based on successful follow-up to optimize spending. Capitation funds follow-up staff and other costs. Travel expenses are paid for by the CC and carefully monitored. Ensure good communication/collaboration between the obstetrics staff that recruit patients and psychologists who do exams. Research staff and CC

share ideas, successes, and challenges. All cases where exam window is missed are reviewed and re-reviewed by the CC and study leadership. No participant is “written off.”

Outcomes: Of those that passed their 5-year window, 93% were seen, including several who missed earlier exams but returned for the 5-year exam.

Conclusions/Future Directions: We have easily exceeded our goal of 85%. Use of technology and flexible travel/exam sites are successful strategies for future follow-up studies.

Poster #18

Title: Evaluating Research START (*Study and Trial Accelerator for Research Teams*)

Authors: Mark Stein, Ph.D.; Michele Shaffer, Ph.D.; Chi Do, M.H.A.; Michael Donohue, B.S.; Jane Edelson, M.P.H.; Michelle M. Doyle, R.N., M.H.A.; Abigail L. Echo-Hawk, M.P.S.; Lucinda Getz, M.S., PMP; Jason Malone, M.P.A.; Stacy Oswald, M.S.; Craig Scott, Ph.D.; Jodi Smith, M.D.; Ann Stapleton, M.D.; and Ann J. Melvin, M.D., M.P.H.

Institution/Organization: Institute for Translational Health Sciences, University of Washington, Seattle Children's Research Institute

Background/Rationale: Inadequate enrollment into clinical trials is widely recognized as a major impediment to translational science and a barrier to attaining needed health outcomes improvement. Trials which fail to recruit sufficiently to address their primary objective put research participants at risk without societal benefit. At present, little generalizable knowledge is available to identify root causes of low enrollment beyond those associated with a specific diagnosis or study. The Institute of Translational Health Sciences (ITHS) has begun a project to (1) identify and study barriers to full enrollment at multiple levels, including regulatory/administrative structure, principal investigator (PI), research coordinator (RC), and potential research participant; and (2) develop interventions to reduce barriers to recruitment.

Objective(s): (1) Identify and study root causes of clinical trials' accrual problems, (2) develop innovative interventions (1 or 2 interventions) to address one or more root causes, (3) pilot the intervention(s) to assess effectiveness and generalizability, and (4) disseminate findings and provide education and support for study recruitment

Strategy/Methodology: This 18-month project has three phases. Phase 1 is a literature review and data-gathering period. Based on the literature review, we developed a survey for investigators and coordinators to collect study-level data designed to identify and prioritize targets for interventions to improve participant accrual. Phase 2 will use a mixed-methods approach. Our multidisciplinary team will review the quantitative study data and generate interventions (e.g., early monitoring system of trial accrual, support team for studies below target, benchmarking of regulatory barriers, educational materials for coordinators) to target barriers at multiple levels. We also will conduct focus groups of investigators, coordinators, participants, and regulators to obtain qualitative data on barriers to recruitment in general and also of minority populations, and to provide input on proposed strategies to inform candidate interventions. Phase 3 will involve an observational or quasi-experimental study on the impact of the proposed intervention(s) on studies where investigators and/or research staff participated in the intervention compared to those studies where they did not. Studies conducted in the ITHS Regional Clinical Research Centers (CRCs) will be included in the interventions to assess generalizability.

Outcomes: 225 trials conducted by 107 PIs that have utilized the CRC at Seattle Children's Hospital or the University of Washington from March 2012 to March 2014 have been identified for study. Forty-five percent of trials open for at least a year (median 3 years) had enrolled fewer than 30% of their enrollment target. These data serve as our historical benchmark. We have developed a 38-item questionnaire for investigators and coordinators ("Strengths and Barriers to Participant Accrual") and are awaiting institutional review board approval to disseminate electronically. Initial study-level results will be presented along with several potential intervention strategies.

Conclusions/Future Directions: Quantitative and qualitative data on barriers and accelerators for participant accrual are being used to develop multi-level interventions for clinical and translational studies. We will evaluate the effects of these interventions and become a central resource to educate, advocate, and improve participant recruitment.

Poster #19

Title: Recruiting Sites to Participate in a Randomized Minority Recruitment Intervention (RECRUIT)

Authors: Barbara C. Tilley, Rossybelle P. Amorrortu, and Veronica I. Landa for RECRUIT Investigators

Institutions: University of Texas Health Science Center School of Public Health at Houston

Background/Rationale: Low minority participation in clinical trials limits our ability to assess and address potential differences in therapeutic responses. Few randomized trials have compared approaches to increase participant diversity in clinical trials.

Goals/Objective: To increase racial/ethnic diversity in clinical trials we are conducting a randomized trial of a recruitment intervention (RECRUIT) funded by the National Institute on Minority Health and Health Disparities. We describe the challenges faced when recruiting clinical sites to participate in this randomized recruitment intervention.

Strategy/Methodology: The RECRUIT intervention will be tested among approximately 60 specialty clinics from 4–5 multisite clinical trials (parent trials). Clinical sites are randomized to the RECRUIT intervention or control group. The intervention is adapted from approaches to healthcare quality improvement and patient navigation. Conditions selected for study in RECRUIT generally require physician referral to the trial (e.g. Parkinson’s disease). Thus the recruitment approach is directed at clinicians and coordinators rather than the community. Parent trial coordinating centers were identified through colleagues and the NIMHD project staff. Parent trial coordinating center principal investigators were contacted and invited to collaborate on the RECRUIT trial. If the coordinating center investigator approved collaboration with RECRUIT, a clinical site address list was requested. The clinical sites were geocoded using ArcGIS and sites with at least 20% minorities within a 30-mile radius were invited to participate. The clinician and coordinator at the clinical sites who agree to participate are required to sign a RECRUIT consent form.

Outcomes: A total of 14 parent trials have been approached to participate in RECRUIT. The first was a prevention trial recruiting only minorities; therefore, either a clinician-directed or community approach could have been used for recruitment. We used that trial to test our methods, materials, and approach and to assist them in recruitment. The remaining trials met our criteria for physician referral. Of those, 4 (31%) agreed to collaborate with RECRUIT and 2 additional parent trials are pending a decision to participate. A total of 86 clinical sites were invited to participate from 2 parent trials and 19 (22%) sites agreed to participate in RECRUIT. We are collecting responses from sites at the other 2 parent trials (49 eligible sites). Barriers to site participation include lack of staff time/resources, unwillingness to be randomized, refusal to change current recruitment processes even though RECRUIT layers the intervention on top of current processes, concern about being randomized without knowing all the details of the

intervention, and ambivalence towards minority recruitment. The primary facilitator has been NIH pressure on trial principal investigators to recruit more minorities.

Conclusions/Future Directions: We continue efforts to recruit clinical sites to participate in the RECRUIT intervention. More pressure from NIH funders regarding minority recruitment could increase the number of trials participating and increase sites participating.

Poster #20

Title: Retention of South African Adolescents in a 54-Month Longitudinal HIV Risk-Reduction Study

Authors: Larry D. Icard, Craig Carty, John B. Jemmott III, Janet Hsu, Lulama Sidloyi, and Joanne C. Tyler

Institution/Organization: Temple University, University of Pennsylvania, University of Fort Hare

Background/Rationale: The initial trial enrolled grade 6 learners who completed the immediate-post and 3-, 6-, and 12-month post-intervention questionnaires by December 2006. Findings revealed that a significantly smaller percentage of participants in the HIV/STD risk-reduction intervention reported HIV sexual risk behaviors compared to those in the control intervention (Jemmott et al., 2010). The 42-month data collection began in April 2008 and the 54-month data collection ended June 2010 (Jemmott, et al., 2014). Retaining adolescents in clinical trials can be challenging. Retaining adolescents in longitudinal HIV prevention trials in developing countries can be even more challenging.

Goal(s)/Objective(s): The objective of the South African Adolescent Health Promotion 54-Month study was to test the sustainability of HIV/STI risk-reduction intervention “Let Us Protect Our Future” effects on young adolescents as they age into middle and late adolescence.

Strategy/Methodology: Obstacles in retaining participants included a 3-year gap between the time the youth completed the 12-month assessment for the main trial and began the 42-month follow-up; participants matriculating to over 200 secondary schools; participants relocating to different geographical areas; inaccurate contact information; and inoperable mobile telephone numbers. Retention strategies consisted of meetings with former teachers, principals, and the study’s CAB; sending letters and holding meetings with parents and guardians explaining the continuation trial; and having retention staff use a case management approach.

Outcomes: Over 90% of 1,057 participants were retained to complete a 42-month and 54-month data-collection session that included biological specimens. From baseline, 3-, 6-, 12- through 42 to 52 month assessments, over 90% of 1,057 learners attended each follow-up session. Attending a follow-up was unrelated to intervention condition, sex, father’s presence in the household, residing in the semi-rural area, or sexual behavior at baseline. However, participants 14 to 18 years of age (96.0%) were less likely to return for follow-up than were those 12 to 13 years of age (99.2%) and those 9 to 11 years of age (99.2%), $P = .003$.

Conclusions/Future Directions: The investment in creating trusting and positive relationships with parents and the community, the retention staff’s use of a case management approach, and strict adherence to retention protocols contributed to the success of retaining participants for the South African Adolescent Health Promotion Project 54-month study. Future research is

needed to explore the use of strategies designed to retain older adolescents in longitudinal HIV prevention clinical trials.

Poster #21

Title: A Program to Remove Barriers to FDA Clinical Trials: Providing Equity Access and Increasing Enrollment, Retention, and Minority Participation

Authors: Dana L. Dornsife

Institution/Organization: Lazarex Cancer Foundation (LCF): a 501 (c)(3) public charity established in 2006

Background/Rationale: Since 2006, Lazarex Cancer Foundation has been giving hope, dignity, and life to end-stage cancer patients and the medically underserved by providing assistance with costs for FDA clinical trial participation, navigation through trial options, community outreach, and education. We are now expanding our efforts through a nationwide pilot partnership with top-notch cancer centers and universities called IMPACT (IMproving Patient Access to Clinical Trials) to improve the methodology of engaging cancer patients in clinical trial participation.

Goal(s)/Objective(s): The primary goal of this program is to establish best practices and facilitate a “boots on the ground” effort in unison with top-notch urban cancer treatment centers and universities nationwide, identifying the most successful methods of reaching and engaging people of all ages, with all cancer clinical indications, from all ethnic and socioeconomic sectors in clinical trial participation and early detection efforts. The secondary goal is to expand the patient pool nationwide, facilitating faster enrollment and reducing the overall costs of conducting clinical trials.

Strategy/Methodology: The LCF IMPACT partnership currently consists of MGH/Harvard, Drexel University, Kimmel Cancer Center at Jefferson, and USC Norris Comprehensive Cancer Center. Through 2016, we are rolling out programs at each institution at the institutional clinical, community clinical, community organization, and government levels to engage with the medical community, community members and cancer patients from all sectors to efficiently remove barriers to clinical trial participation, identified as lack of accurate knowledge, financial constraints, support network interruption, socioeconomic status, and historical and cultural issues.

Outcomes: The preliminary, early-stage, 6-month data from MGH/Harvard indicates that a substantial increase in out-of-state participation and minority participation has already doubled. We will continue to monitor patient enrollment demographics and use statistical analysis with biostatisticians to determine the effectiveness of each arm of the study. Based on historical data, we anticipate an overwhelmingly positive result.

Conclusions/Future Directions: We will continue to participate in and monitor the results of our IMPACT partnership through 2016 and consider adding strategic partners. Preliminary data indicate that knowledge, financial constraints, support network interruption, socioeconomic

status, and historical and cultural barriers have a drastic effect on trial participation. Efforts to address these barriers must be embraced to increase clinical trial enrollment, retention, and minority participation.

Poster #22

Title: Enrollment and Retention Strategies for Young Adult Pacific Islanders in a Smoking Cessation Trial

Authors: Paula Palmer¹, Amanda LaBreche², Zul Surani³, Vanessa Tui`one⁴, Tupou Toilolo⁵, Kaiwi Pang⁶, Dorothy Etimani S. Vaivao⁷, Patchareeya P. Kwan⁸, Nasya Tan¹, Melanie Sabado¹, Bin Xie¹, James Pike⁹, and Sora Park Tanjasiri² for the Weaving an Islander Network for Cancer Awareness, Research, and Training (WINCART) Collaborative

Institution/Organization: ¹Claremont Graduate University, ²California State University, Fullerton, ³University of Southern California, Norris Comprehensive Cancer Center, ⁴Tongan Community Service Center, ⁵Union of Pan Asian Communities, ⁶Pacific Islander Health Partnership, ⁷Samoa National Nurses Association, ⁸California State University, Northridge, ⁹California Media Academic Services

Background/Rationale: Native Hawaiian Pacific Islanders (NHPIs) suffer disproportionately from health disparities compared with other racial/ethnic groups. This includes their relatively high tobacco use prevalence despite an overall decline in the United States. Among the obstacles affecting NHPIs, who want to quit smoking, is a dearth of culturally adapted cessation programs, difficulty of health providers to locate NHPIs due to their small population size and scattered distribution in the general population, and challenges with respect to engagement and building trust within their communities.

Goal(s)/Objective(s): The WINCART collaborative, comprising NHPI-led community-based organizations (CBOs) and academic researchers, utilized a community-based participatory research (CBPR) model to develop a culturally attuned smoking cessation program, Motivating Pasifika against Cigarettes and Tobacco (MPACT) for young adult NHPIs, a group at high risk for progression to addictive smoking. A randomized controlled trial is currently under way to test the efficacy of the MPACT program. Due to low enrollment and participant retention in the early months of the study, the WINCART team developed strategies for improvement.

Strategy/Methodology: Enhancement strategies guided by CBPR processes comprise (1) exclusive use of NHPI recruiters/health coaches, most of whom are young adults and all of whom are trusted by their communities; (2) monthly in-person meetings of the full research team (community and academic) to review enrollment and post-intervention assessment data; (3) monthly teleconferences between recruiters/health coaches to provide support and share field experiences; (4) regular participant scheduling reminders to health coaches via email; (5) re-allocation of funds to augment recruitment/retention activities; (6) consultation with the community advisory board and community stakeholders, and (7) accommodation of participants' time schedules, family commitments, unexpected events, and transportation limitations.

Outcomes: Total enrollment after the first 7 months of the study was 123 participants and completion of immediate post-intervention surveys (after completion of the 2-month cessation program) was 46 (69.8%) with 20 (30.2%) lost to follow-up. With implementation of the enhancement strategies, total enrollment by the end of 10 months had increased to 200 participants and total completion of immediate post-intervention surveys improved to 106 (83.4%) with 21 (16.5%) lost to follow-up.

Conclusions/Future Directions: Lessons learned include importance of (1) dedicating sufficient time, staffing, and financial resources to enrollment and retention efforts; (2) maintaining personal contacts with key community stakeholders; (3) being flexible to meet participants' needs, such as meeting outside of normal work hours and on weekends at locations outside of the clinic/office, or providing transportation to clinic/office sites; (4) considering the use of incentivized recruiting assistants, who are well connected and trusted in the community; (5) designing and utilizing tracking systems to provide ongoing information about enrollment and retention so that successful strategies can be expanded and challenges addressed expeditiously, and (6) encouraging frequent and open communication and problem solving between community members and academic researchers. In summary, understanding the distinctive features of a given community, engaging community members equitably in all phases of the research, and providing adequate funding to carry out comprehensive enrollment and retention strategies are essential to the success of the research projects.

*USC Norris is an IMPACT partner (Improving Patient Access to Clinical Trials)